

# ETHICAL ISSUES OF THE SARS-COV-2 Outbreak in East-Central Europe and Beyond

Edited by  
Assya Pascalev / Gergely Tari





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*Ethical Issues of the  
SARS-CoV-2 Outbreak in  
East-Central Europe and Beyond*

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Assya Pascalev and Gergely Tari

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Ethical Issues of the SARS-CoV-2 Outbreak in East-Central Europe and Beyond

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# INTRODUCTION

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Gergely Tari, Assya Pascalev

On May 5, 2023, the World Health Organization declared the end of COVID-19 as a worldwide health emergency. Yet, the disease is not fully eradicated. Countries and their citizens continue efforts to recover from the social, economic and psychological consequences of the pandemic, and we are still looking for answers regarding its origin and causes, and still reflecting on the mistakes to be avoided and the lessons to be learned for a future pandemic. COVID-19 set humanity on a radically new path. Healthcare systems worldwide had to be mobilized quickly, and far-reaching decisions had to be made in a short period of time with limited information and limited resources. Societies found themselves in a difficult situation: measures to stop the spread of the disease had to be implemented swiftly, often at the expense of long-standing ethical principles and in violation of citizens' human rights, which in turn affected the level of public trust in governments and health officials, and in the policies intended to curtail the pandemic. The emergency magnified the extant challenges and problems facing healthcare systems in ordinary times. While there were clear reasons for implementing mutually cooperative strategies, countries were not prepared to cooperate internationally. Moreover, the pandemic laid bare the existing inequities within societies and increased the disparities within and among countries. The pandemic also shook the moral foundations of medicine. Developed countries, which were generally characterised by a harmonised and egalitarian approach to health care, faced dilemmas about resource allocation of health care services. Grim images from Bergamo, Italy, quickly flooded the media with dramatic footage showing how the health care system in a developed country was being devastated in a matter of hours. Governments around the world, health care professionals, and lay people alike were overwhelmed by fear and uncertainty caused by the new, invisible threat of the SARS-Covid-19 virus. To varying degrees, we all felt the sword of Damocles hanging over our heads.

The need for life-saving, specialised intensive care for the ever-growing number of COVID-19 patients created a macro- and micro-allocation crises across vast parts of the world putting the spotlight on the bioethical principle of justice. Triage activity became inevitable bringing with it the risk of discrimination in utilizing the scarce healthcare resources. Large numbers of healthcare professionals (nurses, physicians, physiotherapists, etc.) had to be assigned to COVID emergency care, putting the healthcare system's continuity, including primary care, at risk due to the intensive workload. Scientific evidence suggests that under the pressure of high mortality, healthcare workers were exposed to high levels of moral distress and burnout. In the swing of the pandemic, providing care for critically ill COVID-19 patients took priority over all other healthcare needs and research activities. The bioethical principles of harm reduction and beneficence gave way to administering life-saving measures and triaging of COVID-19 patients.



The core values of the doctor-patient relationship as we know it in ordinary times, i.e., respect for autonomy, and the dominance of individualistic morality became marginalised. Almost everywhere in the world, the focus shifted to the protection of society as a whole, and an effort was made to identify and protect those most vulnerable, e.g., the elderly and first responders. Citizens faced unprecedented restrictive measures, some of which impinged on basic human rights such as the right to free movement and free assembly. The restrictions also created dilemmas for the management of technology information by professionals: in some countries, contact tracing apps and electronic immunity passports became widely discussed and, in some countries, they were implemented and widely tolerated as a prerequisite for those who wanted to travel, or simply to enjoy a meal at a restaurant.

Our book is dedicated to the moral, social, legal, clinical and policy issues of this first pandemic in modern human history. Readers are presented with a collection of scientific publications that analyse the responses to the pandemic in the Central and East-European region (Austria, Bulgaria, Croatia, Czech Republic, Hungary, Romania and Serbia). The challenges faced by the COVID-19 emergency are approached from multiple angles offering ethical, legal, social, clinical and policy insights, which highlight the need for a theoretical and empirical bioethical understanding of the pandemic, the measures taken to curtail it, and the human, social, economic and political price paid in the process. It is our hope that, in addition to offering an in-depth, comprehensive and multi-faceted view of the challenges the world faced, the essays in this collection also serve as a historical document of the various responses and their effects on the societies in Central and Eastern Europe and beyond.

The book is divided into 2 main chapters: COVID-19: Philosophical, Legal and Social Policy Challenges and Ethical Challenges in the Clinical Context. This collection of papers provides original analyses of the societal aspects of the COVID-outbreak in an unprecedented way. Most of the essays were written in 2022 and cover the most devastating months of the virus in the East and Central European countries. These countries are connected not only temporally but geographically. They also share common political and historical roots. In the 20<sup>th</sup> century, almost all of these nations experienced the oppressive power of totalitarian political regimes working in close coordination with the Soviet Union. The defining values of the regimes favoured collectivist considerations over the welfare of the individual, and medical paternalism and disproportionate limitation of patient rights such as self-determination and confidentiality were the norm before the transition to democracy in the late 1980s. It was only then that the Anglo-centric principles of respect for autonomy and patient rights started to change the moral framework of health care in Central and Eastern Europe.

From this perspective, the countries of this region represent a fascinating case study of the efforts to navigate the remnants of political authoritarianism and medical paternalism. This book is a unique collection of nation-specific reports documenting the efforts to balance the tenet of autonomy and benevolence under the highest pressure of the pandemic in Eastern and Central Europe, and beyond.

# **PART 1.**

**COVID-19:**

**Philosophical, Legal and Social Policy Challenges**



# FAIRNESS, DISCRIMINATION, AND LIFE CYCLE ALLOCATION PRINCIPLES DURING THE COVID-19 PANDEMIC

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Thomas May,<sup>\*</sup> Mark Christopher Navin,<sup>\*\*</sup> Heidi Malm<sup>\*\*\*</sup>

## **Abstract**

A prominent triage policy proffered by scholars at the University of Pittsburgh supplements the principle of “saving the most lives” with commitments to save life years and promote equal opportunity to live through all of life’s stages (“life cycles”). These supplemental principles – Life Years and Life Cycles – have created controversy surrounding discrimination based on age, because each prioritizes the young over older patients who have similar needs and prognoses. The Protocol authors have defended their use of life cycles, in particular, on grounds of fairness that echo themes from Rawlsian work on social justice. They claim that everyone should have an equal opportunity to live through the various stages of life, and that those who have lived through fewer life cycles are “worse off.” Here, we argue that these supplemental principles are inconsistent with the Rawlsian framework. We argue that in circumstances of scarcity, triage principles should be grounded in the purpose(s) of the resource in question. In the current COVID-19 pandemic, this would allocate ventilators, hospital beds, medications and personnel according to principles promoting survival of the greatest number.

## **I. Introduction**

COVID-19 has seen bioethics engaged as never before in response planning. Perhaps the area of most visible planning activity focuses on the allocation of scarce medical resources.<sup>1</sup> A number of triage protocols have been proposed by various task forces,

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<sup>1</sup> Baker, M. and Fink, S., “At the Top of the Covid-19 Curve, How Do Hospitals Decide Who Gets Treatment?” *New York Times*, March 31, 2020. [www.nytimes.com/2020/03/31/us/coronavirus-covid-triage-rationing-ventilators.html](http://www.nytimes.com/2020/03/31/us/coronavirus-covid-triage-rationing-ventilators.html) (last accessed Aug. 21, 2020).

organizations, and study groups; they have been sponsored by think tanks, universities, state governments and medical societies.<sup>2</sup> In the context of COVID-19, one of the most influential policies for allocating scarce medical resources has come from a group led by Douglas White of the University of Pittsburgh’s Department of Critical Care Medicine (hereafter “the Pitt Protocol”).<sup>3</sup> The authors of the Pitt Protocol maintain that their protocol has been adopted by “several hundred hospitals,” as well as state health departments across the U.S.<sup>4</sup>

The Pitt Protocol has been influential, but it has also been controversial. The most controversial distinguishing feature of the Pitt Protocol is its direction to incorporate considerations of ‘saving the most life years’ when making decisions between patients who need the same scarce resources. A Life Years Principle directs triage managers to prioritize those patients who are likely to live longer when allocating scarce medical resources. In this way, a Life Years Principle supplements more traditional triage criteria, which focus on “saving the greatest number of lives” without attention to the differences in the number of years in the lives that are saved. (This is sometimes called a Survival Principle.) A March 2020 draft of the Pitt Protocol explicitly identifies its inclusion of a Life Years Principle – and the extension of its focus beyond survival in general – as one of two important ways it differs from other allocation frameworks.<sup>5</sup> However, the Pitt Protocol has been criticized for its Life Years Principle, on the grounds that the principle would unjustly discriminate against disabled persons and the elderly, i.e. persons whose lives matter, but who have fewer expected years to live. (Articulation of this criticism can be found in the quotes from legal complaints filed by advocacy groups below.)

The need for adding the Life Years Principle to supplement “survival” is articulated by White in a March 27, 2020 Viewpoint in JAMA, co-authored with

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<sup>2</sup> Association of Bioethics Program Directors (ABPD), Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated with Members of the Association of Bioethics Program Directors. *Annals of Internal Medicine* (2020). DOI: 10.7326/M20-1738.

Berlinger, N. et al. 2020. “Ethical Framework for Health Care Institutions & Guidelines for Institutional Ethics Services Responding to the Coronavirus Pandemic: Managing Uncertainty, Safeguarding Communities, Guiding Practice,” *The Hastings Center*, [www.thehastingscenter.org/ethicalframeworkcovid19/](http://www.thehastingscenter.org/ethicalframeworkcovid19/) (last accessed Aug. 21, 2020).

New York State Department of Health. 2015. New York State Task Force on Life and the Law, Ventilator allocation guidelines. Accessed at: [https://www.health.ny.gov/press/releases/2015/2015-11-25\\_ventilator\\_allocation\\_guidelines.htm](https://www.health.ny.gov/press/releases/2015/2015-11-25_ventilator_allocation_guidelines.htm) (last accessed Aug. 21, 2020).

Washington State Department of Health, 2019. Northwest Healthcare Response Network. Scarce resource management & crisis standards of care. Accessed at: [https://nwhrn.org/wp-content/uploads/2020/03/Scarce\\_Resource\\_Management\\_and\\_Crisis\\_Standards\\_of\\_Care\\_Overview\\_and\\_Materials-2020-3-16.pdf](https://nwhrn.org/wp-content/uploads/2020/03/Scarce_Resource_Management_and_Crisis_Standards_of_Care_Overview_and_Materials-2020-3-16.pdf) (last accessed Aug. 21, 2020).

<sup>3</sup> University of Pittsburgh, Department of Critical Care Medicine, 2020. Allocation of Scarce Critical Care Resources During a Public Health Emergency, [https://ccm.pitt.edu/sites/default/files/UnivPittsburgh\\_ModelHospitalResourcePolicy\\_2020\\_04\\_15.pdf](https://ccm.pitt.edu/sites/default/files/UnivPittsburgh_ModelHospitalResourcePolicy_2020_04_15.pdf). (last accessed Aug. 21, 2020).

<sup>4</sup> UPMC, 2020. <https://ccm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now> (last accessed Aug. 21, 2020).

<sup>5</sup> University of Pittsburgh, Department of Critical Care Medicine, 2020. Allocation of Scarce Critical Care Resources During a Public Health Emergency, [https://ccm.pitt.edu/sites/default/files/UnivPittsburgh\\_ModelHospitalResourcePolicy\\_2020\\_04\\_15.pdf](https://ccm.pitt.edu/sites/default/files/UnivPittsburgh_ModelHospitalResourcePolicy_2020_04_15.pdf). (last accessed Aug. 21, 2020).

Bernard Lo.<sup>6</sup> White and Lo explain that a focus on survival is “ethically insufficient” for allocation of scarce resources, and so must be supplemented with principles focused on life years and, most importantly for our purposes here, life cycles. A ‘life cycle’ is a stage of life marked by meaningfully different activities and goals. A Life Cycle Principle prioritizes the allocation of scarce resources to those who have experienced the fewest life cycles. Different models define specific categories of life cycles differently, although all focus on age range: Maryland, for example, outlines ranges of 0-49, 50-69, 70-84, and >84<sup>7</sup>; while the Pitt Protocol recommends ranges of 12-40, 41-60, 61-75, and >75.<sup>8</sup> The Pitt Protocol adopts Life Cycles as a tie-breaker to prioritize between patients with similar needs and prognosis as defined by “primary” triage categorization.

Despite the focus on cycles rather than years, Life Cycle Principles seem vulnerable to the same kinds of objections that can be leveled against a Life Years Principle. Consider the following statement from State of Michigan Guidelines, which reject the use of either principle in the allocation of scarce resources:

“It may be fair to allow a younger person to have the chance to live to an older age, given that older people have already had the opportunity to experience those phases of life. But this approach goes against equality in the sense that it is making an explicit differentiation between people on the basis of numerical age. It also undermines attempts to achieve intergenerational equity in allocation decisions.”<sup>9</sup>

More recently, activists have filed legal complaints against allocation plans that prioritize resources for younger people, either on a Life Years Principle or Life Cycles Principle. For example, Disability Rights Washington filed a complaint that states that “[published plans...give priority to treating people who are younger and healthier and leaves those who are older and sicker – people with disabilities – to die.]”<sup>10</sup>

Pitt Protocol authors have defended their framework, arguing that it is not discriminatory, because it includes no categorical exclusions based upon judgments of social worth. They explain that “it’s a simple matter of fairness”, elaborating:

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<sup>6</sup> White, D. and Lo, B., “A Framework for Rationing Ventilators and Critical Care Beds During the COVID-19 Pandemic,” *JAMA* (2020) (online ahead of print), March 27, 2020.

<sup>7</sup> Maryland Framework for the Allocation of Scarce Life-Sustaining Medical Resources in a Catastrophic Public Health Emergency (August 24, 2017). [https://www.law.umaryland.edu/media/SOL/pdfs/Programs/Health-Law/MHECN/ASR\\_Framework\\_Final.pdf](https://www.law.umaryland.edu/media/SOL/pdfs/Programs/Health-Law/MHECN/ASR_Framework_Final.pdf) (last accessed Aug. 21, 2020).

<sup>8</sup> UPMC, 2020. <https://cm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now> (last accessed Aug. 21, 2020).

<sup>9</sup> State of Michigan, Guidelines for ethical allocation of scarce medical resources and services during public health emergencies in Michigan (2012).

<sup>10</sup> Disability Rights Washington, Complaint of Disability Rights Washington, Self Advocates in Leadership, The Arc of the United States, and Ivanova Smith Against the Washington State Department of Health (WA DOH), the Northwest Healthcare Response Network (NHRN) and the University of Washington Medical Center (UWMC) (2020) <http://www.bazelon.org/wp-content/uploads/2020/03/3-24-20-AL-OCR-Complaint.docx.pdf> (last accessed Aug. 21, 2020).

“This is a framework that is grounded in medical principles of survival, with no judgment of whether one’s broad social worth, with no inclusion of consideration of individuals’ perceived social worth...Our framework treats as equal a homeless person and a hospital president.”<sup>11</sup>

This statement does not, however, respond to the heart of activists’ objections. The fact that the Pitt Protocol advocates for a Life Cycles Principle (or Life Years Principle) that does not discriminate against, for example, poor or homeless people is not a defense against claims of discrimination based on age. Therefore, advocates of the Pitt Protocol still must explain how they can incorporate age, life years, life cycles, and “long term survival” into fair allocation frameworks, without making objectionable judgments about the “worth” of people’s lives.<sup>12</sup> Indeed, the U.S. Civil Rights Office was sufficiently troubled by such concerns that it issued a bulletin to remind various entities of their “obligations under laws and regulations that prohibit discrimination,” citing age and disability status among other potential criteria.<sup>13</sup> States like California have “pulled” their guidelines (which were based largely on the Pitt Protocol) for review, in light of these worries.

While controversy about age, disability and discrimination continues, there seems to be a consensus that allocation principles should not include presumptions about which lives are more valuable. Use of any allocation criteria, then, must justify its differential treatment of individuals in its allocation of “goods.” In the case of Life Cycles, White and Lo have attempted such a justification in their recent Viewpoint publication in *JAMA*. There, they seem to invoke a Rawlsian idea of fairness to justify the use of Life Cycle considerations as a supplement to a focus on survival:

“Another ethically relevant consideration that should be incorporated into allocation decisions is giving individuals equal opportunity to pass through the stages of life – childhood, young adulthood, middle age, and old age. Younger individuals should receive priority, not because of any claims about social worth or utility, but because they are the worst off, in the sense that they have had the least opportunity to live through life’s stages.”<sup>14</sup>

White and Lo do not explicitly cite the work of John Rawls (or other Rawlsian or even contractarian theories of justice). But their invocation of fairness as well as their justification for differential treatment of individuals, their allusion to a principle of “equal opportunity” for distributing scarce goods, and their direction to prioritize

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<sup>11</sup> Robbins, Rebecca, “A System for Allocating Scarce Ventilators and ICU beds gains traction for not counting any group out,” *STAT News Service* (2020), <https://www.statnews.com/2020/04/02/ventilator-icu-rationing-pittsburgh-framework/> (last accessed Aug. 21, 2020).

<sup>12</sup> May, T. and Aulisio, M., “Age, Life Cycles, and the Allocation of Scarce Resources During COVID-19 Pandemic,” *CHEST* (2020): doi: 10.1016/j.chest.2020.06.019 [Epub ahead of print].

<sup>13</sup> Office of Civil Rights, 2020. [www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20-PDF](http://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20-PDF) (last time accessed Aug. 21, 2020). Fink, Sheri, “U.S. Civil Rights Office Rejects rationing Medical Care Based on Disability, Age,” *New York Times*, March 28, 2020.

<sup>14</sup> White, D. and Lo, B., “A Framework for Rationing Ventilators and Critical Care Beds During the COVID-19 Pandemic,” *JAMA* (2020) (online ahead of print), March 27, 2020 (White and Lo, 2020, p. E1).

outcomes for “the worst off” seem, taken together, to appeal to the intellectual persuasiveness of Rawlsian concepts of fairness and justice.<sup>15</sup> John Rawls was among the most prominent political philosophers of the 20th century, and his work has often been imported to bioethics work that touches on political topics (e.g. Daniels, 1985)<sup>16</sup>. So, it should not be surprising that advocates of a controversial triage principle – for unequal distribution of scarce medical supplies – would invoke the appeal of the Rawlsian social justice project.

Below, we argue that a Life Cycle Principle cannot be justified on Rawlsian grounds of fairness in the context of allocation of scarce resources during an emergency (such as COVID-19). In short, we argue Rawls’s ‘free and equal persons’ would not choose Life Cycle Principle to distribute scarce medical resources, because such principles are not sufficiently neutral concerning what makes life valuable; also, Rawlsian principles of ‘equal opportunity’ and ‘priority for the worst off’ do not apply to zero-sum games about the allocation of scarce life-saving resources. Rather than appeal to Rawls and Rawlsian ideas, we argue that allocation of scarce resources should focus on the purpose(s) served by the resources in question. In the case of allocation of scarce medical resources during COVID-19, this means that allocation should focus on medical criteria related to survival of the greatest number of people.

## **II. Fairness and Life Cycles in conditions of scarcity**

White and Lo invoke the value of fairness to defend the use of Life Cycle Principles for distributing scarce medical resources. But what is fairness? Fairness can be an attribute of either the implementation or the justification of principles for distributing goods. Fairness in the implementation of a distributive principle requires only that one demonstrate consistency, i.e. that one’s allocation decisions not be made for arbitrary reasons, but only for the reasons identified by the distributive principle in question. It is the idea that we should treat things that have the same kind of moral value in the same way. For example, Jeremy Bentham’s utilitarian calculus – according to which “each person is to count for one and no one for more than one” – aims to realize a kind of implementation fairness, by focusing only on utility, and not on arbitrary social facts, in determining how social goods should be distributed. That does not mean that each person should be treated identically, but only that each person’s utility function should be taken into account. White and Lo may be invoking a similar idea of implementation fairness when they defend the role of Life Cycle considerations in their protocol. It is fair to use Life Cycle considerations, they seem to say, because doing so avoids discriminatory and stigmatizing judgments about people’s “social worth,” e.g. regarding the lives of persons with disabilities, and focuses only on what really matters, i.e. life cycles.

But the fact that someone is committed to implementing a given distributive principle in a fair manner does not show that the principle itself is fair. Indeed,

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<sup>15</sup> Rawls, John, *A Theory of Justice*, Rev. ed. (Cambridge, Mass: Belknap Press of Harvard University Press, 1999).

Rawls, John, *Justice as Fairness: A Restatement* (Cambridge: Harvard University Press, 2001).

<sup>16</sup> Daniels, Norman, *Just Health Care* (Cambridge University Press, 1985).



implementation fairness matters only after one has reason to believe that the distributive principle is itself fair. (Consistency in the performance of vice is not a virtue.) Therefore, if White and Lo aim to defend their use of life cycle considerations on the grounds that it is fair to use such considerations, then they will have to show that their principle can be justified in terms of fairness.

As described above (toward the end of the previous section), White and Lo seem to offer a fairness-based justification for their use of life cycle principles that invokes Rawlsian principles of social justice. According to Rawls, fair principles for regulating the major institutions of society<sup>17</sup> – conceived of as a system of social cooperation among free and equal people<sup>18</sup> – consist of the principles that people would choose for themselves<sup>19</sup>. The fact that free and equal people can agree to be governed by a set of principles is what justifies those principles<sup>20</sup>. And each individual can check whether a principle would be chosen by everyone else, and thus be justified as fair, if they consider whether they would choose that principle without knowing the role they will have in society<sup>21</sup>. (This is the idea of the Veil of Ignorance.) Rawls argues that people behind the Veil of Ignorance will choose (1) an equal distribution of a set of liberties, and that (2) inequalities in the distribution of social and economic goods would be allowed only if they (i) were attached to positions for which all people have an equal opportunity to compete, and (ii) were to the advantage of the least well-off members of society<sup>22</sup>. Thus, although White and Lo do not explicitly cite Rawls, they do seem to defend their allocation principle in Rawlsian terms saying that, for example, their allocation principle is “fair,” that it protects “equal opportunity,” and that it demonstrates “priority... [for] the worst off.”

We do not think these efforts to establish the fairness – and justify the use – of the Life Cycle Principle on Rawlsian grounds of “justice as fairness” can succeed. We arrive at this conclusion on three grounds: (1) The idea of natural versus social goods; (2) Neutrality about what makes life valuable; and (3) The allocation of surplus versus scarce resources to the “worst off”.

Natural vs. Social Goods: First, Rawlsian contractors do not concern themselves directly with the distribution of health or life (or life cycles), but only with the goods that are created and directly controlled by social cooperation<sup>23</sup>. Fairness, for Rawls, is about ensuring that the major institutions of society create and distribute goods in ways that all members of society can accept. The major institutions of society create and distribute what Rawls calls the social primary goods, which include rights, liberties, opportunities, income, wealth, and the social bases of self-respect<sup>24</sup>. In contrast, the natural primary goods – which include intelligence, imagination, health, and vigor – are not created and distributed by society’s major institutions, and

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<sup>17</sup> Rawls, John, *A Theory of Justice*, Rev. ed. (Cambridge, Mass: Belknap Press of Harvard University Press, v). (Rawls, 1999, 7).

<sup>18</sup> Rawls, 1999, 4.

<sup>19</sup> Rawls, 1999, 10.

<sup>20</sup> Rawls, 1999, 12.

<sup>21</sup> Rawls, 1999, 17, 118.

<sup>22</sup> Rawls, 1999, 266.

<sup>23</sup> Rawls, 1999, 54, 79.

<sup>24</sup> Rawls, 1999, 54.

therefore their distribution is not considered part of ‘justice as fairness’. It would be absurd to say that everyone should have an equal amount of intelligence or an equal opportunity to have an imagination. On Rawls’ view, it would be similarly odd to think that principles of social justice should concern themselves with the distribution of health, life, or life cycles. So, if White and Lo are focused on the fair distribution of life cycles, they seem to have made a category mistake, in light of the fact that fairness governs the distribution of the goods that social cooperation creates, and social cooperation does not create and distribute life or life cycles.

Neutrality: Second, life cycles are not sufficiently neutral with respect to different conceptions of the good life and, therefore, principles for distributing life cycles would not be endorsed by all members of society. Suppose, contra what was said above, that White and Lo can show that life cycles are a sufficiently social good. Let us assume that one’s possession of a set of life cycles is under sufficient control of society’s major institutions that someone who is concerned about the fair regulation of these institutions should be concerned about the distribution of life cycles. That would still not be enough to show that Rawlsian contractors would choose principles that distribute life cycles. This is because Rawls’ principles distribute primary goods, which are goods that all rational people desire, regardless of their particular conception of the good life<sup>25</sup>. The fact we all desire the social bases of self-respect, the freedom to practice our religion (or lack thereof), and sufficient money to purchase other goods makes it possible for the principles that distribute these goods to receive unilateral endorsement. But not everyone values (all of the) life cycles.

We suggest that Rawlsian contractors would not endorse a principle of an equal “opportunity to live through all of life’s stages” because ‘living through all of life’s stages’ is highly unlikely to be something that all people desire. Even a little imagination suffices to demonstrate that some rational people may value some of their life cycles more than others, or may place no value at all on some of their life cycles. For example, consider the difference between a professional boxer (Mike) and a retirement planner (Susan). Suppose that at age 30, Mike has lived half of the one life cycle he values most (20-40), because the only thing he lives for is boxing, and because boxing is not an activity for later life. In contrast, at age 55, Susan has still not yet been able to experience any of the life cycles she values most. She spends all of her time working a demanding job to prepare for a life of travel and luxury upon retirement. Susan has experienced more life cycles than Mike, but she will not consider herself better off in that respect. Accordingly, “all of life’s stages” cannot be a social primary good. What people care about is the quality of life that they experience within the life cycles that they value.

Allocating Surplus versus Scarce Goods: Finally, Rawlsian principles of justice focus on distributive principles for organizing the macro-level productive institutions of society; they are not allocative principles for determining how to divide pre-existing sets of social goods<sup>26</sup>. More importantly, Rawls’ principles tell us how to fairly create and distribute a social surplus; they do not tell us who lives and who dies when there are not enough goods for everyone to survive. A language of Rawls’

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<sup>25</sup> Rawls, 1999, 54, 79, 223, 348-9.

<sup>26</sup> Rawls, 1999, 229.

Difference Principle (his ‘priority for the worst off’ principle) may lend itself to misunderstanding on this point. Rawls asserts that social and economic inequalities should be “to the greatest benefit of the least advantaged”<sup>27</sup>, and it may seem as if Rawls is talking about people who are experiencing forms of absolute material deprivation. Indeed, it is common for other moral theories to advocate a priority for persons who are worst off in their (in)ability to meet their basic needs. Consider that Roman Catholic Social Teaching preaches a ‘preferential option for the poor’, as a necessary consequence of the Gospel message<sup>28</sup>; and utilitarians may prioritize interventions for those who are suffering the most, on the grounds of marginal utility.

But Rawls’ ‘least advantaged’ are not poor and they are not lacking their basic needs. Rawls’ Difference Principle aims instead to incentivize productive people to increase the social surplus enjoyed by all<sup>29</sup>. The idea is that everyone in society can benefit if especially intelligent and productive people put their talents to socially beneficial uses. Some of the most socially productive labor is burdensome, so it would only be fair to ask someone to provide that burdensome but socially useful labor if you offered them additional compensation. Likewise, it would only be fair for some people to make more money than others if the people who made less money (and, indeed the least money) also benefited from that inequality. For example, you may have to offer talented physicians higher salaries, if you want them to undergo decades of training and work long shifts in clinic. This kind of inequality is fair because everyone – including the least well advantaged – is better off in a world in which we have physicians.

However, White and Lo are not identifying macro-level principles for regulating major social institutions. They are not focused on questions about how to incentivize the production of social goods. Instead, they are trying to find a solution to a zero-sum game: there are only so many beds, ventilators, or dialysis machines, and not everyone who needs one can get one. Rawlsian principles of equal opportunity, or of priority for the worst off, do not speak to how we should respond to this kind of problem.

### III. ‘Survival’ as the Basis of Triage during COVID-19 Pandemic

In the context of zero-sum games, where not everyone can have access to the resource in question, distributive justice would do well to focus on the basic purposes of the resource in question, allocating (where possible) on the basis of optimizing realization of the fundamental purpose of those resources. For the specific resources in question – hospital beds, ICU care, ventilators, etc. – this translates to a focus on the purposes of healthcare. The most basic purpose here, we argue (the purpose that rational agents would be most likely to accept), is survival. Basic triage categories

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<sup>27</sup> Rawls, 1999, 266.

<sup>28</sup> John Paul II, *Centesimus Annus. The Holy See* (1991). [http://www.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf\\_jp-ii\\_enc\\_01051991\\_centesimus-annus.html](http://www.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_01051991_centesimus-annus.html) (last accessed Aug. 21, 2020).

<sup>29</sup> Rawls, John, *A Theory of Justice*, Rev. ed. (Cambridge, Mass: Belknap Press of Harvard University Press, 1999), 131. Rawls, John, *Justice as Fairness: A Restatement* (Cambridge: Harvard University Press, 2001), 76, 124.

propose just such an allocation: by sorting out those whose survival (or lack of survival) will not be influenced by access to the resource, resources can be allocated in a way that optimizes their purpose.

Our above claim about survival is one supported by community engagement efforts cited by White and Lo themselves. Those efforts found survival to be an allocation principle that more than 70% of participants advocated for use “often” or “always” in the context of scarcity. Importantly, less than 8% expressed objection to its use. Life cycles, by contrast, were supported by only 29.5% of participants, with a similar number (28.4%) advocating that such principles “never” or “rarely” be used.<sup>30</sup> Indeed, no other proposed allocation principle enjoyed anything even close to the level of support and lack of objection expressed for survival, including “number of life years saved.”

The real work in times of significant shortages will be done by tie-breakers within the category of “likely to survive with/likely to die without” access to the resource in question. Here, optimizing the purpose of the resources in question would best be accomplished through clinical assessment of chances of survival, with priority assigned to those most likely to recover with access to the resource (but who would not recover without it). This will require evidence-based assessment of how patient co-morbidities influence chances of survivability in the context of the acute event in question, although not in the context of long-term prognosis.

The above will inevitably lead to the practical issue of how to define survival/recovery? Although survival to discharge from the acute event is the “cleanest” criterion, it would be acceptable, in our estimation, to extend the definition of “survival” somewhat beyond discharge, so long as this did not undermine the core focus on survival/recovery by re-focusing on life years or quality of life. For example, a patient in the final stages of a terminal cancer diagnosis, and not expected to live more than a few weeks beyond discharge, may be said not to “recover” even if they do not die in the hospital. Here, the idea is that the unlikelihood to survival past a particular threshold of time undermines the characterization of that patient realizing the purpose of the resource – in essence failing to “benefit” in a meaningful sense. So a shortened life expectancy due to a chronic health condition or disability would not be a legitimate consideration, but the fact that a particular comorbidity is associated with low recovery from COVID-19, for example, would. More specifically, this means that if a consideration like age were strongly associated with an inability to recover, it might legitimately be used as an allocation criterion (depending on how strong the correlation to recovery is), but age used to indicate “life years saved” would not.

Exactly how strong this association would need to be is a point in need of clinical – and social policy – debate. Likewise, exactly how long beyond discharge is required is a matter of debate. There are limits, however: weeks or months instead of years, if the focus is to plausibly remain on the “ability to recover” if provided access to the resources.

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<sup>30</sup> Biddison, ELD, Gwon, HS, Schoch-Spana, M, et al, “Scarce Resource Allocation During Disasters: A Mixed Method Community Engagement Study,” *Chest* 153 (2018):187-195.

The Pittsburgh protocol attempts to capture this idea, we believe, though concepts of short- and long-term prognosis incorporated into its primary triage scoring system. However, the criteria embodied in this system explicitly move from a focus on “lives saved” to “life years,” undermining the focus on survival/recovery and subjecting the system to the same concerns outlined by disability rights advocates as described in the Introduction. Specifically, the Pitt Protocol adds two points (addition of a point lowers one’s priority) to patients whose death is expected within five years, and four points for patients whose death is expected within one year. In a table provided within the Pitt Protocol, the protocol explicitly distinguishes the basis of this scoring from that of the comorbidities included in their Sequential Organ Failure Assessment (SOFA). The latter are explicitly categorized as considerations concerned to “save lives” and the former are distinguished in their categorization as considerations concerned to “save life years.” Any focus on life years saved will inevitably, and we think unfairly, disadvantage at least some of those with conditions or traits that are tied to shortened life expectancy.

Perhaps the most promising avenue to operationalizing the focus on survival/recovery is one already reflected in current clinical judgements of survival and benefit from aggressive intervention: that of hospice care. Hospice eligibility reflects a clinical judgment that, although aggressive intervention could increase survival of an acute episode (such as cardiac arrest), the presence of the recognized disease process is indicative of such short life expectancy, even absent the acute episode, that employing aggressive intervention for the purpose of curing is not warranted. The basic idea of hospice care is defined by the National Association for Home Care and Hospice as follows:

“A model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach in the provision of medical care, pain management and emotional and spiritual support. The emphasis is on comfort, not curing. It can be provided in the patient’s home as well as freestanding hospice facilities, hospitals, nursing homes and other long-term care facilities.”<sup>31</sup>

Of course, defining life expectancy is far from an exact science; and this fact is one of the deepest problems with attempts to allocate according to principles seeking to maximize life years in general. Life expectancy itself is an average, or median, age of death rather than a “norm.” Its significance is limited, and only applicable at a macro level. Only a limited number of variables that influence the number of years that any particular individual will actually live are understood in ways applicable at the micro level. Thus, predictions of individual life spans are, above all, deeply fallible. This fallibility is more pronounced the farther out one looks. As argued by a consortium on standards for non-discrimination in crisis standards:

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<sup>31</sup> National Association for Home Care and Hospice, nd. <https://www.nahc.org/about/faq/#111> (last accessed Aug. 21, 2020).

“Long-term survival projections are significantly less certain than the assessment of short-term survival. Medical innovations such as new pharmaceuticals, surgical techniques and other interventions can shift the long-term prognosis for many conditions... Any consideration of long-term survival in plans or allocation criteria, whether it comes in the form of explicit consideration of long-term survival or implicit consideration through prioritization of number of “life-years” saved rather than the number of “lives” saved, is inconsistent with disability rights laws.”<sup>32</sup>

Nonetheless, clinical evaluations of broad thresholds of survival – especially for very short-term prognostication (e.g. more than or less than six months) tied to recognized disease processes – are generally applicable in modern medical practice, even if even they lack precision. As described in Medicaid/Medicare guidelines for determining hospice eligibility:

“Section 1814(a)(7) of the Social Security Act (the Act) specifies that certification of terminal illness for hospice benefits shall be based on the clinical judgment of the hospice medical director or physician member of the interdisciplinary group (IDG) and the individual’s attending physician, if he/she has one, regarding the normal course of the individual’s illness. No one other than a medical doctor or doctor of osteopathy can certify or re-certify a terminal illness. Predicting of life expectancy is not always exact. The fact that a beneficiary lives longer than expected in itself is not cause to terminate benefits.”<sup>33</sup>

Such guidelines – focused on survival/recovery – would preclude adjusting prioritization scores based on 5-year, and likely even 1-year, survival. However, they would capture the concern that resources should not be “un-optimally” allocated to those whose survival beyond discharge would be of such short duration as to call into question their ability to truly “benefit” from their receipt of scarce resources.

At root, the most important operative notion is that allocation decisions be tied to survival, reflecting the most fundamental purpose of the healthcare resources in question. In this, we are in agreement with the American College of Physicians, who issued the following statement on “Non-Discrimination in the Stewardship and Allocation of Resources During Health System Catastrophes Including COVID-19”:

“...resource allocation decisions should be made based on patient need, prognosis (determined by objective scientific measures and informed clinical judgment) and effectiveness (i.e., the likelihood that the therapy will help the patient recover). Allocation of treatments must maximize

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<sup>32</sup> Center for Public Representation, 2020. Evaluation Framework for Crisis Standard of Care Plans. <https://autisticadvocacy.org/wp-content/uploads/2020/04/Evaluation-framework-for-crisis-standards-of-care-plans-4.9.20-final.pdf> (last accessed Aug. 21, 2020).

<sup>33</sup> Medicaid/Medicare Guidelines, nd. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf> (last accessed Aug. 21, 2020).

the number of patients who will recover, not the number of “life-years,” which is inherently biased against the elderly and the disabled.”<sup>34</sup>

While life year and life cycle considerations may, as noted, achieve a sense of implementation justice, we have argued that they inherently incorporate judgments of what makes life valuable, albeit in terms of numbers (of years or life cycles) rather than “social status” or “social worth.” In this, they are unacceptable as a basis for prioritizing patients for medical resources needed to preserve life (or chance of recovery).

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<sup>34</sup> American College of Physicians (ACP), 2020. “Non-Discrimination in the Stewardship and Allocation of Resources During Health System Catastrophes Including COVID-19,” approved by the Executive Committee of the Board of Regents March 26, 2020. [www.acponline.org/acp\\_policy/policies/acp\\_policy\\_on\\_non-discrimination\\_in\\_the\\_stewardship\\_of\\_healthcare\\_resources\\_in\\_health\\_system\\_catastrophes\\_including\\_covid-19\\_2020.pdf](http://www.acponline.org/acp_policy/policies/acp_policy_on_non-discrimination_in_the_stewardship_of_healthcare_resources_in_health_system_catastrophes_including_covid-19_2020.pdf) (last accessed Aug. 21, 2020).

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# THE COVID PANDEMIC IN HUNGARY: LESSONS FROM A HUMAN RIGHTS PERSPECTIVE

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## **Abstract**

The medical, epidemiological, virological, economic, and other consequences of the Covid-19 pandemic are still acutely felt a year and a half later. In this chapter, I will analyze the human rights aspects of this public health crisis and, in particular, those related to bioethics. However, I have not covered the assessment of the environmental impact of the Covid-19 pandemic, as this would call for a separate study. Pandemics have been experienced many times in human history, yet there are several unique characteristics of the current pandemic caused by the SARS-Cov-2 coronavirus. The evolution of the Covid-19 epidemic shows the most similarities with the Spanish flu epidemic between 1918 and 1919. The Spanish flu is estimated to have claimed the lives of more than 50 million people worldwide. Admittedly, there were no vaccines available at that time and, in any case, the war was claiming terrible casualties while intensive care was still in its infancy. In recent decades, the SARS, MERS and Ebola epidemics have also claimed many victims, but the current epidemic caused by the SARS-Cov-2 virus, now sweeping the globe in several waves, is in many ways unique.

## **I. Restricting Freedoms to Combat the Pandemic**

The Covid-19 pandemic has had a serious impact on virtually all human rights: privacy, freedom of speech, freedom of assembly and freedom to work. Restrictions on all these rights have been imposed to deal with medical emergencies worldwide.<sup>1</sup>

Even in the first phase of the pandemic, in April 2020, the WHO emphasized that the right to health and a global response must be given priority in combating the epidemic. Despite this, there have not been many examples of international cooperation regarding epidemiological measures.

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<sup>1</sup> Paolo Giordano, *How Contagion Works* (London: Weidenfeld and Nicolson, 2020).

With curfews imposed on several continents as a consequence of the worldwide spread of the coronavirus in 2020, the largest mass quarantine of the modern era has been created, as no global shutdown or lockdown of this scale has ever taken place before.<sup>2</sup> During the initial phase of the pandemic, most people put up with the unusual restrictions for quite a long time, even though they had enjoyed a wide range of liberties. They were ready to accept temporary restrictions on their rights for the benefit of an important shared interest: maintaining and protecting health, which suddenly overrode a number of other considerations.

However, as more and more new regulations were adopted, some tightening while others easing restrictions from one day to the next, even affecting rights unrelated to the epidemic, more and more questions were raised about the necessity of limiting human rights. How long and to what extent should individual rights be restricted, how could it be done in a lawful and proportionate manner, even in the context of such a serious epidemic?

## **II. The First Wave of the Pandemic in Hungary**

After the first infection cases emerged in Hungary in March 2020, severe measures were imposed in our country, as well. Schools had to switch to online operation overnight, shops were open only on a limited basis, and even grocery stores introduced specific time slots available only for the elderly population. The first measure related to the epidemic was Government Decision 1012/2020 (I. 31.) on the establishment of a Competent Task Force. Subsequently, one of the most significant and controversial laws was adopted by the National Assembly on 30 March 2020, when it passed Act XII of 2020 on protection against the coronavirus, which gave the government the authority to extend the scope of the relevant decrees.

The management of healthcare institutions was turned over to the military; hospitals were ordered to focus on fighting the pandemic and reduce the provision of other healthcare services. There was no previous model for this radical change, which is likely to shape the relationship between health professionals and health authorities on the one hand, and between doctor and patient, society and healthcare on the other, for a long period of time. At the very beginning of the epidemic, both doctors and patients had to cope with a strange, hitherto unknown measure. Previously, prevention was one of the key elements of any health awareness campaign. In other words, the main advice was that everyone should see a doctor in time, have regular screening tests and see their doctor immediately if they noticed any abnormality. This ingrained message seemed to have suddenly gone with the wind in mid-March. It was replaced by a completely different slogan: “Everyone should stay at home and only contact a health care provider by phone in case of urgent need”. Most general practitioners, specialist clinics and hospitals suddenly became inaccessible to large numbers of patients. This radically new message can only be changed by a huge awareness campaign and by making our hospitals safe

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<sup>2</sup> Geoff Manaugh and Nicola Twilley, *Until Proven Safe: The History and Future of Quarantine* (Dublin: Picador, 2021).

again. Waiting lists increased by several months after the third wave of the epidemic subsided.<sup>3</sup>

Such a radical transformation of the doctor–patient relationship has also encouraged bioethical thinking to be innovative. On 14 April 2020, the Hungarian Medical Chamber (HMC) published a document entitled “Ethical Considerations for the Allocation of Medical Resources during the Covid-19 Pandemic”.<sup>4</sup> This is a rather unique and, in many respects, forward-looking recommendation in the history of the Chamber. By publishing ethical considerations, the Chamber’s main ambition was obviously to try to address, in an open manner, not only the strictly medical aspects of triage but also its philosophical and ethical perspectives, i.e. how scarce resources must be allocated during the epidemic. It is important to note that the HMC respects the concept of non-discrimination in this resolution, in that it emphasizes that no one should be disadvantaged simply because of their age or gender; that is, the authors of the document did not confine themselves to any single factor in their classification.

The HMC recommendation was made just after the massive and abrupt reduction in inpatient numbers before Easter 2020, and a month after many outpatient and inpatient facilities became inaccessible to a wide range of patients for an indefinitely long period. Even to those who have paid health insurance contributions throughout their lives, and who could rightly expect not to have to give up their health care in their old age, after a lifetime of hard work, and that this care would accompany them for the rest of their lives, were unable to access health care facilities and services.

Therefore, first of all, it is necessary to fight with all means to guarantee these rights in a justified way because the premature surrender of patients’ rights may permanently distort the doctor-patient relationship.

The ethical dilemmas of turning ventilators on and off have been so far discussed in bioethics regarding patients with incurable and terminal conditions. For the past 30 years, ethical standards have been based on the need to respect the intent of the person most affected, the patient. As this was the basic bioethical situation known so far, and since access to ventilators also plays a role in the case of Covid-infected patients, the decisions on when and how and how long ventilators should be used may have been overly stressed, not only in Hungarian but also in the recommendations of Italian anesthesiologists. (Since then, many intensive care physicians have seriously questioned whether it is in any way appropriate to focus on the ventilator in cases of severe Covid infections.)<sup>5</sup>

Human rights issues are also raised in the work of healthcare staff. For example, how can healthcare workers’ freedom of expression be protected when they come to an important conclusion about the epidemic, or when they discover the efficacy or even ineffectiveness of a therapy? According to what ethical principles do ethics committees evaluate Covid-19 protocols? How should they treat seriously ill, dying

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<sup>3</sup> [https://jogviszony.neak.gov.hu/varolista\\_pub/elojegyzesi-listak-hosszanak-lekerdezese/?ocsk=133](https://jogviszony.neak.gov.hu/varolista_pub/elojegyzesi-listak-hosszanak-lekerdezese/?ocsk=133),

<sup>4</sup> Hungarian Medical Chamber (2020) “Ethical Considerations for the Allocation of Medical Resources during the Covid-19 Pandemic”. <https://mok.hu/koronavirus/tajekoztatok/etikai-megfontolasok-az-orvosi-eroforrasok-elosztasahoz-covid-19-pandemia-idejen-magyarorszagon>.

<sup>5</sup> <https://www.statnews.com/2020/04/08/doctors-say-ventilators-overused-for-covid-19/>.

people who cannot be visited by their relatives? There have been cases in Italy and the United States where nurses have given the opportunity for patients and their relatives to see each other on a smartphone. But psychological support is also needed to cope with the trauma of isolation. This is obviously the responsibility of psychiatrists and psychologists in the first place. The lack of care for relatives, the inability to say goodbye to the dying and the postponement of funerals cause traumatic experiences all over the world. We cannot hold the hands of dying patients, and pregnant women can't have their partners around while they are in labor. For many, assisted reproduction processes have had to be stopped, and millions are not going for screening examinations or rehabilitation.

### III. The Second and Third Waves of the Epidemic

The second wave was characterized by the closure of Hungary's borders on 1<sup>st</sup> September 2020 and the introduction of a number of new measures. Special rules were established in relation to the state of emergency under Government Decree 478/2020 (XI. 3.) on the declaration of a state of emergency. The goal was to avert the consequences of the SARS-CoV-2 pandemic, which caused widespread illness and threatened the safety of life and property. Successive waves brought about different epidemiological measures<sup>6</sup> and each of the problems that emerged raised bioethical and human rights issues as well.<sup>7</sup>

While Central Europe came through the first wave of the pandemic relatively easily, these very countries suffered much greater losses in the second and third waves. As there was no data indicating that this was due to biological differences between populations, the high mortality rates can be attributed to the flaws in the post-socialist healthcare system. In the old socialist regime, healthcare was accessible to the population at the current standards of that time. However, this sector has weakened as a consequence of market dynamics following the fall of the regime, with many healthcare workers even leaving this sector due to low wages. For this very reason, society experienced an almost catastrophic disaster in that most healthcare services had become inaccessible. As a result, in the spring of 2020, many surgical procedures and medical interventions were canceled, or amputations were required instead of vascular surgery. Having control over one's body is also closely linked to personal rights and human dignity.

Altogether 140,900 Hungarian citizens died in 2020, which is a significant increase compared to the previous year. Statistics also reveal that September 2020 saw a real spike in death rates.

While the first wave of the epidemic was relatively mild in Hungary, the greatest problem in the spring of 2020 was the *ad hoc* evacuation of hospitals, rendering the Hungarian healthcare system almost inaccessible to the uninfected.

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<sup>6</sup> Act CIX of 2020 dealt with protection against the second wave of the coronavirus pandemic, while Government Decision 2030/2020 (29.XII.) addressed support for the development of a national coronavirus vaccine.

<sup>7</sup> Judit Sándor, Health and Legal Policy in Hungary at the time of Covid-19 Pandemic, *Medicine and Law*, vol. 39, no. 2 (June 2020), 191–202.

### **III. Before the Fourth Wave**

By mid-August 2021 in Hungary, more than 5.6 million people received anti-covid vaccines and the total number of doses administered reached 11.2 million. While before June Hungary was among the countries with highest vaccination rates in the world, many other European countries have accelerated their vaccination programs since then. As of August 15, 2021, Malta had the highest COVID-19 vaccination rate in Europe having administered 176.83 doses per 100 people in the country.<sup>8</sup>

The initial success in reaching a high vaccination rate in Hungary prompted the government to relax the public health measures. During the summer, wearing masks is not obligatory any longer, not even in shops and at public events, and although immunity and vaccination cards had been introduced already in the spring, showing these cards is no longer required to enter cinemas, theaters, restaurants, and other indoor facilities. In June, the Puskás Stadium in Budapest hosted Euro 2020 (European Soccer Championship) matches and the UEFA had allowed full capacity crowds of 68.000 people on each occasion.

At the end of the summer, in 2021, Hungary was the first country in Europe to allow the administration of a third vaccine, only four months after the second jab. People with low antibody levels may register for the third shot, especially those senior citizens above 65 who had received the Chinese Sinopharm vaccine, as tests showed that their antibody levels were not high enough to ensure protection against the coronavirus.

Hungary is lagging behind other EU countries in PCR testing. PCR testing is mandatory only before an invasive medical intervention, and even then, it has to be paid by the patient.

On July 13, 2021, twelve EU countries (Austria, Belgium, Denmark, France, Germany, Greece, Italy, Latvia, Luxembourg, Portugal, Slovakia and Spain) received approval for recovery and resilience funds, and on July 28, 2021, Croatia, Cyprus, Lithuania, and Slovenia also became eligible. The main aim of these funds is to boost economies and recover from the COVID-19 fallout. The European Commission has delayed approval of Hungary's recovery plan<sup>9</sup> partially because Hungary does not go far enough in combating corruption, and it potentially risks the timely arrival of billions of euros in funding. In July 2021, the European Commission's Rule of Law Report was published. It showed severe deficiencies in the rule of law in Hungary. This is especially worrying that Hungary may lose EU funds due to rule of law deficiencies.

The decision to withhold the approval of the Hungarian recovery and resilience plan<sup>10</sup> has been also motivated by the political controversy surrounding a new law

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<sup>8</sup> [www.euronews.com/travel/2021/09/14/which-eu-country-is-leading-the-covid-19-vaccination-race](https://www.euronews.com/travel/2021/09/14/which-eu-country-is-leading-the-covid-19-vaccination-race).

<sup>9</sup> The Recovery and Resilience Facility (RRF) is the largest component of Next Generation EU, the European Union's landmark recovery and structural transformation instrument. EU countries must submit recovery and resilience plans, which are assessed by the European Commission and approved by the Council.

<sup>10</sup> European Member States had to set out in their recovery and resilience plan the reforms and investments that they aim to implement by 2026. Once submitted, then the Commission assesses

passed by the country's parliament on pedophilia. The stated purpose of the law is to fight pedophilia and protect the children's wellbeing. The *Parliamentary Act No. LXXIX of 2021 on the fight against pedophile offenders and amending certain laws to protect children* was adopted in June. The contested law wanted to fix gender status at the moment of birth without the possibility to change. The new law includes a provision in the child protection system, by which the state protects the right of children to self-identity according to their gender of birth. Furthermore, in the adopted law homosexuality is regarded as harmful for children requiring minors to be protected from the "representations and popularization" of LGBTQ content in the media, and therefore children should be protected in the same way as in the case of pedophilia. As a result, the European Commission launched legal action against Hungary because of the violations of LGBTQ rights.

This indicates that the EU may start sanctioning the violation of rule-of-law by using a so-called "conditionality mechanism to freeze funds from its pandemic stimulus package before they have been disbursed. Hungary's government could potentially miss out on as much as 7.2 billion euros (\$8.5 billion) of grants from the EU recovery plan compounding Hungary's many losses during the third wave of the pandemic.

Although the government communicated that "Brussels" attacked the country and that the European Union promotes gender reassignment surgeries among minors, the EU Rule of Law Report focuses instead on the violation of media freedoms, on narrowing the independence of the judiciary branch of power, and on the emergency measures irrelevant to the public health crisis of the pandemic.

#### **IV. The Right to Health and Healthcare**

By early summer 2021, 178 million people had been infected and 3,800,000 people had died as a result of the pandemic.<sup>11</sup> In absolute figures, the United States, India, Brazil, France, Turkey, Russia, England, Argentina and Italy were the biggest losers in this pandemic.<sup>12</sup> However, if we consider the figures in proportion to the population, with more than 30,000 Covid-related deaths, Hungary had also moved into the "vanguard" by the beginning of the summer.

The pandemic has affected all human rights, from respect for privacy to freedom of speech, from freedom of assembly to freedom of employment, but one of the most important fields where everyone has been affected simultaneously is the right to health.

It would be hard to find a more controversial or ambiguous human right than the "right to health." It derives primarily, though not exclusively, from Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), and requires governments to acknowledge "the right of everyone to the highest attainable

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Member States' recovery and resilience plans within two months after submission and translates their content into legally binding acts.

<sup>11</sup> Since the submission of this chapter by the end of May 2022, 529 million people had been infected and 6,280,000 people had died as a result of the pandemic.

<sup>12</sup> Johns Hopkins University Coronavirus Resource Center, [coronavirus.jhu.edu/map.html](https://coronavirus.jhu.edu/map.html), last accessed on September 15, 2021.

standard of physical and mental health.”<sup>13</sup> The pandemic situation has drawn our attention to the fact that the right to health has a fundamental role underpinning all other rights and it is instrumental in the exercise of other fundamental human rights, as well. If I have no access to basic and necessary healthcare, I cannot exercise my right to free speech or any other rights while I am ill, feverish or lacking medical care, and my right to freedom of assembly is also restricted in the event of an epidemic.<sup>14</sup>

The right to health has always been strongly influenced by the nature of government involvement, by a stronger or weaker form of welfare society, or its complete rejection, and by healthcare expenditure.<sup>15</sup> In the first wave of the Covid epidemic, the problem was not only related to the availability of Covid-related care and tests; a wide range of healthcare services also became simultaneously inaccessible.

In the field of healthcare, the greatest disruption has been the challenge to maintain treatment for conditions unrelated to the Covid pandemic. One thing that soon became clear was that our healthcare system was facing a serious ordeal. Fortunately, Hungary was only minimally affected by the spring wave of the epidemic but, despite this, the healthcare system is being almost completely reorganized, with most healthcare services becoming inaccessible. During the epidemic, it became obvious that while equipment purchases can be implemented relatively quickly, it is however impossible to remedy infrastructure deficiencies, train healthcare staff or increase capacity in a suddenly unfolding crisis.

The right to health has been seen by many as a mere exaggeration of the human rights optimism emerging after World War II. In recent years, neo-liberal economic approaches have given the market a dominant role in this area, and in many cases, they have also intended to build health care on pure market foundations.

Apart from the many tragic ramifications of the Covid-19 epidemic, the prime lesson to be drawn is that the right to health is an integral part of the catalogue of fundamental rights, and that without health, or where health is permanently threatened, people cannot exercise their fundamental freedoms. Moreover, the right to health is also closely linked to the right to life, and therefore any sudden, drastic restriction of the right to health may have a negative impact on the right to life, as well.

Although the provision of healthcare services undoubtedly requires substantial budgetary resources, this pandemic has shown that health care must have priority over many other state-subsidized activities. During the epidemic, human lives were reduced to mere figures, reported daily. In the third wave, by early summer 2021, the epidemic had already claimed the lives of nearly 30,000 of our fellow citizens, representing one of the worst mortality rates per capita in the world. The epidemic has not only isolated people physically, socially but also emotionally, and to date there

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<sup>13</sup> Jennifer Prah Ruger, 'Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements', *Yale Journal of Law and Humanities*, vol. 18, no. 2 (January 2006): 3.

<sup>14</sup> Judit Sándor, 'Rebalancing Human Rights at the Time of Covid-19 Pandemic', *Právni zprávy*, vol. 11, no. 2 (2020): 385–412.

<sup>15</sup> Máté Julesz, *Az egészséghez való jog* [The Right to Health] (Budapest: Medicina, 2020), p.105.



has been no collective mourning, apart from a few individual initiatives. All this is a conscious evasion of what is undoubtedly a trauma that is hard to handle.<sup>16</sup>

Since the primary responsibility for dealing with the epidemic lies with our healthcare system, at what stage it is confronted with such a serious epidemic is not irrelevant. The main lesson of the epidemic so far is that, when planning healthcare resources, it is always worth planning for a little more in anticipation of just such an unanticipated event. The epidemic also showed that, in spite of the existence of private health care, many elements of the epidemic typically require community-based care. Even those who thought they could afford higher levels of care and therefore could opt out of the community perspective, are dependent on public health measures to eliminate the pandemic.

The Hungarian Government did everything to avoid facing moral questions raised by the pandemic. One method for keeping this cold-minded approach was applying military rhetoric in government communication that would not allow any expression of empathy, any mechanism of deliberation involving the negotiation of expert recommendations, or any debate or critical remark on handling the pandemic. Just like in times of war, measures were announced on a weekly basis and had to be followed without any reflection for the sake of public safety. In the media the Chief Medical Officer, police officers on her side, declared the actual policy. General measures that represented a turning point in handling the pandemic were always announced by the Prime Minister.

Besides the militarization of pandemic control that required discipline from everyone, the other official way the government dealt with the pandemic was based on pure rational, economic calculations. Not showing any compassion towards the victims and their families, the daily report of the government only listed the age and the underlying disease of the victims, reducing human beings into numbers.

After the second wave, economic arguments against lockdowns became more frequent. The government faced the choice between safeguarding public health and fostering economic recovery and stability. A large segment of the population also wanted to return to their normal lives without limitations. Although Sandel's analysis of the moral limits of the market does not deal with healthcare, the issue can be approached not only from a human rights perspective but also from a moral angle.

Prolonged limitations on the right to health not only endanger the right to life and healthcare, but also seriously impact human dignity. Many people who suffered pain and uncertainty due to delayed or unavailable diagnosis felt that their dignity was not respected. Individual needs were erased as the major focus was on containing the spread of infections. Those who were hospitalized and died at the hospital could not see their relatives before their deaths. Because of the serious workload imposed on the health care workers they were often not able to communicate with the victims' relatives in time.

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<sup>16</sup> Judit Sándor, *Az eutanázia kontextusai* [Contexts for Euthanasia], *Litera*, June 29, 2021, available online at [litera.hu/irodalom/publicisztika/sandor-judit-az-eutanazia-kontextusai-szeljegyzetek.html](http://litera.hu/irodalom/publicisztika/sandor-judit-az-eutanazia-kontextusai-szeljegyzetek.html), last accessed on September 15, 2021.

Intensive care units have become total black boxes, especially because the media could not enter, and the Hungarian public saw COVID departments and intensive care units only from the foreign press.

Article 3 of the Oviedo Convention lays down the principle of equitable access to health care. According to this article, “Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.” The Bioethics Committee of the Council of Europe also highlights the importance of this passage in the implementation of the vaccination procedures that are just starting. The interpretation of equity in the context of the epidemic is not clear. Although there are different possible principles of classification, the question is how applicable the classification principles used during disasters are in the event of a prolonged epidemic. Thus, while for a shorter period of time it is easy to give up treatment in favour of the epidemiological care of others without endangering one’s health or life, in the longer term this is a disproportionate burden. There are some interventions that, if not performed, will result in a permanent deterioration of one’s quality of life. Although not incompatible with life, the outlook for and quality of life will be permanently impacted if vascular surgery is not performed because of the epidemic and an otherwise salvageable leg must be amputated instead.

## **V. Vaccination Order and Certification**

As soon as vaccines against coronavirus became available, new questions emerged that had also not yet been resolved. For example, who should have priority in the order of vaccination, and based on their age, occupation or illness?

The CDBI document<sup>17</sup> also deals with the vaccination of people in vulnerable situations, so the vaccination of people with physical and mental disabilities, minorities, homeless people, refugees, asylum seekers and even migrants should also be provided. This is not only dictated for humanitarian reasons, it is also necessary for the protection of society at large, as vaccination is also in the interest of society as a whole.

The choice of being vaccinated or not was so far clear in the Hungarian public health law. There are compulsory vaccinations listed and voluntary ones. During the COVID pandemic, however, a new category has emerged, as in the case of the various COVID-19 vaccines, it was voluntary and not compulsory, but people without vaccination faced several restrictions in their daily lives. As to the choice between various types of anti-covid vaccination, the decision should be based on medical aspects and discussed with the patient. After all, it is the patient who bears the consequences of the decision. Since this type of vaccination is voluntary, and the patient is protecting both themselves and the community by deciding to have the vaccine, then the patient cannot be circumvented in any way. The health aspects of the vaccine provided to the patients must be transparent and providing it must not be based on coercion. In 2021 in Hungary, there was strong political pressure in favor

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<sup>17</sup> Covid-19 and Vaccines Ensuring Equitable Access to Vaccination during the Current and Future Pandemics [rm.coe.int/dh-bio-statement-vaccines-e/1680a12785](https://rm.coe.int/dh-bio-statement-vaccines-e/1680a12785), downloaded on 17 June 2021.

of the so-called Eastern vaccines, Sinopharm and Sputnik-V. Minister for Foreign Affairs often appeared in the airport receiving help from Russia and China while the help from the European Union was not mediated.

From a legal and ethical perspective, patient rights in relation to voluntary vaccines against Covid are highly individual. The first fundamental difference compared to mandatory vaccination is that the patient voluntarily decides to take the Covid vaccine. This also implies, for example, that they have fewer rights in terms of government compensation than in the case of mandatory vaccinations. This is because, in the case of mandatory vaccination, if a person subject to the vaccination requirement suffers serious impairment to their health, disability or death as a result of the vaccination, the government will compensate them or their dependents. At the same time, the voluntary nature and the enhanced risks and responsibility placed on the individual also imply that they should be able to decide, in consultation with their general practitioner and taking their health considerations into account, to receive the most appropriate vaccine for their age group. Of course, the picture is nuanced by the fact that this voluntary vaccine is free of charge, so the person being vaccinated does not pay the direct monetary costs themselves. In addition, many different vaccines are available based on a variety of principles, and there are health and age-specific criteria to differentiate between vaccines. When the pandemic was raging, the priority was to get as many people as possible vaccinated as early as possible. However, everyone was also free to consider whether to choose an early vaccine, whatever it was, or whether to wait for the vaccine that best suited their condition, perhaps later. Nevertheless, we can only determine the differences once we know enough about the vaccines. In any event, the administration of a voluntary vaccine must not be based on extortion, deception or even on the basis of consent obtained through pressure, because then it is no longer voluntary but coercive. Uncertainty over vaccines was also fueled by lack of information. A medical consultation hotline could have been established, or the online registration system made more interactive, allowing feedback to the patient on their expected date of vaccination and the choice of vaccines. This is because a great deal of stress is caused by people who, being unsure whether their registration was successful because they do not receive any information, would call their general practitioner, who becomes overwhelmed and unable to answer these questions, every day.

As vaccines became available to an increasing number of people, the idea of giving special rights to those holding vaccination certificates was developed. It raises important questions as to what the consequences might be of unilaterally restoring rights in the case of voluntary vaccination, as long as vaccination is not available to everyone.

In March 2021, the Council of Europe published a document on the human rights aspects of vaccination certificates.<sup>18</sup> The document also addresses the protection of sensitive data on vaccine certificates. The issues of privacy and data security have always been at the core of epidemic management.

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<sup>18</sup> Council of Europe (2021) Protection of Human Rights and the “Vaccine Pass”, [rm.coe.int/protection-of-human-rights-and-the-vaccine-pass/1680a1fac4](https://rm.coe.int/protection-of-human-rights-and-the-vaccine-pass/1680a1fac4).

The European Court of Human Rights issued a ruling on mandatory vaccinations in April 2021. Although the vaccine involved in the case is not related to the Covid-19 pandemic, the court's reasoning may provide guidance in other vaccine-related disputes. In the *Vavricka* case<sup>19</sup>, the parents objected to the fact that their child could enroll in a Czech day-care center only after mandatory vaccination. According to the applicant, mandatory vaccination would be contrary to the right to privacy. However, the Court did not agree with this argument. "The obligation to vaccinate and the exclusion of [unvaccinated persons] was based on a law approved by parliament, and this legitimizes mandatory vaccination." The obligation to vaccinate undoubtedly interferes with autonomous decision-making, but it is justified by the protection of (the rights) of others and public health. According to the Court, this restriction is necessary and proportionate to the objective to be achieved, namely, the protection of public health. Based on the Court's arguments, it follows that, once vaccines against Covid-19 are proven safe to use, public health interests may justify making them mandatory.

As soon as vaccines against coronavirus became available, new questions emerged that had also not yet been resolved. For example, who should have priority in the order of vaccination, and based on their age, occupation or illness?

By October 15, 2021, the Hungarian Constitutional Court had received about 823 petitions related to the regulation granting benefits to the so-called covid protection certificate. The Council of the Constitutional Court accepted the joint constitutional complaints and opened a substantive investigation. In its decision published on 19 October 2021, the Constitutional Court ruled that the provisions challenged with the petition were not unconstitutional.

The mandatory vaccination of COVID-19 for healthcare workers were subject of several constitutional complaints. By October 15, 2021, about 250 petitions had been received in the field. In its decision published on December 3, 2021, the Constitutional Court found that the impugned provisions were not unconstitutional.

## **VI. Reconciliation of Autonomy and Community Aspects**

One of the most important 20th-century achievements of bioethics and human rights is the recognition of autonomy in health interventions. Informed consent based on autonomy lays the ethical foundation for medical care. We are used to this, and perhaps the most difficult aspect during the epidemic was the temporary surrender of autonomy because of community interests regarding the epidemic. People were not allowed to choose their medical treatment; they were often deprived of access to medical care and had to endure many restrictive measures. In the same time, as Paolo Giordano put it, "[the] epidemic encourages us to think of ourselves as belonging to a collective. ... In the contagion we become, again, a community."<sup>20</sup>

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<sup>19</sup> *Vavříčka and Others v. the Czech Republic*, ECtHR, Applications no. 47621/13 and 5 others, judgment of April 8, 2021.

<sup>20</sup> Paolo Giordano, *How Contagion Works, Science, Awareness and Community in Times of Global Crises* (London: Weidenfeld & Nicolson, 2020).

The Charter of Fundamental Rights expresses caution in Article 35, stating that “Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union’s policies and activities.” However, it was the epidemic that showed the need for cooperation in a pandemic. While in the first wave, the most severely affected countries themselves tried to find a solution individually, in the second and third waves of the epidemic, European countries decided on a common procurement of vaccines.

From the point of view of healthcare workers, inconsistent and sudden actions, withdrawal, and reorganization of treatments are issues that deeply affect their own professional integrity and also cause unpredictable traumas. Not only have many health workers and doctors around the world died from the infection, but we know of suicide cases<sup>21</sup> and mental breakdowns that can apparently persist even after the epidemic has subsided. A wider ethical approach also takes into account the psychological support that health workers exposed to increased mental-physical strain receive, including more frequently available rest periods.

Only if all these steps are taken together, they can alleviate the psychological stresses generated during the health care carved in military form, so that a physician-patient relationship which is ideal for healing, yet honest and humane, can develop after the pandemic has subsided. By curbing the epidemic, we hope that we will soon find ourselves once again in the health conditions of the 21st century, and that we will once again be able to report on the positive health effects of the latest technologies.

Health is closely associated with the concept of human dignity. Wiktor Osiatyński also refers to the fact that the right to health is as closely associated with human dignity as the first-generation rights in the human rights catalogue.<sup>22</sup> The rigid separation of the different generational rights is based only on a taxonomic, structural distinction rather than a justifiable, principled one. At the same time, the right to health obviously does not mean a legal assurance or guarantee of health, since health has many genetic, environmental and other factors, but no one can be excluded from the conditions for maintaining and preserving their health.<sup>23</sup>

## **VII. Data Protection, Surveillance, Epidemic Management**

The pandemic management has also seriously affected the rights to privacy and data protection. Five days after the declaration of the state of emergency on March 11, 2020, Government Decree 46/2020 (III.16) stipulated that the Minister in charge of innovation and technology is entitled to access and manage any personal details in the possession of state and municipal bodies, business organizations and even private

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<sup>21</sup> Bryn Nelson and David B. Kaminsky, COVID-19’s Crushing Mental Health Toll on Health Care Workers, *Cancer Cytopathology*, vol. 128, no. 9 (September 2020), 597–598. Available at [acsjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/cncy.22347](https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/cncy.22347), last accessed on September 15, 2021.

<sup>22</sup> Wiktor Osiatyński, *Human Rights and Their Limits* (Cambridge: Cambridge University Press, 2009), 129.

<sup>23</sup> Thérèse Murphy, *Health and Human Rights* (Oxford: Hart, 2013), 42–43.

individuals. The same authorization was granted to the so-called Operational Corps by Government Decree 83/2020 (IV.3.) with regard to personal data processed in the Electronic Health Service Space. The Government Decree 179/2020 (V.4) suspended the right of the person concerned to be informed in advance before the start of data processing, and increased the time limit for the release of data of public interest from fifteen days to two periods of forty-five days, i.e. ninety 90 days. Registration for vaccinations was also based on a central registration system run by the government. Later on, an immunity certificate confirming vaccination against the disease, which also included the passport number and the personal identity card number was adopted. Centralization of data management can be also observed elsewhere due to the epidemic, as well as the implementation of regulatory monitoring and epidemiological surveillance through a digital application for cell phones. After the third wave has abated, checking passengers according to various criteria, taking their temperature, testing them and accepting their immunity certificates in whole or in part also means that surveillance has been normalized. It is important to see the difference between monitoring and health care. While these regulatory epidemiological measures aim to curb an epidemic, they do not amount to the provision of health care. No matter how perfect the application, or even if it is downloaded voluntarily, monitoring alone does not result in health care. A technocentric view may complement it, but in no way replaces health care.

Even before the Covid pandemic, the widespread use of artificial intelligence, robotics, and information technology, capable of being used for surveillance, urged the rapid inclusion in human rights law. Without it, this model seeks to build up complete surveillance: to map the movements and contacts of the individual. During the pandemic, these tools are useful, and this digital monitoring is in many ways more convenient. However, there are fears that the resulting convenient governance will persist through the management of data, and that certain rights, such as travel and freedom of movement, will become the privilege of a privileged class.

Numerous countries have introduced applications for contact tracking and reporting. Apart from containing useful information, such as test sites near a person's home, they also indicate contact with an infected person. In France, the StopCovid application, developed by INRIA (National Research Institute for Digital Science and Technology), was released on June 2, 2020. On May 29, 2020, a decree (Decree No. 2020-650 of 29 May 2020 on data processing, known as "StopCovid") was issued, which lays down the final legal framework for implementing the application.<sup>24</sup>

In China, the social credit system that was already in use<sup>25</sup> has rendered monitoring individuals an integral part of everyday life. When personal data are collected and used for public safety purposes, the consent of the persons concerned is not required. The publication on COVID-19 monitoring mechanisms issued by

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<sup>24</sup> <https://www.gouvernement.fr/info-coronavirus/tousanticovid>, last accessed on September 15, 2021.

<sup>25</sup> Katja Drinhausen and Vincent Brussee, China's Social Credit System in 2021: From Fragmentation towards Integration, *MERICCS China Monitor*, March 3, 2021, available at [merics.org/en/report/chinas-social-credit-system-2021-fragmentation-towards-integration](https://merics.org/en/report/chinas-social-credit-system-2021-fragmentation-towards-integration) download date, last accessed on September 15, 2021.

the Chinese Cybersecurity Directorate stipulates that organizations authorized by the National Health Committee are entitled to collect this data without a permit.<sup>26</sup>

Tracking for epidemiological reasons must not be more extensive than justified, nor may it be self-serving, threatening, or withholding data or sharing it for other purposes. Tracking that complies with human rights standards must be aimed at combating the epidemic, providing access to care and should in no way be a substitute for health care.

### **VIII. What could be the Human Rights Implications of the Pandemic?**

Digitized management of the pandemic, with tracking, can become permanent if citizens become used to making their data available. Another possible scenario leads to improving health care, rebuilding elements of the welfare state based on lessons learned from the epidemic. Reallocating budgetary resources to health, for example from prestige projects, or through expressing solidarity in the taxation system. Increased recognition of the work of healthcare staff, especially nurses and specialist nurses, and adequate financial recognition of their work is also an important element of preparedness for epidemics. But this model does not mean abolishing freedoms or limiting privacy and liberty. After curbing the epidemic, making up for missed interventions, accelerating interventions on waiting lists and mental health care will increase demand for health care for years to come.

The current slow-down<sup>27</sup> of the Covid pandemic in Europe is not only a time for relief, but also calls for important and urgent social changes. This global human catastrophe has drawn attention to the vulnerability of human dignity and health, and of humans in general. It is not enough to cover ethics in a formal way, as there is a need for more serious environmental, veterinary and food monitoring, more social control of virological laboratories, and closer international cooperation and solidarity during a pandemic. Many people have already emphasized the need for a new social contract<sup>28</sup>, but after this pandemic we simply cannot continue where we left off. Updating the catalogue of human rights and ensuring that second generation human rights, in particular the right to health, are duly recognized and that appropriate conditions for their enjoyment are provided are absolutely necessary.

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<sup>27</sup> During the summer of 2021.

<sup>28</sup> Minouche Shafik, *What We Owe Each Other: A New Social Contract* (London: The Bodley Head, 2021), 71–93.

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# THE COVID-19 SYNDEMIC IN THE AGE OF DISTRUST

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“Humans are an intensely cultural species.”  
Joseph Henrich

## **Abstract**

The COVID-19 syndemic has arrived in a neoliberal era, an age of rising distrust in authorities, be it the state, science, or medicine. This attitude appears in the vaccination scepticism or anti-wax movement. Vaccination is the most expected solution and, simultaneously, the most suspicious weapon against the virus. The vaccine-distrust problem cannot be tackled only by following some causal lines; the phenomenon can be understood if it is put in the context of the atmosphere of contemporary Western culture. In this age of distrust, a new relationship, a dialogue between the professional and lay knowledge, is unavoidable.

## **I. The virus as a mirror – of what?**

Byung-Chul Han - one of the most influential thinkers these days – stated, “The virus is a mirror. It shows what society we live in.”<sup>1</sup> We could say that a mirror can be a good tool for seeing ourselves exactly how we are, not leaving space for narrating self-phantasies. The mirror can show things as they are – without distortion. In the late 19th century, photography was a mirror, a new scientific tool for guaranteeing objectivity. We know now that an image in a mirror or a photo is not so straightforward and always provokes interpretation: the mechanical objectivity as an expression of the scientist’s fight against his “inner enemy”, that is, subjectivity, has turned into expert knowledge.

“Subjectivity became an important feature of classification because the objects did not demonstrate universal essential properties and because in

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<sup>1</sup> Byung-Chul Han: COVID-19 has reduced us to a “society of survival”, [www.efc.com/efc/english/destacada/byung-chul-han-covid-19-has-reduced-us-to-a-society-of-survival/50000261-4244328/](http://www.efc.com/efc/english/destacada/byung-chul-han-covid-19-has-reduced-us-to-a-society-of-survival/50000261-4244328/) (accessed July 21, 2021).

the mid-twentieth century a growing number of scientists across many fields began to take it as a good thing that people could be trained to classify objects univalently even in the absence of strict protocols.”<sup>2</sup>

Therefore, the idealized impartiality and objectivity of the photo images as pure mirrors of the things in the world have lost their plausibility. Even high-tech imaging and medical technologies (CT, MR, PET scan) can provide images that need interpretation by trained experts – these interpretations can differ among experts. So an image in a mirror or a photo is not a sanitized picture of the “real thing” – it gets an interpretation of what was never a pure something.

In the documentary “The Perfect Vagina”<sup>3</sup> (presented by Lisa Rogers), a young mother who has been preparing for her labia plastic surgery (“trimming it”) is not able to see her genitals in a mirror because she is so “spooked” or even frightened by the image. She escapes from the situation and needs some time to return and be brave enough to get accustomed to the view. So the mirror image can help to accept this part of her body which was at the same time a “closed notebook” with stories about her life and her identity in it. In this context, the virus is a mirror where we can see what we are afraid to see.

We can also refer to another meaning of the mirror in Jaques Lacan’s theory on a mirror phase of a person’s psychic development.<sup>4</sup> The fragmented feeling of the body of a very young child is a basis of an alienated but at the same time ordered and unified image of the self by creating this integrated self-image looking in the mirror of the mother’s reactions. In this context, the virus is a mirror through which we can organize and make an orderly image of a seemingly disconnected and fragmented social and cultural landscape.

Furthermore, of course, the mirror can be a vehicle for creating a narcissistic self-image. In this case, it profoundly differs from the original myth, where Narcissus’s love for himself is seemingly purely a relationship between him and his mirror image. Narcissus could not love somebody else and was punished with self-love; the post-modern narcissistic personality self-love may be a reaction to being raised in an emotionally unstable and less supporting environment. In this context, the mirror is a vehicle by which we can adore our superior culture, offering tools and means for controlling the threatening aspects of our lives. “We are the best; therefore, we can control the virus in the best possible way.”

The philosopher’s intention in connecting the virus pandemic and a mirror is that the mirror image is not only a “truth-to-nature picture” of the pandemic but a kind of image in an atlas of viruses, but the virus means much more than a purely biological agent. It is a social and cultural agent at the same time. It is open to attraction and can be the focal point of different meanings; it can even have a mesmerizing power that some meanings can have severe consequences without a

<sup>2</sup> Lorraine Daston, Peter Galison, *Objectivity* (New York: Zone Books, 2007), 335.

<sup>3</sup> <https://www.youtube.com/watch?v=nw9qKBI4D3o> (accessed July 21, 2021).

<sup>4</sup> “...the mirror stage is the advent of coenaesthetic subjectivity preceded by the feeling that one’s own body is in pieces. The reflection of the body is, then, salutary in that it is unitary and localized in time and space.” Anika Lemaire, Jaques Lacan, (London, Boston and Henley: Routledge & Kegan Paul, 1981), 81.

factually strict basis. In Franz Anton Mesmer's case, the scientific committee led by Benjamin Franklin decided that the scientific-like theory that was well-embedded in the scientific era of that period could not be proven, but the therapy worked in some way. In a similar way, the power and capacity to prevent a severe disease are so straightforward from a scientific point of view. It is not understandable why it is unacceptable or at least suspicious for many people; how distrust could work, even if it is against scientific rationality. The vaccine and its appearance in our cultural mirror could straightforwardly show what kind of life we live; we cannot escape from the context of our lives, and we are obliged to see ourselves in the mirror of the virus and its consequences.

COVID-19 arrived in a culture and a society that is increasingly exhausted, depressed, chronically fatigued, and open for bodily disorders as asylums and "safe places". People of high modernity can hide and get some rest from the challenge of neoliberal norms and consumer lifestyle requirements. In a culture where the meaning of life is systematically and consequently undermined, the virus can appear as a life-threatening danger and, at the same time, a phenomenon that can cover and overwrite our culturally constructed life problems and change the intangible burdens into a clearly defined enemy. In this role, the virus is not part of us, is not connected to us, and is not coming from us. Still, by substituting anxiety and exhaustion, which has no detectable causes, it is an almost perfect "material" to suck into itself the life difficulties and change them into "real" medical problems. Of course, the virus is materially actual, and precisely this is what makes it a proper tool with which we can sweep all the dirt of our cultured life under the carpet. It is more than symbolic that the so-called introverted people often feel better in a lockdown-like situation than the extroverted ones. They could get some holiday from an uncertain, anxiety-provoking, exhausting life. The performance and competition principles have weakened, and the appearance and cosmetics, both literal and metaphoric, are unnecessary, at least for the time being.

"While suffering afflicted many during lockdown, others, less exposed to its various stresses, began to flourish in unexpected ways, which was the side of the story that new capitalism, judging by the coverage, was far less likely to report. [...] Our COVID confinement, it seems, had brought deep questioning of our pre-COVID neo-liberal lives. Many people were relieved to be temporarily away from jobs they disliked or found dissatisfying and unengaging. Others found unsought-for opportunities to spend more time with immediate family, to rekindle and deepen connections, to read, to reflect, to walk and to exercise. As the everyday maelstrom of neo-liberal living dissipated, so our vision also provisionally cleared. With fewer distractions, many were able to adopt a more philosophical cast of mind, bringing neglected feelings, thoughts and life questions to the fore. We were forced to shop and consume less, to live life more slowly and modestly."<sup>5</sup>

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<sup>5</sup> James Davis, *Sedated* (London: Atlantic Books, 2021), 232-233.

In this way, homes (home offices) have become caves. One does not exist (to the outside world) for the time being. The pressures and challenges of the “out there” can be disclosed by referring to the virus. Like in Plato’s cave, the truths of life may be distorted, but this kind of untruth can have soothing and slowing down effects on the prevailing thoughts and actions. People can “annihilate” themselves for the world outside the “cave” and for themselves. This attitude can alleviate the exploitative power of the performance principle: “It does not matter whether I am able to do anything at all because I do not have to do them ‘thanks to the virus.’”

The virus is not only a life-threatening entity to our biological being but a lifesaving one for providing a kind of oasis in the desert of neoliberal life (c.f. cave and oasis, a circumscribed place different from the surrounding environment) as well. This life in the cave and the oasis is another kind of life.

A mandatory rest now is unavoidable and legitimate without a bad conscience. Of course, this “without” is not a perfect expression because the taste of the pace and pressures of the pre-COVID-19 era are still with us as part of the wished returning to the previous way of life and as a threat of returning to the so-called normalcy of everyday life as well. The addiction of the experience that we can only be alive if we keep pace with the rules and orders of achievement culture causes “withdrawal effects”. The feeling that some things are missing in our life more than the often superficial socializing, we are not good enough, and cannot meet the requirements of the neoliberal performance principle. Bad consciousness arises because we are not doing something we should do; the virus holiday is not well-deserved.

The extroversion and introversion dimensional distinction (C.G. Jung) is not purely about inbuilt character differences but two different lifestyles in various cultures as well. The extroverted fare better, at least seemingly, in a neoliberal society, while the introverted may like a slower, less competitive lifestyle. That is why the failure of the extroverted person to follow the mainstream requirements is more apparent than the already abnormal lower, seemingly depressed, or even autistic mood of the introverted. If we take depression not as a valid DSM-like disorder category but rather as a psychic reaction pattern, an up-to-date reflection of the harms of contemporary Western life, then the disorder has become as orderly as any other kind of normal adaptation to a human environment. Behaviour that seems disordered from an outside perspective can give the “abnormal” person a feeling that “everything is in order if I am allowed to follow my style of life”.

Against any essentialist approach, it seems that the contemporary kind of depression that is feeling hopelessness, helplessness, the emptiness of life is not an old-fashioned experience, a variety of essentially the same mood in every culture and period, but something relatively new from a historical point of view, which was never before in Western history. Therefore, it has a different kind of psychic aetiology. It seems that the contemporary “deep sadness” has a double-faced characteristic. On the one hand, it causes suffering, sometimes on an unlivable level. This feature gravitates towards the disorder category, hence the current deep-seated medicalizing processes in our culture, i.e., every aspect of life that is not positive and causes a little worse than good feelings, should be seen as disorders, therefore, diseases. Bad

experiences are abnormal and should not be parts of everyday, normally happy, contented life.

On the other hand, one of the biggest problems with this abnormalcy is that it is so widespread. The WHO announced a few years ago that depression is among the highest disease burdens.<sup>6</sup> Even if we put aside the issues related to the validity and reliability of depression as a diagnostic category, we have to accept that the tendencies regarding our mental life expressed in the WHO statement are actual and almost typical in our culture. So, depression is, at the same time, a disorder and an experience in order; it is a disease because it causes suffering and a general mood or mental reaction to how we live in these times.

“... [depression] erupts at the moment when the achievement-subject is no longer able to be able [nicht mehr können kann]. First and foremost, depression is creative fatigue and exhausted ability [Schaffens- und Könnensmüdigkeit]. The complaint of the depressive individual, ‘Nothing is possible,’ can only occur in a society that thinks, ‘Nothing is impossible.’ No-longer-being-able-to-be-able leads to destructive self-reproach and auto-aggression. The achievement-subject finds itself fighting with itself. The depressive has been wounded by internalized war. Depression is the sickness of a society that suffers from excessive positivity. It reflects humanity waging war on itself.”<sup>7</sup>

This depression is not that Freudian kind that one can fight against trying to find the roots of the repressed guilt feelings, and after realizing the “true” story of one’s life, one can build a new narrative for new meanings. The old-fashioned depression era has an embedded optimism: the deep sadness could be changed because it is rooted in the individual’s history, and one can and should work on it with a therapist (surrogate priest). There is no effective medical therapy for the “new edition” of depression as it is a product of the final phase of a Western culture seemingly without alternatives. It seems fundamental and unchangeable partly because the individual has no mental and moral capacity to escape it. “Before we can throw bricks through windows, we need to be able to get out of bed.”<sup>8</sup>

As in the previous era, there was also a hope that the sufferings it caused (e.g., Freudian depression) could be alleviated beyond individual therapies by emancipatory social movement – there were visions and beliefs that could give some hope. As it seems neoliberal capitalism has no alternative (end of history), the hope

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<sup>6</sup> “By the year 2020, if current trends for demographic and epidemiological transition continue, the burden of depression will increase to 5.7% of the total burden of disease, becoming the second leading cause of DALYs lost. Worldwide it will be second only to ischaemic heart disease for DALYs lost for both sexes. In the developed regions, depression will then be the highest ranking cause of burden of disease.” The World health report: 2001: Mental health: new understanding, new hope, 30., [https://apps.who.int/iris/bitstream/handle/10665/42390/WHR\\_2001.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/42390/WHR_2001.pdf?sequence=1&isAllowed=y) (accessed July 21, 2021).

<sup>7</sup> Byung-Chul Han, *The Burnout Society* (Stanford, California: Stanford University Press, 2015), 10-11.

<sup>8</sup> Mikkel Krause Frantzen, *A Future with No Future: Depression, the Left, and the Politics of Mental Health* (Los Angeles Review of Books, December 16, 2019.) <https://lareviewofbooks.org/article/future-no-future-depression-left-politics-mental-health> (accessed July 21, 2021).

has been lost that related mental suffering can be changed. It is one's personal problem, closed in one's mind, but one has no power to solve it. People cannot fight against the system because they are forced into their beds or sedated by a consumeristic lifestyle or medications.

“What goes wrong, when people suffer our contemporary form of depression, is not simply that they cease to experience pleasure or happiness, but that they lose the will or ability to seek pleasure or happiness. It is not that they become unhappy per se, but that they lose the mental – and often the physical – resources to pursue things that might make them happy. In becoming masters of their own lifestyles and values, they discover that they lack the energy to act upon them.”<sup>9</sup>

“Depressed individuals were not speaking in terms of shame or repressed desires any longer, but merely in terms of their own weakness and inadequacy. If anything, it was an absence of desire that afflicted them, more than a bottling up.”<sup>10</sup>

Maybe the depression, the lost capacity for desire, is a good mirror because it can show how things typically run nowadays. The COVID-19 virus broke suddenly into this culture-wide depression. The virus is like a stone thrown into the “comfortable, smooth, reasonable, democratic unfreedom”<sup>11</sup> surface of the mirror of our advanced industrial civilization. People who are not able to get out of their beds cannot be subversive agents. The virus could crack the mirror's smooth surface, or at least it could scratch it. That is how the light gets in, or at least another kind of diffraction was created by COVID-19. The cultural reality and its mental mirror (depression) cannot live on in their taken-for-granted way; hence the pieces of the mirror show how our seemingly ordered (even depressingly organized) life is so disordered from a humanistic perspective and that depression is not a health problem that can be narrowed into a medical view. It is instead a cultural problem of wholeness (health). Beyond the seemingly benevolent surface of the happiness industry plays an unforgettable part in the production of depression, a catastrophe had been prepared and waiting for a triggering episode. This event would show the failure to cheat ourselves that our existentially anchored depression can be treated with medical technology following our cultural self-deception that our existence is not as fragile as before the modern technological culture. In reality, it is more fragile because this culture-wide depression is not caused by some “biochemical imbalance in the brain” but by severe imbalances in our existence.

## II. COVID-19 as a syndemic

The arrival of COVID-19 seems to be this kind of trigger episode. The COVID-19 virus is running around the globe, propelled and influenced by our culture's complex way of life. To express this multi-level phenomenon, a particular, previously coined

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<sup>9</sup> William Davies, *The Happiness Industry* (London-New York: Verso, 2016), 176-177.

<sup>10</sup> *Ibid.*, 164.

<sup>11</sup> Herbert Marcuse, *One-Dimensional Man* (London and New York: Routledge Classics, 2007), 3.

term was reused to show the complexity of the problem - that is syndemic. By this concept, the Editor-in-Chief of *The Lancet* has the aim to express special features of this pandemic: "Syndemics are characterized by biological and social interactions between conditions and states, interactions that increase a person's susceptibility to harm or worsen their health outcomes."<sup>12</sup>

Syndemic theory<sup>13</sup> is more or less translating the biopsychosocial model of diseases into the population level and connected to a system or network approach. It is a relationship between different biological agents and social and cultural factors. Every factor is plural in a syndemic: disease, cultural and social factors.

In his editorial, R. Horton used the term as a sign of an unavoidable reframing of the new pandemic because our societies need hope. "Approaching COVID-19 as a syndemic will invite a larger vision, one encompassing education, employment, housing, food, and environment."<sup>14</sup>

Taking into account this "beyond pure virology" approach of the "COVID-19 complex," a broader point of view is needed to understand what is happening with us these days, what kind of cultural milieu the COVID-19 has arrived in because the biological agent in itself can only be one "player" in a game of a syndemic.

Of course, neither pandemic nor endemic was taken as a purely biological phenomenon before. The natural agent was always considered a necessary but insufficient cause of an epidemic. The famous example in New Guinea in the late fifties and early sixties of the 20th century, the Kuru disease, was partly caused by an unknown biological agent (prion) and cannibalism as a cultural habit of the Fore people. However, the biological agent was not detected initially, mainly because of the highly long incubation period in the lab experiment. Therefore the researchers were compelled to turn to epidemiological data, and the official ban on cannibalism was related to the disappearance of new cases among children. So the primacy of biological as the usual "habit" coming from the value hierarchy of biomedical research was not tenable. This case is a clear example of the co-working of biology and culture. The Kuru could not have been one of the leading causes of death or even existed in that tribe if one of these causal factors had not been present. The Kuru epidemic is prion + cannibalism.

The other famous and founding example of our contemporary complex view is Thomas Mackeown's thesis that the decline of the death rate from infectious diseases is generally but questionably referred to as one of the biggest successes of biomedicine, namely using a "bioweapon," i.e., vaccination. He showed that decreasing death cases started much earlier and stronger before the population-level vaccination programs. Again cultural-social forces played a significant role in the

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<sup>12</sup> Richard Horton, "Offline: COVID-19 is not a pandemic," *The Lancet*, Vol. 396 (2020): 874.

<sup>13</sup> "Syndemics are defined as the aggregation of two or more diseases or other health conditions in a population in which there is some level of deleterious biological or behaviour interface that exacerbates the negative health effects of any or all of the diseases involved. Syndemics involve the adverse interaction of diseases of all types (eg, infections, chronic non-communicable diseases, mental health problems, behavioural conditions, toxic exposure, and malnutrition)." Merrill Singer, Nicola Bulled, Bayla Ostrach, Emily Mendenhall, "Syndemics and the biosocial conception of health," [www.thelancet.com](http://www.thelancet.com) Vol 389 March 4, (2017): 941-950

<sup>14</sup> Horton, *Offline: COVID-19 is not a pandemic*.



development: of hygiene and, generally speaking, better life regarding its material aspects. Medicine's direct impact was less critical than its indirect role.<sup>15</sup>

Even after debates about MacKeown's legacy, there is an agreement about the message of his book "The Role of Medicine: Dream, Mirage or Nemesis":

"In general, medical measures (both chemotherapeutic and prophylactic) appear to have contributed little to the overall decline in mortality in the United States since about 1900 – having in many instances been introduced several decades after a marked decline had already set in and having no detectable influence in most instances. More specifically, with reference to those five conditions (influenza, pneumonia, diphtheria, whooping cough, and poliomyelitis) for which the decline in mortality appears substantial after the point of intervention – and on the unlikely assumption that all of this decline is attributable to the intervention – it is estimated that at most 3.5 percent of the total decline in mortality since 1900 could be ascribed to medical measures introduced for the diseases considered here."<sup>16</sup>

All of these arguments point to the conclusion that diseases/pandemics are always more than biological phenomena. Therefore, giving a name to a disease based on a causing biological agent can create a casual imbalance. It can make an impression with the help of a culturally deeply rooted biomedical ideology that the cause and the solution of a syndemic are mainly biological. "We are against a purely natural agent; we, as cultural beings, are fighting against a natural alien outsider."

The military metaphors we regularly use in reporting events in the health care system can even strengthen this impression: the enemy vs us dichotomy. The drama script emphasizes the clash between the diabolic enemy (virus) and us as fighters with the elite troops of medicine and the healthcare system. And like in the case of any big war, the problems in the heartland can be put into brackets because the main aim is to serve the fighting troops with munitions. The enemy is on the other side of the front line. In this movement, the structure of hypostatic abstraction, by which the quality of an object or a person can be detached and can be investigated as a stand-alone feature, could serve as a vehicle for a biomedical regression. At first sight, there is no considerable difference between "honey is sweet" or "honey has sweetness" sentences.

"...the hypostatic abstraction permits two affordances: first, it allows us to ask whether the first subject can be preserved analytically or empirically independently of the second subject – that is, it allows us to

<sup>15</sup> "During the first 8 decades of the 20th century, the infectious disease mortality rate in the United States declined substantially, consistent with the concept of epidemiologic transition. Improvements in living conditions, sanitation, and medical care probably accounted for this trend." Gregory, L. Armstrong, Laura A. Conn, Robert, W. Pinner, "Trends in Infectious Disease Mortality in the United States During the 20th Century", *JAMA*, Vol. 281. No. 1. (1999): 61-66.

<sup>16</sup> John B. McKinlay, Sonja M. McKinlay, "The Questionable Contribution of Medical Measures to the Decline of Mortality in the United States in the Twentieth Century", *The Milbank Quarterly* 55(3) (1977): 405-428.

interrogate essentiality; second, the reification afforded by the hypostatic abstraction allows the abstracted property to feature in judgments independently of the first subject. Applied to medicine, the hypostatic abstraction allows us to talk of conditions, disorders, and diseases – of ‘things’ a person ‘has’. It then allows us to interrogate whether those “things” belong to the person’s essential nature (the first affordance noted above). Clinical diagnosis is a form of hypostatic abstraction; it transforms a suffering human being into a human being plus suffering. Instead of saying Mahmoud is depressed, we say Mahmoud is affected with depression; instead of saying Lisandra is schizophrenic, we say Lisandra is affected with schizophrenia. Medicine operates in the logical and semantic space made possible by the hypostatic abstraction.”<sup>17</sup>

In this way, creating a diagnostic category is equal to giving birth to a new medical being; that is, a diagnosis is not only detachable from the person, but at the same time, it seems a purely biological phenomenon in its essence. The COVID-19 infection can be “walked around” without considering its broader context. With hypostatic abstraction, the name of a disease can be disconnected from the person and his/her environment. As if the title can express the essence of the whole issue.

However, the diagnostic category can be opened to a broader interpretation if we take the disease name, not simply as an expression of crucial biological factors. From a broader perspective, the COVID-19 syndemic seems like a cyclic movement between the virus as a biological agent and the complex social and cultural settings in which it is blossoming. Its habitat is not purely a “cream on the cake” aspect of the whole syndemic complex, a kind of secondary quality that enhances or lessens the impact of the virus as a biological object. Still, we must take seriously that the virus cannot live and spread without this cultural milieu. The lockdown rules have not just introduced some short-lived changes to our lives and put obstacles in the way of spreading the virus. But the lockdown lifestyle – as we discussed previously – has some features which could force some elements to create an alternative way of life: slowing down the pace of living; the closer relationship among close relatives; less action, more contemplation; more looking inside instead of taking care of more superficial aspects of personality, e.g., appearance, learning how to do nothing, not to be “useful,” purely existing, cultivating more human relationships instead of promoting relationships as social capital. As we can see, the virus does not like a slow, with few but close human relations way of life. As the virus could blossom in the post-modern fast life with lots of but superficial connections among people, the appearance of the virus put pressure on its habitat to change, namely the everyday life in our culture. The challenge of the virus compels us to change our life to find a proper response. Therefore, the virus has a survival tendency to find the most efficient way to spread, but at the same time, by compelling a change in people’s way of life, it has a suicidal tendency. It means that the biological response, a vaccine,

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<sup>17</sup> Mohammed Abouelleil Rashed, “The Identity of Psychiatry and the Challenge of Mad Activism: Rethinking the Clinical Encounter,” *The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine*, Volume 45, Issue 6, December (2020): 598–622.

would not be enough without a permanent change in how we live – returning to the “before virus status quo” is impossible unless we risk another outbreak. If we can change our way of life, then – like in the case of Kuru stopping cannibalism – we can put an obstacle in the way of the virus spreading. The virus compels us to change our lives; if we change our culture, the virus will withdraw.

The Plague was argued to be a punishment from God for the low-level moral life. The COVID-19 syndemic – even without any religious tone – is a notice (with countless other ones) that:

“To say it clear, to say it cold  
It’s over, it ain’t going  
Any further”<sup>18</sup>

### III. The WEIRD health

Western culture from the medieval centuries – especially due to the strong influence of the Catholic Church – changed and developed uniquely, creating a particular type of “weird” people (western, educated, industrial, rich, democratic). It means that the whole cultural setting, inc. the psychological, and behavioral patterns of this society, are atypical from a global historical point of view, and differ from the rest of the world. The main differences between the premodern, kin-based society and the modern one are:

- Analytic thinking: [...] people increasingly thought about the world more analytically and less holistically/relationally. [...]
- Internal attributions: As the key substrates of social life shifted from relationships to individuals’ internal attributes, thinkers increasingly highlighted the relevance of individuals’ internal attributes. [...]
- Independence and nonconformity: weak kin ties, [...] favoring individualism, independence, and nonconformity, not to mention overconfidence and self-promotion. [...]
- Impersonal prosociality: people came to prefer impartial rules and impersonal laws that applied to those in their groups or communities [...] independent of social relationships, tribal identity, or social class.”<sup>19</sup>

The main tendency is to evolve the individual, the undivided (atom) being, as the final building block of modern society with its niche and mental qualities. (From around Freud’s era, they are not undivided anymore, but “dividual” (divided)).

A unique culture was raised from a tribal, kin-based society regarding its basic norms, values, and institutions. On the one hand, by way of a materialistically highly developed environment could diminish or even eliminate some difficulties of the premodern society but, on the other hand, left the individual, the person, defenceless towards the problems created by following the requirements of a separated, individualistic lifestyle.

<sup>18</sup> Leonard Cohen, *The Future* <http://www.songlyrics.com/leonard-cohen/the-future-lyrics/> (accessed: July 21, 2021).

<sup>19</sup> Joseph Henrich, *The Weirdest People in the World* (UK, USA: Allen Lane, 2020), 396-98.

“...as society modernized, people found themselves able to live independently from any communal group. A person living in a modern city or suburb can, for the first time in history, go through an entire day – or an entire life – mostly encountering complete strangers. They can be surrounded by others and yet feel deeply, dangerously alone.”<sup>20</sup>

Life’s traumas flourish not in a society where many rough events could happen in persons’ lives but in a culture where getting wounds is relatively rare in everyday life, and the meanings of these bad experiences are weak or missing.

In the age of the Plague, life was extremely fragile, but the epidemic had some meanings (punishment from God), and death was not the end of everything but a gate into another life. The terror of the knowledge of the certainty of death was surrounded by the certainty of the afterlife. There were no effective preventive tools and means for postponing death. Still, the survival system provided culturally constructed meanings in which life was livable even in these extreme, so-called boundary situations. Tragedies did not turn into traumas.

“[Our forebears] had it worse than we did with the not-so-difficult things in life – above all when it came to securing a physical existence – but that the tough things in life, death and dying especially, were not as difficult for them. The main reason for this lay in the fact that their worldview reached further than simply the end of life on this earth.”<sup>21</sup>

Modern culture achieved some successes in postponing the moment of death (which is an accurate statement from a biological point of view). Still, parallelly, the eternal life has been lost: a little, relatively longer material life was the price for the lost eternity. As moderns, we can react to this eternal life with a faint smile; hence the more extended life on earth is real, but life after death is only an old-fashioned fantasy to us. Culture has the power to define reality. When riding a high horse, we do not realize that our value system judges our “supremacy”. We are seemingly better than our ancestors because our values are part of our culturally defined value system.

“Once the life cycle was secularized, the earthly portion of life became much more important than in earlier times, since it was all that remained. As a result, the body and everything associated with it assumed much greater significance: from diet and clothing to fitness fads, health cures, cosmetics, and the inflated claims of medicine. Good health, a perfectly functioning body, became the sole guarantee of life, indeed of one’s entire life.”<sup>22</sup>

This new reality of the relationship between life and death redefined the primary duties of medicine by giving a new one which was announced first by Francis Bacon: “...the third part of medicine which I have set down is that which relates to the

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<sup>20</sup> Sebastian Junger: *Tribes* (London: 4th Estate, 2016), 18.

<sup>21</sup> Arthur E. Imhof, *Lost Worlds* (Charlottesville and London: University Press of Virginia, 1996), 185-186.

<sup>22</sup> *Ibid*, 182.

prolongation of life, which is new, and deficient; and the most noble of all.”<sup>23</sup> (The previous two ones: preservation of health and the cure of diseases.)

Modernity, by way of secularization, destroyed the double world: immanent and transcendent ones. With the new knowledge about our inevitable death without resurrection, we lost one of the most potent cultural means for taming and alleviating the terror of death. Without the hope of an eternal afterlife, the whole complex fell back to the proper functionality of the human body, keeping it workable as long as possible. The belief that our life is not governed by transcendent powers anymore changed into the idea that our life based on our naturally given body should be controlled by the power of our (technical) knowledge. This new constellation did not bring relief or freedom experience, but more anxiety and fear of death.

The new “updated” attitude towards death also redefined the role of health. In a kind of binary opposition, two versions of health have been created:

1, in the upper one cultural position, is the new health as keeping biological death away as long as possible; keeping up the body’s working ability as long as possible

2, in the secondary, culturally lower position, the older version of health can be found. This kind of health is a life full of vital energy, and aims and purposes drive it. The proper functioning of the body is only a vehicle for attaining these horizons.

G. K. Chesterton’s reflections in this context showed a transitional period when the older position was turning upside down, and the new 20th-century health ideal was getting central place:

“The mistake of all that medical talk lies in the very fact that it connects the idea of health with the idea of care. What has health to do with care? Health has to do with carelessness. In special and abnormal cases it is necessary to have care. When we are peculiarly unhealthy it may be necessary to be careful to be healthy. But even then we are only trying to be healthy in order to be careless. [...] And humanity ought to be told to be recklessness itself. For all the fundamental functions of a healthy man ought emphatically to be performed with pleasure and for pleasure; they emphatically ought not to be performed with precaution or for precaution. A man ought to eat because he has a good appetite to satisfy, and emphatically not because he has a body to sustain. A man ought to take exercise not because he is too fat, but because he loves foils or horses or high mountains, and loves them for their own sake. And a man ought to marry because he has fallen in love, and emphatically not because the world requires to be populated. The food will really renovate his tissues as long as he is not thinking about his tissues. The exercise will really get him into training so long as he is thinking about something else. And the marriage will really stand some chance of producing a generous-blooded generation if it had its origin in its own natural and generous excitement. It is the first law of health that our necessities should not be accepted as necessities; they should be accepted as luxuries. Let us, then,

<sup>23</sup> Darrel W. Amundsen, “The Physician’s Obligation to Prolong Life: A Medical Duty without Classical Roots,” *The Hastings Center Report*, Vol. 8, No.4. (1978): 23-30.

be careful about the small things, such as a scratch or a slight illness, or anything that can be managed with care. But in the name of all sanity, let us be careless about the important things, such as marriage, or the fountain of our very life will fail.”<sup>24</sup>

Chesterton’s attitude towards health is a little strange or even seems absurd from the contemporary perspective. For him, health that is equal to a feeling whole should only be an outcome or consequence of life with aims, meanings, and a tendency towards something beyond and higher than the proper functioning of the body. If attaining a healthy, properly functioning body is the primary meaning and content of life, then - seemingly paradoxically - that life is not healthy; it cannot provide a “wholeness” experience. What was detectable in the early 20th century as a new attitude is now already one of the outstanding features of Western culture. The Chestertonian value of health has become almost entirely outdated. Today Western societies have historically and culturally unique attitudes towards health:

“Health is not inspired by any wider social vision. On the contrary, it reflects the outlook of a society which has abandoned any grand project, in which the horizons of the individual have been reduced to their own body. [...] Health is reduced to a source of consolation for people who have given up on any higher ambition. In a society of low expectations, the goal of human existence is redefined as the quest to prolong its duration.”<sup>25</sup>

We always hear that health should be the highest value. But what kind of health? What is the content and meaning of this concept nowadays? Maybe it is part of why it is so difficult to attach spirituality to the reasonably old WHO health definition, which tries to express what is later called a biopsychosocial point of view. (It seems that in the mainstream practice, it is more wishful thinking after 70 years of its announcement.) It is clear that missing spirituality is the basis for many health problems. (Especially the so-called depression.) Without which “the fountain of our very life will fail,” as Chesterton said. The missing and destructed spirituality is also a “blindspot” as well. Its absence is painful but, at the same time, rejected as a less critical factor regarding our health. It seems not inevitable in the fight to keep us alive – spirituality is not part of the surviving biomechanism of our body.

“The capitalist economy absolutizes survival. It is not concerned with the good life. [...] Concern about living the good life yields to the hysteria of surviving. The reduction of life to biological, vital processes makes life itself bare and strips it of all narrativity. It takes livingness from life, which is much more complex than simple vitality and health. The mania for health emerges when life has become as flat as a coin and stripped of all narrative content, all value. Given the atomization of society and the erosion of the social, all that remains is the body of the ego, which is to

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<sup>24</sup> Gilbert Keith Chesterton, *Heretics* (New York, London: John Lane Company, 1909), 77-78.

<sup>25</sup> Michael Fitzpatrick, *The Tyranny of Health* (London and New York: Routledge, 2005), 7-8.

be kept healthy at any cost. The loss of ideal values leaves, other than the healthy at any cost. The loss of ideal values leaves, other than the exhibition value of the ego, only health value behind. Bare life makes all teleology vanish – every in-order-to [jedes Umzu] would give reason to remain healthy. Health becomes self-referential and voids itself into purposiveness without purpose. [...] Life reduced to bare, vital functioning is life to be kept healthy unconditionally. Health is the new goddess. That is why bare life is holy.”<sup>26</sup>

If we conclude the main differences between the Chestertonian and the neoliberal health conceptions, then we find these oppositions:

<b>Chestertonian health</b>		<b>Neoliberal health</b>
carelessness	vs	care, precaution
meanings, aims	vs	prolongation of life
purposes	vs	reduced to body
		consolation (after Marx: health is the opium of the people today.
grand horizons	vs	Keep your body functional and live as long as possible.)

Health (wholeness) disappeared (in reality) but became a central theme (as the highest value) together with its reduction to the proper working of the body (medicalization). This culture-wide conversion (hysteria) of life problems gives outstanding importance to (bio)medical discourse.

The syndemic has arrived in this “bare life” culture, which is different from traditional ones, especially regarding life and death. Their definitions are almost antagonistic: life is not a life without meaning vs life is equal with proper body functioning, death is an entrance gate to another life vs death is the entrance into nothing, the end of everything.

“The pandemic brings death, which we have carefully suppressed and outsourced, visible again. The constant presence of death in mass media makes people nervous. The hysteria of survival makes society so inhumane. Your neighbor is a potential virus carrier to stay away from. Older people have to die alone in their nursing homes because nobody is allowed to visit them because of the risk of infection. Is prolonging life by a few months better than dying alone? In our hysteria of survival, we completely forget what a good life is. For survival, we willingly sacrifice everything that makes life worth living: sociability, community and proximity. In view of the pandemic, the radical restriction of fundamental rights is unquestionably accepted.”<sup>27</sup>

<sup>26</sup> Byung-Chul Han, *The Burnout Society*, 50-51.

<sup>27</sup> Byung-Chul Han: Covid-19 has reduced us to a “society of survival”.

In neoliberal culture, the inbuilt tendencies of modernity regarding health and illness topics have been exaggerated. This situation is a perfect cultural background of why the mystical not-disappearance of the otherwise outdated biomedical ideology can be detected. There are endless publications on the wished coming era of the biopsychosocial model. Still, the new, more holistic model is related to the open curricula of Western medicine, but the much more powerful ideology of the hidden curricula has been the biomedical one. In textbooks and ceremonial speeches, the biopsychosocial model prevails. Still, in the everyday work of the healthcare system, a bio-bio-bio doctrine provides the steam for the engine of the factory-like operation.

The biomedical ideology with its institutions is the adequate medicine for the “keeping up the bare life alive” cultural project. The other aspects of life related to good life can only be an ornament of the monstrous building of the properly working biomechanical body.

How these fundamental issues could be situated in different healing ideologies and systems can be shown in a chart-like comparison of two pairs of concepts:

1, “The agential (story) framework of thought and the pathology (impersonal cause–effect processes) framework of thought are incommensurable, incompatible, and antagonistic. In the first, human events and actions are connected and explained by ‘because’, not cause. ‘Because’ connects elements of a story in terms of meaning, not in terms of cause and effect. In the agential framework, a person feels depressed because of something (rejection, loss, disability, etc.), but the story may be exceedingly complex and idiosyncratic. In the pathology framework a person has become depressed because of the operation of impersonal causal processes. If one wants to propose that an individual is depressed because he or she suffers from a mood disorder, then story becomes irrelevant.”<sup>28</sup>

2, “A tension has been present from classical times in European medicine between, on the one hand, an ‘internalizing’ discourse that gives weight to recognition of bodily distress and its medical management and in which disease is decontextualized; and, on the other hand, an ‘externalizing’ discourse that emphasizes familial, social, political, and environmental contributions to ill health.”<sup>29</sup>

As can be seen, biomedicine is a “pathology + internalizing” framework (casual, internal factors, impersonal) in clear opposition to the “agential + externalizing” framework (idiosyncratic, external factors, contextual). We are not only WEIRD people, but we also have adequate medicine for this “abnormal” cultural-historical position. Our treatment is also unique in its philosophy because other healing systems

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<sup>28</sup> David H. Jacobs, and David Cohen, “Does ‘Psychological Dysfunction’ Mean Anything? A Critical Essay on Pathology Versus Agency”, *Journal of Humanistic Psychology*, 50(3) (2009) 312–334.

<sup>29</sup> Margaret Lock and Vinh-Kim Nguyen, *An Anthropology of Biomedicine* (Chichester: Wiley & Blackwell, 2010), 43.



(inc. premodern Western one) are mostly related to the “agential-externalizing” framework. This constellation has double-sided consequences:

1, The neoliberal culture supports the pathology + internalizing framework, inc. layman’s belief attitudes. Anxious people feel they cannot control essential aspects of their life and try to run away from responsibility. The biomedical model seems an appropriate “asylum” for those who need this kind of anxiety and guilt feelings alleviating shelter. The diseases can provide identity and meaning, at least for the time being. The diseases are the Schopenhauerian ballast of the ship of our life for not being extremely unstable and can go (seemingly) straight. The diseases are life-threatening but, at the same time, life-supporting factors in a late-modern culture. They are dangerous to our biological life, but they could also substitute the missing spirituality by creating a surrogate meaning, even identity.

2, The workings of the social institutions, inc. science and medicine are embedded and surrounded by the neoliberal era that undermines trust and security feeling.

“The biomedical discourse translates a concern into biomedical language and, through this, assigns biomedical meaning and significance to the concern, while the neoliberal discourse tries to make human beings accountable for their predicaments and circumstances instead of looking at the larger structural and institutional forces.”<sup>30</sup>

In the neoliberal regime, the privatization of the economy and the withdrawal of the state as representative of the community (even in an alienated edition) is followed by the privatization of life problems. As a consequence, suffering has been closed into the person and lost its social and cultural context:

“Firstly, our sector [mental health- A.B.] has depoliticized suffering: conceptualizing suffering in ways that protect the current economy from criticism – i.e. reframing suffering as rooted in individual rather than social causes, thus favoring self over social and economic reform. Secondly, it has privatized suffering: redefining individual ‘mental health’ in terms consistent with the goals of the economy. Here ‘health’ is characterized as comprising those feelings, values and behaviours (e.g. personal ambition, industriousness and positivity) that serve economic growth, increased productivity and cultural conformity, irrespective of whether they are actually good for the individual and the community. Thirdly, it has widely pathologized suffering: turning behaviors and feelings deemed inconvenient from the standpoint of certain authorities (i.e. things that perturb and disrupt the established order), into pathologies that require medical framing and intervention. Fourthly, it has commodified suffering: transfiguring suffering into a vibrant market opportunity; making it highly lucrative to big business as it manufactures its so-called solutions from which increased tax revenues, profits and higher share value can be extracted. Finally, it has decollectivised

<sup>30</sup> Krishna Ballabh Chaudhary, *Are Biomedical and neoliberal Responses to COVID-19 Good Enough?* <https://criticaledges.com/2020/10/26/biomedical-neoliberal-covid19/> (accessed July 21, 2021).

suffering: dispersing our socially caused suffering into different self-residing dysfunctions, thereby diminishing the shared and collective experiences that have so often in the past been a vital spur for social change.”<sup>31</sup>

This “privatization of suffering” tendency is embedded in a sentiment in which there are no social-level solutions for the fundamental problems of Western societies. It is proven by different social movements in the last decades that even when people expressed their dissatisfaction with the ruling social-political system, they could not provide any viable alternatives. They could occupy the symbolic or physically important places (streets, squares, institutions), or they could show their anger or even rage against the social status quo by marching on streets and destroying shops, and cafes and fighting against the police and guards, but they had no programs for introducing a fundamental change in the working of society. The frustration of hopelessness of any revolt has been turning into a depressive state and a feeling that they are “not able to be able”. What is valid on an individual level now is ruling on the social level as well.

“...we have entered a historical period of revolutionary change that cannot achieve consummation. Institutions are drained of trust and legitimacy but survive in a zombie-like state.”<sup>32</sup>

“The result [...] has been the bleeding out of legitimacy and the living death of many democratic institutions”<sup>33</sup>

Our institutions’ zombi-like or living dead state expressed an in-between cultural state of affairs when the belief in, trust in, and spirit of our established institutions weakened. Still, at the same time, there is a constant reproduction of this “nowhere land” situation. So when we try to understand the uncertainty in people’s attitude towards the COVID-19 virus and the vaccination, we have to put vaccine denial and hesitancy into this cultural context.

The “vaccine hesitancy” is a microexpression of the macro or global hesitancy in our culture about “where to go?”<sup>34</sup>

At first sight, this ambivalent attitude towards vaccination is a negative surprise taking into account that vaccination is connected to one of the few vast successes or so-called breakthroughs of modern medicine related to the “magic bullet” idea where there is one more or less specific and simple biological cause of a disease that a specific effective remedy can eliminate. One of the most critical contradictions of

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<sup>31</sup> James Barnes: *The Politics of Distrust: A Discussion With Dr. James Davies on His New Book, “Sedated”* <https://www.madinamerica.com/2021/06/interview-james-davies/> (accessed July 21, 2021)

<sup>32</sup> Martin Gurri, *The Revolt of the Public and the Crisis of Authority in the New Millenium* (San Francisco: Stripe Press, 2018), 323.

<sup>33</sup> Ibid, 341.

<sup>34</sup> “...vaccine hesitancy refers to delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place and vaccines. It is influenced by factors such as complacency, convenience and confidence.” Noni MacDonald and SAGE Working Group, “Vaccine Hesitancy: Definition, Scope, Determinants”, *Vaccine* 33, no. (August 14) (2015): 4161–64.

contemporary medicine is that it has been chasing the mirage of magic bullet treatment yet. Still, the “magic bullets” have been relatively rare in the last decades. The biologically monocausal diseases of the golden era of modern medicine (late 19th and first half of 20th century) mostly disappeared or are forced back partly because of effective medical interventions. However, today the most important diseases are multicausal and multifactorial, considering their aetiology. It means that following the “magic bullet” idea is like searching for the holy grail. It is not attainable and sets a trap for medicine as it helps to keep the medical practice in a simplistic biomedical worldview. One of the most severe consequences of this orientation:

“...it is not the case that contemporary methodology has shown present-day medical interventions, on the whole, to be much more effective than past interventions.”<sup>35</sup>

We repeatedly hear and read the mantra that “modern medicine is rapidly developing, and it is one of the biggest successes of modern Western society with its technoscientific culture”. However, we can have the impression that behind the surface of these kinds of propaganda panels, the accurate picture of modern medicine is much more controversial and full of “on the one and the other” arguments. Even it can be argued that:

“In sum, a dark secret of medicine is that the best evidence available today suggests that many new medical interventions are barely effective, and the available evidence is often discordant.”<sup>36</sup>

So medicine in the era of post-modern/neoliberal culture is, on the one hand, a blossoming professional field and extremely popular, primarily due to the successes of the first two-thirds of the 20th century and the contemporary medicalization, which offers a medical, technological solution for several everyday life problems. Still, medicine’s “dark secret” keeps the situation reasonably unstable and prone to provoke adverse reactions. It is like the transference phenomenon in dynamic psychology (formerly psychoanalysis). Medicine is a God-like institution that can be the container of people’s positive feelings, hopes, and trust in life, a kind of saviour (substituting God), and a screen onto which negative emotions and thoughts can be projected full of distrust, dissatisfaction, and frustration. The former saviour is now a cheat that cannot fulfil their promises. Many disorders are untreatable yet, and longevity has limits.

The vaccination is related to the “magic bullet” era; it is connected to the most successful aspects of medicine. Although it is just partly a technological solution because it “only” triggers the natural, self-healing mechanism of the human body, therefore its logic is a mixture of the approach of modern medicine and natural, alternative healing practices (e.g., homoeopathy); it uses external and internal factors at the same time.

However, because vaccination is strongly related to biomedical ideology, it can revitalize that approach and causes a regressive or nostalgic state in some professionals’ attitude. It is a game in which modern medicine could show itself as a

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<sup>35</sup> Jacob Stegenga, *Medical Nihilism* (Oxford: Oxford University Press, 2018), 169.

<sup>36</sup> Stegenga, “Medical Nihilism,” 175.

potent and effective enterprise. The logic of the effect mechanism has solid scientific ground, and the vaccines are much better regarding their effect size than many current medications. Maybe this is one of the main reasons why the priority of biology seems so taken for granted. And this is why this biomedical tunnel vision puts pressure on these professionals not to understand why the seemingly simple logic of vaccination is not acceptable or understandable for many people in the Western population.

Following the tradition of Enlightenment – the truth has God-like power on people’s minds -for some professionals, the only or the main reason for vaccine denial or hesitancy can be a knowledge deficit. The people against vaccination or who do not embrace it as a beautiful possibility against viral infection should be informed on a cognitive level (the deficit approach to scientific knowledge). If they get insight into this well-based scientific knowledge, they will accept it. Only uneducated persons want to stay in the darkness of ignorance, and the educated want to live in the daylight of truth of evidence-based medicine. The medical professional should raise - regarding the most critical points - these ignorant people’s knowledge onto their level of expert knowledge. A bridge or a ladder should be built between the scientifically informed understanding and the inferior lay one.

Nevertheless, the technoscientific tunnel vision cannot recognize and realize the complexity of the cultural context of which the knowledge of shiny facts is only one aspect. If uncertainty prevails, the fragments of faith or worldview become even more powerful and leave a smaller territory for the facts in the decision game than in a stable belief system. Consequently, if facts cannot fit or cannot be embedded in this weak belief system, foreign factors will be thrown out to stabilize a seemingly straightforward, contradiction-free attitude. Alternatively, facts should be modified or reshaped to get support from the belief system. Some scientists and educators strongly believe that the “unnatural” primacy of facts should be the rule as it is the desired and correct approach. However, the scientific lifestyle is far from the ideal existential mode. Ordinary people turn to the world with a biased attitude, emotions, value preferences, prejudices, etc. Although it is idealized in our culture, the sciences’ perspective towards nature would be strange or abnormal in other cultures: “science is an alien thought form”.<sup>37</sup>

If we make efforts not to see the culture of sciences from an inside point of view, we can realize that, e.g., objectivity – as one of the most critical values in sciences – that is, the “sterilization” of knowledge from human subjectivity requires an artificial, not natural human attitude.

“Science [...] requires of its practitioners the strategic suppression of human nature, indeed, the suppression of the highest element of human nature, the rational mind.”<sup>38</sup>

Let us take the COVID-19 phenomenon as a syndemic that is a complex occurrence, much more complicated than can be reduced to the virus’s natural

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<sup>37</sup> Michael Strevens, *The Knowledge Machine: How Irrationality Created Modern Science* (New York, London: Liverlight Publishing Corporation Kindle Edition, 2020), location 108.

<sup>38</sup> *Ibid*, location 170.

features and their effects. Therefore, the fight to control the syndemic cannot be reduced to a biological armament and a scientifically based technology, namely vaccination. Vaccination acceptance, hesitancy, or denial are also “cultural kinds”. They are embedded in a complex value and behaviour system of the neoliberal Western culture.

“...the predilection to see vaccine hesitancy and refusal as signs of something bigger than what is captured in the language of the debate. We all point to broader social structures in which vaccine controversy takes place.”<sup>39</sup>

“That failure of modern institutions to manage risks and mitigate the harms they had created has led to public distrust of industry, government, experts, and all other facets of modern governance. Vaccines, of course, are scientific marvels, regarded as one of the most significant accomplishments of modern medicine. Adverse events are manufactured risks that came out of this wondrous technological advancement. The public perception that the risk is not managed effectively indicates distrust in the scientific and government institutions that orchestrate current vaccination practices. [...] The failure of experts and institutions to ground that trust leaves the public searching for new sources to trust in order to manage risk.”<sup>40</sup>

Therefore, distrust in vaccines is part of a broad and significant cultural tendency – distrust in governance, institutions, and experts – the most potent players in Western culture. The vaccine hesitancy or denial is mainly based not on separate facts but on the constellation that these facts get in touch with a culture of distrust. As they enter the public sphere, the facts put the colours of culturally motivated doubts on.

The virus is related to another era of medicine, the age of solid modernity. People believed that rational norms or laws – like natural laws – should govern society instead of God. There seemed clear-cut, objective differences between normal and abnormal – not only in the territory of nature but also in human behaviour.

Modern medicine, in its heyday, had been part of this worldview. “Healing becomes medicine when healers recognize laws of nature and seek explanations for the body’s functions only with the help of these laws.”<sup>41</sup> So seemingly, the virus and the fight against it perfectly fit this modern scheme. We know the enemy, and how it works, and we can fool it through vaccination, a wonderfully simple technical intrusion into the natural body processes. At the same time, it uses the biological defence mechanisms of the body. It is an excellent example of how we can control nature by using our sciences and technology.

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<sup>39</sup> Maya J. Goldberg, *Vaccine Hesitancy* (Pittsburgh: The University of Pittsburgh Press, 2021), 18.

<sup>40</sup> *Ibid.*, 165-166.

<sup>41</sup> Paul. U. Unschuld, *What is medicine? Western and Eastern Approaches to Healing* (Los Angeles, London: University of California Press, 2009), 40.

Then this modern phenomenon got into a post-modern context, in the age of liquid modernity where nothing is sure. Where the modern project, with its rational suppositions and a belief that after God, a kind of security can be created or recreated with a technoscientific approach, has become more and more uncertain as doubts started to rise throughout the whole cultural project the vaccination got into the whirlwind of a paranoid distrust. In his love and hate games, viruses are dangerous creatures that challenge and strengthen our immune systems. Vaccination, formerly seen as one of the few miracle cures of modern medicine, has changed to risky intrusion, like most of our technical solutions can create more severe risks than they can solve. (For some unprepared students, biomedicine is now equal to natural, soft healing because of the change in the meaning of the bio prefix in our culture. Bio meant nature(al) some decades ago, which was an enemy and should be defeated; today, Nature should be saved, and the technology has become threatening and risky.)

Vaccine hesitancy is an expression and symptom of culture's diminishing trust in itself. This is like the above-mentioned political movements, an expression of the distrust in our culture's prominent and influential institutions: "a critique from margins to the centre"<sup>42</sup>.

The primary basis for this anger is a perspective repressed and marginalized by those agencies that cannot provide existential safety for the citizens. The silenced perspectives by the prominent institutions, including science and medicine, have not fulfilled the promises yet: the uncontrollable world will be controllable by using the knowledge and technology they can create and use. The people do not believe or are at least sceptical about the "Trust me, and I will make you happy" promises. The uncontrollable seems even more uncontrollable – technologies that promised more safety and security in life lead us into a catastrophe:

"Every Whole is broken now,  
Every light is scattered and flashing,  
Every love is splitting and crashing,  
Every Whole is broken now."<sup>43</sup>

The modern epistemological and technical project was based on the repression of subjectivity and adoration of technological solutions.

"...vaccine sceptics are leery of modernity: they capitalize on anxieties about modern life and appeal to populist sentiment against elites (and thus against scientific expertise), as well as to subjective beliefs over objective science."<sup>44</sup>

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<sup>42</sup> Bernice L. Hausman, *Anti/Vax Reframing the Vaccination Controversy* (Ithaca, London: ILR Press, 2019), 108.

<sup>43</sup> Endre Ady: Tracking On A Cart Tonight, trans. Szabó Attila Henrik [www.magyarulbabelben.net/works/hu/Ady\\_Endre-1877/Kocsi-%C3%BA\\_t\\_az\\_%C3%A9jszak%C3%A1ban/en/38284-Tracking\\_On\\_A\\_Cart\\_Tonight](http://www.magyarulbabelben.net/works/hu/Ady_Endre-1877/Kocsi-%C3%BA_t_az_%C3%A9jszak%C3%A1ban/en/38284-Tracking_On_A_Cart_Tonight) (accessed July 21, 2021).

<sup>44</sup> Hausman, *Anti/Vax*, 60.

Subjective experiences can differ from scientifically proven generalizations; risks expressed by statistical data can have no direct personal validity: “These data on the risks of this vaccine are valid on the populational level, but what about my family and me?”

Here are some outstanding reasons why people are sceptical or resist vaccinations:

- a belief in the value of natural illness
- a desire to avoid unnecessary medicine and treatment
- alternative views about health and medicine, including holistic, herbalist, oriental, integrative, naturopathic, and chiropractic medical systems
- lived experience with illness, especially with illness that is not effectively treated by mainstream medicine
- experience with perceived vaccine injury
- distrust of mainstream scientific studies of vaccine safety
- distrust of medicine’s entanglement with big business (especially “Big Pharma”) and government
- concerns about toxins in the environment, food, medicine, and household goods<sup>45</sup>

#### IV. A need for dialogue

Scientism – only sciences can have valid answers to human questions - as a kind of surrogate religion has a consequence that if we expand our vision beyond the quantifiable natural realm, something is always missing. Wittgenstein got one of the conclusions of his groundbreaking work (*Tractatus Logico-Philosophicus*): “We feel that even if all possible scientific questions be answered, the problems of life have still not been touched at all”<sup>46</sup>. It shows that sciences cannot cover knowledge and meaning in human existence. Paul Unschuld, when he was pondering the issues related to “what is medicine,” question tried to answer the problem of the definition of life: “life is a body augmented by X”<sup>47</sup>. So, even on a natural or biological level (maybe the traditional healers would call it “life energy”), a scientific rule of thumb is not available. Now related to the topic of vaccination, we stumble upon again this “something else” phenomenon.

“Medical controversies in the public sphere are inevitably social controversies, and as such they demand social solutions. [...] public debates about them are always also conversations about something else —questions about what it means to be a person, to be a member of a community, to be a human being living in consonance with other kinds of beings and bodies. To get at the something else, we have to be willing to bracket science and its contribution to understanding the problem. This is not to say that scientific perspectives are unimportant. But we

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<sup>45</sup> Hausman, *Anti/Vax*, 197.

<sup>46</sup> Ludwig Wittgenstein, *Tractatus Logico-Philosophicus* (London: Kegan Paul, Trench, Trubner & Co., Ltd, 1922), 89.

<sup>47</sup> Unschuld, *What is medicine?*, 2.

must recognize that when we allow science and its conclusions to dominate our responses to medical controversies in the public sphere, we limit our understanding of what motivates those controversies and how we might solve them.

The answer is science and something else. [...] The something else has to do with understanding in a deep way the cultural mechanisms and beliefs that support our lives and make them meaningful. The something else is how vaccination controversies point toward fundamental questions about human flourishing and the meaning of illness in healthy lives.”<sup>48</sup>

The gap between this “something else” and the scientific narrative cannot be bridged with more or more rigorous sciences. When people feel that scientific rigour does not accept their life experiences and point of view, then when sciences have lost their outstanding credibility and have been becoming one social institution among the others, at the same time, they are part of a socially unjust system. The previously accepted superiority of scientific epistemology has turned into epistemic injustice.

“Testimonial injustice occurs when prejudice causes a hearer to give a deflated level of credibility to a speaker’s word; hermeneutical injustice occurs at a prior stage when a gap in collective interpretive resources puts someone at an unfair disadvantage when it comes to making sense of their social experiences.”<sup>49</sup>

The “revolt of the public from the margin” now is extending to the territory of knowledge in a kind of defiance against scientific products.

In this situation, only more dialogues and discussions can be helpful between the lay population and the professionals. From the borderland of biomedicine, namely from psychiatry, as it is in one of the deepest phases of its never-ending crisis, some excellent examples can be found for finding the best ways to help with a solid moral but less stable epistemological basis. Psychiatry is situated in our culture, on the one hand, as a (bio)medical speciality. Still, on the other hand, it shows all the problems of biomedicine in more open forms than in other medical fields. Now psychiatry is a laboratory or excellent place for experiments on how a professional guild in the mids of raising scepticism of the “lay populace” tries to heal itself and search for new ways of professional identity and therapeutic effectivity.

It is inherent in the biomedical worldview that the professional (doctor) knows everything. The patients (layperson) are ignorant, do not, and could not know anything about their disease – only they are the carrier and reporter of symptoms. In psychiatry, the latest developments have been undermining the all-knower image of the professional, mainly because the healing technology is pretty questionable. (e. g. there is raising doubt about the long-term beneficial effects of medications.) The prestige of the clients’ knowledge took some “territories” of the professional knowledge, creating a more balanced relationship between the two: expert by profession and expert by experience. The voice-hearer movement is an outstanding

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<sup>48</sup> Hausman, *Anti/Vax*, 219.

<sup>49</sup> Miranda Fricker, *Epistemic Injustice* (Oxford: Oxford University Press, 2007), 1.



example for providing viable and plausible arguments for understanding and treating hallucinations, not as biochemical brain problems but as potentially meaningful “messages” from the client’s past.

The “Open Dialogue” method that started in Finland initiated an institutional system inside psychiatry based on the assumptions that the client, psychiatrist, and other professionals are equally important. Their approaches and narratives are likewise crucial in solving the client’s life problems.

These kinds of innovations in psychiatry should be examples for other medical fields that the different imbalances, inc. epistemological ones, are obstacles to an adequately handled syndemic. The puzzle should be solved only by using the professionals’ points of view and civilians’ ones. The syndemic should be approached not only from complex perspectives, but the solutions or at least the alleviation need mutual efforts. It is impossible to disqualify people’s arguments from the start only because they are not professionally scientific. Trust in vaccination cannot be built between arrogant, all-knowing professionals and ignorant laypersons, but only in a dialogue with mutually respected partners, putting every argument from all sides on the table.

From a scientific point of view, the truth cannot be decided by dialogue. However, in the age of distrust, compelling and mobilizing truths about COVID-19 cannot be created purely following the logic of scientific arguments.

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# TRUSTING CITIZENS? INDIVIDUAL RESPONSIBILITY AND MANDATORY STATE MEASURES IN THE COVID-19 ERA

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## **Abstract**

From the beginning of the coronavirus pandemic, the government in Greece has emphasized the necessity for the individual responsibility of citizens. Individual responsibility implies self-restriction in exercising certain aspects of personal autonomy, mainly those related to the freedom of movement and the right to health. In parallel, as has happened worldwide, the government has started to adopt mandatory measures. Under this situation, a key question emerges: to what extent emphasis on individual responsibility expressing trust in the conduct of citizens may be compatible with mandatory measures implying, in principle, distrust of personal self-limitation and *in extremis* state paternalism? The paper argues that these diverging approaches are fundamentally incompatible.

## **I. Introduction**

The COVID-19 experience illustrates critical challenges not only for modern Medicine and Pharmacology but also for the function of democratic states when they face a global threat to public health. These challenges are closely related; the lack of efficient means for prevention and therapy, even several months after the pandemic outbreak, created highly unsafe conditions that made it difficult for the state's responses to ensure the protection of public health. In a democratic state, any policy intending to serve the common good should be developed in accordance with the constitutional framework and the international legal instruments relevant to the protection of human rights. This means that even before an unprecedented threat with the characteristics of an aggressive global pandemic, the means that democratic governments are allowed to mobilize are not unlimited, particularly when it comes to mandatory measures; they need to be justified specifically within a given legal framework.

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On the other hand, besides the necessity for adopting mandatory for citizens measures, states must consider initiatives aiming at the citizens' appropriate information about the characteristics of the threat and individual measures of precaution. Moreover, they can also refer to a citizen's duty of social solidarity, implying self-restriction in social activities to protect others from spreading the disease. Such policies of social awareness may be proven equally or more efficient compared to mandatory measures since they encourage the citizens' willingness to adapt their everyday behavior to necessary acts of precaution.

In urgent situations, when the dimension of time is crucial for achieving the best results in defending public health, any government is, in reality, obliged to follow a mixed policy that combines mandatory measures with public awareness initiatives. This is because mandatory measures may ensure immediate results, since they are backed by sanctions in case of violation, but they risk general disapproval by citizens. Initiatives promoting public awareness, on the one hand, may be proven more successful in ensuring the citizens' conscious participation; on the other, they require time spent and continuous efforts by the state.

Here, a difficult question is relevant to the government's responsibility regarding the mixture of these two options under the specific circumstances that need to be addressed. To what extent may a government refer to the "irresponsible" behavior of citizens when a certain policy of public health protection seems to fail? Moreover, is the government justified, on that ground, to impose mandatory measures for achieving the policy goals? This paper explores some aspects of such problems given the experience in Greece, where the combination of the COVID-19 policies remains an open topic of reflection.

## **II. The experience in Greece**

Although the coronavirus disease did not hit Greece heavily during the first months of the outbreak, the government decided to follow a dual policy for the protection of public health, based, on the one hand, on the citizens' conscious collaboration and, on the other, on mandatory measures restricting, in particular, the right to movement.

The first aspect of that policy was expressed by evoking "individual responsibility" as the appropriate ethical attitude that all citizens should share when exercising their autonomy in protecting others' health. Individual responsibility was considered a conscious expression of social solidarity requiring self-limitation in exercising several fundamental rights. This included all rights involving frequent social contacts, particularly the right to free movement, the right to assemble, economic rights, the right to work, and the freedom of religious worship. In parallel (and under the fear that the Italian experience provoked, with multiple victims in the early months of the outbreak), the government adopted a general lockdown of one month, putting the right to movement and associated freedoms under a system of mandatory licensing.

For some months after that first lockdown, the figures for confirmed incidents, hospitalizations, and deaths remained relatively low, but this changed afterward. The opening of social activities for the summer tourist season has been the main reason

for the explosion of the pandemic figures. The result was the governmental decision for a new lockdown, which was long-lasting this time and was a sign of a policy change towards more confidence in mandatory measures.

After the introduction of vaccines, the government considered that it was feasible to achieve immunity for the population, which presupposed a certain vaccination rate in a limited period<sup>1</sup>. To achieve that purpose, the “individual responsibility” policy needed to find a new expression, as an individual duty to be vaccinated for social solidarity reasons. To convince the citizens, the government launched a campaign named “Freedom Operation”, structured around the idea of “more freedom for the vaccinated”, concerning the exercise of most of the above rights. The prime minister himself used for this campaign, like a motto, the phrase “No freedom for those who are not entitled to it”. The basic motivation for reluctant citizens remained that of “gaining” a bigger part of freedom in their everyday activities<sup>2</sup>. This included even releasing vaccinated citizens from conventional precautionary measures, like mask-wearing, keeping social distancing, or undergoing diagnostic tests.

Still, the “Freedom Operation” seems to fail, as the rate of vaccinations in the country remains lower than the average of the EU and far below the threshold of population immunity, as announced at the beginning of the “Freedom Operation”, even several months after the expiration of the determined period. One can attribute that failure to the poor information of citizens about the characteristics, the benefits, and the potential side effects of the vaccines. On the other hand, it is worth noting that during that campaign, the government introduced a specific measure for healthcare workers: mandatory vaccination, backed by a strict sanction according to which non-vaccinated physicians and other healthcare professionals remain in a regime of unpaid leave<sup>3</sup>. An additional mandatory measure for non-vaccinated employees (in both the public and the private sector) and university students requires periodical diagnostic rapid or molecular tests at their own expense. These measures have opened a lively public debate on the government’s option to generalize such a mandatory policy in a desperate effort to achieve the initial immunity goal. Judging from the figures showing no considerable vaccination progress, it seems that the mandatory measures have a negative impact on social attitudes eventually, or, at least, they fail to force non-vaccinated citizens (particularly the youngsters) to change their attitudes<sup>4</sup>.

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<sup>1</sup> According to the former minister of Health, the official target was set at 70% of the population until the end of August 2021. Until now (Oct 2021), the rate still remains at 61% (source: *Politico*, <https://www.politico.eu/article/coronavirus-vaccination-europe-live-data-tracker-coverage/> accessed 25.10.2021). After the full dominance of the “Delta” mutation, this corresponds to even lower immunity compared to the initially calculated level.

<sup>2</sup> See Hellenic Republic, *National Operational Plan for Vaccination against COVID-19 – Freedom Operation*, December 2020, [https://emvolio.gov.gr/sites/default/files/ethniko\\_epiheirisiako\\_shedio\\_emvolias\\_mon\\_kata\\_toy\\_covid-19\\_v6.1\\_1.pdf?t=1](https://emvolio.gov.gr/sites/default/files/ethniko_epiheirisiako_shedio_emvolias_mon_kata_toy_covid-19_v6.1_1.pdf?t=1) (accessed 25.10.2021 - in Greek only).

<sup>3</sup> Law 4820/2021 (art. 206).

<sup>4</sup> According to the more recent survey (Oct 2021), there are 58% negative opinions in the population regarding the COVID-19 governmental policy, compared to 18% in March 2020 (source: *Prorata*, <https://prorata.gr/2021/10/18/sfigmos-oktovriou-2021/>, accessed 25.10.2021).

The Greek example illustrates a mixture of public health policy in which the encouragement of citizens to consciously participate in a plan of social solidarity is combined with mandatory measures, expressing by definition the state's mistrust of the citizens' behavior. Eventually, this particular mixture failed, as indicated by the relatively low vaccination rates and the high rate of deaths compared to the EU average figures.

### III. The legal framework

To what extent is a democratic government allowed to combine measures for promoting public awareness and encouraging the citizens' conscious participation in the protection of public health, with mandatory measures backed by sanctions? To answer that question, it is necessary to visit the legal framework that governs the exercise of crucial fundamental rights in front of serious threats to public health, such as the COVID-19 pandemic.

The relevant law includes mainly international and constitutional provisions for the protection of human rights. Even if constitutions (as national legislation) present some differences, these are rather insignificant. At the level of fundamental rights, we can observe common characteristics in legal regulation pertinent to all democratic states that make valid analyses with no necessary reference to national particularities. Nevertheless, to be more specific, we can focus on the common European legal system, where we have more detailed regulations in terms of human rights law. Legal instruments of reference with binding force are, here, the European Convention on Human Rights (ECHR), the European Convention on Human Rights and Biomedicine (Oviedo Convention), and (for the EU member states) the EU Charter of Fundamental Rights.

The ECHR is the basic law in Europe that protects all fundamental rights, including some influenced directly by an infectious disease outbreak. There are specific provisions regarding the right to life, the right to liberty (that encompasses the right to free movement), the freedom of assembly, and the freedom of religious worship.

In Article 5, the ECHR explicitly refers to the "prevention of infectious diseases" as a legitimate reason for restricting the free movement of persons. This is the only reference in the Convention's text to the protection of public health. However, the European Court of Human Rights (Strasbourg Court), responsible for the Convention's common application at the European level, has developed that protection through its case law, particularly regarding the acceptance of mandatory vaccination in children<sup>5</sup>. Public health, thus, is not considered a legitimate reason for rights restriction pertaining only to one particular right (the free movement), but it

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<sup>5</sup> See ECtHR, *Vavříčka vs the Czech Republic* (2021), *Solomakhin v. Ukraine* (2012), *Jebonab's Witnesses of Moscow v. Russia* (2010), *Boffa et al. v. San Marino* (1998), and Anja Krasser, "Compulsory Vaccination in a Fundamental Rights Perspective: Lessons from the ECtHR," *ICL Journal* 15(2) (2021), 207–233, <https://doi.org/10.1515/icl-2021-0010>. (accessed 25.10.2021).

may justify restrictions on other rights, too, such as the right to physical integrity<sup>6</sup> in the example of mandatory vaccinations.

The Oviedo Convention confirms this remark explicitly. It is important to notice that this Convention is the first binding instrument of the international law governing the field of Medicine. In that sense, it may be considered more specific in regulating health issues, including public health topics. The Oviedo Convention refers to fundamental rights also, as expressed in the patient/doctor relationship. It accepts explicitly that individual interests always prevail over the sole interest of science and society (Art. 2); this is a principle reflecting the primacy of the human value and respect for human dignity, as traditionally recognized in continental constitutional texts<sup>7</sup>, according to which no instrumentalization of persons is legally accepted.

Furthermore, the Convention is the first international legislation that is structured on the basis of the informed consent rule in medical practice (Art. 5, et seq), reflecting the era of patient autonomy in modern Medicine. As a legal rule, informed consent is a prerequisite for any medical act, including preventive acts that protect public health. These two provisions are essential for understanding the attitude of modern law in all health-related situations; they clearly express a priority of the individual will that needs to be taken seriously when governments develop their policy on public health.

However, in Article 26, the Oviedo Convention provides a general possibility for restricting recognized rights for the sake of public health protection (among other public interests). There are two relevant conditions: a) Restrictions must be established by law, and b) they need to be considered necessary in a democratic society.

This provision sets the legal framework for balancing the exercise of rights with the potential risk for public health in specific circumstances, or, in other words, the legal margin for introducing mandatory measures despite the free will of citizens. The first of the above conditions requires an explicit governmental decision that needs to be adopted in the form of an Act by the parliament, or at least, to be based on the specific authorization of a relevant Act. This is important for securing the government's responsibility (and political accountability) when it intervenes in the area of fundamental rights. The second condition requires the application of the proportionality principle, meaning strict relevance of any restrictions on rights with the specific purpose observed; mandatory measures "necessary in a democratic society" are considered only the milder possible ones with the minimal effect on the right concerned for achieving the purpose in question.

The proportionality condition becomes clearer if we visit the EU Charter of Fundamental Rights. In Article 52 para 1<sup>8</sup>, the Charter makes an explicit reference to that principle. In addition, it refers to the respect of the rights and freedoms

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<sup>6</sup> See, explicitly, the EU Charter of Fundamental Rights, art. 3 para 1, corresponding to art 3 ECHR (prohibition of torture).

<sup>7</sup> Explicitly recognized by the EU Charter also (art. 1).

<sup>8</sup> "Any limitation on the exercise of the rights and freedoms recognized by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognized by the Union or the need to protect the rights and freedoms of others."



“essence” in case of limitations, implying that a violation of that essence with mandatory measures is legally unacceptable.

Even if these legal stipulations leave a broad space for democratic governments to develop flexible policies for the protection of public health, they put some “limits-to-limitations” that need to be explored specifically. For instance, although the Oviedo Convention generalizes the possibility of restrictions for exercising any individual right in the patient/doctor relationship, it seems impossible to accept a certain restriction on the informed consent rule, that is, the basic right of patients and all persons receiving health services. This is because, if we assume that a person may undergo medical intervention without consent, we cannot escape from the human dignity reservation and the prohibition of humans’ instrumentalization. Indeed, consent to medical acts guarantees that persons (even vulnerable ones) continue to hold direct control over their body and biological functions; that is the crucial element for preserving not only a specific fundamental right (the right to bodily integrity) but, far beyond, the very notion of human dignity and self-determination as a logical prerequisite for enjoying any fundamental right. To secure personal control over the body represents a “red line;” if we cross it, we radically change the status of individual humans, as we understand it in a democratic society<sup>9</sup>.

The provision of the EU Charter regarding respect of the rights and freedoms “essence” is equally important. At least for the EU countries (where the Charter is applicable law), this represents another “red line” or a limit to the limitations of rights, such as the right to movement, the freedom of assembly, the right to work, privacy rights (regarding data processing, and tracking by state authorities), etc. A general quarantine imposed on the population, or measures restricting access to workplaces, or policies of data collection and tracking of citizens’ movements for preventive reasons cannot be justified in terms of law if the persons concerned are entirely deprived of these rights. Measures preserving the very essence of these rights by allowing acts for their reasonable enjoyment should be considered a legal obligation of the government, even in front of serious threats to public health.

That priority of rights should be understood under the view of the well-known distinctions between “rights”/ “goals” and “principles”/ “policies” in the modern philosophy of law. According to these distinctions, in a democratic community, the fundamental rights are related to the category of principles, meaning normative requirements of justice or fairness; as such, they can be evoked by any citizen as “political trumps”<sup>10</sup> in relationships with the state, that is, as normative barriers that preclude state intervention. On the other hand, goals relate to policies meant to serve common interests that are deemed desirable<sup>11</sup>, but their normative state remains inferior since their justification derives from governmental acts based on a temporary majority of citizens. Governments may determine common interests differently at

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<sup>9</sup> Even referring to its wording, the Oviedo Convention guides us to the above conclusion. Indeed, the principle that recognizes the priority of the individual’s interests over the interests of science or society (Art. 1) is not, as such, subject to the legitimate limitations that article 26 states, and, moreover, it would be logically meaningless if we accepted any condition of human bodies instrumentalization.

<sup>10</sup> See, Ronald Dworkin, *Taking Rights Seriously* (London: Duckworth, 1977), xi.

<sup>11</sup> *Ibid.*, 22, 90 et seq.

different times, but in any case, they can refer only to that partial justification, not the strong one of a principle. Hence, unlike rights, policies are always subject to criticism by the government's political opponents or dissenting citizens.

This essential confrontation between principles-rights and policies-goals emerges in public health issues also, and the relevant behavior of the state. Even if policies aiming at preventing serious threats to public health may be approved by a vast majority of political forces and citizens, they cannot challenge the dominant status of fundamental rights. It is the constitutional and the international legal framework that organizes the governmental discretion for developing a public health policy by allowing certain restrictions to the exercise of concrete rights, but never by questioning the normative priority of the latter.

#### **IV. Individual responsibility: The significance of trust**

Given the above legal framework, any government has to consider alternative options for engaging the population in a policy aiming at protecting public health, as we already mentioned. First, there is the option of imposing mandatory measures as legitimate restrictions on the exercise of certain rights. The second option is to encourage the citizens' self-restriction by referring to their individual responsibility and the duty of social solidarity.

The main difference between these options concerns the degree of government trust in citizens. Even if the law accepts, to some extent, public health policies based on mandatory measures, without undermining the priority of individual rights as a value, to opt for such measures means that the government does not trust the willingness of the population to follow a certain policy.

In that line, citizens have to comply regardless of their motivation and, moreover, regardless of their conscious engagement in the policy goals. On the other hand, a policy focusing on the citizens' individual responsibility reveals the government's trust that the announced goals are widely accepted, to the extent that everybody is ready to exercise their fundamental rights following a conscious self-restriction.

Although the latter option seems by far preferable, from a right-based aspect, since the free will of citizens holds its dominant position, questions on efficiency are obvious. This is because individual behaviors cannot be foreseen, particularly under conditions of time pressure and in front of serious danger to public health, like in epidemics. In such circumstances, social solidarity cannot be considered a given element, and personal attitudes may change rapidly. In contrast, a policy based on mandatory measures is more promising in terms of the citizens' compliance, or in other words, their behavior is more predictable, just because it is quasi "automatic" and personal attitudes have only minimal influence.

To address this problem, it is not sufficient for the government to trust the citizens; it is necessary to gain their confidence also. In a pandemic with unprecedented characteristics (like the COVID-19 experience), measures promoting accurate information, transparency in decision-making, and investments in the weak parts of the national health system are crucial.

Accurate information (which is also a subject of a fundamental right, according to Art. 11 of the EU Charter) is related, in particular, to an efficient system of disease

incident tracing with the large availability of easily accessible tests and reliable infrastructure of the relevant data collection and processing. Addressing misinformation (occurring mostly through social media activity) is equally important to prevent confusion in public awareness. This is a susceptible task as state control over social media may influence the citizens' freedom of expression. However, an independent authority may strike a legally sound balance between the right to information and the freedom of expression.

Transparency in decision-making presupposes a clear distinction between medical recommendations and political decisions at the central level and also involves individual decisions of a sensitive nature, such as the prioritization of vaccinations or access to hospitalization and ICUs. These procedures need to ensure that both the scientific and the political responsibility in decision-making can be attributed to specific competent organs or persons, which are accountable to the public. Moreover, they need to confirm the relevance and concrete implementation of the fundamental principles of medical ethics (autonomy, beneficence, non-maleficence, justice), particularly when the allocation of healthcare resources is at stake.

Investments in strengthening the national health system are equally critical. The lack of resources in health, due to other priorities in public funding is ethically unacceptable when society faces a lethal infectious disease. The engagement of the health's private sector in covering urgent needs is an important part of the state's investment policy. Investments should also target the stability of healthcare services covering other than the pandemic pathologies. The COVID-19 experience showed that, in many cases, the appropriate coverage of other pathologies (including cancer, cardiovascular diseases, and psychiatric diseases) was compromised seriously as the pandemic dominated the healthcare systems<sup>12</sup>.

Such governmental initiatives start from the assumption that the citizens realize the seriousness of the threat and the relevance of specific preventive measures of self-restriction that the government suggests, and they are able to adopt these measures consciously<sup>13</sup>. This is the attitude of trust on the part of the state: No need for any external regulation in the exercise of fundamental rights since that exercise will be self-regulated by the rights' subjects themselves. Therefore, the element of trust keeps the status of rights unaffected, even when a legitimate reason for imposing "external" restrictions emerges.

Paradoxically, the government plays a crucial role in maintaining the citizens' willingness (and confirming the attitude of trust), more active than the authoritative role involving strict controls and sanctions when mandatory measures are adopted. Indeed, to promote public awareness and encourage the population's conscious participation in a public health policy presupposes measures of citizens' motivation<sup>14</sup>,

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<sup>12</sup> Indicatively, see the report for the UK in British Medical Association's, *The hidden impact of COVID-19 on patient care in the NHS in England* (London, July 2020), [https://www.bma.org.uk/media/2840/the-hidden-impact-of-covid\\_web-pdf.pdf](https://www.bma.org.uk/media/2840/the-hidden-impact-of-covid_web-pdf.pdf) (accessed 25.10.2021).

<sup>13</sup> On the relation between risk perception and support of policies in various domains, see Levente Dudás, Richard Szántó, "Nudging in the time of coronavirus? Comparing public support for soft and hard preventive measures, highlighting the role of risk perception and experience", *PLoS ONE* 16(8): e0256241 (2021). <https://doi.org/10.1371/journal.pone.0256241>. (accessed 25.10.2021).

<sup>14</sup> Considering policies based on nudges too. See, *ibid.*, with further references.

that is, measures of permissive nature, after acquiring thorough knowledge not only of the epidemiological data but also of the diversity of the people's stances before the danger.

Due to the nature of that state's role, and the vast range of motives that a government may mobilize for engaging citizens in a relevant public health policy, it is difficult to characterize an entire population (and not only isolated individuals) as non-responsible, in case of that policy failure. Indeed, irresponsibility in that sense would mean that the government did not have other options for convincing the citizens about the policy goals. Yet, this argument could be challenged easily, because, if options are proved limited, then the goals need to be revisited as possibly non-feasible. If, for instance, the goal is to vaccinate 70% of the population to achieve herd immunity, and there are multiple objections among the citizens due to the safety or efficiency of the vaccine, despite the official information, the government must consider a lower rate in combination with alternative options to limit the disease spread.

From a normative aspect, a policy based upon the mutual trust between the state and the citizens, promoting the idea of "individual responsibility" as an expression of social solidarity, and requiring state initiatives with permissive measures for public awareness and conscious self-restriction of personal autonomy, should be the top priority of any democratic government. Although very demanding, in terms of the government's continuous engagement, a policy of that type is harmonized with the prevalence of fundamental rights over the interests of society, in the democratic classification of values.

Indeed, even if national constitutions and international or EU legal instruments accept restrictions on the free exercise of rights for public interest reasons, this does not mean that governments are justified to impose such restrictions with mandatory measures before exhausting all the reasonable options for achieving their goals without influencing the normal status of rights.

## **V. Mandatory restrictions and the question of state paternalism**

Still, this does not mean that the necessary level of citizens' awareness and conscious self-restriction is always feasible under time pressure and a rapidly increasing danger to public health. Even if governments remain responsible for the negative outcomes of such a policy, compared to its original goals, they are equally responsible to opt for a right-restrictive policy, by activating the relevant legal provisions we mentioned previously, as an ultimate effort to achieve these goals. That kind of policy may promise better results regarding the citizens' behavior, but it is associated with two crucial elements.

First, obtaining results with mandatory measures presupposes that an efficient system of preventive and coercive controls is in place. In the COVID-19 case, preventive controls were those requiring mandatory state licensing from the citizens for important activities, particularly during national or local lockdowns. This measure included the right to movement, the right to economic acts (such as shopping), and the right to work (when distance work was impossible). It was organized on the basis of the data collection, mainly through electronic applications (mobile phones, etc.),

which raised questions on privacy safeguards: Citizens needed to accept risks concerning the unauthorized flow of their personal data (sensitive data, mostly), in order to “gain” a small part of their everyday freedom. On the other hand, coercive controls involved frequent police interventions and sanctioning of individual deviations.

The second and more crucial element is that of challenging trust. Even if restrictions on rights are legitimate and suitable for achieving the policy goals, mandatory measures indicate that, on its part, the government does not trust citizens to pursue these goals. The government prefers to “dictate” behaviors, considering that it is better to treat the population as a passive recipient of measures for ensuring the achievement of goals rather than making citizens active and willing contributors to a general mobilization for protecting public health. In that perception, the population is expected to comply automatically, regardless of that compliance’s motives. A breach of trust emerges from the opposite side too. In front of mandatory measures, even people realizing the need for regulating their behavior and willing to self-restricting receive the message that the state does not consider them as “allies” but rather as potential “reactionists”; this is a message inconvenient to mature persons and responsible citizens. Sometimes, that state’s attitude risks dividing people into those agreeing and those disagreeing with the measures, both believing that the “opponents” are really immature!

The mutual breach of trust between the government and the population is the worst condition for developing an efficient public health policy and, moreover, for addressing an urgent danger like a pandemic. Still, mandatory measures may be necessary if policies based on individual responsibility have failed. In that case, a democratic government under pressure must be cautious before the risk of state paternalism. Mandatory measures imply the assumption that the government is the only “expert” to address an urgent situation, having access to the necessary data and absolute knowledge for its processing. This creates the impression that any different approach, even providing valid scientific evidence, should be discarded for the sake of firm guidance of society towards the state policy’s success.

That definition of state paternalism was confirmed during the COVID-19 experience, sometimes through unethical practices regarding data handling and restrictions on the freedom of expression or free information<sup>15</sup>. Right-restricted policies always involve temptations of state paternalism unless the necessity for adopting mandatory measures is confirmed under certain conditions.

The legal prerequisites pertinent to the limitations of fundamental rights are the real guarantees against that danger. A government acting in compliance with the proportionality principle realizes that mandatory measures are exceptional, temporary, and strictly dependent on the goal they are meant to serve. If the goal becomes not feasible, the government has evidence of a wrong evaluation of the circumstances and needs to accept that without insisting on inappropriate restrictions on rights. This is a sign of abandoning the role of “expert” and admitting insufficient

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<sup>15</sup> See, for instance, Naja Bentzen, Thomas Smith, *The Impact of Coronavirus on Media Freedom* (Strasbourg: European Parliamentary Research Service, May 2020), [https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/651905/EPRS\\_BRI\(2020\)651905\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/651905/EPRS_BRI(2020)651905_EN.pdf). (accessed 25.10.2021).

knowledge that requires deliberative practices instead of arrogant orders. Most of all, the proportionality principle binds the government to the axiom of the prevalence of rights, which, by definition, is incompatible with a paternalistic approach. The additional guarantee that requires respect for the essence of fundamental rights goes one step beyond since it excludes a minimal content of rights from any policy arrangement, that is, from any state intervention.

In a democratic state, these guarantees need to be enforced by all legislative and administrative organs and, mostly, by the judiciary, which is the last instance for rights protection. Courts should be seen as a crucial factor in addressing the danger of state paternalism when mandatory measures are in place and citizens denounce violations of rights. In front of an urgent situation, like a pandemic, judges live and function within a quasi-war environment shaped by the government's official information and guidance, not always tolerant of independent approaches and, moreover, judgments reviewing state actions. This may challenge the role of the courts unless the judges insist on a certain "esprit de corps", sticking to the independent consideration of each specific case under strictly legal methodology and evidence<sup>16</sup>.

## **VI. Conclusions**

If fundamental rights always prevail over public interests in the classification of a democratic society's values, this also affects the means that policy-makers mobilize to encounter threats to public health.

An authentic right-based policy promotes public awareness and encourages citizens to voluntary self-restriction in the exercise of certain rights on the grounds of individual responsibility and social solidarity. This is because the person's free will remains at the center of such a policy, and the state trusts free will as a necessary condition for pursuing the determined goals successfully. Still, that policy presupposes the state's active role in motivating the population with positive measures<sup>17</sup>.

A policy based on mandatory measures involving restrictions on fundamental rights may be acceptable under certain conditions in terms of law, but it implies a situation of essential distrust against the citizens and vice-versa. Here, policy-makers defend an attitude hostile to free will, assuming that the citizens are unable to realize decided goals and participate in its success willingly. If non-compliant with the proportionality principle and the inviolability of the essence of the rights, according to the existing law, that policy risks deviating from the axiom of the fundamental rights prioritization in terms both of means and ends and embraces the attitude of state paternalism: State paternalism adopts unlimited restrictions often arguing in the name of (a never defined, and permanently unsafe) "freedom".

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<sup>16</sup> Contrary to a "managerial" deviation of their function, that compromises their independence. See on that issue, Cecile Vigour, "Justice: l'introduction d'une rationalité managériale comme euphémisation des enjeux politiques", *Droit et société* 63-64 (2006): 425-455.

<sup>17</sup> Following the line adopted by the Hellenic National Bioethics Commission also, [*Recommendation on the Ethical Dimension of Individual Responsibility for Addressing COVID-19*, Athens, 2020 (in Greek only)].

Because of their diametric divergence on the question of trust, these two policies are fundamentally incompatible, and their mixture leads to disappointing results, as demonstrated in the current example of the situation in Greece. Moreover, on the initial question of responsibility, a government that justifies mandatory restrictive measures referring to the “irresponsible behavior” of citizens must first demonstrate its previous active performance in promoting mutual trust. Again, this is the magic word, and any government remains accountable on that ground.

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# IMMUNITY PASSPORTS – BETWEEN HEALTH NECESSITY AND SOCIAL PRIVILEGE. HOW IS THE PANDEMIC RESHAPING SOCIAL IDENTITY?

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## **Abstract**

The COVID-19 pandemic represents a health risk faced by all countries in the world. As an answer to the pandemic, immunity passports with the goal of easing the movement of citizens who have developed an immune resistance have emerged. Even though such documents seem a medical necessity, they undoubtedly bring certain risks and privileges that can further increase existing inequalities. This paper discusses the introduction and use of such documents, and possible consequences within the post-pandemic society with special regards to overviews and examples from the European Union and member country Croatia.

## **I. Introduction**

A new virus that was discovered in China in 2019 and named SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus-2) caused the worldwide illness COVID-19. World Health Organisation (WHO) proclaimed a pandemic on the 11<sup>th</sup> of March 2020 after the number of cases outside of China rose, and social isolation and distancing measures were suggested even for countries with no registered cases.<sup>1</sup> With a lack of pharmaceutical solutions for suppressing the spread of the pandemic, and considering that vaccines are still being developed and tested, guidelines for preventing contagion were focused on wearing preventative masks, hygiene and physical distancing. Digital contact tracing via mobile phone applications was presented as a public health intervention with the goal of monitoring the spread of

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<sup>1</sup> Domenico Cucinotta and Maurizio Vanelli, “WHO Declares COVID-19 a Pandemic,” *Acta Biomedica* 91, no. 1 (2020): 157.



the virus.<sup>2</sup> Larger gatherings were prohibited and a mandatory distance between individuals was introduced, as well as the term social distancing being used by key figures. While social distancing was meant to indicate the importance of physical distancing, it is paramount to examine what is exactly included in social distancing. Are we become entangled in terminology and opened a path for the COVID-19 pandemic to truly lead to social distancing, social divides, and new inequalities? In sociology, social distancing relates to how people experience certain closeness, i.e., distance and distinction between oneself and people who belong to other social, ethnic, religious and professional groups.<sup>3</sup> One of the biggest challenges that this-century society faces is suppressing the pandemic. According to World Health Organisation, it took almost four million human lives until the 6<sup>th</sup> of July 2021, with more than 184 million people having been affected.<sup>4</sup> With great human losses, health challenges, stresses on health systems all over the world and significant economic losses, the experience of the pandemic most certainly left many negative consequences on social dynamics. People, social groups, members of certain nations and races began to be perceived as potential sources of contagion which led to social stigmatisation and marginalisation.<sup>5</sup> The post-pandemic society that everyone hopes for due to approved vaccines and successful vaccine campaigns poses new societal challenges. Introducing Digital Passports for members of the European Union, as well as global discussions about immunity passports, can potentially cause new divides. For example, on those who had recovered from the illness and those who had not, for those who are vaccinated and those who are not, as well we are dividing social privileges that some will have access to, while others will not. Immunity becomes an important aspect in determining identity and individual introduction, and it is important to critically consider the concept of immunity passports – are they a health necessity and need or are they a social privilege for privileged social groups that can lead to further inequalities, discrimination and social distance between social groups.

## II. Social identity of the (post)pandemic age

Identity is a set of features that define a person who has a certain role in society, is a member of a certain group and has special characteristics that identify them as a unique person, and every person possesses multiple identities as they belong to different groups, they fulfil multiple roles.<sup>6</sup> Identity is knowledge of who is being who, who we are, how do we perceive others, how do they perceive us.<sup>7</sup> Identity as

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<sup>2</sup> Vittoria Colizza et al., “Time to Evaluate COVID-19 Contact-Tracing Apps,” *Nature Medicine* 27, no. 3 (2021): 361.

<sup>3</sup> Darrin Hodgetts and Otilie Stolte, “Social Distance,” in *Encyclopedia of Critical Psychology*, ed. Thomas Teo (New York, NY: Springer New York, 2014), 1776–78.

<sup>4</sup> World Health Organization, “WHO Coronavirus (COVID-19) Dashboard,” n.d., <https://covid19.who.int/>.

<sup>5</sup> Divya Bhanot et al., “Stigma and Discrimination During COVID-19 Pandemic,” *Frontiers in Public Health* 8, no. January (2021): 4-7.

<sup>6</sup> Peter J. Burke and Jan E. Stets, *Identity Theory* (Oxford University Press, 2009), 3.

<sup>7</sup> Richard Jenkins, *Social Identity*, 2014, 17-19.

a personal characteristic is related to the society and community where the individual is, and as such, those are under mutual influence.

Social identity is related to the fact that individuals perceive themselves in comparison to others with whom they share certain characteristics (we), from whom they differ (them), i.e., based on in-group similarities and differences between groups.<sup>8</sup> Social identity is founded in belonging to a particular group based on political, religious, or ethnic affiliations, and we differentiate social from personal identity that is founded in roles within specific social structures like a worker, spouse, or parent.<sup>9</sup> The social component of identity is, in such a way, related to similarities between members of a group.<sup>10</sup> Erving Goffman notes the difference between social and personal identity, where social identity implies a group of visible features. In contrast, personal identity implies a group of particularities and biographical characteristics that are not initially visible.<sup>11</sup> Tajfel and Turner introduced the theory of social identity in the 1970s and 1980s, and they focused on membership, belonging to certain social groups and relationships between groups. For membership in a particular group, i.e., for belonging based on shared traits with no regard to context or meaning, the incentive for members of one group to discriminate against others outside of it is sufficient.<sup>12</sup> Knowledge of different groups is enough to prefer members of one's own group and to create a discriminatory answer.<sup>13</sup> Tajfel and Turner (2004) define a group as a set of individuals who perceive and define themselves as members of a particular group. A group is not necessarily a set of individuals that are interacting and communicating with each other, but also individuals who share certain practices and beliefs, as well as mutually recognizing them.<sup>14</sup> Any circumstance that can endanger an individual's membership in a group and damage their identification can cause identity disorders.<sup>15</sup> Experience of the pandemic as an unforeseeable circumstance can lead to significant disturbances and endanger identification based on work or health status.

Individuals strive for a positive social identity that stems from comparison to other relevant groups. If social identity is unsatisfactory, individuals will join a group with a positive connotation.<sup>16</sup> Introducing immunity passports has created a divide

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<sup>8</sup> Jean-Claude Deschamps and Thierry Devos, "Representations of Self and Group," in *Social Identity-Intentional Perspectives*, ed. Stephan Worchel et al. (London: Sage Publishing, 1998), 2–3., 2-3.

<sup>9</sup> Burke and Stets, *Identity Theory*, 3.

<sup>10</sup> Vlado Šakić, "Suvremeni pristupi identitetu s posebnim osvrtom na nacionalni identitet, [Contemporary Approaches to Identity with Special Reference to National Identity], in *Identitet Like: Korijen i Razvoj [Identity of Like: Root and Development]*, ed. Željko Holjevac (Zagreb: Institute of Social Sciences - Ivo Pilar, 2009), 24.

<sup>11</sup> Jenkins, *Social Identity*, 97.

<sup>12</sup> Jenkins, 114.

<sup>13</sup> Henri Tajfel and John C. Turner, *The Social Identity Theory of Intergroup Behavior*, *Political Psychology: Key Readings*, (New York: Psychology Press, 2004), 281.

<sup>14</sup> Katie Attwel and David T. Smith, "Parenting as Politics: Social Identity Theory and Vaccine Hesitant Communities," *International Journal of Health Governance* 22, no. 3 (2017): 2.

<sup>15</sup> Danijela Godinic, Bojan Obrenovic, and Akmal Khudaykulov, "Effects of Economic Uncertainty on Mental Health in the COVID-19 Pandemic Context: Social Identity Disturbance, Job Uncertainty and Psychological Well-Being Model," *International Journal of Innovation and Economic Development* 6, no. 1 (2020): 63.

<sup>16</sup> Tajfel and Turner, *The Social Identity Theory of Intergroup Behavior*, 284.

on those who will have easier movement (primarily travels, then other social activities) and those that do not meet the requirements for issuing such a document. Vaccination has served as a simple way of receiving immunity passports that can provide certain social privileges. It is the fear of losing privileges or a desire to get those privileges that can incentivise individuals who have shown resistance towards vaccination and make them reshape their opinions. In accordance with the nudge theory (Thaler & Sunstein),<sup>17</sup> immunity passports can serve as a simple and effective push system for reshaping people's opinions towards a wanted goal. Attwel and Smith bring an earlier example from Australia where individuals who identified themselves as vaccine opposers were incentivised without using force which was done via privileges (child support etc.) in order to motivate them to change their way of thinking and their practices.<sup>18</sup> As the COVID-19 pandemic has had a negative impact on Croatia's economy, the Government of the Republic of Croatia implemented an array of measures to preserve economic activities, especially for entrepreneurs and their workplaces. Employers have a right to financial support for preserving workplaces in the amount of 4.000,00HRK (530€) per employee.<sup>19</sup> With earlier conditions that employers had to fulfil in order to achieve that right, during a media conference on 1<sup>st</sup> of July 2021, Prime Minister Plenković mentioned a possibility of mandatory vaccination. According to his statements, vaccination of employees of a company that is receiving financial support is a logical move in the fight against the illness and the pandemic.<sup>20</sup> This sort of stimulation can incentivise employers to pressure their employees and demand them to get vaccinated in order for them to keep their jobs or for vaccinated employees to receive privileges. One company from Zagreb has published on their social media sites that they care about their workers and clients and any worker that brings a digital proof of vaccination will receive a financial reward. Considering that according to Eurofound data, 27% of European Union citizens do not plan to get vaccinated, introducing a digital verification can be seen as a subtle method in service of the vaccination campaign and making individuals leave the "opposing group" and enter the "vaccinated group". On one hand, basing immunity passports on vaccination paves the way for creating collective immunity which is available for the entire population and in such a way, nobody will be discriminated against as there is a solution for all community members.<sup>21</sup>

### *A. Social media and their role in reshaping identity*

The experience of quarantine and isolation has a different effect on individuals. Due to their inability to control the conditions around them, some have lost their jobs,

<sup>17</sup> Richard H. Thaler and Cass R. Sunstein, *Nudge - Improving Decisions About Health, Wealth and Happiness* (Yale University Press, 2008).

<sup>18</sup> Attwel i Smith "Parenting as Politics", 5.

<sup>19</sup> Koronavirus.hr, "Vladine Mjere [Government measures]."

<sup>20</sup> HRT, "Potpore Za Očuvanje Radnih Mjesta Samo Za Cijepljene," 2021, <https://vijesti.hrt.hr/hrvatska/plenkovic-kozy-potpore-za-ocuvanje-radnih-mjesta-morat-ce-se-cijepiti-2241702>.

<sup>21</sup> Rebecca C.H. Brown et al., "The Scientific and Ethical Feasibility of Immunity Passports," *The Lancet Infectious Diseases* 21, no. 3 (2021): 59.

and some had no problems with switching to the online world. Interactions were happening less face to face, and individuals have moved all of their social interaction into the virtual setting.<sup>22</sup> On social media Facebook, one can find several private groups like *Experiences of the COVID19 positive*, *Life after covid* that gather tens of thousands of members exchanging their experiences with strict rules that those who do not believe in COVID-19 are not welcome. It is possible to find groups that gather individuals who are vaccinated (*I got the COVID Vaccine*, *COVID-19 Vaccine- Evidence-Based Group*, etc.), as well as groups intended for persons vaccinated with a particular vaccine, e.g., *Pfizer-BioNTech Vaccinated*.

Communication via the Internet that is intertwined with mutual sharing of experiences and finding solace or inspiration has been noticed even earlier in people who declare themselves as vaccine opposers and, in such a way, feel connected to other members of the group.<sup>23</sup> Even in the case of COVID-19, it is possible to find online groups that bring together individuals who share the same opinion about rejecting vaccination. Eurofound has published statistical data on the intent of vaccination for countries of the European Union. The data shows that persons with tendencies towards using social media as an information source show a greater resistance to COVID-19 vaccination.<sup>24</sup> The large role social media played in informing during the pandemic can be seen through the social media platform called TikTok. Videos with the hashtag *#covid19vaccine* were viewed more than 120 million times in total, while short videos with the hashtag *#covid19* were viewed 70.5 billion times.<sup>25</sup> During the pandemic, social media, TikTok especially, served as a place of resocialisation for the youth. The analysis of videos from 2020 shows that videos recorded with a COVID-19 description were mostly related to a satirical representation of life during quarantine, pragmatic health information, official advice, and recovery journals.<sup>26</sup> Most viewed video recordings with the hashtag *#covid19vaccine* show the social benefits of vaccinated people. Many videos are focused on mocking side effects and differences between different vaccines. One of them showed what meeting people will look like in the year 2022, when the main information people give about themselves will be which vaccine they had received. The experience of the pandemic became a piece of important information while introducing oneself on social media. Individuals group themselves via online groups and find ways to mock those who do not share the same stance or do not go through the same experience. A frequent question that appears in interactions is – *What vaccine did you receive?* The need for distinction and creating differences emerged with vaccines and each of them has a certain meaning related to it, as well as the need for

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<sup>22</sup> Rebecca C.H. Brown et al., “Passport to Freedom? Immunity Passports for COVID-19,” *Journal of Medical Ethics* 46, no. 10 (2020): 654.

<sup>23</sup> Attwel and Smith, “Parenting as Politics: Social Identity Theory and Vaccine Hesitant Communities.”<sup>19</sup>.

<sup>24</sup> Eurofound, “Living, Working and COVID-19 (Update April 2021): Mental Health and Trust Decline across EU as Pandemic Enters Another Year,” 2021: 17.

<sup>25</sup> Tik-Tok analytics on July 20, 2021.

<sup>26</sup> Adam M. Ostrovsky and Joshua R. Chen, “TikTok and Its Role in COVID-19 Information Propagation,” *Journal of Adolescent Health* 67, no. 5 (2020): 730.

hierarchy.<sup>27</sup> One Internet portal in Croatia published an article titled “People who don’t want to get vaccinated are less smart than those who want to” referring to study Batty et al. This title alluded to the superiority of those vaccinated, creating direct divisions between the two groups. However, the study concludes that social media reports can complicate decision-making in people with lower cognitive abilities, leading to greater resistance to vaccination.<sup>28</sup>

### III. Immunity passports – Digital COVID Certificate

In order for life to get back to the “old normal” as soon as possible, immunity passports have been suggested in order to identify and document individuals’ immunity status.<sup>29</sup> In May 2020, Chile considered introducing a ‘release certificate’. By doing so, it became the first country that aimed to issue COVID-19 recovery verifications, which caused many questions about discrimination, creating an antibody elite and insufficient information about immunity duration.<sup>30</sup> At the end of May 2020, Estonia tested the first application that served as a confirmation about a person’s immunity status, and it enables sharing that information with a third party, for example, an employer.<sup>31</sup> At the end of April 2020, World Health Organisation spoke about immunity passports, noting that there is still no evidence that persons that had recovered from COVID-19 have enough immunity to prevent future contagion.<sup>32</sup> The concept developed in many countries around the world with the goal of finding a way of enabling simpler movement and for life to return to normal. Leader in vaccination, Israel, issued green verifications to its citizens.<sup>33</sup>

Such documents are not new to public health systems. A yellow card is a typical travel document that indicates an individual has been vaccinated against yellow fever and is a requirement for entering many African and South American countries. But this is the first time that the world has been supplied with digital solutions for tracking and suppressing the pandemic, from contact tracing applications to digital immunity passports.<sup>34</sup> When crossing the border and entering a foreign country, it is common practice to ask for an identifying document, which is used to determine from which country the person is coming, their age, sex, and nationality. Identification is a

<sup>27</sup> Tyler Cowen, “Which Vaccine Did You Get? It’s a Fraught Question,” [www.bloomberg.com](https://www.bloomberg.com/opinion/articles/2021-04-23/which-vaccine-did-you-get-each-has-its-own-reputation?srnd=technology-vp), 2021, <https://www.bloomberg.com/opinion/articles/2021-04-23/which-vaccine-did-you-get-each-has-its-own-reputation?srnd=technology-vp>.

<sup>28</sup> G. David Batty et al., “Pre-Pandemic Cognitive Function and COVID-19 Vaccine Hesitancy: Cohort Study,” *Brain, Behavior, and Immunity* 96, no. May (2021): 100.

<sup>29</sup> Brown et al., “The Scientific and Ethical Feasibility of Immunity Passports,” 58.

<sup>30</sup> Andrew Webb, “Coronavirus: How ‘Immunity Passports’ Could Create an Antibody Elite,” [www.bbc.com](http://www.bbc.com), 2020; Barbara Fraser, “Chile Plans Controversial COVID-19 Certificates,” *Lancet (London, England)* 395, no. 10235 (2020): 1473.

<sup>31</sup> E&T editorial staff, “Estonia Tests First Digital Immunity Passports for Workplaces,” 2020.

<sup>32</sup> World Health Organization, “Immunity Passports” in the Context of COVID-19,” *Scientific Brief*, 2020: 1.

<sup>33</sup> Mark A. Hall and David M. Studdert, “‘Vaccine Passport’ Certification — Policy and Ethical Considerations,” *The New England Journal of Medicine*, 2021, 1.

<sup>34</sup> Ignacio Cofone, “Immunity Passports and Contact Tracing Surveillance,” *Stan.Tech.L.Rev* 176 (2021): 177.

common practice in society, and it has the aim of establishing a meaning between individuals, the collective, and their similarities and differences.<sup>35</sup> These identification documents consist of identifiers that will be connected to an immunity system, i.e., status in regards to the coronavirus. Along with COVID-19 passports, there are many concerns, primarily insufficient knowledge about antibody efficiency in the case of a new contagion, test reliability, number of false negatives etc.<sup>36</sup> All of that can lead to privileges for one portion of society – immunoprivileged, while it can also lead to denying certain rights and freedoms to immunodeprived.<sup>37</sup> Historical examples show that we had already seen immunity-based divides in society. Yellow fever immunity had, throughout the 19<sup>th</sup> century, divided people into those who had survived and thus secured their immunity and those who had not. Advantages for those that had the “immunocapital” were reflected in their position in society, i.e., relations which resulted in creating an elite and increasing inequalities in society.<sup>38</sup> As vaccine availability enables almost everyone to create immunity, a question about timely and unique access arises as there are insufficient doses in certain parts of the world.<sup>39</sup> The long-term effects of the vaccine are still relatively unknown, as is its effect on new strains and how it affects particular groups, which leave enough room for fear and individuals refusing the vaccine. On the other hand, individuals who had recovered from the illness or are vaccinated will consider themselves not likely to transmit the disease and will not think themselves as a risk, thus preventing their free movement would be unjustified and unfair.<sup>40</sup> Individuals who had received the vaccine regard that as a “remedy” for returning to the “old normal”, which would mean free movement and social gatherings. In order to ease travel, immunity passports also offer an option of being tested via a test. The Civil Protection Headquarters of the Republic of Croatia made testing via quick antigen tests mandatory in Croatia for all who wish to attend certain events (wedding ceremonies, night club entry, festivals) and who do not have a Digital Certificate. Subjecting oneself to biomedical tests is a voluntary act. When a person resists testing, they could feel pressured and required to be tested, along with the fear that rejection could lead to their stigmatization in society.<sup>41</sup> Nuffield Council for Bioethics warns that if there will be testing pressure, there will also be pressure to reveal test results as a social norm which would mean that those who do not comply to the norm could be vulnerable to stigmatisation. In the context of employment, employers could favour persons that are “seropositive”, that have developed antibodies, also keeping in mind that they are

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<sup>35</sup> Jenkins, *Social Identity*.

<sup>36</sup> Jakov Vuković, “Imunološke Putovnice [Immunity Passports],” *Hrvatski Časopis Za Javno Zdravstvo* [Croatian Journal of Public Health] 17, no. 56 (2021): 29–30.

<sup>37</sup> Chee H. Liew and Gerard T. Flaherty, “Immunity Passports to Travel during the COVID-19 Pandemic: Controversies and Public Health Risks,” *Journal of Public Health (Oxford, England)* 43, no. 1 (2021): e135.

<sup>38</sup> Kathryn Olivarius, “The Dangerous History of Immunoprivilege,” *The New York Times*, 2020; Natalie Kofler and Françoise Baylis, “Ten Reasons Why Immunity Passports Are a Bad Idea,” *Nature* 581 (2020): 379–81.

<sup>39</sup> Brown et al., “The Scientific and Ethical Feasibility of Immunity Passports.”, e59.

<sup>40</sup> Brown et al., e60.

<sup>41</sup> Nuffield Council on Bioethics, “Rapid Policy Briefing,” no. March (2020): 3.

less prone to contagion, sick leave or transmitting the disease to their co-workers and clients. Such a stance could create an immunocertified workforce on the market that will be more desirable, and that could lead to negative social consequences.<sup>42</sup> Digital certificates provide a digital proof for three options: that the person is vaccinated, that the person has a negative test, or that the person has recovered from COVID-19. This can also lead to negative consequences for those that are against vaccines or do not have access to it due to some other reasons, and are not able to financially access the test. Their way of receiving the verification could mean deliberate exposure to the illness which would constitute a health issue on a public scale. Potentially imposed restrictions ranging from social, urban to economic could encourage individuals who cannot afford exclusion from the workforce or some other social activity to get infected.<sup>43</sup> Private companies or individuals exploiting such identifications could have a negative effect on others. For example, it could lead to people who are not yet immune paying higher insurance rates.<sup>44</sup> A question about individuals' privacy also arose with such a way of identifying. Certain tools and steps are needed to avoid issuing false passports, as well as care and protection of data and managing the said data as sensitive information is being gathered.<sup>45</sup> Research conducted on a sample of over 12 thousand scientists from around 60 countries shows that 36,5% of examinees believe that issuing immunity verifications will not be fair to those that do not have immunity, and 45,5% think that such certificates will only deepen social inequalities.<sup>46</sup>

On 17<sup>th</sup> of March 2021, the European Council suggested implementing a Digital Certificate that would ease traveling across the European Union during the COVID-19 pandemic. The purpose of such a certificate is a document that will serve as proof that the person has been vaccinated against COVID-19, that they have a negative test result, or that they have recovered from the illness. Following the Council's proposal, vice-president for values and transparency, Věra Jourová, said: "Our key goals are to offer a simple, non-discriminatory and safe tool that will completely comply with data protection."<sup>47</sup> In April, representatives of member countries agreed upon guidelines for technical system specifications, which signified the first step towards establishing the required infrastructure, as well as necessity and readiness on a national level in order for everything to be prepared for such verifications to be introduced in June 2021.<sup>48</sup> Council and Parliament reached a temporary agreement on the 20<sup>th</sup> of May 2021 where they stated that the certificate will not be a

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<sup>42</sup> Nuffield Council on Bioethics, 1; Brown et al., "Passport to Freedom? Immunity Passports for COVID-19.", e60.

<sup>43</sup> Alexandra L. Phelan, "COVID-19 Immunity Passports and Vaccination Certificates: Scientific, Equitable, and Legal Challenges," *The Lancet* 395, no. 10237 (2020): 1596.; Kofler and Baylis, "Ten Reasons Why Immunity Passports Are a Bad Idea", 381; Liew and Flaherty, "Immunity Passports to Travel during the COVID-19 Pandemic: Controversies and Public Health Risks.", e135.

<sup>44</sup> Teck Chuan Voo et al., "Immunity Certification for COVID-19: Ethical Considerations," *Bulletin of the World Health Organization* 99, no. 2 (2021): 157.

<sup>45</sup> Brown et al., "The Scientific and Ethical Feasibility of Immunity Passports.", e60.

<sup>46</sup> Ivan Aranzales et al., "Scientists' Opinions on Immunity Certificates: Evidence from a Large-Scale Survey among More than 12,000 Scientists.": 4.

<sup>47</sup> European Commission, 2021a.

<sup>48</sup> European Commission, 2021b.

requirement for the right of free movement and that they will not be considered a travel document. Certificates will be accepted in countries that are members of the EU and the countries themselves should not impose any further restrictions (e.g., quarantine, self-isolation, additional testing except if there is a greater need with a goal of protecting public health and the Council and other member countries should be notified of such a restriction at least 48 hours before it takes effect).<sup>49</sup> As of July 1<sup>st</sup>, 2021, Digital certificates are used in all member countries of the European Union.

European Digital Certificate on vaccination, testing or recovery information consists of basic information about an individual that has been recognised as the most necessary information. According to the passport information, all health data remains stored only in the country that issued the certificate. However, it is unclear whether third parties, except border control and activities that were earlier stipulated to be in need of such a verification, may request insight. With doing so brings individuals into an uncomfortable situation where they are required to display their medical information in order to achieve a particular social privilege. There is a question: will it be possible to attend a theatre play, rent accommodation, or take public transit in the near future if an individual does not have an immunity passport? Moscow already tried to restrict entry to restaurants only to those with a certificate, but that proved inefficient from an economic point of view.<sup>50</sup> At the end of June 2021, citizens have a CovidGo application at their disposal and it does not process personal information, but uses colours to inform about the person's status. Green if the verification is valid and red if it is not. In such a way, everyone has a possibility of scanning a certificate, their own as well as someone else's. As of July 1<sup>st</sup>, 2021, The Civil Protection Headquarters of the Republic of Croatia eased restrictions in regards to gatherings, socialising and parties, but a requirement for attending such an event is still a Digital Certificate. Event's organiser will examine all certificates at the entrance using a mobile application and those who do not fit into any of the designated categories will need to be tested using a rapid antigen test. Night clubs carry out testing in front of the entrance at promotional prices, but as it was already stated, pressure to get tested and display the results is in itself problematic and can lead to stigmatisation.

It is necessary to note the advantages of immunity passports in such a surrounding. This document could confirm a reduced risk of a particular individual and enable them to help in certain systems infringed by the coronavirus, e.g., volunteering in retirement homes, health institutions etc.<sup>51</sup> The already mentioned advantage is also eased movement to those who correspond to desired categories, as well as using passports as a "reward tool" for vaccination which can incentivise citizens for greater percentage of vaccinations that can in turn reduce the spread of the disease.

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<sup>49</sup> European Parliament, "EU-Ova Digitalna Potvrda o Covidu: Privremeni Dogovor Parlamenta i Vijeća.[EU Digital Certificate on Covid: An Interim Agreement between Parliament and the Council.]" 2021.

<sup>50</sup> Euronews, "Moscow Drops COVID Vaccination Proof Demand for Restaurant Clients," [www.europenews.com](http://www.europenews.com), 2021.

<sup>51</sup> Brown et al, "Passport to Freedom? Immunity Passports for COVID-19", 655.



#### IV. (In)equality of the COVID-19 age

Even though the primary function of immunity verifications or passports is to enable citizens to move and travel more easily, they also have another purpose. One of the first examples was Israel that uses a Green pass for entering objects like hotels, gyms, restaurants, theatres and concert halls.<sup>52</sup> At the beginning of June 2021, Israel stopped using Green passes for their citizens due to a good epidemiology situation and a good percentage of vaccinations, but it still remains closed for tourists, except smaller vaccinated groups.<sup>53</sup> Considering the initial function of such a document, it can also be used for other purposes. For example, prevent members of society who had not received the vaccine, who have not recovered from the disease, or do not have a negative test from attending social events and functions. Even though the Israeli verification is not in use and the European one is foreseen to be in function for 12 months, undoubtedly, it is necessary to critically consider the implications of a post-pandemic society that will, with or without a certificate, be vulnerable to new divides. New components of social identity could in such a way be based on immunity characteristics and vaccination.

Using immunity status verifications inevitably requires equal conditions for all in need of the certificate. If the person has not received the vaccine or has not recovered from the disease, they must have a negative test. Testing costs, and price of a PCR test in Zagreb is 390HRK, little over 50 euros, as is in Istria and Osijek County, while the same test in Zadar County is available at a price of 650HRK (87€).<sup>54</sup> A question arises why such test are not available to citizens all around the country at the same price. Hall and Studdert note it is necessary to ensure a just system of test availability if such verifications are to be used for different purposes.<sup>55</sup> As the strongest pandemic wave was underway, price was doubled. Hence, it is no surprise that, in particular counties, patients were rejected for testing if they had a family member that was infected or they were sent to quick antigen testing. At the same time, it was logistically impossible to track all contacts and those that maybe had less visible symptoms. It is precisely that practise that proved itself problematic for issuing digital verifications as individuals that were not tested nor has their data of recovery from COVID-19 been entered into the system now have no foundation for issuing the document. According to the media, many Croats found themselves in grey area because they were not registered in the system. The reason for that was official epidemiology guidelines and general practitioners' advice not to refer people for testing.<sup>56</sup>

The problem with contagion itself is certainly the stigmatisation that has occurred. Individuals identify themselves, but are also identified by others who differentiate them from other individuals.<sup>57</sup> Differences and similarities of individuals are reflected

<sup>52</sup> Hall and Studdert, "Vaccine Passport' Certification — Policy and Ethical Considerations.", 1.

<sup>53</sup> Reuters, "Israel to End COVID-19 Restrictions after Vaccine Success," 2021.

<sup>54</sup> Prices in June 2021.

<sup>55</sup> Hall and Studdert "Vaccine Passport' Certification — Policy and Ethical Considerations."

<sup>56</sup> Poslovni.hr, "[Many Croats Will Have the Same Problem Because They Have Fallen into the Gray Zone: 'They Don't Give Me a COVID Passport!]."

<sup>57</sup> Jenkins, *Social Identity*, 104.

in mutual characteristics with which we learn who we are, who we are not, where do we belong and where we do not (ibid.) In the context of social identity and COVID-19, individuals perceive members of their own group (with whom they share mutual traits) as less likely to be carriers of the disease.<sup>58</sup> Members of different groups are perceived as having a greater risk of spreading the disease. Negative association with a particular group that shares mutual characteristics is, according to the World Health Organisation, stigmatisation that can lead to labelling, creating stereotypes, discrimination.<sup>59</sup> Stigmatisation can serve those with more power to create and maintain inequalities between groups in order to keep their own position of power.<sup>60</sup>

The pandemic experience, as something new which presents a certain level of danger, can cause fear in people. The COVID-19 disease is a traumatic experience that differs from other trauma in its unpredictability, inability to be controlled, it creates fear from contagion, economic situations and isolation.<sup>61</sup> Individuals that had fallen ill had to remain in isolation because of it and felt worried about their health, as well as fearing stigmatisation by their family members, friends or work colleagues.<sup>62</sup> Stigmatisation related to the COVID-19 disease which began in early 2020 presents a significant danger to patients' and health workers' quality of life, along with all of those that had recovered.<sup>63</sup> Historically, epidemics and viral infections were related to stigmatisation and discrimination. An example from the last century is the Ebola epidemic that was spreading in West African countries and which caused social consequences such as exclusion and unemployment of those who were affected and recovered from the illness.<sup>64</sup> World Health Organisation defines social stigma in the context of health as a negative link between an individual or a group that shares certain characteristics and a particular disease which can, in times of epidemics and pandemics, lead to people being discriminated, labelled, treated in a special way, excluded and them losing their earlier social status.<sup>65</sup> During the COVID-19 pandemic, along with already mentioned patients and health workers, it was members of ethnical groups, most notably the Chinese, that faced those consequences. In Italy, that was reflected in the avoidance of social gatherings and events in spaces where there were members of the already mentioned ethnical community as they were

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<sup>58</sup> Tegan Cruwys, Mark Stevens, and Katharine H. Greenaway, "A Social Identity Perspective on COVID-19: Health Risk Is Affected by Shared Group Membership," *British Journal of Social Psychology* 59, no. 3 (2020): 588.

<sup>59</sup> K K Chopra and V K Arora, "Covid-19 and Social Stigma: Role of Scientific Community," *Indidan Journal of Tuberculosis* 67 (2020): 284.

<sup>60</sup> Arjan E.R. Bos et al., "Stigma: Advances in Theory and Research," *Basic and Applied Social Psychology* 35, no. 1 (2013): 2.

<sup>61</sup> Ibrahim A. Kira et al., "The Effects of COVID-19 and Collective Identity Trauma (Intersectional Discrimination) on Social Status and Well-Being," *Traumatology* 27, no. 1 (2020): 29.

<sup>62</sup> Penlioglou Theano et al., "Sarscov-2 Psychosomatic Effects and Fear of Stigma on the Discharge Day of Infected Individuals: Sapfo Study," *Psychiatria Danubina* 32, no. 3–4 (2021): 579.

<sup>63</sup> Sanjeet Bagcchi, "Stigma during the COVID-19 Pandemic," *The Lancet. Infectious Diseases* 20, no. 7 (2020): 782.

<sup>64</sup> Simone Villa et al., "Stigma at the Time of the COVID-19 Pandemic," *Clinical Microbiology and Infection* 26, no. 11 (2020): 1450.

<sup>65</sup> World Health Organization, "Social Stigma Associated with COVID-19 A Guide to Preventing and Addressing," no. February (2020): 1.

considered the source of the contagion.<sup>66</sup> Some politicians in Italy accused this group of poor hygiene and unhealthy cultural practices like eating mice, while the American president described COVID-19 as a Chinese virus which served as the foundation for stigmatising those persons.<sup>67</sup> According to a study that encompassed Chinese residents of 70 different countries, during the pandemic 25,11% of examinees encountered some form of discrimination or social exclusion.<sup>68</sup> Other research is in favour of such results which confirms that during the health crisis, the Asian population faced stigmatisation, discrimination and social exclusion.<sup>69</sup> The presence of the pandemic worsened the already existing inequalities amongst ethnical and cultural groups, which can be seen in the example of Canada.<sup>70</sup>

The ability to work based on one's immunity status could also create social stigma.<sup>71</sup> Stigma could go in the direction of those who had not been affected by the disease and because of their lack of antibodies, they could be perceived as individuals at great risk of spreading the virus. In a society where some had recovered from the disease or received the vaccine and those who had not, due to privileges, advantages, and pressure, individuals could change the group with which they identify and take steps that will make them a part of the other group. Many studies paint how the feeling of stigmatisation motivates individuals to reshape their social identity.<sup>72</sup> During the pandemic, stigmatisation was also important in restricting behaviour. During the 'lockdown' in many countries across the world, individuals were invited to refrain from leaving their houses unless absolutely necessary. Refraining from leaving one's house was considered a social norm in Japan, and public opinion on outgoings without a valid reason was considered antisocial behaviour, with all people who infringed on that norm being stigmatised due to their unethical behaviour.<sup>73</sup>

Kofler & Baylis note how immunity passports can easily serve as a new form of discrimination.<sup>74</sup> Today's immunity passport could become in the future a comprehensive biomedicine passport used by insurance companies, employers and public officers. Considering an immunity passport a health necessity can lay foundations for accepting such comprehensive passports where person's private data such as their health status will be considered mandatory information for identifying

<sup>66</sup> Chopra and Arora, "Covid-19 and Social Stigma: Role of Scientific Community.", 285.

<sup>67</sup> Villa et al., "Stigma at the Time of the COVID-19 Pandemic.", 1450.

<sup>68</sup> Jun He et al., "Discrimination and Social Exclusion in the Outbreak of COVID-19," *International Journal of Environmental Research and Public Health* 17, no. 8 (2020): 17-18.

<sup>69</sup> Cary Wu, Yue Qian, and Rima Wilkes, "Anti-Asian Discrimination and the Asian-White Mental Health Gap during COVID-19," *Ethnic and Racial Studies* 44, no. 5 (2021): 830.

<sup>70</sup> Diana Miconi et al., "Ethno-Cultural Disparities in Mental Health during the COVID-19 Pandemic: A Cross-Sectional Study on the Impact of Exposure to the Virus and COVID-19-Related Discrimination and Stigma on Mental Health across Ethno-Cultural Groups in Quebec (Canada)," *BJPsych Open* 7, no. 1 (2021): 1.

<sup>71</sup> Teck Chuan Voo, Hannah Clapham, and Clarence C. Tam, "Ethical Implementation of Immunity Passports during the COVID-19 Pandemic," *Journal of Infectious Diseases* 222, no. 5 (2020): 716.

<sup>72</sup> Teck Chuan Voo, Hannah Clapham, and Clarence C. Tam, "Ethical Implementation of Immunity Passports during the COVID-19 Pandemic," *Journal of Infectious Diseases* 222, no. 5 (2020): 716.

<sup>73</sup> Yuya Katafuchi, Kenichi Kurita, and Shunsuke Managi, "COVID-19 with Stigma: Theory and Evidence from Mobility Data," *Economics of Disasters and Climate Change* 5, no. 1 (2021): 73.

<sup>74</sup> Kofler and Baylis, "Ten Reasons Why Immunity Passports Are a Bad Idea," 380.

a high-quality worker or attaining civil rights. Such documents also have their use outside of crisis like the pandemic. The experience of current possession of such verification can become a trigger for further development. The already existing situation can serve as a testing phase for something that we can accept as normal, usual, and necessary in the future. Authors suggest for future research to focus on inequalities created by the pandemic,<sup>75</sup> changing identity and identifying with one's profession.<sup>76</sup> However, it is also important to examine the reasons for accepting documents like immunity passports and readiness for implementing such verifications as a part of the identifying process once the pandemic comes to its close.

## **V. Conclusion**

The coronavirus pandemic has been marking our society for the past two years and it continues to change social patterns on a daily level. Fear and many unknowns that have emerged with the virus have caused stigmatisation of those affected or of certain groups that were perceived as carriers of the disease. Introducing documents such as immunity verifications (passports, digital certificate) have paved the way for stigmatisation and discrimination of persons that have not yet created an immunity. In order to prevent that from spreading, it is necessary to ensure protective governance mechanisms and tools for suppressing discrimination. Immunity certificates can have the function of creating an infrastructure of stigmatisation that will, due to political decisions and tools of public health such as an immunity passport, potentially only deepen the already existing inequalities. Social activities are not available under equal conditions, and people who do not own a verification are denied easier access to events and gatherings. Even though one can understand the necessity of introducing such documents and their positive effect that is seen in easier movement across different countries, it is paramount to note that they can also serve as a foundation upon which persons with immunity can increase their privileges in the future. In the future, it is necessary to consider whether such passports are truly a health requirement or a privilege of those with better immunities. Immunity certificate can serve as a push tool for the vaccination campaign and in such a way motivate those who refuse the vaccine to receive their dosage in order to enjoy social privileges.

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<sup>75</sup> Anne Templeton et al., “Inequalities and Identity Processes in Crises: Recommendations for Facilitating Safe Response to the COVID-19 Pandemic,” *British Journal of Social Psychology* 59, no. 3 (2020): 680.

<sup>76</sup> Blake E. Ashforth, “Identity and Identification During and After the Pandemic: How Might COVID-19 Change the Research Questions We Ask?,” *Journal of Management Studies* 57, no. 8 (2020): 1765.

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# ETHICAL, LEGAL AND POLICY CHALLENGES IN COVID-19 CONTACT TRACING APPS: A EUROPEAN PERSPECTIVE

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## Abstract

In an effort to combat the global pandemic caused by COVID-19, countries around the world swiftly developed contact tracing mobile applications with the aim of fastening and objectivizing manual contact tracing of people infected with SARS-CoV-2 virus. The apps encountered worldwide scepticism regarding their ethics, especially considering the privacy issue. The idea was supported by several joint documents in theory, but only a few Member States implemented it in practice, with some of them differing even from the commonly agreed technical points. This reveals a lack of solidarity and political weakness, pointing to deeper political issues within the EU.

## I. Introductory remarks

The world faces one of the biggest health challenges in history: the global outbreak of the COVID-19 infection caused by SARS-CoV-2 virus, with already more than 4 million deaths<sup>1</sup> after World Health Organization's proclamation of the pandemic on 11 March 2020<sup>2</sup>. The outbreak, which had severely affected healthcare systems, demands tough choices and quick decisions to be made. Governments worldwide promptly introduced epidemiological measures to prevent the spread of the virus and stop its circulation among population. Besides personal hygiene, social distancing and

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<sup>1</sup> World Health Organization, "WHO Coronavirus (COVID-19) Dashboard With Vaccination Data," World Health Organization, 2021, <https://covid19.who.int/%0A>; <https://covid19.who.int/region/searo/country/bd>.

<sup>2</sup> WHO World Health Organization, "WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 - 11 March 2020," WHO Director General's speeches, March 11, 2020, <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19--11-march-2020>.

self-isolation, one of the most effective measures proved to be tracing contacts of those infected with COVID-19 through an app. Its primary aim is to identify possible transmitters of the infection and their isolation, thereby slowing down the transmission of the virus and flattening the pandemic curve. Traditionally, contact tracing was done manually by epidemiologists, but ever since the Ebola outbreak in 2014-2016 in West Africa there has been an increasing shift to new solutions using digital technologies, particularly mobile technology in the form of smartphone applications<sup>3</sup>. These new apps (hereinafter referred to as: (COVID-19) contact tracing apps) might help track and trace those infected and warn others of being in contact or proximity with COVID-19 positive person. To that end, two technology giants, Apple and Google partnered in building the application programming interfaces (APIs)<sup>4</sup>, which were adopted by the majority of European States, whereas some States in the USA are reluctant to agree to their usage<sup>5</sup>. Although this high-tech solution might seem promising in suppressing the spread of SARS-CoV-2 virus<sup>6</sup>, appearing altruistic and benevolent in protecting our health and the health of others, it also puts forward a lot of unanswered questions and issues relating to privacy, location tracking, and health data sharing, thus inciting a considerable amount of public debate. With the pandemic surging and, in that context, a necessity to act quickly and find an adequate solution to stop the outbreak requires an inevitable trade-off between health and privacy or, to push it even further, between democracy and technocracy. In this regard, this paper aims to provide a brief overview of the various existing approaches to COVID-19 contact tracing apps and their global implementation, with a focus on the EU, and to depict the legal framework and underlying ethical issues surrounding their development and implementation.

## II. State of the art

The global landscape of COVID-19 contact tracing apps presents various approaches, indicating a lack of global consensus. The apps differ in the technology they use, the information they collect, store, or share, the duration of information storage, the conditions to access the data, and the functions they perform. However, for the purpose of this paper, they can roughly be separated between those collecting vast amounts of personal data, particularly data on user's location, using GPS (Global Positioning System) and those using more privacy-friendly technologies such as Bluetooth, thus avoiding location tracing. The GPS based apps represent a vertical approach that uses the location history of the user to map their movement in order

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<sup>3</sup> Lisa O. Danquah et al., "Use of a Mobile Application for Ebola Contact Tracing and Monitoring in Northern Sierra Leone: A Proof-of-Concept Study," *BMC Infectious Diseases* 19, no. 1 (December 18, 2019): 810, <https://doi.org/10.1186/s12879-019-4354-z>.

<sup>4</sup> Google and Apple, "Privacy-Preserving Contact Tracing - Apple and Google," Apple.com, 2020, <https://covid19.apple.com/contacttracing>.

<sup>5</sup> Aaron Holmes and Hugh Langley, "Apple and Google's COVID-19 Contact-Tracing Tech," *Businessinsider.com*, June 10, 2020, <https://www.businessinsider.com/apple-google-coronavirus-contact-tracing-tech-states-dont-plan-using-2020-6>.

<sup>6</sup> Máté Julesz, "Health equity and health data protection related to telemedicine amid the COVID-19 pandemic", *Információs Társadalom XXII*, no. 2 (2022): 27–38, <https://dx.doi.org/10.22503/inftars.XXII.2022.2.2>.

to determine whether the user has been in close contact with someone infected or, if the user has been recognized and registered as COVID-19 positive, to alert other users who crossed paths with her/him<sup>7</sup>. The apps based on Bluetooth technology represent a horizontal approach to detecting the proximity of two app users with the purpose of subsequent alerts, but they do not track their location history or share any other data since the app generates only anonymous codes to be exchanged between the devices or a device and a server<sup>8</sup>. Considering their broad usage of technology and low sensitivity to government surveillance, the first group is predictably predominant in Asian countries, such as South Korea<sup>9</sup> and China, but it was also adopted by the Israeli<sup>10</sup> government. A particularly interesting example of this approach is China's system which generates red, yellow or green QR code based on the data inserted by a user, thereby allowing or prohibiting their entrance in public transport vehicles, restaurants, airports, shops and even their own neighbourhood. Although the app is not explicitly mandatory, many places demand the customers' QR codes as the only way to enter the place<sup>11</sup>. As an exemption in Asia, Singapore's TraceTogether app<sup>12</sup> relies on Bluetooth technology instead, and so the app does not record locations where its users have been, but only traces whom they have been close to. The data on proximity is only shared with the Singaporean Ministry of Health upon its request and user's consent. This approach, followed by most European countries, can be further subdivided according to the location where the data is stored, separating those that store data centrally on a server usually owned by the government or the Ministry of Health from those that opted for decentralized storage of data on users' smartphones. The European response to building contact tracing apps started as early as the spring of 2020 with the project called Pan-European Privacy-Preserving Proximity Tracing (PEPP-PT), "created to assist national initiatives by supplying ready-to-use, well-tested, and properly assessed mechanisms and standards, as well as support for interoperability, outreach, and operation when needed."<sup>13</sup> However, on 19 April 2020 over 300 international scientists signed a Joint Statement on Contact Tracing in which they endorsed usage of Bluetooth technology instead of geolocation, but also warn against some of Bluetooth-based proposals that do not respect privacy due to the so-called

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<sup>7</sup> Shaoxiong Wang, Shuizi Ding, and Li Xiong, "A New System for Surveillance and Digital Contact Tracing for COVID-19: Spatiotemporal Reporting over Network and GPS," *JMIR MHealth and UHealth* 8, no. 6 (June 10, 2020): e19457–e19457, <https://doi.org/10.2196/19457>.

<sup>8</sup> Johannes Abeler et al., "Covid-19 Contact Tracing and Data Protection Can Go Together", *JMIR MHealth and UHealth* 8, no. 4 (2020): e19359, <https://doi.org/10.2196/19359>.

<sup>9</sup> Cuthbertson A., "Coronavirus Apps Let People Avoid High-Risk Locations in South Korea," *Independent*, March 3, 2020, <https://www.independent.co.uk/life-style/gadgets-and-tech/news/coronavirus-news-app-south-korea-latest-cases-deaths-location-a9371651.html>.

<sup>10</sup> Joe Tidy, "Coronavirus: Israel Enables Emergency Spy Powers," *BBC News*, March 17, 2020, <https://www.bbc.com/news/technology-51930681>.

<sup>11</sup> Paul Mozur, Raymond Zhong, and Aaron Krolik, "In Coronavirus Fight, China Gives Citizens a Color Code, With Red Flags - The New York Times," *New York Times*, March 1, 2020, <https://www.nytimes.com/2020/03/01/business/china-coronavirus-surveillance.html>.

<sup>12</sup> Government of Singapore, "TraceTogether," accessed July 27, 2021, [www.tracetgether.gov.sg/](http://www.tracetgether.gov.sg/).

<sup>13</sup> Media Information PEPP-PT, "Privacy Protecting Proximity Tracing to Fight Corona," April 1, 2020, <https://www.ga4gh.org/wp-content/uploads/2020-04-01-PEPP-PT-Press-Realease.pdf>.

centralized approach<sup>14</sup>. The Statement strongly praises a joint initiative launched by Google and Apple and other privacy-preserving methods developed by different initiatives worldwide, including Swiss-led Decentralized Privacy-Preserving Proximity Tracing (DP-3T), but it does not mention PEPP-PT, which was interpreted as withdrawal of European experts from PEPP-PT project, as later also explicitly confirmed by some of them<sup>15</sup>. In line with that argumentation, the European Parliament also recommended a decentralized approach, calling for coordinated action between Member States<sup>16</sup>. Nevertheless, some of the EU Member States use centralised approach and some even use GPS tracking, as shown in Table 1.

**Table 1. Overview of contact tracing apps currently in use in EU Member States**

EU Member State	Name of the app	GPS or Bluetooth	Centralised (C) or decentralised (D) approach	Voluntary (V) or mandatory (M) use	Legal basis for data processing
Austria	Stopp Corona	Bluetooth	D (Google/Apple)	V	Consent
Belgium	Coronalert	Bluetooth	D (Google/Apple)	V	Consent
Bulgaria	Virusafe	GPS	C	V	Consent
Croatia	Stop COVID-19	Bluetooth	D (Google/Apple)	V	Public interest
Cyprus	CovTracer	GPS	C	V	Consent
Czech Republic	eRouska	Bluetooth	D (Google/Apple)	V	Public interest
Denmark	Smittestop	Bluetooth	D (Google/Apple)	V	Public interest
Estonia	HOLA	Bluetooth	D (Google/Apple, DP-3T)	V	Consent
Finland	Koronavilkku	Bluetooth	D (Google/Apple)	V	Public interest
France	TousAntiCovid	Bluetooth	C	V	Public interest

<sup>14</sup> Sebastian Klöckner, “Contact Tracing Joint Statement,” Helmholtz Center for Information Security, April 19, 2020, <https://cisa.saarland/de/2020/04/20/joint-statement-on-contact-tracing.html>.

<sup>15</sup> Vincent Manancourt, Laurens Cerulus, and Joanosch Delcker, “Tech Feud Complicates EU Search for Coronavirus Tracking App – POLITICO,” Politico, April 20, 2020, [www.politico.eu/article/tech-feud-complicates-eu-search-for-coronavirus-tracking-app/](http://www.politico.eu/article/tech-feud-complicates-eu-search-for-coronavirus-tracking-app/).

<sup>16</sup> European Parliament (EP), ‘Resolution of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences’ (2020/2616(RSP)) P9\_TA(2020)0054.

EU Member State	Name of the app	GPS or Bluetooth	Centralised (C) or decentralised (D) approach	Voluntary (V) or mandatory (M) use	Legal basis for data processing
Germany	Corona-Warn-App	Bluetooth	D (Google/Apple)	V	Consent
Hungary	VirusRadar	Bluetooth	C	V	Consent
Ireland	COVID Tracker	Bluetooth	D (Google/Apple)	V	Consent
Italy	Immuni	Bluetooth	D (Google/Apple)	V	Public interest
Latvia	Apturi Covid	Bluetooth	D (Google/Apple)	V	Public interest
Lithuania	Karantinas	Bluetooth	D (Google/Apple)	V	Consent
Malta	COVID Alert Malta	Bluetooth	D (Google/Apple)	V	Consent
Netherlands	CoronaMelder	Bluetooth	D (Google/Apple)	V	Public interest
Norway <sup>17</sup>	Smittestop	Bluetooth and GPS	C	V	Consent
Poland	ProteGO	Bluetooth	D (Google/Apple)	V	Public interest
Portugal	STAYAWAY COVID	Bluetooth	D (Google/Apple)	V	Public interest
Slovenia	#OstaniZdrav	Bluetooth	D (Google/Apple)	V	Consent
Spain	Radar COVID	Bluetooth	D (Google/Apple)	V	Public interest

Table 1. reveals the predominance of a voluntary approach in contact-tracing app usage in all Member States that developed an app. Member States not included in Table 1. have either not developed an app yet (Slovakia and Greece) or do not intend to build it at all (Sweden, Luxembourg and Romania). Table 1. also shows consistent adoption of Bluetooth technology among Member States that released an app, with the exception of Bulgaria and Cyprus who opted for GPS tracking. It also seems that the use of a Bluetooth technology comes in pair with the decentralised approach and the use of Google and Apple's APIs, thus making the French and Hungarian exception a significant one. The legal basis for data processing within the app therefore remains the only major point of difference between Member States, although consent is favoured as a legal basis in most of them. However, the table serves as a strong indication that there is no common European approach to the

<sup>17</sup> Although it is not part of the EU, Norway is relevant as part of the European Economic Area and part of the eHealth Network and therefore relevant for this overview.

development and implementation of contact tracing apps, stirring concern for the future of the EU internal market and solidarity among Member States.

### III. Challenges in the development and implementation of COVID-19 contact tracing apps

Ethical, legal and policy issues related to the contact tracing apps can roughly be divided into three categories: issues relating to app's usage and effectiveness, privacy issues and questions regarding further implications of contact tracing apps.

Regarding the voluntariness of use, the EU Member States opted for a voluntary approach, thereby leaving the decision of whether they want to use an app to each individual user. This approach is not accepted just in the EU, but overwhelmingly around the world, with the exception of China, Qatar, Turkey and India<sup>18</sup>. From the libertarian perspective, this solution is welcomed, but leaves space for debating its effectiveness since the success of contact tracing apps largely depends on their broad usage. According to some studies for these apps to be effective, they should be used by at least 60% of a country's population<sup>19</sup>. One survey has earlier shown that almost 70% of population in the USA, France, Italy, the UK and Germany would definitely or probably install the app<sup>20</sup>. However, although some apps were indeed downloaded many times, it seems like the download rate is nowhere close to the desired 60%<sup>21</sup>, even in the most tech-prone countries, such as Singapore<sup>22</sup>. That is why some authors argue that, in the context of the pandemic, not using contact tracing apps could, in fact, be unethical and irresponsible<sup>23</sup>, especially given the fact that tracking via geolocation became so acceptable with the use of social media and other apps, such as those for carpooling and deliveries<sup>24</sup>. At first sight, it seems that such an approach is far from being adopted by the EU Member States, but on 14 October 2020 Portuguese government adopted a law proposal which would, subject to the Parliament's approval, make installation of the Portuguese app obligatory in certain contexts, including armed forces, employment, education and public service<sup>25</sup>. In

<sup>18</sup> TUM Institute for Ethics in Artificial Intelligence (IEAI), "Ethics and the Use of AI-Based Tracing Tools to Manage the COVID-19 Pandemic" 17, no. June (June 2020): 1–13, [https://ieai.mcts.tum.de/wp-content/uploads/2020/06/Research-Brief\\_ContactTracingAppsFinal-1.pdf](https://ieai.mcts.tum.de/wp-content/uploads/2020/06/Research-Brief_ContactTracingAppsFinal-1.pdf).

<sup>19</sup> Luca Ferretti et al. "Quantifying SARS-CoV-2 Transmission Suggests Epidemic Control with Digital Contact Tracing," *Science* 368, no. 6491 (May 8, 2020): eabb6936, <https://doi.org/10.1126/science.abb6936>.

<sup>20</sup> Abeler, "Covid-19 Contact Tracing", e19359.

<sup>21</sup> Alessandro Blasimme and Effy Vayena, "What's next for COVID-19 Apps? Governance and Oversight," *Science* 370, no. 6518 (November 2020): 760–62, <https://doi.org/10.1126/science.abd9006>.

<sup>22</sup> Michelle M. Mello and C. Jason Wang, "Ethics and Governance for Digital Disease Surveillance," *Science* 368, no. 6494 (May 2020): 951–54, <https://doi.org/10.1126/science.abb9045>.

<sup>23</sup> Jessica Morley et al., "Ethical Guidelines for COVID-19 Tracing Apps," *Nature* 582, no. 7810 (June 2020): 29–31, <https://doi.org/10.1038/d41586-020-01578-0>.

<sup>24</sup> Wang, "A New System for Surveillance", e19457.

<sup>25</sup> REPÚBLICA PORTUGUESA, "Comunicado Do Conselho de Ministros de 22 de Outubro de 2020," October 31, 2020, <https://www.portugal.gov.pt/pt/gc22/governo/comunicado-de-conselho-de-ministros?i=376>.

France, however, upon the government's request French supervisory authority for data protection (the CNIL) issued a preliminary opinion on the French app<sup>26</sup>. The opinion stresses that the voluntary basis of the app's usage means that there cannot be negative consequences, in terms of access to healthcare, as well as to some services, such as public transport, for citizens that opt not to use the app. Another issue related to the app's usage arises from the fact that not every person possesses a smartphone and, thus, they are not able to instal and use the app either. Ironically, those are predominantly older people who are not that prone to technology<sup>27</sup> and who happen to also be the most vulnerable to the virus contagion<sup>28</sup>. Taking into account the fact that almost 20% of the EU's population is of age 65 years or more, this becomes a significant factor in assessing the overall effectiveness of the app<sup>29</sup>. Some authors consider it so important that they propose governmental incentives in form of specially designed and freely distributed smartphones which would be more user friendly to elderly people<sup>30</sup>. From the technological perspective, using Bluetooth technology, besides all positive aspects, certainly has disadvantages too, the first one being its lack of precision in terms of proximity, enabling, for example, false positive infection alerts because two people were close to each other, but separated by a wall<sup>31</sup>. This technological approach also requires users to keep their Bluetooth constantly turned on, which can incite some privacy risks<sup>32</sup> and also quickly exhaust the battery, posing another practical problem of using contact tracing apps and diminishing user satisfaction. Furthermore, the German Corona Warn App encountered some serious difficulties in its functioning<sup>33</sup>, and currently implemented apps did not receive very high marks. For example, three apps from the largest EU countries, France, Germany and Italy, received an average mark of 3.0 with more than 150,000 reviews<sup>34</sup>. This may seem like a secondary issue, but an average app user's decision on whether he

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<sup>26</sup> Commission Nationale de l'Informatique et des Libertés, "Délibération N° 2020-046 Du 24 Avril 2020 Portant Avis Sur Un Projet d'application Mobile Dénommée « StopCovid »,» April 24, 2020, <https://www.cnil.fr/fr/publication-de-lavis-de-la-cnil-sur-le-projet-dapplication-mobile-stopcovid>.

<sup>27</sup> Ionut Andone et al., "How Age and Gender Affect Smartphone Usage," in *UbiComp 2016 Adjunct - Proceedings of the 2016 ACM International Joint Conference on Pervasive and Ubiquitous Computing, UbiComp '16* (New York, NY, USA: Association for Computing Machinery, 2016), 9–12, <https://doi.org/10.1145/2968219.2971451>.

<sup>28</sup> Jérémie Cohen et al., "COVID-19-Related Mortality by Age Groups in Europe: A Meta-Analysis," *Frontiers in Medicine*, 2020, 2020.04.11.20061721, <https://doi.org/10.1101/2020.04.11.20061721>.

<sup>29</sup> Eurostat, "Statistics on Regional Typologies in the EU - Statistics Explained," June 11, 2018, [https://ec.europa.eu/eurostat/statistics-explained/index.php/Statistics\\_on\\_regional\\_typologies\\_in\\_the\\_EU#Urban-rural\\_typology](https://ec.europa.eu/eurostat/statistics-explained/index.php/Statistics_on_regional_typologies_in_the_EU#Urban-rural_typology).

<sup>30</sup> Michele Loi, "How to Fairly Incentivise Digital Contact Tracing," *Journal of Medical Ethics*, July 9, 2020, medethics-2020-106388, <https://doi.org/10.1136/medethics-2020-106388>.

<sup>31</sup> Morley, "Ethical Guidelines for COVID-19 Tracing Apps", 29–31.

<sup>32</sup> Urs Gasser et al., "Digital Tools against COVID-19: Taxonomy, Ethical Challenges, and Navigation Aid," *The Lancet Digital Health* 2, no. 8 (August 1, 2020): e425–34, [https://doi.org/10.1016/S2589-7500\(20\)30137-0](https://doi.org/10.1016/S2589-7500(20)30137-0).

<sup>33</sup> Deutsche Welle, "Germany Launches 'best' Coronavirus Tracing App," Deutsche Welle, 2020, <https://www.dw.com/en/germanys-coronavirus-tracing-app-criticized-over-warning-failures/a-54305099>.

<sup>34</sup> "Data from Google Play Store Verified on 4 November 2020," accessed July 27, 2021, <https://play.google.com/store/movies>.



or she shall use an app depends also on whether the app is properly functioning and easy to use. Given that the effectiveness of the app depends on its broad usage, this issue should not be easily disregarded<sup>35</sup>.

One of the main concerns that arises with the use of contact tracing apps is an issue of privacy in terms of collecting and processing personal data. Due to the famous privacy by-design principle embodied in Article 25 of the General Data Protection Regulation (hereinafter referred to as GDPR), the EU Member States were obliged to consider data protection when developing a contact tracing app<sup>36</sup>. In some countries the debate on data protection within contact tracing apps has been a very heated and difficult one, with various stakeholders voicing their opinions and governments having to balance between protection of health and protection of privacy<sup>37</sup>. As to the legitimacy of data processing within the app, most of the EU Member States decided to use consent as the basis for data processing, pursuant to Art 6.(1)(a) of the GDPR. This has to be differentiated from voluntary installation and use of the app, since it concerns data processing within the app, i.e. when the app is already installed. However, “consent will not be considered to be free if the data subject is unable to refuse or withdraw his or her consent without detriment” and “where there is any element of compulsion, pressure or inability to exercise free will”<sup>38</sup>. These elements of compulsion and pressure are taken broadly, particularly in situations where there is an imbalance of power, which is typical for a relationship between a government and an individual. Thus, to be legitimate, the consent-based processing within contact tracing apps has to be truly free of any coercion or pressure whatsoever by a government, including, for example, stigmatization and shaming of citizens who opt not to share their data with the app. Except for consent, the GDPR offers another legal basis for processing the data within the framework of contact tracing apps, considered by the European Data Protection Board as “the most relevant legal basis for the processing”<sup>39</sup>, and used by several EU Member States: the necessity for the performance of a task in the public interest set out in the Art. 6(1)(e) GDPR. Therefore, the processing of data within the app could also be mandatory once a citizen opts to use the app if it is regarded as a necessity for combating the pandemic. However, to be legitimate this legal basis must be established within the legal framework of the Union or a Member State (Art. 6(3) GDPR). Location and duration of storage of data collected through contact tracing apps also appear to be

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<sup>35</sup> Kerstin N. Vokinger et al., “Digital Health and the COVID-19 Epidemic: An Assessment Framework for Apps from an Epidemiological and Legal Perspective,” *Swiss Medical Weekly* 150, no. 19–20 (May 2020): w20282, <https://doi.org/10.4414/sm.w.2020.20282>.

<sup>36</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1.

<sup>37</sup> IEAI, “Ethics and the Use of AI-Based Tracing”, 1-13.

<sup>38</sup> Article 29 Data Protection Working Party. Guidelines on Consent under Regulation 2016/679 (Adopted on 28 November 2017).

<sup>39</sup> European Data Protection Board, “Guidelines 04 / 2020 on the Use of Location Data and Contact Tracing Tools in the Context of the COVID-19 Outbreak,” April 21, 2020, [https://edpb.europa.eu/sites/edpb/files/files/file1/edpb\\_guidelines\\_20200420\\_contact\\_tracing\\_covid\\_with\\_annex\\_en.pdf](https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_20200420_contact_tracing_covid_with_annex_en.pdf).

one of the central privacy issues. While the location is determined by choosing a centralized or decentralized model, the period of time for which the data is stored seems to be more obscure. Some apps indicate in their privacy policies that the data will be deleted once the pandemic is over<sup>40</sup>, but it remains unclear who will proclaim that end or how it ought to be done, especially after the experience of a “fourth wave” of the pandemic in Europe bringing new lockdowns and further measures. This issue is particularly sensitive for those apps that use a centralized model and, therefore, store the data on a server, such is the case in France, Hungary, Cyprus, and Bulgaria. Lack of transparency, clear rules and open communication about the app’s features could lead to a loss of public trust and thus undermine the use and, consequently, the effectiveness of the application<sup>41</sup>.

Another question worth assessing is the issue of further use of the data and their possible misuse. Where there is technology there is also a danger of technology misuse and abuse or even dual use. In its privacy policy the Maltese app explicitly confirms that “there is a certain likelihood that, when someone is notified of a possible exposure, their recollection of social contacts over recent days may allow them to deduce the identity of the infected individual. (...) As a result of using the app, persons may thus potentially be identified”<sup>42</sup>. In this context, the Common EU Toolbox developed by the European Commission emphasizes a need for strong cyberattack protection, which probably goes without saying. However, the public could also be alarmed if the development of the app lacks transparency or even if its development is partially funded by Chinese investors, which was an issue with Italy’s app<sup>43</sup>. The misuse could also occur should the data collected through the app be further analysed for different purposes, even by the government and even on a legitimate basis<sup>44</sup>. According to Article 6.4. of the GDPR, different purpose for data processing must be explained before collecting the data. Thus, if the data from the contact tracing apps is to be used for different purposes, that should be emphasized at the outset. The Hungarian app, for example, notifies its users of further processing of the data by the national health authority with the purpose of taking measures necessary in the interests of public health and epidemiology<sup>45</sup>. Considering the value of these data to future research, this approach is not surprising<sup>46</sup>. On the other hand, Norwegian data protection authority issued temporary ban on the processing of

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<sup>40</sup> Austrian red cross, “Datenschutzerklärung-Stopp-Corona-App – Rotes Kreuz,” accessed July 27, 2021, <https://www.roteskreuz.at/datenschutzerklaerung-stopp-corona-app>.

<sup>41</sup> IEAI, “Ethics and the Use of AI-Based Tracing”, 1-13.

<sup>42</sup> Ministry of Health, “COVID Alert Malta Privacy Policy,” accessed July 27, 2021, [https://deputyprimeminister.gov.mt/en/administration-and-communication/Documents/data-protction/Covid\\_Alert\\_App\\_-\\_Privacy\\_Policy.pdf](https://deputyprimeminister.gov.mt/en/administration-and-communication/Documents/data-protction/Covid_Alert_App_-_Privacy_Policy.pdf).

<sup>43</sup> IEAI, “Ethics and the Use of AI-Based Tracing”, 1-13.

<sup>44</sup> Marielle S Gross, Robert C Miller, and Assya Pascalev, “Ethical Implementation of Wearables in Pandemic Response: A Call for a Paradigm Shift,” Edmond J. Safra Center for Ethics, May 18, 2020, 1–24.

<sup>45</sup> VirusRadar, “VirusRadar - a Koronavírus Követésére És a COVID-19 Elleni Védekezésre,” accessed July 27, 2021, <https://virusradar.hu/privacy-policy>.

<sup>46</sup> Michael J. Parker et al., “Ethics of Instantaneous Contact Tracing Using Mobile Phone Apps in the Control of the COVID-19 Pandemic,” *Journal of Medical Ethics* 46, no. 7 (July 1, 2020): 427–31, <https://doi.org/10.1136/medethics-2020-106314>.

personal data collected through the contact tracing app precisely because the data was further processed for analysis and research, concluding that “the app interferes disproportionately in user privacy based on the current transmission rate in Norway, the chosen technical solution and the general support for the app”<sup>47</sup>. This led to a temporary deactivation of the app and erasure of all the collected data.

#### IV. European legal framework: a failed opportunity?

Considering freedom of movement as one of the four fundamental freedoms of the EU, which was severely hampered by the coronavirus crisis, a common approach to the development of contact tracing apps should have aimed at preventing closing down the borders between the Member States and preserving freedom of movement within the EU. However, the overview from the Table 1. shows that such common approach was more a dream and less a reality.

In terms of policy making, the EU reacted promptly on announcements about the coronavirus tracking apps. With the support of the European Commission most of the Member States who opted for Bluetooth technology combined with decentralised approach agreed on certain technical points<sup>48</sup>. Those are embodied in the Guidelines developed by the eHealth Network, a voluntary cooperative body set up by Member States and Norway<sup>49</sup>. The Guidelines should have enabled interoperability and undisturbed functioning of the apps for users across the EU’s internal borders. Besides those Guidelines and the Resolution issued by the European Parliament, the European Commission also issued the Recommendation on a common Union toolbox for the use of technology and data for combat and exit from the COVID-19 crisis, particularly concerning mobile applications and the use of anonymized mobility data<sup>50</sup>. The Toolbox adopts some main recommendations for a common approach to mobile tracing apps, which range from epidemiologically relevant features, through technical requirements, cybersecurity and safeguards, to necessary prerequisites for cross-border interoperability. Again, one of the main goals of the Toolbox was the adoption of a common EU approach to mobile tracing apps, which would have ensured interoperability and consistency among the apps developed by the Member States. Furthermore, the EU data protection highest authority, the European Data Protection Board (EDPB) issued Guidelines on the use of location data and contact tracing tools in the context of the COVID-19 outbreak<sup>51</sup>. The Guidelines recommend using proximity tracing instead of location

<sup>47</sup> NIPH, “NIPH Stops Collection of Personal Data in Smittestopp,” Norwegian Institution of Public Health, June 15, 2020, <https://www.fhi.no/en/news/2020/niph-stops-collection-of-personal-data-in-smittestopp/>.

<sup>48</sup> European Commission, “Coronavirus: Member States Agree on an Interoperability,” June 16, 2020, [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_20\\_1043](https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1043).

<sup>49</sup> European Union, “E-Health Network Guidelines,” EU Member States and the European Commission, June 12, 2020, [https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev\\_2019\\_0611\\_co922\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_2019_0611_co922_en.pdf).

<sup>50</sup> eHealth Network, “Mobile Applications to Support Contact Tracing in the EU’s Fight against COVID-19,” Eu report. Common EU Toolbox for Member States Version 1.0 15.04.2020, April 15, 2020, [https://ec.europa.eu/health/sites/health/files/ehealth/docs/covid-19\\_apps\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/covid-19_apps_en.pdf).

<sup>51</sup> European Union, “E-Health Network Guidelines”.

data and they also clearly favour storing data on users' terminal equipment thereby opting for a decentralized approach to data storage.

Although privacy is a heavily debated topic in most of the world countries, it is fair to claim that the EU went one step further in designing a comprehensive legal framework of privacy protection embodied foremostly in the GDPR and directly enforceable in all the EU Member States. In that regard, the apps developed by the Member States dedicated serious effort to preserving privacy by the majority of them opting for the decentralized model and by choosing either consent or public interest as the legal basis for processing the data within the app. However, there are fears that accepting generous help from Apple and Google, who are already planning to integrate their technology directly into their operating systems instead of using it through an application, might have built the foundation for a new era in mass surveillance<sup>52</sup>. By using Apple and Google's APIs most of the Member States accepted the interference of those two giant tech companies in the realm of politics and decision making, which could have unprecedented implications for future governing<sup>53</sup>, especially in the context of the inexistent common European approach to the development of the apps. Having that in mind, it seems that the centralized model could have been more apt considering the broader danger of privatization of public service<sup>54</sup>.

Even if those fears are unfounded, it is fair to say that the EU missed its chance to use its own technology and resources which could have arguably strengthened the public trust in contact tracing apps. Furthermore, the "made in EU" apps could have ensured interoperability even if each Member State still developed its own app and this could have been a key for preserving the freedom of movement within the EU. Yet, it seems that the second wave prompted some change: according to the European Commission's data, German, Italian, Irish, Latvian, Croatian, Danish and Spanish contact tracing apps are already interoperable, in the sense that they can already "talk" to another app, i.e. exchange data with it<sup>55</sup>. The same source claims potential interoperability that is yet to be established for all other contact tracing apps except French and Hungarian ones which did not envisage the interoperability as its feature. It remains to be seen how this interoperability is going to be implemented in practice, especially having in mind the voluntary character of the apps. Firstly, as already mentioned, the studies show a correlation between the app's effectiveness and its broad usage. It is not probable that governments would invest that much effort, money and time into app development and then leave it all to voluntary acceptance. Secondly, and being especially relevant for the cross-border

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<sup>52</sup> J.H. Hoepman, "Stop the Apple and Google Contact Tracing Platform. (Or Be Ready to Ditch Your Smartphone.)," April 11, 2020, <https://blog.xot.nl/2020/04/11/stop-the-apple-and-google-contact-tracing-platform-or-be-ready-to-ditch-your-smartphone/>.

<sup>53</sup> Tamar Sharon, "Blind-Sided by Privacy? Digital Contact Tracing, the Apple/Google API and Big Tech's Newfound Role as Global Health Policy Makers," *Ethics and Information Technology*, July 18, 2020, 1–13, <https://doi.org/10.1007/s10676-020-09547-x>.

<sup>54</sup> *Ibidem*.

<sup>55</sup> European Commission, "Mobile Contact Tracing Apps in EU Member States," 2020, [https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/travel-during-coronavirus-pandemic/mobile-contact-tracing-apps-eu-member-states\\_en](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/travel-during-coronavirus-pandemic/mobile-contact-tracing-apps-eu-member-states_en).

interoperability, it is possible that the Member States would in some way tie freedom of movement in and out of their territory with the contact tracing apps usage. This could undermine the concept of a voluntary approach and make use of the apps mandatory in practice. Although it is not likely that European states would follow the Indian government's approach and exercise coercion on its citizens to use the app<sup>56</sup>, we can almost certainly expect governments advertising, recommending and strongly encouraging the usage of the app, supported by most of the media, institutions, scientific and medical community, celebrities and a wider community. In such an atmosphere not using the app could seem as an act of treason or at least as civil disobedience. That is why governments should not portray the use of contact tracing apps as an all-encompassing, quick, and easy solution for the outbreak<sup>57</sup>. Instead, they should develop frameworks to assess, understand and present clear public benefit in using the contact tracing apps<sup>58</sup>, as a tool that should be used together with other measures and within an elaborated infrastructure for combating the epidemic<sup>59</sup>. Given the known risks and (yet) unknown or uncertain benefits, an adaptive governance with respect to contact tracing apps, implying social learning, reassessment of apps' effectiveness and engaging the public, seems to be reasonable and recommendable approach<sup>60</sup>.

## V. Conclusion

Mobile applications have become indispensable for our everyday life in a very short period. We use them for all kinds of purposes, and we got used to having an app as a solution for every problem there is. This is reflected in the rapid development of apps that would search and trace contacts instead of relying on epidemiologists to do it. As usual with the mobile apps, the idea is that the contact tracing apps would save us time and enable us to concentrate on more important things. However, that approach can have downfalls, mainly in terms of giving the impression that governments are doing something to combat the epidemic, but without a clear aim and evaluation of the effectiveness of such apps. After a relatively calm summer, the so-called "second wave" of the coronavirus outbreak in the autumn of 2020 brought some new developments in contact tracing apps in the EU Member States. This particularly concerns the strengthening of interoperability between the apps, which could enable their cross-border functioning within EU territory, thus maintaining freedom of movement as one of the key freedoms of the EU. However, this potential is seriously undermined by the nonexistent common approach of the Member States, testifying to a lack of cooperation and solidarity between them and consequently diminishing the effectiveness of the apps. It seems that beyond privacy, ethical and legal issues there is also a deeper political crisis emerging in this pandemic. The saying

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<sup>56</sup> Morley, "Ethical Guidelines for COVID-19 Tracing Apps", 29–31.

<sup>57</sup> Federica Lucivero et al., "COVID-19 and Contact Tracing Apps: Ethical Challenges for a Social Experiment on a Global Scale," *Journal of Bioethical Inquiry* 17, no. 4 (2020): 835–39, <https://doi.org/10.1007/s11673-020-10016-9>.

<sup>58</sup> Gasser, "Digital Tools against COVID-19", e425–34.

<sup>59</sup> Parker, "Ethics of Instantaneous Contact Tracing, 427–31.

<sup>60</sup> Blasimme "What's next for COVID-19 Apps?", 760–62.

goes that a friend in need is a friend indeed, and there appears to be little friendship left on the Old Continent.

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# THE IMPACT OF CONSPIRACY THEORIES ON THE PUBLIC PERCEPTION OF THE COVID-19 PANDEMIC AND THE VACCINATION PROGRAM IN THE REPUBLIC OF CROATIA

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## **Abstract**

With the first information about vaccines against the COVID-19 virus in November last year, the world was given hope that the end of the pandemic that caused the most prominent global health crisis in a hundred years is looming. Additionally, the global economy has fallen into a deep economic crisis due to lockdown policies and social distancing measures. Vaccination has proven to be one of the most successful public health measures, and the vaccine is the most effective global strategy to end the COVID-19 pandemic. Despite significant advances in vaccination over the past century, the World Health Organization recognised hesitation and mistrust in vaccination as a substantial threat to global health. The decline in confidence in vaccination, and the strong growth of the anti-vaccine movement, contributed to the worldwide decrease in vaccination acceptance and removed barriers to infectious diseases and epidemics. Information is one of the main factors in forming opinions, including vaccines and vaccination against the COVID-19 virus. Today, the Internet is the largest and fastest source of information. Exposure to misinformation, untruths and conspiracy theories on the Internet is critical in distrust of vaccines. The effect of disinformation is growing to the rapid spread of unfounded and inaccurate information through the mass media. In Croatia, internet portals promoting conspiracy theories and social networks play a crucial role in strengthening the anti-vaccination movement and directly influencing individuals in their vaccination decisions. This paper will analyse the leading theories about the harmfulness of vaccination, the political and social reasons for the increase in vaccination rejection and hesitation, and, consequently, the failure of the vaccination campaign in Croatia.

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## I. Introduction

According to anthropologist Heidi Larson, rumours serve as a collective problem-solving and a means of managing insecurity by sharing new, unverified information and gathering the views of others. Rumours thrive in situations of uncertainty as to whether a new and unknown disease is occurring, as in the case of the recent COVID-19 pandemic and the associated vaccine, or more catastrophic events such as wars, natural disasters, or pandemics.<sup>1</sup> Although rumours, as a type of human interaction, have existed since man existed, rumours seem to pose a particularly significant danger in the age of the COVID-19 pandemic.

Thanks to social networks, rumours spread exponentially fast and uncontrollably, thus presenting an increasing problem in the successful fight against the pandemic – furthermore, rumours fuel sceptics who doubt the vaccine’s effectiveness against the COVID-19 virus. For antivaxers, rumours are the primary means of spreading conspiracy theories about the harmfulness of vaccination. In this paper, we will focus on the currently most popular rumours and conspiracy theories about vaccination in Croatia and their impact on the vaccination process in Croatia. The paper consists of three parts. The first part will show the emergence of the most popular rumours and conspiracy theories about the vaccine against COVID-19. In the second part, we will analyse Vaccine Literacy in Croatia and the role of social networks in refusing vaccination in Croatia. The third part will determine Croatia’s political and social situation and its impact on the vaccination process against COVID-19.

## II. Conspiracy theories on vaccines against COVID-19 and their impact on the vaccination process in Croatia

After more than a year and a half of living in a pandemic, many people are tired of living in a pandemic and have been reduced to living in a virtual world and a physical lockdown. Many hoped that with the successful development of the COVID-19 vaccine, the pandemic would finally end, and life would return to the old normal, as the “new normal” reduced to social distance, alienation, and constant fear of infection take a heavy psychological toll. However, it turned out that a significant part of Croatian citizens are reluctant or directly refuse vaccination. Thus, society is divided into those who want to get vaccinated and move on with life and those who refuse to be vaccinated for the reasons we will list below. Although from the very beginning of the vaccination campaign, it has been emphasised that it is “voluntary”<sup>2</sup>, it seems less and less voluntary because there is less and less choice of activities, content and opportunities that an unvaccinated person can choose. While all people (or at least most of them) sincerely hoped for a better future, and now for the present times, wherewith vaccination everything will be possible for those who do not get vaccinated, following the “herd immunity” and great vaccination, this idyllic time did

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<sup>1</sup> Heidi Larson, *Stuck – How Vaccine Rumors Start – and Why They Dont Go Away*, (Oxford University Press, New York 2020), xiv.

<sup>2</sup> Hrvatski zavod za javno zdravstvo, *Cijepljenje protiv COVID-19 bolesti: Najčešća pitanja i odgovori*, <https://www.koronavirus.hr/cijepljenje-protiv-covid-19-bolesti-najcesca-pitanja-i-odgovori/892> (accessed: August 1, 2021).

not dawn in the version expected. New epidemiological measures arrive now and then, and what awaits us all soon can now be guessed. The differences between vaccinated and unvaccinated are growing. One will say that vaccination is the solution, and others will deny it, saying all this is a fabrication. Several surveys were conducted among the citizens of the Republic of Croatia, which gave a more transparent and more precise picture of the attitudes and thoughts of citizens but also stated the reasons why the results are so divided in some surveys.

The research results conducted from 15 to March 17 on a sample of 1,400 respondents were presented in the central Dnevnik of HTV on March 21, 2021. The most significant possible error of the sample is +/- 2.62%, and the reliability of the research is as high as 95%. The survey asked the respondents a few questions, but the essential question for our paper is – Will you be vaccinated when the vaccine is available? On this issue, the researchers concluded that neither the lack of vaccines nor the controversy over the AstraZeneca vaccine had affected the intention of citizens to be vaccinated. Most respondents want to be vaccinated or have already been vaccinated. About 65% of them, 38.2%, want it as soon as possible, and 15.6% want to be vaccinated, but only when they see the consequences for others. 25.5% do not want to be vaccinated, while almost 11% have already been vaccinated. About 10% are still undecided, i.e. they do not know whether they will be vaccinated.<sup>3</sup>

A survey conducted by Nova TV in December 2020 shows a significantly divided nation. At the time, 46 per cent of respondents answered that they would probably be vaccinated, while as many as 44 per cent of respondents - likely or certainly will not. In addition, 10 per cent of them have not yet decided.<sup>4</sup>

A comparison of the results of these two studies shows that, within a few months, the vaccination campaign and the work of scientists and experts (both domestic and foreign) and their media exposure nevertheless contributed to the partial development of awareness of the importance of vaccination in fighting pandemics. It is interesting to see the regional division of opinions and attitudes, so recent research brings results and data: “In the North Adriatic, which shows the best results from the beginning, most of those who want to be vaccinated, 46.7%, while 8% vaccinated when they see what the consequences will be for others. 24% do not intend to be vaccinated, and 11% have already been vaccinated. More than 10% do not know if they will be vaccinated. In the Zagreb region, 45.6% of respondents want to be vaccinated as soon as possible, and as many as 15.8% of them also want to be vaccinated, but when they see the consequences for others. 24.4% do not intend to be vaccinated, and 9.6% have already been vaccinated. Only about 5% do not know if they want to be vaccinated. In Dalmatia, 39.4% want to be vaccinated, and 13.8% would wait. There, 10% have already been vaccinated, and 26% do not intend to. 10.5% do not know if they will be vaccinated. 39.2% of respondents in Northwestern

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<sup>3</sup> Jutarnji.hr, *Neočekivani rezultati ankete: Evo koliko Hrvata se želi cijepiti, a koliko ih se ne boji korone*, <https://www.jutarnji.hr/vijesti/hrvatska/neocekivani-rezultati-ankete-evo-koliko-hrvata-se-zeli-cijepiti-a-koliko-ih-se-ne-boji-korone-15059623> (accessed: August 1, 2021).

<sup>4</sup> Dnevnik.hr, *Dnevnik Nove TV donosi ekskluzivno istraživanje o tome kako Hrvati gledaju na cijepljenje protiv korona virusa – jesu li već odlučili hoće li se cijepiti, koji su razlozi za i protiv te treba li cjepivo biti obavezno za građane*, <https://dnevnik.hr/vijesti/hrvatska/istrazivanje-dnevnika-nove-tv-hoce-li-se-hrvati-cijepiti-protiv-koronavirusa---632922.html> (accessed: August 1, 2021).

Croatia would be vaccinated immediately, along with another 18.7% who would be vaccinated when they see the consequences for others. 7.3% of those surveyed have already been vaccinated, and 24.4% do not want to do so. About 10% of them do not know yet. They would be least vaccinated in Central and Mountain Croatia and Slavonia. In Slavonia, almost 30% of them would do so immediately, while 18% would wait. 28.7% do not intend to be vaccinated, and almost 11% have already been vaccinated. As many as 13% of them still do not know. In Central and Mountain Croatia, only 28% of respondents answered that they want to be vaccinated as soon as possible, while 15% want to, but first, to see the consequences for others. Fewer inhabitants, most vaccinated - as many as 19%. 24% have no intention of getting vaccinated, and as many as 13% still do not know.”<sup>5</sup>

The results of these surveys coincide with the decline in interest in vaccination among Croatian citizens. The vaccination campaign started on December 27, 2020; the first person in Croatia to be vaccinated against COVID-19 was retired pharmaceutical technician Branka Aničić, a protégé of the Trešnjevka Home for the Elderly in Zagreb, at the beginning of the vaccination campaign under the slogan “Think of others, get vaccinated”. After receiving the first dose of vaccine in the Republic of Croatia, Aničić, said: “We are overjoyed to have been chosen, our home for the elderly, to be the first, to finally get vaccinated and finally start a more normal life, and I hope that it will be fast.” Aničić called on all citizens to accept vaccination to save not only themselves but also their family, relatives and friends from the disease COVID-19.<sup>6</sup> While at the very beginning of the vaccination campaign, while the vaccine was arriving in almost symbolic quantities, there were scandals in the media due to the excessive vaccination of citizens who were not in the priority group. For example, the news that the Rector of Zagreb University, Damir Boras, was vaccinated against coronavirus and his wife caused great public outrage. However, although Rector Boras contracted the coronavirus two months ago, he and his wife were “accidentally” undergoing a dental examination at the Rebro Clinic, where health workers were being vaccinated at the same time, and “accidentally” there was a surplus of vaccines for Rector Boras and his wife.<sup>7</sup> Moreover, after the scandal with Rector Boras, the public learned that many “social elite” members in Croatia had been vaccinated in the same manner.

Moreover, according to the Ministry of Health, from the start of vaccination to Wednesday, February 10, 107,080 doses were administered. Of that number, 44,344 doses went to the revaccination of previously vaccinated citizens. Thus, with 18,392 people who received only one dose, we come to a total of 62,736 Croatian citizens who have so far been vaccinated against coronavirus. Of the 107,080 doses of vaccine

<sup>5</sup> Jutarnji.hr, *Neočekivani rezultati ankete: Evo koliko Hrvata se želi cijepiti, a koliko ih se ne boji korone*, <https://www.jutarnji.hr/vijesti/hrvatska/neocekivani-rezultati-ankete-evo-koliko-hrvata-se-zeli-cijepiti-a-koliko-ih-se-ne-boji-korone-15059623> (accessed: August 1, 2021).

<sup>6</sup> Stipe Majić, *Hrvatska: Prva osoba cijepljena protiv COVID-19 štićenica Doma za starije Trešnjevka*, <https://www.aa.com.tr/ba/balkan/hrvatska-prva-osoba-cijepljena-protiv-covid-19-shticenica-doma-za-starije-tresnjevka/2090144#> (accessed: August 1, 2021).

<sup>7</sup> Davor Tomšić, *Ovo je popis “uglednika” koji su se cijepili preko reda (nadopunjavat ćemo ga)*, <https://www.index.hr/vijesti/clanak/ovo-je-popis-uglednika-koji-su-se-cijepili-preko-reda-nadopunjavat-cemo-ga/2254571.aspx> (accessed: August 1, 2021).

used so far, 4,635 were given to people who do not belong to the priority groups, nor are they in line with the coronavirus vaccination plan in Croatia.<sup>8</sup>

It should not be emphasised that the actions of Rector Boras and other “elite” members should be condemned since their acts once again showed that not all citizens in Croatia are equal. Their selfish and irresponsible behaviour causes immeasurable damage to vulnerable citizens, denying them a life-saving dose of vaccine. Thus, the very beginning of the vaccination campaign in Croatia was marked by scandals. Still, as we will see below, Croatia soon found itself in a situation where too much vaccine was available to citizens, and citizens showed less interest in vaccination. The plan of the Government of the Republic of Croatia was to vaccinate 55% of the adult population by the end of June, but this goal was not achieved due to many reasons, which we will write about in more detail below.

Nevertheless, after initial problems with vaccine shortages and cross-line vaccination, the vaccination process accelerated after satisfactory amounts of the vaccine arrived. According to the Ministry of Health, 1,025,701 doses of vaccine have been administered in the Republic of Croatia since May 6. As a result, 796,909 people were vaccinated, of whom 228,792 received the second dose; this is 19.6% of the total population, which is 23.7% of the adult population of Croatia. The most significant amount of Pfizer vaccine was 606,997 doses, followed by AstraZeneca with 275,131 doses. On May 6, 46,520 doses of vaccine were administered. Thus, in one day of vaccination, we approached the record achieved on Thursday, April 29, 2021, when a record 46,887 doses of the COVID-19 vaccine were administered.<sup>9</sup>

The dynamics of vaccination continued in May, so on Thursday, May 20, 57,184 doses were administered, which set a new record in daily vaccination 4,125 doses were more than the previous one set on Friday, May 7. Croatia also exceeded 1.5 million doses of COVID-19 vaccine consumed on the same day. To date, 1,507,353 doses of vaccine have been administered. A total of 1,149,941 persons were vaccinated with the first dose, of which 357,412 were vaccinated with two doses. Thus, 28.3% of the total population and 34.2% of the adult population were vaccinated.<sup>10</sup> However, at the beginning of June, interest in vaccination begins to decline. By June 25 in Croatia, only about 30% of the adult population had been fully vaccinated, i.e., about 25% of the total, while collective immunity requires 85% of the total population.<sup>11</sup> These figures show that the Government’s plan to vaccinate

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<sup>8</sup> Danas.hr, *NIJE BORAS JEDINI: / Dosad je u Hrvatskoj 4635 doza cjepiva iskoriseno preko reda; Evo tko se sve cijepio i zašto*, <https://net.hr/danas/hrvatska/nije-boras-jedini-dosad-je-u-hrvatskoj-4635-doza-cjepiva-iskoriseno-preko-reda-evo-tko-se-sve-cijepio-i-zasto-7292b166-b1c6-11eb-9acb-0242ac130032> (accessed: August 1, 2021).

<sup>9</sup> Hrvatski zavod za javno zdravstvo, *Utrosena milijunta doza cjepiva!*, <https://www.hzjz.hr/sluzba-epidemiologija-zarazne-bolesti/utrosena-milijunta-doza-cjepiva/> (accessed: August 1, 2021).

<sup>10</sup> Hrvatski zavod za javno zdravstvo, *Ostvaren je dvostruki uspjeh: Utrosen rekordan broj doza u jednom danu i premašeno 1,5 milijun doza!*, <https://www.hzjz.hr/priopcenja-mediji/ostvaren-je-dvostruki-uspjeh-utrosen-je-rekordan-broj-doza-u-jednom-danu-i-premaseno-je-15-milijun-doza/> (accessed: August 1, 2021).

<sup>11</sup> Nenad Jarić Dauenhauer, *Propao plan o cijepjenju pola ljudi do 1. srpnja. Posljedice bi mogle biti kobne*, <https://www.index.hr/vijesti/clanak/propao-plan-o-cijepjenju-pola-ljudi-do-1-srpnja-posljedice-bi-mogle-bit-ozbiljne/2286154.aspx> (accessed: August 1, 2021).

55% of the adult population has failed. Unfortunately, in the following weeks, interest in vaccination declined further.

According to the official data of the Ministry of Health, as of August 5, 3,110,259 doses of vaccine were administered, and 40.8% of the total Croatian population and 49.1% of adults were vaccinated. On August 5, only 668 doses of vaccine were distributed, of which 508 people were vaccinated with the first dose. Therefore, as of August 5, 1,657,443 people were vaccinated with at least one dose, of which 1,506,924 people (1,452,816 people vaccinated with two doses and 54,108 people vaccinated with Janssen) were completed, which is 44.71% of the adult's population.<sup>12</sup> The European average for vaccinations is about 60 percent of the adult population, and Croatia has not even reached 45 percent. Currently, Croatia has about 800,000 unused doses because interest among citizens has declined. Since there is a surplus of vaccines, Croatia has donated 370,000 doses. In addition, 240,000 doses went to Bosnia and Herzegovina, 30,000 to Montenegro and Kosovo, 20,000 to Albania, Northern Macedonia and Kyrgyzstan, and 10,000 to Bhutan.<sup>13</sup>

The data on the vaccination process shows that the fight against the pandemic in the Republic of Croatia is challenging and strenuous because conspiracy theorists are not only among our fellow citizens but also among senior political and church officials who occupy ample media space on social networks easily accessible to many citizens. Furthermore, because of their positions, they easily deceive people with various conspiracy theories. What is debated is undoubted whether an mRNA-based vaccine can change human DNA, whether women can remain infertile due to vaccination, whether a previous infection protects against a new infection better than vaccination, and the like.<sup>14</sup> Below we will look at the most popular conspiracy theories in Croatia.

### *A. The COVID-19 vaccine causes infertility*

Undoubtedly one of the most widespread and “most popular” conspiracy theories in Croatia. Even young, highly educated women employed in educational and medical activities are subject to it for fear that they will not conceive and give birth to a healthy child one day. The research showed that precisely because of this fear and this theory, 43% of nurses in Croatia were not vaccinated. Out of 33,594 nurses and technicians in Croatia, almost half, or 14,447, were not vaccinated, which is 43%.<sup>15</sup>

<sup>12</sup> Koronavirus.hr, *108 novih slučajeva u protekla 24 sata, utrošeno 668 doza cjepiva*, <https://www.koronavirus.hr/najnovije/218-novih-slucajeva-u-protekla-24-sata-utroseno-12-190-do-za-cjepiva/35> (accessed: August 6, 2021).

<sup>13</sup> Dubrovackidnevnik.hr, *EVO DOKAD JE ROK TRAJANJA Hoće li nam propasti cjepivo?* <https://dubrovackidnevnik.net.hr/vijesti/hrvatska/evo-dokad-je-rok-trajanja-hoce-li-nam-propasti-cjepivo> (accessed: August 1, 2021).

<sup>14</sup> Katja Sterzik, Uta Steinwehr, Ines Eisele, *Provjera činjenica: mitovi o cjepivima protiv korone*, <https://www.dw.com/hr/provjera-cinjenica-mitovi-o-cjepivima-protiv-korone/a-57336476> (accessed: August 1, 2021).

<sup>15</sup> Martina Pauček Šljivak, *Čak 43% medicinskih sestara se nije cijepilo: “Boje se da neće moći zatrudnjeti”*, <https://www.index.hr/vijesti/clanak/doznajemo-kompletne-brojke-evo-koliko-se-medicinskih-djelatnika-u-hrvatskoj-cijepilo/2290360.aspx> (accessed: August 1, 2021).

This figure is devastating because medical professionals could be among the first vaccinated. As a result, their exposure to the virus is significantly higher than other citizens and, most importantly, given their education and work experience background. The myth that vaccines could cause infertility was primarily due to German physician and epidemiologist Wolfgang Wodarg, who had previously been sceptical about the need for vaccines in other pandemics. During this time, he became notorious among German scientists for reducing the dangers of COVID-19. They teamed up with a former Pfizer employee to ask the European Medicines Agency (EMA) for a detailed study of the Pfizer vaccine. One of the concerns expressed by the duo was that the Syncytin-1 protein shares some genetic instructions with part of the code for the spike protein of the new coronavirus. Namely, the problem is that Syncytin-1 is essential for mammal placental development. Thus, if the vaccine caused the anti-viral protein S antibodies to attack Syncytin-1 simultaneously, the body would block that protein in the human placenta, making women infertile. Namely, the proteins of Spike coronavirus and Syncytin-1 share only small parts of the same genetic code, which are not enough for the same antibodies that block Spike to block Syncytin-1.<sup>16</sup> Numerous studies and research conducted by the US Centers for Disease Control (CDC) and the World Health Organization (WHO) have concluded similarly.<sup>17</sup> They state that, to date, no evidence has been found to suggest an association between vaccination and female or male infertility and erectile dysfunction.<sup>18</sup> Unfortunately, these data are not sufficiently placed in the media, nor are women provided with the education and presentation of these data. Hence, it is unsurprising that the theory still has many supporters who refuse the vaccine and endanger their health, especially hormonal picture and normal thyroid function.<sup>19</sup>

That there is no reason for concern is confirmed by Prof. Hrvoje Vršćić, at the Faculty of Medicine in Zagreb, a specialist in gynaecology and obstetrics whose specialisation is human reproduction, “I recommend that patients who are not pregnant become pregnant after receiving the second dose of the vaccine. Furthermore, I recommend medically assisted fertilisation to infertile women two months after the second dose of the vaccine to have a double safety period. It will probably only be a month soon. I advise pregnant women to be vaccinated after the 12th week of pregnancy when embryogenesis is over. Of course, it is always necessary to check whether there are risks of allergic reactions to the vaccine’s contents. A

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<sup>16</sup> Nenad Jarić Dauenhauer, *Ne, cjepiva ne uzrokuju neplodnost*, <https://www.index.hr/vijesti/clanak/ne-cjepiva-ne-uzrokuju-neplodnost/2290597.aspx> (accessed: August 1, 2021).

<sup>17</sup> Pria Joi, *Do COVID-19 vaccines affect menstruation and fertility*, <https://www.gavi.org/vaccineswork/do-covid-19-vaccines-affect-menstruation-and-fertility> (accessed: August 1, 2021).

<sup>18</sup> Cdc.gov, *COVID-19 Vaccines While Pregnant or Breastfeeding*, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html> (accessed: August 1, 2021).

<sup>19</sup> Ilaria, Muller; Daniele, Cannavaro; Davide, Dazzi; Danila, Covelli; Giovanna, Mantovani; Antonio Muscatello; Emanuele, Ferrante; Emanuela Orsi; Veronica, Resi; Virgilio, Longari; Marco Cuzzocrea; Alessandra Bandera; Elisa Lazzaroni; Alessia Dolci; Ferruccio Ceriotti; Tiziana E, Re; Andrea, Gori; Maura, Arosio and Mario, Salvi, “SARS-CoV-2-related atypical thyroiditis,” *The Lancet Diabetes & Endocrinology* 13 (10/2020): 3-5. doi: 10.1016/S2213-8587(20)30266-7.



personalised approach to each person is the best possible approach in diagnosing, treating, and preventing disease.”<sup>20</sup>

### *B. Young and healthy people do not need vaccinations*

This theory is quite popular in the United States, and scientists are fighting it with numbers and data. This theory is prevalent in our country where a large number of young people, digging into, in their own opinion, immunologically perfect breasts with the statement “I’ve never been sick or sick”, believe that their immunity is strong enough so the COVID-19 virus can do nothing. However, American research has shown that the victims of the coronavirus are increasingly young people, and, as they say, the coronavirus does not have to take lives but significantly reduces the quality of life because the consequences remain up to 9 months after the disease in 30% of patients. Jonathan Reiner, a professor of medicine and surgery at George Washington University, says that more and more young people in their twenties have ended up on a respirator. This is because their immune systems often react too strongly and aggressively to the disease, leading to complications. In addition, young people are often asymptomatic carriers of the virus, injuring older and sick members of society.<sup>21</sup> Therefore, collective coronavirus immunity is unlikely to be achieved without vaccinating children and adolescents, the German Society of Immunology (DGfI) has announced. According to estimates by the German Robert Koch Institute for Disease Control (RKI), at least 85 percent of the population between the ages of 12 and 59 and 90 percent of those over 60 must be vaccinated to combat the delta variant successfully.<sup>22</sup>

### *C. Don’t poison our children!*

This theory builds on the previous one but is aimed at an even younger population. Although scientists are still debating<sup>23</sup> the age limit above which children will be vaccinated, in some countries and Croatia<sup>24</sup>, where approved vaccination began for children ages 12 to 16, proponents of conspiracy theories loudly oppose the idea of vaccinating children. All the previously mentioned conspiracy theories oppose the

<sup>20</sup> Ante Srzić, *Razgovarali smo sa stručnjakom o raširenom mitu da cjepivo protiv Covida-19 uzrokuje neplodnost: Nema dokaza za to, kaže i otkriva što savjetuje svojim pacijenticama*, <https://www.tportal.hr/vijesti/clanak/razgovarali-smo-sa-strucnjakom-o-rasirenom-mitu-da-cjepivo-protiv-covida-19-uzrokuje-neplodnost-nema-dokaza-za-to-kaze-i-otkriva-sto-savjetuje-svojim-pacijenticama-foto-20210715> (accessed: August 1, 2021).

<sup>21</sup> Holly Jan, *Covid-19 vaccine myths: These reasons for not getting a shot don’t hold up. In fact, they’ll set the US back*, <https://edition.cnn.com/2021/07/19/health/covid-vaccine-myths-debunked/index.html> (accessed: August 1, 2021).

<sup>22</sup> Thelocal.de, *Unvaccinated children could jeopardise herd immunity, German health experts warn*, <https://www.thelocal.de/20210706/unvaccinated-children-could-jeopardise-herd-immunity-german-health-experts-warn/> (accessed: August 1, 2021).

<sup>23</sup> Heidi Ledford, “Should children get COVID vaccines? What the science says,” *Nature* 595 (2021): 638-639.

<sup>24</sup> Anja Perković, *Počelo je cijepljenje djece puno je koncerata ne želim da me korona sprječava*, <https://hr.n1info.com/vijesti/pocelo-je-cijepjenje-djece-puno-je-koncerata-ne-zelim-da-me-korona-sprjecava/> (accessed: August 1, 2021).

vaccination of children with the view that children are healthy and resistant and do not need the vaccine. In the world, young children are increasingly hospitalised for a more severe form of coronavirus with increasingly severe immune and neurological health consequences, which doctors have only recently begun to pay more attention to and link to the COVID-19 virus.<sup>25</sup> In the UK, up to 100 children are hospitalized for multisystem inflammatory syndrome (MIS-C) every week. The COVID-19 pandemic already brought multisystem inflammatory syndrome (MIS-C) in the first wave, from which an 11-year-old boy died in Croatia in January. Nikolaus Haas, director of the Children's Cardiology Department and Pediatric Intensive Care Medicine at the University Clinic in Munich, told DW back then that this syndrome was not unknown: "Within the framework of various infectious diseases in patients with a certain predisposition, such a clinical picture can occur, in which the whole body reacts with severe inflammation."<sup>26</sup> Thus, we can conclude that children are also a risk group and that the disease can lead to severe complications. It is known that children are often carriers of various viruses and diseases, including COVID-19 and thus endanger older members of their families. The issue of vaccinating children is still current, and the President of the United States, Joe Biden, stated on July 22, 2021, that he hopes that vaccination of children under 12 will start within a few months to protect the younger population, the elderly, but also normalise the educational process.<sup>27</sup> This procedure, if it starts, will meet with significant resistance from parents in Croatia. So far, less than a hundred children under the age of 15 have been vaccinated in Croatia. Those slightly older, up to 17, were vaccinated with more than 1,300 with parental consent. Doctors say that priority is given to children with chronic diseases, such as asthma and diabetes. The goal is to vaccinate as many students as possible before the start of the new school year.<sup>28</sup> Vaccination of children is a major bioethical problem, as according to current scientific knowledge, children are the least vulnerable to the effects of the COVID-19 virus. Therefore, many concerned parents ask the logical question, why vaccinate their healthy child against a disease from which it will have no consequences and expose themselves to the possible harmful side effects of the vaccine? To this question, reports say that conspiracy theorists offer their answer in bombastic headlines, like "A teenager passed away in a dream after receiving Pfizer's vaccine for COVID-19".<sup>29</sup> Such headlines and cases further spread distrust of the vaccine and further complicate the

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<sup>25</sup> Jen Christensen, *Some children's hospitals see a surge in rare Covid-19 complication MIS-C*, <https://edition.cnn.com/2021/03/06/health/mis-c-covid-19-case-increase-wellness/index.html> (accessed: August 1, 2021).

<sup>26</sup> Gudrun Heise, *Sve češći postviralni sindrom kod britanske djece*, <https://www.dw.com/hr/sve-češći-postviralni-sindrom-kod-britanske-djece/a-56493296> (accessed: August 1, 2021).

<sup>27</sup> Maanvi Singh, *Biden says children under 12 could be eligible for Covid vaccines within months*, <https://www.theguardian.com/world/2021/jul/21/us-covid-vaccines-children-under-12-biden> (accessed: August 1, 2021).

<sup>28</sup> Anja Perković, *Počelo je cijepljenje djece puno je koncerata ne želim da me korona sprječava*, <https://hr.n1info.com/vijesti/pocelo-je-cijepljenje-djece-puno-je-koncerata-ne-zelim-da-me-korona-sprjecava/> (accessed: August 1, 2021).

<sup>29</sup> Logicno.com, *Tinejder preminuo u snu nakon što je primio Pfizerovo cjepivo za COVID-19, kažu izvještaji*, <https://www.logicno.com/hrana-zdravlje/tinejder-preminuo-u-snu-nakon-sto-je-primio-pfizerov-o-cjepivo-za-covid-19-kazu-izvjestaji.html> (accessed: August 1, 2021).

fight against the pandemic. Nevertheless, when we look at the latest research, it increasingly confirms the suspicion of the emergence of TVZ. “Long covid in children “Long covid was first described in adults. However, several recent studies have demonstrated a similar phenomenon in children, including symptoms such as headache, fatigue, and palpitations, although they rarely have severe initial symptoms of COVID-19. Estimates of how common long covid is in children often vary. Researchers say this is crucial because decisions to close schools and introduce vaccines for children may depend on the virus’s risk. Pediatrician Danilo Buonsenso of Gemelli University Hospital in Rome led the first attempt to quantify long covid in children. He and his colleagues examined 129 children aged 6 to 16 diagnosed with COVID-19 between March and November 2020. Their work reported that more than one-third had one or two long-term symptoms four months or more after infection, and a further quarter had three or more symptoms. Insomnia, fatigue, muscle aches and persistent cold-like ailments were common among those surveyed - a pattern similar to that of adults with long covid. Even children with mild initial symptoms or asymptomatic were not spared these long-term effects.<sup>30</sup> Data from the UK’s Office for National Statistics from April showed that 9.8% of children aged 2 to 11 years and 13% aged 12 to 16 years had at least one long-term symptom five weeks after a positive diagnosis.<sup>31</sup> On the other hand, vaccines are safe for young people now. Several vaccines have been tested on young people over 12 years of age, including those made by Moderna, and Pfizer, with vaccines approved for children between 12 and 16 years of age in the United States. However, since children are less likely to get sick and very rarely have severe symptoms, their vaccination is more important to protect the elderly and generally stop the virus’s circulation than to protect themselves. Namely, as new, more contagious versions of the coronavirus emerge, there is growing concern about the possible transmission from children and adolescents to the elderly and the possibility of children becoming incubators for new strains.<sup>32</sup>

#### *D. After vaccination, more people died from the vaccine than from coronavirus*

Social networks and websites that advocate conspiracy theories spread misinformation wildly about the number of people who died after receiving the vaccine and directly link the death to the composition of the vaccine that, according to them, caused the death.<sup>33</sup> According to the texts published on these pages, all four

<sup>30</sup>Danilo Buonsenso, Daniel Munblit, Cristina De Rose, Dario Sinatti, Antonia Ricchiuto, Angelo Carfi and Piero Valentini, “Preliminary evidence on long COVID in children,” *Acta Paediatrica* 110, 7 (2021): 2208-2211. doi.org/10.1111/apa.15870.

<sup>31</sup> Helen Thomson, “Children with long Covid,” *New Scientist* 3323, 249 (2021): 10-11. doi: 10.1016/S0262-4079(21)00303-1.

<sup>32</sup> Nenad Jarić Dauenhauer, *Većina necijepljenih nisu antvakseri i idioti. Ovo su njihovi razlozi*, <https://www.index.hr/vijesti/clanak/vecina-necijepljenih-nisu-antvakseri-i-idioti-ovo-su-njihovi-ra-zlozi/2292368.aspx> (accessed: August 1, 2021).

<sup>33</sup> Biran Shilhavy, *Europska baza podataka: Nakon cijepjenja 10.570 MRTVIH i 405.259 ozljeda!* <http://www.istinomprotivlazi.info/novosti/1917-europska-baza-podataka-nakon-cijepjenja-10-570-mrtvih-i-405-259-ozljeda> (accessed: August 1, 2021).

vaccines available in Croatia (AstraZeneca, Pfizer, Moderna and Johnson & Johnson) are experimental and do more damage than the coronavirus. Vaccines have so far caused over 10,000 deaths and over 400,000 serious side effects in those who have been vaccinated<sup>34</sup>. One such website is called “Truth Against Lies”, and with a very provocative headline such as *The latest EU database data: 18928 DEAD, 1.8 million INJURED*, and some scientific facts underlying it creates a frightening and false story with unconfirmed facts and untruths numbers whose sole purpose is to spread fear in public and further deepen distrust of coronavirus vaccines.<sup>35</sup> When quoting figures, the authors of these pages cite the EudraVigilance database, which they present as a service of the European Medicines Agency (EMA), without interpreting what it is, its purpose, or how it works. Furthermore, they state that the data was issued on May 8, 2021, without an adequate interpretation of the numbers in the database. Thus, by June 30, almost two months after May 8, 3887 reports of suspected side effects of the vaccine with a fatal outcome (Comirnaty - 2835, AZ - 743, Moderna - 256, Janssen - 53) were reported to the European database of side effects of EudraVigilance. EEA (European Economic Area).

In other words, no more than 10,000 but less than 4,000, which is almost two months after many more vaccinations. Why is there such a difference? The deaths listed in the EudraVigilance side effects database relate to the outcome of reactions received by regulatory authorities directly from citizens themselves, healthcare professionals and marketing authorisation holders of medicines and vaccines. One death can be recorded in the database more than once.<sup>36</sup> The European Medicines Agency states in its latest report on the safety of the Pfizer vaccine the newest data as of July 4. It points out that a total of 206,668 suspected cases of side effects and 3,848 reports of suspected side effects of the vaccine have been reported to the EudraVigilance database.

Furthermore, the report emphasises:

“These reports describe suspected side effects in individuals, i.e. medical events observed following the use of a vaccine. The fact that someone has had a medical issue or died after vaccination does not necessarily mean that the vaccine caused this. For example, this may have been caused by health problems unrelated to vaccination.”<sup>37</sup>

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<sup>34</sup> Nenad Jarić Dauenhauer, *Antivakseri mahmito šire laž o 10.000 umrlih nakon cijepljenja*, <https://www.index.hr/vijesti/clanak/antivakseri-tvrde-da-je-od-cjepiva-u-eu-umrlo-vise-od-10000-ljudi-naravno-da-nije/2290118.aspx/> (accessed: August 1, 2021).

<sup>35</sup> Istinomprotivlazi.info, *Najnoviji podaci baze podataka EU-a: 18928 MRTVIH, 1,8 milijuna OZLIJEĐENIH*, <http://www.istinomprotivlazi.info/novosti/1788-najnoviji-podaci-baze-podataka-eu-a-18-928-mrtvih-1-8-milijuna-ozlijedenih> (accessed: August 1, 2021).

<sup>36</sup> Nenad Jarić Dauenhauer, *Antivakseri mahmito šire laž o 10.000 umrlih nakon cijepljenja*, <https://www.index.hr/vijesti/clanak/antivakseri-tvrde-da-je-od-cjepiva-u-eu-umrlo-vise-od-10000-ljudi-naravno-da-nije/2290118.aspx/> (accessed: August 1, 2021).

<sup>37</sup> Ema.europa.eu, *COVID-19 vaccine safety update*, [https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-14-july-2021\\_en.pdf](https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-14-july-2021_en.pdf) (accessed: August 1, 2021).

Thus, the official numbers and statistics of the European Medicines Agency are misrepresented, and misrepresent data, as it is easy to deceive people with numbers and statistics because they act officially, professionally and professionally. It is not surprising that this conspiracy theory has taken on such proportions. Krešimir Pavelić also promoted this theory, now a former dean of the “Faculty of Medicine” in Pula, where he has no medical studies. Pavelić’s charlatan statements raise the question of how a person who promotes unscientific, factually unfounded claims is of particular concern since Krešimir Pavelić is an exceptional expert in his field of science. Still, he is also an ardent promoter of the most obscure conspiracy theories, which have been demystified many times. Nevertheless, his influence on the confused and intimidated public should not be underestimated, as his resignation from the position of dean of the “Faculty of Medicine” in Pula is seen in the eyes of his supporters as another proof of the persecution of all who dare to tell the truth. While the exact opposite is true, the unwarranted spread of misinformation and notorious lies aimed at intimidating the public is incompatible with the performance of duties in higher education.<sup>38</sup>

### *E. I do not need vaccinations because God and my faith keep me safe from COVID-19*

This view is prevalent in the US, where individuals place so much hope in faith and religion as the only proper protection against pandemics due to distrust of local governments and politics. Moreover, while in the US, the loudest religious anti-vaxers are members of the Evangelical Church<sup>39</sup>, in Croatia, they are members of the Roman Catholic Church led by some extremely loud priests who completely deny the existence of the coronavirus and pandemic, such as the priest Tomislav Vlaović, who became famous in public with the statement “All who believe in Jesus cannot receive the coronavirus.” In his parish, Vlaović told the faithful at Mass that the coronavirus did not exist and that it was all one big world conspiracy against the Catholic Church.<sup>40</sup> Unfortunately, the mentioned priest is not the only one who spreads misinformation among members of the Catholic Church. Some priests and engaged lay members of the Catholic Church vehemently resist vaccination. For example, Ivan Dominik Ilčić, priest and student chaplain of the Archdiocese of Rijeka posted a video encouraging Facebook “believers and people of goodwill” not to be vaccinated against coronavirus. The video makes the inaccurate claim that mRNA vaccines (such as Pfizer’s or Modern’s vaccine) can affect the genetic code of the recipient. In the video, he manipulatively talks about the vaccine they “want to

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<sup>38</sup> Nenad Jarić Dauenhauer, *Dekan pulske medicine je smijenjen. Evo koje je sve idiotarije izrekao o cijepljenju*, <https://www.index.hr/vijesti/clanak/dekan-pulske-medicine-je-smijenjen-evo-koje-je-sve-idiotarije-izrekao-o-cijepljenju/2287189.aspx> (accessed: August 1, 2021).

<sup>39</sup> Holly Yan, *Covid-19 vaccine myths: These reasons for not getting a shot don't hold up. In fact, they'll set the US back*, <https://edition.cnn.com/2021/07/19/health/covid-vaccine-myths-debunked/index.html> (accessed: August 1, 2021).

<sup>40</sup> Ivica Neveščanin, “Svećenik s Dugog otoka u novom skandalu, sukobio se s vjernikom: ‘Svi koji vjeruju u Isusa ne mogu dobiti koronu’,” *Jutarnji list*, 16. 4. 2021.

impose” on us, insinuating that vaccination will be mandatory.<sup>41</sup> Ilčić further presents the Vatican’s incomplete conclusions from 2005 about vaccines obtained based on cell cultures made from aborted fetal tissues and claims that the Pontifical Academy for Life condemned it as a terrible evil and called on believers not to participate in that evil by receiving such vaccines.

However, contrary to this claim, the Pontifical Academy for Life points out in its 2017 statement regarding the situation of drastic decline in rubella and measles population in Italy that vaccines based on fetal cell lines can be used despite their remote association with abortion only if there is no alternative vaccine and until that alternative vaccine becomes available. The statement emphasises a strict moral obligation to pressure governments, legislators, pharmaceutical companies and all other actors involved in vaccine production to produce vaccines that will not have this dimension of moral defilement.<sup>42</sup> That the official Catholic Church does not have too many doubts about the use of the vaccine is confirmed by the announcement of Andre Arcangeli, director of the Vatican Health Service, on December 11, 2020. He said he would soon start vaccinating Vatican residents, employees and their families with the Pfizer vaccine, saying: “Only widespread immunisation of the population will be able to achieve real public health benefits to control the pandemic.”<sup>43</sup> Eventually, Pope Francis himself and retired Pope Benedict XIV were vaccinated, and their example encouraged Catholic believers to be vaccinated. However, despite clear guidelines from the Vatican and Pope Francis himself on the usefulness and ethical justification of vaccination, some priests and theologians in Croatia further widespread suspicions public, including Vladimir Dugalić, the dean of the Catholic Theological Faculty in Đakovo. Dugalić, on the show called Bujica on December 16, 2020, the radical right-wing host Velimir Bujanac reiterated his views on the ethical unacceptability of certain vaccines against coronavirus. Speaking on the show about the ethical unacceptability of vaccines related to aborted human embryos, Dugalić said:

“In the scientific world, it is not even a secret (...) In the statement of the Pontifical Academy for Life from 2005, while there was no coronavirus, vaccines against some other diseases were enumerated, in the making of which human lines from aborted fetuses were used. It is well known that these are two human cell lines obtained from aborted fetuses in 1964 and 1970. Every scientist knows that these cells were taken from one boy and one girl and that vaccines were made on that basis. These pluripotent cells have a great potential for regeneration, where antibodies are produced, and vaccines are still made. In 2005, vaccines against rubella, measles, mumps, chickenpox, hepatitis were

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<sup>41</sup> Indeks.hr, *Riječki svećenik: Pozivam vjernike da se ne cijepe protiv korone*, <https://www.index.hr/vijesti/clanak/rijecki-svecenik-pozivam-vjernike-da-se-ne-cijepe-protiv-korone/2238173.aspx> (accessed: August 1, 2021).

<sup>42</sup> Zorica Maros, “Stav Crkve o korištenju fetalnih staničnih linija u izradi virusnih cjepiva,” *Vrbbosnensia* 24 (2/2020) 412.

<sup>43</sup> Hrvatsko katoličko sveučilište, *Medicinski i moralni aspekti cjepiva protiv COVID-19*, [www.unicath.hr/medicinski-i-moralni-aspekti-cjepiva-protiv-covid19](http://www.unicath.hr/medicinski-i-moralni-aspekti-cjepiva-protiv-covid19) (accessed: August 1, 2021).

mentioned, polio, rabies, etc. (...). And here the Pontifical Academy for Life made it clear that a believer, if he knows that these vaccines were obtained in an immoral way, must refuse such vaccines in his conscience!”<sup>44</sup>

Unfortunately, an attitude that a faithful Catholic believer must reject some vaccines (primarily AstraZeneca) is significant for Catholic believers in Croatia. These are highly religious people who do not question church authority and are otherwise more inclined to interpret a pandemic as one big conspiracy aimed at enslaving believers by Bill Gates, George Soros and the like. The statements of one dean of the Catholic Theological Faculty give an incentive to such believers to reject vaccination with a clear conscience.

#### *F. The vaccine causes magnetism in humans*

A video has been shared thousands of times on Facebook showing a magnet standing on a woman’s shoulder where the alleged site of the COVID-19 vaccine was injected. From the description of the viral post, we also find out which vaccine allegedly managed to “attract the magnet”: “After the vaccination with Pfizer, the magnet stands firmly on the lady at the vaccination site,” the author of the post wrote. In the video, we also hear a male voice suggesting that there is something suspicious: “How firm is the magnet? Obviously, there is something.”<sup>45</sup>

Medical experts, however, say these videos are nothing more than a conspiracy theory typical of the disinformation about the novel coronavirus. “No. Getting a COVID-19 vaccine cannot cause your arm to be magnetised. This is a hoax, plain and simple,” said Dr Stephen Schrantz, an infectious diseases specialist at the University of Chicago Medicine. “There is absolutely no way that a vaccine can lead to the reaction shown in these videos posted to Instagram and/or YouTube. It is better explained by two-sided tape on the metal disk being applied to the skin rather than a magnetic reaction,” he added. Asked about the claim, Thomas Hope, vaccine researcher and professor of cell and developmental biology at Northwestern University Feinberg School of Medicine, said: “This is impossible. There’s nothing there that a magnet can interact with; it’s protein and lipids, salts, water and chemicals that maintain the pH. That’s basically it, so this is not possible.”<sup>46</sup>

It should also be mentioned that none of the approved vaccines contain metals in their ingredients, as is shown by the approvals of the US Food and Drug Administration, which include Pfizer’s ingredients, Moderna, and Johnson &

<sup>44</sup> SirokiBrijeg.info, *BUJICA TV: Mons. dr. Vladimir Dugalić o koroni i cijepljenju – “Cilj ne opravdava sredstva!* <https://sirokibrijeg.info/bujica-tv-mons-dr-vladimir-dugalic-o-koroni-i-cijepljenju-cilj-ne-opravdava-sredstva/> (accessed: August 1, 2021).

<sup>45</sup> Melita Vrsaljko, *Cjepivo kod ljudi ne uzrokuje magnetska svojstva*, <https://faktograf.hr/2021/05/24/cjepivo-kod-ljudi-ne-uzrokuje-magnetna-svojstva/> (accessed: August 1, 2021).

<sup>46</sup> Natalie Wade, *Covid-19 vaccines do not contain magnetic microchips*, <https://factcheck.afp.com/covid-19-vaccines-do-not-contain-magnetic-microchips> (accessed: August 1, 2021).

Johnson<sup>47</sup> vaccines. Such videos are related to the theory that vaccines against COVID-19 are microchips, which is related to the conspiracy theory that Bill Gates wants to implant chips through vaccines and thus monitor the world's population. In Croatia, this theory is mainly promoted by Srećko Sladovljev, who claims that people also become mobile devices and the appearance of magnetism after vaccination.<sup>48</sup> Although this is an insane conspiracy theory, unfortunately, too many people in Croatia tend to believe it because of Sladovljev, undoubtedly the leading conspiracy theorist about the pandemic and the coronavirus vaccine, as we will see in the next chapter.

### **III. Vaccine Literacy in Croatia and the role of social networks in refusing vaccination in Croatia**

The problem of vaccination refusal did not arise with the COVID-19 pandemic in Croatia. However, a growing health problem recently is the refusal of compulsory vaccination of children by an increasing number of parents in Croatia. The anti-vaccination movement took off with the advent of social networks, primarily Facebook, as they proved to be the most effective in organising parents and conveying their messages. In the first study of its kind, published in 2017, research was conducted in Croatia and Southeast Europe to provide systematic, population-based insights about the prevalence and correlations of childhood vaccine refusal and hesitancy. Almost a third of participants reported childhood vaccine refusal and hesitancy intention. One of the study's conclusions is that the number of parents with childhood vaccine refusal and hesitancy intention is growing.<sup>49</sup> This growing trend of distrust in the reach of modern medicine exploded with a pandemic in the emergence of various conspiracy theories. What is particularly interesting is that only a few individuals and their organisations are responsible for the vast majority of anti-vaccine content posted on Facebook and Twitter.

The US-British Center for Countering Digital Hate has published research revealing who is behind the growing online anti-vaccine propaganda. The results of their study were published under the title *The Disinformation Dozen*<sup>50</sup>, which immediately indicates the proper background of the vast majority of all vaccination resistance initiatives. Disinformation Dozen, or the twelve people responsible for spreading misinformation, is responsible for more than half of the anti-vaccine content circulating on social media. These twelve people have a significant following

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<sup>47</sup> [Fda.gov, Fact Sheet For Recipients And Caregivers Emergency Use Authorization \(Eua\) Of The Janssen Covid-19 Vaccine To Prevent Coronavirus Disease 2019 \(Covid-19\) In Individuals 18 Years Of Age And Older](https://www.fda.gov/media/146305/download), <https://www.fda.gov/media/146305/download> (accessed: August 1, 2021).

<sup>48</sup> Index Vijesti, *Bivši šef Imunološkog: Primitkom cjepiva postajemo mobilni uredjaji*, <https://www.index.hr/vijesti/clanak/sladoljev-primitkom-cjepiva-postajemo-mobilni-uredjaji/2290771.aspx> (last accessed: August 1, 2021).

<sup>49</sup> Anja Repalust, Sandra Šević, Stanko Rihtar, Aleksandar Štulhofer, "Childhood vaccine refusal and hesitancy intentions in Croatia: insights from a population-based study," *Psychology, Health & Medicine* 22 (9/2017): 1045-1055 doi: 10.1080/13548506.2016.1263756.

<sup>50</sup> Center for Countering Digital Hate, *The Disinformation Dozen*, [https://252f2edd-1c8b-49f5-9bb2cb57bb47e4ba.filesusr.com/ugd/f4d9b9\\_b7cedc0553604720b7137f8663366ce5.pdf](https://252f2edd-1c8b-49f5-9bb2cb57bb47e4ba.filesusr.com/ugd/f4d9b9_b7cedc0553604720b7137f8663366ce5.pdf) (last accessed: August 1, 2021).



on social media and produce a large amount of content which is then easily and quickly spread through the networks. The CCDH survey was conducted during February and March 2021, and covered nearly 1.5 million posts on Facebook and Twitter, and analysts tried to find the source of those posts. It turns out that 65% of posts on Twitter and 73% on Facebook can be followed to the source - and he is right within the circle of twelve leading authors, determined to expand their agenda to followers. In their report, CCDH researchers named twelve people who are active in disseminating anti-vaccination information: Joseph Mercola, Robert F. Kennedy, Jr., Ty and Charlene Bollinger, Sherri Tenpenny, Rizza Islam, Rashid Buttar, Erin Elizabeth, Sayer Ji, Kelly Brogan, Christiane Northrup, Ben Tapper and Kevin Jenkins. These names do not mean much to ordinary people. Still, the Centre's report has a detailed profile for each of them that reveals their accounts and shows what content they have spread on social media and how much of an impact they have on spreading anti-vaccination information.<sup>51</sup> A recent report by Media Matters For America showed that, in addition to the 12 major influencers mentioned, many micro-influencers on Instagram encourage misinformation and have more and more followers.<sup>52</sup> Why fake news spreads so easily and quickly was established by a study by scientists from the prestigious MIT University in the US in 2018 published in *Science*. The study showed that fake news spreads 10 to 20 times faster than trustworthy news. The authors of the research explained this difference by the so-called hypothesis of novelty, that is, the thesis that people react more strongly to the news that has some surprise factor in them, which is certainly more characteristic of conspiracy theories and news that goes against the establishment, mainstream and established scientific facts, and this is especially evident now in times of pandemic and devastating spreading conspiracy theories.<sup>53</sup>

Since we do not have similar data for Croatia, below, we will single out some of the most well-known long-term spreaders of fear of vaccination, some of whom were more and less engaged during the COVID-19 pandemic. Most of them claim that they are not anti-vaxers. They all present themselves as reasonable sceptics who think for themselves, question things, and do not believe like ordinary uninformed people. Nevertheless, all of these have in common that their actions have contributed to relativising the justified fear of COVID-19 and other infectious diseases and maximising the fear of vaccination. The list of people who promote anti-vaccination mood in Croatia is long, so it would be challenging to present it in its entirety here. Because we do not have the necessary studies to quantify the popularity and reach of their misinformation, we will single out only those most recognisable in the media and on social networks, primarily Facebook.

Indeed, the most famous and most active anti-vaxer in Croatia is **Srećko Sladovljević**. This biologist became known to the Croatian public in 2009 as a

<sup>51</sup> Sandro Vrbanus, *Samo dvanaest antivaksera odgovorno je za većinu takvog sadržaja na društvenim mrežama*, <https://www.bug.hr/internet/samo-dvanaest-antivaksera-odgovorno-je-za-vecinu-takvog-sadrzaja-na-drustvenim-20008> (accessed: August 1, 2021).

<sup>52</sup> Silva Spencer, *Vaccine misinformation still runs wild on Instagram*, <https://www.mediamatters.org/coronavirus-covid-19/vaccine-misinformation-still-runs-wild-instagram> (accessed: August 1, 2021).

<sup>53</sup> Soroush Vosoughi, Deb Roy, Sinan Aral, "The spread of true and false news online," *Science* 359 (2018): 1146–1151.

whistleblower against the swine flu vaccine from the Institute of Immunology. Interestingly, due to this fact, he managed to impose himself as a vaccine expert, immunologist and epidemiologist, although he did not publish practically any scientific papers in these areas. According to the data available on the Research Gate website, in about 30 years of “scientific activity”, he has published only three scientific papers. He is not the first author, and only one of them deals with viruses. In numerous appearances in the media, he showed a surprising ignorance of the key concepts in medicine he spoke about. For example, he has been shown to confuse ALS (Lou Gehrig’s disease) and GBS (Guillain-Barre syndrome). He regularly spreads all sorts of conspiracy theories on his Facebook profile, from those about chemtrails dusting and the HAARP project as the cause of natural disasters to those about Freemasons and the Illuminati. During the pandemic, he became famous for several insane conspiracy theories, from the conversion mentioned above of humans to mobile devices to numerological calculations linking the name of Bill Gates and the coronavirus to Satan’s number 666.<sup>54</sup> His Facebook profile, which persistently calls for resistance to epidemiological measures and vaccinations, had 17,500 followers in April 2021. Still, at the time of writing this paper in early August 2021, the number of followers has grown by more than 50% to 27,500. This exceptional growth of Srećko Sladovljević’s followers clearly shows us that he is undoubtedly the biggest star among anti-vaxers on social networks in Croatia.

Croatian singer of popular music, **Toni Cetinski**, only recently, in May 2020, turned into an ardent, open opponent of vaccination. He caused a lot of media dust by participating in protests against epidemiological measures and open anti-vaccination attitudes. For example, in early June 2020, in the show Good Morning, Croatia invited viewers to light a virtual candle in honour of vaccine victims “Today is Vaccine Victims’ Day, so we are signing virtual candles on lightakandle.eu. Here we celebrate today by clicking on the candle, and together we contribute to raising awareness of how vaccine victims exist”, he said.<sup>55</sup> Although he claims he is not an anti-vaccine, he supported anti-vaccination protests in Belgrade. On Facebook, he founded the group *I have the right to know and choose - #pravoizbora*, with more than four thousand members. The group regularly mentions conspiracy theories on vaccination, the harmful effects of the 5G network, the coronavirus and other popular conspiracy theories. Cetinski has met much criticism for his performances, but his influence is undoubtedly significant as the local pop star, followed by more than 386,000 people on Facebook alone.<sup>56</sup>

**Ivan Pernar** is a former member of the Croatian Parliament for Živi Zid political party (The Living Wall), which became famous for its ridiculous populist outbursts in the Croatian Parliament and its anti-vaccination and promotion of the most nebulous conspiracy theories. Being a medical technician, he considers himself a

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<sup>54</sup> Nenad Jarić Dauenhauer, *Ovo su imena najvećih hrvatskih antivaksera*, <https://www.index.hr/vijesti/clanak/ovo-su-imena-najvecih-hrvatskih-antivaksera/2265042.aspx> (accessed: August 1, 2021).

<sup>55</sup> Maja Kruhac, *VIDEO: TONY ZA JUTARNJI Nisam antivaxer, ali na HRT-u nemaju hrabrosti otvoriti tu temu*, <https://www.jutarnji.hr/scena/domace-zvijezde/video-tony-za-jutarnji-nisam-antivaxer-alina-hrt-u-nemaju-hrabrosti-otvoriti-tu-temu-10370449> (accessed: August 1, 2021).

<sup>56</sup> Nenad Jarić Dauenhauer, *Ovo su imena najvećih hrvatskih antivaksera*, <https://www.index.hr/vijesti/clanak/ovo-su-imena-najvecih-hrvatskih-antivaksera/2265042.aspx> (accessed: August 1, 2021).

health authority, so he often mentions this topic on his own Facebook profile and in various groups, such as the Detox 2 group, which had about 29,000 members before it closed. Pernar himself had over 300,000 followers on his Facebook profile before Facebook permanently closed his profile due to the constant spread of conspiracy theories. At the protest against vaccination in Split, he publicly announced that he would not vaccinate his son and claimed he was still sticking to it on social media. Interestingly, despite this, little Noi himself was diagnosed with a spectrum of autism and prescribed therapy with selenium and some other dietary supplements that can be dangerous if not given under a doctor's supervision. He criticised antibiotics and antidepressants, claiming they could do more harm than good, and instead promoted vitamin C therapies and walks in the woods. He called for the belief in instinct instead of medicine. Although he does not hold any political or public office and has been banned from accessing Facebook, Pernar is rightly considered one of Croatia's greatest and most influential conspiracy theorists.<sup>57</sup>

Nutritionist **Anita Šupa** is the *Rights and Freedoms Initiative* initiator, which fights against epidemiological measures, COVID passport, and compulsory vaccination and has about 22,000 followers on Facebook. On the Truth Against Lies web portal, which promotes the most diverse conspiracy theories, she published an article entitled *The Beginning of the End of a False Pandemic! Finally, doctors and journalists come out with the truth!* She presents a series of misinformation and conspiracy theories that relativise the pandemic and epidemiological measures and glorify other anti-vaccines, such as the clerical-conservative member of the Croatian Parliament Karolina Vidović Krišto.<sup>58</sup>

Journalist and host of the TV show *Na rubu znanosti* (On the Edge of Science) **Krešimir Mišak**, which is shown on public television, is well known to the Croatian public as a promoter of pseudoscience and conspiracy theories of all kinds. Since the beginning of the pandemic, he has been promoting various conspiracy theories about the coronavirus, and he has exposed several of them in a video he posted on Facebook. Among other things, he lays out the theory that Bill Gates, who has invested billions in vaccines against various diseases, including COVID-19, is a eugenicist who wants to reduce the population on Earth by vaccination. He concludes by linking two of Gates' independent statements - one that poor people should be vaccinated against various diseases and the other that the world's population should be reduced - into one that vaccination is a way to reduce the population. Facebook labelled the video as a source of misinformation, but the work went viral nonetheless.<sup>59</sup>

We conclude our list of the most famous Croatian conspiracy theorists with TV host **Velimir Bujanec**, the most famous extreme right-wing journalist in Croatia and host of the highly watched and influential TV show *Bujica*. He primarily hosts guests

<sup>57</sup> Ibidem.

<sup>58</sup> Petar Vidov, *Ne postoje ugledni stručnjaci koji "izlaze sa istinom" o Covidu-19*, <https://faktograf.hr/2020/08/04/ne-postoje-ugledni-strucnjaci-koji-izlaze-sa-istinom-o-covidu-19/> (accessed: August 1, 2021).

<sup>59</sup> Nenad Jarić Dauenhauer, *Ovo su imena najvećih hrvatskih antivaksera*, <https://www.index.hr/vijesti/clanak/ovo-su-imena-najvecih-hrvatskih-antivaksera/2265042.aspx> (accessed: August 1, 2021).

of right and extreme right political views. However, in addition to them, Bujanec hosted more and more prominent anti-vaxers and conspiracy promoters in Croatia than Krešimir Pavelić, dean of the Medical Faculty in Pula and one of the most media-exposed opponents of vaccination. Pavelić used the media space in Bujica to spread conspiracy theories to a broad audience.<sup>60</sup> Furthermore, the philosopher and physicist Stipe Kutleša who expressed many conspiracy theories about the pandemic, was also a guest on the show.

Furthermore, finally, one of the guests on the show was the very popular conspiracy theorist Nada Jurinčić, a retired paediatrician. She presented many conspiracy theories in the show, such as: that the SARS-CoV-2 virus is not isolated and that viruses do not exist but are secretions of our cells. Therefore, the virus is not deadly and has similar fabrications.<sup>61</sup> In addition to giving space to various conspiracy theorists in his show, Bujanec, on his Facebook profile with over 95,000 followers, regularly spreads all current conspiracy theories about the pandemic and the harmfulness of vaccines.

One of the reasons for the success of the above promoters of conspiracy theories in Croatia indeed lies in the lack of public education about the benefits of the dangers of coronavirus and the benefits of vaccines. Therefore, a survey was conducted in Croatia, and this study aimed to evaluate COVID-19 vaccine literacy in the Croatian adult general population before vaccination began. The specific objectives were to test differences regarding socio-demographic characteristics and to examine perceptions and attitudes about vaccination against COVID-19, considering the level of vaccine literacy against COVID-19. A cross-sectional study with a translated and psychometrically tested questionnaire was conducted on 1227 participants before the start of vaccination, from 15 to January 31 2021. The study results show a medium level of vaccine literacy and a significant difference between functional and interactive critical vaccine literacy. The level of vaccine literacy grew with the level of education and reduced with age. The employed participants had chronic diseases, took medicine, or consumed alcohol daily and had a lower level of vaccine literacy. A satisfactory level of vaccine literacy in the population is necessary because it can contribute to the fight against the pandemic.<sup>62</sup> Furthermore, when we include politics and political circumstances in the whole pandemic reality, it is no wonder that there is so much distrust in the Croatian public in the inventions of modern science and so much faith in the most diverse conspiracy theories.

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<sup>60</sup> Narod.hr, Prof. Krešimir Pavelić: 'Korona-kriza je i manipulacija informacijama, sijanje straha', <https://narod.hr/koronavirus/prof-kresimir-pavelic-korona-kriza-je-i-manipulacija-informacijama-sijanje-straha> (ccessed: August 1, 2021).

<sup>61</sup> Margarita Perić, Bujica dezinformacija Nade Jurinčić, <https://faktograf.hr/2021/02/22/bujica-dezinformacija-nade-jurincic/> (accessed: August 1, 2021).

<sup>62</sup> Ivana Gusar, Suzana Konjevoda, Grozdana Babić, Dijana Hnatešen, Maja Čebihin, Rahela Orlandini, Boris Dželalija, "Pre-Vaccination COVID-19 Vaccine Literacy in a Croatian Adult Population: A Cross-Sectional Study," *International Journal of Environmental Research and Public Health* 2021, 18(13), 7073 <https://doi.org/10.3390/ijerph18137073>.

#### IV. The impact of political and social circumstances on the vaccination process

Politics plays a crucial role in combating a pandemic. Politicians who have won citizens' trust in the elections to run the country provide a vaccine for citizens, promote vaccination safety and enact various protection measures. Unfortunately, Croatia has been ruled for years by the center-right HDZ party, which the Croatian public perceives as a generator of corruption and mistrust in institutions. Therefore, it is unsurprising that Croatian citizens distrust the newly formed headquarters for fighting the pandemic and his measures to fight against the COVID-19 pandemic. The public perceives the headquarters for fighting the pandemic as a political body that implements decisions in the party's political interest in power, not as a professional and scientific body. The Croatian public is tired of confusing and hypocritical decisions. Messages of the headquarters for fighting the pandemic, which allows, for example, mass public gatherings that suit politicians and the Catholic Church, as was the case with organising church processions during the strictest lockdown in the spring of 2020 when the whole country was closed in a lockdown,<sup>63</sup> or the occasional declaration of victory over the pandemic in the summer of 2020 by Prime Minister Andrej Plenković during the parliamentary election campaign, who stated: "Croatia has won COVID-19, this Government has won COVID-19, we have overcome the epidemic. What would it be like in the atmosphere in Croatia if we had 3000 dead? Moreover, it could have happened. Instead, we managed to limit the number of infected and the number of dead, and I am sorry for every life."<sup>64</sup> Unfortunately, it turned out that the political victory over the coronavirus was premature. According to the Ministry of Health, Croatia had 364,832 cases by August 7 2021, of which 8,271 people died.<sup>65</sup> The Government's strategy to fight the pandemic can be characterised as a failure and has cost the lives of thousands of Croatian citizens. The government and the headquarter for fighting the pandemic made unrealistic promises to the public, decisions were made that were not in line with the latest scientific facts, and it is not surprising that there is a massive distrust of the people towards the Government's decisions and the headquarter for fighting the pandemic. The Government's current vaccination strategy, which envisioned this scenario for at least half of the citizens by the end of June, could in many ways be characterised as a failure. The plan failed spectacularly, so it is time for the second part. Judging by the Government's announcements after the vaccination campaign's failure, various forms of direct and indirect pressure, including coercion, will follow. According to these announcements, COVID-passports will be mandatory for public

<sup>63</sup> Mirko Crnčević, *Stožer dao dozvolu za procesiju na Hvaru: 'Za Križen' ide po 15 osoba, Capak vjeruje da se neće ništa loše dogoditi*, <https://slobodnadalmacija.hr/dalmacija/otoci/stozer-dao-dozvolu-za-procesiju-na-hvaru-za-krizen-ide-po-15-osoba-capak-vjeruje-da-se-nee-nista-lose-dogoditi-1015195> (accessed: August 1, 2021).

<sup>64</sup> Indeks Vijesti, *Plenković: Ova je vlada pobijedila koronavirus*, <https://www.index.hr/vijesti/clanak/plenkovic-ova-vlada-je-pobijedila-koronavirus/2185893.aspx> (accessed: August 1, 2021)

<sup>65</sup> Koronavirus.hr, *233 nova slučaja u protekla 24 sata, utrošeno 8905 doza cjepiva*, [www.koronavirus.hr/najnovije/233-nova-slucaja-u-protekla-24-sata-utroseno-8905-doza-cjepiva/35](http://www.koronavirus.hr/najnovije/233-nova-slucaja-u-protekla-24-sata-utroseno-8905-doza-cjepiva/35) (accessed: August 1, 2021).

gatherings, stays in shopping malls, public institutions, concerts, and similar open events with mass attendance. According to the latest information, mandatory testing will be provided for those not vaccinated and who want to enter such facilities.<sup>66</sup> Such scenarios and statements that change daily are not surprising that people have lost confidence in the authorities. It is essential to mention that Croatian citizens had great faith in the headquarters for fighting the pandemic at the beginning of the pandemic, and the headquarters for fighting the pandemic instructions were heeded. Suppose the communication between the Government, the headquarters for fighting the pandemic as a government body in the fight against the pandemic and the citizens is not honest, open, and transparent. In that case, the toxicity of conspiracy theories comes to the fore with a powerful argument - the Government does not work for you but for its own benefit; which is true? Political circumstances have contributed to this, and now the situation with the refusal to vaccinate is becoming more serious, endangering not only the tourist season in a country that lives off tourism but also the coming autumn and the fight against a new highly contagious delta strain. Only with a positive change in attitudes towards citizens and citizen education and a new marketing approach may the current Government change the opinion of a few people, but not enough to achieve 70% vaccination. Although they now state that the problem is not new strains but antivaxers<sup>67</sup>, The Government must be aware that their inconsistent work and attitude towards their fellow citizens have significantly contributed to the development of conspiracy theories in the Republic of Croatia. On the other hand, citizens should not attach so much importance to their shortcomings because the public is accustomed to government shortcomings but rely on foreign sources, research, science and the desire to protect themselves and fellow citizens adequately, and this is possible only through vaccination and common sense to politicians currently in power. Although politicians in power bear much responsibility for some citizens refusing or hesitating to be vaccinated, below are examples of opposition politicians whose statements and statuses on social media further raise the level of distrust in the vaccination campaign.

A similar view is shared by committed politicians, such as Marin Miletić, a member of the Croatian Parliament from the right-wing clerical political party MOST (The Bridge), Marin Miletić, who uses social networks to spread distrust and fear of the vaccine and thus manipulates the masses. Miletić's primary profession is a religious teacher, and he invokes religion in his views while promoting numerous misinformation. Therefore, in June 2021, Miletić published several posts on social networks, primarily videos, in which he questioned the safety and efficacy of the vaccine against COVID-19. With his announcements, Miletić encourages people, mainly the younger population, to refuse vaccination, presenting a personal decision as an act of resistance to the state system.<sup>68</sup> As one of the role models for his anti-

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<sup>66</sup> Hrvoje Šimičević, *Ne cijepi me*, [www.portalnovosti.com/ne-cijepi-me](http://www.portalnovosti.com/ne-cijepi-me) (accessed: August 1, 2021).

<sup>67</sup> Nenad Jarić Dauenhauer, *Nije problem u delta soju nego u antivakserima*, <https://www.index.hr/vijesti/clanak/nije-problem-u-delta-soju-nego-u-antivakserima/2287748.aspx> (accessed: August 1, 2021).

<sup>68</sup> Petar Vidov, *Marin Miletić na društvenim mrežama vodi antivaksersku kampanju*, <https://faktograf.hr/2021/07/05/marin-miletic-covid-cijepjenje-antivakseri/> (accessed: August 1, 2021).

vaccine attitudes, Miletić mentions a member of the headquarters for fighting the pandemic, molecular biologist Gordan Lauc, who said:

“that the idea of vaccinating others by vaccination has no biological logic, that SARS-CoV-2 are just vaccinated, not unvaccinated generators of new viral variants, that only those at risk should be vaccinated, and that people who survive COVID-19 develop a much broader immune response, which is then much more resistant to some future new variants.”<sup>69</sup>

Lauc’s theory and many other statements have provoked numerous criticisms in the Croatian academic community. Still, it has also met with supporters, especially among those who are distrustful of science.

In Croatian daily political practice, theses that undermine confidence in the safety and effectiveness of vaccines in public space are placed by members of the MOST and Domovinski pokret (The Homeland Movement), i.e. radical and conservative right-wingers, who took an opposing position in public policy in the Republic of Croatia towards the vaccination campaign. Given such a political picture, selfishness and association with God’s protection are nothing out of the ordinary. Still, it creates a severe problem in reaching the goal of vaccinating 70% of the adult population. In this context, the statement written on his Facebook page by Stephen Nikola Bartulica, Member of the Croatian Parliament and President of the Parliamentary Club of Domovinski pokret, should be singled out. Bartulica published an unfounded claim that forced mass vaccination of children is being prepared, i.e. that the state is preparing to vaccinate children en masse without the consent of their parents:

“Capak’s deputy Ivana Pavić-Šimetin announced today the mass vaccination of children. It will not go that way without parental consent, and I am the first to express my opposition to this decision. I argue that from the beginning, hysteria about the Chinese virus has been dangerous and very harmful, especially for our children. Unfortunately, of the total number of deaths in Croatia, six are children under 19, confirming that this disease is not a threat to minors. Such pressures are sure to provoke great and justified resistance from parents. Now they would impose the vaccination of children who are not a risk group in any way!” wrote Bartulica.<sup>70</sup>

However, Pavić-Šimetin never said that the state was already preparing for any mass vaccination of children, but only that it was preparing for that possibility. More importantly, Pavić-Šimetin did not say that the vaccination of children would be mandatory or that it would be carried out against the parents’ wishes. Vaccination

<sup>69</sup> Nenad Jarić Dauenhauer, *Znanstvenici o Laucu: Tvrdnja da je bolje preboljeti nego se cijepiti izaziva užas*, <https://www.index.hr/vijesti/clanak/znanstvenici-o-laucu-tvrdnja-da-je-bolje-preboljeti-nego-se-cijepiti-izaziva-uzas/2291210.aspx> (accessed: August 1, 2021).

<sup>70</sup> Narod.hr, *Bartulica o izjavi Capakove zamjenice: 'Nametnuli bi cijepljenje djece koja ni po čemu nisu rizična skupina!'* <https://narod.hr/hrvatska/bartulica-o-izjavi-capakove-zamjenice-nametnuli-bi-cijepljenje-djece-koja-ni-po-cemu-nisu-rizicna-skupina> (accessed: August 1, 2021).

against COVID-19 in Croatia is voluntary, as in all other EU member states. There is currently no official information or announcement to conclude that compulsory vaccination against COVID-19 will be introduced, which means that organised vaccination of children over 12 years of age should also be voluntary if it occurs. After stirring up the public with his interpretation of the mass vaccination of children, Bartulica declared himself not an anti-vaccine but shifted the responsibility to the politicians in power: “I am not like that. I am for freedom, and if the people do not want to be vaccinated, it is up to politicians who have failed to convince them of that.”<sup>71</sup> Bartulica does not understand that he is responsible to the Croatian public as a politician and member of the Croatian Parliament. This spread of false news does not help the vaccination campaign. It is especially worrying that Miletić and Bartulica are prominent politicians - believers and thus indirectly influence some citizens who refuse or hesitate to vaccinate for religious reasons. In addition to the politicians above in Croatia, We must also mention the case of two Croatian members of the European Parliament, Ivan Vilibor Sinčić from Živi Zid (The Living Wall) and independent MP Mislav Kolakušić. For months, they have consistently spread misinformation and conspiracy theories about Brussels’s coronavirus pandemic, vaccination, and protection measures. Sinčić and Kolakušić have turned into one of the largest and most ardent anti-vaxers and opponents of vaccination in Croatia, and it is especially worrying that they are using their European Parliament as a stage for spreading the worst theories about the coronavirus pandemic and vaccination. On February 12, 2021, Sinčić posted a video on his official Facebook page in which he asked a question to the President of the European Commission, Ursula von der Leyen, in the European Parliament, which in the meantime was viewed more than 400 thousand times and collected more than 10 thousand likes. It has been divided more than five thousand times.

“Ms. von der Leyen, do you think it is in the interest of pharmaceutical companies that this crisis ever actually ends? This whole crisis is not so much about health as it is about control and money. Why would people die of heart, cancer or flu when it can all be reposted in the coronavirus? You did everything you could to get the numbers you wanted”<sup>72</sup>

Sinčić said without any evidence, accusing “political centres of power” of fabricating deaths from COVID-19. Over 102,000 followers on Facebook follow Sinčić, and he uses Facebook to spread misinformation about the COVID-19 pandemic and frequently places incorrect claims about the safety of vaccines against the disease. Part of Sinčić’s followers can thank the constant incendiary posts he publishes on his profile. He presents himself as a brave MEP, one of the few who asks the right questions and, at the same time, knows medicine better than the army of doctors

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<sup>71</sup> Narod.hr, *Bartulica o historiji oko cijepljenja: 'Nema nametanja bez pristanka roditelja'*, <https://narod.hr/hrvatska/bartulica-o-historiji-oko-cijepljenja-nema-nametanja-bez-pristanaka-roditelja> (accessed: August 1, 2021).

<sup>72</sup> Petar Stošić, *Poslali smo Sinčića i Kolakušića u Bruxelles. Sad tamo šire teorije zavjere o koroni*, <https://www.index.hr/vijesti/clanak/sto-kolakusic-i-sincic-rade-u-eu-parlamentu-sire-teorije-o-koronacizmu/2256118.aspx> (accessed: August 1, 2021).



who, according to Sinčić, do not want to treat their patients with COVID-19. Sinčić's Facebook profile is full of the most absurd conspiracy theories. For example, in a post from August 1, he announced:

“Pakistani authorities in the process of blocking SIM cards unvaccinated. Australian authorities sent tanks to Sydney yesterday to carry out a lockdown. The biggest culprits are the citizens who warned us about this total deprivation of liberty - conspiracy theorists - and trusted the Gates / Plenković / Beroš / Capak / Von der Leyen / Markotić team. It is not unrealistic for anyone that about 10 of the same people appear to promote this circus in Croatia and the world. Years of enriching the minority and impoverishing and endangering the health of the majority follow.”<sup>73</sup>

This statement had over 3200 likes and 791 comments in less than 24 hours and was shared 756 times, which confirms the significant impact of such and similar statements by MEP Ivan Vilibor Sinčić on the public. Mislav Kolakušić is even more engaged in sowing suspicion of a pandemic and spreading conspiracy theories about epidemiological measures and vaccination, at least judging by the content he publishes on his official Facebook page. For example, in a speech excerpt published on February 17, 2021, he claims that we are “facing the emergence of a new powerful and unscrupulous mafia, which is more dangerous than all previous forms of organised crime” and which “uses media of all forms to fear their products” to force “every man in the world to use their product at least twice a year for the rest of his life.” What this is about is clearer from the video published by Kolakušić on February 9, 2021, where he calls the coronavirus testing nothing less than a “crime against humanity” and the fight against the pandemic “Nazism and fascism.” In this speech, whose video has been liked 15,000 times and shared almost 8,000 times, Kolakusic makes frightening claims:

“Lockdown, PCR tests and a fear campaign have deprived citizens of their freedom, right to move and right to work. Individual citizens are banned from working, and millions of jobs have been lost. The introduction of PCR tests to determine disease and the cause of death is a crime against humanity. It is a crime against each person personally. In history, the united states have defeated Nazism and fascism. Now, a new Nazism that is growing and that no one wants to end on behalf of states will be put to an end by free citizens. It is time for free citizens to come together and say ‘Enough. We want the truth, many lies, and fear. Once wars were fought with weapons, now they will be fought with the truth.’”<sup>74</sup>

Kolakušić does not have his profile on Facebook. Still, his statements are transmitted via a Facebook page aptly populist called “Citizens for Mislav Kolakušić”

<sup>73</sup> Ivan Vilibor Sinčić, *ivsincic*, <https://www.facebook.com/ivsincic> (accessed: August 1, 2021).

<sup>74</sup> Stošić, *Poslali smo Sinčića i Kolakušića u Bruxelles. Sad tamo šire teorije zavjere o koroni*.

and has more than 165,000 followers. We can conclude that Kolakušić has an even greater influence on the public and is abusing his influence with such statements, such as the one of July 13, 2021: “Mandatory vaccination against COVID-19 is like mandatory Russian roulette.”<sup>75</sup> The above statement has over 3200 likes and 343 comments and has been shared over 1100 times. We can conclude that two Croatian MEPs, Sinčić and Kolakušić, use their excessive parliamentary salaries and the benefits they have as members of the European Parliament to spread fear and mistrust in public and the international embarrassment of Croatia since, fortunately, there are not many such conspiracy theorists in the European Parliament as the two mentioned.

## **V. Conclusion**

As we have seen in the paper, vaccination against COVID-19 in Croatia is a severe crisis, not because of the lack of vaccines (as was the case at the beginning of the vaccination process) but because of the resistance of a particular part of the public. This does not mean that we can and should not critically take all these conspiracy theories as entirely equal and treat them as equally valuable as countless scientific studies and the almost unanimous view of science on the necessity and usefulness of coronavirus vaccination. Proponents and promoters of these conspiracy theories should be approached with due consideration and understanding, bearing in mind that the vast majority of those who refuse or hesitate to receive the vaccine are not concerned with anti-vaxers but simply people who cannot cope with the cacophony of opposing opinions and attitudes about vaccination. From a bioethical position, it is necessary to include empathy and understanding of their fears and doubts. How much this pandemic and the social and psychological crisis will affect man remains to be seen. While politicians in power interpret all measures taken in the fight against the pandemic as an effort to benefit citizens and preserve their health and protect the elderly and infirm (because: “we think of others”), it is evident from public reactions that there is a deep distrust of citizens towards political and scientific authorities. The mistrust that conspiracy theorists spread and politicians further deepen with their dishonest behaviour. The current goal of the vaccination campaign has failed, as we have seen in the paper, for many reasons. We cannot attribute all the responsibility for the failure of the vaccination campaign to conspiracy theorists alone, even though they bear much of the blame. However, in addition to them, a large part of the responsibility lies with politicians, specifically the Government of Croatia headed by Andrej Plenković, which has lost a large part of its credibility and authority in public to its political interests. In addition, a specific part of the responsibility lies with some members of the Catholic Church, who, through their irresponsible behaviour and denial of the pandemic, additionally sowed suspicion and distrust among some believers. Let us not forget some public figures and scientists, such as Gordan Lauc, who often misled the public about scientific knowledge with his often contradictory messages and views regarding the pandemic.

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<sup>75</sup> Građani za Mislava Kolakušića, *sudacmislavkolakusic*, <https://www.facebook.com/sudacmislavkolakusic> (accessed: August 1, 2021).

What is the future of the fight against the pandemic in Croatia? It is ungrateful to predict. It is difficult to say whether there will be a mandatory vaccination of the population or a mandatory vaccination of employees of essential social services, such as health and education. If this measure is taken, there is no doubt that it will cause new conflicts and divisions in Croatian society. Although Croatia does not have a long history of democracy, the fact is that Croatian citizens are very sensitive to the restriction of their rights, and mandatory vaccination is rightly perceived as a restriction of human and civil rights. Such a pandemic has not been recorded in the history of humankind (which has affected the whole world and so many people globally). In this fight, everyone must be committed, persistent, and trust in science because science has brought humanity to a high level of development. It is the science that has stopped many diseases, so why not this one? However, it also requires common sense. Anti-vaxers and conspiracy theorists certainly slow down the process, presenting unsubstantiated facts that try to match scientific facts. The question remains why so many theories have developed, whether fear and insecurity, the desire to blame someone for illness or lack of education and intelligence, because studies have shown that people who refuse vaccination have reduced cognitive abilities<sup>76</sup>. What is worrying, of course, is the number of these people, or they are only seemingly louder because, out of their fear, they take up space on social networks, perceiving them as a battleground in the fight against vaccination. The pandemic has brought humanity into an unprecedented public health crisis in the last hundred years and is also a major bioethical problem. From a bioethical perspective, life is a fundamental value, not just physical life. Still, we argue that this also applies to social, cultural, religious, and other aspects of human life. Each of the listed aspects of life is endangered in a pandemic, about which, unfortunately, we all have much experience, from insisting on social distance to online teaching and a dramatic transition to virtual life. Vaccination is a light at the end of a long and dark pandemic tunnel, but we must also be aware that vaccines are not the only solution to our problems, but only one of the solutions. The pandemic encourages us again and reminds us how fragile, precious and worth fighting life is.

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<sup>76</sup> G. David Batty, Ian J. Deary, Chloe Fawns-Ritchie, Catharine R. Gale and Drew Altschul, "Pre-pandemic cognitive function and COVID-19 vaccine hesitancy: cohort study", *Brain, Behavior, and Immunity* 96 (2021): 100-105, doi.org/10.1016/j.bbi.2021.05.016.

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# THE EFFECTS OF THE COVID-19 PANDEMIC IN ROMANIA IN TERMS OF ETHICS AND ORGANIZATION

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## Abstract

The SARS-COV-2 pandemic is far from over, even though various measures were implemented by the government such as social distancing and the obligation to wear face masks. Notwithstanding that there are several variants of vaccines available, by August 31, 2021, just over 26,6% of the population received the complete vaccine scheme<sup>1</sup>. However, in Romania, the number of infections continues to increase, with over 1 million cases so far and over 34,000 deaths. Given the circumstances, medical staff had to deal with a wide range of problems, including organizational, ethical, administrative, and, last but not least, economic ones.

Ethical issues have also existed since the beginning of the global pandemic because of quarantine, the restriction of free movement, home isolation, and travel constraints. We were all faced with a situation for which no one seemed to have a final solution, and due to this, the community, economy, health system, medical staff, and patients suffered enormously.

Romania, like other countries, was not prepared for such a pandemic. Initially, this led to overcrowded hospitals due to inadequate case management - depending on the form of the disease - and hospitalising patients with mild forms. Ambiguous discharge criteria, time lost in intermediate units until receiving the results of the SARS-COV-2 test and the management of positive patients with other associated pathologies were added issues. Also, many Romanian hospitals had to deal with the

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<sup>1</sup> “Actualizare zilnică (31/08) – evidența persoanelor vaccinate împotriva COVID-19” (August 31, 2021) [Daily update (31/08) - records of people vaccinated against COVID-19] available online at: <https://vaccinare-covid.gov.ro/actualizare-zilnica-31-08-evidenta-persoanelor-vaccinate-impotriva-covid-19/> (accessed June 20, 2022).

infection of a large number of medical staff, which resulted in doubling the workload of those who remained, or resorting to even more drastic measures such as temporarily closing some departments in order to extinguish existing outbreaks. Last but not least, despite all the collective efforts and the provision of a vaccine, there is still a considerable percentage of 40,5% unvaccinated medical staff<sup>2</sup>.

## I. Introduction

Without a doubt, the year 2020 changed everyone's lives. With the onset of the COVID-19 pandemic, the planet's entire population has had to reorganize itself by implementing lockdowns, social distancing, population screening policies, or none of the above, depending on the severity of each affected area<sup>3</sup>. We are experiencing a moment in time when most countries, regions and cities had to come to grips with their shortcomings and acknowledge the lack of preparation regarding this event. Some of the reasons would be: underestimation of the risk when the outbreak occurred, insufficient protective equipment, lack of hospital beds, reduced investment in the health care system and the lack of crisis management plans for pandemics. The exceptions were Asian countries that have gone through the Severe Acute Respiratory Syndrome (SARS) pandemic and others such as the Nordic countries, where crisis management plans are needed<sup>4</sup>. In addition, Romania has the lowest health expenditure of all European Union (EU) countries in both percentage of gross domestic product (GDP) and per capita expenditure<sup>5</sup>.

The 1st case was confirmed in Romania on February 26, 2020<sup>6</sup>. On March 11, 2020, World Health Organization (WHO) declared that the coronavirus outbreak had become a pandemic<sup>7</sup>. In response to this, Romania, as well as other countries, concentrated its initial efforts on blocking transmission resorting to quarantine and isolation.

The isolation of positive patients – one of the first measures implemented - probably had one of the biggest emotional impacts on them and their families. This

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<sup>2</sup> “Sanitas: Vaccinarea obligatorie pentru personalul medical din România nu se justifică” (August 9, 2021) [Sanitas: Compulsory vaccination for medical staff in Romania is not justified] available online at: <https://www.digi24.ro/stiri/actualitate/sanitas-vaccinarea-obligatorie-pentru-personalul-medical-din-romania-nu-se-justifica-1627989> (accessed August 12, 2021).

<sup>3</sup> Coronavirus Pandemic (COVID-19) <https://ourworldindata.org/coronavirus> (accessed June 19, 2022). COVID-19 Government response tracker <https://www.bsg.ox.ac.uk/research/research-projects/covid-19-government-response-tracker> (accessed June 19, 2022).

<sup>4</sup> Allain-Dupré D., Chatry I., Kornprobst A., Michalun M.V., Lafitte C., Moisis A., Phung L., Power K., Wu Y., Zapata I., “The territorial impact of COVID-19: Managing the crisis across levels of government”, OECD Policy Responses to Coronavirus (COVID-19), Updated 10 November 2020.

<sup>5</sup> World Health Organization Global Health Expenditure Database. Available online at: <https://apps.who.int/nha/database/Select/Indicators/en> (accessed June 20, 2022)

<sup>6</sup> “Primul caz de coronavirus în România. Suspiciuni despre un al doilea caz în Gorj” [First coronavirus case in Romania. Suspicions about a second case in Gorj]. Digi24 (in Romanian), (February 26, 2020) <https://www.digi24.ro/stiri/actualitate/primul-caz-de-coronavirus-in-romania-1266806> (accessed May 10, 2021).

<sup>7</sup> Cucinotta D., Vanelli M., “WHO Declares COVID-19 a Pandemic”, *Acta Biomed* (Mar 19, 2020):157-160.

was a difficult compromise, with psychological consequences, but necessary in order to meet medical requirements and protect the population.

Quarantine was a difficult measure for both hospitalized patients and the general population. In addition to banning outpatient visits, contact between physicians and patients was also diminished to minimize medical staff's exposure to the virus and reduce contact between patients and the hospital environment.

The Romanian health system also faced other challenges. The decision to hospitalize all positive cases led to the overloading of the sections treating COVID-19 and the Emergency Room (ER). The rapid filling of the initial wards reserved for COVID-19 patients meant a lack of space for new cases, and this resulted in the transformation of other clinical and surgical wards into red areas, the latter treating only COVID-19-positive patients. Another problem in our health system is the low rate of vaccination against SARS-COV-2 among medical staff and the fact that in Romania there are doctors who support anti-vaccination campaigns.

All these aspects should be deepened and attempts should be made to resolve them in order to have the best possible outcome and to manage the pandemic as well as possible.

## **II. Hospitalization of all confirmed cases at the beginning - a mistake?**

Because not much information was yet known about COVID-19 when the number of cases in Romania began to increase, the government and the National Committee for Special Emergency Situations introduced a series of rules and protocols to manage the pandemic. The threat that awaited us proved to be growing as we could see from the negative effects of the disease in China and Italy<sup>8</sup>. In March 2020, the government implemented a number of restrictions during lockdown and declared a state of emergency. Because the best possible start was sought after, a decision was made to hospitalize all positive cases, including a mandatory hospitalization of asymptomatic cases<sup>9</sup>.

This decision was probably taken in the hope of avoiding the difficulties faced by Italy and China at that time, but it quickly led to the overcrowding of the dedicated COVID-19 wards. The President of Romania declared a state of emergency based on the following reasons: the experience of countries severely affected by the evolution of the virus; a massive increase in the number of infected people; the failure

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<sup>8</sup> Pisano G.P., Sadun R., Zanini M., "Lessons from Italy's response to Coronavirus", *Harvard Business Review* (March 27, 2020), <https://hbr.org/2020/03/lessons-from-italysresponse-to-coronavirus> (accessed June 23, 2021).

<sup>9</sup> Dascalu S., "The successes and failures of the initial COVID-19 Pandemic response in Romania. *Front Public Heal.*" (2020) 8:344. 10.3389/fpubh.2020.00344

"Modificarea criteriilor de externare pentru pacienții cu afecțiunea COVID-19" (June 23, 2020) [Modification of discharge criteria for patients with COVID-19] [www.ms.ro/2020/06/23/modificarea-criteriilor-de-externare-pentru-pacientii-cu-afectiunea-covid-19/](http://www.ms.ro/2020/06/23/modificarea-criteriilor-de-externare-pentru-pacientii-cu-afectiunea-covid-19/) (accessed June 20, 2022).

"Subiect: Internarea forțată în spitale a persoanelor testate pozitiv cu coronavirus și asimptomatice, fără a avea acceptul scris al acestora" [Subject: Forced hospitalization of people tested positive for coronavirus and asymptomatic without their written consent] available online at: [www.europarl.europa.eu/doceo/document/E-9-2020-004380\\_RO.html](http://www.europarl.europa.eu/doceo/document/E-9-2020-004380_RO.html) (accessed June 20, 2022).

to take urgent measures had a severe impact on people's right to life and right to health, highlighting the need to establish a state of emergency in order to reduce the adverse effects on the economy. During the state of emergency, the following rights were restricted: free movement, the right to family and private life, the inviolability of the home, the right to education, freedom of assembly, the right to private property, the right to strike, and economic freedom<sup>10</sup>.

The treatment was determined by the form of the disease - from mild to severe - and this could have been an essential criterion for hospitalization as well. In this way, only cases from medium to severe forms that could not be treated at home would have been hospitalised. Therefore, the availability of beds for severe cases could have been increased, and implicitly, waiting time for patients in the ER could have been halved, and specialized treatment could have been given faster. Asymptomatic patients and patients with mild forms would have also benefited, the emotional impact would not have been as great, had patients been allowed to stay at home and not be separated from their families. The hospital environment could itself be a stress factor for these patients, as they may share the hospital room with critically ill patients or witness deaths, which may have a negative impact on them.

What happened was a congestion and lack of beds in the COVID-19 wards, also known as red areas in Romania, and this led to the overpopulation of the emergency departments because the patients admitted to the Emergency Room (ER) who tested positive for SARS-COV-2 could not be hospitalized immediately. Under these circumstances, the period of time in which the patients who were positive stayed in the ER longer, increasing the risk of transmitting the disease to other patients and medical staff.

At the same time, an even bigger problem was the fact that sometimes the patients admitted to the ER had more severe forms of the disease than those already hospitalized, many of whom had become asymptomatic, but still had a positive real-time polymerase chain reaction (RT-PCR) test.

Finding a quick and efficient solution was vital because the Romanian medical system was running out of resources. People were not eager to be hospitalized and isolated from their families, regardless of the severity of their symptoms, because many of them did not fully understand the seriousness of the situation, showing a lot of reluctance, mistrust, fear and noncooperation. Many refused transfer to intensive care on aggravation or even transfer to more specialized clinics in Germany<sup>11</sup>.

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<sup>10</sup> "Decret nr. 195 din 16 martie 2020 privind instituirea stării de urgență pe teritoriul României, emitenț președintele României, Publicat în Monitorul Oficial nr. 212 din 16 martie 2020" [Decree no. 195 of March 16, 2020 regarding the establishment of the state of emergency on the Romanian territory, issuer of the president of Romania, published in the Official Gazette no. 212 of March 16, 2020] available online at : <https://legislatie.just.ro/Public/DetaliiDocumentAfis/223831> (accessed June 22, 2022).

<sup>11</sup> Carla Tănăsie, "Epidemie de frică în rândul pacienților COVID. Refuză tratamentul care i-ar putea salva" (November 14, 2021) [Fear epidemic among COVID patients. He refuses the treatment that could save them] <https://www.digi24.ro/stiri/actualitate/sanatate/pacient-in-romania/epidemie-de-frica-in-randul-pacientilor-covid-teoriile-conspiratiei-ii-fac-sa-creada-ca-sunt-victimele-unor-experimente-1730255> (accessed June 23, 2022).

Subsequently, hospitalization became a choice; patients with mild forms were able to stay isolated at home with daily telephone monitoring by the family doctor. Telemedicine was one of the methods that helped Italy as well<sup>12</sup>. In order to be sure that this inpatient triage was done correctly, positive patients were initially called for an evaluation with blood tests, chest x-rays and chest Computed Tomography (CT) scans to rule out possible lung damage in asymptomatic patients or patients with mild forms.

There were certain rules related to quarantine and isolation in March, 2020. Quarantine was established for all people who did not show symptoms but were returning from areas with extended community transmission of the new coronavirus. The quarantine lasted 14 days and was organized in special spaces, made available by the local authority, in collaboration with the public health directorate<sup>13</sup>, abbreviated in Romanian as DSP.

Self-isolation was applied to people who did not show symptoms but: had traveled in the last 14 days to affected areas, other than those with extended community transmission; had come into direct contact with people with symptoms and who had traveled to areas with extended community transmission; had come into direct contact with persons who had been confirmed with COVID-19. These people were self-isolated at home for 14 days. During this time, they would be monitored by the family doctor or, in his absence, by the DSP<sup>14</sup>.

In October 2020, Nelu Tătaru, Minister of Health, approved Order no. 1,513/2020 in a press release, which specified that all patients detected on RT-PCR testing with a positive result for SARS-COV-2 had an obligation to contact and inform the family doctor, who will put them on record and monitor them. After the telephone evaluation performed by the family doctor, the patient is classified into one of the following categories: asymptomatic or mildly symptomatic patients who do not require hospitalization; symptomatic patients with risk factors, who are recommended by the family doctor to be taken to the hospital by ambulance and evaluated clinically; symptomatic patients with moderate or severe forms will be hospitalized with their consent.

These asymptomatic and mild symptomatic patients who have completed the 14-day isolation period from the first positive test will be declared cured without the second control test. After this period, they can resume their current and professional

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Dascalu S., Geambasu O., Valentin Raiu C., Azoicai D., Damian Popovici E., Apetrei C., "COVID-19 in Romania: What Went Wrong? Front Public Health." 2021 Dec 17; 9:813941. doi: 10.3389/fpubh.2021.813941. PMID: 34976942; PMCID: PMC8718595.

<sup>12</sup> Ferorelli D., et al. "Medical Legal Aspects of Telemedicine in Italy: Application Fields, Professional Liability and Focus on Care Services During the COVID-19 Health Emergency," *Journal of primary care & community health* vol. 11 (2020).

<sup>13</sup> "Precizări privind conduita de autoizolare" [Clarifications regarding self-isolation conduct] available at [www.cnsbct.ro/index.php/info-populatie/1537-precizari-privind-conduita-in-autoizolare/file](http://www.cnsbct.ro/index.php/info-populatie/1537-precizari-privind-conduita-in-autoizolare/file) (accessed June 23, 2022).

<sup>14</sup> "Precizări privind conduita de autoizolare" [Clarifications regarding self-isolation conduct] available at [www.cnsbct.ro/index.php/info-populatie/1537-precizari-privind-conduita-in-autoizolare/file](http://www.cnsbct.ro/index.php/info-populatie/1537-precizari-privind-conduita-in-autoizolare/file) (accessed June 23, 2022).

activities by keeping their distance and wearing a face mask at home for another ten days<sup>15</sup>.

Compulsory hospitalization, quarantine and isolation were some of the measures that could have a social and psychological impact on the population, even if later the criteria changed, and the positive asymptomatic or mild forms were consulted using telemedicine and hospitalized only in case of aggravation, by consent.

### III. Discharge criteria

Treatment protocols have undergone many changes in Romania after seeing and analyzing treatment plans in other countries with good results. Initially, the main criterion for discharge was to obtain a negative result on two RT-PCR tests within 24 hours after completing eight full days of treatment<sup>16</sup>.

There are several issues to pinpoint here. One of them is keeping asymptomatic patients in the hospital because they still had positive RT-PCR results which again contributed to the congestion of hospitals. Many patients exceeded 14 days of hospitalization because of this. Another problem was the mental state of these patients, who, although they felt well, had to remain hospitalized and away from their families. Both circumstances could potentially lead to depression. The first study in this direction occurred at IRCCS San Raffaele Hospital in Milan on 402 patients surviving COVID-19, in October 2020. They reported high rates of PTSD, depression, anxiety, insomnia, and obsessive-compulsive symptomatology<sup>17</sup>. A study on changes in mental health during the COVID-19 crisis was conducted in Romania. Data collection was carried out between May 9 - May 15, 2020 (first survey) and November 8 - November 14, 2020 (second survey). Approximately one in five respondents (1st survey = 19.2% and 2nd survey = 17.8%) had moderate to severe levels of depressive symptoms<sup>18</sup>.

The solution related to the hospitalization of asymptomatic patients and patients with mild symptoms was found once the triage was implemented at the hospitalization stage. Patients could go home upon request, even if they did not have a negative result, provided they were isolated for up to 14 days after the first positive test. Nowadays only one negative RT-PCR test is required for discharge. These

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<sup>15</sup> “Ordin privind modificarea și completarea Ordinului ministrului sănătății nr. 1.513/2020” [Order on amending and supplementing the Order of the Minister of Health no. 1,513 / 2020] available online at [www.ms.ro/2020/10/28/ordin-privind-modificarea-si-completarea-ordinului-ministrului-sanatatii-nr-1-513-2020/](http://www.ms.ro/2020/10/28/ordin-privind-modificarea-si-completarea-ordinului-ministrului-sanatatii-nr-1-513-2020/) (accessed June 23, 2022).

<sup>16</sup> “Modificarea criteriilor de externare pentru pacienții cu afecțiunea COVID-19” (June 23, 2020) [Modification of discharge criteria for patients with COVID-19] <https://www.ms.ro/2020/06/23/modificarea-criteriilor-de-externare-pentru-pacientii-cu-afectiunea-covid-19/> (accessed June 20, 2022).

<sup>17</sup> Mazza M. G., De Lorenzo R., Conte C., Poletti S., Vai B., Bollettini I., Melloni E., Furlan R., Ciceri F., Rovere-Querini P., “COVID-19 BioB Outpatient Clinic Study group, & Benedetti, F. (2020). Anxiety and depression in COVID-19 survivors: Role of inflammatory and clinical predictors. *Brain, behavior, and immunity*”, 89 (2020), 594–600.

<sup>18</sup> Vancea F., Apostol MȘ., “Changes in mental health during the COVID-19 crisis in Romania: A repeated cross-section study based on the measurement of subjective perceptions and experiences”. *Sci Prog.* 2021 Apr-Jun; 104.

solutions are much more ethical as they do not force patients to stay hospitalized if they do not need to, as discussed in the previous chapter. Given the pandemic, the decision to hospitalize all cases during the emergency situation did not necessarily violate ethical principles. The central subject of medical ethics remains the fundamental duty to always act in the interest of the patient. During the pandemic, regulations appeared that limited the rights of patients, such as quarantine, mandatory isolation, or limiting the access of chronic patients to hospitals. Non-voluntary hospitalization and compulsory treatment are regulated in psychiatry, but these provisions can be extended to other medical fields, especially in the case of danger to others or oneself<sup>19</sup>.

#### IV. Hospital departments going through rapid and necessary reorganization

The outbreak of the pandemic has led to numerous organizational problems in all hospital departments. Like other European countries, Romania faced ward reorganization, which meant postponing or reducing other scheduled activities. The Ministry of Internal Affairs has approved the issuance of the order for establishing the necessary measures to limit the spread of SARS-COV-2 infection in public and private health units, such as planned surgeries, scheduled outpatient consultations, and discharge within 48 hours of cases that are no longer urgent, in favor of receiving and treating COVID-19 patients<sup>20</sup>.

The medical staff had to adapt as soon as possible to last-minute organizational changes on top of handling a new and potentially lethal pathology. Every effort was made to increase the number of beds in red areas and in intensive care units (ICU) to the point of creating mobile intensive care units<sup>21</sup>.

In order to cope with the demand for more beds, resources and medical staff, several departments were transformed and dedicated to the SARS-COV-2 pathology and named red zones. Infectious Diseases departments were the first to be completely converted to red zones; this means that only SARS-COV-2 patients are admitted and treated in this unit<sup>22</sup>. In the city of Arad, within the County Emergency

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<sup>19</sup> “Internarea nevoluntară, Lege 487/2002” [Involuntary hospitalization, Law 487/2002] available at: <https://lege5.ro/gratuit/gmzdzqnbxge/internarea-nevoluntara-lege-487-2002?dp=gyzdknrsga3tg> (accessed June 23, 2022).

<sup>20</sup> Blot F., Dumont S.N., Vigouret-Viant L., et al, “Ethical issues related to the COVID-19 pandemic in patients with cancer: experience and organisations in a French comprehensive cancer centre,” *BMJ Supportive & Palliative Care* (August 27, 2020).

<sup>21</sup> “Ministerul Afacerilor Interne, Informare 23.03.2020” [Ministry of Internal Affairs, Information 23.03.2020] available online at: [www.cnpromania.ro/upload/blog/informare\\_suspendare\\_intern\\_ari.pdf](http://www.cnpromania.ro/upload/blog/informare_suspendare_intern_ari.pdf) (accessed June 21, 2022).

<sup>22</sup> “Prima unitate mobilă de terapie intensivă, achiziționată la inițiativa fundației pentru smurd, cu sprijinul lidl românia” [The first mobile intensive care unit, purchased at the initiative of the smurd foundation, with the support of lidl romania] available online at: <https://ambasadasustenabilitatii.ro/prima-unitate-mobila-de-terapie-intensiva-achizitionata-la-initiativa-fundatiei-pentru-smurd-cu-sprijnul-lidl-romania/> (accessed June 24, 2022).

<sup>23</sup> “Ministerul Sănătății, Ordin 533/29.03.2020 pentru aprobarea Planului de măsuri de pregătire a spitalelor în contextul epidemiei de Coronavirus COVID-19 și a Listei spitalelor de sprijin pentru pacienții testați pozitiv cu SARS-COV-2 virus” [Ministry of Health, Order 533 / 29.03.2020 for the approval of the Plan of measures for the preparation of hospitals in the context of the COVID-19



Clinical Hospital, the transformed departments were: Adult Infectious Diseases, Children Infectious Diseases, ICU 4, ICU 2, Tuberculosis department, Pneumology, Urology, Internal Medicine 2, Physical Recovery and Balneology, Occupational Medicine, Orthopedics and General Surgery 2. Such changes were made in other cities from Arad county, such as Ineu, Lipova, and Sebiş, but the departments could not be completely transformed due to the fact that there is only one hospital per city and there was a need for beds in order to treat patients with negative tests but who needed hospitalization<sup>23</sup>.

During this time, the spread of the infection among the medical staff increased; this aspect led to the complete closure of some departments, and the patients were either transferred to the same hospital or to other medical units. The rapid spread among hospital employees and patients resulted in the quarantine of entire hospitals and even cities. A tragic example of such a scenario took place at Suceava County Hospital, in northeastern Romania<sup>24</sup>. There, improper management, lack of protocols and inadequate protective equipment led to an explosion of COVID-19 cases. In addition, the hospital management tried to hide the irregularities and not report initial cases among medical staff. Unfortunately, patients with critical illnesses have been infected and many of them have died from complications associated with COVID-19<sup>25</sup>.

Considering all these problems, the aim was to transform the departments that were best suited for taking care of infected patients. The main goal was providing as many oxygen sources as possible; having enough space and resources to build a safe circuit and reduce the risk of transmission, and facilitating access to investigations such as CT and chest x-rays were all factors taken into account. Arad County's

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Coronavirus epidemic and of the List of support hospitals for patients tested positive with SARS-COV-2 virus] available online at: [https://scjucluj.ro/pdf/covid19/OMS533\\_Ordin\\_spitale\\_suport\\_pdf.pdf](https://scjucluj.ro/pdf/covid19/OMS533_Ordin_spitale_suport_pdf.pdf) (accessed June 22, 2022).

<sup>23</sup> "Planul de reziliență al județului Arad față de recrudescența COVID-19, completat în 28.06.2021" [The resilience plan of Arad county against the recrudescence of COVID-19, completed on 28.06.2021] available online at: [www.dsparad.ro/include/noutati/Plan\\_rezilienta\\_judet\\_ARAD\\_2021.pdf](http://www.dsparad.ro/include/noutati/Plan_rezilienta_judet_ARAD_2021.pdf) (accessed June 23, 2022).

"Arad: Spitalul județean a dublat numărul paturilor pentru bolnavii de COVID-19, 26.08.2021" [Arad: The county hospital doubled the number of beds for patients with COVID-19, 26.08.2021] available online at: <https://www.agerpres.ro/sanatate/2021/08/26/arad-spitalul-judetean-a-dublat-numarul-paturilor-pentru-bolnavii-de-covid-19--769278> (accessed June 23, 2022).

"Ministerul sănătății, direcția de sănătate publică a județului Arad, planul de reziliență al județului Arad față de recrudescența COVID-19, 02.12.2021" [Ministry of Health, Public Health Directorate of Arad County, resilience plan of Arad County against the resurgence of COVID-19, 02.12.2021] available online at: [www.dsparad.ro/include/noutati/Plan\\_rezilienta\\_judet\\_ARAD\\_actualizat\\_02\\_12\\_21\\_B.pdf](http://www.dsparad.ro/include/noutati/Plan_rezilienta_judet_ARAD_actualizat_02_12_21_B.pdf) (accessed June 23, 2022).

<sup>24</sup> Mutler A., "Romania's "Lombardy": How A Small Romanian Region Got So Badly Infected By the Coronavirus. Radio Free Europe; (2020)", available online at: <https://www.rferl.org/a/romania-s-lombardy-how-a-small-romanian-region-got-so-badly-infected-by-the-coronavirus/30520630.html> (accessed June 24, 2022).

<sup>25</sup> Dascalu S., "The Successes and Failures of the Initial COVID-19 Pandemic Response in Romania. Front Public Health." 2020 Jul 10;8:344.

resilience plan for COVID-19 recrudescence and the reorganization criteria were implemented by the Ministry of Health and Arad County Public Health Directorate<sup>26</sup>.

Surgical wards were among the converted wards, the patients being cared for by teams of surgeons under the supervision of an infectionist or pulmonologist. Not only did the surgeons leave the operating rooms during this time but many anesthesiologists also joined the resuscitation and intensive care teams in red areas. This was a similar situation to what was going on in countries such as France<sup>27</sup>.

With the increasing conversion of the wards, there were other shortcomings for non-COVID patients who needed hospitalization for urological, orthopedic, pulmonary, or other infectious problems. Another aspect was the postponement of the treatment of chronic diseases. Patients with non-COVID infectious pathologies who had to be hospitalized posed one of the biggest logistical and ethical challenges. Because the infectious disease departments were entirely dedicated to the SARS-COV-2 pathology, such patients were admitted to departments like internal medicine or gastroenterology. Therefore, pathologies such as *Clostridium Difficile* infection, enterocolitis, acute hepatitis, together with other acute pathologies in the infectious sphere, have come to be treated mostly by gastroenterologists and internal medicine doctors.

The wards that took over these patients had to be reorganized, as they needed isolation rooms and separate circuits for contagious patients in order to prevent the transmission of infections to other hospitalized patients<sup>28</sup>.

While this was a necessary compromise regarding non-COVID patients, other compromises that had to be made are debatable. Many COVID-19-positive patients had multiple pathologies, and the provision of a specialized consultation and treatment was problematic for those with cardiological pathology, diabetes, obesity, cancer, and other chronic illnesses due to their isolation in the red zone. We tried to perform all specialized consultations of positive patients in the emergency unit as much as possible, before hospitalizing them in a red area, so that patients were covered for both acute pathology and decompensation of chronic diseases.

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<sup>26</sup> “Ministerul sănătății, direcția de sănătate publică a județului Arad, planul de reziliență al județului Arad față de recrudescența COVID-19, 02.12.2021” [Ministry of Health, Public Health Directorate of Arad County, resilience plan of Arad County against the resurgence of COVID-19, 02.12.2021 ] available online at: [www.dsparad.ro/include/noutati/Plan\\_rezilienta\\_judet\\_ARAD\\_actualizat\\_02\\_12\\_21\\_B.pdf](http://www.dsparad.ro/include/noutati/Plan_rezilienta_judet_ARAD_actualizat_02_12_21_B.pdf) (accessed June 23, 2022).

<sup>27</sup> National Advisory Committee on Ethics, “Covid-19- Contribution du comité consultatif national d'éthique: enjeux éthiques face une pandémie,” (2020), <https://www.ccne-ethique.fr/fr/publications/la-contribution-du-ccne-la-lutte-contre-covid-19-enjeux-ethiques-face-une-pandemie> (accessed August 17, 2021).

<sup>28</sup> “Ordinul nr. 555/2020 privind aprobarea Planului de măsuri pentru pregătirea spitalelor în contextul epidemiei de coronavirus COVID19” [Order no. 555/2020 on the approval of the Plan of measures for the preparation of hospitals in the context of the coronavirus epidemic COVID19] available online at: <https://www.cnsct.ro/index.php/lex/1753-ordinul-nr-555-2020-privind- aprobarea-planului-de-masuri-pentru-pregatirea-spitalelor-in-contextul-epidemiei-de-coronavirus-covid-19-a-listei-spitalelor-care-asigura-asistenta-medicala-pacientilor-tes/file> (accessed June 21, 2022).

Communication was ongoing between departments, and telemedicine was adopted as well, a method that worked for countries such as Italy<sup>29</sup>. After obtaining negative SARS-CoV-2 results, the patients were transferred to specialized departments to complete the treatment and the delayed investigations. During the state of emergency, telemedicine was also adopted by family doctors and specialists from the outpatient clinic. The latter provided distance consultations with a maximum of 8 consultations per hour, as provided by the government. Compensated prescriptions were also prescribed for patients with chronic treatment and sent online to pharmacies, from where the medication was released to patients, without them having to expose themselves to the hospital environment. This method did not work for everyone because there were many elderly patients who could not cope with the technology or did not have the necessary electronic equipment. Others did not trust the way the consultations were conducted or had technical problems during the conversations. We also lacked a digital infrastructure to ensure secure connections between patients and doctors<sup>30</sup>.

Another challenging category of patients were those admitted to the ER with a different acute pathology, but were found positive for COVID-19 as well. The reason why these cases were more difficult to manage was primarily the need for admission to specialized departments such as interventional cardiology, gastroenterology, neurology or general surgery. Emergency consultations by specialists had to be performed with complete protective equipment, which made it difficult to consult, gain trust and collect biological samples by nurses. It was also an extra effort for the surgical team in case they had to operate these patients urgently.

Action was taken depending on the severity of the pathology. For patients with acute myocardial infarction, upper gastrointestinal bleeding, stroke or those in need of emergency surgery, two isolation chambers were prepared, one for women and one for men in the aforementioned sections and were also called red zones. Here, patients could be hospitalized and monitored until stabilization and treated for acute pathology. Due to these changes in the wards, the medical staff had to be very careful when equipping and unequipping the protective equipment when entering the red zones and respecting the circuits to avoid becoming contaminated and not to risk spreading the virus to other patients hospitalized there. At the same time, positive patients had to be clearly told and carefully supervised by the medical staff not to

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<sup>29</sup> Nardini S., Sanguinetti C.M., De Benedetto F., et al, "SARS-CoV-2 pandemic in Italy: ethical and organizational considerations," *Multidisciplinary Respiratory Medicine* vol. 15 (May 25, 2020): 672.

<sup>30</sup> "Telemedicina, un instrument vital în combaterea pandemiei COVID-19. Care sunt soluțiile implementate în România?" [Telemedicine, a vital tool in combating the COVID-19 pandemic. What are the solutions implemented in Romania?] Available online at: <https://raportuldegarda.ro/telemedicina-instrument-vital-combatere-pandemie-implementare-romania/> (accessed June 25, 2022).

"Hotărâre privind stabilirea unor măsuri în domeniul sanatații pe perioada instituirii stării de urgență pe teritoriul României" [Decision on the establishment of measures in the field of health during the establishment of the state of emergency on the territory of Romania] available online at: <https://rgmedia.raportuldegarda.ro/HG-49.pdf> (accessed June 25, 2022).

"Ordonanță de urgență nr. 196 din 18 noiembrie 2020" [Emergency ordinance no. 196 of 18 November 2020] available online at: <https://legislatie.just.ro/Public/DetaliuDocumentAfis/233458> (accessed June 26, 2022).

leave the isolation rooms and spread the infection within the ward. After the stabilization and remission of acute problems, patients were transferred to the SARS-COV-2 department to be treated for COVID-19. The advantage is that in this department, they can be treated with specific medication for COVID-19, and the disadvantage is that they can no longer be monitored directly by doctors in other specialties, and investigations such as angiography, cardiac ultrasound, and digestive endoscopy are very difficult to perform. Thus, this category of patients cannot be fully monitored and investigated<sup>31</sup>.

## V. Vaccination - still unpopular among Romanian medical staff

Coming in daily contact with a large number of patients, medical staff is at high risk of contacting the virus and can be significant vectors for the infection. Despite the fact that we have several vaccine variants against the SARS-COV-2 virus in Romania (AstraZeneca/Vaxzevria, Pfizer/Comirnaty, Moderna/Spikevax, J&J/Janssen), we still face a large number of unvaccinated staff in hospitals<sup>32</sup> just as we face a large number of nosocomial infections such as *Clostridium difficile* colitis, bloodstream infections, catheter-associated urinary tract infections, ventilator-associated pneumonia, hospital acquired pneumonia, in spite of countless efforts to reduce them<sup>33</sup>.

At the time of writing this article, August 2021, 59.48% of the medical staff in contact with patients in public health facilities has been vaccinated against COVID-19 - 58.08% with both doses and 1.4% with the first dose only. 1.79% did not declare vaccine status. This data was collected by public health directorates at national level at the end of July 2021. By professional functions, the highest rate is registered among doctors (71.36%) and the lowest among auxiliary health personnel (52.8%)<sup>34</sup>.

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<sup>31</sup> "Protocolul de gestionare a pacientului În institutul inimii "niculae stăncioiu" cluj napoca, în contextul epidemiei cu covid-19, versiunea 1 din 23.03. 2020" [Patient management protocol in the heart institute "niculae stăncioiu" cluj napoca, in the context of the covid-19 epidemic, version 1 of 23.03. 2020] available online at: [http://institutulinimii.ro/fileadmin/user\\_upload/Protocoale/Protocol\\_COVID19\\_ver1\\_small.pdf](http://institutulinimii.ro/fileadmin/user_upload/Protocoale/Protocol_COVID19_ver1_small.pdf) (accessed June 25, 2022).

"Ministerul sănătății, direcția de sănătate publică a județului Arad, planul de reziliență al județului Arad față de recrudescența COVID-19, 02.12.2021" [Ministry of Health, Public Health Directorate of Arad County, resilience plan of Arad County against the resurgence of COVID-19, 02.12.2021 ] available online at: [www.dsparad.ro/include/noutati/Plan\\_rezilienta\\_judet\\_ARAD\\_actualizat\\_02\\_12\\_21\\_B.pdf](http://www.dsparad.ro/include/noutati/Plan_rezilienta_judet_ARAD_actualizat_02_12_21_B.pdf) (accessed June 23, 2022).

<sup>32</sup> Manolescu L., Zaharia C., Dumitrescu A., Prasacu I., Radu M., Boeru A., Boidache L., Nita I., Neculescu A., Chivu R., "Early COVID-19 Vaccination of Romanian Medical and Social Personnel" , 2021, *Vaccines* 9, no. 10: 1127.

<sup>33</sup> Marincu, I.; Bratosin, F.; Vidican, I.; Cerbu, B.; Turaiche, M.; Tirnea, L.; Timircan, M., "Predictive Factors for the First Recurrence of *Clostridioides difficile* Infection in the Elderly from Western Romania. ", *Medicina* 2020, 56, 439.

Szabó S., Feier B., Capatina D., Tertis M., Cristea C., Popa A., " An Overview of Healthcare Associated Infections and Their Detection Methods Caused by Pathogen Bacteria in Romania and Europe.", *J Clin Med.* 2022 Jun 4;11(11):3204.

<sup>34</sup> "Sanitas: Vaccinarea obligatorie pentru personalul medical din România nu se justifică" (August 9, 2021) [Sanitas: Compulsory vaccination for medical staff in Romania is not justified] available online at: <https://www.digi24.ro/stiri/actualitate/sanitas-vaccinarea-obligatorie-pentru-personalul-medical-din-romania-nu-se-justifica-1627989> (accessed August 12, 2021).

Some medical staff refuse the vaccine because they still consider it new and made much too quickly compared to other vaccines. Others believe that not enough tests have been done. Most attribute their reluctance to fears about possible side effects. On August 31, 2021, the Romanian Ministry of Health reported a total of 17,010 post-vaccination side effects, of which 1,810 were local and 15,200 were general (Pfizer=8,430; Moderna=2,021; AstraZeneca=6,147; Johnson&Johnson=412)<sup>35</sup>. Some severe side effects have occurred among those vaccinated, such as anaphylactic shock and thrombocytopenic events, but despite these reactions, the Food and Drug Administration (FDA) considers the benefits of vaccination to outweigh the risks<sup>36</sup>.

The eradication of past diseases, such as Polio in 1979, with the development of a vaccine in 1955, and Smallpox in 1977, also due to vaccination<sup>37</sup>, has shown us that vaccines are widely considered a symbol of success in human history. It is also true that vaccination has had side effects in the past. According to the Institute of Medicine, epidemiologic and mechanistic evidence reveals a connection between anaphylaxis and several vaccines: Measles, Mumps and Rubella (MMR), Chickenpox, Influenza, Hepatitis B, Meningococcus, Human Papillomavirus, Combined Diphtheria vaccine, Tetanus, Pertussis (DTaP or Tdap)<sup>38</sup>. Past errors have led to greater caution in approving vaccines<sup>39</sup>. However, Pfizer BioNTech BNT162b2 was the first vaccine to receive temporary authorization by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the U.K. and emergency use authorization (EUA) by the U.S. FDA. EUA can facilitate the accessibility of vaccines in emergency situations, and with their consent the FDA can use unapproved medical products, including vaccines, in life-threatening situations, meeting certain criteria. The other types of COVID-19 vaccine were soon approved under the same circumstances. To produce such a vaccine, a balance should be maintained between the immediate need for rapid vaccine research and the inherent need to protect research subjects, which is the main concern of research ethics.

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Manolescu L., Zaharia C., Dumitrescu A., Prasacu I., Radu M., Boeru A., Boidache L., Nita I., Neculescu A., Chivu R., “Early COVID-19 Vaccination of Romanian Medical and Social Personnel” , 2021, *Vaccines* 9, no. 10: 1127.

<sup>35</sup> “Actualizare zilnică (31/08) – evidența persoanelor vaccinate împotriva COVID-19” [Daily update (31/08) - records of people vaccinated against COVID-19] available online at: <https://vaccinare-covid.gov.ro/actualizare-zilnica-31-08-evidenta-persoanelor-vaccinate-impotriva-covid-19/> (accessed June 25, 2022).

<sup>36</sup> Lee E., Cines D.B., Gernsheimer T., Kessler C., Michel M., Tarantino M.D., Semple J.W., Arnold D.M., Godeau B., Lambert M.P., et al., “Thrombocytopenia following Pfizer and Moderna SARS-CoV-2 vaccination,” *Am. J. Hematol.* (2021),96:534–537.

<sup>37</sup> “History of Vaccines” <https://historyofvaccines.org/vaccines-101/what-do-vaccines-do/disease-eradication> (accessed June 25, 2022).

<sup>38</sup> Sampath V., Rabinowitz G., Shah M., Jain S., Diamant Z., Jesenak M., Rabin R., Vieths S., Agache I., Akdis M., Barber D., Breiteneder H., Chinthrajah S., Chivato T., Collins W., Eiwegger T., Fast K., Fokkens W., O’Hehir R.E., Ollert M., O’Mahony L., Palomares O., Pfaar O., Riggioni C., Shamji M.H., Sokolowska M., Jose Torres M., Traidl-Hoffmann C., van Zelm M., Wang Y., Zhang L., Akdis C.A., Nadeau K.C., “Vaccines and allergic reactions: The past, the current COVID-19 pandemic, and future perspectives.” *Allergy*. 2021 Jun;76(6):1640-1660.

<sup>39</sup> Helfert S.M., “Historical aspects of immunization and vaccine safety communication,” *Curr. Drug Saf.* (2015), 10:5–8.

After Romania acquired the vaccine, the medical staff was the first category to benefit from vaccination in the country. The Ministry of Health published, on September 27, 2021, in decisional transparency, a draft law on establishing measures in the health field. According to the document, staff in public and private health facilities are required to present an EU COVID-19 digital certificate in order to carry out their activities. The certificate must certify that one of the following conditions is met: vaccination against the SARS-COV-2 virus and for which ten days have elapsed since the completion of the complete scheme; is in the period between the 15th and 180th day after confirmation of SARS-COV-2 virus infection; certified negative result of an RT-PCR test or a rapid antigen test. If the medical staff does not present the EU COVID-19 digital certificate, the legal suspension of the contracts on the basis of which they carry out their activity shall be regulated for a period of 30 days<sup>40</sup>.

Even after the publication of the draft law, most of the medical staff chose periodic testing instead of vaccination. This was a negative example for the general population, which could be influenced by the decisions of those working in the medical system. The professional responsibility of the medical staff was to encourage vaccination and to set an example to society in trying to combat the pandemic.

Moreover, there were doctors in Romania who promoted anti-vaccination campaigns and frequently posted anti-vaccine messages on social networks. These situations have appeared before in Romania, on May 27, 2021, 116 doctors signed a letter against the law of mandatory vaccines<sup>41</sup> (vaccination against Hepatitis B, Tuberculosis, anti-Diphtheria, Tetanus, Pertussis, Polio, Influenzae B, Measles, Rubella, Mumps)<sup>42</sup> claiming that vaccines contain toxic adjuvants such as aluminum hydroxide and mercury compounds and claimed to violate human rights.

In the case of the SARS-COV-2 pandemic, the urgent need for a vaccine was evident, as it has by far exceeded the H1N1 influenza virus, as well as the SARS and MERS coronaviruses in terms of the total number of cases and deaths worldwide<sup>43</sup>. We must indeed balance individual risks and the common good, but given the

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<sup>40</sup> "Certificatul COVID va fi obligatoriu pentru personalul medical. Cei care refuză vaccinarea sau testarea vor avea contractul suspendat" (September 27, 2021) [The COVID certificate will be mandatory for medical staff. Those who refuse vaccination or testing will have their contract suspended] available online at: <https://www.digi24.ro/stiri/actualitate/sanatate/certificatul-covid-va-fi-obligatoriu-pentru-personalul-medical-cei-care-refuza-vaccinarea-sau-testarea-vor-avea-contractul-suspendat-1682197> (accessed June 26, 2022).

<sup>41</sup> "Cine sunt și ce vor medicii din România care au semnat o scrisoare împotriva legii vaccinării?" [Who are and what do the doctors in Romania who signed a letter against the vaccination law want?] available online at: <https://pressone.ro/cine-sunt-si-ce-vor-medicii-din-romania-care-au-semnat-o-scrisoare-impotriva-legii-vaccinarii> (accessed June 26, 2022). <https://images.pressone.ro/wp-content/uploads/2020/05/27191819/Medici-Impotriva-Obligativitatii-Vaccinarii-2.pdf> (accessed June 26, 2022).

<sup>42</sup> "Schema vaccinurilor obligatorii si gratuite in Romania" [Scheme of compulsory and free vaccines in Romania] available online at: [www.romeurope.org/IMG/pdf/Schema\\_20vaccinurilor\\_20obligatorii\\_20si\\_20gratuite\\_20in\\_20ROMANIA.pdf](http://www.romeurope.org/IMG/pdf/Schema_20vaccinurilor_20obligatorii_20si_20gratuite_20in_20ROMANIA.pdf) (accessed June 26, 2022).

<sup>43</sup> Abdelrahman Z., Li M., Wang X., "Comparative Review of SARS-CoV-2, SARS-CoV, MERS-CoV, and Influenza A Respiratory Viruses," *Front. Immunol.* (2020):11.

situation caused by the pandemic and the urgent need for a vaccine, the benefits outweighed the risks.

## VI. Conclusions

The SARS-COV-2 pandemic has taught us how to cooperate better within the hospital, at a national and global level.

The first important lesson would be to ask ourselves how to handle such a situation as the COVID-19 pandemic with minimal harm and maximum benefit so that we can make the best decisions. Another observation is that theory is always different from real life. Despite being an unpleasant measure, isolation has helped considerably in limiting the transmission of the infection. On April 17, 2020, the number of cases increased to 396 per day, and on May 4, 2020, the number of cases began lowering to 315 per day<sup>44</sup>. However, we must also consider those people and families who need help to remain isolated.

At a hospital organization level, the best case management option proved to be a prior assessment of cases by the family doctor who decided if a more complex evaluation is necessary at the hospital. After each patient underwent the necessary test, it was decided whether to discharge them with 14 days of isolation, or hospitalize them, the latter being applicable only to those who needed it, so that hospitals would not become overcrowded. The Minister of Health approved Order no. 1,513/2020 which specified that all patients detected on RT-PCR testing with a positive result for SARS-COV-2 have the obligation to contact and inform the family doctor. Patients were classified in one of the following categories: asymptomatic or mildly symptomatic who do not require hospitalization; symptomatic patients with risk factors, who, on the recommendation of the family doctor, will be taken to the hospital by ambulance and evaluated clinically; symptomatic patients with moderate or severe forms will be hospitalized with their consent<sup>45</sup>.

Another lesson was that hospital departments should be adaptable, because it is not known which unit could be transformed into a red zone when needed. Also, hospitals that do not have well-defined circuits in terms of the hospitalization of COVID-19 and non-COVID patients, should be reorganized in advance in order to be prepared for unforeseen situations. These circuits are designed to separate the red area from the green area, the uncontaminated area so that each of them has a separate entrance. This prevents the positive patient from reaching the space where the medical staff carries out their activity when they are not in the red zone and are not equipped with complete equipment.

The low vaccination rate among medical staff and the anti-vaccination propaganda made by some doctors have influenced the population not to get vaccinated, instead of setting an example of civic responsibility and helping to limit

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<sup>44</sup> Worldometer, available online at: <https://www.worldometers.info/coronavirus/country/romania/> (accessed June 25, 2022).

<sup>45</sup> "Ordin privind modificarea și completarea Ordinului ministrului sănătății nr. 1.513 / 2020" [Order on amending and supplementing the Order of the Minister of Health no. 1,513 / 2020] available online at: <https://www.ms.ro/2020/10/28/ordin-privind-modificarea-si-completarea-ordinului-ministrului-sanatatii-nr-1-513-2020/> (accessed June 23, 2022).

the spread of the infection. Vaccination of a higher percentage of medical staff, which has no contraindications in this regard, would be necessary. For those over 180 days from the date of the first positive test who refuse the vaccine and for those with a contraindication to the vaccine, periodic testing should continue to be implemented. Those who do not respect any of these aspects face the legal suspension, for a period of 30 days, of the contracts on the basis of which they carry out their activity. After 30 days of suspension, the employer may order either the extension of the suspension or the termination of the employment contract<sup>46</sup>.

Contact with possible positive patients most often takes place in the hospital. Hundreds of people come in every day, and medical staff are exposed for long periods of time to the risk of contracting the infection. This situation works in both directions; the medical staff may risk the transmission of the virus if they are not vaccinated or if they do not comply with the hospital regulations regarding the criteria by which they can carry out their activity. Vaccination is ultimately a collective responsibility. This action should be a moral responsibility that the community should develop in favor of its own well-being and in the event of similar future situations.

Therefore, the COVID-19 pandemic brought to the surface the problems in the Romanian Health System, such as lack of equipment; lack of beds; congestion of departments; small funds allocated to the Sanitary System; the need to close some departments due to the appearance of outbreaks, or transform others in red zones; the constant modification of the admission and discharge criteria and the non-vaccination of the medical staff. These issues should draw attention to the attempt to address them ethically, morally, and economically in terms of medical resources, organization, and in terms of protocols.

Although some rights were restricted, the goal was collective welfare, and the measures implemented were designed to essentially protect the population.

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<sup>46</sup> “Certificatul COVID va fi obligatoriu pentru personalul medical. Cei care refuză vaccinarea sau testarea vor avea contractul suspendat” (September 27, 2021) [The COVID certificate will be mandatory for medical staff. Those who refuse vaccination or testing will have their contract suspended] available online at: <https://www.digi24.ro/stiri/actualitate/sanatate/certificatul-covid-va-fi-obligatoriu-pentru-personalul-medical-cei-care-refuza-vaccinarea-sau-testarea-vor-avea-contractul-suspendat-1682197> (accessed June 26, 2022).



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# AN ETHICAL AND SPIRITUAL APPROACH TO TERMINALLY ILL PATIENTS: AN ILLUMINATED PATH THROUGH THE COVID-19 DARKNESS

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## **Abstract**

Caring for terminally ill patients is one of the most important challenges of the 21st century. The COVID-19 pandemic is an individual and collective traumatic event, directly or indirectly affecting every individual worldwide. This crisis has brought a tsunami of suffering, devastating even well-resourced countries. End-of-life care is guided by the same ethical principles that inform other types of medical care. Management of chronic critically ill patients and alleviation of suffering in all its forms is an emerging challenge for today's healthcare systems and needs to be a crucial part of their response.

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## I. Introduction

“Crucial ethical issues are involved not just in the great questions of life and death, but also in those clinical decisions that, at first sight, appear to be the simplest and most straightforward.”<sup>1</sup>

Caring for terminally ill patients is one of the most important challenges of the 21st century.<sup>2</sup> In developed countries, the geriatric population is growing at an unprecedented rate.<sup>2,3</sup> Many studies have documented the increased prevalence of chronic medical conditions and lower physiologic reserve in the elderly compared to their younger counterparts.<sup>2</sup> Multimorbidity is the presence of two or more chronic diseases and is common in the elderly, with a prevalence of 40 to 80 percent.<sup>2,4</sup> It has a substantial impact on mental health, quality of life, and overall health outcomes and is associated with a significant increase in mortality.<sup>2</sup> Disability in the elderly may have an even greater impact on mortality than multimorbidity.<sup>2,4</sup> This population comprises an increasing proportion of the patients admitted to intensive care units (ICUs), and the mortality rate for these patients is high. Equally important is the significantly decreased physical function and overall health of ICU survivors.<sup>2</sup> Most persons will eventually become elderly, and the medical community must focus its efforts not only on improving the life expectancy of its patients, but also on improving the quality of life and care, especially for those in the later decades of life.<sup>2</sup>

Management of chronic critical illness (CCI) patients is an emerging challenge for today’s healthcare systems.<sup>4-5,6</sup> Despite the significant burden on the healthcare system afforded by CCI, more guideline-based recommendations regarding the management of this patient cohort need to be made.<sup>6</sup> One of the major obstacles remains the early identification of patients who meet the definition of CCI.<sup>4,6</sup> There can also be various venues where these patients receive care, including ICUs, step-down units, weaning units, and floors in acute care hospitals, as well as specialized centers, such as long-term acute care hospitals (LTACHs).<sup>6</sup> Variation in care is affected not only by the venue, but also by the staffing ratios.<sup>6,7</sup> Ideally, the composition of a care team should be multidisciplinary, including physicians, nurses,

<sup>1</sup> Truog RD, Brown SD, Browning D, Hundert EM, Rider EA, Bell SK, et al., “Microethics: the ethics of everyday clinical practice,” *Hast Cent Rep* 2015;45(1): 11-17.

<sup>2</sup> Oliveira K and Maerz LL., “Epidemiology of critical illness in the elderly,” in: *Principles of Geriatric Critical Care*, eds. Akhtar S and Rosenbaum S. (Cambridge: Cambridge University Press, 2018), 1-8.

<sup>3</sup> Vučević D, Pantić I, Samardžić J, Jorgačević B, Paunović Pantić J, Radosavljević T. “Ethical Issues and Spiritual Challenges in End-Of-Life Care,” in: *Heading Towards Humans Again: Aspects of Bioethics in the New Age of Science*, ed. Radenković M. Available online at <http://trivent-publishing.eu>. doi: 10.22618/TP.AEBIO.20214.231011

<sup>4</sup> Curtis JR, Vincent JL. “Ethics and end-of-life care for adults in the intensive care unit,” *Lancet* 375 (2010):1347-53.

<sup>5</sup> Speers P, Walker T., *The inspired caregiver: finding joy while caring for those you love* (Charlston, NC: Create Space Independent Publishing Platform, 2015).

<sup>6</sup> Bardia A, Akhtar S., “Chronic critical illness in geriatric patients,” in: *Principles of Geriatric Critical Care*, eds. Akhtar S and Rosenbaum S. (Cambridge: Cambridge University Press, 2018), 11-27.

<sup>7</sup> Allen SR, Kaplan LJ., “Geriatric critical care units: Model for interdisciplinary approach,” in: *Principles of Geriatric Critical Care*, eds. Akhtar S and Rosenbaum S. (Cambridge: Cambridge University Press, 2018), 210-222.

respiratory therapists, physical therapists, speech and language specialists, and nutritionists who continue to deliver critical care like most ICUs.<sup>7</sup>

## II. Palliative care as the key response to the COVID-19 tsunami of suffering

Since the World Health Organization (WHO) declared the coronavirus disease 2019 (COVID-19) pandemic on 11 March 2020, the world lives in a redefining scenario where one acute disease brought disruption in several aspects of society, such as health (physical and mental), economy, social security, environment, among others.<sup>8</sup> COVID-19 is an individual and collective traumatic event, directly or indirectly affecting every individual worldwide.<sup>9</sup> All efforts should be directed toward minimizing the negative effects of this traumatic pandemic event on survivors.<sup>9,10</sup> Vulnerable populations, such as children, older adults, pregnant women, people with existing physical and mental illnesses, victims of abuse and violence, those living with abusers and perpetrators, people living below the poverty line and other individuals are susceptible to not just contracting the coronavirus, but the psychological trauma as well.<sup>9</sup> Thus, many people are going through interpersonal traumatic events as well in addition to the collective traumatic experience of COVID-19, such as domestic violence (gender-based violence), abuse, financial burden, loneliness, emotional and behavioral problems, grief and bereavement, fear of losing family, mental health issues, and physical injuries or fatalities.<sup>9,10,11</sup> Importantly, older adults and people with severe comorbidities are particularly vulnerable to worse outcomes from COVID-19.<sup>9</sup>

The COVID-19 pandemic also contributes to psychological distress due to the stigma of the illness.<sup>12</sup> In such context, Wafaa, an Egyptian nurse who recovered from COVID-19 disease, described the society's view of her after she left quarantine. Wafaa said:

“Our hospital was receiving suspicious cases; the positive ones were taken to quarantine, the negative ones were sent home, and my result came out after three days. Doctors took blood samples from me and discovered that my case was positive. I entered a quarantine for ten days, and with treatment, my case turned negative. I did not suffer from any

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<sup>8</sup> Prazeres F, Passos L, Simoes JA, Martins C, Teixeira A., “COVID-19-related fear and anxiety: spiritual-religious coping in healthcare workers in Portugal,” *Int J Environ Res Public Health* 18 (2021):220 doi:10.3390/ijerph18010220.

<sup>9</sup> Mukhtar S., “Psychological health during the coronavirus disease 2019 pandemic outbreak,” *IJSP* 66 (2020): 512-516.

<sup>10</sup> Lee SA, Jobe MC, Mathis AA., “Mental health characteristics associate with dysfunctional coronavirus anxiety,” *Psychol Med* (2020); doi:10.1017/S003329172000121X.

<sup>11</sup> Arora A, Jha AK, Alat P, Das SS., “Understanding coronaphobia,” *Asian J Psychiatr* 54 (2020):102384. doi:10.1016/j.ajp.2020.102384.

<sup>12</sup> Rao KS, Singhai P, Salins N, Rao SR., “The pathway to comfort: Role of palliative care for serious COVID-19 illness,” *Indian J Med Sci* 72 (2020): 95-100.



symptoms, and for ten days I did not feel anything, but the main problem was people's perception. I felt that the disease is a disgrace."<sup>13</sup>

As previously mentioned, patients with advanced age and severe life-limiting illnesses are at increased risk of death from COVID-19.<sup>12</sup> Not all patients presenting with severe illness will be eligible for aggressive intensive treatment.<sup>12,14,15,16,17</sup> In a limited resource setting, patients may be triaged for supportive care only.<sup>12</sup> This subset of patients should be promptly identified<sup>12,14,15,16,17</sup> and receive appropriate palliative care with adequate symptom control strategies and psychosocial support (Table 1). Critical criteria that may be most relevant for COVID-19 patients are: (1) status post cardiopulmonary arrest, (2) multiorgan dysfunction involving  $\geq 2$  organ systems, and (3) consideration of mechanical ventilator withdrawal with death expected.<sup>17</sup>

**Table 1. ICU Palliative care referral checklist**

INDICATORS	Criteria
Poor candidate for critical care Continuing intensive care will not confer overall benefit	-Status post cardiac arrest -Active stage IV malignancy -Advanced dementia -End-stage valvular heart disease/heart failure, i.e. New York Heart Association (NYHA) Class III or IV, not for surgery -End stage renal disease not for renal replacement therapy -Clinical frailty score $\geq 7$
Poor treatment response The underlying condition is irreversible, or the desired outcome cannot be achieved	-Multisystem organ dysfunction syndrome $\geq$ organ systems -Consideration of mechanical ventilator withdrawal after which death is expected
Extremely poor anticipated quality of life There is anticipated poor neurological recovery, or	-Extensive intracerebral/subarachnoid hemorrhage with poor neurological prognosis -Massive ischemic stroke with poor neurological recovery

<sup>13</sup> *Coronaphobia. States' policies guide people's behavior towards infected people. The Euro-Mediterranean Human Rights Monitor*, April 2020; <https://euromedmonitor.org/coronaphobia>, pdf, p.19, accessed 30 Aug 2021.

<sup>14</sup> Fadul N, Elsayem AF, Bruera E., "Integration of palliative care into COVID-19 pandemic planning," *BMJ Supportive & Palliative Care* 11 (2021): 40-44.

<sup>15</sup> Sullivan DR and Curtis JR., "A view from the frontline: palliative and ethical considerations of the COVID-19 pandemic," *J Palliat Med* 24 (2021): 293-295.

<sup>16</sup> Davies A and Hayes J., "Palliative care in the context of a pandemic: similar but different," *Clin Med* 20 (2020): 274-277.

<sup>17</sup> Poi CH, Koh MYH, Neo HY., "Palliative care in a COVID-19 intensive care unit (ICU): Challenges and recommendations for palliative care teams in a pandemic ICU," *Annals, Academy of Medicine, Singapore* 49 (2020): 517-522.

long-term ventilator dependence	-Hypoxic ischemic encephalopathy/ anoxic encephalopathy
Decisional conflicts/special considerations	-Difficult control physical symptoms despite usual treatment approaches -Upon initiation of extracorporeal membrane oxygenation -Complex family dynamics impacting decisions about use of life-sustaining treatments -Conflicts among staff or between staff and patients/surrogates about prognosis and/or use of life-sustaining treatments -Patients/surrogates wish to explore non-ICU supportive care options, such as hospice services

In such cases, palliative care may become the sole focus of care since it emphasizes early identification of symptoms and their control, empathetic communication, psychosocial and spiritual support, as well as end-of-life care and bereavement care.<sup>3:12</sup>

### III. Ethical considerations in the context of the COVID-19 pandemic

Clinicians’ care of terminally ill patients is guided by the same ethical principles that inform other types of medical care.<sup>1:3</sup> Foremost among these are truth-telling, nonmaleficence (to do no harm), beneficence (to do good), autonomy (to respect individuals’ rights to make their own decisions), confidentiality (to follow through and to keep promises), and procedural and distributive justice (to treat others fairly). The promise of non-abandonment is the central principle of end-of-life care.<sup>3</sup> Broadly, this means that no matter how poor the patient’s condition is, something can be done, and the skills of palliative care can and should be applied.<sup>3:18</sup> This principle has profound implications in the present pandemic, and reminds us of our professional obligation not to surrender to nihilism. Namely, where supportive intensive treatment, such as ventilatory support, is not offered or exhausted and rationing or triaging processes have been triggered based on resource scarcity, doctors may surrender to nihilism. They may feel nothing more can be done.<sup>18</sup> However, the promise of non-abandonment is a clinician’s pledge to serve a caring partner, a resource for creative problem solving and relief of suffering, a guide during uncertain times, and a witness to the patient’s experiences, no matter what happens.<sup>3</sup>

The guiding ethical principle of managing patients during pandemics and other healthcare emergencies is that “everyone matters equally”, although this does not mean that everyone is treated the same.<sup>16</sup> Patients who are not for escalation of treatment, or are for de-escalation of treatment deserve adequate “basic care”, and timely appropriate management of symptoms and other end-of-life care problems.

<sup>18</sup> Sheahan L, Brennan F., “What matters? Palliative care, ethics, and the COVID-19,” *Journal of Bioethics Inquiry* 17(2020): 793-796.

Moreover, they need empathy and “safe” personal interactions<sup>14,16</sup>, especially in the absence of families (Table 2).<sup>16</sup>

**Table 2. ICU Palliative care referral checklist**

<u>Engage as much as possible with patient:</u>
-Verbal communication, i.e. explanation, general “chit-chat”
-Nonverbal communication, for example, “thumbs up/down”
-Appropriate (safe) touching, for instance, hold their hand
Ensure that basic care needs are met
Ensure that symptoms are controlled
Facilitate remote contact with family (using mobile phones, etc.)
Facilitate direct contact with family for end-of-life care patients
Communicate regularly with family
Consider modifications to the environment to improve patient experience
Manage expectations, for example, preferred place of care/death

Caregivers should embrace the mentality espoused by Rachel Coghlan in her article regarding compassion through the barrier of personal protective equipment (PPE):

“The PPE may disguise countenance, restrict normal human touch, and create an unfamiliar gulf between you and your patient. Your eyes, voice and body language become your greatest assets. Use them to spread warmth and kindness. Make your eyes dance, your voice sing, your body show caring through the simple gesture of a thumbs-up sign, a pat on the shoulder or a little wave, even through your blue-gloved hand”.<sup>19</sup>

Besides, all patients and their families should be treated with dignity and be given the voice to express their concerns irrespective of gender, religion, culture, race, sexual orientation and disability.<sup>3</sup>

#### **IV. Challenges with family communication**

Frequent family communication was a crucial and time-consuming component of supportive care in the ICU to provide families with patient updates, obtain surrogate consent, and discuss transitions in goals of care. These functions are particularly silent during the pandemic, as many hospitalized patients required mechanical ventilation. Face to face family meetings, usually an integral component of establishing trust and rapport in the ICU, were rare, due to the restrictive family presence policies. As a result, clinicians described a transition in “family meeting” to phone or video conferencing. In such circumstances, telecommunication technologies are used to provide medical information and services (telemedicine).<sup>20</sup> The COVID-19

<sup>19</sup> Coghlan R., “COVID-19: projecting compassion through the barrier of PPE.” <https://insightplus.mja.com.au/2020/13/covid-19-projecting-compassion-through-the-barrier-of-personal-protective-equipment/> (accessed May 2, 2021).

<sup>20</sup> Dobrovic D, Pelicic D., “Telemedicine in the COVID-19 pandemic,” *Health Care* 49(2020): 68-74.

pandemic has focused on the use of digital technologies to enable the doctor to contact the patient via a secure network without personal contact.<sup>15,20</sup> Restrictive family presence policies also necessitate more frequent family contact by phone to replace interactions on ICU rounds and at the bedside.<sup>15</sup> Furthermore, clinicians talked about how without body language clues, a heightened sensitivity of speech flow and intonation was essential.<sup>15,20</sup> Generally speaking, clinicians must become proficient at delivering serious news, and then dealing with its consequences.<sup>3</sup> In relation to, it is suggested this kind of language for physicians providing support to a patient or family member who is denied intensive care because of resource scarcity:

“Normally, when somebody develops critical illness, the medical team would offer them intensive care (a combination of medications and machines to support their vital organs), provided that the medical team felt that they had a reasonable chance of survival. However, because of the COVID-19 outbreak, we are currently unable to offer intensive care to everyone who is critically ill. As a result, our hospital is working under triage guidelines, which means that we are offering intensive care only to those who are most likely to be able to survive and recover from their critical illness. You probably have heard about this in the news, all hospitals in the region are working under these guidelines. I regret to inform you that we are unable to offer you intensive care treatments at this time, as a result of the triage guidelines. Because of your medical condition, the likelihood that you would survive even with intensive care is considered to be too low for us to offer intensive care. The team has made this decision based on the following information: \_\_\_\_\_. I am deeply sorry about this situation. This is not the way we ordinarily make these decisions, and I can only imagine how you must feel right now. I want you to know that even though we cannot offer intensive care, we will do everything else that could conceivably give you a chance of recovering, including: \_\_\_\_\_. And I promise you that, no matter what, we will also use medication to treat any discomfort, such as pain or shortness of breath. We know that when we treat discomfort appropriately, this is not harmful and may actually help improve your condition.”<sup>21</sup>

When life-sustaining therapy is indicated for someone who is unlikely to survive a CCI, caregivers are recommended to discuss that treatment plan like this:

“You (your loved one) is currently suffering from \_\_\_\_\_. We have given you treatments, including \_\_\_\_\_, but it seems as though your body is not responding well to them. If this continues, we would need to consider the use of life-sustaining treatments to support your body. I am very concerned about this scenario; although it is very easy to start life-sustaining treatments, there are many scenarios where we strongly prefer

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<sup>21</sup> Arya A, Buchman S, Gagnon B, Downar J., “Pandemic palliative care: beyond ventilators and saving lives,” *CMAJ* 192(2020): E400-404. doi: 10.1503/cmaj.200465.

not to because the chances of recovery are poor. That is usually when someone has chronic or incurable medical conditions, or their body has become weaker than it used to be. The other concern is that these treatments can cause a lot of discomfort. Of course, many people are willing to experience discomfort if there is a reasonable chance of a good recovery. But if the treatments cause discomfort and the chances of recovery are poor, we are very hesitant to offer those treatments. I would like to propose an alternative plan. I would like to suggest that we continue doing the things that we are currently doing, including \_\_\_\_\_, in the hope that you might still respond and recover. We do not want to take away that opportunity. But if your body does not respond and you get worse, I would suggest that we do not start life-sustaining treatments. Instead, if you get worse, I would suggest that we focus on keeping you comfortable, understanding that any further escalation of care would probably do more harm than good. What do you think about that?”<sup>21</sup>

## V. Conflicting feelings about video calls

Because family members could not see, touch, or hold their loved ones in the ICU, video calls were introduced to allow family members to visit the patient virtually. However, some family members described that seeing their loved ones virtually contributed to their suffering. One family member described how she cried when she saw the patient lying in the bed, unconscious and connected to the machines. One man who had seven children, explained that he had to stop having video calls with his wife who was intubated, because it was so disturbing to his children.

“It was not necessarily a positive or pleasant experience. People were saying you feel so much better because you will be able to see him. I did not find that and I did not get any comfort from it.”<sup>22</sup> (Family member 1)

Family members were conflicted about video calls because they wanted the opportunity to see the patient, yet the images of their loved ones lying there was upsetting. However, family members who could not have video calls shared their deep disappointment.

“I wish we could either do a video conference, but their computer system and my computer system are not compatible. Most importantly, I wish we could have been there with him going through that, living with them being there while he handles procedures [being] done.”<sup>22</sup> (Family member 2)

“Right now, video talk is not helping. If the person sleeps, the nurse [is] just showing you the face. That makes you stressed. We have not heard

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<sup>22</sup> Chen C, Wittenberg E, Sullivan SS, Lorenz RA, Chang YP., „The experiences of family members of ventilated COVID-19 patients in the intensive care unit: a qualitative study,” *Am J Hosp Palliat Care* 38(2021): 869-876.

a voice, and we have not talked. She is not opening her eyes. If you compare it to when she was healthy, it will take you back. It makes you feel things [are] not normal.”<sup>22</sup> (Family member 3)

## VI. Healthcare professional narratives on end-of-life care in the COVID-19 period

“When I entered this profession, I did it because it was particularly difficult for a workman’s son like myself. And then I had to see people die. I saw that I could never get hardened to it.”<sup>23</sup> Dr Rieux in Camus’ *The Plague*

Terminally ill patients contracting COVID-19 lead to a highly stressful situation for themselves and their families on one side and for healthcare professionals on the other side.<sup>24</sup> One of the most heartbreaking aspects of the coronavirus infection is that many patients die alone. Nurses who sat alone with patients with COVID-19 in their final hours told the survey they felt they absorbed the emotions of the death and had to shoulder that “huge responsibility” on behalf of families.<sup>25</sup>

Lochan Shah, an internal medicine resident.- The last thing Jessica said to John, her fiancé of 10 years, was, “I love you” before he drove to work. Hours later, after suddenly experiencing a cardiac arrest at the office, he was in an ICU bed attached to a ventilator. He was pale and unresponsive, on multiple medications to artificially augment his blood pressure, hooked up to a machine that did the work of his kidneys, and cooled to 91.4°F to preserve whatever brain function was left. He could not speak; Jessica could not visit.<sup>26</sup>

This is yet another blow provided by COVID-19: to contain the spread of the virus, visitors are not allowed in the hospital for almost any reason – even if their loved one does not have COVID. At my hospital, the only way a family member can see their loved one in person is if the patient is actively dying, or if they request the medical team to withdraw life-sustaining care and the doctors are in the process of doing so. This means that not only are people in distress alone, but because family cannot see their loved ones in person, it is so much more difficult for them to understand what is happening medically. What does it mean to be on a ventilator? To do everything that modern medicine can provide? Until I reached my third year of medical school and saw it for myself, I certainly had no clue.<sup>26</sup>

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<sup>23</sup> Nash W, ed., *The Health Humanities and Camus’s The Plague* (Kent, OH: Kent State University Press, 1989).

<sup>24</sup> Ghosh D, Gupta B., “End-of-life issues in the era of the COVID-19,” *Korean J Hosp Palliat Care* 23(2020): 162-165.

<sup>25</sup> Munn F., *End of life care in a pandemic: the emotional cost to nurses*. Posted 30 October 2020. <https://rcni.com/nursing-standard/opinion/editorial/end-of-life-care-a-pandemic-emotional-cost-to-nurses-168386> (accessed 28 Aug 2021).

<sup>26</sup> Shah L., *The COVID-19 pandemic is changing end-of-life care. We’re not ready*. Posted 18 Aug, 2020; <https://www.kevinmd.com/blog/2020/08/the-covid-19-pandemic-is-changing-end-of-life-care-were-not-ready.html> (accessed 28 Aug 2021).

In a pre-COVID-19 world, families would see their loved ones on the verge of death. While it was incredibly painful, being at the bedside allowed them to understand when their loved ones would not meaningfully improve or if they would never be able to be themselves again. Now, families must decide to stop “doing everything” in the abstract, armed only with video chats of their loved one, brief phone calls with the doctor, and information from Google.<sup>26</sup>

As I tried to answer Jessica’s questions that day, I realized just how unprepared we are as a society for this wave of patients who are at the end of life in the COVID-19 era.<sup>26</sup>

Because of its nuanced social, ethical, and medical nature, there are no strict criteria on when to withhold or withdraw life-sustaining care. I have had patients, for example, who wanted us to do everything we could as long as they had a beating heart. Other patients have felt that if they could not visit family in Italy, play with their grandkids, or ever eat food through their mouth, then they would not want to proceed with medical interventions. Ideally, these discussions happen before a patient gets critically ill, and are documented into something called an advance directive. Unfortunately, two-thirds of Americans do not complete advance directives for end of life care, leaving those of us caring for them without any guidance on how to handle these hard decisions... As I answered Jessica’s questions over the course of the next 36 hours, however, I realized that advance directives are only half the story.<sup>26</sup> “Do you think there is a chance my fiancé will make it?” I remember her asking.” I had taken 30 minutes of CPR in the emergency department to get John’s heart beating again, all of his organs were failing, and preliminary CT scans of his brain had not looked promising. There was a very good chance he was not going to “make it” – and he was even more unlikely to be the person that she had known and loved. Yet, 10,4 of patients with an out-of-hospital cardiac arrest survive to discharge, and doctors typically wait at least 72 hours after cardiac arrest to make an official prognosis. When patients like him are cooled to 89.6-93.2°F, we typically wait until the cooling protocol is complete, as there is some evidence that early prediction of poor prognosis can lead to the inappropriate withdrawal of care for some patients. I will never forget what she said next. “If there is any hope that he will make it, I want you to do everything,” she told me. “But if you don’t think he will, then I want to withdraw today; I don’t want to prolong this anymore for me or for him. I can’t eat, I can’t sleep, I can’t wait, I just want to hold him, doctor.” I couldn’t help, but wonder what kind of incentive system our visitation restriction policy had inadvertently set up. Was she rushed into making the decision to withdraw care, because that was the only opportunity she had to be at his bedside? How can our hospitals adapt so that we can better help the families of patients who are dying make informed decisions.<sup>26</sup>

Ultimately, Jessica ended up coming into the hospital later that evening, remaining bedside as we turned off the ventilator and gave John medications to keep him comfortable. He died moments later, at peace and without pain. I’m grateful that we were able to reunite Jessica with her fiancé, but I will never be able to get her story out of my mind. If she had been able to be present at the bedside, would she have waited until the cooling protocol had finished? What else could we have done to support her? And, most importantly, is this what the end of life will inevitably look like for the

foreseeable future, as long as COVID-19 remains a threat? I understand that these constraints exist for everyone's safety, and even allowing family to be present at death is a privilege that many dying of COVID-19 are not afforded. But we must come up with a better solution.<sup>26</sup>

Jan Hoffman, *New York Times* - The coronavirus patient, a 75-year-old man, was dying. No family member was allowed in the room with him, only a young nurse. In full protective gear, she dimmed the lights and put on quiet music. She freshened his pillows, dabbed his lips with moistened swabs, held his hand, spoke softly to him. He wasn't even her patient, but everyone else was slammed. Finally, she held an iPad close to him, so he could see the face and hear the voice of a grief-stricken relative Skyping from the hospital corridor. After the man died, the nurse found a secluded hallway, and wept.<sup>27</sup>

Anthony Almojera, a senior paramedic in New York - "It's an Asian family who cannot believe their uncle has died. I see in their eyes they can't believe it. They keep imploring me to do something, to take him to the hospital, and I tell them we couldn't, even if we wanted to. The hospitals are not working on anyone who has no signs of life. They keep saying "you have to save him, you have to save him". The son asks why we can't just start his heart again. The hard thing about wearing the mask is it covers half my face. All he's hearing are the words. If I'm able to show my face it lets the patient's family see the emotion behind it. Now all they see is my eyes and my eyes are in terror because I don't know if I can convince this kid that there's nothing more we can do... ."<sup>28</sup>

"I'm on this call with the medics who were with me at the house with the daughter who lost both parents. They come outside and see me sitting on the stoop. I've had to tell 10 families we couldn't do any more. I am beside myself with feelings of bewilderment. I've never had to do a day like this in my career. I'm emotionally drained. The things we see are sometimes difficult to shake. And with this, people are going to be different afterwards. There's no way that the majority of EMS workers are going to come out of this happy-go-lucky. Maybe some of them will have these moments of clarity and appreciate the flowers and the sunrise, but for a lot of us, when we close our eyes, we're going to see this. The medics see me and come over and sit next to me. They both put their arms around me and we support each other."<sup>28</sup>

## VII. Spiritual support in the time of COVID-19

"Keep silent because the world of silence is a vast of fullness."  
Jalaluddin Rumi

Spirituality is the attempt to understand or accept the underlying meaning of life, one's relationships to oneself and other people, one's place in the universe, one's legacy, and

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<sup>27</sup> [The Professional is Personal] Hoffman J. "I Can't Turn My Brain Off: PTSD and Burnout Threaten Medical Workers," *The New York Times*, 16 May 2020, <https://www.nytimes.com/2020/05/16/health/coronavirus-ptsd-medical-workers.html> (accessed 28 Aug 2021.)

<sup>28</sup> [The Professional is Personal] Cuddy A., *Coronavirus in New York. A paramedic's diary*. BBC News, 10 Apr "2020; accessed 12 Apr 2020 – a harrowing description of what Anthony Almojera, calls the toughest day of his 17-year career.



the possibility of a “higher power” in the universe.<sup>3</sup> As a multidimensional concept, spiritual care includes religious care (worship and prayer with patients, talking to them about God) and nonreligious care (respect for the client, support, protection of the patient’s privacy, therapeutic touch, listening carefully to the speech of patients, and helping them to be aware of their illness).<sup>29</sup> However, in terms of COVID-19, some of the activities, such as the involvement of chaplains and spiritual practices, can be limited because of precautionary measures for infection control.<sup>29,30</sup> Under the current circumstances, healthcare professionals should be extra-sensitive to the spiritual needs of their patients and their own, as studies have reported that patients’ reliance on spirituality increases during life-changing events.<sup>30</sup>

Current researches reveal the intimate link between health and spirituality. Among vulnerable populations, spirituality serves a critical purpose in a person’s well-being. One of the many established values of spirituality is that it helps people to deal with major life stressors. This has become more pronounced as the world grapples with the challenges brought by the COVID-19 pandemic.<sup>31</sup>

The effects of COVID-19 have had a major impact on people’s and front-line health workers’ activities, routines, livelihoods, mental health and well-being. Healthcare workers risk their lives to save people who have COVID-19 while promoting compassionate care. People who have COVID-19 tend to present with severe distress associated with the disease that affects different aspects of their wholeness including physical, emotional, mental, social and spiritual components. This means that the healthcare workers need to create a supportive environment that could promote interdependence through a transformative approach of spiritual care.<sup>30</sup>

Although spiritual care has always been a part of the domain of religious beliefs, a more contemporary perspective is that spiritual care forms part of the human psyche and thus forms part of human care, health and well-being for families, patients and healthcare workers. Spiritual care deals with the provision of compassion and empathy during periods of heightened stress, distress and anxiety within care.<sup>30</sup>

### VIII. Spirituality care and the family

The family, as the cornerstone of society, is a social determinant of health.<sup>32</sup> For example, when families engage in health-risking behaviour, such as smoking, substance abuse, not exercising or not eating correctly, their behaviours could result in non-communicable diseases such as diabetes, hypertension, etc. Not only do they place themselves at risk but they also create a negative social atmosphere for their growing children. These patterns could then culminate in health challenges for the next generation. However, families also provide care and support – care of children, the

<sup>29</sup> Bahramnezhad F, Asgari P., “Spiritual care for COVID-19 patients: a neglected necessity,” *Infectious Diseases in Clinical Practice* 29(2021): e63.

<sup>30</sup> Roman NV, Mthembu TG, Hoosen M., “Spiritual care – ‘A deeper immunity’ – A response to Covid-19 pandemic,” *Afr J Prm Health Care Fam Med* 12(2020): doi:10.4102/phcfm.v12i1.2456.

<sup>31</sup> del Castillo FA., “Health, spirituality and COVID-19: Themes and insights,” *J Public Health* 1-2 (2020) doi:10.1093/pubmed/f-daa121.

<sup>32</sup> McNeill T., “Family as a social determinant of health: Implications for governments and institution to promote the health and well-being of families,” *Healthc Q.* (2010) 60–67. 10.12927/hcq.2010.21984.

sick and the elderly and support in times of challenges. The most challenging time requiring family support and support to families is during a chronic illness, when one is critically ill and during end of life.<sup>30,33</sup>

## **IX. Conclusion**

The COVID-19 pandemic has brought a tsunami of suffering that is devastating even well resourced countries. In the 21st century, the COVID-19 crisis has put human civilizational, systemic, and institutional strengths to the test. In challenging times, decision makers, policy creators and the society itself, must adhere to the proven benefits of science and professional expertise. Managing CCI patients and alleviating suffering in all its forms is an emerging challenge for today's healthcare systems and needs to be a key part of their response. Effective triage is of the utmost importance in any situation where there are mass casualties, which includes pandemics, since a great number of patients can very quickly overwhelm the limited available staff and resources. An adaptation to the post-covid-19 era should be the implementation of personalized end-of-life care, in order to meet the needs of CCI patients and their relatives. Close collaboration among caregivers, CCI patients and their family members is a fundamental prerequisite for successful personalization of end-of-life care. Currently, personalized health care, as evidence-based individualized medicine that delivers the right care to the right patient at the right time, has been applied in oncology, infectious diseases, and cardiology. In order to improve patient outcomes it is necessary to identify patients' wishes while they are still able to express them. In such context, physicians should encourage CCI patients to write their own documents (advanced care plans). Unfortunately, to help mitigate against spiritual distress, the doctors role in the era of COVID got complicated, since they often serves as the only possible link to fulfill patients' spiritual needs.

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## **Note**

This paper is dedicated to our HERO, anesthesiologist Nenad Maksimović (1983-2021), who passed through the COVID-19 darkness as a light bearer and illuminated it forever.

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<sup>33</sup> Johnson JR, Engelberg RA, Nielsen EL, et al. The association of spiritual care providers' activities with family members' satisfaction with care after a death in the ICU. *Crit Care Med* 2014;42(9):1991–2000.

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Johnson JR, Engelberg RA, Nielsen EL, et al. „The association of spiritual care providers' activities with family members' satisfaction with care after a death in the ICU.” *Crit Care Med* 42(2014): 1991–2000.

## **PART 2.**

### **Ethical Challenges in the Clinical Context**



# COVID-19 IN PREGNANT WOMEN: ETHICAL ISSUES AND DILEMMAS

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## Abstract

Treatment of pregnant women with acute respiratory syndrome, coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19), is still very much a burning ethical issue. Pregnant women belong to the increased-risk population, and dilemmas have arisen regarding COVID-19 infection such as therapeutic options, vaccine safety, pregnancy outcomes, pain management, etc. Women who plan pregnancy during the pandemic face many psychological dilemmas, like safe delivery, the threat of transplacental transmission of the virus, the consequences it may have on the fetus. Specific socioeconomic and cultural factors contribute to an increased risk of developing psychiatric disorders related to pregnancy and childbirth, especially postpartum depression.

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## I. Introduction

The coronavirus 2 (SARS-COV-2) pandemic began in 2019. The COVID 19 pandemic and all the restrictive measures that characterize it, alongside direct risk to people's physical health, also leave numerous psychological consequences for the health of the population. A more passive way of life, partial or absolute social isolation, has significantly disrupted everyday life. Uncertainty of the outcome of the pandemic itself and economic uncertainty (both, globally and personally, in terms of uncertainty for work and existence that has affected many nations in the world) – are the main factors that can affect existing psychological problems or that can lead to some psychological problems de novo.<sup>1</sup> During 2020, among the adult population worldwide has been recorded a higher rate of anxiety, depressive disorders, posttraumatic stress disorder (PTSD), and disorders related to the abuse of psychoactive substances. Women are more likely to have disorders related to affective changes and symptoms of PTSD.<sup>2,3</sup> As a consequence of psychological changes and abuse of psychoactive substances, every so often it is recorded an increase in domestic violence, in which the most common victims are women and children.<sup>4</sup>

Pregnancy and the postpartum periods are typically special periods in a woman's life in terms of her increased psychological vulnerability. According to some data, even one in seven women shows increased nervousness and changes in mood in this period. Women who have had or have high-risk pregnancies are at an increased risk of mental illness.<sup>5</sup> Because of all the health risks and medical challenges that the COVID-19 pandemic has brought, women who planned to become mothers during this period belong to a particularly vulnerable group for the development and manifestation of psychological problems.

The virus can have potential adverse fetal and neonatal effects, just like the drugs used for the treatment of the infection. The usage of different drugs is a primary concern before administering the treatment of COVID-19 during pregnancy. Pregnant women are a vulnerable group of patients and they are high-risk population during infectious disease and their condition is associated with mortality and morbidity compared to the general population. The number of publications on Covid-19 in pregnancy has risen steeply through individual case reports, case series, observational studies, and systematic reviews during the pandemic. According to one

<sup>1</sup> Altig Dave, Scott Baker, Jose Maria Barrero, Nicholas Bloom, Philip Bunn, Scarlet Chen, Steven J. et al., "Economic uncertainty before and during the COVID-19 pandemic," *Journal of Public Economics*, 191, (2020):104274. <https://doi.org/10.1016/j.jpubeco.2020.104274>.

<sup>2</sup> J.M. Twenge, Joiner TE. "U.S. Census Bureau-assessed prevalence of anxiety and depressive symptoms in 2019 and during the 2020 COVID-19 pandemic," *Depress Anxiety*, 37 (2020):954-956. <https://doi.org/10.1002/da.23077>.

<sup>3</sup> N. Liu, Zhang F, Wei C, et al. "Prevalence and predictors of PTSS during COVID-19 outbreak in China hardest-hit areas: Gender differences matter," *Psychiatry Res*, 287 (2020):112921.

<sup>4</sup> Kathryn Humphreys, Myo Thwin Myint, Charles H. Zeanah. "Increased Risk for Family Violence During the COVID-19 Pandemic," *Pediatrics*, 146 (2020): e20200982.

<sup>5</sup> N. Fairbrother, N, Young AH, Zhang A, Janssen P, Antony MM. "The prevalence and incidence of perinatal anxiety disorders among women experiencing a medically complicated pregnancy," *Arch Womens Ment Health* 20 (2017): 311–319.

of the latest systemic reviews which included 73 studies and 67 271 women, three quarters of participants were asymptomatic (73%, from 62% to 82%; based on 38 studies). About 10% (95% CI 7-12%;) of pregnant and recently pregnant women were diagnosed as having suspected or confirmed Covid-19 and admitted to hospital. Fever (40%) and cough (41%) were the most common clinical manifestations of COVID-19 in pregnancy. Compared with non-pregnant women of reproductive age, pregnant and recently pregnant women with Covid-19 were less likely to have symptoms or report symptoms of fever, dyspnoea and myalgia.<sup>6</sup>

The pandemic called to attention numerous ethical issues concerning COVID-19 infection in pregnant women. Some of them are the treatment of the infection, medication use, vaccination, labor, pain management, vertical transmission on the babies, and the psychological state of the women.

Effective treatment should not be denied to pregnant women, regardless of hypothetical concerns related to the safety of using these therapeutic agents during pregnancy. Decisions regarding the use of drugs approved for other indications or investigational agents for the treatment of COVID-19 in pregnant patients should be made between the patient and the clinical team, considering the safety of the medication for the woman and the fetus and the severity of maternal disease.

Historically, clinical trials were rarely conducted among pregnant women for safety reasons. Medication used in the general population cannot be administered to pregnant women due to the lack of knowledge of side effects, and there is no difference with COVID-19 therapeutic agents. Most SARS-CoV-2-related clinical trials have excluded or included small numbers of pregnant and lactating women. This makes it difficult to make evidence-based recommendations for this vulnerable population and potentially limits their COVID-19 treatment options.

## II. Ethical issues regarding the management of COVID-19 pregnant patients

It is equally likely for pregnant women to contract COVID-19 infection compared to the general population. Most will only have mild to moderate forms of the disease and recover without consequences.<sup>7,8,9</sup> Data indicated that pregnant patients with

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<sup>6</sup> John Allotey, Elena Stallings, Mercedes Bonet, Magnus Yap, Shaunak Chatterjee, Tania Kew, Luke Debenham, et al., "Clinical Manifestations, Risk Factors, and Maternal and Perinatal Outcomes of Coronavirus Disease 2019 in Pregnancy: Living Systematic Review and Meta-Analysis," *BMJ*, 370 (2020) :m3320. <https://doi.org/10.1136/bmj.m3320>.

<sup>7</sup> Lian Chen, Qin Li, Danni Zheng, Hai Jiang, Yuan Wei, Li Zou, Ling Feng, et al., "Clinical Characteristics of Pregnant Women with Covid-19 in Wuhan, China," *New England Journal of Medicine*, 382 (2020): e100 <https://doi.org/10.1056/nejmc2009226>.

<sup>8</sup> Annemarie B. Docherty, Ewen M. Harrison, Christopher A. Green, Hayley E. Hardwick, Riinu Pius, Lisa Norman, Karl A. Holden, et al., "Features of 20 133 UK Patients in Hospital with Covid-19 Using the ISARIC WHO Clinical Characterisation Protocol: Prospective Observational Cohort Study," *BMJ* 369 (2020):m1985. <https://doi.org/10.1136/bmj.m1985>.

<sup>9</sup> Daniele Di Mascio, Asma Khalil, Gabriele Saccone, Giuseppe Rizzo, Danilo Buca, Marco Liberati, Jacopo Vecchiet, et al., "Outcome of Coronavirus Spectrum Infections (SARS, MERS, COVID 1 - 19) during Pregnancy: A Systematic Review and Meta-Analysis," *American Journal of Obstetrics & Gynecology MFM*, 2(2020): 100107. <https://doi.org/10.1016/j.ajogmf.2020.100107>.

COVID-19 are at increased risk for intensive care unit admission, invasive ventilation, extracorporeal membrane oxygenation, and death.<sup>10,11</sup> Risk factors that have been associated with severe COVID-19 infection, ICU admission, or invasive ventilation during pregnancy include maternal age over 35, BMI over 30, and pre-existing maternal comorbidity (specifically chronic hypertension and pre-pregnancy diabetes).

Protocols for the clinical management of pregnant COVID-19 patients are still being established.<sup>12,13</sup> The treatment of infectious diseases in pregnant patients often presents a unique dilemma due to the many known and unknown adverse effects of medicaments on the developing fetus. It is difficult to offer evidence-based recommendations to this vulnerable population because pregnant women are usually excluded from therapeutic drugs and vaccine trials. Choosing the best drug in terms of effectiveness and safety profile for both the mother and the fetus remains challenging for the physicians.<sup>14</sup> Depending on the stadium of the pregnancy, there are several ethical considerations in treating pregnant patients with COVID-19.

Due to the course of the pandemic and already known limitations of wide objective studies involving pregnant women, therapy recommendations usually do not have a high level of evidence. For some medications, decisions were made according to results of in-vitro studies, uncontrolled case reports/series and studies that involve small numbers of exposed pregnancies (e.g. Ramdesivir, Tocilizumab, Anakinra). Some medications were administered to pregnant women, according to recommendations used in general population, only for those same medications to be established non-effective in COVID-19 treatment (e.g. azytromycin, hydroxychloroquine, lopinavir/ritonavir).<sup>15,16</sup> For some of these medications, adverse pregnancy outcomes have been described (cases of congenital anomaly,

<sup>10</sup> Julius Collin, Emma Byström, Anna Sara Carnahan, and Malin Ahrne, “Pregnant and Postpartum Women with SARS-CoV-2 Infection in Intensive Care in Sweden,” *Acta Obstetrica et Gynecologica Scandinavica*, 99(2020):819-822. <https://doi.org/10.1111/aogs.13901>.

<sup>11</sup> Laura D. Zambrano, Sascha Ellington, Penelope Strid, Romeo R. Galang, Titilope Oduyebo, Van T. Tong, Kate R. Woodworth, et al., “Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020,” *MMWR. Morbidity and Mortality Weekly Report* 69 (2020): 1641–1647 <https://doi.org/10.15585/mmwr.mm6944e3>.

<sup>12</sup> James M. Sanders, Marguerite L. Monogue, Tomasz Z. Jodlowski, and James B. Cutrell, “Pharmacologic Treatments for Coronavirus Disease 2019 (COVID-19),” *JAMA* 323 (2020): 1824–1836. <https://doi.org/10.1001/jama.2020.6019>.

<sup>13</sup> Guillaume Favre, Léo Pomar, Xiaolong Qi, Karin Nielsen-Saines, Didier Musso, and David Baud, “Guidelines for Pregnant Women with Suspected SARS-CoV-2 Infection,” *The Lancet Infectious Diseases*, 20 (2020): 652-653. [https://doi.org/10.1016/s1473-3099\(20\)30157-2](https://doi.org/10.1016/s1473-3099(20)30157-2).

<sup>14</sup> Clare L. Whitehead, and Susan P. Walker, “Consider Pregnancy in COVID-19 Therapeutic Drug and Vaccine Trials,” *The Lancet*, 395(2020): e92. [https://doi.org/10.1016/s0140-6736\(20\)31029-1](https://doi.org/10.1016/s0140-6736(20)31029-1).

<sup>15</sup> Bhagteshwar Singh, Hannah Ryan, Tamara Kreda, Marty Chaplin, and Tom Fletcher, “Chloroquine or Hydroxychloroquine for Prevention and Treatment of COVID-19,” *Cochrane Database of Systematic Reviews*, 2 (2021):1465-1858 <https://doi.org/10.1002/14651858.cd013587.pub2>.

<sup>16</sup> Ahmed M. Kamel, Mona S. A. Monem, Nour A. Sharaf, Nada Magdy, and Samar F. Farid, “Efficacy and Safety of Azithromycin in Covid-19 Patients: A Systematic Review and Meta-Analysis of Randomized Clinical Trials,” *Reviews in Medical Virology* (2021): e2258. <https://doi.org/10.1002/rmv.2258>.

miscarriages, and preterm deliveries), but still, there is no reliable evidence of increased risks.<sup>17,18,19,20</sup> Balancing potential benefits, potential risks and alternatives is the most challenging task for the physician. On the other hand, patients have to make informed consent based on limited and incomplete data. Potentially effective treatment for COVID-19 should not be withheld from pregnant women because of theoretical concerns related to the safety of therapeutic agents in pregnancy.

The results of our preliminary study on pregnant women with COVID-19 infection support previous data. The authors conducted a prospective study on 45 pregnant women (aged 18-39 years) who were hospitalized in the Obstetrics/Gynecology Hospital, Clinical-Hospital Center “Dragiša Mišović” in Serbia during a six-month period (from June to August 2020). The study and its duration were approved by the Institutional Ethics Board. All pregnant women had positive nasopharyngeal smears for SARS-CoV-2 and clinical symptoms of infection. Pregnant women were in different gestation ages, from 31 to 41 weeks. Eleven (24.4%) COVID-19 pregnant women had pneumonia which was confirmed on the chest CT and / or X-ray and more severe form of the disease. Twenty-three patients (51.1%) had comorbidities such as hypertension, diabetes, anemia, or thrombophilia. Usually, symptoms were cough, shortness of breath, and muscle and joint pain. 15 (33.3%) of the patients had loss of sense of taste and malaise. Values of biochemical parameters leucocytes, lymphocytes, ferritin, interleukin 6, C-reactive protein, and D-dimer were elevated. Three pregnant women were admitted to the intensive care unit. Almost all pregnant women were on antibiotic therapy, 43 patients (95.5%), and the most commonly used antibiotics were third-generation cephalosporins and lincosamides. In addition to antibiotics, pregnant women with pneumonia received antiviral therapy (lopinavir / ritonavir) during 10-14 days.

Critical forms of COVID-19 are predominantly associated with respiratory failure and systemic multiorgane dysfunction. The decreasing ability to properly oxygenate the pregnant patient puts the fetal patient at risk of organ injury. If hospitalization is indicated, further care should be conducted in a tertiary medical center by a multidisciplinary medical team. The team should ideally include obstetric, maternal-fetal medicine, infectious disease, pulmonary and critical care, and pediatric specialists

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<sup>17</sup> Rohan D'Souza, Rizwana Ashraf, Hilary Rowe, Jonathan Zipursky, Lauren Clarfield, Cynthia Maxwell, Cristian Arzola, et al., “Pregnancy and COVID -19: Pharmacologic Considerations,” *Ultrasound in Obstetrics & Gynecology* 57 (2021): 195–203. <https://doi.org/10.1002/uog.23116>.

<sup>18</sup> De la Calle Fernández-Miranda Martínez-Sánchez, and J. L. Bartha, “Safety Profile of Treatments Administered in COVID 19 Infection in Pregnant Women,” *Clinica E Investigacion En Ginecologia Y Obstetricia* 48 (2021): 100663. <https://doi.org/10.1016/j.gine.2021.01.004>.

<sup>19</sup> Rebecca A. M. Pierce-Williams, Julia Burd, Laura Felder, Rasha Khoury, Peter S. Bernstein, Karina Avila, Christina A. Penfield, et al., “Clinical Course of Severe and Critical Coronavirus Disease 2019 in Hospitalized Pregnancies: A United States Cohort Study,” *American Journal of Obstetrics & Gynecology* MFM 2 (2020): 100134. <https://doi.org/10.1016/j.ajogmf.2020.100134>.

<sup>20</sup> Malavika Prabhu, Kristen Cagino, Kathy C. Matthews, Rachel L. Friedlander, Shannon M. Glynn, Jeffrey M. Kubiak, Yawei J. Yang, et al., “Pregnancy and Postpartum Outcomes in a Universally Tested Population for SARS-CoV-2 in New York City: A Prospective Cohort Study,” *BJOG: An International Journal of Obstetrics and Gynaecology* 127 (2020): 1548–56. <https://doi.org/10.1111/1471-0528.16403>.

and make an individualized delivery plan, depending on maternal and fetal condition.<sup>21,22,23</sup>

After hospitalizing the pregnant patient, it is important to determine the most accurate gestational age and viability of the fetus. Later gestational age after viability (23–24 weeks of gestation) is correlated with fewer risks associated with prematurity.<sup>24</sup> The obstetrician and critical care team should enable pregnant patients or their decision makers (when the patient does not have decision-making capacity) to make informed decisions about the use of maternal and fetal monitoring and the timing of delivery, according to the team’s clinical evaluation.

There is often uncertainty about the timing and mode of delivery because of the challenge in balancing maternal and fetal interests in reducing morbidity and mortality. Maternal considerations are focused on potential lung function improvement after early delivery. The risk of severe hypoxemia may be increased in critically ill pregnant patients during the third semester due to uterine compression and elevation of the diaphragm.<sup>25</sup> Data are still unclear on whether delivery and uterine decompression will improve respiratory status, and these are based on case reports and case series.<sup>26</sup> Fetal considerations are focused on the impact of prolonged maternal hypoxemia, through the course of COVID-19 and the risks associated with delivery at an early gestational age. Evidence is still not clear if fetal distress from maternal hypoxemia can be resolved with aggressive maternal care, or with spontaneous recovery of the patient.<sup>27</sup>

<sup>21</sup> Corrina Oxford-Horrey, Megan Savage, Malavika Prabhu, Sharon Abramovitz, Kelly Griffin, Elyse LaFond, Laura Riley, and Sarah Rae Easter, “Putting It All Together: Clinical Considerations in the Care of Critically Ill Obstetric Patients with COVID-19,” *American Journal of Perinatology* 37 (2020): 1044–51. <https://doi.org/10.1055/s-0040-1713121>.

<sup>22</sup> Sonja A. Rasmussen, John C. Smulian, John A. Lednický, Tony S. Wen, and Denise J. Jamieson, “Coronavirus Disease 2019 (COVID-19) and Pregnancy: What Obstetricians Need to Know.” *American Journal of Obstetrics and Gynecology* 222 (2020), 415–426. <https://pubmed.ncbi.nlm.nih.gov/32105680/>.

<sup>23</sup> Andrea Giampreti, Georgios Eleftheriou, Mariapina Gallo, Raffaella Butera, Gioia Contessa, Lorella Faraoni, Anna Sangiovanni, Giulia Negri, Giovanna Falchi, and Giuseppe Bacis, “Medications Prescriptions in COVID-19 Pregnant and Lactating Women: The Bergamo Teratology Information Service Experience during COVID-19 Outbreak in Italy,” *Journal of Perinatal Medicine* 48 (2020): 1001–1007. <https://doi.org/10.1515/jpm-2020-0339>.

<sup>24</sup> Tracy A. Manuck, Madeline Murguia Rice, Jennifer L. Bailit, William A. Grobman, Uma M. Reddy, Ronald J. Wapner, John M. Thorp, et al., “Preterm Neonatal Morbidity and Mortality by Gestational Age: A Contemporary Cohort,” *American Journal of Obstetrics and Gynecology* 215 (2016): 103.e1–14. <https://doi.org/10.1016/j.ajog.2016.01.004>.

<sup>25</sup> Carl H. Rose, Michelle A. Wyatt, Kavita Narang, Kathleen E. Lorenz, Linda M. Szymanski, and Arthur J. Vaught, “Timing of Delivery with Coronavirus Disease 2019 Pneumonia Requiring Intensive Care Unit Admission,” *American Journal of Obstetrics & Gynecology MFM* 3 (2021): 100373. <https://doi.org/10.1016/j.ajogmf.2021.100373>

<sup>26</sup> Daniel E. Cole, Tara L. Taylor, Deirdre M. McCullough, Catherine T. Shoff, and Stephen Derdak, “Acute Respiratory Distress Syndrome in Pregnancy,” *Critical Care Medicine* 33 (2005): 269–278. <https://doi.org/10.1097/01.ccm.0000182478.14181.da>.

<sup>27</sup> Shu Qin Wei, Marianne Bilodeau-Bertrand, Shiliang Liu, and Nathalie Auger, “The Impact of COVID-19 on Pregnancy Outcomes: A Systematic Review and Meta-Analysis,” *Canadian Medical Association Journal*, 193(2021), E540–E548. <https://doi.org/10.1503/cmaj.202604>.

In pregnant and recently pregnant women with COVID-19, the overall rate of preterm birth was 17% (95% CI 14-19%; 70 studies, 9369 women) and of spontaneous preterm birth was 6% (4- 9%; 17 studies, 1629 women). Neonates born to women with COVID-19 had a higher risk of neonatal intensive care unit (NICU) admission, with admission rate of 33% (95% CI 24-43%; 41 studies, 3323 women).<sup>28</sup> In cases of birth, perinatal mortality is about 7%, while the most common adverse perinatal outcome is fetal distress (43%). Fortunately, vertical transmission of COVID-19 to the neonate is rare (3.2%).<sup>29</sup>

In our study, 57% of pregnant women with COVID-19 had a live birth, 13% had an abortion, and 30% were discharged and continued to maintain the pregnancy (Figure 1).

Some of the children were premature, especially those who were in the 32 and 33 gestation weeks of pregnancy. Contrary to the literature data, 71% of women in our study had a natural labor and 29% of women were labored by caesarean section (Figure 2). All newborns did not have COVID-19 infection. It was noticed that higher clinical course of disease had lower birth weight and length, which is associated with premature birth.

If pregnant patients with COVID-19 progress to critical illness and require delivery, cesarean birth would be the preferred modality of delivery. Planned cesarean delivery is usually safer than emergency cesarean delivery. However, this procedure is still associated with higher maternal morbidity and mortality and it could affect further recovery in critical patients.<sup>30</sup> Compared with patients with no SARS-CoV-2 infection in pregnancy, COVID-19 was associated with preeclampsia, preterm birth and stillbirth. Compared with mild forms of COVID-19, severe forms were strongly associated with preeclampsia, preterm birth, gestational diabetes and low birth weight.

These situations represent a clinical ethical challenge, where additional information does not reduce uncertainty or even increase uncertainty in clinical judgment. It is up to a physician to morally manage medical uncertainty, which means reducing variation in clinical judgment and practice to a minimum. This is usually achieved by respecting relevant ethical concepts and by using clinical rules to formulate sound and beneficence-based clinical judgment. Clinical judgment should be evidence-based (in accordance with the best available, critically appraised evidence), rigorous (to identify and reduce bias), transparent (the physician must be able to explain the judgment to other clinicians, especially team members and the

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<sup>28</sup> John Allotey, Elena Stallings, Mercedes Bonet, Magnus Yap, Shaunak Chatterjee, Tania Kew, Luke Debenham, et al., "Clinical Manifestations, Risk Factors, and Maternal and Perinatal Outcomes of Coronavirus Disease 2019 in Pregnancy: Living Systematic Review and Meta-Analysis," *BMJ*, 370 (2020): m3320. <https://doi.org/10.1136/bmj.m3320>

<sup>29</sup> Alexander M. Kotlyar, Olga Grechukhina, Alice Chen, Shota Popkhadze, Alyssa Grimshaw, Oded Tal, Hugh S. Taylor, and Reshef Tal, "Vertical Transmission of Coronavirus Disease 2019: A Systematic Review and Meta-Analysis," *American Journal of Obstetrics and Gynecology* 224 (2021): 35-53.e3. <https://doi.org/10.1016/j.ajog.2020.07.049>.

<sup>30</sup> Shu Qin Wei, Marianne Bilodeau-Bertrand, Shiliang Liu, and Nathalie Auger, "The Impact of COVID-19 on Pregnancy Outcomes: A Systematic Review and Meta-Analysis," *Canadian Medical Association Journal*, 193(2021), E540–E548. <https://doi.org/10.1503/cmaj.202604>.

patient), and accountable (of good quality and patients safe). Physicians should also follow the ethical principle of respect for patient autonomy in obstetrics. This involves the ethical obligation to empower the pregnant patient to make informed and voluntary decisions about managing her pregnancy by providing her with information about the medically reasonable alternatives for its clinical management.<sup>31</sup>

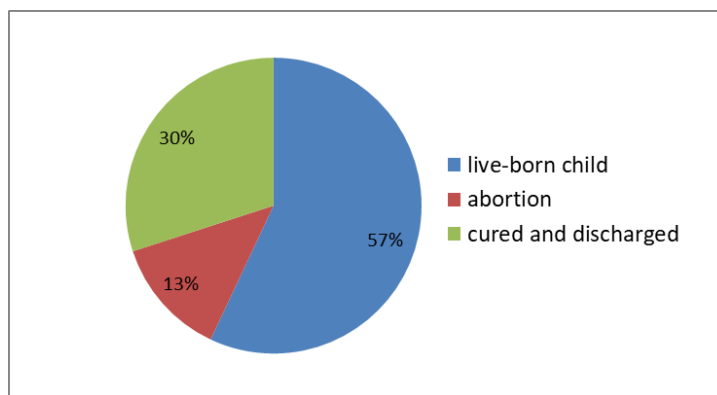


Figure 1. Pregnancy outcome in patients with COVID-19

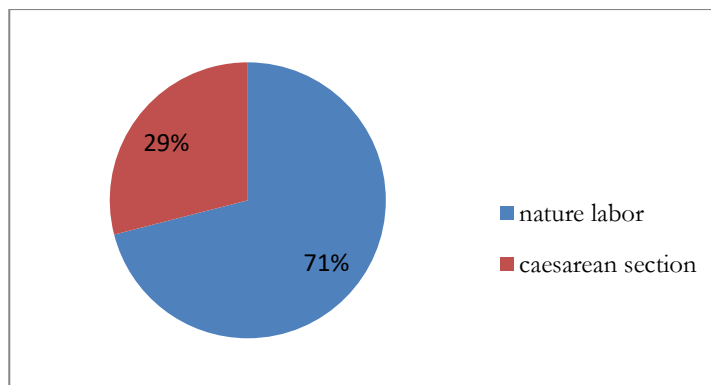


Figure 2. Labor outcome in patients with COVID-19

When high-quality evidence is lacking, such as in managing pregnancy during COVID-19 infection, physicians should not rely only on their individual clinical judgment but should consider professional input from a team of colleagues involving critical care medicine, obstetrics, and neonatology.<sup>32</sup>From the standpoint of

<sup>31</sup> Laurence McCullough, Frank Chervenak, and John Coverdale Frontmatter. “Professional Ethics in Obstetrics and Gynecology.” *Professional Ethics in Obstetrics and Gynecology*. Cambridge: University Press, 2020.

<sup>32</sup> Moti Gulersen, Burton Rochelson, Eran Bornstein, Laurence B. McCullough, and Frank A. Chervenak, “Ethical Challenges in Management of Critically Ill Pregnant Patients with Coronavirus

preventive ethics, the timing of delivery should be planned as soon as the diagnosis of severe or critical COVID-19 has been made. Advance directives are also an important preventive ethics tool.<sup>33</sup> In cases of lost capacity to participate in the informed consent process and state their decisions, the patient can appoint someone who will act as their decision maker, and communicate their decisions timely to this individual.

### III. Ethical issues regarding the inclusion of pregnant women in COVID-19 treatment trials

Historically, pregnant women were considered a specific population whose inclusion in clinical research should be done with much consideration. In fear of fetal harm, pregnant women and non-pregnant women of childbearing age were excluded from all clinical trials until the 1993 Council for International Organizations of Medical Sciences declared such an approach unjust. In the USA, pregnant women were removed from the list of vulnerable populations only recently, in 2018.<sup>34</sup>

There are several considerations regarding pregnant women and their inclusion in clinical trials. Physiological and anatomical changes accompanying pregnancy might alter responses to pharmacological agents and increase the risks of morbidity and mortality from infectious diseases compared to the general population.<sup>35,36</sup> Assessment of acceptable risks for women to expose themselves during pregnancy and the impact of those decisions on the well-being of their future newborns should be done prior to inclusion.<sup>37</sup> In addition, pregnant women's interests and actions are often the subject of public ethical debate. Society's values and beliefs about women's autonomous choices during pregnancy are often at odds with women's reported interests and priorities.

Multiple calls for inclusion of pregnant women in clinical trials and surveillance studies have recently been published supporting consensus views of numerous medical societies and organizations, including the American College of Obstetricians and Gynecologists, Society for Maternal-Fetal Medicine, American Academy of

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Disease 2019 (COVID-19)," *Journal of Perinatal Medicine* 49 (2021), 650-655. <https://doi.org/10.1515/jpm-2021-0254>.

<sup>33</sup> Frank A. Chervenak, and Laurence B. McCullough, "The Unlimited-Rights Model of Obstetric Ethics Threatens Professionalism," *BJOG: An International Journal of Obstetrics & Gynaecology* 124 (2017): 1144-47. <https://doi.org/10.1111/1471-0528.14495>.

<sup>34</sup> Bethany Bruno, David I. Shalowitz, and Kavita Shah Arora, "Ethical Challenges for Women's Healthcare Highlighted by the COVID-19 Pandemic," *Journal of Medical Ethics* 47 (2021): 69-72. <https://doi.org/10.1136/medethics-2020-106646>.

<sup>35</sup> Alicia M. Siston, Sonja A. Rasmussen, Margaret A. Honein, Alicia M. Fry, Katherine Seib, William M. Callaghan, Janice Louie, et al., "Pandemic 2009 Influenza A(H1N1) Virus Illness among Pregnant Women in the United States," *JAMA* 303 (2010): 1517. <https://doi.org/10.1001/jama.2010.479>.

<sup>36</sup> Priya Soma-Pillay, Catherine Nelson-Piercy, Heli Tolppanen, and Alexandre Mebazaa, "Physiological Changes in Pregnancy," *Cardiovascular Journal of Africa* 27 (2016): 89-94. <https://doi.org/10.5830/cvja-2016-021>.

<sup>37</sup> Ruth Farrell, Marsha Michie, and Rachel Pope, "Pregnant Women in Trials of COVID-19: A Critical Time to Consider Ethical Frameworks of Inclusion in Clinical Trials," *Ethics & Human Research*, 42 (2020): 17-23. <https://doi.org/10.1002/eahr.500060>.



Pediatrics, etc.<sup>38,39,40,41</sup> The fact that the largest multicenter trials (which include the WHO-sponsored SOLIDARITY trial in more than 90 countries; ISRCTN83971151; the National Institutes of Health NIH-sponsored ORCHID (hydroxychloroquine; NCT04332991 and ACTT remdesivir; NCT04280705 trial), all excluded pregnant women in their original protocol (Whitehead and Walker 2020) further illustrate this problem.<sup>42</sup> There have been some recent advances in the revision of inclusion protocols for pregnant women, but still, a high number of trials list pregnancy as an exclusion criterion.<sup>43</sup> During COVID-19 pandemic, pregnant and lactating women became a highly vulnerable population. Systematically excluded from clinical trials, their access to evidence-based care and potentially life-saving treatment is severely limited.

It became obvious that, during the COVID-19 pandemic, existing principles for including pregnant women in research should be revised. To prevent and manage the SARS-CoV-2 infection, pregnant women must be able to make autonomous, informed decisions about participating in clinical and vaccine trials. This would help understand the efficacy and side effects of potential treatment and improve understanding of pregnancy and perinatal-associated transmission of the SARS-CoV-2 virus.

#### IV. Ethical issues regarding COVID-19 vaccination during pregnancy

In 2019, Pregnancy Research Ethics for Vaccines, Epidemics, and New Technologies Working Group published a document concerning ethical guidance for preparedness, research, and response for pregnant women and vaccines against emerging epidemic threats.<sup>44</sup> A number of specific strategies to promote the ethically responsible, socially just, and respectful inclusion of the interests of pregnant women in the development and deployment of vaccines against emerging pathogens were described. In the same

<sup>38</sup> Sharon Einav, Mariachiara Ippolito, and Andrea Cortegiani, “Inclusion of Pregnant Women in Clinical Trials of COVID-19 Therapies: What Have We Learned?” *British Journal of Anaesthesia*, 125(2020): e326–e328. <https://doi.org/10.1016/j.bja.2020.05.020>.

<sup>39</sup> Maged M. Costantine, Mark B. Landon, and George R. Saade, “Protection by Exclusion,” *Obstetrics & Gynecology*, 136(2020):26–28. <https://doi.org/10.1097/aog.0000000000003924>.

<sup>40</sup> Diana W. Bianchi, Lisa Kaeser, and Alison N. Cernich, “Involving Pregnant Individuals in Clinical Research on COVID-19 Vaccines,” *JAMA* 325 (2021): 1041. <https://doi.org/10.1001/jama.2021.1865>.

<sup>41</sup> Laura E. Riley, and Denise J. Jamieson, “Inclusion of Pregnant and Lactating Persons in COVID-19 Vaccination Efforts,” *Annals of Internal Medicine* 174 (2021): 701–702. <https://doi.org/10.7326/m21-0173>.

<sup>42</sup> Clare L. Whitehead, and Susan P. Walker, “Consider Pregnancy in COVID-19 Therapeutic Drug and Vaccine Trials,” *The Lancet*, 395(2020): e92. [https://doi.org/10.1016/s0140-6736\(20\)31029-1](https://doi.org/10.1016/s0140-6736(20)31029-1).

<sup>43</sup> Melanie M. Taylor, Loulou Kobeissi, Caron Kim, Avni Amin, Anna E. Thorson, Nita B. Bellare, Vanessa Brizuela, et al., “Inclusion of Pregnant Women in COVID-19 Treatment Trials: A Review and Global Call to Action,” *The Lancet Global Health* 0 (2020): E366-E371. [https://doi.org/10.1016/S2214-109X\(20\)30484-8](https://doi.org/10.1016/S2214-109X(20)30484-8).

<sup>44</sup> Carleigh B. Krubiner, Ruth R. Faden, Ruth A. Karron, Margaret O. Little, Anne D. Lyerly, Jon S. Abramson, Richard H. Beigi, et al., “Pregnant Women & Vaccines against Emerging Epidemic Threats: Ethics Guidance for Preparedness, Research, and Response,” *Vaccine*, 39(2019): 85–120. <https://doi.org/10.1016/j.vaccine.2019.01.011>.

year, The WHO Scientific Advisory Group of Experts suggested the document should be extended to lactating women.<sup>45</sup>

The COVID-19 pandemic seems to be far from over. There is no certainty about short-term and long-term burden of COVID-19 in pregnant women, the fetus, and infants in population and specific ethnic groups. The extent of the asymptomatic or mild infection effect of COVID-19 on miscarriage, intrauterine fetal growth restriction, congenital anomalies, long-term growth, and neurodevelopmental outcomes is unknown.<sup>46</sup> Due to previously described maternal and fetal complications in severe cases of COVID-19, there is a need to include pregnant and lactating women in the development of COVID-19 vaccines. This will provide clear benefits and ultimately protect the mother, fetus, and newborn from severe cases of the disease. Early data from a few preliminary trials for mRNA vaccines are encouraging. There are no significant adverse effects, and short-term obstetric and neonatal outcomes are favorable.<sup>47,48,49</sup> Despite strong support for recommending COVID-19 vaccines, caution must be taken when administering them to pregnant and lactating women in the absence of more safety data. Also, it is crucial that available vaccine safety data in one population should not be directly extrapolated to another population.

Another ethical issue that should be considered is if pregnant women want to participate in vaccine trials and if they are open to being vaccinated at all. A multinational, cross-sectional, web-based study was performed in six European countries (Belgium, Norway, Netherlands, Switzerland, Ireland and UK) between April and July 2020. and included 16,063 women who participated (6661 pregnant and 9402 breastfeeding women). COVID-19 vaccine hesitancy was identified among 40–50% of the respondents at the end of the first wave of the pandemic and was higher among pregnant women. Education level and employment status were associated with vaccine hesitancy.<sup>50</sup> Certain positive predictors of SARS-CoV-2

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<sup>45</sup> World Health Organization, “Meeting of the Strategic Advisory Group of Experts on Immunization, October 2018 – Conclusions and recommendations,” *Weekly Epidemiological Record* 93 (2018): 661 - 679.

<sup>46</sup> Paul T. Heath, Kirsty Le Doare, and Asma Khalil, “Inclusion of Pregnant Women in COVID-19 Vaccine Development,” *The Lancet Infectious Diseases* 20 (2020): 1007–1008. [https://doi.org/10.1016/S1473-3099\(20\)30638-1](https://doi.org/10.1016/S1473-3099(20)30638-1).

<sup>47</sup> Peretz Bookstein, S., N. Regev, L. Novick, M. Nachshol, E. Goffer, A. Ben-David, K. Asraf, et al. 2021. “Short-Term Outcome of Pregnant Women Vaccinated by BNT162b2 mRNA COVID-19 Vaccine,” *Ultrasound in Obstetrics & Gynecology* (2021)<https://doi.org/10.1002/uog.23729>.

<sup>48</sup> Tom T. Shimabukuro, Shin Y. Kim, Tanya R. Myers, Pedro L. Moro, Titilope Oduyebo, Lakshmi Panagiotakopoulos, Paige L. Marquez, et al., “Preliminary Findings of MRNA Covid-19 Vaccine Safety in Pregnant Persons,” *New England Journal of Medicine*, 384 (2021):2273-2282 <https://doi.org/10.1056/nejmoa2104983>.

<sup>49</sup> Gilbert G. G. Donders, Svitrigaile Grinceviciene, Kai Haldre, Risa Lonnee-Hoffmann, Francesca Donders, Aristotelis Tsiakalos, Albert Adriaanse, et al., “ISIDOG Consensus Guidelines on COVID-19 Vaccination for Women Before, during and after Pregnancy,” *Journal of Clinical Medicine*, 10 (2021): 2902 <https://doi.org/10.3390/jcm10132902>.

<sup>50</sup> Michael Ceulemans, Veerle Foulon, Alice Panchaud, Ursula Winterfeld, Léo Pomar, Valentine Lambelet, Brian Cleary, et al. 2021. “Vaccine Willingness and Impact of the COVID-19 Pandemic on Women’s Perinatal Experiences and Practices—a Multinational, Cross-Sectional Study Covering the

vaccine acceptance were identified in another study: age older than 40 years, a higher educational level, history of influenza vaccination within the previous year, having an obstetrician as the primary healthcare practitioner, and being in their third trimester of pregnancy.<sup>51</sup>

To deprive somebody of their opportunity to participate in research or make medical evidence-based decisions because of a natural condition could also be deemed unequal and unjust. The exclusion of pregnant and lactating women from vaccine trials leaves women and healthcare workers without the necessary evidence to make a decision about vaccination. There is no other way other than to advocate for change. In order to accept a new vaccine, there has to be transparent and compelling evidence about the benefits, safety, and risks that the new vaccine implicates.

## V. Ethical issues regarding pain in pregnant women

The WHO Pain Relief Ladder recommends the administration of different pain medications, depending on the severity of pain, and is the basis of modern pain management. For mild pain, the WHO calls for basic pain relievers, usually widely available without a prescription. For mild to moderate pain, it recommends a combination of basic pain relievers and a weak opioid, such as codeine. For treating moderate to severe pain, strong opioids, such as morphine, are necessary.<sup>52,53</sup> Ethical issues regarding pain in pregnant women, especially in women with COVID-19 infection are numerous.

Severe forms of the disease imply critical care and mechanical ventilation in order to treat respiratory failure. These patients usually require a prolonged period of mechanical ventilation (3 to 4 weeks) in isolation and minimal droplet exposure.<sup>54</sup> The aim of managing critically ill patients is to preserve vital organ function and to maintain comfort and safety by sedation and pain management while preserving the patient's ability to cooperate, communicate, and engage with caregivers to facilitate

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First Wave of the Pandemic," *International Journal of Environmental Research and Public Health* 18 (7): 3367. <https://doi.org/10.3390/ijerph18073367>.

<sup>51</sup> Sarah Stuckelberger, Guillaume Favre, Michael Ceulemans, Hedvig Nordeng, Eva Gerbier, Valentine Lambelet, Milos Stojanov, et al. "SARS-CoV-2 Vaccine Willingness among Pregnant and Breastfeeding Women during the First Pandemic Wave: A Cross-Sectional Study in Switzerland," *Viruses*, 13 (2021): 1199. <https://doi.org/10.3390/v13071199>.

<sup>52</sup> V. Ventafridda, Saita, L., Ripamonti C., and De Conno F., "WHO Guidelines for the Use of Analgesics in Cancer Pain," *International Journal of Tissue Reactions*, 7 (1985): 93–96. <https://pubmed.ncbi.nlm.nih.gov/2409039/>.

<sup>53</sup> Frank Brennan, Lohman, Diederik, and Gwyther, Liz, "Access to Pain Management as a Human Right," *American journal of public health* 109(2019): 61–65. <https://doi.org/10.2105/AJPH.2018.304743>

<sup>54</sup> Hannah Wunsch, "Mechanical Ventilation in COVID-19: Interpreting the Current Epidemiology," *American Journal of Respiratory and Critical Care Medicine* 202 (2020): 1–4. <https://doi.org/10.1164/rccm.202004-1385ed>.

physical and cognitive recovery.<sup>55, 56</sup> Sedation and pain management require an aggressive approach in order to prevent sudden uncontrolled agitation and/or self-extubation due to cough. In pregnant women requiring critical care, maternal and fetal mortality is high (up to 14% and 34% respectively).<sup>57</sup> Data on medication use in pregnant critically ill women are limited. Teratogenicity concerns should not influence the choice of therapy in critically ill pregnant women, but the clinical team should be mindful of the concerns of family members in this regard. There are studies that reported that the risk of fetal teratogenicity due to exposure of pregnant women to surgery and anesthesia is low, but data that are more accurate are needed.<sup>58</sup>

General anesthesia with airway instrumentation leads to aerosol generation and dispersion of viral particles, which exposes the anesthesiologists and obstetrics to the risk of COVID-19 transmission. During labor, whenever possible, neuraxial anesthesia, peripheral nerve blocks and interfascial plane blocks have become the first choice for anesthetic management of patients with COVID-19 infection.<sup>59</sup>

At the beginning of the pandemic, there were some concerns about using NSAIDs for postpartum analgesia in patients with SARS-CoV-2 infection. NSAIDs can be safely used for analgesia in postpartum women with COVID-19, which was supported by several publications.<sup>60, 61</sup> Acetaminophen is another safe medication for postpartum analgesia. Opioids should be used with caution because of the risks of respiratory depression.<sup>62</sup>

In our study, 45 pregnant women were hospitalized and underwent labor in the Obstetrics/Gynecology Hospital, Clinical-Hospital Center “Dragisa Misovic” in Serbia. We assessed pain during labor using a visual analog scale (VAS; 0-100 mm) and with Numeric Rating Scale (NRS). The VAS was arranged as a 100-mm horizontal line with 2 end points (no pain and worst pain possible). The women were asked by

<sup>55</sup> Mehta, Sangeeta, Claudia Spies, and Yahya Shehabi, “Ten Tips for ICU Sedation,” *Intensive Care Medicine* 44 (2017): 1141–43. <https://doi.org/10.1007/s00134-017-4992-9>.

<sup>56</sup> Shehabi, Yahya, Wisam Al-Bassam, Adrian Pakavakis, Brendan Murfin, and Belinda Howe, “Optimal Sedation and Pain Management: A Patient- and Symptom-Oriented Paradigm,” *Seminars in Respiratory and Critical Care Medicine* 42 (2021): 98–111. <https://doi.org/10.1055/s-0040-1716736>.

<sup>57</sup> Vasquez, Daniela N., Andrea V. Das Neves, Laura Vidal, Miriam Moseinco, Jorge Lapadula, Graciela Zakalik, Analía Santa-Maria, et al., “Characteristics, Outcomes, and Predictability of Critically Ill Obstetric Patients: A Multicenter Prospective Cohort Study,” *Critical Care Medicine* 43 (2015): 1887–97. <https://doi.org/10.1097/CCM.0000000000001139>.

<sup>58</sup> Kazuyoshi Aoyama, Gareth Seaward, and Stephen E. Lapinsky, “Fetal Outcome in the Critically Ill Pregnant Woman,” *Critical Care* 18 (2014): 307. <https://doi.org/10.1186/cc13895>.

<sup>59</sup> Melissa E. Bauer, Kyra Bernstein, Emily Dinges, Carlos Delgado, Nadir El-Sharawi, Pervez Sultan, Jill M. Mhyre, and Ruth Landau, “Obstetric Anesthesia during the COVID-19 Pandemic,” *Anesthesia and Analgesia* 131 (2020): 7–15. <https://doi.org/10.1213/ANE.00000000000004856>.

<sup>60</sup> WHO, “The Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in Patients with COVID-19.” (2020) [https://www.who.int/news-room/commentaries/detail/the-use-of-non-steroidal-anti-inflammatory-drugs-\(nsaids\)-in-patients-with-covid-19](https://www.who.int/news-room/commentaries/detail/the-use-of-non-steroidal-anti-inflammatory-drugs-(nsaids)-in-patients-with-covid-19) (accessed July 14, 2021)

<sup>61</sup> Jungchan Park, Seung-Hwa Lee, Seng Chan You, Jinseob Kim, and Kwangmo Yang, “Non-Steroidal Anti-Inflammatory Agent Use May Not Be Associated with Mortality of Coronavirus Disease 19,” *Scientific Reports* 11 (2021): 5087. <https://doi.org/10.1038/s41598-021-84539-5>.

<sup>62</sup> Rohan D’Souza, Rizwana Ashraf, Hilary Rowe, Jonathan Zipursky, Lauren Clarfield, Cynthia Maxwell, et al., “Pregnancy and COVID-19: Pharmacologic Considerations,” *Ultrasound in Obstetrics & Gynecology* 57 (2021): 195–203. <https://doi.org/10.1002/uog.23116>.

a physician to place a mark on the line at a point which they feel that represents the intensity of their pain. The VAS was scored by measuring from no pain to the point selected on the scale. Information and explanations on how to use the VAS scale were provided to women upon hospital admittance. Measurements were made when contraction started and repeated every 2 hours. It was measured before the labor, and every two hours after labor (24 hours after labor). There were no differences between COVID-19 and non-COVID-19 women in the pain measurement by VAS scale during the labor. There were no differences in the level of arthralgia and myalgia between these two groups. The Numeric Rating Scale (NRS) is the simplest and most commonly used numeric scale in which the patient rates the pain from 0 (no pain) to 10 (worst pain). The results of NRS between COVID-19 patients during labor are presented in Figure 3. There were no significant differences between COVID-19 and non-COVID-19 pregnant women in NRS in terms of labor.

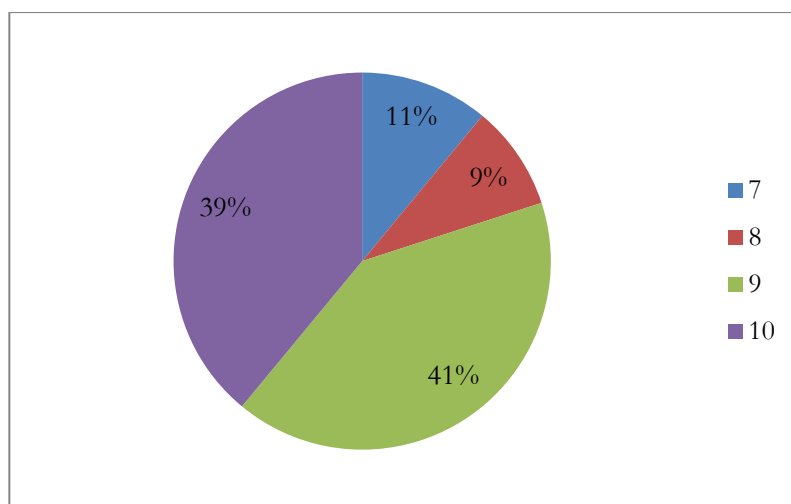


Figure 3. Numerical scale of pain in labor in patients with COVID-19 infection

In recent years, there have been numerous researches about pregnant women’s autonomy in decision-making during labor. It was observed that the standard or routine care practices limit the autonomy of decision making during labor and childbirth.<sup>63</sup> It is presumed that women in labor are incapable of deciding the care they need, and therefore are forced to accept the care and treatment imposed by health workers. Women who want to make decisions about process of labor, perinatal and postpartum care that differ from those suggested by healthcare

<sup>63</sup> Ibone Olza, Patricia Leahy-Warren, Yael Benyamini, Maria Kazmierczak, Sigfridur Inga Karlsdottir, Andria Spyridou, Esther Crespo-Mirasol, et al., “Women’s Psychological Experiences of Physiological Childbirth: A Meta-Synthesis,” *BMJ Open* 8 (2018): e020347. <https://doi.org/10.1136/bmjopen-2017-020347>.

professionals are often labeled as selfish or irresponsible.<sup>64</sup> Some obstetrics interventions may not be needed, but are still performed sometimes without proper informed consent (like abusive use of oxytocin, Kristeller's manoeuvre, or episiotomy). It was also observed that non-use of pain relief methods and analgesia in childbirth was frequent. When a health professional trivializes or does not consider physical complaints of the patient, believing that the pain of childbirth is necessary, there are serious concerns of inflicted imposition and even violence.<sup>65</sup>

Clearly, the recognition and full implementation of women's rights by the health workers, along with changes in the perception of those involved in childbirth regarding the conceptual and ethical aspects of women's autonomy regarding their own bodies and childbirth should be made.

## VI. Ethical issues regarding mental health during pregnancy and the postpartum period

The COVID-19 pandemic is a period of unique challenge for both – pregnant women and medical staff who care for the reproductive health and mental health of pregnant women and women in the postpartum period. Starting from the period of planning the pregnancy and during the pregnancy itself, as well as the months following the birth, it is necessary to have a specific approach, to provide adequate social support, as well as medical care - in order to prevent potential risks to the somatic and mental health of future mothers. On the one hand, unreliable data on the impact of maternal infection on the fetus, limited therapeutic possibilities for treating COVID infection, with difficult access to doctors and professional information (due to their engagement in COVID centers) have led to delaying pregnancy or at least having difficulty deciding on this step. On the other hand, measures about restricted movement and staying indoors, with individual fear of getting the infection, lead to personal decisions to reduce visits to doctors only when it is necessary and urgent. According to a survey conducted by Micelli and colleagues in 2020 in Italy, even a third of respondents gave up their intention to have progeny during a pandemic.<sup>66</sup> Pregnancy and childbirth themselves are particularly vulnerable conditions in which a woman is disposed to relapses or deterioration of an existing psychiatric illness. The most common are mood disorders, depression, and anxiety.<sup>67</sup> Symptoms of depression, no matter if they were caused by pregnancy or they appeared more recently, still have a negative impact on the pregnancy itself and the

<sup>64</sup> Rakime Elmir, Virginia Schmied, Lesley Wilkes, and Debra Jackson, "Women's Perceptions and Experiences of a Traumatic Birth: A Meta-Ethnography," *Journal of Advanced Nursing* 66 (2010): 2142–2153. <https://doi.org/10.1111/j.1365-2648.2010.05391.x>.

<sup>65</sup> Thamiza Laureany da Rosa Dos Reis, Stela Maris de Mello Padoin, Thayla Rafaella Pasa Toebe, Cristiane Cardoso de Paula, and Jacqueline Silveira de Quadros, "Women's Autonomy in the Process of Labour and Childbirth: Integrative Literature Review," *Revista Gaucha de Enfermagem* 38 (2017): e64677. <https://doi.org/10.1590/1983-1447.2017.01.64677>.

<sup>66</sup> E. Micelli, Cito G, Cocci A, Polloni G, Russo GI, Minervini A, Carini M, et al., "Desire for parenthood at the time of COVID-19 pandemic: an insight into the Italian situation," *J Psychosom Obstet Gynaecol* 41(2020):183–190. <https://doi.org/10.1080/0167482X.2020.1759545>.

<sup>67</sup> M. N. Norhayati, Hazlina NH, Asrenee AR, and Emilin WM, "Magnitude and risk factors for postpartum symptoms: a litpandemicture review," *J Affect Disord* 175 (2015):34–52.

recovery period after childbirth, which in turn can cyclically deepen the mental disorder. There are numerous findings on the negative impact of maternal depression on the later emotional development of the child.<sup>68, 69, 70</sup>

If we know that the probability of postpartum depression is higher if a pregnant woman is exposed to traumatic events – whether it is personal trauma or global catastrophe – then it is clear why there has been registered a high prevalence of postpartum depression during COVID 19 pandemic.<sup>71</sup>

Earlier studies, about the topic of the occurrence of mental disorders in connection with pregnancy and childbirth, indicate the importance of the style of achieving close emotional connections. So, anxious and dismissive styles of attachment are more often associated with the development of PTSD disorders. Lack of support and help from loved ones is more often associated with the development of postpartum depression. Quarantine measures, which, on the one hand, lead to the restriction of broader social relations, on the other hand, keep people indoors more time, which leads to the fact that household members necessarily spend more time together and that can potentially strengthen the attachment among household members. This indirect effect of restrictive quarantine measures can lead to greater emotional security of the mother, which can also be seen as a protective effect on the mental health of the mother. Some studies record lower rates of postpartum depression during periods of the strongest epidemic waves. However, more time together in quarantine conditions can lead to increased conflicts and even to an increase in violent behaviors, which has been proven to increase the risk of mental disorders.<sup>72</sup>

Shorter hospital stays, which are, again, conditioned by preventive pandemic measured, can also be considered as a factor that reduces the probability of postpartum mood disorders.<sup>73,74</sup> Protective equipment, protective suits, masks, and visors limit the appropriate emotional mimicry exchange of information between patients and medical staff, which can increase the feeling of isolation, and lead to an increase in stress anxiety, and depression. Still, according to experts, the crucial importance for the development of postpartum depression has prenatal negative

<sup>68</sup> Sion M. Yedid, Harlev A, Weintraub AY, Sergienko R, Sheiner E “Is antenatal depression associated with adverse obstetric and perinatal outcomes?” *J Matern Fetal Neonatal Med* 29 (2016):863–867.

<sup>69</sup> L. M. Howard, Molyneaux E, Dennis CL, Rochat T, Stein A, and Milgrom J, “Non-psychotic mental disorders in the perinatal perio,” *Lancet* 384 (2014):1775–1788.

<sup>70</sup> S. K. Brooks, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, and Rubin GJ, “The psychological impact of quarantine and how to reduce it: rapid review of the evidence,” *Lancet* 395 (2020):912-920. [https://doi.org/10.1016/S0140-6736\(20\)30460-8](https://doi.org/10.1016/S0140-6736(20)30460-8).

<sup>71</sup> V. Zanardo, Manghina V, Giliberti L, Vettore M, Severino L, Straface G, “Psychological impact of COVID-19 quarantine measures in northeastern Italy on mothers in the immediate postpartum period,” *Int J Gynaecol Obstet* 150 (2020):184-188. doi: 10.1002/ijgo.13249.

<sup>72</sup> M. Almeida, Shrestha, A., Stojanac, D. et al. “The impact of the COVID-19 pandemic on women’s mental health,” *Arch Women’s Ment Health* 23 (2020): 741–748 <https://doi.org/10.1007/s00737-020-01092-2>.

<sup>73</sup> L. Ostacoli, Cosma S, Bevilacqua F, Berchiolla P, Bovetti M, Carosso AR, Malandrone F, et al., “Psychosocial factors associated with postpartum psychological distress during the Covid-19 pandemic: a cross-sectional study,” *BMC Pregnancy Childbirth* 20 (2020):703. doi: 10.1186/s12884-020-03399-5.

<sup>74</sup> I. Brockington, “Postpartum psychiatric disorders,” *Lancet* 363 (2004):303–31.

experiences. In the study, where were compared pregnant women with high-risk pregnancies, who were hospitalized before the outbreak of the pandemic, with those who were hospitalized for the same reasons at the time of the pandemic, no difference was found in the number of women suffering from mental illness.<sup>75, 76</sup>

As the degree of trauma exposure is a significant factor for the development and manifestation of PTSD symptoms, restrictive quarantine measures and social isolation can be considered as protective factors for pregnant women during a pandemic.<sup>77,78</sup> The postpartum period brings new worries again. One of the sources of the tension that mothers can feel in this period is the potential separation anxiety - due to the risk of separation from the baby, but also due to the unknown treatments in the case of COVID-19 and the risks that those treatments carry. The question of the safety and importance of breastfeeding during a pandemic creates additional anxiety, especially for infected mothers. Some findings indicate that there is a risk of transmitting the infection through breast milk, but it is cited in the study that its limitation is the fact that mothers breastfed without a protective mask. Pediatric associations generally recommend breastfeeding because of all potential benefits, but with respecting hygienic measures.<sup>79</sup>

The lack of help and support from older grandparents, due to the restriction of social contacts, also contributes to feelings of sadness and increased anxiety in the postpartum period. The existential and economic problems that the pandemic brings do not prevent pregnant women, so they represent additional factors that affect their mental well-being. Single mothers are certainly at higher risk during this period.

All these factors and dilemmas related to pregnancy in a pandemic increase fear and concern along with those already existing, risk factors based on biological and psychological vulnerability, as well as specific socio-economic and cultural circumstances. They all together contribute to the risk of developing psychiatric disorders related to pregnancy and childbirth, especially postpartum depression.

## VII. Conclusion

The COVID-19 pandemic made us focus on specific weaknesses of medical research and medical care of pregnant women. Care and treatment recommendations, informed decision making, and consent are based on insufficient evidence due to the exclusion of pregnant women from clinical and vaccine trials. Data from the literature to support certain therapy options are also lacking. Decisions regarding treatment,

<sup>75</sup> S. Sade, Sheiner E, Wainstock T, Hermon N, Yaniv Salem S, Kosef T, Lanxner Battat T, et al., "Risk for depressive symptoms among hospitalized women in high-risk pregnancy units during the COVID-19 pandemic". *J Clin Med* 9 (2020):2449.

<sup>76</sup> J. Milgrom, Hirshler Y, Reece J et al., "Social support—a protective factor for depressed perinatal women?" *Int J Environ Res Public Health* 16 (2019): 1429.

<sup>77</sup> D. M. Fergusson, Horwood LJ, Boden JM, Mulder RT, "Impact of a major disaster on the mental health of a well-studied cohort," *JAMA Psychiatry* 71 (2014): 1025–1031.

<sup>78</sup> L. M. Matthies, Müller M, Doster A, Sohn C, Wallwiener M, Reck C, Wallwiener S, "Maternal-fetal attachment protects against postpartum anxiety: the mediating role of postpartum bonding and partnership satisfaction," *Arch Gynecol Obstet* 301 (2020): 107–117.

<sup>79</sup> <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/breastfeeding-guidance-post-hospital-discharge/>. Accessed 18 Sept 2020



labor and postnatal care in pregnant COVID-19 patients should be made by the patient and the clinical team, considering the safety of the procedure for the woman and the fetus and the severity of maternal disease. Pregnant women should be empowered to make informed decisions based on the best available, critically appraised evidence. Health professionals must also have high regard for pregnant patients' autonomy to make decisions about their conditions and treatment.

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# PSYCHIATRY, ETHICS AND COVID-19 IN HUNGARY

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## Abstract

Psychiatric service has always been sensitive to ethical perspectives. It became relevant in the COVID-19 pandemic as well. From an ethical angle, different service levels can be investigated. We divided our investigation into three layers, and analysed each one through the lens of the main types of rationing: macro-and microallocation. We classified the first layer as ‘the social’ in which, at the beginning, a lot of resources (beds, nurses, physicians, etc.) were taken from psychiatry as well as to support the disease-related services according to the governmental orders. The second layer is the ‘local hospital and outpatient system’, wherein the main question was where and until when to treat the COVID -19 infected psychiatric patients. Should they be treated among other infected patients, or within specialised departments or wards? The third layer is the ‘interpersonal’ level, reflecting on the different angles of real patient-physician interactions and the most common human conflicts within the medical staff on site.

## I. Introduction

The COVID-19 pandemic has highlighted many ethical aspects of medicine in various fields (preventive, curative, palliative, biomedical research, etc.). Almost all principles of medical ethics were relevant under these controversial and unusual circumstances. To mention a few: the beneficence and non-maleficence principles emerged in relation to off label treatments.<sup>1</sup> In regard to preventive medicine, vaccinations raised many questions and misbeliefs, such as if immunization of people causes more harm than benefits. Instead of accepting the up-to-date treatment

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<sup>1</sup> Kalil A. C. “Treating COVID-19—off-label drug use, compassionate use, and randomized clinical trials during pandemics.” *JAMA*. (2020) 323 (19):1897-1898. doi: 10.1001/jama.2020.4742.



options, some healthcare workers even spread ideas about denying the existence of the COVID pandemic. Their attitude is worrisome from a moral point of view as well. In addition, patients' autonomy was strictly restricted due to the collective/social interests. In connection with that, all the confusing information of the "info-demic" did not help lay people to make autonomous decisions, and hindered the essentially important practice of informed consent. Finally, justice has also been a central topic since the very beginning of the pandemic outbreak. Furthermore, a special term, the "Bergamo effect" was coined<sup>2,3</sup> to describe the breakdown of a healthcare system that cannot serve society's unexpectedly increased medical needs. The pandemic highlighted how essential the reflection on the ethical, philosophical, and economic aspects of distributive justice was. The scenarios of 'disaster bioethics' that most Hungarian healthcare workers have only seen in books became a real-life experience. They had to implement their knowledge regarding the ethically appropriate ways of macro-and microallocation.

Later, this topic emerged in the debate on the distribution of vaccines.<sup>4</sup> Despite the fact that people trusted and supported comprehensive restrictions in their everyday lives, shortly after the Hungarian authorities confirmed the first few COVID-19-positive cases<sup>5</sup>, their global attitude changed significantly. Boosted by the internet (at least in Hungary) we realised that almost everyone had become an "expert" in medical ethics, epidemiology and pandemic health care, possessing the "lapis philosophorum" (the philosopher's stone- the fundamental solution). This situation resulted in Babylonian chaos and supported the rapid spread of various conspirational theories ("pandemic denial," "China intentionally infected humanity," "pharmaceutical companies created the virus itself," "vaccines contain microchips", etc.) resulting in vaccine hesitancy.<sup>6</sup>

In psychiatry, all of the above-mentioned aspects have been presented, sometimes in specific or even extreme ways.<sup>7</sup>

This paper will summarise our experience in this field, primarily focusing the readers' attention on the ethical-legal challenges related to psychiatric care in Hungary.

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<sup>3</sup> Jaziri R. & Alnahdi S. "Choosing which COVID-19 patient to save? The ethical triage and rationing dilemma." *Ethics, Medicine and Public Health*. (2020) 15:100570. 1-12. doi: 10.1016/j.jemep.2020.100570. 15.

<sup>4</sup> Grossman V. A. "The COVID-19 Vaccine: Why the Hesitancy?" *Journal of Radiology Nursing* (2021) 40(2):116-119. doi: 10.1016/j.jradnu.2021.02.011.

<sup>5</sup> Szabo A., Ábel K., Boros Sz. "Attitudes toward COVID-19 and stress levels in Hungary: Effects of age, perceived health status, and gender." *Psychological Trauma*. (2020) 12(6):572-575. doi: 10.1037/tra0000665.

<sup>6</sup> Bíró-Nagy A. & Szászi Á. J. "The Roots of COVID-19 Vaccine Hesitancy: Evidence from Hungary." *Journal of Behavioral Medicine* (2022) 14;1-16. doi: 10.1007/s10865-022-00314-5.

<sup>7</sup> American Psychiatric Association (APA). "COVID-19 Related Opinions of the APA Ethics Committee" APA (2021) 1-11. Retrieved Nov. 3, 2022, from [www.psychiatry.org/File%20Library/Psychiatrists/Practice/Ethics/APA-COVID-19-Ethics-Opinions.pdf](http://www.psychiatry.org/File%20Library/Psychiatrists/Practice/Ethics/APA-COVID-19-Ethics-Opinions.pdf).

## **II. The ethical perspective of psychiatry in Hungary**

As we tried to collect the ethical dilemmas that had emerged since the beginning of the COVID-19 pandemic, we realized that they should be separately investigated on different service levels. Due to this realization, we divided our work into three layers.

We can refer to the first degree as the ‘social level,’ meaning the spectrum of the whole society, including the complete medical sector of the given country. The fair and sound distribution of limited medical resources (human, financial, and infrastructural) has become a central problem at this level. Certainly, the areas directly connected to this pandemic’s first-line somatic treatment gain extra monetary and human resources. The ‘social level’ does not only cover the health care system since governments had to reorganize the legislative mechanisms from the bottom to the top in each country. Therefore, COVID-19 resulted in a crisis on the level of macroallocation: re-distributing the previously set goods between the most fundamental societal agencies (education, health care, etc.) meant an unprecedented challenge in the post-war era of Hungary and its neighbouring countries.

From the perspective of mental health care - as not directly connected to the pandemic- psychiatric service became less important at the beginning. As a consequence of macroallocative decisions, a lot of capacity (human and other resources, funding, etc.) was taken to support disease-related services from psychiatry to other fields of medicine. Beds, even complete departments, were moved to serve this higher interest. Besides many other somatic departments, the psychiatric service was also deeply involved. Adjacent to the non-human resources, the reallocation of professionals was a crucial demand during the pandemic. Many nurses and physicians were directed to the COVID-affected healthcare services to reduce the crisis. Obviously, since the beginning of the reassignment of the trained nurses as well as specialists from the psychiatric clinics to the “front line”, we had to organize the care of psychiatric patients as well. Many were requested to leave the hospitals and use outpatient or internet-based, telemedical services. This sounds bad at first, but in our experience, most patients could cooperate since they wanted to leave the inpatient care for fear of being infected.

As we experienced later on, the need for mental help had grown gradually, and this demand affected the acute and post-COVID patients as well. Besides the direct medical results of the pandemic (near-death experiences, PTSD, etc.), grief and fear of quarantine, unemployment, and financial effects have also emerged as consequences of COVID-19. All these phenomena highlighted the psychological aspects and the growing need for mental help services. Overall, as a conclusion of professional analysis of the unusual public health crisis, our colleagues decided to restrict mental services (especially inpatient care), and a kind of “forced NON-hospitalisation” practice became a routine. The outpatient care was emphasised, thereby first using the contact-free telephone services, and later the different online video calling platforms emerged. From the ethical point of view, it is crucial to emphasize that the prioritization of somatic COVID departments and the re-distribution of human and financial resources as a consequence of the pandemic was an explicit, transparent form of macroallocation.

Let us highlight the second level of the ethical layers in regard to the most typical transformation of the local hospital and outpatient care that we referred to as the level of the 'local hospital and outpatient system'. Outpatient psychiatric care remained effective by changing personal interactions to telemedical service. Phone calls became the easiest and cheapest, therefore the most widely used form to satisfy the everyday needs of our well-balanced patients (prescribing medications, keeping contacts, etc.). Most of the patients who had ongoing psychotherapy could have adapted to telemedical care as well, however it was challenging to find the best online platform. Financial barriers made this process even more complicated since our colleagues who provided mental health services did not get any monetary support from the local hospitals, nor from the government, to buy a Zoom account, for instance. Patients who continued the online consultations had to face some ethically and legally stressful obstacles, such as creating a safe private space when consulting their doctor. Often, it was impossible because of the presence of relatives at the time of the meetings. Hence, private and confidential information sharing was arduous, according to our patients.

Nonetheless, at the end of the first wave of the pandemic, although only to a limited extent, but the question of how to care in need of acute hospitalisation, remained unresolved. The main problem was where to cure the COVID-19-infected acute psychiatric patients. Because of the lack of previous experience, there were no centrally issued recommendations (e.g.: governmental or professional, like by the Hungarian Psychiatric Association or Hungarian Medical Chamber) to apply immediately, so in different hospitals different solutions were developed.<sup>8</sup> The moral and legal idea(l) of equal access to health care according to the patients' medical needs - regardless of their location - did not work because of several reasons (infrastructural/financial/HR-limitations/lack of unified national psychiatric care-specific guidelines).

In many cases it seemed obvious, to treat them in the specialised COVID departments, like other infected patients. It seemed evident at first, but in cases of psychiatric patients with severe symptoms, that form of hospitalization meant physical restrictions and resulted in the suspension of effective psychological help. As a consequence, the dignity and autonomy of these patients with severe psychiatric but mild COVID symptoms were highly impaired, hence many colleagues experienced different levels of moral distress because they could not provide the best, client-specific treatments.

In some hospitals, other solutions were developed. In Bács-Kiskun County Hospital, we suggested creating a COVID subdepartment within the Psychiatric Department. Of course, the patients who needed continuous respirational support were transferred to the somatic COVID department, but their acute mental/psychiatric needs were limited by the presence of the infection. On the other side, we have to emphasize that many of the acute psychiatric patients with mild COVID symptoms, could stay in psychiatric care, hence we favoured regularly

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<sup>8</sup> All things considered, the Hungarian Medical Chamber reacted as fast as they could to the pandemic and published an online guideline in April 2020 to help bedside doctors concerning the ethically appropriate ways of resource allocation.

monitoring their general condition to be able to apply the principle of beneficence the most: fulfilling their infection and mental health-related needs at the same time. Later, as the pressure increased on the health care system, many patients with dementia and elderly somatic patients with mild COVID symptoms were asked to be transferred to our Psychiatric Department. It should be mentioned at this point that even other hospitals where psychiatric care was severely restricted in our county, especially from the south and southeast regions, reached out to us to help them because they heard we created this special unit dedicated to COVID-infected patients who are otherwise in need of continuous psychiatric care. From the ethical perspective, the highest level of autonomy and dignity was preserved in this way- and proper treatment could be delivered to the affected patients.

As mentioned already, the positive consequences of such specialized care are obviously in accordance with the most fundamental principles of bioethics. We could remain in accordance with core components of the principle of justice (transparent medical decision-making, rationing) if we had to decide who to send home and who to keep being hospitalized, or who to transfer to the somatic COVID-department from our COVID subdepartment. Personalized, well-explained medical decision-making for the patients was the gold standard of rationing in regard to microallocation.

In addition, the limitations of our practice should also be highlighted. The negative aspect of this system was that it required higher resources for the psychiatric department. To develop this special subdepartment, the ventilation system and the special disinfection were just some of the challenges to be solved. On the other hand, here in our specialized unit, all of the doctors and nurses had to use special protective clothes and equipment, which also meant a higher number of nurses on duty, in accordance with the prescribed frequent turns of shifts.<sup>9</sup>

Another problem was the need for separated transitional units, in which the patients whose COVID status is unsure had to wait until the reliable PCR test results arrived. In summary, our experience supports the benefits of such sub-departments belonging to psychiatric services.

As a limitation, however we must note that in case of such a specialized form of care extra human and non-human resources should be applied, hence probably not all psychiatric departments, but only some assigned centres would be able to fulfil the medical need of these patients.

The third layer could be the ‘interpersonal level’ wherein the ethical issues of allocation of the human resources are also presented. Despite that, we highlighted the positive aspects (transparent reorganization of health care with the intention to minimize the potential of high mortality rates) of macroallocation, we should focus on the deficiencies as well. Especially among the nurses: it was officially, systematically unregulated how to choose those colleagues who should go to the COVID departments. There was no clear, transparent guideline for the selection. Concerning microallocation, mainly implicit, unexpressed regulations, soft rationing

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<sup>9</sup> According to the official recommendations, 3 hours are allowed to be spent in such areas and clothes at a time - then the used clothes should be changed and the crew should rest.

per se has begun to work; protection of those who have little child/children, raising their child alone, have a higher risk for the complications of COVID and so forth.

The other side of the ‘interpersonal level’ was the conflict manifested in the real patient-physician interactions. COVID-related fear on the one hand and the misleading information and conspiracy theories on the other also challenged the service. Psychiatric patients are highly vulnerable in such a situation. Especially those with limited social connections, extra sensitivity, the tendency to paranoid elaboration are defenseless to such “info-demic” situations. Giving proper and credible information to our patients or helping them get the vaccination became an ethically primarily important part of our service’s inherited ethical duty. At the beginning of the pandemic, there were some particular questions raised, such as the following. Could psychiatric disorders, as chronic conditions, cause higher vulnerability to COVID complications? Should we use vaccinations for patients taking special psychiatric drugs? Could the vaccination cause psychotic relapses in patients with schizophrenia (supporting the immune theories in psychiatric etiology)? To highlight the issue of credibility and misleading concepts in regard to vaccination, we would like to summarize a case study. One Romani woman stated that COVID only endangers “white” (Caucasian) people because the immune system of the Romani people is much stronger. Hence, they do not need to be vaccinated at all. Others, supported by their religious environment, also stated that COVID and the vaccination are also related to the devil, so they denied taking the injection. These experiences highlighted the need for a larger effort to reach and inform the minorities (especially those who have received poor health education), religious groups besides the elderly population, and last but not least, psychiatric patients. Authentic, credible voices are important to persuade them.

Furthermore, we faced a lack of proficiency in internet use on our patients’ side: they are unfamiliar where and how to search for controlled up-to-date information, they are often open to misleading click baiting sites. The fact that a major part of our patient population had only basic internet skills was rather problematic since many aspects of care had become internet-dependent. The application for vaccination did not remain an exception. When we approached our clients, it turned out that many elderly or chronic patients deferred the vaccination because they needed help filling out the internet application form. It raises the questions, who is responsible for managing these situations? Social workers? Epidemiologists? Trained nurses? Doctors? Of course, we tried to help and solve their problems, but in the future, it might require a proper system. - Even by the third wave, nothing has changed in this regard. However, the Hungarian vaccination system started to acknowledge some cases in which special preparation is essential to manage some patients’ immunization (e.g. autistic people). In a pandemic situation, addressing the conflict between individual and societal interests is crucial. It is widely accepted to prioritize community needs to respect individual preferences. However, we have to consider that helping to enhance the level of protection of those who are living with severe constraints (including people with mental health issues) serves public health interests as well. Following the ethical considerations of the Royal College of Psychiatrists, we

believe that synchronizing individual and societal needs would be a particularly important ethical duty of our profession.<sup>10</sup>

“Forced dehospitalisation”, related to the reduction of psychiatric beds, and human resources, was a high debate within the psychiatrist community at the beginning. Of course, this issue mainly affected the patients who were in better condition at that time. To tell the truth, it was rather hypothetical. According to our experiences, most patients wanted to leave the hospitals because of the strong fear of the infection.

Additionally, we faced other dilemmas, especially when we had to use, or continue the hospitalisation in the patient’s medical interest. Let us approach the question in the following case. One elderly patient with Parkinson related dementia was admitted to our department, after a suicide attempt. His wife was quite afraid that the patient would get the COVID infection, but the acute suicide threat surpassed her concern. During the initial hospitalisation he got better from the psychiatric point of view, but despite of all our precautions he caught the infection and died. That case brought up question of prioritization of beneficence and non- maleficence principle versus patient autonomy so tangible.

Another question was also related to the principle of beneficence, but in a different way. Although we had COVID subdepartment for psychiatric patients, some cases challenged the clear decision making processes. What should be the best care for the patients? Where should we draw the line, or how can we balance between the somatic (COVID), and the psychiatric conditions? What would be the true medical interest of a psychiatric patient in the area of the top of the wave of the COVID-pandemic?

Another case illustrates the complexity of the question of hospitalization within these times. Our chronic schizophrenic patient with a severe psychotic relapse (the court inspection orders compulsory medical treatment) got the infection. She got pneumonia and needed to get oxygen treatment as well, but at the same time, she still had severe psychotic symptoms and showed concerning agitated behavior. The question arose: Should we transfer her to the COVID department to get proper treatment for her infection, but to a department in which it is clear that colleagues with different professional focus-points could not handle her psychotic symptoms, and will use physical restraint? Or should we keep her hospitalized in the psychiatric department? Not to mention the well described stigmatisations of the psychiatric patients in these situation.<sup>11</sup> In this case, we continued her treatment in the psychiatric department with permanent, regular pulmonological supervision, with the possibility of acute transmission to the COVID (pulmonological) department. In her case, luckily, we could control her care in the psychiatry ward.

Other moral dilemmas were related to the uncertain, COVID-suspicious cases. We had no intermedier room – (but even if we had, the question still relevant) –

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<sup>10</sup> Royal College of Psychiatrists (RCP). “COVID-19: Ethical Considerations. Particular Dilemmas for Psychiatrists” (n. d.) RCP. Retrieved Nov. 3, 2022, from <https://www.rcpsych.ac.uk/news-and-features/podcasts/detail/ethical-considerations-arising-from-covid-19> .

<sup>11</sup> Óri, D., Molnár, T., Szocsics, P., 2021. Mental health-related stigma among psychiatrists in light of Covid-19. *Asian J. Psychiatr.* (2021) 58:102620. doi: 10.1016/j.ajp.2021.102620.

therefore it was a question where to place the newcoming patient until the PCR test results arrived. We decided to manage these patients as potential COVID patients, so we decided to place them in the COVID department. But what should be done if the test result came back negative? Can we place our patient to the non-COVID part of the department after spending a couple of hours among the confirmed infected patients? These typical dilemmas meant truly challenging cases for the physicians from an ethical aspect.

Finally, we should mention another ethically and legally severe problem within the COVID subdepartments that also connects to the ‘interpersonal level’. Patients’ relatives could not visit them, and especially at the beginning of the outbreak we had to solve the question how to provide the communication and contact between them. In the case of inpatient psychiatric units, it was very hard to find the balance between the right to self-determination (providing space and time to meet with relatives) and non-maleficence (decreasing exposure to infection). The legal and ethical aspects of appropriate ways of restriction of hospitalized psychiatric patients have now been cleared in various useful guidelines; however, in the first year of the pandemic, the practice of hospitalization and ethical aspects of discharging patients from healthcare facilities were not unified.<sup>12</sup>

For months, according to a higher level regulation, it was prohibited to use their mobile telephones while hospitalized. Later, after going through some hygienic steps they had a limited access to the mobile phones of the department to keep contact with their loved ones. Of course, we tried to call all the relatives to provide up-to-date information, but this was only possible in a limited time while professionals spent their compulsory break time after finishing their COVID-shift. Especially in those periods when the inflow pressure was high, and the ward was full of patients it was quite difficult.

### III. Conclusions

All in all, we believe that it is crucial to understand that psychiatric patients were particularly vulnerable in the era of COVID-19. As Julia Stoll puts, if the majority of the population reacts with stress, anxiety and fear to the pandemic, we should presume an increased emotional response from those who have mental disorders.<sup>13</sup> According to the basic principles of bioethics, we face a moral duty to reduce the harm to our patients. Therefore, every effort has to be taken to make the treatment of psychiatric patients continuous. As Yao and his colleagues warn, those patients who underestimate the risk of the epidemic as a consequence of their disease (such as paranoia or delusional disorders) are potentially more susceptible to being infected.<sup>14</sup> Autonomy of those psychiatric patients who tested positive for COVID-

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<sup>12</sup> Belfer R., Gardner L.E., Broutman E., Alpert J.E. “Ethical and Safe Discharge from Psychiatric Units during the COVID-19 Pandemic.” *Journal of the American Academy of Psychiatry and the Law Online* (2022) 50(2):273-281. doi: 10.29158/JAAPL.210074-21.

<sup>13</sup> Stoll J., Sadler J.Z., Trachsel M. “The Ethical Use of Telepsychiatry in the COVID-19 Pandemic.” *Frontiers in Psychiatry* (2020) 14;11:665. doi: 10.3389/fpsyt.2020.00665. 1-3.

<sup>14</sup> Yao H., Chen J.H., Xu Y.F. “Patients with Mental Health Disorders in the COVID-19 epidemic” *Lancet Psychiatry* (2020) 7(4):e21. doi: 10.1016/S2215-0366(20)30090-0.21.

19 should also be restricted, and as a result, may require informal/formal quarantine or hospitalization.

We pointed out several systemic difficulties in regard to providing good-quality psychiatric care for this patient population. Hence we stress that each healthcare system has a moral responsibility to minimize their patients' chance of being infected. Let us emphasize the importance of prevention in the case of psychiatric patients from a moral point of view. First, when we organized a COVID psychiatric unit, we faced the issue of a lack of resources: our colleagues (nurses and doctors as well) had been missing from other COVID wards, too. The heads of psychiatric departments were officially called to delegate their colleagues to other healthcare facilities. The answers to the question of who got sent and who stayed remained hardly justifiable. Second, those patients who were hospitalized with psychiatric comorbidities were not able to get a comprehensive treatment, integrating the psychiatric treatments automatically.

In conclusion, it is essential to promote personalized risk reduction (e.g., regular health education and consultations via telemedicine) as a cheap alternative to minimize the independent, adherent patients' chance of infection. Eliminating the higher chance of disease transmission, Stoll also suggested promoting telepsychiatry for even those who had been ordered to go into formal quarantine<sup>13</sup> as well as the World Health Organization.<sup>15</sup> Healthcare workers, along with higher authorities, have a critical role in monitoring the care-specific guidelines and also helping their colleagues implement up-to-date recommendations for a good quality of in-and outpatient care.

Last but not least, we must emphasize the lessons we learned during these hard months. There is no doubt that establishing similar COVID centres for hospitalized psychiatric patients if a health care facility has the necessary infrastructural, financial and human resources worth the efforts. Our retrospective wisdom suggests that such centres should be organized (at least) at the county level.<sup>16</sup> However, the situation is very complicated because the real demand is unpredictable, while the resources mentioned above are needed in various other sectors of health care.

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<sup>15</sup> World Health Organization (WHO). "Implementing Telemedicine Services during COVID-19: Guiding Principles and Considerations for a Stepwise Approach. WHO (2021) 1-25. Retrieved Nov. 3, 2022, from <https://apps.who.int/iris/handle/10665/336862>.

<sup>16</sup> Hungary has 19 counties with very different population densities. Therefore, it is suggested to set up more than one COVID subdepartment in districts with high populations.



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# THE SIGNIFICANCE OF MORAL DISTRESS IN THE COVID-19 PANDEMIC

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## Abstract

After dealing with the protracted death of a patient, moral distress (MD) of health professionals may occur, particularly in times of crisis, such as the COVID-19 pandemic. Caregivers are facing an increased risk of MD during the COVID-19 pandemic because of changes in clinical practice and resource allocation procedures. MD is often equated with burnout, exhaustion, or an ethical dilemma, but it is distinct. The experience of numerous and continuous traumatic events can inflict ongoing moral injury. Distinguishing MD from other phenomena is essential in order to recognize its impact on caregivers and implement interventions to reduce its detrimental effects.

## I. Introduction

“One mark of moral progress in a community or society might well be the extent to which measures are taken to reduce the incidence of moral distress in members of that community.”  
Bartholome<sup>1</sup>

When the storms of life and unexpected illnesses catch patients and families by surprise, they rely on caregivers’ expertise, goodness and compassion to help navigate their way.<sup>2</sup> Working with the dying requires tolerance of uncertainty, ambiguity, and

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<sup>1</sup> Bartholome W., *Moral distress. Medical College of Wisconsin Bioethics Discussions*. MCW-bioethics@post.its.mcw.edu.1998; Dec 11.

<sup>2</sup> Ulrich CM, Grady C, eds. *Moral distress in the health professions* (Springer International Publishing AG, eBook 2018), doi: 10.1007/978-3-319-64626-8.

existential challenges.<sup>3</sup> Healthcare workers must recognize and respect their own limitations and attend to their own needs in order to avoid being overburdened, overly distressed, or emotionally depleted.<sup>4</sup> However, after dealing with a long, protracted death of a patient, moral distress (MD) of health professionals may occur.<sup>2,5</sup> In such circumstances, they are “like firemen going into a fire. They know they are going to get burned, yet they do it over and over again until the burns no longer hurt.”<sup>5</sup>

Although it was first observed within nursing, caregivers across all disciplines, including physicians, respiratory therapists, social workers and chaplains, experience MD.<sup>2,6</sup> It is the psychological distress that is experienced in relation to a morally challenging situation or event.<sup>6</sup> MD is especially likely to occur during public health emergencies, and in other situations when there are extreme resource limitations affecting patient care and the safety of healthcare workers.<sup>2,7,8</sup> It is often equated with burnout, exhaustion, or an ethical dilemma, but it is distinct.<sup>5</sup> When clinicians experience MD, they likely also experience burnout or psychological distress.<sup>2,5</sup> Conversely, MD is not necessarily present when an individual suffers from burnout or stress<sup>5</sup>, but it can occur more frequently in times of crisis, such as the Coronavirus Disease 2019 (COVID-19) pandemic.<sup>7,8</sup>

As the world lives in an emergency due to the outbreak of the novel coronavirus (COVID-19), which the World Health Organization (WHO) declared a pandemic on March 11 in 2020, the new virus continues to affect millions of people around the world.<sup>9</sup> For most people, life has radically changed for the worse, as unprecedented rates of job loss, isolation, and COVID-19-related deaths and infections continue to soar<sup>9,10</sup>, leading to disruption of medical systems, society and healthcare practices.<sup>8</sup> Moreover, healthcare providers are facing increased risk of MD during the COVID-19 pandemic, because of changes in clinical practice and resource allocation procedures.<sup>7</sup> Most frontline healthcare professionals have never witnessed anything like this before.<sup>8</sup> Particularly, they face extraordinary challenges in response to shifting protocols, triage, shortages of resources, and the astonishing number of patients who require care in expedited time constraints.<sup>7,8</sup> As most healthcare

<sup>3</sup> Curtis JR, Vincent JL, “Ethics and end-of-life care for adults in the intensive care unit,” *Lancet* 375 (2010): 1347-53.

<sup>4</sup> Vučević D, Pantić I, Samardžić J, Jorgačević B, Paunović Pantić J, Radosavljević T., “Ethical Issues and Spiritual Challenges in End-Of-Life Care,” doi: 10.22618/TP.AEBIO.20214.231011, In: Radenković M, ed. *Heading Towards Humans Again: Aspects of Bioethics in the New Age of Science* (Budapest: Trivent, 2021).

<sup>5</sup> Bruce CR, Zimmerman JL., “Like firemen going into a fire”: Moral distress in the intensive care unit,” *ICU Management & Practice* 14(2) (2014): 723-734.

<sup>6</sup> Morley G, Sese D, Rajendram P, Horsburgh CC., “Addressing caregiver moral distress during the COVID-19 pandemic,” *Cleveland clinic journal of medicine* (2020): doi:10.3949/ccjm.87a.ccc047.

<sup>7</sup> Williams RD, Brundage JA, Williams EB., “Moral injury in times of COVID-19,” *J Health Serv Psychol* (2020): 1-5. doi:10.1007/s42843-020-00011-4.

<sup>8</sup> Hossain F, Clatty A., “Self-care strategies in response to nurses’ moral injury during COVID-19 pandemic,” *Nursing Ethics* 28(1) (2021): 23-32.

<sup>9</sup> Lee SA, Jobe MC, Mathis AA., “Mental health characteristics associate with dysfunctional coronavirus anxiety,” *Psychol Med* (2020); doi:10.1017/S003329172000121X.

<sup>10</sup> Arora A, Jha AK, Alat P, Das SS., “Understanding coronaphobia.” *Asian J Psychiatr* 54 (2020): 102384. doi:10.1016/j.ajp.2020.102384.

workers are passionate professionals, frustration and often a sense of powerlessness occur when they find themselves unable to provide needed care to their patients.<sup>8</sup> The overwhelming number of deaths, patients isolated and dying alone, and the ever-present fear of being infected and then infecting colleagues, family, friends due to the lack of protective gear or known protocols takes its toll on emotional and psychological well-being.<sup>6-7-8-9-10</sup> As a result, the experience of numerous and continuous traumatic events can inflict ongoing moral injury that involves a deep emotional wound and is unique to those who bear witness to intense human suffering and cruelty.<sup>8,11</sup>

The concept of moral injury was considered under other concepts, as well, such as stress of conscience, regrets for ethical situations, MD and ethical suffering, guilt without fault, and existential suffering with inflicting pain.<sup>11</sup> The association among these concepts needs further investigation and confirmation through empirical studies, in particular, where to draw the line as to when MD turns into moral injury, leading to severe consequences.<sup>8-11</sup> Distinguishing MD from other phenomena is important in order to recognize its impact on caregivers and implement interventions to reduce its detrimental effects due to education, coping tools, and therapy.<sup>5-8</sup>

## II. Historical development of the MD concept

When theory and practice in healthcare ethics started to evolve in the late 1970s, there emerged a growing consensus about how ethical principles ought to guide healthcare delivery.<sup>12,13</sup> This lack of attention started to change with American philosopher Andrew Jameton’s groundbreaking writing about MD in his book on nursing ethics.<sup>14</sup> Since Jameton in 1984 first defined MD (Table 1), hundreds of qualitative, quantitative and theoretical studies exploring MD have been published.<sup>15</sup> Currently, twenty-six key definitions of MD are identified from the extensive MD literature (Table 1).<sup>16,17</sup>

**Table 1. Evolving definitions of MD (chronological order) modified from.**<sup>16-17</sup>

Authors	Definition
Jameton <sup>14</sup>	MD arises when one knows the right thing to do, but institutional constraints make it nearly impossible to pursue the right course of action.

<sup>11</sup> Čartolovni A, Stolt M, Scott PA, Suhonen R, “Moral injury in healthcare professionals: A scoping review and discussion,” *Nursing Ethics* (2021). doi:10.1177/0969733020966776.

<sup>12</sup> Beauchamp T, Childress J., *Principles of biomedical ethics*. 6th ed. (Oxford: Oxford University Press, 2008).

<sup>13</sup> Storch JL, Rodney P, Starzomski R, editors, *Toward a moral horizon*. 2nd ed. (Don Mills: Pearson, 2013).

<sup>14</sup> Jameton A., *Nursing practice: the ethical issues* (NJ: Prentice-Hall: Englewood Cliffs, 1984), 6.

<sup>15</sup> Morley G., “What is “moral distress” in nursing? How can and should we respond to it?” *Journal of Clinical Nursing* (2018): 3443-3445.

<sup>16</sup> Musto L, Rodney P., “What we know about moral distress,” in Ulrich CM, Grady C, eds., *Moral distress in the health professions* (Springer International Publishing AG, eBook 2018), doi: 10.1007/978-3-319-64626-8, pp. 9-20.

<sup>17</sup> Morley G, Ives J, Bradbury-Jones C, Irvine F., “What is “moral distress”? A narrative synthesis of the literature,” *Nursing Ethics* 26(3) (2019): 646-662.

Wilkinson <sup>18</sup>	MD is defined by the author as the psychological disequilibrium and negative feeling state experienced when a person makes a moral decision but does not follow through by performing the moral behavior indicated by that decision.
Jameton <sup>19</sup>	...a nurse experiences MD when the nurse makes a moral judgment about a case in which he or she is involved and the institution or coworkers make it difficult or impossible for the nurse to act on that judgment.
Corley <sup>20</sup>	Jameton defined MD as painful feelings and/or psychological disequilibrium caused by a situation in which (1) one believes one knows the ethically ideal action to take and (2) that one cannot carry out that action because of (3) institutionalized obstacles, such as lack of time, lack of supervisory support, medical power, institutional policy, or legal limits.
Corley et al. <sup>21</sup>	Jameson <sup>14</sup> defines MD as: the painful psychological disequilibrium that results from recognizing the ethically appropriate action yet not taking it because of such obstacles as lack of time, supervisory reluctance, an inhibiting medical power structure, institution policy, or legal considerations.
Corley <sup>22</sup>	MD is the psychological disequilibrium, negative feeling state, and suffering experienced when nurses make a moral decision and then either do not or feel that they cannot follow through with the chosen action because of institutional constraints.
Austin et al. <sup>23</sup>	MD is the state experienced when moral choices and actions are thwarted by constraints.
Hanna <sup>24</sup>	An „umbrella category”, could include the experience of anguish or suffering associated with facing a moral dilemma, moral uncertainty, as well as certainty accompanied by constraint.
Källemark et al. <sup>25</sup>	Traditional negative stress symptoms occur due to situations involving ethical dimensions and where the healthcare provider feels she/he is not able to preserve all interests and values at stake.

<sup>18</sup> Wilkinson JM. Moral distress in nursing practice: experience and effect. *Nurs Forum* 1988; 23:16-29.

<sup>19</sup> Jameton A. Dilemmas of moral distress: moral responsibility and nursing practice. *AWHONNS Clin Issues Perinat Womens Health Nurs* 1993; 4:542-51.

<sup>20</sup> Corley MC. Moral distress of critical care nurses. *Am J Crit Care* 1995; 4:280-285.

<sup>21</sup> Corley MC, Elswick RK, Gorman M, Clor T. Development and evaluation of a moral distress scale. *J Adv Nurs* 2001; 33:250-256.

<sup>22</sup> Corley MC. Nurse moral distress: a proposed theory and research agenda. *Nurs Ethics* 2002; 6.

<sup>23</sup> Austin WA, Bergum V, Goldberg L. Unable to answer the call of our patients: mental health nurses' experience of moral distress. *Nurs Inq* 2003; 10(3):177-183.

<sup>24</sup> Hanna DR. Moral distress: the state of the science. *Research and Theory for Nursing Practice: An International Journal* 2004; 18:76.

<sup>25</sup> Källemark S, Höglund AT, Hansson MG, et al. Living with conflicts-ethical dilemmas and moral distress in the health care system. *Soc Sci Med* 2004; 58:1082-1083.

Peter and Liaschenko <sup>26</sup>	If moral agency is defined as the capacity to recognize, deliberate/reflect on, and act on moral responsibilities, in order to experience MD, an agent is required to possess at least some autonomy in recognizing and reflecting upon moral concerns. Yet, on the other hand, an agent's autonomy must be at least somewhat constrained in acting upon the very moral responsibilities he/she understands him/herself to have. This apparently irresolvable contradiction is MD.
Corley et al. <sup>27</sup>	Jameson <sup>14</sup> , defined MD as painful feelings and/or the psychological disequilibrium that occurs when nurses are conscious of the morally appropriate action a situation requires but cannot carry out that action because of institutionalized obstacles.
American Association of Critical Care Nurses <sup>28</sup>	MD occurs when: (1) you know the ethically appropriate action to take, but are unable to act upon it; (2) you act in a manner contrary to your personal and professional values, which undermines your integrity and authenticity.
Nathaniel <sup>29</sup>	MD is pain affecting the mind, the body, or relationships that result from a patient care situation in which the nurse is aware of a moral problem, acknowledges moral responsibility, and makes a moral judgment about the correct action, yet, as a result of real or perceived constraints, participates, either by act or omission, in a manner he or she perceives to be wrong.
Canadian Nurses Association <sup>30</sup>	Ethical (or moral) distress arises in situations where nurses know or believe they know the right thing to do but, for various reasons (including fear or circumstances beyond their control), do not or cannot take the right action or prevent a particular harm. When values and commitments are compromised in this way, nurses' identity and integrity as moral agents are affected as they feel MD.
McCarthy and Deady <sup>31</sup>	...An umbrella concept that captures the range of experiences of individuals who are morally constrained. Generally speaking, when individuals make moral judgments about the right course of action to take in a situation, and they are unable to carry it out, they may experience MD. In short, they know what is the right

<sup>26</sup> Peter E, Liaschenko J., "Perils of proximity: a spatiotemporal analysis of moral distress and moral ambiguity," *Nurs Inq* 11 (2004): 221.

<sup>27</sup> Corley MC, Minick P, Elswick R, et al., "Nurse moral distress and ethical work environment," *Nurs Ethics* 12 (2005): 382.

<sup>28</sup> American Association of Critical-Care Nurses. A. AACN Public Policy Position Statement: Moral Distress. Aliso Viejo, CA: American Association of Critical-Care Nurses (AACN), 2006.

<sup>29</sup> Nathaniel A., "Moral Reckoning in Nursing," *West J Nurs Res* 28 (2006): 419-438.

<sup>30</sup> Canadian Nurses Association. C. *Code of Ethics for Registered Nurses*. Ottawa; 2008.

<sup>31</sup> McCarthy J, Deady R., "Moral distress reconsidered," *Nurs Ethics* 15 (2008):254-262.

	thing to do, but they are unable to do it, or they do what they believe is the wrong thing.
Mitton et al. <sup>32</sup>	MD is the suffering experienced as a result of situations in which individuals feel morally responsible and have determined the ethically right action to take, yet due to constraints (real or perceived), they cannot carry out this action, thus committing a moral offense.
Varcoe et al. <sup>33</sup>	MD is the experience of being seriously compromised as a moral agent in practicing in accordance with accepted professional values and standards.
McCarthy <sup>34</sup>	MD is an umbrella concept that describes the psychological, emotional and physiological suffering, which may be experienced when we act in ways that are inconsistent with deeply held ethical values, principles or moral commitments.
Rodney et al. <sup>35</sup>	What nurses (or moral agents) experience when they are constrained from moving from moral choice to moral action; an experience associated with feelings of anger, frustration, guilt, and powerlessness.
Crane et al. <sup>36</sup>	MD is the experience of psychological distress that results from engaging in, or failing to prevent, decisions or behaviours that transgress, or come to transgress, personally held moral or ethical beliefs.
Jameton <sup>37</sup>	MD, a common experience in complex societies, arises when individuals have clear moral judgments about societal practices, but have difficulty in finding a venue in which to express concerns.
Hamric <sup>38</sup>	MD occurs when an individual's moral integrity is seriously compromised, either because one feels unable to act in accordance with core values and obligations, or attempted actions fail to achieve the desired outcome.

<sup>32</sup> Mitton C, Peacock S, Storch J, Smith N, Cornelissen E., "Moral distress among health system managers: exploratory research in two British Columbian health authorities," *Health Care Anal* (2011), <https://doi.org/10.1007/s10728-010-0145-9>.

<sup>33</sup> Varcoe C, Pauly B, Webster G, Storch J., "Moral distress: tensions as springboards for action," *HEC Forum*. 24(1) (2012): 51-62.

<sup>34</sup> McCarty J., "Nursing Ethics and Moral Distress: the story so far," *Nurs Ethics* (2013), Special Online Issue, accessed 28 Aug 2021.

<sup>35</sup> Rodney P, Harrigan M, Jiwani B, Burgess M, Phillips JC., "A further landscape: ethics in health care organizations and health/healthcare policy." In: Storch J, Rodney P, Starzomski R, editors. *Toward a moral horizon*, 2nd ed. (Toronto: Pearson, 2013), 25.

<sup>36</sup> Crane MF, Bayl-Smith P, Cartmill J., "A recommendation for expanding the definition of moral distress experienced in the workplace," *Aust N Z J Organ Psychol* (2013): 6:e1.

<sup>37</sup> Jameton A., "A reflection on moral distress in nursing together with a current application of the concept," *J Bioeth Inq* 10 (2013): 297-308.

<sup>38</sup> Hamric AB., "A case study of moral distress," *J Hosp Palliat Nurs* 16 (2014): 457-463.

Barlem and Ramos <sup>39</sup>	...The feeling of powerlessness experienced during power games in the microspaces of action, which lead the subject to a chain of events that impels him or her to accept imposed individualities, have his or her resistances reduced and few possibilities of moral action; this obstructs the process of moral deliberation, compromises advocacy and moral sensitivity, which results in ethical, political and advocational inexpressivity and a series of physical, psychical and behavioural manifestations.
Fourie <sup>40</sup>	MD is a psychological response to morally challenging situations, such as those of moral constraint or moral conflict, or both.
Campbell et al. <sup>41</sup>	One or more negative self-directed emotions, or attitudes that arise in response to one's perceived involvement in a situation that one perceives to be morally undesirable.
Morley et al. <sup>17</sup>	MD is defined as the combination of (1) the experience of a moral event, (2) the experience of physiological distress, and (3) a direct causal relation between (1) and (2).

As a result of working with an evolving definition, researchers continue to seek to refine the definition, and our full understanding of the concept remains “under construction”.<sup>17,40</sup> One of the consequences is a growing list of definitions that seek to incorporate our developing understanding of MD (Table 1). Table 1 is not intended to be exhaustive. Namely, the intention is to provide examples that illustrate the evolution of the concept as scholars and researches incorporate new insights into the definition of MD in an effort to bring further clarity and move the concept forward.<sup>16</sup>

Understood as a psychological and emotional response to the experience of moral wrongdoing, there is evidence to suggest that if MD is unaddressed, it contributes to staff demoralization, desensitization and burnout, and ultimately, to lower standards of patient safety and quality of care.<sup>42</sup> MD is experienced by all healthcare professionals, regardless of their disciplinary background or gender.<sup>5</sup> The frequency and source of MD, however, might differ depending on professional background.<sup>2,5</sup> A recent study found that social workers were distressed by discharge planning issues.<sup>5,43</sup> Chaplains were distressed by feeling that life-sustaining treatment

<sup>39</sup> Barlem EL.D, Ramos FRS., “Constructing a theoretical model of moral distress,” *Nurs Ethics* 22 (2015): 608-615.

<sup>40</sup> Fourie C., “Moral distress and moral conflict in clinical ethics,” *Bioethics* 29 (2015): 91-97.

<sup>41</sup> Campbell SM, Ulrich CM, Grady C., “A broader understanding of moral distress,” *Am J Bioeth* 16 (2016): 2-9.

<sup>42</sup> McCarthy J, Monteverde S., “The standard account of moral distress and why we should keep it,” *HEC Forum* 30(4) (2018):319-328.

<sup>43</sup> Fantus S., “Social Work Perspective: Moral distress,” in: Ulrich CM, Grady C, eds. *Moral distress in the health professions* (Springer International Publishing AG, eBook 2018), doi: 10.1007/978-3-319-64626-8, pp. 33-37.



was withheld or withdrawn prematurely.<sup>5,44</sup> Critical care nurses and physicians experienced MD from issues pertaining to the continuation of aggressive measures where it was viewed as medically inappropriate, although nurses experienced this with greater frequency than physicians.<sup>5</sup>

Researchers organize the root causes of MD into three broad categories: clinical situations, internal constraints, and external constraints (Table 2).<sup>45,46</sup>

**Table 2. Major root causes of MD modified from.<sup>45,46</sup>**

<b>Clinical situations</b>	
<ul style="list-style-type: none"> <li>- Providing unnecessary/futile treatment</li> <li>- Prolonging the dying process through aggressive treatment</li> <li>- Inadequate informed consent</li> <li>- Working with caregivers who are not as competent as care requires</li> <li>- Lack of consensus retreatment plan</li> <li>- Lack of continuity of care</li> <li>- Conflicting duties</li> </ul>	<ul style="list-style-type: none"> <li>- Using resources inappropriately</li> <li>- Providing care that is not in the best interest of the patient</li> <li>- Providing inadequate pain relief</li> <li>- Providing false hope to patients and families</li> <li>- Hastening the dying process</li> <li>- Lack of truth-telling</li> <li>- Disregard for patient wishes</li> </ul>
<b>Internal constraints</b>	
<ul style="list-style-type: none"> <li>- Perceived powerlessness</li> <li>- Inability to identify the ethical issues</li> <li>- Lack of understanding the full situation</li> <li>- Self-doubt</li> </ul>	<ul style="list-style-type: none"> <li>- Lack of knowledge of alternative treatment plans</li> <li>- Increased moral sensitivity</li> <li>- Lack of assertiveness</li> <li>- Socialization to follow others</li> </ul>
<b>External constraints</b>	
<ul style="list-style-type: none"> <li>- Inadequate communication among team members</li> <li>- Differing interprofessional or intraprofessional perspectives</li> <li>- Inadequate staffing and increased turnover</li> <li>- Lack of administrative support</li> <li>- Policies and priorities that conflict with care needs</li> <li>- Following family wishes of patient care for fear of litigation</li> </ul>	<ul style="list-style-type: none"> <li>- Tolerance of disruptive and abusive behavior</li> <li>- Compromising care due to pressure to reduce costs</li> <li>- Hierarchies within healthcare system</li> <li>- Lack of collegial relationships</li> <li>- Nurses not involved in decision-making</li> <li>- Compromised care due to insurance pressure or fear of litigation</li> </ul>

<sup>44</sup> Lindsey M. A, "Chaplain's Perspective on Moral Distress," in: Ulrich CM, Grady C, eds. *Moral distress in the health professions* (Springer International Publishing AG, eBook 2018), doi: 10.1007/978-3-319-64626-8, pp. 44-46.

<sup>45</sup> Hamric AB., "Empirical research on moral distress: issues, challenges, and opportunities," *HEC Forum* 24 (2012): 39-49.

<sup>46</sup> Walton MK., "Sources of Moral Distress," in: Ulrich CM, Grady C, eds. *Moral distress in the health professions* (Springer International Publishing AG, eBook 2018), doi: 10.1007/978-3-319-64626-8, pp. 79-93.

Although this broad categorization is useful, given the complex nature of healthcare, these categories may overlap, are interrelated, and may not be comprehensive.<sup>46</sup> Further, other causes will likely be identified in the future.<sup>5-46</sup> Scientific advances will introduce new treatment options, and care will be delivered by interprofessional teams to patients who will be expected to be increasingly engaged in their own healthcare.<sup>46</sup> All this will unfold within our complex and pluralistic society.<sup>43-46</sup> Identifying and understanding the root causes of MD emerging from the ever-evolving healthcare environment will continue to be a challenge for clinicians, administrators, and researchers alike.<sup>46</sup> The COVID-19 pandemic has created new challenges for caregivers, leaders, patients and families.<sup>6</sup> Not everyone experiences MD in the same way.<sup>2-5-6</sup> Depending on the person and the event, it can range from being easily manageable to being completely impairing.<sup>2</sup> Studies have shown that symptoms of MD can be emotional, physical, behavioural or spiritual (Table 3).<sup>47</sup>

**Table 3. Selected individual-level responses to MD modified from.<sup>47</sup>**

<p><b>Emotional MD responses</b></p> <ul style="list-style-type: none"> <li>- Feelings of powerlessness or being overwhelmed</li> <li>- Anger</li> <li>- Fear, disgust, discouragement</li> <li>- Depression</li> <li>- Anxiety</li> <li>- Bitterness, cynicism, resentment or sarcasm</li> <li>- Shock</li> <li>- Dismay, sorrow, or grief</li> <li>- Burnout: (1) emotional exhaustion or withdrawal; (2) numbness</li> </ul>
<p><b>Physical MD responses</b></p> <ul style="list-style-type: none"> <li>- Heart palpitations</li> <li>- Gastrointestinal disturbances</li> <li>- Insomnia</li> <li>- Headaches or other pain symptoms</li> <li>- Fatigue, exhaustion, or lethargy</li> <li>- Hyperactivity</li> <li>- Unplanned weight gain or loss</li> <li>- Susceptibility to illness</li> </ul>
<p><b>Behavioral MD responses</b></p> <ul style="list-style-type: none"> <li>- Impaired thinking (forgetfulness, etc.)</li> <li>- Nightmares</li> <li>- Lashing out at others</li> <li>- Addictive behaviors (drinking and taking illicit drugs)</li> <li>- Controlling behaviors (rigidity, the need to be „right” among the others, pervasive cynicism, erosion of relationships, etc.)</li> </ul>

<sup>47</sup> Rushton CH, Caldwell M, Kurtz M, “Morall distress: a catalyst in building moral resilience,” *AJN* 116 (2016): 40-49.

<ul style="list-style-type: none"> <li>- Defensiveness</li> <li>- Avoidance</li> <li>- Agitation</li> <li>- Shaming others</li> <li>- Disengagement or depersonalization</li> <li>- Horizontal or vertical violence</li> </ul>
<p><b>Spiritual MD responses</b></p> <ul style="list-style-type: none"> <li>- Spiritual distress, including crisis of faith or disrupted religious practices</li> <li>- Dampened moral sensitivity; loss of a sense of meaning</li> <li>- Deterioration of moral integrity, moral agency, or both</li> <li>- Loss of self-worth</li> <li>- Disconnection from work or community</li> </ul>

### III. Moral challenges due to COVID-19 pandemic

Healthcare organizations during the COVID-19 pandemic have been required to respond to changing logistical needs in ethically supportable ways.<sup>6</sup> This includes: (1) increasing testing and treatment capability equitably and with sensitivity to need, (2) expanding hospital capacity, while maintaining safety for patients and honoring obligations to caregivers, and (3) minimizing risk to caregivers, patients, and the community, while continuing to provide compassionate patient-centered care.<sup>6,48</sup> The ethical frameworks that guide organizational responses to these value-laden decisions shift in a pandemic from a patient-centered approach toward a community-based approach.<sup>6</sup> In short, some ethical priorities have changed, and as a result, caregivers are now caring for patients in ways that might not have been considered optimal in the context of pre-pandemic ethical frameworks.<sup>6,48</sup> This shift heightens the potential for MD.<sup>6</sup> As one can see, five types of MD have occurred due to COVID-19 (Table 4).<sup>6,49</sup>

**Table 4. Recognizing MDs in the COVID-19 pandemic modified from<sup>6</sup>**

<p><b>MORAL-CONSTRAINT DISTRESS</b></p> <p>We are feeling distressed because we are constrained from doing what we think is the ethically appropriate action. Common emotions.- anger, frustration, sense of injustice, and powerlessness. Trigger phrases.- (1) “I feel like I’m not doing the right thing.” (2) “I feel like I’m complicit in causing suffering.”</p>
<p><b>MORAL-UNCERTAINTY DISTRESS</b></p> <p>We are feeling distressed because we are uncertain about whether you are doing the right thing. Common emotions.- torn, conflicted, uncertain, and frustrated.</p>

<sup>48</sup> Berlinger NF, Cohn L, Bruce R, et al., *COVID-19: Supporting ethical care and responding to moral distress in a public health emergency*. Accessed Aug 28, 2021. <https://www.thehastingscenter.org/wp-content/uploads/SlideDeck-HECCEC-COVID-19-Readiness.pdf>.

<sup>49</sup> Morley G, Bradbury-Jones C, Ives J., “What is “moral distress” in nursing. A feminist empirical bioethics study;” *Nurs Ethics* (2019), doi:10.1177/096973301.

<p>Trigger phrases.- (1) “I feel torn about what we should do.” (2) “I don’t know whether this is the right thing to do.”</p>
<p><b>MORAL-DILEMMA DISTRESS</b>                  We are feeling distressed because we are unable to choose between two or more ethically supportable options. Common emotions: guilt, regret, tornness, sense of injustice, and sadness.                  Trigger phrases.- (1) “I feel like I am stuck between a rock and a hard place.” (2) “Both options seem to be equally bad.”</p>
<p><b>MORAL-CONFLICT DISTRESS</b>                  We are feeling distressed because we are conflicted about the most appropriate ethical action. Common emotions.- conflicted, frustrated, angry and sad.                  Trigger phrases.- (1) “I feel like they don’t understand my point of view.” (2) “I feel like we have different moral perspectives.”</p>
<p><b>MORAL-TENSION DISTRESS</b>                  We are feeling distressed because we are unable to share our beliefs with others (this might include our colleagues, managers, or other providers). Common emotions.- sad, angry, frustrated and powerless. Trigger phrase.- “I don’t feel like I can talk to anyone about my beliefs.”</p>

Visitation restrictions and the impact on patients, families, and healthcare workers.- One of the most significant changes that has affected patients and caregivers across healthcare organizations is visitations.<sup>6</sup> Generally speaking, a patient-centered approach strongly favors generous visitation policies.<sup>6,50</sup> Actively facilitating patients’ access to their support systems optimizes the healing environment and patient well-being.<sup>6</sup> However, with the COVID-19 pandemic, visitation policies have been restricted to minimize the risk of spreading the disease over the interests of individual patients.<sup>6,50</sup> Consider, for example, the healthcare team caring for an oncology patient who has an aggressive disease course and is undergoing chemotherapy as an inpatient.<sup>6</sup> He is in pain and constantly nauseous and terrified, but their condition is not considered terminal. As such, he must go through treatment alone each day. The physician and nurse believe that keeping this patient isolated from their loved ones is not justified. This is considered moral-constraint distress, because they are constrained from doing it (Table 4).<sup>6</sup> Restricted visitation policies may also affect the decision-making process.<sup>6,50</sup> Many patients may be temporarily unable to communicate or lack the capacity to make decisions for themselves.<sup>6</sup> This situation requires input from the patients’ surrogate and yet, the surrogate is being asked to make these decisions remotely.<sup>6,50</sup> Even when virtual visits are possible, caregivers may wonder whether the surrogate understands the medical complexity of the case when they are unable to see their loved one or the machines required to sustain their life.<sup>6</sup>

Risk to personal safety and loved ones.- Healthcare workers have been asked to be courageous when caring for patients during the pandemic as the scientific

<sup>50</sup> Daubman BR, Black L, Goodman A., “Recognizing moral distress in the COVID-19 pandemic,” *Journal of Hospital Medicine* 15 (2020): 696-698.

community learns more about the risk profile of COVID-19.<sup>6</sup> They are required to weigh the (not fully understood) risks of personal illness and death and being an asymptomatic carrier with their responsibilities to patients, the community, their employer, and their families.<sup>6,50</sup> This causes moral dilemma distress, as caregivers feel torn and conflicted when faced with these obligations.<sup>6</sup> The requirement to conserve personal protective equipment (PPE) increases the emotional and mental strain on bedside caregivers, who must disproportionately carry the burden of risk.<sup>6,50</sup> Bedside caregivers are assured that they are not obligated to provide care if the risk threatens their own safety.<sup>6</sup> However, this may create moral-conflict distress for providers, if they feel that maintaining their own safety leads to substandard care (e.g., taking an additional few minutes to don PPE, as a patient suddenly experiences cardiac arrest) (Table 4).<sup>6,50</sup>

Reduced provision of healthcare services.- Outpatient providers whose visits have been limited to virtual visits or limited face-to-face interactions, may experience moral-dilemma and moral-uncertainty distress, as they try to balance their obligation to provide high quality reliable care with the need to maintain current infection prevention and social distancing precautions (Table 4).<sup>6</sup> In addition, patients with existing comorbidities, or those experiencing symptoms (possibly not related to COVID-19) may avoid accessing the healthcare system, due to a fear of being exposed to the virus, potentially placing them at increased harm.<sup>6,50</sup> This can cause moral-constraint distress for caregivers, who may unjustifiably feel responsible for these patients' outcomes (Table 4).<sup>6</sup> Caregivers may also experience moral-constraint distress, because of an inability to perform in-person physical examinations.<sup>2,6</sup> While the provision of patient care via virtual technologies is not novel, caregivers may feel frustrated as they adjust to the new skills required to deliver virtual care. Furthermore, sharing life-altering diagnoses, or a poor prognosis virtually adds a layer of complexity to difficult conversations as it eliminates the "caring touch". This can result in feeling constrained and forced to provide care that is felt to be suboptimal.<sup>6</sup>

Triage and allocation of resources.- Clinical decisions that are made based on resource scarcity occur when there is a shift to crisis standards of care.<sup>6</sup> The need to make such difficult decisions feels inconsistent with the core values of many healthcare professionals who want to deliver patient-centered care.<sup>6,7,8,9</sup> This shift can be painful and distressing.<sup>6</sup> The requirement to choose between two equally undesirable moral options causes moral dilemma distress.<sup>2,6</sup> Besides, some might experience moral-constraint distress, if they feel that the circumstances and protocols constrain their ability to make independent ethically supportable decisions and violate their own values.<sup>6,7</sup> Some caregivers might feel unable to express or discuss their moral perspectives with others during this uniquely trying time, and therefore experience moral-tension distress (Table 4).<sup>6</sup> This might be because they feel that they lack the vocabulary to discuss ethical issues, or they work in a team in which it does not feel safe to express their views.<sup>6,7,8,9</sup>

The intense and debilitating feelings of unexpected loss and helplessness faced by clinicians who are making challenging choices about medical interventions can be better understood by applying a theoretical framework that has the three main stages in the evolution and response to MD: indignation, resignation and acclimation.<sup>50</sup>

**Indignation.**- When working in a disaster setting, an initial period of indignation is common.<sup>50</sup> The caregiver is shocked and horrified by the conditions encountered.<sup>9:10:50</sup> As he or she bears witness to the many healthcare providers who have fallen ill and died, caregivers fear for his/her own safety in choosing to care for patients sick with COVID-19:

“I’m risking my life caring for patients on the front lines, and it’s unacceptable that I’m not even being provided with adequate PPE!... How can I be a compassionate healthcare provider, when my patients are forced to die alone?!... I took an oath to care for and protect my patients. How could I possibly tell a patient we have no more ventilators to put them on? Who makes the decision of which patients deserve to live or die?...”<sup>50</sup>

**Resignation.**- After the initial indignation stage, resignation often follows: “I guess I can’t fix healthcare in this new setting, and I was foolish for even trying...”<sup>50</sup> Caregivers go through the motions and continue to care for patients but feel disillusioned.<sup>7:9:50</sup> Part of the ongoing stress involves the concern that they aren’t making a difference.<sup>9:50</sup> The suffering of patients and families may feel overwhelming and insurmountable:

“I know I have to comply with my hospital’s visitor restriction policies, but it’s hard to see my patients suffering alone, and know there’s nothing I can do to help them.”<sup>50</sup>

**Acclimation.**- Acclimation follows the indignation and resignation stages.<sup>50</sup> Even amid disasters, a productive rhythm develops as teams coalesce and are galvanized by a shared sense of purpose [8, 50]. Caregivers make meaning out of their role in the crisis and in the care of the patients they can help, despite often deep and significant obstacles: “There’s a lot of suffering and a lot that I may not be able to fix, but some that I can.”<sup>50</sup> Clinicians who have been deployed to unfamiliar roles, may start to habituate and even enjoy having responsibilities and challenges that are different from those they typically face.<sup>10:50</sup> Innovation during a pandemic may feel empowering:

“I’m committed to making sure my dying patients and their families can say goodbye however possible. Although it’s not ideal, I’ve been using technology for virtual communication and advocating for families to visit in person when possible.”<sup>50</sup>

#### **IV. The interplay between moral injury and MD in the context of the COVID-19 crisis**

Many healthcare professionals are likely to experience posttraumatic stress disorder (PTSD), as a consequence of serving during the COVID-19 crisis.<sup>8:11</sup> Nurses are critical to the administration of excellent care.<sup>8</sup> As previously mentioned, they are even more focal during this crisis, since they play expanded and multiple roles simultaneously, such as performing diverse roles, conducting screening processes,

attending to the critically ill, deciding triage protocols, contacting and updating families, and informing the family of the death of a loved one.<sup>7,8</sup> Although prepared to face many difficult situations during their professional education and career, working on the frontline in times of the COVID-19 pandemic is likely to exceed their worst fears and will potentially affect them severely and have long-term consequences.<sup>11</sup> Making difficult, even impossible decisions, working under pressure and not fulfilling their non-negotiable moral and professional principle “first do not harm” may lead to moral injury.<sup>8-11</sup>

The term moral injury is used in the military<sup>8</sup> in the PTSD context.<sup>11</sup> In the 1990s, the psychiatrist Shay observed that some Vietnam veterans carried within themselves a kind of wound, which they named moral injury.<sup>51</sup> Shay emphasizes three requirements for something to be recognized as moral injury: (1) a betrayal of what is morally right, (2) someone who holds legitimate authority, and (3) a high-stakes situation.<sup>11,51</sup> It is a long-lasting emotional, psychological, social and spiritual effect from actions taken that run contrary to one’s moral values.<sup>8</sup> The stress the nurses experience will not only create MD, but will have a lasting impact.<sup>7,8</sup> This is why the term moral injury is best used in the context of the COVID-19 crisis.<sup>8</sup> Murray and colleagues demonstrated that the witnessing experiences of medical students in the emergency medicine wards, of events challenging one’s moral code, acts of violence, particularly those including children, having consequences in the form of secondary/vicarious trauma seem most effectively encompassed in the notion of moral injury.<sup>52</sup> The actions taken, including violations of human rights, restrictions, or violations of autonomy or similar, are harmful to individuals, and non-action in such situations may sleep into daily practice.<sup>11</sup> This has been presented in the literature on ethics and is called a slippery slope.<sup>53</sup> Over time, these moral injury experiences may affect daily practice, thus undermining and dehumanising healthcare.<sup>11</sup> In this context, witnessing severe immoral actions or behaviours may have profound consequences, which can lead to moral injury.<sup>8-11</sup> Since the COVID-19 pandemic has generated many sources of stress and subsequent distress for healthcare workers, patients and families<sup>6,7</sup>, it is critical to be aware of the various feelings that may arise (Table 3), and try not to hide emotional reactions.<sup>7,8,9,50</sup>

Sustained MD can evolve into moral injury, which is an erosion of trust in self, leadership, and the system as a whole.<sup>54</sup> Taking into consideration the psychological aspect of MD and moral injury, it may be perceived that they have some mutual consequences, such as a sense of guilt, blame towards self and others, anguish, and a sense of powerlessness.<sup>11</sup> One may also notice that moral injury and MD differ in terms of the context where they occur.<sup>8-11</sup> Thus, moral injury emerges from the potentially morally injurious events (PMIEs) followed by internal moral conflict caused by traumatic events and immorality of the action.<sup>11</sup> It occurs in PMIEs

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<sup>51</sup> Shay J., *Achilles in Vietnam: combat trauma and the undoing of character* (New York: Simon & Shuster, 1995).

<sup>52</sup> Murray E, Krahé C, Goodman D., “Are medical students in prehospital care at risk of moral injury,” *Emerg Med J* 35 (2018): 590-594.

<sup>53</sup> Welsh DT, Ordóñez LD, Snyder DG, et al., “The slippery slope: how small ethical transgressions pave the way for larger future transgressions,” *J Appl Psychol* 100 (2015):114-127.

<sup>54</sup> Shay J., “Moral injury,” *Psychoanalytic Psychology* 31 (2014): 182-191.

consisting of external factors (high-stakes situations, beyond our control and broken system) and internal factors (perpetrating, failing to prevent, or bearing witness to the transgression of deeply held moral beliefs, etc.).<sup>8</sup>11 On the contrary, as it is previously mentioned (Table 2), MD emerges from moral conflict in morally distressing situations caused by internal or external constraints.<sup>11</sup> In fact, MD represents a challenge that may be relatively easy to prevent if the external constraints are removed and the internal constraints mitigated by reinforcing and increasing moral resilience.<sup>11</sup>47 As a result, an increase in moral sensitivity level and quality of care provision ensue.<sup>55</sup> On the other hand, moral injury results in long-term emotional scarring or damage, contributing to permanent numbness, malfunctioning and social isolation.<sup>11</sup>

## V. Interventions to mitigate MD

MD is an inevitable byproduct of a pluralistic society and a natural response to morally difficult encounters in the provision of patient care.<sup>56</sup> Healthcare professionals are real HEROs (High Expectation and Risk Occupation).<sup>57</sup> The profession broadly, and the organizations that employ them, must be well aware of the needs of HEROs.<sup>8</sup> Individual and collective interdisciplinary approaches, measures to improve an institution's overall moral climate due to the implementation of ethics committees, ethics rounds, and ethics-based forums, as well as strategies to increase the transparency of communication between administrators and practitioners, are crucial steps in empowering caregivers to handle MD with resilience.<sup>47</sup>

Effectively addressing MD requires moving from victimhood toward a more empowered stance, one that understands MD to be an indicator of moral conscientiousness rather than of moral failure.<sup>47</sup> Cognitive, emotional, and behavioral strategies can all be useful in helping caregivers transform their MD into moral agency and resilience.<sup>8</sup>47 Thus, ethics education is a vital component in building an individual's coping capacities and decreasing the intensity and frequency of MD.<sup>47</sup> Other promising interventions that may easily or diminish the detrimental effects of MD include practices that increase mindfulness and self-reflection, as well as tactics to foster resiliency and overall well-being.<sup>8</sup>47 The literature on neuroscience and social psychology has described how having a more positive, empathic mindset can facilitate engagement, problem-solving, and creative thinking.<sup>47</sup> Moreover, it has been registered that applying this knowledge to clinical ethics may lead to greater self-awareness, better attunement to patient and family concerns, and stronger communication and teamwork.<sup>5</sup>8:47 Means for developing a more positive affect

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<sup>55</sup> Lachman VD., "Moral resilience: managing and preventing moral distress and moral residue," *Medsurg Nurs* 25 (2016):121-124.

<sup>56</sup> Tigard DW., "Rethinking moral distress: conceptual demands for a troubling phenomenon affecting healthcare professionals," *Med Health Care Philos* 21 (2018):479-488.

<sup>57</sup> Asken MJ., "Now it is moral injury: the COVID-19 pandemic and moral distress," *Medical Economics*. <https://www.medicaleconomics.com/news/now-it-moral-injury-covid-19-pandemic-and-moral-distress> (accessed 28 Aug 2021.)



include self-reflective writing<sup>58,59</sup> and using narrative methods to “rehabilitate” stories associated with MD.<sup>60</sup>

## VI. Conclusion

It should not be forgotten that end-of-life care and facilitating peaceful transitions are worthy actions of all caregivers, not just those in palliative medicine. Since there is a duty to be well for oneself and one’s family, as well as for patients and colleagues, MD training is of key importance to any healthy work environment. It is important to focus on one’s efforts and not just the outcome. Clearly, a successful outcome is the gold standard for physicians. However, some factors are uncontrollable, unknowable, or unpredictable. Thus, although much progress has been made to recognize the MD as an ongoing global multidisciplinary health-threatening problem during and beyond the COVID-19 crisis, many physicians and other caregivers have lingered on its negative effects, such as depression, anxiety, grief, hypervigilance, survivor guilt, scapegoating, and sleep disturbance. Therefore, mitigating MD requires a temporary “philosophical reconciliation”, where self-care and inter-collegial support should be enhanced. In such circumstances, monitoring of staff and colleagues’ adjustment is an essential component of post-pandemic planning and return to more normal daily professional care and life. Finally, there is a necessity for further MD research in order to avoid or alleviate its detrimental effects. Public policy implementation to reduce the adverse effects of MD needs to be developed, too.

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<sup>58</sup> Pennebaker JW., “Why write about trauma or emotional upheaval?” In: *Writing to heal: a guided journal for recovering from trauma and emotional upheaval* (Oakland, CA: New Harbinger Publications, 2004), 3-16.

<sup>59</sup> Sexton JD, Pennebaker JW., “The healing powers of expressive writing,” In: Kaufman SB, Kaufman JC, eds. *The psychology of creative writing* (New York. Cambridge University Press, 2009), 264-73.

<sup>60</sup> Nelson HL. *Damaged identities, narrative repair* (Ithaca, NY: Cornell University Press; 2001).

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# PHARMACOGENETICS AND COVID-19: ETHICAL CHALLENGES AND CONSIDERATIONS

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## Abstract

Pharmacogenetics represents the science of how genetic variability could influence drug treatment outcomes. COVID-19 represents a novel systemic disease in which different therapeutic outcomes have been recorded, as well as the occurrence of serious side effects of applied pharmacotherapy in individual patients. The application of pharmacogenetic tests in the future could improve the pharmacotherapeutic response and reduce the complications of this infection. However, before a definitive recommendation on the introduction of this type of testing into clinical practice, it is necessary to conduct appropriate clinical studies but also to consider the ethical questions related to this type of testing. In this chapter, we aim to analyze various ethical challenges that could influence the decision to introduce pharmacogenetic tests in patients with COVID-19.

## I. Introduction

Pharmacogenetics represents the science of how genetic variability could influence drug treatment outcomes. The importance of pharmacogenetic studies has evolved

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significantly in the past 20 years among healthcare professionals. These tests are the basis of “personalized medicine”, a medical term presented in modern medicine for over a decade. Personalized medicine means that the right drug should be prescribed for the right patient based on genetic data. Besides this, research in this field could contribute to a better understanding of the pathogenesis of the disease itself, thereby improving the efficacy and safety of applied drugs and predicting potential outcomes, especially in high-risk patients.<sup>1</sup>

The current pharmacogenomic literature available for COVID-19 drug therapies includes different drugs, such as hydroxychloroquine, chloroquine, azithromycin, remdesivir, favipiravir, ribavirin, lopinavir, monoclonal antibodies, corticosteroids etc. So far, some research has emerged in this field that suggests that individual variants in different genes (such as CYP3A4, CYP3A5, CYP2C8, CY2D6 and others) could play a significant role in response to therapy.<sup>2</sup>

Pharmacogenetic tests could explain the variation and improve patients' outcomes in COVID-19 positive patients and may allow individualization of these drugs. On the other hand, such new and modern diagnostic procedures bring several unresolved issues and ethical dilemmas.

For example, the successful implementation of pharmacogenetic tests in COVID-19 positive patients will require acceptance and adequate knowledge of healthcare workers, especially physicians, yet such expertise is often lacking because of limited training programs in healthcare institutions and universities. Also, there are no guidelines for pharmacogenetic testing implementation. Medical doctors often lack the confidence to counsel and/or recommend these tests to patients. Furthermore, the absence of clear regulations and legislative frameworks for genetic testing also poses challenges.

It is very important to note that many drugs that do not establish clinical effectiveness are being administered to tackle the COVID-19 pandemic situation. A repurposing strategy might be more effective and successful if pharmacogenetic interventions for these drugs are considered in future clinical studies/trials. Additionally, the safety and effectiveness of several repurposed drugs currently being used for the management of COVID-19 may be affected by the CYP/transporter genetic variants.

In most cases, a pharmacogenetic test uses a sample of saliva (spit), a buccal (cheek) swab, or blood. The sample goes to a lab, which runs tests on the genes that determine how the body will handle some medicines. Although these procedures are simple from the point of view of medical professionals, there are situations when

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<sup>1</sup> Pooneh S, Bagher L. “Ethical Issues Surrounding Personalized Medicine: A Literature Review”, *Acta Med Iran* 55(3) (2017): 209-217.

Korngiebel DM, Thummel KE, Burke W. “Implementing Precision Medicine: The Ethical Challenges”, *Trends Pharmacol Sci* 38(1) (2017): 8–14.

<sup>2</sup> Schmidlen T, Sturm AC, Shelly H, Scheinfeldt L, Scott JR, Morr L, McElroy J, Toland AE, Christman M, O’Daniel JM, Erynn S, Bernhardt AB, Kelly E, Sweet K. “Operationalizing the Reciprocal Engagement Model of Genetic Counseling Practice: A Framework for the Scalable Delivery of Genomic Counseling and Testing”, *J Genet Couns* 27(5) (2018): 1111–1129.

Fricke-Galindo I, Falfán-Valencia R. “Pharmacogenetics Approach for the Improvement of COVID-19 Treatment”, *Viruses* 13 (2021): 413.

individual patients may refuse or hesitate to perform such tests for religious, cultural and other reasons.

From this point of view, we can also raise ethical questions about how to conduct pharmacogenetic testing in particularly vulnerable groups of patients (pregnant or breastfeeding women, minors, older people, people suffering from multiple chronic conditions or terminally ill, people affected by mental health disorders, ethnic minorities etc.). The implementation of clinical pharmacogenetic testing also poses a financial burden on already challenged public healthcare systems.<sup>3</sup>

This paper is focused on patients who can benefit clinically from pharmacogenetic tests, including COVID-19 patients. In this chapter, we aim to analyze various ethical challenges that could influence the decision to introduce pharmacogenetic tests in patients with COVID-19.

## II. Pharmacogenetics and COVID-19: general considerations

In recent decades, terms such as genomic medicine, personalized medicine, precision medicine, pharmacogenetics, pharmacogenomics etc., have become increasingly important both in scientific studies and in everyday clinical practice.

Genomic medicine can be defined as “an emerging medical discipline that uses genomic information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use.”<sup>4</sup>

Personalized medicine represents an “emerging practice of medicine that uses an individual’s genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease. Knowledge of a patient’s genetic profile can help doctors select the proper medication or therapy and administer it using the proper dose or regimen.”<sup>5</sup> Personalized medicine actually means that the approach of “one size fits all” is replaced with the “right drug”.

Precision medicine is defined as “an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person.”<sup>6</sup>

<sup>3</sup> Pooneh S, Bagher L. “Ethical Issues Surrounding Personalized Medicine: A Literature Review”, *Acta Med Iran* 55 (3)(2017): 209-217.

Korngiebel DM, Thummel KE, Burke W. “Implementing Precision Medicine: The Ethical Challenges”, *Trends Pharmacol Sci* 38(1) (2017): 8–14.

Schmidlen T, Sturm AC, Shelly H, Scheinfeldt L, Scott JR, Morr L, McElroy J, Toland AE, Christman M, O’Daniel JM, Erynn S, Bernhardt AB, Kelly E, Sweet K. “Operationalizing the Reciprocal Engagement Model of Genetic Counseling Practice: A Framework for the Scalable Delivery of Genomic Counseling and Testing”, *J Genet Couns* 27(5)(2018): 1111–1129.

Fricke-Galindo I, Falfán-Valencia R. “Pharmacogenetics Approach for the Improvement of COVID-19 Treatment”, *Viruses* 13 (2021): 413.

<sup>4</sup> NHGRI: Genomics and medicine [www.genome.gov/health/Genomicsand-Medicine](http://www.genome.gov/health/Genomicsand-Medicine) (accessed Aug. 22, 2021)

<sup>5</sup> NHGRI: Talking glossary of genetic terms. Personalized medicine. [www.genome.gov/genetics-glossary/Personalized-Medicine](http://www.genome.gov/genetics-glossary/Personalized-Medicine) (accessed August 22, 2021)

<sup>6</sup> NCI: NCI dictionary of cancer terms. Precision medicine. [www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine](http://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine) (accessed August 22, 2021)

Pharmacogenetics represents the science that studies how heredity can influence variability in drug response. Such studies may have an impact on the efficacy of certain drugs, as well as on safety, i.e., the occurrence of side effects during the application of a therapy. While pharmacogenetics usually examines a variation in one single gene (single nucleotide polymorphism – SNP) and its influence on the response to a single drug, pharmacogenomics represents a broader term, and it studies how all genes (the genome) can influence responses to drugs.<sup>7</sup>

It is well known that single nucleotide polymorphisms (SNPs) are the most common type of genetic variation among people. Especially important for clinical practice is the genetic variation in genes encoding phase 1 cytochrome P450 (CYP) or phase 2 drug-metabolizing enzymes, transporters and other drug targets, and predict drug efficacy or toxicity. COVID-19 is an infection that has shown numerous different manifestations to date, concerning the clinical presentation, the course of the disease and the final outcome of treatment. The virus SARS, for example, is affecting several organ systems and can lead to severe acute respiratory syndrome. In most cases, the disease clinically manifests itself with self-limiting mild-to-moderate symptoms of an upper respiratory tract infection and general symptoms such as myalgia and fatigue. However, some affected patients develop an uncontrolled immune response, leading to an increase of pro-inflammatory cytokines and chemokines, when hospital care is necessary. In severe COVID-19-positive patients, complications such as acute kidney injury, renal failure, myocardial injury, liver dysfunction, blood leukocyte abnormalities, septic shock, disseminated intravascular coagulation etc. have been described.<sup>8</sup>

The pharmacotherapy of a COVID-19 infection has proven to be very challenging and controversial, and new information from clinical trials is continuously generated.

A large number of drugs have been used and tested worldwide with variable efficacy and safety. It has also been shown that the same therapeutic protocol does not show the same clinical results in all infected patients. For example, certain drugs have been used with extremely high efficacy and safety in certain patients, while in some other patients, they have been shown to be insufficiently effective and/or safe.

To date, there is a lack of a completely effective and safe pharmacotherapy for COVID-19. The available treatment for COVID-19 mainly includes drugs and therapy that have been used for other infectious and non-infectious diseases to treat symptoms based on disease severity. The use of antiviral agents (remdesivir, lopinavir/ritonavir, oseltamivir), antibiotics (azithromycin), antiparasitics

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<sup>7</sup> Kurnat-Thoma E. “Educational and Ethical Considerations for Genetic Test Implementation Within Health Care Systems”, *Network and Systems Medicine* 3 (1) (2020) <http://online.liebertpub.com/doi/10.1089/nsm.2019.0010>.

<sup>8</sup> Roberts CM, Levi M, McKee M, Schilling R, Lim WS, Grocott MP. “COVID-19: A complex multisystem disorder”, *Br J Anaesth* 125 (2020): 238–242.  
Zheng KI, Feng G, Liu WY, Targher G, Byrne CD, Zheng MH. “Extrapulmonary complications of COVID-19: A multisystem disease?”, *J Med Virol* 93 (2020): 323–335.



(chloroquine, hydroxychloroquine, ivermectin), and corticosteroids (dexamethasone) have been reported in the literature.<sup>9</sup>

Taking all this into account, pharmacogenetics could explain the inter-individual variability in drug response based on the individual genetic characteristics of COVID-19 patients. Variants in genes encoding drug-metabolizing enzymes, transporters, or receptors have been reported, and they could provide insight into achieving personalized therapy that will lead to a better outcome for this complex infection. However, it should be noted that besides pharmacogenetic variants reported for drugs used to treat COVID-19, scientists and clinicians need to consider other genetic and non-genetic factors when interpreting the obtained results.<sup>10</sup> For example, the pharmacogenetic studies need to analyze the impact of the interaction between genes and some nongenetic factors (e.g., age, gender, co-treatment, disease severity) as well as genes-drugs and genes-inflammation/ infection processes in COVID-19 relations.<sup>11</sup>

Due to all of the above, the fact that knowledge about the COVID-19 infection is continuously expanding and being supplemented, we believe that pharmacogenetic tests will especially gain importance in the coming period, primarily in improving the outcome of pharmacotherapy for patients with this disease.

### III. Pharmacogenetics and COVID-19: Ethical challenges

#### A. Risk/benefit assessment

Based on the previous observations, pharmacogenetics represents a possible basis for the transition from modern medicine to personalized medicine. Such an approach to therapy is particularly important in the treatment of COVID-19 infection. The current practice has shown great diversity when it comes to the variety of symptoms, their severity, as well as the response to the prescribed therapy. Doctors have called COVID-19 “the disease with a thousand faces”, and the fact that the pharmacotherapy protocols have been changed more than ten times so far speaks for itself.

However, many questions should be raised and considered before recommending pharmacogenetic testing to improve the efficacy and safety of COVID-19 therapy.

It is necessary to consider which patients or groups of patients are most likely to have a significant health benefit from such expensive and complex procedures. In such studies, one should be sure that investing financial and scientific resources in individuals needs to have a significant positive impact on public health.

<sup>9</sup> Rochweg B, Agarwal A, Zeng L, Leo YS, Appiah JA, Agoritsas T, Bartoszko J, Brignardello-Petersen R, Ergon B, Ge L. “Rapid recommendations Remdesivir for severe covid-19: A clinical practice guideline”, *BMJ* 370 (2020): 2924.

<sup>10</sup> Bishop J.R. “Pharmacogenetics” in *Handbook of Clinical Neurology* (Amsterdam, The Netherlands: Elsevier, 2018) 147: 59–73.

<sup>11</sup> Smit RA, Noordam R, le Cessie S, Trompet S, Jukema JW. “A critical appraisal of pharmacogenetic inference”, *Clin Genet* 93 (2018): 498–507.

1Shah RR. “Pharmacogenetics and precision medicine: Is inflammation a covert threat to effective genotype-based therapy?” *Ther Adv Drug Saf* 8 (2017): 267–272.

In this way, the appropriate selection of patients who will be more likely to benefit from a certain drug in the treatment of COVID-19 infection will be crucial. In this way, smaller groups of patients/cohorts would be formed with lower costs. Still, some authors continue to point out this issue as very controversial and report many significant obstacles concerning pharmacogenetic testing.<sup>12</sup>

### B. Selection of participants

Proper patient selection is one of the most important steps in pharmacogenetic studies. It is known that only some patients developed moderate and severe clinical presentations of COVID-19 infection and that in some patients the response to the prescribed therapeutic protocols is not satisfactory.

Many drugs used in the treatment of COVID-19 are metabolized by a number of drug-metabolizing enzymes called cytochrome P450 (CYP) enzymes. Genetic variants of the CYP genes encoding these important CYP enzymes may regulate their expression and may also contribute to drug response variability. Therefore, to achieve optimal efficacy or safety in COVID-19 treatment, CYP genes of interest should be considered in future clinical studies to investigate such genetic associations. In addition to this, a number of patients may develop serious unwanted reactions related to the drugs used in the treatment of COVID infection. It is also necessary to take into account the influence of gender, age, and the presence of other diseases.<sup>13</sup>

All these are data that can affect the correct interpretation of the obtained results. It should be pointed out that before introducing any recommendation regarding pharmacogenetic testing related to COVID-19, it is necessary to have appropriate reliable and scientifically proven data.

### C. Informed consent

The importance of informed consent in clinical medicine is well-known from an ethical point of view. Personalized medicine and genetic testing have introduced new ethical considerations. In some cases, it seems that there is no individual benefit from these kinds of tests. Having in mind the specificity of such tests, as well as the interpretation of the obtained results, the question arises whether it is necessary to create a special form of informed consent for pharmacogenetic testing. Such testing sometimes involves testing the patient's family and relatives to determine the exact link between the genetic basis and the effect of the drug. Such research can be particularly important, as it is common for entire families to be infected with the virus (which is SARS-CoV-2), but the clinical forms of the disease and the patient's response to therapy can be highly individual. Generally, the issue of informed consent

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<sup>12</sup> Breckenridge A, Lindpaintner K, Lipton P, McLeod H, Rothstein M, Wallace H. "Pharmacogenetics: ethical problems and solutions", *Nat Rev Genet* 5 (2004): 676-80.

Petersen KE, Prows CA, Martin LJ, Maglo KN. "Personalized medicine, availability and group disparity: an inquiry into how physicians perceive and rate the elements and barriers of personalized medicine", *Public Health Genomics* 17 (2014): 209-20.

<sup>13</sup> Webster A, Martin P, Lewis G, Smart A. "Integrating pharmacogenetics into society: in search of a model", *Nat Rev Genet* 5 (2004): 663-9.

is the most challenging ethical question because it should contain important information about sample storage, usage, as well as anonymity and coding system.

A special ethical issue is a need for informed consent for vulnerable categories of patients (pregnant or breastfeeding women, minors, older people, people suffering from multiple chronic conditions or terminally ill, people affected by mental health disorders, ethnic minorities etc.). Each of the listed groups of vulnerable patients has its specific need, which has to be taken into consideration. Additionally, some ethical issues related to these groups of patients need to be also part of ethical codes of conduct or local legislation. These include additional requirements related to the objectives of the study, risk-benefit assessment, strict adherence to the study protocol and additional steps in the course of obtaining informed consent.<sup>14</sup>

In addition to the above, the specificity of pharmacogenetic testing in patients with COVID-19 infection is due to the fact that it is a novel and still insufficiently researched disease. Also, there is a lot of contradictory data about this infection, which can make it difficult for patients to accept additional (e.g. pharmacogenetic) testing. In this sense, short educational videos or other informative content could facilitate the understanding and consent for this type of testing for patients and/or their caregivers.

#### *D. Health care system procedures and the physician-patient relationship*

Personalized medicine can be defined as “patient-centric medicine” based on each individual’s condition in order to raise the quality of healthcare services and improve the clinical outcome. It is very important to respect the dignity of individuals, regardless of their genetic characteristics, sex, age, race, age, etc.<sup>15</sup>

Additionally, there is often a lack of well-trained medical doctors and other healthcare workers to implement and interpret such complex results. This also can lead to a loss of confidence in the national health system. This trend of distrust in medical doctors, medicine and science, in general, is particularly pronounced and growing worldwide during the current COVID-19 pandemic. In addition to the lack of adequate medical knowledge, one of the challenges that health systems can have is the lack of appropriate, necessary medical equipment to conduct such complex studies. Besides, the implementation of clinical pharmacogenetic tests for COVID-19 infection poses a financial burden on the already challenged public healthcare systems in many countries.

Therefore, it is imperative that this type of pharmacogenetic testing is recommended and performed just in medical centres that have adequate professional, technical and financial support.

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<sup>14</sup> Badzek L, Henaghan M, Turner M, Monsen R. “Ethical, legal, and social issues in the translation of genomics into health”, *J Nurs Scholarsh* 45 (2013): 15-24.

<sup>15</sup> Badzek L, Henaghan M, Turner M, Monsen R. “Ethical, legal, and social issues in the translation of genomics into health”, *J Nurs Scholarsh* 45 (2013): 15-24.

### *E. Interpretation and availability of obtained results*

We have already mentioned that the interpretation of the results obtained from pharmacogenetic tests is very specific and complex. Interpreting such tests in a novel, systemic and highly unpredictable disease, such as COVID-19, is even more challenging. For example, Hansson et al., indicate that personalized medicine may cause a crisis of confidence and recommend balancing individual interests in protecting genetic information versus society's interests in the limited use of such data for public health benefit.<sup>16</sup>

A particular problem in the interpretation of all pharmacogenetic tests is the appearance of so-called “incidental findings”. Incidental findings have been defined as “observations of potential clinical significance unexpectedly discovered in research participants and unrelated to the purpose or variables of the study”. These kinds of results are detected unexpectedly during the analysis and are also unrelated to the primary testing indication. This represents the finding of one or more gene variants, which may have serious health implications for individuals or even other family members. Nevertheless, the possibility of such findings is not easily predictable, and sometimes the importance of these data may not be fully understood.<sup>17</sup>

Recently, the American College of Medical Genetics and Genomics (ACMG) recommended disclosure of incidental findings and analysis which will take the four bioethical principles of autonomy, justice, beneficence and non-maleficence under debate in pharmacogenetic tests and personalized medicine in general.<sup>18</sup> ACMG recommends that the study participants should not be permitted to choose to inform about incidental findings. The report also departs from long-standing consensus recommendations on testing children. The ACMG acknowledges that “The standards for predictive testing in clinical genetics recognize a distinction between providing results to adults and providing results to children and adolescents, with consistent recommendations that predictive testing for adult-onset diseases not be offered to children.”<sup>19</sup>

Other authors assume that knowledge of incidentals should be considered and analyzed based on the patient's preferences. In the context of genetic testing, the “right not to know” refers to the idea that adults should be permitted to control whether they receive genetic information – particularly information about the risk of future illness – and that their desire not to know certain kinds of information should be respected. The “right not to know” in this context represents a leading ethical principle, and it is also the law in the EU countries.<sup>20</sup>

Also, it should be pointed out that current pharmacogenetic tests possess some limitations which include the following:

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<sup>16</sup> Hansson MG. “Taking the patients side: the ethics of pharmacogenetics”, *Per Med* 75 (2010): 75-85.

<sup>17</sup> Evans JP, Rothschild BB. “Return of results: not that complicated?”, *Genet Med* 14 (2012): 358-60.

<sup>18</sup> Green R, Berg J, Grody W, Kalia SS, Korf BR, Martin CL. “ACMG recommendation for reporting of incidental findings in clinical exome and genome sequencing”, *Genet Med* 15 (2013): 565-74.

<sup>19</sup> Wolf S, Annas G, Elias S. “Point-counterpoint. Patient autonomy and incidental findings in clinical genomics”, *Science* 340 (2013): 1049-50.

<sup>20</sup> Offit K, Groeger E, Turner S, Wadsworth EA, Weiser MA. “The ‘duty to warn’ a patient's family members about hereditary disease risks”, *JAMA* 292 (2004): 1469-73.

- One single pharmacogenomic test cannot be used to determine how you will respond to all medications;
- Pharmacogenomic tests are not available for all medications.

We can conclude from this discussion that the interpretation of the results obtained by pharmacogenetic testing is very complex and requires highly educated medical professionals.

#### IV. Conclusion

Conducting pharmacogenetic tests on individual patients suffering from COVID-19 infection could be of great clinical and scientific importance. This would allow for the individualization of pharmacotherapy and it would make it easier to understand the complex mechanisms of interactions at the level of the individual patient's genes, on one hand, and viruses and applied therapy, on the other hand. However, before implementing such specific analyses, the benefits and limitations of these procedures should be considered. Particular attention should be paid to ethical considerations that exist in the performance of pharmacogenetic tests.

Since COVID-19 represents a novel and still insufficiently researched disease about which new information is continuously revealed, pharmacogenetic tests may further accelerate the development of precision COVID-19 therapies in real-world clinical settings. However before a definitive recommendation for the introduction these tests into clinical practice, additional knowledge and the implementation of clinical studies are necessary that would indicate the real advantages and improvement of pharmacotherapy in these patients. In the end, we can conclude that pharmacogenetics could help but needs to be regulated to avoid ethical and clinical pitfalls.

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# THE ETHICAL CHALLENGES OF DECENTRALIZED CLINICAL RESEARCH DURING AND AFTER THE COVID-19 PANDEMIC

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## **Abstract**

The COVID-19 pandemic brought multiple challenges to societies worldwide and proved to be particularly disruptive to clinical research. To mitigate the impact of the pandemic on clinical studies, governmental agencies and research institutions turned to technical solutions, which allowed studies to be carried out virtually using the tools of telemedicine and remote health monitoring. This relatively new form of clinical research is known as Decentralized Clinical Trials (hereafter DCT). In this chapter, we explain the concept of DCT and its main characteristics, and offer a brief overview of the purported advantages of DCT for pandemic research. Next, we identify and analyze some key ethical challenges specific to DCT and consider possible or already implemented solutions. We conclude by providing ten key messages to researchers for the ethical implementation of DCT.

## **I. The Impact of COVID-19 on Clinical Research**

The COVID-19 pandemic brought multiple challenges to societies worldwide due to its unprecedented impact on healthcare systems, economies, finance, and education. The pandemic has been particularly disruptive for clinical research, which is defined as the study of disease prevention and causation, diagnostic methods, treatments, and the effects of and response to illness in human subjects. Clinical trials are considered a subset of clinical research. Clinical research is guided by the ethical principles of respect, justice, non-maleficence, beneficence, and research merit and integrity, which have been enshrined in national and international laws and regulations<sup>1</sup>. The

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<sup>1</sup> National Health and Medical Research Council, Australian Research Council, and Universities Australia (2018). National Statement on Ethical Conduct in Human Research (2007) [Updated 2018].

exigencies of the pandemic posed serious logistical and ethical challenges to clinical researchers. Many ongoing studies were brought to a halt because of concerns about the health and safety of research participants and staff, and due to lockdowns, restricted access to healthcare facilities and laboratories, and the urgent need to preserve medical resources and direct all efforts to the clinical care of those infected with COVID-19<sup>2</sup>. At the same time, clinical research became paramount in the efforts to understand the novel SARS-CoV-2 virus, to confine its spread, to understand its effects on other health conditions, and to develop treatments and vaccines against the disease. Hospitals and medical research organizations had to adapt quickly to the new circumstances and needs, and to mobilize their efforts to facilitate the emerging COVID-19-focused research projects in a timely manner. Many researchers and institutions made an effort to streamline their practices in conducting research during the pandemic. This required finding solutions to the major logistical and ethical challenges posed by the pandemic while adhering to all pre-pandemic scientific and regulatory standards for human subject research. Specifically, researchers had to ensure that participant safety remained the highest priority, and that the benefits of conducting a clinical study during the pandemic outweighed the risks to the research participants and staff. Of particular concern were participants from vulnerable populations at high risk of death or serious complications from COVID-19, such as adults over seventy years of age, older adults with chronic health conditions, residents in elderly care facilities, immunocompromised patients (e.g. due to chemotherapy), and certain minority groups whose socio-economic circumstances made them more susceptible to the disease. The risk of cross-infection between infected asymptomatic participants and research staff also had to be considered and minimized.

As part of the fundamental duty of care to research participants, researchers had to develop COVID-safe protocols<sup>3</sup> and emergency planning and to manage time-critical research work while responding to pressures related to deadlines, funding, and reduced access to facilities and laboratories<sup>4</sup>. The ethical and logistical challenges

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<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018> (accessed July 7, 2021)

<sup>2</sup> Aaron van Dorn. (2020). "COVID-19 and readjusting clinical trials," *The Lancet*, 396(10250), 523-524. [https://doi.org/10.1016/S0140-6736\(20\)31787-6](https://doi.org/10.1016/S0140-6736(20)31787-6) (accessed August 29, 2021)

<sup>3</sup> An example of this is the "Macquarie University COVID Safe plan," [https://www.mq.edu.au/\\_\\_data/assets/pdf\\_file/0007/989728/MQ-COVIDSafe-Plan.pdf](https://www.mq.edu.au/__data/assets/pdf_file/0007/989728/MQ-COVIDSafe-Plan.pdf) (accessed August 2, 2021)

<sup>4</sup> In March 2020, the US FDA published "Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: Guidance for Industry, Investigators, and Institutional Review Boards," <https://www.hhs.gov/guidance/document/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health> (accessed July 7, 2021)

The World Health Organization issued its guidelines entitled "Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D," <https://www.who.int/publications/i/item/WHO-RFH-20.1> (accessed July 7, 2021)

The European Medicinal Agency followed with "Guidance on the Management of Clinical Trials During the Covid-19(Coronavirus) Pandemic: Version 4," 04/02/2021, [https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/guidanceclinicaltrials\\_covid19\\_en.pdf](https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/guidanceclinicaltrials_covid19_en.pdf) (accessed July 7, 2021)

The Bulgarian Drug Agency followed with "Recommendations to the Sponsors for managing of Clinical Trials during the COVID-19 pandemic and the declared State of emergency in the Republic



posed by the pandemic called for quick decisions by clinical researchers regarding the implementation and modification of research protocols and methodologies to allow study activities to continue remotely through alternative means of communication and data collection via digital technologies.

Initially, however, there was a lack of guidelines to facilitate decision making about research in pandemic and, in the early stages of the pandemic, decisions had to be guided by the basic principles of research ethics and the common sense of the clinicians and researchers. To mitigate the impact of COVID-19 on clinical studies, governmental agencies and research institutions turned to technical solutions, which allowed studies to be carried out virtually using the tools of telemedicine (e.g. teleconferencing) and remote health monitoring via connected digital devices and platforms and smartphone health applications.

This relatively new form of clinical research is known as Decentralized Clinical Trials (hereafter DCT). Heralded as the solution to the challenges of human subjects research during the pandemic, DCT are viewed by many as a model for the trials of the future<sup>5</sup>. The adoption of DCT was accelerated by the pandemic and was considered a positive side effect of COVID-19<sup>6</sup>.

Even though DCT utilize already-existing technologies for telehealth, they are a relatively new concept which is at the early stages of adoption, and which employs technological solutions which have not been developed specifically for clinical trials<sup>7</sup>. Additionally, clinical researchers, ethics review boards, and research participants lack the necessary technical expertise to evaluate adequately the risks and benefits of using different digital platforms and tools<sup>8</sup>. For these reasons, DCT in general and the individual digital tools they rely on should be analyzed carefully to determine whether they can meet the needs of clinical research and solve the logistical and ethical challenges of conducting clinical research during and after the pandemic, while adhering to the established ethical, scientific, and regulatory standards.

This chapter is a step in this direction: we offer an ethical evaluation of DCT, examine the ethical and regulatory challenges they pose, and consider possible solutions to these challenges. The focus of the chapter is the use of DCT during the COVID-19 pandemic, however, the discussion identifies challenges, opportunities and solutions related to DCT in general, and, therefore, most of the analysis applies

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of Bulgaria,” <https://www.bda.bg/en/information-for-companies/118-clinical-trials-category/1810-recommendations-to-the-sponsors-for-managing-of-clinical-trials-during-the-covid-19-pandemic-and-the-declared-state-of-emergency-in-the-republic-of-bulgaria> (accessed July 7, 2021)

<sup>5</sup> Barbara Widmann, “Is a decentralized approach the future for clinical trials?” *Congenius*, 22.07.2021. <https://congenius.ch/decentralized-clinical-trials/> accessed 18 Aug. 2021.

Fan Gao, Maurice Solomon, Arnab Roy et al. “Why Decentralized Clinical Trials Are the Way of the Future,” *Applied Clinical Trials*, Apr. 05, 2021. <https://www.appliedclinicaltrials.com/view/why-decentralized-clinical-trials-are-the-way-of-the-future>. Accessed 18 Aug., 2021.

<sup>6</sup> Victoria Reese, “How will clinical trials change in light of COVID-19?” *European Pharmaceutical Review*, 14 Sept., 2020: URL: <https://www.europeanpharmaceuticalreview.com/article/128289/how-will-clinical-trials-change-in-light-of-covid-19/> (accessed August 17, 2021)

<sup>7</sup> Assya Pascalev. OHRP meets ToS: Cloud-based technologies in human subject research. *Journal of Clinical and Translational Science*, 2(S1), 85-85. June 2018 doi:10.1017/cts.2018.294

<sup>8</sup> Inan, O.T., Tenaerts, P., Prindiville, S.A. et al. “Digitizing clinical trials,” *npj Digit. Med.*3, 101 (2020). <https://doi.org/10.1038/s41746-020-0302-y> (accessed August 17, 2021)

equally to the use of DCT before, during and after the pandemic. Consequently, the solutions proposed here would apply, for the most part, to any clinical research that utilizes DCT.

The chapter has the following structure: first, we explain the concept of DCT, outline their main characteristics, and offer a brief overview of the ostensible advantages of DCT for pandemic research. Next, we identify and analyze some key ethical issues related to DCT and consider possible or already implemented solutions. We conclude by providing ten key messages to researchers.

## **II. Decentralized clinical trials as a solution to the challenges of conducting clinical research during a pandemic**

The Clinical Trials Transformation Initiative (CTTI) defines decentralized clinical trials (DCT) as trials executed through telemedicine and mobile/local healthcare providers (HCPs) using procedures that vary from the traditional clinical trial model (e.g. the investigational medical product [IMP] is shipped directly to the trial participant)<sup>9</sup>. DCT are also known as “virtual” or “direct-to-participant” trials because they operate with little to no physical contact between the study participants and the research team, which makes them particularly suitable when trying to limit person-to-person transmissions. DCT make little or no use of traditional research facilities and support staff for data collection, utilizing instead virtual means and automated tools, e.g. wearable devices and sensors, home visits, telehealth platforms and virtual patient portals, and delivery of study medications and other necessary materials directly to the participants’ homes.<sup>10</sup>

The remote nature of DCT allows research to proceed during emergencies such as lockdowns and despite shortages of healthcare staff. DCT become possible thanks to the fast development and adoption of internet-based connected digital devices and platforms, such as “smart” phones, wellness trackers (e.g. FitBit), remote monitoring devices and wearables (e.g. sleep trackers like the Oura ring used for early COVID-19 detection<sup>11</sup>, electronic health records, patient portals, remote monitoring devices and video conferencing (e.g. Zoom)<sup>12</sup>. The first entirely decentralized clinical trial

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<sup>9</sup> Clinical Trials Transformation Initiative. CTTI Recommendations: Decentralized Clinical Trials, 2018, <https://www.ctti-clinicaltrials.org/briefing-room/recommendations/ctti-recommendations-decentralized-clinical-trials> (accessed August 7, 2021)

<sup>10</sup> Inan, Tenaerts, Prindiville, et al. “Digitizing clinical trials”  
Van Norman Gail A., “Decentralized Clinical Trials,” 2021 *JACC: Basic to Translational Science* p. 384–387, Vol. 6 (4). doi:10.1016/j.jacbts.2021.01.011, <https://www.jacc.org/doi/abs/10.1016/j.jacbts.2021.01.011> (accessed August 7, 2021)

<sup>11</sup> Marielle S. Gross, Robert C. Miller, and Assya Pascalev. “Ethical Implementation of Wearables in Pandemic Response: A Call for a Paradigm Shift.” Harvard University Rapid Response Impact Initiatives/COVID-19, May, 2020. <https://ethics.harvard.edu/ethical-wearables> (accessed 16 August, 2021)

<sup>12</sup> Van Norman. “Decentralized Clinical Trials.” Data from Trials.Gov by the Harvard University team led by Marra et al. shows a 34% increase in the use of connected devices in clinical trials between 2000-2018. See Marra, Caroline et al., “Quantifying the use of connected digital products in clinical research,” *NPJ digital medicine* vol. 3 50. 3 Apr. 2020, doi: 10.1038/s41746-020-0259-x. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7125096/#MOESM2>. (accessed August 16, 2021)

was REMOTE (Research on Electronic Monitoring of Overactive Bladder Treatment Experience).<sup>8</sup> It was conducted in 2011 by Pfizer and took place entirely online. All its components, from subject recruitment to medication delivery and data collection, were implemented virtually without in-person contact between the study team and the participants. Even though DCT (or certain decentralized components) had already been part of clinical research before the pandemic, it was only with the onset of COVID-19 that decentralization became the primary way of conducting clinical research<sup>13</sup>. To carry on during the pandemic, the traditionally designed studies had to be modified accordingly to allow for online and decentralized data collection and delivery of health interventions (e.g. in the patient's home or community). The new studies also had to be designed as digital trials. Such modifications of research methodology impact many key components of a study, from incorporating digital tools to changes in the inclusion and exclusion criteria to reflect the use of these tools, as well as corresponding changes in the informed consent process, interventions, and the communication with the research subjects. Table 1, adapted from Dorsey et al., summarizes the main characteristics of traditional trials (before COVID-19) and DCT (during and after COVID-19)<sup>14</sup>.

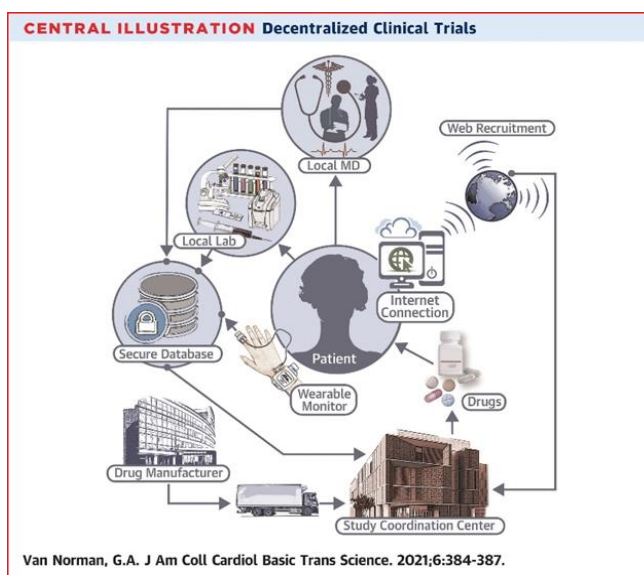


Fig. 1. Illustration of DCT (Adapted from Van Norman et al, *J Am Coll Cardiol Basic Trans Science* 2021, 6:384-387)

<sup>13</sup> FDA, Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency.

<sup>14</sup> Dorsey ER, Kluger B, Lipset CH (2020) "The New Normal in Clinical Trials: Decentralized Studies," *Ann Neurol* 88, 863–866. <https://pubmed.ncbi.nlm.nih.gov/32869367/>

**Table 1. Comparison of Clinical Trial Approaches Before, During, and After the COVID-19 Pandemic (Adapted from Dorsey ER et al, (2020) The New Normal in Clinical Trials: Decentralized Studies. *Ann Neurol* 88, 863–866)**

Characteristic	Before COVID-19	During and after COVID-19
Recruitment	Mainly from sites	Mainly online
Consent	In person	Electronic
Study visit location	Primarily in clinic	Primarily in home
Access to study drug	Via investigator	Via courier or visiting nurse
Method of assessing participants	In person	By telephone or video
End points	Often investigator-derived	Patient-reported or device-captured
Study oversight	On-site monitoring	Remote/central monitoring
Sponsor culture	Flexibility viewed as risk	Flexibility viewed as strength
Participant burden	High	Moderate
Participant involvement	Low and late	High and early

Notwithstanding the exigencies of the pandemic, DCT ought to meet the established ethical and regulatory requirements for human subject research and ensure participant safety while maintaining the research merit and scientific integrity and validity. In response, many national and international regulatory agencies issued guidance on incorporating digital tools and decentralized components in clinical research, and, in December 2020, the Decentralized Trials & Research Alliance (DTRA) was formed with the explicit purpose of promoting decentralized clinical research<sup>15</sup>. In response to the growing DCT activity in Australia and the need for national guidance, in early 2021 the Australian Government Department of Health issued a compendium to assist organizations engaged in clinical trials and to standardize their procedures for key operations related to clinical trials and specifically to DCT<sup>16</sup>. Consequently, many organizations had to rapidly implement new ways of supporting their clinical research activities while balancing the safety and well-being of the study participants, their families, the researchers, and other clinical trial staff. As a result, DCT, a research innovation before COVID-19, became the primary mode of conducting clinical trials in the pandemic. Compared to traditionally designed clinical research, DCT offers several advantages which were noted well before the pandemic and have led proponents to promote DCT as “the way of the

<sup>15</sup> Decentralized Trials & Research Alliance (DTRA) website <https://www.dtra.org/> (accessed August 18, 2021).

<sup>16</sup> The standards aimed to assure the public that the rights, safety, and well-being of trial participants are protected and comply with the ethical principles outlined in the Helsinki Declaration and that the data generated from the clinical trials is credible. See: Australian Government Department of Health. National principles for teletrials in Australia, 2021, <https://www.health.gov.au/sites/default/files/documents/2021/03/national-principles-for-teletrials-in-australia.pdf> (accessed July 24, 2021)

future”<sup>17</sup>, and “an opportunity to fundamentally change how we perform clinical research”<sup>18</sup>.

Below, we outline the main potential advantages of DCT research, namely: (1) broader geographical coverage, (2) increased participant diversity, (3) improved access to research for members of vulnerable groups, (4) improved recruitment and retention of study participants, (5) putting the needs of research participants at the center of the process (patient-centricity), (6) improved scientific quality, and (7) lower cost of clinical research.

Firstly, because DCT are not restricted to a particular site, they allow researchers to reach participants in remote and hard-to-access locations and in different regions, which allows for broader geographical coverage. This in turn gives patients from those isolated areas the opportunity to participate in clinical studies, which would not be available to them in a centralized model<sup>19</sup>.

Secondly, by overcoming geographic barriers, DCT also have the potential to overcome one of the major challenges for traditional clinical research, the lack of diversity among the study participants<sup>20</sup>. By improving participant access in general, DCT also make it easier for subjects from vulnerable populations who are currently most underrepresented in clinical trials (i.e., the elderly, ethnic minorities, the poor and/or those living in rural locations) to participate in research<sup>21</sup>. This is an essential aspect of DCT because the inclusion of participants from diverse ethnic and socio-economic backgrounds not only generates more reliable research data but also promotes trust in the research process and in the resulting product, be it a medical device, medication, or intervention.

A third and related benefit of DCT is the potential for faster and more efficient recruitment of study subjects and their improved retention. Digital participation reduces the logistical burdens for the participants, e.g. taking time off to travel to a central location, the cost of travel, the disruption of daily routines, or the lack of

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<sup>17</sup> B. Widmann, “Is a decentralized approach the future for clinical trials?” *Congenius*, 22.07.2021, <https://congenius.ch/decentralized-clinical-trials/> (accessed August 18, 2021).

Fan Gao, Maurice Solomon, Arnab Roy et al. “Why Decentralized Clinical Trials Are the Way of the Future,” *Applied Clinical Trials*, Apr. 05, 2021. <https://www.appliedclinicaltrials.com/view/why-decentralized-clinical-trials-are-the-way-of-the-future> (accessed August 18, 2021)

<sup>18</sup> Gao, Solomon, Roy et al. “Why Decentralized Clinical Trials Are the Way of the Future.”

<sup>19</sup> Inan, Tenaerts, Prindiville, et al. “Digitizing clinical trials.”

<sup>20</sup> Stephen J Walters, Ines Bonacho dos Anjos Henriques-Cadby, Oscar Bortolami, et al. Recruitment and retention of participants in randomized controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme,” *BMJ Open* 2017;7:e015276. doi: 10.1136/bmjopen-2016-015276, <https://bmjopen.bmj.com/content/7/3/e015276> (accessed August 18, 2021)

Carsten Sommer, Diego Zuccolin, Valdo Arnera et al. “Building clinical trials around patients: Evaluation and comparison of decentralized and conventional site models in patients with low back pain.” *Contemporary clinical trials communications* vol. 11 120-126. 28 Jun. 2018, doi:10.1016/j.conctc.2018.06.008,

<https://www.sciencedirect.com/science/article/pii/S2451865418300358> (accessed August 18, 2021)

Van Norman. “Decentralized Clinical Trials.” Inan, Tenaerts, Prindiville, et al. “Digitizing Clinical Trials.”

<sup>21</sup> Van Norman. “Decentralized Clinical Trials.”

physical mobility<sup>22</sup>. By removing such common logistical obstacles, DCT make it easier to participate in a trial and to remain in it, which in turn improves retention rates.

Perhaps the most significant advantage of DCT over traditionally designed trials is their patient centricity, a term that refers to the ability of DCT to design the study protocols around the individual needs of the research subjects and to give participants and their caregivers greater flexibility and control during the trial. Patient-centered protocols take into consideration the lifestyle of the person and his or her caregivers, their level of health literacy and other relevant factors, and offer them various options for meeting the study requirements (e.g. communicating with the study team via teleconferences, emails, text messages, or phone calls). Participants also receive education and support to enable them to participate in the study based on their actual needs, e.g. how to use a device, application or platform<sup>23</sup>. In DCT, the interactions between participants and research staff take place virtually and could be scheduled at a frequency desired by the participants and at the time most convenient for them. The patient-centered orientation of DCT could not only enhance the experience of the participants and their willingness to participate in research. It could also improve compliance and the safety of the study<sup>24</sup>.

Another advantage of DCT is their ability to achieve data refinement and to decrease the sample size of a trial, which can improve the scientific quality of the research data<sup>25</sup>. Thanks to the use of digital tools, which allow real-time monitoring, data collection, and continuous transmission of information, DCT provide more comprehensive and accurate information enhancing the scientific validity of the research e.g. “by enabling the development of individualized thresholds for measuring treatment effects. Digitalized tools such as biometric sensors may allow more objective methods of measuring pain, quality of life, functional status, and cognitive function, permitting a better understanding of individual responses to treatment and individualized patient toxicities.”<sup>26</sup> Unlike traditional trials, DCT can capture “data in a real-life setting that reflects the circumstances where the intervention will ultimately occur and across diverse populations.”<sup>27</sup> This could speed up the recruitment of research participants and help to reach the expected recruitment target faster.

Another consideration in favor of DCT is the lower cost of conducting research remotely. It has been estimated that, compared to a traditional study, a well-executed digital trial can reduce the cost per trial participant by 50% because of reduced travel

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<sup>22</sup> Van Norman. “Decentralized Clinical Trials.”

Gao, Solomon, Roy et al. “Why Decentralized Clinical Trials Are the Way of the Future.”

<sup>23</sup> Neha Shankar Sharma. “Patient centric approach for clinical trials: Current trend and new opportunities,” *Perspectives in clinical research* vol. 6,3 (2015): 134-8. doi:10.4103/2229-3485.159936 (accessed 18 August, 2021)

<sup>24</sup> Van Norman. “Decentralized Clinical Trials.”

<sup>25</sup> Van Norman. “Decentralized Clinical Trials.”

<sup>26</sup> Romée Melanie Helena Coert et al. “Stakeholder Perspectives on Barriers and Facilitators for the Adoption of Virtual Clinical Trials: Qualitative Study,” *Journal of medical Internet research* vol. 23,7 e26813. 6 Jul. 2021, doi:10.2196/26813 (accessed 24 August 2021)

<sup>27</sup> Coert et al. “Stakeholder Perspectives”

for testing, and minimal or no face-to-face contact<sup>28</sup>. The automation of data collection also reduces or eliminates the need for trained staff such as nurses, research assistants, and study coordinators to collect data because, in DCT, this is accomplished virtually via digital tools<sup>29</sup>. This could mean smaller teams and lower overall trial costs to the sponsor.

The above potential advantages of DCT notwithstanding remain a novelty that needs further critical examination<sup>30</sup>. Central to such an analysis is the ethical evaluation of the challenges, risks, and benefits of DCT, so as to ensure the safety and wellbeing of study participants in the new digital environment of clinical research. Our review of the published literature to date revealed that, with very few exceptions, most of the articles on DCT have been written by authors who are technical experts, researchers or representatives of the pharmaceutical industry. There are hardly any independent or multidisciplinary analyses, e.g. by ethicists, medical sociologists, or patients, which evaluate DCT. This suggests that, at present, many of the above-mentioned advantages of digitized clinical research are based on expectations and assumptions<sup>31</sup>, which are still to be tested empirically and confirmed independently. Ethical analyses of DCT are particularly scant, which points to a gap in our current understanding of the ethical implications of digitally delivered research. In the next section, we identify and discuss key ethical issues raised by DCT.

### III. Key challenges related to DCT

While DCT offer logistical solutions to many of the challenges posed by the pandemic, DCT also pose their own set of ethical and regulatory challenges due to the nature of digital technology on which DCT rely, and the risks inherent in it. The ethical challenges of virtual research include (1) modifying research protocols to allow for decentralized activities while meeting all ethical requirements for clinical trials, (2) lack of expertise in ethical reviews and the approval of digital tools for DCT, (3) different regulatory standards of privacy for clinical trials and for commercial digital tools, (4) risks to participants' privacy and confidentiality involving both data and physical privacy, e.g. in the participants' homes where digital communications and data collection occurs, (5) the impact of the digital divide on DCT, (6) a related risk of technology-related subject selection bias and the digital marginalization of vulnerable groups, (7) imposing new burdens on research participants and caregivers due to the technology needs of DCT and the smaller research teams, (8) creating a sense of isolation and restricted access to the PI and the study team, and (9) the impact of digital technology of the informed consent process and on the research

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<sup>28</sup> Coert et al. "Stakeholder Perspectives"

Sommer, Zuccolin, et al. "Building clinical trials around patients."

<sup>29</sup> Van Norman. "Decentralized Clinical Trials."

<sup>30</sup> Van Norman. "Decentralized Clinical Trials."

<sup>31</sup> Gaurav Agrawal, Rachel Moss, Ralf Raschke, Stephan Wurzer, and John Xue. "No place like home? Stepping up the decentralization of clinical trials." June 10, 2021: <https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials> (accessed 24 August 2021)

subject's understanding<sup>32</sup>. In the remainder of the chapter, we analyze these ethical challenges and propose possible solutions.

### *1. Modifying research protocols for DCT.*

A major challenge of decentralized research is the need to modify substantially the traditional research methodology to allow for the remote trial activities. The changes could impact any aspect of a clinical trial, from identifying and recruiting potential participants to informed consent, the delivery of investigational products, data collection and the delivery of health interventions or diagnosis, the use of mobile health care providers, communication between the study subjects and the research team, and the right to withdraw. Additional protocol amendments may also become necessary as the situation changes in response to the pandemic, the needs of participants, or to the local resources (e.g., if the participants have to travel to local sites to obtain more specialized medical tests of interventions). The modifications needed for DCT could negatively impact the scientific validity and the ethical aspects of the research. A further challenge is that researchers, ethics review boards (e.g. IRBs), and study participants may lack the technological and legal expertise necessary to identify and address the various risks that may arise when conducting research in a decentralized, digital environment, e.g. privacy, data security, or regulatory differences across state or national jurisdictions, which are particularly important for multi-site trials. To address the challenges arising from protocol modifications for DCT, researchers should adhere to the same ethical principles which apply to traditional clinical trials, and protocols for DCT ought to meet the same standards of research ethics, scientific merit, and integrity as traditional studies. Likewise, the process of ethical review for DCT should also be the same and should ensure that participant safety and well-being remain paramount. An important step in this process is the engagement of patient representatives at all stages of research and taking their concerns into consideration<sup>33</sup>. Indeed, it is recommended to engage all stakeholders in the planning and design of a decentralized study<sup>34</sup>.

### *2. Lack of expertise in ethical reviews and approval of digital tools for DCT.*

Ensuring the integrity and confidentiality of research data is a fundamental responsibility of researchers<sup>35</sup>. In the virtual environment of DCT, implementing this ethical requirement becomes both particularly important and challenging due to the fact that the health data of research subjects is collected and transmitted online. The process involves different encryption protocols and storing the data on cloud-based platforms. Ethics committees which evaluate virtual technology for use in DCT should ensure that it meets the requirements for data validity and participant safety

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<sup>32</sup> Van Norman. "Decentralized Clinical Trials."

<sup>33</sup> CTTI [https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI\\_Patient\\_Group\\_Executive-Summary.pdf](https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Patient_Group_Executive-Summary.pdf).

<sup>34</sup> [https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI\\_DCT\\_Recs.pdf](https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_DCT_Recs.pdf), Especially p. 6

<sup>35</sup> See 21 CFR 56.111 (FDA) and 45 CFR 46.111 (OHRP/Common Rule): "Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects."



by considering two questions: 1) does the technology generate reliable data? and 2) are the data adequately protected? Answering these questions will likely require technological expertise regarding data transmission and storage, cloud-based platforms, and encryption protocols. Yet ethics review boards may not have sufficient information and the necessary technological expertise to assess adequately the digital tools and platforms to be used in DCT. To meet the need for technological expertise, IT specialists should be included in the protocol review process, e.g. as IRB members<sup>36</sup>, or as ad hoc advisers. At the same time, members of ethics review boards, and data safety and monitoring boards should receive training in the ethical, safe and effective use of digital technology, the risks associated with it, and best practices for privacy and cybersecurity in health care<sup>37</sup>. As noted by Inan et al., “the research teams of the future will have a different composition compared with those of today [and] will be transformed to include computer scientists and engineers as critical partners for both technology development, but also data collection, analysis, security, and privacy... so that they have a common language with their technical partners and know which questions they should be asking.”<sup>38</sup>

### *3. Different regulatory standards of privacy for clinical trials and for commercial digital tools.*

Most of the technologies used for DCT have not been developed for clinical use and research but for very different commercial purposes. Under the exigencies of the COVID-19 pandemic, online tools such as Zoom, Google Meet, Skype for business, and Microsoft Teams have been widely adopted internationally and became the primary means of communication during the lockdowns, including for clinical trials. However, the compliance of these platforms (or the lack of compliance) with the Health Insurance Portability and Accountability Act [HIPAA], the EU General Data Protection Regulation [GDPR] and local laws such as the California Consumer Privacy Act [CCPA] has not been explored. Such tools are not required to meet the applicable legal and ethical requirements for clinical use and do not comply with the necessary privacy standards for clinical trials<sup>39</sup>. Moreover, as we note elsewhere, the regulatory standards for user consent and the privacy of tools developed for commercial purposes are very different from those for health use<sup>40</sup>. While consenting to data collection and sharing in clinical trials is a tightly regulated, opt-in process, commercial vendors typically use opt-outs as the default for data collection and use. Such vendors gather large amounts of users’ personally identifiable information (including health data) under opaque and poorly understood terms of

<sup>36</sup> The Harvard Catalyst, Providing IT expertise to the IRB: <https://catalyst.harvard.edu/publications-documents/providing-it-expertise-to-the-irb/>

James Riddle, IRB Review of Virtual Trial Technologies, 13 Aug., 2020: <https://www.advarra.com/blog/irb-review-of-virtual-trial-technologies/> (accessed 18 August 2021)

<sup>37</sup> Inan, Tenaerts, Prindiville, et al. “Digitizing clinical trials.”

<sup>38</sup> Inan, Tenaerts, Prindiville, et al. “Digitizing clinical trials.”

<sup>39</sup> Pascalev A, “OHRP meets ToS.”

Inan et al. “Digitizing clinical trials.”

<sup>40</sup> Pascalev A, “OHRP meets ToS.”

service agreements. They allow the companies to have broad access to user data, and to engage in cross-platform aggregation and tracking, and data retention and sale. They also use personal data for targeted marketing and for other secondary applications. A case in point is Treato, a commercial data mining company, which operated between 2007 and 2018 monitoring the conversations of millions of patients on social media (Facebook, Twitter) and patient forums in real time using big data analytics. It then made the data available to pharmaceutical companies for research and development purposes<sup>41</sup>. Such questionable practices, while not illegal under the vendor's terms of service, raise serious ethical concerns and expose the regulatory gap that exists between human subject research and the commercially available technology for DCT<sup>42</sup>. Additionally, the IT specialists who develop these technologies presently do not partner with clinical researchers, who, in turn, lack the expertise to support DCT technologically. Because of that, authors caution that merely “purchasing app development from a third-party vendor will not be enough to sustain a digital clinical trial”<sup>43</sup>. They also warn against the use of participants' own devices because their privacy settings may compromise the confidentiality of the data.

To address the regulatory challenges of DCT, research teams must establish partnerships with the IT community and work together to develop digital tools specifically tailored to the needs of clinical research in compliance with the regulatory standards of safety and privacy for clinical trials. While this is a long-term goal, more immediate solutions to the regulatory gap between the terms of service of commercial platforms and the more stringent data regulations of clinical research are also available. Research organizations should consider using existing industry certifications standards for privacy and confidentiality, e.g. HITRUST<sup>44</sup> or ONC<sup>45</sup>. It is also recommended that researchers and review boards consider obtaining a Certificate for Confidentiality, which allows researchers to protect participant data from disclosure in legal proceedings<sup>46</sup>.

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<sup>41</sup> Sharma, NS. “Patient centric approach for clinical trials: Current trend and new opportunities.”

<sup>42</sup> This is the case in the USA, which lacks a federal privacy law such as the EU General Data Protection Regulation and relies instead on obsolete rules for consumer data use developed several decades ago and regulated by the Federal Trade Commission. See “Privacy Online: Fair Information Practices in the Electronic Marketplace: A Federal Trade Commission Report to Congress,” Federal Trade Commission. 2000-05-01. Retrieved 2021-11-24. It has been acknowledged that there is lack of guidance for the use of social media in recruitment (See A. Pascalev, “Soc. Media in Recruitment, and Inan].”

<sup>43</sup> Inan et al. “Digitizing clinical trials.”

<sup>44</sup> HITRUST, Data Protection, Information Risk Management and Compliance Program <https://hitrustalliance.net/the-hitrust-approach/> (accessed 23 August 2021)

<sup>45</sup> The Office of the National Coordinator for Health Information Technology (ONC), Certification of Health, IT <https://www.healthit.gov/topic/certification-ehrs/certification-health-it> (accessed 23 August 2021)

<sup>46</sup> Harvard Catalyst, Important IT Considerations For IRB Members, V5/11/13/2018: “Is a Certificate of Confidentiality appropriate for the study?” <https://www.google.com/search?client=firefox-b-d&q=Harvard+catalyst%2C+IMPORTANT+IT+CONSIDERATIONS+FOR+IRB+MEMBERS%2C+V5%2F11%2F13%2F2018%3A+%E2%80%9CIs+a+Certificate+of+Confidentiality+appropriate+for+the+study%3F+> (accessed 23 August 2021)

#### 4. *Data privacy and confidentiality in DCT*

As the above discussion shows, the use of different technologies to conduct DCT and the need to manage the privacy implications of recording, transmitting, storing, and sharing participant data raise important privacy considerations concerning both the digital data and the physical privacy of the study subjects. In a traditional trial, participant data is stored under lock and key in a physical location and can only be accessed by designated staff. In a DCT, however, the data is collected virtually and travels through the internet. The data is stored on third party servers (clouds), has varying levels of protection through encryption protocols, and is accessible to third parties such as commercial technology vendors. This makes digitally collected data more exposed to unauthorized access and breaches<sup>47</sup>. These risks make data privacy and confidentiality in DCT a primary ethical concern because ensuring the integrity of participants' data and protecting their confidentiality are as important for the ethical conduct of the trial as the actual intervention. A further ethical challenge to participants' privacy and consent in a virtual environment is the ambient presence of a new third party - the technology vendor. Consequently, even though a clinical research team which utilizes a commercial tool is both required and capable of providing robust data protection of the participants' data (once it enters the study's institution), that data remains "visible" to commercial third parties such as the internet provider or the browser vendor during the data collection and transfer process. This reinforces the need to implement robust data security and privacy measures throughout the life cycle of the study<sup>48</sup>. This is important not only for compliance purposes but also for building trust in medical research among study participants and especially those from historically disenfranchised groups. A recent study by Liu et al. found that minorities and other vulnerable populations are concerned about sharing their health data with research teams. Most of the concerns related to "information collected through apps that could be sold or shared without their permission."<sup>49</sup>

It is the responsibility of researchers, and the ethics review boards to ensure that the technology used in a virtual trial provides adequate protections of privacy and confidentiality. Special consideration should be given to the risks of geolocation tracking, cloud storage and data transfer in other countries, or the use of participants' own devices, which may lack adequate protections. Any risks to the data must be clearly stated and fully disclosed in the informed consent, which should explain complex concepts like "encryption" and "data aggregation" in terms that the participants can understand. Researchers should also consider using technological solutions which offer greater levels of protection for data privacy and security such

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<sup>47</sup> A. Pascalev, "OHRP meets ToS."

<sup>48</sup> Inan, Tenaerts, Prindiville, et al. "Digitizing clinical trials."

<sup>49</sup> Patrick Liu, Katia Astudillo, Damaris Velez, Lauren Kelley, Darcey Cobbs-Lomax, Erica S. Spatz, , Use of Mobile Health Applications in Low-Income Populations, A Prospective Study of Facilitators and Barriers. *Circulation: Cardiovascular Quality and Outcomes*. 2020 | Volume 13, Issue 9, <https://doi.org/10.1161/CIRCOUTCOMES.120.007031> (accessed 24 August 2021)

as blockchain, allowing participants to exercise greater control and ownership over their data<sup>50</sup>.

Another facet of privacy risks associated with DCT are the risks to the physical and psychosocial privacy of the participant and the members of the participant's household. For example, videoconferencing may be intrusive to participants who share their living space with other individuals who might be inadvertently captured by the camera or overhear the conversation between the participant and research staff. What is more, a participant may withhold relevant information because of the presence of other individuals in the room. Researchers should be mindful of the limitations of DCT regarding the physical privacy and confidentiality of the research subject, which would be safeguarded in a traditional trial with a centralized location. In DCT, researchers should consider how a particular technology may affect not only the study subject but also other members of the household and should offer flexible options and less intrusive alternatives such as off-camera contact and phone calls to protect the privacy and confidentiality of research subjects and those around them.

### *5. Digital Exclusion*

The successful and timely completion of a clinical study is dependent on the successful recruitment and retention of study participants. However, they often face barriers to participation due to the cost, time demands, and travel burdens associated with trial participation<sup>51</sup>. DCT offer a solution to such logistical challenges by eliminating the need to travel to a central location. In the context of DCT, the expectation from participants is their digital participation. This requirement, however, poses its own ethical challenges pertaining to the digital divide and digital exclusion. The digital divide refers to the differences among groups of people “in their ability to engage with the digital world”<sup>52</sup>. OECD defines the digital divide as “the gap between individuals, households, businesses and geographic areas at different socio-economic levels with regard to both their opportunities to access information and communication technologies (ICTs) and to their use of the Internet for a wide variety of activities.”<sup>53</sup> There are two main causes of the digital divide, income and education, but “household size and type, age, gender, racial and linguistic

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<sup>50</sup> Van Norman characterizes blockchain technology “as a form of decentralized data management system first associated with ‘bitcoin’ commerce... In blockchain, two or more parties can exchange information without the need of a ‘trusted’ centralized third party to maintain the shared database and to resolve discrepancies between participating parties with a ‘consensus’ mechanism among parties. Blockchain interactions are therefore also potentially more secure than centralized data management. In a health care blockchain, for example, patients would ‘own’ their own data, which would be stored at multiple ‘nodes’ and failure at any one node containing the patient’s data would not lead to significant data loss [2].”

<sup>51</sup> Danielle Beck, Aliya Asghar et al, “Increasing access to clinical research using an innovative mobile recruitment approach: The(MoRe)concept,” *Contemporary Clinical Trials Communications* URL: <https://www.sciencedirect.com/science/article/pii/S2451865420301071> (accessed 18 August 2021)

<sup>52</sup> Panagiotis Spanakis, Emily Peckham, Alice Mathers, David Shiers and Simon Gilbody. The digital divide: amplifying health inequalities for people with severe mental illness in the time of COVID-19, *Br J Psychiatry*. 2021 Oct; 219(4): 529–531. doi: 10.1192/bjp.2021.56 (Accessed 24 August 2021)

<sup>53</sup> OECD, “Understanding the Digital Divide,” Aug. 2002, page 5. Available at: <http://www.oecd.org/dataoecd/38/57/1888451.pdf> (Accessed 24 August 2021)

backgrounds and location also play an important role.” People affected by the digital divide may miss out on important social benefits, an experience referred to as digital exclusion<sup>54</sup>. With the proliferation of smartphones, connectivity, and access to the internet have improved across social groups. Yet recent studies show that even though the digital divide is closing, the use of telehealth and online platforms lags among certain groups. The authors suggest that we should consider another factor instead – digital literacy: “Underserved communities have and use technology, but digital health solutions are not tailored to older people or those with lower digital literacy.”<sup>55</sup> The authors warn that “continuing to prioritize and innovate exclusively for digitally savvy patients, will broaden the digital divide and exacerbate health inequity,” as the pandemic demonstrated. The negative implications of the anti-pandemic restrictions on vulnerable groups included missing out on access to new treatments, worsened mental health and limited access to basic medical care.<sup>56</sup>

To address the issues stemming from the digital divide and/or digital exclusion and the related access barriers, researchers should address the issues of accessibility, acceptability, and usability of, and education regarding the digital tools for DCT early in the design phase, and before a DCT is fully implemented.<sup>57</sup>

## 6. Selection bias

One important modification of research protocols for DCT which has direct methodological and ethical implications is the change in inclusion and exclusion criteria. Because DCT take place remotely and online, they require the use of the internet, computer devices, mobile phones, and other internet-based tools and platforms for the collection of patient data. In most cases this would entail the active participation of the research subjects and/or their caregivers in the collection and reporting of data, e.g. by entering it in a log on the patients portal. This in turn would require that the participants in DCT possess the necessary cognitive, physical, and

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<sup>54</sup> Spanakis, Peckham et al. “The digital divide”.

<sup>55</sup> Lisa Fitzpatrick, Neal Sikka, Karin Underwood. “The Digital Divide in Healthcare: It’s Not Just Access,” HIMSS Digital Health, February 24, 2021. <https://www.himss.org/resources/digital-divide-healthcare-its-not-just-access>

“Older racial and ethnic minorities are less likely than whites to use certain technologies when managing their health...Compared to whites, older blacks and Hispanics were less likely to use technology for health-related purposes after accounting for demographic characteristics, education, and health conditions. They were also less likely to make or receive phone calls, use health management sites, search the web for health information, and use brain games for their health. See: Mitchell UA, Chebli PG, Ruggiero L, Muramatsu N. The Digital Divide in Health-Related Technology Use: The Significance of Race/Ethnicity. *Gerontologist*. 2019 Jan 9;59(1):6-14. doi: 10.1093/geront/gny138. PMID: 30452660

<sup>56</sup> To reduce the spread of COVID-19, many clinical trials sites in Australia adopted their own policies and procedures for DTC by performing remote visits and supplying investigational products. The trial participants were informed of the changes in the conduct of the trial and in the supply of the investigational product. In Bulgaria, however, there is a shortage of vendors to perform home visits and take blood tests and other clinical examinations, because they have to be trained in Good Clinical Practice [GCP], not only being social workers or health workers. This makes DCT hard to implement and hinders participant access to new ways of conducting clinical research.

<sup>57</sup> Spanakis, Peckham et al. “The digital divide.”

technical capabilities to perform these tasks. Consequently, DCT would have to exclude individuals who lack the physical or cognitive capacity to use a given technology or who do not have access to the necessary technology and infrastructure such as a reliable internet connection, a computer or a cell phone, and an appropriate data plan. Access to those necessities would become an inclusion criterion for DCT and, as a result, certain populations who live in remote locations or do not own a smartphone would be excluded from participating in DCT. This would skew the trial sample in favor of groups who have access to the technology and would bias the research in their favor. Researchers should be aware of these risks when considering sites and should make conscious efforts to offer alternative means for participation to ensure diversity and equity.

### *7. Imposing new burdens on research subjects and caregivers in DCT*

It has been noted that the sheer use of novel technologies and remote interaction do not necessarily translate into a more participant-friendly trial. In fact, the use of different tools and platforms may create confusion and added stress for the patients due to the limited number of research staff and the technological demands of DCT. The smaller clinical trial teams characteristic of DCT may necessitate greater involvement on the part of the participants in the process of data recording and reporting, which in turn may require greater time commitment increasing the burden of participation for the subjects. Additionally, relying on remote technologies for communication and the lack of face-to-face contact between the participant and the research team may create a sense of isolation and lack of access to the PI on the part of the study subject. In the light of these challenges, access to a dedicated physical site of the traditional type remains important for participants during any trial. IRBs should be mindful of these risks and should assess the reasonableness of the burden to participants, e.g. by asking researchers to provide “time to be completed” estimates.<sup>58</sup>

### *8. Impact of DCT and digital technology on the informed consent process*

A key ethical principle of clinical research is the requirement to obtain informed consent from participants and to ascertain their understanding of the risks and benefits of the research. A major feature of DCT is the lack of direct human interaction. This can have a negative impact on the participant’s understanding and the validity of informed consent. The World Health Organization (WHO) guidelines related to informed consent during emergencies stipulate that research participants must be able to assess the risks and benefits of their participation, which could be challenging during a pandemic.<sup>59</sup> Also, the cultural differences of the participants and

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<sup>58</sup> Hasan Hashem, et al., Obstacles and Considerations Related to Clinical Trial Research During the COVID-19 Pandemic. *Frontiers in Medicine*, 23 December 2020. 7[979] <https://doi.org/10.3389/fmed.2020.598038>

<sup>59</sup> World Health Organization, “Ethical standards”.

the risk of therapeutic misconception<sup>60</sup> experienced with the dual role of some clinician researchers who may also provide clinical care to the participant will necessitate consultation with local communities when developing the consent forms and the process of obtaining and recording the consent. In addition, the researchers need to be transparent about how participant data or samples might be shared.<sup>61</sup> Many studies have shown the benefits of reading on paper for cognition.<sup>62</sup> Mangen et al. compared the comprehension of linear texts read on paper and computer screen and found that students reading printed text performed better than students reading on screen. They concluded that certain features of digitized text display may impede aspects of reading comprehension.<sup>63</sup> The authors also found that writing and reading comprehension were also impacted by the medium and that the performance of the same task on a computer was inferior to the performance when using paper. Moreover, those who read on a computer experienced higher level of stress and tiredness compared to those reading from paper<sup>64</sup> leading to the conclusion that reading and working with a computer result in a higher cognitive workload compared with paper.<sup>65</sup>

During the COVID-19 pandemic, some researchers adopted the method of electronic consent [eConsent] in an effort to minimize the risk of transmission while adhering to the principles of voluntary informed consent. As noted by Zeps et al. “eConsent is not simply a conversion of a paper Participant Informed Consent Form (PICF) into an electronically delivered version. It also holds the promise of improving participant engagement in clinical trials through a variety of features that

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<sup>60</sup> “Therapeutic misconception occurs “when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial” See: Henderson G.E, Churchill L.R, et al, Clinical trials and medical care: defining the therapeutic misconception, *PLoS Med.* 2007;4(11):e324. doi:10.1371/journal.pmed.0040324

<sup>61</sup> WHO, Ethical standards.

<sup>62</sup> Singer LM, Alexander PA. “Reading on Paper and Digitally: What the Past Decades of Empirical Research Reveal.” *Review of Educational Research.* 2017;87(6):1007-1041. doi:10.3102/0034654317722961 (accessed 23 August 2021)

Pablo Delgado, Cristina Vargas, Rakefet Ackerman, Ladislao Salmerón, “Don't throw away your printed books: A meta-analysis on the effects of reading media on reading comprehension,” *Educational Research Review*, Vol. 25, 2018, Pages 23-38, ISSN 1747-938X, <https://doi.org/10.1016/j.edurev.2018.09.003>.

Clinton, V. (2019) “Reading from paper compared to screens: A systematic review and meta-analysis,” *Journal of Research in Reading*, 42: 288– 325. <https://doi.org/10.1111/1467-9817.12269>. (Accessed 24 August 2021)

<sup>63</sup> Anne Mangen, Bente R. Walgermo, Kolbjørn Brønnick, “Reading linear texts on paper versus computer screen: Effects on reading comprehension,” *International Journal of Educational Research*, Volume 58, 2013, Pages 61-68, ISSN 0883-0355, <https://doi.org/10.1016/j.ijer.2012.12.002>. (<https://www.sciencedirect.com/science/article/pii/S0883035512001127>) (accessed 24 August 2021)

<sup>64</sup> Mangen et al, “Reading linear texts”

<sup>65</sup> Wästlund, E., Reinikka, H., Norlander, T., & Archer, T. (2005). Effects of VDT and paper presentation on consumption and production of information: Psychological and physiological factors. *Computers in human behavior*, 21(2), 377-394.

Wästlund, E. (2007). Experimental studies of human-computer interaction: Working memory and mental workload in complex cognition. Department of Psychology.

include: the use of multimedia tools to enhance comprehension; ready conversion into multiple languages as a means to track consent in a highly portable manner; and the opportunity to provide information in a more convenient way to persons with an inability to attend clinics.”<sup>66</sup> An important requirement for the use of eConsent is that the electronic system for virtual consent must include a method to verify the identity of the consenting person.<sup>67</sup> One of the barriers to eConsent identified by the authors is the physical infrastructure which may not be capable of supporting eConsent, e.g. Wi-Fi blind spots or inadequate infrastructure updates within the public health system.<sup>68</sup>

There are several possible solutions to the problems with obtaining consent during a pandemic or for the purposes of DCT in general. One is the use of video and other visual means to obtain consent. Another solution (for clinical study participants who are under quarantine) is, initially, to obtain only verbal consent in the presence of a witness, and to follow up with written consent when the participants are released from quarantine.<sup>69</sup> Researchers may also consider embedding multi-media inside the eConsent form to provide the participants with more accessible and comprehensible information “on-demand.”

#### **IV. Conclusions**

The COVID-19 pandemic accelerated the adoption of DCT, which not only offered an alternative to traditionally designed clinical research but, in many cases, became the only solution to the challenge of conducting clinical research during the pandemic. Often presented as a superior alternative to traditionally designed clinical trials, DCT raise numerous ethical and regulatory issues of their own mostly related to the technologies on which DCT rely. This calls for a careful and objective ethical analysis to ensure the safety and wellbeing of all participants in DCT, and the quality of data obtained therein. Yet, to date, most of the publications on DCT have been written by IT experts, researchers or representatives of the pharma industry suggesting that the potential advantages of digitized clinical research are mostly aspirational and still to be tested empirically and confirmed independently. Moreover, there is a dearth of ethical analyses of DCT, which in turn creates a gap in the current understanding of the ethical and regulatory implications of DCT and the issues they raise.

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<sup>66</sup> Nikolajs Zeps, Nicholas Northcott and Leanne Weekes, “Opportunities for eConsent to enhance consumer engagement in clinical trials,” *Med J Aust* 2020; 213 (6): 260-262.e1.doi: 10.5694/mja2.50732; <https://www.mja.com.au/journal/2020/213/6/opportunities-econsent-enhance-consumer-engagement-clinical-trials> (accessed 24 August 2021)

<sup>67</sup> Hashem, H., et al., “Obstacles and Considerations”.

EConsent is legal in some countries (e.g. Australia and USA) but not in others. A recent study on use of eConsent conducted by Australian researchers involved 179 participants who were cautiously positive toward its use. An important finding was that there was optimism that the use of electronic formats would enable participants to drive the information-seeking process in a way that best suited their needs. See: Zeps N, Northcott N, Weekes L, “Opportunities for eConsent to enhance consumer engagement in clinical trials,” *Med J Aust* 2020; 213 (6): 260-262.e1.doi: 10.5694/mja2.50732;

<sup>68</sup> Zeps et al, “Opportunities for eConsent”

<sup>69</sup> Hashem, H., et al., “Obstacles and Considerations”



In this chapter, we identified the major ethical and regulatory challenges posed by this novel form of clinical research and offered solutions and insights for researchers and institutions engaged or contemplating DCT both during and after a pandemic. We suggest the following considerations in the design and conduct of DCT: (1) Given the opportunities and challenges presented by DCT, it is important to emphasize that, all ethical principles and regulations for traditional clinical research should apply fully to DCT. (2) Any modifications to a research protocol should be guided by the established ethical principles and should comply with the goals and standards of ethical research. (3) Notwithstanding the exigencies of the pandemic, participant safety should remain the highest priority. (4) All research conducted during a public health emergency must have scientific validity and social value. Proceeding otherwise exposes participants and researchers to unnecessary risk and is ethically unacceptable.<sup>70</sup> (5) It is recommended to engage all stakeholders in the planning and design of a decentralized study<sup>71</sup> and to contextualize and adapt DCT to local and regional specifics, including cultural and social contexts and circumstances. (6) Within each trial, sponsors should strive to enable a range of technical options for individual patients based on their engagement preferences. (7) To reduce barriers to access and prevent digital exclusion of the study participants, the accessibility, acceptability, and usability of the digital tools for DCT should be tested by researchers early in the design phase, and before the full implementation of the study. (8) To address the regulatory challenges of DCT, research teams must establish partnerships with the IT community to develop digital tools specifically tailored to the needs of clinical research in compliance with the regulatory standards of safety and privacy for clinical trials. (9) Researchers have an ethical responsibility to ensure the integrity of the data collected, transmitted, and stored digitally. They ought to protect participants' privacy and confidentiality as these are just as important for the ethical conduct of research as the actual intervention. (10) IRB members should be educated about DCT and the technologies they rely on and about new developments in the field (e.g. blockchain), so that they can ensure that there are necessary procedures in place to maintain the integrity of the trials and the rights, safety, and wellbeing of trial participants and trial staff while also allowing for flexibility so that research could continue during a public health crisis such as the COVID-19 pandemic.<sup>72</sup>

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<sup>70</sup> World Health Organization, Ethical standards.”

<sup>71</sup> CTTI, [https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI\\_DCT\\_Recs.pdf](https://ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_DCT_Recs.pdf) especially p. 6.

<sup>72</sup> The European Medicinal Agency, “Guidance on the Management of Clinical Trials During the Covid-19 (Coronavirus) Pandemic.”

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# UNEXPECTED ETHICAL ISSUES IN THE COVID-19 PANDEMIC OUTBREAK – NOT JUST A ROMANIAN PERSPECTIVE

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## Abstract

With the outbreak of the COVID-19 pandemic, humanity was forced to find new solutions in the fight against an unknown disease. In this challenge, medical staff played a key role in caring for patients and limiting the spread of the disease. The reorganisation of the medical system has created a series of moral dilemmas with immediate practical implications. The medical staff was forced to find immediate answers to new, unimaginable ethical problems. Through this, they became moral agents with individual, community, and social responsibility. With the help of a questionnaire disseminated through social networks, we identified the ethical problems and perceptions of 93 respondents. The ethical solutions identified were related to the level of knowledge, the emotional state, the lack of pre-existing protocols, and the historical and individual context. The paper also looks at informed consent as an example of a transplanted procedure, which was adopted in Romania without real debate and careful consideration and ended up being reconsidered during the pandemic. In times of crisis, different areas of ethics become issues of interest for bioethics. This paper draws upon some of these ethical issues, such as the consequences of infodemics and the church's involvement in shaping the public's attitude towards political decisions and vaccination.

## I. Introduction

At the beginning of 2020, a huge surprise came into the world. Even if we watched movies about epidemic outbreaks or read fantasy books on this topic, what followed was unimaginable for most people. In the beginning, a strange lethal infection from China caused by a bat virus seemed a story from far away, but soon enough, it became a significant concern for people worldwide. Gradually, COVID-19 absorbed all our

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intellect, interest, and emotions and disrupted many lifestyles. The declaration of the infection with Coronavirus as a pandemic disease by the WHO came as a surprise. Several questions and feelings popped up: “Is it for real?”; “They are doing it for the money!”; “I live to see this too!”; “Aren't they overreacting?”; “It is a war?” or “How interesting!”. The nuances of psychological reactions, even if presented colloquially or catastrophically, are essential because the psychological response plays an important role in the decision process and modulates people's reactions. In Romania, the decisional process was dynamic, and the public scrutinized and changed some critical resolutions under the influence of those psychological reactions. The public took part and became an active agent in ethical debates.

When it comes to medical ethics, a new set of hospital rules and procedures were elaborated in the context of the Coronavirus pandemic. This process stimulated a revision of the basic principles of medical ethics. In Romania, the health system adopted a European Union set of good practices regarding the rights and duties of the patients without real debate and reflection. The COVID-19 outbreak brings to attention those practices and other issues such as hospital admission without consent, discharge on request of a patient with Coronavirus, discharge on request of a patient with delirium, access of the family in the hospital, neglect of other diseases or patients, selection of the patient/triage, self-protection vs duty, priority research, clinical trials, life support technology, pollution, informed consent, shared decision, and generated new concepts such as infodemics.<sup>1</sup>

The above-mentioned topics are just a review of some of the ethical concerns that interfere with topics in bioethics and highlight the context of the COVID-19 pandemic for the medical system. This paper draws upon these issues in relation to the work of medical staff and the process of decision-making in times of crisis. Medical personnel play a key role in caring for patients and limiting the spread of the virus. The reorganization of the medical system during the pandemic has created a series of moral dilemmas with immediate practical implications. The medical staff was forced to find immediate answers to new, unimaginable ethical issues. With the help of a questionnaire disseminated through social media, we identified the ethical issues perceived subjectively by 93 respondents. The ethical solutions identified were influenced by the level of knowledge, the emotional state, the lack of pre-existing protocols, the historical and individual context. Medical staff are not necessarily trained to partake in ethical travaux, debate, or ethical regulations and are oftentimes influenced by different discourses (religious, mass media discourses). In times of crisis, medical staff are forced to become moral agents with individual, community, and social responsibility. The paper also looks at informed consent as an example of a replicated procedure, which was adopted in Romania without real debate and reflection and was reconsidered during the pandemic.

By reviewing the ethical topics generated by the COVID-19 outbreak, a long list of problems surfaces. Ethical issues in the COVID-19 outbreak question the relationship between economics and health, resources distribution, priority for vaccinations, home education, home office, labour market, and adapting the

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<sup>1</sup> Sam Bradd, “Infodemic” WHO, [https://www.who.int/health-topics/infodemic#tab=tab\\_1](https://www.who.int/health-topics/infodemic#tab=tab_1) (accessed 01 August 2021)

economy to the new context. Previously, some of those issues were not part of bioethics, but they have a bioethical significance in the new context.

## II. Bioethics from the medical personnel's perspective

We analyse the main bioethical problems of a sample of healthcare professionals. The pandemic outbreak provoked this group to become ethical agents with the full power to decide in a field without previous regulations and theoretical armamentaria.

During the pandemic, medical staff changed their primal role as caregivers for individuals to agents that must make decisions for the wellbeing of the collective public. Dunham observes that this new situation brings much confusion:

“Clinicians who excel at caring for the individual patient at the bedside are now being reoriented into a system where they are being asked to see the collective public as their responsibility. [...] There were many unknowns about Coronavirus disease in 2019, which makes it challenging to provide consistent recommendations and guidelines that uniformly apply to all situations. This lack of consensus leads to the clinicians’ confusion and distress.”<sup>2</sup>

In order to highlight these struggles and the ethical dilemmas provoked by the Covid 19 pandemic, we designed a cross-sectional survey with 18 items, which we distributed via social media to healthcare practitioners (HCP) from 03 July 2021 to 05 August 2021. The questionnaire addressed all employee categories of public and private healthcare facilities, including physicians, nurses, psychologists, managers, physical therapists, pharmacists, technicians, researchers, etc. The survey investigated the attitudes and practices of professionals during the COVID-19 pandemic in 2020. It contained five sections: demographics, personal experience with COVID-19, the psychological impact of the pandemic, appraisal of mass-media information and the measures taken by the Romanian government, and the attitudes and beliefs towards respecting or infringing ethical principles. A total of 93 respondents completed the survey. Most of the responders were doctors 64 (68,81%), 5 psychologists (5,37%), 3 pharmacists (3,2%), 3 persons from the pharma industry (3,2%), 4 persons from management (4,3%), 5 nurses (5,37%), and 9 others (9,66%) have responded to the questionnaire. Most respondents are from the Banat region in Romania; the other regions are under-represented in this study. Table 1 illustrates participants’ results regarding their personal experience with COVID-19: half of the sample (49.46%) reported having attended COVID-19-positive patients, and almost half (40.86%) had at least one family member or friend with the disease. Less than half of the respondents (37.63%) reported having acquired information about COVID-19 through reading. Of note, only a quarter of the sample (24.9%) had experienced the disease as a patient, with either mild, moderate, or severe symptoms. The personal experience with COVID-19 modulates the attitudes about regulations (social

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<sup>2</sup> Dunham, Alexandra M et al. “A Bioethical Perspective for Navigating Moral Dilemmas Amidst the COVID-19 Pandemic.” *The Journal of the American Academy of Orthopaedic Surgeons* vol. 28,11 (2020): 471-476. doi:10.5435/JAAOS-D-20-00371



distancing, burying COVID-19 victims, wearing masks, vaccination) and ethics related to pandemics.

**Table 1. Personal experience with COVID-19**

<b>Variable: Personal experience with COVID-19 (Please check all that apply)</b>	<b>N</b>	<b>Percentage</b>
Attended patients with COVID-19	46	49.46%
One or more family members/close friends had the disease	38	40.86%
Read a lot about the virus, disease, and vaccine	35	37.63%
I had no direct experience	16	17.2%
Had the disease – asymptomatic/mild symptoms	15	16.13%
Suffered the loss of a family member/friend due to COVID-19	15	16.13%
Had the disease – moderate/severe symptoms	8	8.6%
Managed COVID-19 organisation and prevention activities in the hospital	2	2.15%
Administered COVID-19 tests	1	1.075%
Worked in radiological centres	1	1.075%
Provided psychological counselling to COVID-19 patients	1	1.075%

Concerning decision-making during the pandemic in 2020, more than half of the sample (63.44%) reported having been in the situation of deciding for family. Half of the participants (54.84%) endorsed the position of taking decisions that affected patients and 25 (26,88%) persons reported that they decided for subordinates. We suppose that people responsible for others in leadership positions are more sensitive to the consequences of their choices. Eight people (8,60%) denied being in a situation to decide for another person except themselves. This answer seems improbable but could reflect the inner feeling of non-responsibility toward others. Over 90% of the subjects are aware of their critical position regarding deciding for others and feel the responsibility.

Regarding the question “What was the most complicated ethical decision you had to make in the COVID-19 pandemic 2020” 18 (19,35%) skipped the question, and 36 (38,70%) denied having been in a position to take decisions. Together they represent 58,06% of the responders. The rest of the responders acknowledged ethical issues such as:

- retaining asymptomatic people against their will in the hospital, with a positive COVID PCR or not
- quarantine for asymptomatic persons
- closing the pharmacy to protect the personnel

- vaccination
- the principle of non-maleficent
- fighting with adopters of the conspiracy theories and anti-vaxers “because they are inflexible in their stupid ideas”,
- to prohibit the plasma donation from one ex-COVID patient despite his desire to save a life
- to impose restrictions,
- the justice,
- to recommend or not vaccination,
- the truth, finding the truth, discerning the reality (n.a., same answer from a few subjects, as a reaction to infodemics)
- resource distributions,
- to treat according to protocols without individual adaptation of the treatment
- parents’ vaccination - to recommend or not,
- limitation of some fundamental rights,
- to avoid the admission of the mother to the rehabilitation centre (not to be exposed to a possible infection),
- to be unable to promote a healthy lifestyle as an alternative to mass vaccination,
- “I do not know”,
- to transfer a non-COVID child to a support COVID hospital,
- to decide prompt medical measures for worsening COVID patients in a pavilioned hospital without all the facilities,
- autonomy,
- transgressing the principle of evidence-based medicine,
- maintaining the balance between patients, arbitrarily postponing the patients,
- prioritising the patients depending on comorbidities,
- denied admission to hospital for chronic patients (non-emergency),
- penalty for failure to comply with the internal regulation
- restricted access of the patients in the consultation room and to the doctor
- non-maleficent,
- give-up, renunciation
- assuming the infectious risk
- admission to the hospital without consent of the patient
- discharge of a COVID patient on request
- forbidding the family visit to the patient

The answers to the open question are laconically formulated, and some demand background information to be understood. Some of them have opposite positions regarding vaccination, family visits, admission, or hospital discharge. Neglecting chronic patients and diseases appears to be an important ethical issue for Romanian healthcare professionals (3 respondents). The responders mention some important ethical themes such as the shortage of resources, the selection of COVID- patients

that receive intensive care, the autonomy of the patient, and duty versus self-protection. Some HCP is uncomfortable applying protocols based on expert consensus without evidence-based information. Another sensitive topic was the “truth”. This answer is undetailed. We can suppose it refers to misinformation or lack of credibility of the communicated information. To understand the content of these answers, it is essential to highlight the pandemic context in Romania. If in Italy and Spain, we had a critical growth in number of cases in March of 2020 and a real crisis of the medical system; in Romania, the pandemic peak was delayed until the autumn of 2020. This means the medical system had time to adapt and prepare, resulting in the development of protocols, assurance of stocks of medical supplies, creation the infrastructure, circuits, and isolated treatment areas, and increasing ventilators and intensive care units. By the autumn of 2020, there already was advanced knowledge regarding the infection with the new Coronavirus. Because of that, not many doctors complained about the lack of supply, the dilemma regarding duty versus risk, and the problematic triage of patients needing ventilators.

Regarding the question: “How likely are you to sacrifice personal freedom in favour of the greater good of humanity?” (visual analogue scale question from 1 to 100), the respondents scored 73. This value reflects the value of individual freedom in relation to the public good and could be a cultural heritage of the socialist past. In the socialist ethos, personal freedom was not a promoted value.

For the question “How likely are you to recommend the Romanian policies regarding the Covid-19 pandemic to other states?” the average answer was 55 per cent. This shows relatively good support of the public policies by the medical staff. These two questions could also reflect a deontological approach to ethical problems, meaning medical staff have a high sense of duty.

Three responders show a hesitancy towards vaccination. One of the responders is unhappy with vaccination as a unique means to combat the pandemic. This responder regrets being unable to promote a healthy lifestyle as an alternative to mass vaccination. Another has concerns regarding the vaccination of his/her parents. A third one has cognitive difficulties recommending the vaccination in specific situations. In our group, we did not find examples of preoccupation with conspiracy theories, biopower, pandemic as a tool for social control or Agamben Giorgio-like theories.

### **III. Refreshed perception of ethics. The Culture of informed consent and its revision during the COVID Pandemic**

The Informed Consent has a short history in Romania. In the process of modernising the medical system, a set of new rules was implemented, copying the Western model. One of these regulations refers to the usage of the Informed Consent.

The National Authority of Quality Management in Health Systems (A.N.M.C.S.) was created in September 2015. The purpose of this structure is to assure a continuous amelioration of the health services and the patient’s security through

standardisation, evaluation, and accreditation of the health units.<sup>3</sup> A.N.M.C.S. creates normative acts aimed at correlating the national quality of medical services with international standards and directives. A long list of norms was imposed to obtain accreditation for public hospitals. The ethics chapter of the normative act comprises the following principles: respect for the autonomy of the patient, justice principle, beneficence and non-maleficence principle, procedures for informed consent, rules for medical confidentiality, rules for access to medical data, rules for prevention of discrimination, regulations for mass media access, and functional Ethics Commission.<sup>4</sup> The ethical requirements were implemented in a short time, many of them being copied from an international source (International Society for Quality in Health Care, WHO Europe, and Joint Commission International Org.), without serious consideration or debate.

The Informed Consent was not part of the traditional Romanian health system. Traditionally, the doctor is a father figure with assigned decisional power over the patient: “If the doctor said so, we must obey”. This sort of power diminishes the autonomy of the patient but also reduces the patient’s responsibility for personal health. This relationship between doctor and patient generates a field of secondary play and negotiations. Patients receive recommendations but feel autonomous and free to escape some of the prescriptions outside of the hospital. Because of that, the patient’s family is part of the doctor’s armamentarium to coerce the patient to comply with medical recommendations. For a long time, in the Romanian medical system, all medical problems were discussed first with the family. Doctors informed the family about the diagnosis and possible solutions and treatments. Secondly, the family or the doctors provided patients with a resumé of the clinical status. In this traditional view, patients are suffering, and because of the suffering, they are debilitated and incapacitated to judge their health problems for themselves. The family decides the better option on behalf of the patient. They determine whether the patient will be operated on, if the patient goes for a second opinion, or in another clinic. The family is first contacted when some complications or problems arise. Culturally, it is the prerogative of women to take care of children, the elderly and, if necessary, their husbands. Frequently, the medical information is communicated to a female member of the family to “protect” the husband, father, or father-in-law from psychological distress. The assumed strong family ties generate those informal rules because the family is seen as the nuclear unit of society. In this vision, the individual has no particular social value without family.

Contrary to this position, which is grounded in family values and community, the Western vision constructed at the beginning of the XVIII century proposes the primacy of the individual, an autonomous human being, self-determined and able to decide in a universal framework of values. Autonomy, liberty, property, and

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<sup>3</sup> Cepoi, Vasile, De Ceppo, Nicoleta, “Manualul-standardelor-de-acreditare”, 6. <https://anmcs.gov.ro/web/wp-content/uploads/2021/02/Manualul-standardelor-de-acreditare-2020.pdf> (accessed 01 August 2021)

<sup>4</sup> Cepoi, Vasile, De Ceppo, Nicoleta, “Manualul-standardelor-de-acreditare”, 83-87, <https://anmcs.gov.ro/web/wp-content/uploads/2021/02/Manualul-standardelor-de-acreditare-2020.pdf> (accessed 01 August 2021)

freedom of speech are fundamentals in Western culture. They build the matrix for modern values and create a basis for bioethical principles. Romania imported and assumed those principles but just as a thin superficial layer. Under this layer, people adhere to the same old practices. The theoretical background of Informed Consent is mainly unknown to the regular medical team. Informed Consent was adopted without any consideration. Informed Consent became just another paper to fill in.

The COVID pandemic unearthed a real debate about Informed Consent. At the beginning of the pandemic, all detected COVID positive people were transported in isolation pods, forcefully admitted to hospital, and treated with all possible drugs. The general fear was high enough to sustain such oppressive treatment. Soon, it became evident that this protocol affects individual liberty and does not necessarily benefit the person and the community. Some people suffered adverse effects from the imposed medication, as well as nosocomial infections, isolation, and fear. Voices of the patients and their families arose to stop these rules. There was also plenty of evidence from other countries stating that admission to the hospital is unnecessary in most cases. On the other hand, the number of cases increased after the vacations, and the medical system was overwhelmed by severe and symptomatic cases. The new context enforced a careful examination of the patient's consent. In this new situation, the medical staff was more attentive towards the consent of the patient, and medical decisions were made accordingly. The abuses that occurred at the beginning of the pandemic in Romania were diminished. Furthermore, patients became more aware of their rights and the value of Informed Consent. From being just "a paper to fill in", a real consideration regarding consent emerged for each patient. The discharge of COVID-positive patients, even those with confusion, became possible. Under the pressure of patients and some HCP, protocols and procedures have been changed, and patients could withdraw Informed Consent. Discharge on request became operable. This evolution shows the increased awareness of the patient's autonomy and rights.

#### **IV. In a time of a health crisis, bioethics overcomes other ethics domains**

In regular times we see a branching of ethical theories, and each field has its adepts. Applied ethics are highly specific to the corresponding domain. Bioethics do not include business ethics or journalism ethics. During the COVID-19 pandemic, several areas of applied ethics became an interest in bioethics due to the threat. One of them is journalism ethics and social media ethics. Regarding the information flow, bioethics raises concerns about mass media's and social media's role in modelling the public's behaviour through disinformation, manipulation, and conspiracy theories. Often called an infodemic, the overabundance of information (real or fake) occurring during an epidemic has a real effect on the development of the pandemic. The spread of misinformation happens via different communication channels, not only through social media but also through the press and mass media, which have a role in this. The coexistence of a bombardment of highly sophisticated information about the virus, the disease, and the pharmacological techniques to obtain vaccines, together with a stream of misinformation, had a perverse effect on the population, resulting in large masses of people refusing vaccination (in Romania a total of 85,6 COVID-

19 vaccine doses administered per 100 people compared with 227,82 in France or 176,71 in European Union).<sup>5</sup> Even before the pandemic, WHO observed the negative effect of anti-vaccine propaganda on public health and considered it necessary to develop projects to stop the spread of misinformation. The WHO considers hesitancy towards vaccination as a top threat to public health.<sup>6</sup> Fuelled by messages that spread fear, this hesitancy determines the prolongment of the pandemic. The availability of a safe and effective vaccine for COVID-19 is well-recognized as an additional tool to contribute to the control of the pandemic.<sup>7</sup> In Romania, we noticed not just a refusal to wear a mask and a rejection of social distancing measures, but like in other parts of the world, hesitancy and refusal towards vaccination against COVID-19. Because of this effect, journalism and mass media ethics justify a bioethical approach.

Another category of ethical issues that are not per se a concern of bioethics but become a bioethical issue is linked with the intervention of the Romanian Orthodox Church in denying or questioning the utility of social distancing measures, in promoting “God’s vaccination” (promoting the idea of immunisation only through disease, and not vaccination), or promoting false information. This area has a long history of debates and conflicts between science and religion. Under the influence of religion and conspiracy theories during the pandemic, the coronavirus became an object of belief/faith (despite its genotyping since the beginning of 2020). Expressions such as: “I do not believe in COVID” prove this transfer of the objective, scientifically proven facts to the area of faith. In the first year of the pandemic, the Romanian Orthodox Church promoted the idea that COVID-19 did not exist and that the pandemic was unreal. Consequently, some adepts deny the existence of the virus, and others do not „believe” in COVID.

## **V. Conclusions**

During the COVID-19 pandemic, several bioethical problems have arisen. Each of these requires an individual approach. In this paper, we tried to find the ethical issues acknowledged by medical staff. Another aim was to see how the ethical process during the pandemic differed from regular times. In this respect, we noticed that laypersons become ethical decision-makers, and ethics become personal. We identified a few features of the ethical thinking of medical staff in pandemic times: emotional involvement, a focus on immediate practical problems, and dependence on the zeitgeist. We observed the direct implication of medical staff in ethical concerns and, from some of the responders, a reluctance to reveal personal bioethical challenges or deny them. The private belief system, emotions, and attitudes influence the decision-making process. In times of crisis, a part of HCP are committed to a

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<sup>5</sup> Our World in Data. <https://ourworldindata.org/covid-vaccinations?country=ROU~FRA> (accessed 01 August 2023)

<sup>6</sup> Hotez, Peter. “COVID Vaccines: Time to Confront anti-Vax Aggression.” 2021, <https://doi.org/10.1038/d41586-021-01084-x> (Accessed 10 Aug. 2021)

<sup>7</sup> WHO. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/accelerating-a-safe-and-effective-covid-19-vaccine> (accessed 03 August 2023)

“deeper value” (i.e. general good) and supports political decisions. We discovered that the medical staff tend to sacrifice individual freedom for the common good. The ethical choices made by healthcare professionals are influenced by their profession’s moral principles and values.

The COVID crisis imposed a closer look at some bioethical problems and shows the practical importance of theoretical debates. The bioethical issues of the COVID-19 pandemic, not necessarily unique, engaged many people. In consequence, some medical protocols were revised. We highlighted the Informed Consent as an example of this process. From being an imported tool, informed consent became a preoccupation and a source of questions for medical staff and patients.

Finally, we acknowledged the widening areas of bioethical issues and themes under the influence of a global threat such as the role of mass media, the role of social media, and governance under crisis. The topics mentioned above (bioethics issues as a personal concern, HCP commitment to the general good, the influence of professional deontology in ethical choices, the influences of infodemics in spreading confusion, and dynamics of Informed Consent through the COVID-19 pandemic) represent only a short review of the unexpected development of the bioethical effort.

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# HUNGARIAN ADAPTABILITY OF GERMAN AND AUSTRIAN MEDICAL ETHICS EXPERIENCE AND GOOD PRACTICES IN PANDEMIC RESPONSE

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Veronika Szilasi

## I. Introduction

The Covid-19 pandemic has entailed dramatic consequences: there is hardly any field in global health care not affected by either the virus itself or by the wide-ranging ethical and social disputes evoked by the coronavirus situation. Prevention has been associated with significant economic sacrifice influencing people's private lives as well, which has also considerably impacted their mental well-being in the short term. This public health emergency, together with the mandatory quarantine has often violated the right to personal liberty<sup>1</sup>, as well as the right to health care. There has been a clash in the decisions concerning the protection of the community and individual health protection or prevention. Since human resources have been redeployed in health care, the establishment of some kind of patient hierarchy has become inevitable<sup>2</sup>.

This paper responds to particular issues that emerged in the past two years, so it does not provide a thorough analysis of the adaptation of any specific good practice. The study reviews the medical ethics aspects of some Austrian and German measures (quarantine, travel restrictions, communication, wearing face masks, potential introduction of a vaccine passport, ongoing smooth provision of primary care, treatment of risk groups, prevention, mental health prevention of health care staff, the role of telemedicine) and examines how some theoretical considerations and specific measures could be adapted effectively to the Hungarian practice. I chose these two countries because, despite significant differences in economy and social structure, there are historical links and cultural similarities that allow for adequate

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<sup>1</sup> Dippold Á. *Kant azt akarná, hogy oltasd be magad, de várd ki, míg sorra kerülsz*. Qubit, 03.14. <https://qubit.hu/2021/03/14/kant-azt-akarna-hogy-oltasd-be-magad-de-var-d-ki-mig-sorra-kerulsz> (accessed 2021.06.28.)

<sup>2</sup> *Szegeden a daganatos és sürgős ellátást igénylő betegek között is szelektálni kell*. [https://hvg.hu/itthon/20210321\\_szeged\\_daganatos\\_beteg\\_surgos\\_ellatas](https://hvg.hu/itthon/20210321_szeged_daganatos_beteg_surgos_ellatas) (accessed 2021.07.21.)



comparison and adaptation of good practice. In addition, Hungary considered these countries “model laboratories” and closely monitored the measures they implemented for success.<sup>3</sup>

## II. Restrictions and Covid-passports

From the point of view of medical ethics, the protection, care and treatment of both the community and the individuals are equally important; however, during epidemics both the law and ethics prioritize the protection of the community. The survival of the community is superior to the life of the individuals; no matter how painful and irreplaceable the loss of a family member is, the society as a whole still prioritizes the community over the individuals.

There were several models whose aim was to harmonize the protection of the community and that of the individuals. The less strict measures concerning school attendance and service provision applied in Sweden did not automatically result in a better economic situation, compared to countries with stricter restrictions. However, according to researchers from Tübingen, stricter measures could have resulted in fewer cases and lower mortality rates. A relatively high number of people refrained from travelling and started working from home even though there were no governmental restrictions that would have required them to do so. Consequently, a reasonable degree of self-limitation and proactivity can be effective in certain social structures.<sup>4</sup> This type of social solidarity and prevention is based on altruistic behaviour, but it may be associated with a special routine of work organisation.

The initial measures introduced in Austria, Germany and Hungary as well all included quarantine, travel restrictions, social distancing, restriction of social interactions and wearing face masks as a means of protecting both the community and the individuals. The rigor of restrictive measures and the partial easing of these measures differed in these three countries to match the actual phase of the pandemic, but since the EU Digital COVID Certificate, commonly known as COVID passport, entered into force on July 1, 2021 in all member states of the European Union, all of them have been applying the so-called “3G Rule” (“3-G-Regel“). All travellers aged 12 or older can only enter the country without mandatory quarantine regulations if they 1.) can present the results of a negative PCR /antigen test that is no more than 72/ 48 hours old, respectively (“Getestet”); 2.) have received the first or second vaccine (valid for 90 and 270 days) (“Geimpft”); 3.) can prove that they have recovered from the disease (“Genesen”).<sup>5</sup>

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<sup>3</sup> Csátári FD, Dezső A. *Európában már nem tabu az iskolák újranyitása*. HVG, 2020.04.15. [https://index.hu/kulfold/2020/04/15/europa\\_korlatozo\\_intezkedesek\\_enyhitesek\\_koronavirus/](https://index.hu/kulfold/2020/04/15/europa_korlatozo_intezkedesek_enyhitesek_koronavirus/) (accessed 2021.07.28.)

<sup>4</sup> Westerhaus C. *Die Strategie der Regierung in Stockholm geht nicht auf*. Deutschlandfunk, 11.05.2021. [https://www.deutschlandfunk.de/corona-pandemie-in-schweden-die-strategie-der-regierung-in.676.de.html?dram:article\\_id=497067](https://www.deutschlandfunk.de/corona-pandemie-in-schweden-die-strategie-der-regierung-in.676.de.html?dram:article_id=497067) (accessed 2021.06.25.)

<sup>5</sup> <https://www.sozialministerium.at/Informationen-zum-Coronavirus/Coronavirus---Haefug-gestellt-e-Fragen/FAQ-Einreise-nach-Oesterreich.html> (accessed 2021.08.07.)

Both Germany and Austria accept the EU Digital COVID Certificate (“Grüner Pass”); however, this guarantees free movement only to those vaccinated with vaccines authorised by the European Medicines Agency (EMA).

The Hungarian application of Sinopharm and Sputnik vaccines, which have not been authorised by the EMA, might pose some difficulties for Hungarian citizens. Austria exerts no restrictions on the entry of those vaccinated with Sinopharm; however, those who received Sputnik vaccines can only transit through the country.<sup>6</sup> Entry to Germany (except for entry by air) is not restricted for people vaccinated with the following vaccines: BioNtech/Pfizer, AstraZeneca, Johnson & Johnson, Moderna, Sinopharm, Sinovac, Sputnik.<sup>7</sup>

Any foreign nationals holding a valid EU Digital COVID Certificate can enter the territory of Hungary with no restrictions, and they are granted the same benefits as Hungarian citizens holding the official Hungarian immunity certificate when it comes to making use of various services (e.g., taking part in festivals, visiting museums).

The equivalent of the Hungarian immunity certificate does not exist in Austria or in Germany; neither country grants extra privileges or licences for being vaccinated even though the introduction of such benefits was associated with heated social debates.<sup>8,9</sup> The obvious aim of the Hungarian immunity certificate was to popularise the vaccine by providing the certificate holders with certain benefits. The objective of the Hungarian government was to reach a high proportion of vaccinated citizens, which is a proactive measure that can be effective against further waves of the virus and contribute to the protection of several lives. Short films produced by the Hungarian Academy of Sciences served to illustrate the mechanism of action of vaccines, thereby facilitating authentic information and weakening the misconceptions spread by anti-vaccine movements.<sup>10</sup>

### III. Moral values and ethics in the foreground

During the pandemic, governments worldwide introduced strict social restrictions that significantly altered the everyday life and work habits of their citizens, thereby negatively affecting their quality of life in several cases. The restriction of social interactions and emotional relationships significantly impaired the mental status of most people. The Covid pandemic highlighted and intensified several individual and

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<sup>6</sup> *Einreise nach Österreich*. Advantage Austria. 18. August 2021. [https://www.advantageaustria.org/hu/news/Coronavirus\\_Situation\\_in\\_Ungarn.de.html](https://www.advantageaustria.org/hu/news/Coronavirus_Situation_in_Ungarn.de.html) (accessed 2021.08.21.)

<sup>7</sup> Konzuli tájékoztatás. <https://konzuliszolgalat.kormany.hu/europa-utazasi-tanacsok?nemetorszag> (accessed 2021.08.21)

<sup>8</sup> Deutscher Ethikrat: *Immunitätsbescheinigungen in der Covid-19-Pandemie. Stellungnahme*. Herausgegeben vom Deutschen Ethikrat, 22. September 2020. <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-immunitaetsbescheinigungen.pdf> (accessed 2021.06.25.)

<sup>9</sup> Körtner UHJ. *Freiheit für Geimpfte?* DerStandard. 19. März 2021. [www.derstandard.at/story/2000125167684/freiheit-fuer-geimpfte](http://www.derstandard.at/story/2000125167684/freiheit-fuer-geimpfte) (accessed 2021.06.26.)

<sup>10</sup> *Így véd meg minket a koronavírus elleni vakcina – az MTA animációja*. MTA, 2021. Március 19. [https://mta.hu/mta\\_hirei/igy-ved-meg-minket-a-koronavirus-elleni-vakcina-az-mta-animacioja-111299](https://mta.hu/mta_hirei/igy-ved-meg-minket-a-koronavirus-elleni-vakcina-az-mta-animacioja-111299) (accessed 2021.06.26.)

collective ethical dilemmas that belong to the sphere of social responsibility and ethics (Veantwortungsethik).

Some governmental restrictive measures were readily controllable (closure of kindergartens, schools, shopping and entertainment facilities, visitor bans in health care institutions, etc.), while others (travelling, wearing face masks, social distancing, voluntary isolation, hygiene, etc.) were highly dependent on the compliance and disciplined attitude of the citizens. The clash between responsibility to the community and to ourselves, as well as between individual freedom and collective solidarity raised a multitude of ethical and moral issues not only in theory but also in the field of everyday activities. Hubert Kleinert, a university professor from Giessen, Germany referred to this phenomenon as the return of the duality of the Ethic of Moral Conviction (Gesinnungsethik) and the Ethic of Responsibility (Max Weber).<sup>11</sup>

Christoph Stückelberger, a Swiss professor of theology, asked the following questions in connection with the epical approach to the pandemic situation: "Whether you call it ethics or not, there are always questions of values, such as: What is health worth to us? Who should be protected? How are scarce resources to be distributed? The current crisis is particularly about balancing priorities: Which values are most important in which situation?"<sup>12</sup>

The moral and ethical issues accompanying the pandemic are also intensively dealt with both in Germany and in Austria in the form of social discussions as well as publications compiled either for the experts or the public.

In Germany, the German Ethics Council (Deutscher Ethikrat), which is an independent body dealing with important social and bioethical issues operating under the aegis of the parliament and the government, published an Ad hoc Recommendation titled, "Solidarity and Responsibility during the Coronavirus Crisis".<sup>13</sup> The Austrian Diakonie Österreich (IöThe) published a similar recommendation; both guidelines aimed to provide a basis and orientation for handling social and individual conflicts evoked by the pandemic.<sup>14</sup> Such an ethical position paper would be valuable in Hungary as well, as it could enhance social sensitivity and, at the same time it could serve as guidance for both healthcare workers and laypeople by introducing indisputable minimal moral standards and standpoints, and also by addressing crucial issues (e.g.: vaccination of social groups

<sup>11</sup>Hubert Kleinert über Verantwortungsethik. *Wider die Zurschaustellung des moralischen Prinzips*. Moderation: Nicole Dittmer. [https://www.deutschlandfunkkultur.de/hubert-kleinert-ueber-verantwortungsethik-wider-die.1008.de.html?dram:article\\_id=488641](https://www.deutschlandfunkkultur.de/hubert-kleinert-ueber-verantwortungsethik-wider-die.1008.de.html?dram:article_id=488641) (accessed 2021.08.07.)

<sup>12</sup>Stückelberger C. *A koronavírus válság idején az erkölcsei „aranyzabály” fontosabb, mint valaha*. Magyarországi Református Egyház, Külügyi Iroda 2020. május 4. Forrás: oikoumene.org. Az interjú eredetileg április 3-án jelent meg német nyelven a reformiert.info hasábjain. Fordította: Farkas Bálint. <https://reformatus.hu/vilagban/hirek/a-koronavirus-valsag-idejen-az-erkolcsi-aranyzabaly-fonto-sabb-mint-valaha/> (accessed 2021.08.07.)

<sup>13</sup>Deutscher Ethikrat: *Solidarität und Verantwortung in der Corona-Krise AD-HOC-EMPFEHLUNG*. Deutscher Ethikrat, Berlin, 27. März 2020. <https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/deutsch/ad-hoc-empfehlung-corona-krise.pdf> (Accessed: 2021.08.07.)

<sup>14</sup>*Ethische Konflikte in Zeiten von Corona*. IöThe Argumentarium – Living Paper Corona Version 1 (Mai 2020) Medieninhaber: Institut für öffentliche Theologie und Ethik der Diakonie. Herausgeberin und Autorin: Dr. Maria Katharina Moser. [https://diakonie.at/sites/default/files/diakonie\\_oesterreich/ethik/argumentarium\\_corona-200525.pdf](https://diakonie.at/sites/default/files/diakonie_oesterreich/ethik/argumentarium_corona-200525.pdf) (accessed 2021.08.07.)

suffering from deprivation or cumulative disadvantage<sup>15</sup>, handling vaccination envy<sup>16</sup>).

The German Ethics Council published a position paper on the legal, ethical and practical aspects of the fair access to vaccines, and the ethical conditions and implications regarding the immunity certificate were also listed at the request of the health minister.<sup>17</sup>

In Austria, the bioethical counselling body of the Austrian Federal Chancellery, the Austrian Bioethics Commission (Bioethikkommission) issued its detailed position and recommendations on vaccination.<sup>18</sup>

In Hungary, literature on the moral and ethical aspects of the pandemic is rather scarce.<sup>19</sup> The recommendation published by the *Ethical College* of the Hungarian Medical Chamber primarily focuses on the distribution and allocation of resources as well as the ethical issues of the triage system.<sup>20</sup> German, Austrian and Swiss stakeholders also addressed the grave moral and ethical issues posed by the allocation problems of intensive care.<sup>21, 22, 23</sup>

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<sup>15</sup> *Azonnali és komoly kormányzati intézkedésekre van szükség a bátrányos helyzeti településeken a járvány hatásainak mérséklésére.* Készítette: Társaság a Szabadságjogokért Budapest, 2021.március 5. [https://tasz.hu/a/img/level\\_koronavirus\\_szegenyseg.pdf](https://tasz.hu/a/img/level_koronavirus_szegenyseg.pdf) (accessed 2021.07.23.)

<sup>16</sup> Hercsel A. *Egyre jobban eluralkodik rajtunk a vakcinairigység.* Index, 2021.04.10. <https://index.hu/gazdasag/2021/04/10/vakcinairigység/> (Accessed 2021.07.23.)

<sup>17</sup> *Wie soll der Zugang zu einem COVID-19-Impfstoff geregelt werden?* Positionspapier der gemeinsamen Arbeitsgruppe aus Mitgliedern der Ständigen Impfkommision, des Deutschen Ethikrates und der Nationalen Akademie der Wissenschaften Leopoldina. Berlin, 9. November 2020. <https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/deutsch/gemeinsames-positionspapier-stiko-der-leopoldina-impfstoffpriorisierung.pdf> (Accessed 2021.08.07.)

<sup>18</sup> *Ethische Fragen einer Impfung gegen COVID-19.* Stellungnahme der Bioethikkommission. Wien 2020. <https://www.bundeskanzleramt.gv.at/themen/bioethikkommission/pressemittelungen-bioethik/stellungnahme-ethische-fragen-einer-impfung-gegen-covid-19.html> (Accessed 2021.08.07.)

<sup>19</sup> Zala M. *Koronavírus és etika.* Ellensúly. 2020/1-2. <https://ellensuly.hu/koronavirus-es-etika/> (Accessed 2021.07.23.)

<sup>20</sup> *Étikai megfontolások az orvosi erőforrások elosztásához COVID-19-pandémia idején Magyarországon.* Magyar Orvosi Kamara – 2020. április 14. [https://mok.hu/public/media/source/KORONAV%CC%83%8DRUS/MOK\\_Etikai%20megfontola%CC%81sok\\_Covid19\\_final.pdf](https://mok.hu/public/media/source/KORONAV%CC%83%8DRUS/MOK_Etikai%20megfontola%CC%81sok_Covid19_final.pdf) (Accessed 2021.07.23.)

<sup>21</sup> *Entscheidungen über die Zuteilung von Ressourcen in der Notfall- und der Intensivmedizin im Kontext der COVID-19-Pandemie.* Klinisch-ethische Empfehlungen (Deutsche Interdisziplinäre Vereinigung für Intensiv- und Notfallmedizin) <https://www.divi.de/empfehlungen/publikationen/covid-19-dokumente/covid-19-ethik-empfehlung> (Accessed 2021.08.07.)

<sup>22</sup> *Allokation intensivmedizinischer Ressourcen aus Anlass der Covid-19-Pandemie.* Klinisch-ethische Empfehlungen für Beginn, Durchführung und Beendigung von Intensivtherapie bei Covid-19-PatientInnen. Statement der Arbeitsgruppe Ethik der Österreichischen Gesellschaft für Anästhesiologie, Reanimation und Intensivmedizin (ARGE Ethik ÖGARI) vom 17.03.2020. [https://www.oegari.at/web\\_files/cms\\_daten/covid-19\\_ressourcenallokation\\_gari-statement\\_v1.7\\_final\\_2020-03-17.pdf](https://www.oegari.at/web_files/cms_daten/covid-19_ressourcenallokation_gari-statement_v1.7_final_2020-03-17.pdf) (Accessed 2021.08.07.)

<sup>23</sup> *Covid-19-Pandemie: Triage von intensivmedizinischen Behandlungen bei Ressourcenknappheit.* Schweizerische Akademie der Medizinischen Wissenschaften, Schweizerische Gesellschaft für Intensivmedizin. <https://www.samw.ch/de/Ethik/Themen-A-bis-Z/Intensivmedizin.html> (Accessed 2021.08.07.)

#### IV. Health care systems, protection of health care workers

All healthcare systems worldwide are struck by a lack of workforce, and this situation only intensified during the pandemic. The economic situation varies from country to country, and the same goes for the cultural traditions and legal background of the healthcare systems. Thus, these factors are not sufficient if we want to compare epidemic control. However, there are some measures that could serve as universal assistance should the intention meet social acceptance. Increasing financial resources in itself is not supposed to guarantee long-lasting results, whereas strengthening the recognition of healthcare workers and highlighting the moral stress they have to endure could facilitate social discussion and bring forth potential solutions.

In Hungary, effective care was meant to be ensured via the redeployment and secondment of doctors. However, doctors cannot be redeployed if they are pregnant, have a child under the age of 3, provide prolonged care for a family member personally, if their disability rating reaches 50%, if they are the sole caretakers of a child younger than 16 years of age or if they work at an organisation unit of the National Ambulance Service that is directly involved in handling the crisis situation.<sup>24</sup> The legal guide of the professional organization “Marburger Bund” (an Association of employed and civil servant doctors in Germany) has compiled a legal vade mecum that covers the regulations of the individual states doctors working in Germany: doctors can refuse redeployment if they are pregnant; or it depends on the specific work contract whether a doctor can be redeployed to another health care facility. The above-mentioned vade mecum also addresses situations when doctors are reluctant to get vaccinated, whether they can be forced to interrupt their holiday or what should be done if child care is not available. Discussion concerning doctors’ sense of vocation significantly intensified during the pandemic; nevertheless, the aim of the above-mentioned regulations was primarily to clarify the legal background of ethical dilemmas arising when doctors cannot fulfill their professional requirements.<sup>25</sup>

Even if we disregard the exceptional cases or redeployment, the psychological burden and the emotional stress of the pandemic still exceedingly affected healthcare workers working at their usual workplace. The care they provided throughout the pandemic drew the attention of multiple parties, including politicians, leaders in health care, the media, as well as patients and their family members. This heightened attention brought forward intense discussions on requirements and responsibilities as well.

During the pandemic, doctors’ everyday work was characterised by increased workload, unexpected and/ or exceptional situations and ever-changing teams. Further stress factors should also be mentioned, such as fear of getting infected, fear of infecting family members, difficulties of having to wear personal protective

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<sup>24</sup> Zeller J. *Koronavírus: mire kötelezhetik az egészségügyi dolgozókat?* Társaság a Szabadságjogokért. 2020. március 17. [https://ataszjelenti.blog.hu/2020/03/17/koronavirus\\_mire\\_kotelezhetok\\_az\\_egeszsegu\\_gyi\\_dolgozok](https://ataszjelenti.blog.hu/2020/03/17/koronavirus_mire_kotelezhetok_az_egeszsegu_gyi_dolgozok) (Accessed 2021.07.23.)

<sup>25</sup> Marburger Bund: *FAQs zur Corona Pandemie aus arbeitsrechtlicher Sicht für Ärztinnen und Ärzte*. Stand: 10.05.2021. [https://www.marburger-bund.de/sites/default/files/2021-05/FAQs-Corona-Stand\\_10-05-2021.pdf](https://www.marburger-bund.de/sites/default/files/2021-05/FAQs-Corona-Stand_10-05-2021.pdf) (Accessed 2021.08.21.)

equipment and the Covid-stigma<sup>26</sup>. A further dilemma arises when a healthcare worker is reluctant to get vaccinated. It raises the question of whether individual consideration is permissible in this case, i.e. whether the individual ethics of responsibility and its consequences or the ethics of moral conviction should be prioritised? Is the moral aspect of the sense of vocation supposed to make the reluctant doctor change their opinion?

In addition, healthcare workers had to tolerate the significant emotional burden of having to inform families of the death of their loved ones considerably more frequently than before. All members of society have to understand how dedicated healthcare workers are, and the support and prevention of their mental health is crucial in the successful fight against the Covid-19 epidemic.<sup>27</sup> Once the pandemic has subsided, the experience has to be analysed and conclusions have to be drawn so that the findings can be used when preparing for future waves of the infection.

Understandably, recent international literature mainly focuses on the health and psychological issues of patients and those who have already recovered from the infection.<sup>28,29</sup> However, some surveys conducted in different countries, have already warned us about the severe mental health damage sustained by healthcare workers as a result of the pandemic: depression, apprehension, insomnia, post-traumatic stress disorder, increased alcohol and nicotine consumption, as well as addiction as a negative coping strategy.<sup>30,31</sup>

Some suggested solutions are connected to the healthcare sector (improving the infrastructure, increasing the number of employees and broadening their qualifications), thus they are not likely to be realised in the near future. Other solutions are expected to bring faster results: better organisation and planning, team stability, better communication, making up for lost holidays and free time, adequate preventive measures and first of all appropriate psychosocial support without stigmatisation.<sup>32</sup> Compulsory vaccination of health care workers is being discussed in

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<sup>26</sup> Villa S, Jaramillo E, Mangioni D, et al. *Stigma at the time of the COVID-19 pandemic*. Clinical Microbiology and Infection, (26) 2020, 1451-1452. DOI: <https://doi.org/10.1016/j.cmi.2020.08.001>

<sup>27</sup> Weigl M, Schreyer J. *Die parallele Pandemie? Maßnahmen zur Verbesserung der Arbeits- und Beanspruchungssituation bei Personal in der Krankenversorgung*. Internist 62, 928–936 (2021). <https://doi.org/10.1007/s00108-021-01120-y>

<sup>28</sup> Studien: *Stress und psychische Probleme haben in der Pandemie zugenommen*. Aerzteblatt, 4. Mai 2021. <https://www.aerzteblatt.de/nachrichten/123573/Studien-Stress-und-psychische-Probleme-haben-in-der-Pandemie-zugenommen> (Accessed 2021.07.23.)

<sup>29</sup> Lenzen-Schulte M. *Long COVID: Der lange Schatten von COVID-19*. Dtsch Arztebl 2020; 117(49): A-2416 / B-2036

<sup>30</sup> Gilleen J, Santaolalla A, Valdearenas L, et al. *The impact of the COVID-19 pandemic on the mental health and wellbeing of UK healthcare workers*. BJPsych Open, Volume 7, Issue 3, May 2021, e88 DOI: <https://doi.org/10.1192/bjo.2021.42>

<sup>31</sup> Chew NWS, Lee, GKH, Tan BYQ, et al. *A multinational, multicentre study on the psychological outcomes and associated physical symptoms amongst healthcare workers during COVID-19 outbreak*. Brain, Behavior, and Immunity. Volume 88, August 2020, Pages 559-565. <https://doi.org/10.1016/j.bbi.2020.04.049>

<sup>32</sup> Kramer V, Thoma A, Kunz M. *Medizinisches Fachpersonal in der COVID-19-Pandemie: Psyche am Limit*. InFo Neurologie 23, 46–53 (2021). <https://doi.org/10.1007/s15005-021-1975-8>. Krammer S., Augstburger R., Haack M, et al. *Anpassungsstörung, Depression, Stresssymptome, Corona bezogene Sorgen und Bewältigungsstrategien während der Corona Pandemie (COVID-19) bei Schweizer Klinikpersonal*. Psychother Psychosom Med Psychol 2020; 70(07): 272-282. DOI: 10.1055/a-1192-6608. Schulze S, Holmberg C.

several countries, but as of 1 August 2021 in Hungary the vaccine is mandatory for all health care staff working either in state-financed or private health care.<sup>33</sup>

When this study was written, neither the German nor the Austrian government was planning to introduce similar measures. Like Italy and France, Hungary puts a lot of emphasis on vaccines as part of prevention since health care facilities are struck by a relatively high number of nosocomial infections and vaccination provides more effective protection for both the staff and the patients. There are some countries where vaccination is compulsory for the majority of citizens, but the legal system of these countries is rather peculiar.<sup>34</sup>

In Hungary, it was justifiable to involve residents, medical students and other volunteers in health care; however, their preparation was not always exhaustive and it was not based on thorough professional guidelines<sup>35</sup> - even though, according to German experience, it would have been essential. Kühlmeyer et al. published a survey of the increased moral stress levels of German medical students and recently graduated doctors during the epidemic, and they concluded that these two groups were subjected to more and more intensive moral stressors. This is partly due to the fact that at the beginning of their career doctors tend to have less experience and routine, while ethically they are (still) susceptible. The authors highlight the concerning nature of this problem, as some recently graduated doctors will even consider interrupting their studies or choosing another profession due to the overwhelming nature of these emotional and ethical challenges.<sup>36</sup>

In Hungary, several publications<sup>37,38</sup> focused on the severe mental and psychological burden affecting doctors, nurses, and other health professionals, but so far, hardly any systematic surveys have been conducted.

Recommendations for Covid-related institutional regulations have been compiled by the Semmelweis University (Hungary).<sup>39</sup>

"Bedeutung und Belastung von Pflegekräften während der Corona-Krise" Public Health Forum, vol. 29, no. 1, 2021, pp. 32-35. <https://doi.org/10.1515/pubhgef-2020-0114>.

<sup>33</sup> <https://koronavirus.gov.hu/cikkek/nnk-az-alapimmunizalas-kotelezo-lesz-az-egeszsegugyben-dolg-ozoknak> (Accessed 2021.08.21.)

<sup>34</sup> Zsoldos Á. *Magyarország nincs egyedül a kötelező védőoltással: egyre több ország lépi meg*. Portfolio, 2021. július 21. <https://www.portfolio.hu/global/20210721/magyarorszag-nincs-egyedul-a-kotelezo-vedooltass-al-egyre-tobb-oroszag-lepi-meg-493446> (Accessed 2021.08.22.)

<sup>35</sup> Szurovecz I. *Önkénteseket toboroznak a kórházakba*. <https://444.hu/2021/03/22/onkenteseket-toboroznak-az-intenziv-osztalyokra> (Accessed 2021.08.22.)

<sup>36</sup> Kühlmeyer K, Kuhn E, Knochel K, et al. *Moralischer Stress bei Medizinstudierenden und ärztlichen Berufseinsteigenden: Forschungsdesiderate im Rahmen der COVID-19-Pandemie*. Bundesgesundheitsbl 63, 1483–1490 (2020). <https://doi.org/10.1007/s00103-020-03244-2>

<sup>37</sup> Bordás G, Benke Á. *Kezdeni kell valamit az orvosok és ápolók traumáival, különben baj lesz*. <https://24.hu/belfold/2021/05/26/orvosok-apolok-koronavirus-trauma-pszichologus/> (Accessed 2021.07.23.)

<sup>38</sup> *Veszélyben az egészségügyi dolgozók. Házipatika*, 2021. március 11. [https://www.hazi-patika.com/eletmod/veszelyben/cikkek/veszelyben\\_az\\_egeszsegugyi\\_dolgozok/20210311125022](https://www.hazi-patika.com/eletmod/veszelyben/cikkek/veszelyben_az_egeszsegugyi_dolgozok/20210311125022) (Accessed 2021.07.23.)

<sup>39</sup> *Egészségügyi Menedzserképző Központ, Semmelweis Egyetem: Lelki terhelés csökkentése krízishelyzetben*. <https://semmelweis.hu/emk/covid-19-menedzsment-ajanlasaink/lelki-terheles-csokkentese-krizishelyzetben/> (Accessed 2021.07.23.)

## V. Is it possible to measure the success of prevention?

The question is whether the *global* success of prevention is measurable, and if it is, how: are we going to succeed in establishing an international distributing team<sup>40</sup> which makes sure that the gap in vaccine availability between high- and low-income countries does not increase leading to a grotesque situation<sup>41</sup>, will we manage to eradicate the virus in the foreseeable future, are we going to reach global vaccine coverage, can we mitigate negative economic effects and improve mental well-being as a result?

Also, how can you measure the success of prevention at the level of *society*: is it the number of lives saved, the number of people vaccinated per unit of time, and the number of available types of vaccines that grant personal autonomy unless there are no contraindications? Does it also include successful education campaigns aimed at anti-vaccination supporters using rational arguments and scientific evidence or establishing several well-equipped purpose-built hospitals or the smooth provision of primary care in spite of the pandemic? Could it also entail effective burn-out prevention strategies for healthcare workers?

The success of prevention at the level of *individuals* is also another potential question: does it mean the number of saved life years, preserved subjective quality of life, a low number of PTSD cases among Covid survivors or the effective treatment of mental health disorders caused by isolation?

One of the most severely affected social groups is undeniably school-aged children, whose isolation from their peers has led to the development of serious problems: introversion and sleep disorders, sometimes accompanied by aggression and lack of motivation.<sup>42</sup> Several Hungarian and German studies have highlighted further collateral health damage in vulnerable families. Low-income Hungarian families were more likely to report negative mental effects of the pandemic; 35% of low-income families reported anxiety in their adolescent children, while the prevalence of anxiety was only 15% in middle- and high-income families.<sup>43</sup> A German study has indicated unhealthy eating habits and the lack of physical exercise as risk factors besides depressive symptoms.<sup>44</sup>

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<sup>40</sup> Gates B. *Jövőre az egész világon visszatérhet az élet a normális kerékvágásba*. HVG, 2021. április 25. [https://hvg.hu/gazdasag/20210425\\_Bill\\_Gates\\_Jovore\\_az\\_egesz\\_vilagon\\_visszaterhet\\_az\\_elet\\_a\\_normalis\\_kerekvagasba](https://hvg.hu/gazdasag/20210425_Bill_Gates_Jovore_az_egesz_vilagon_visszaterhet_az_elet_a_normalis_kerekvagasba) (Accessed 2021.07.23.)

<sup>41</sup> *Growing global Covid vaccine inequity 'grotesque', says WHO*. France 24 Issued on: 22/03/2021. <https://www.france24.com/en/health/20210322-covid-19-who-slams-grotesque-growing-global-vaccine-inequity> (Accessed 2021.07.24.)

<sup>42</sup> *Kutatási eredmény: a magyar szülők fele szerint romlott a gyerekek mentális egészsége a járvány alatt*. UNICEF, 2021. június 15. <https://unicef.hu/igy-segitunk/hireink/kutatasi-eredmeny-a-magyar-szulok-fele-szerint-romlott-a-gyerekek-mentalis-egeszsege-a-jarvany-alatt> (Accessed 2021.07.24.)

<sup>43</sup> *Kutatási eredmény: a magyar szülők fele szerint romlott a gyerekek mentális egészsége a járvány alatt*. UNICEF, 2021. június 15. <https://unicef.hu/igy-segitunk/hireink/kutatasi-eredmeny-a-magyar-szulok-fele-szerint-romlott-a-gyerekek-mentalis-egeszsege-a-jarvany-alatt> (Accessed 2021.07.24.)

<sup>44</sup> *Coronapandemie: Psychische Gesundheit von Kindern hat sich weiter verschlechtert*. Aerzteblatt, 2021. Februar 10. <https://www.aerzteblatt.de/nachrichten/121027/Coronapandemie-Psychische-Gesundheit-von-Kindern-hat-sich-weiter-verschlechtert> (Accessed 2021.07.23.)



## VI. Communication

One of the most important means of epidemic control is effective and trustworthy communication. Governmental information was presented via newly established communication channels in Germany<sup>45</sup>, Austria<sup>46</sup> and Hungary<sup>47</sup>. All these channels aimed to inform and educate the citizens thereby indirectly serving as a means of prevention. These communication interfaces are updated regularly, and they use an easily understandable and well-arranged question-and-answer format to address general questions, such as why it is necessary to get vaccinated, who can get vaccinated, when and under what conditions, how safe the vaccine is, what its mechanism of action is, how many vaccines you need for full immunity, how you can register for the vaccine. Current statistical data are also presented showing the number of people vaccinated, infected, hospitalised and deceased. Some questions address country-specific issues and reflect public thinking.

The Hungarian website also aims to clear up common misconceptions about the virus, namely that the influenza virus does not grant immunity against the coronavirus and there is no need to stockpile shelf-stable food since fresh supply is continuous. In addition, it also tries to establish a solidarity-based society by asking people who have already recovered from the virus to donate plasma so that others can overcome the disease as well.

Austria does not allow its citizens to register for vaccination individually online; the distribution of vaccines is decided and monitored centrally in order to meet the actual demand, and the order of priority cannot be bypassed. Austria also emphasizes the importance of EU vaccine acquisition and why it is essential to follow a uniform vaccination strategy Europe-wide.<sup>48</sup> The Hungarian government, however, highlights the advantages of vaccines originating from several sources (outside the EU) as the availability of more vaccines allows for faster vaccination and higher vaccine coverage, which in turn facilitates economic recovery and indirectly affects the mental stability of the whole society.

In Hungary, the governmental Covid website does not specifically address the role of telemedicine or the risks and limitations of online consultations compared to personal ones. Neither does it deal with the problems associated with registering for vaccination online. In the future, these areas should be paid more attention to as patients' data are extremely sensitive, and patients' rights, especially the right of confidentiality, must not be violated.

The German governmental website has a separate menu item for the latest recommendations on AstraZeneca vaccine since the trust of German citizens in the vaccine faded when the risk of potential adverse effects was revealed. Such a wave

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<sup>45</sup> <https://www.bundesregierung.de/breg-de/themen/coronavirus/coronavirus-impfung-faq-1788988> (Accessed 2021.08.3.)

<sup>46</sup> <https://www.sozialministerium.at/Corona-Schutzimpfung/Corona-Schutzimpfung---Haeufig-gestellte-Fragen.html> (Accessed 2021.08.3.)

<sup>47</sup> <https://koronavirus.gov.hu/gyik> (Accessed 2021.08.3.)

<sup>48</sup> <https://www.sozialministerium.at/Corona-Schutzimpfung/Corona-Schutzimpfung---Haeufig-gestellte-Fragen/Corona-Schutzimpfung-%E2%80%93-Haeufig-gestellte-Fragen---Beschaffung.html> (Accessed 2021.08.3.)

of mistrust and uncertainty was also detectable in Hungary, but here the website does not present any highlighted questions and answers related to this topic.

In 2019, the WHO listed vaccine hesitancy among the top 10 threats to global health.<sup>49</sup> The intensification of anti-vaccination views and movements has been noticeable all over the world recently. This phenomenon can be caused by several factors<sup>50</sup>, which include social prejudices, as well as many conspiracy theories. The most widespread misconceptions include natural immunity being superior to vaccination, vaccines causing autism or vaccines containing a microchip for future tracking of the carrier.<sup>51</sup> At the same time, there has been growing mistrust towards modern, western medicine giving rise to increased interest in alternative medicine. Hungarian people have grown to believe that boosting their immune system is as effective in controlling the spread of the virus as vaccination, and this trust in their own body has superseded arguments emphasising the importance of vaccination.<sup>52</sup> The ideology of antivaccination is particularly widespread in deprived social groups living in deep poverty.<sup>53</sup> The probable risks and expected benefits have to be considered with every vaccine, but many people think that if the majority of the society has already got vaccinated, they do not need to do so, it is not their patriotic duty.<sup>54</sup> The discourse of antivaccination can actually be studied in texts already as it is present online, providing an excellent breeding ground for the spread of the ideology. Therefore, trustworthy communication and scientific control of online content are of utmost importance.<sup>55</sup>

According to a recent study, 33% of German people think that the virus can be controlled by vaccinating adults only, while 67% of them believe that children and adolescents have to be vaccinated as well.<sup>56</sup> Some Hungarian paediatricians also stated that school-aged children should have been vaccinated even before the summer holiday. Nevertheless, their vaccination cannot be made compulsory as the vaccine was not developed for children and, at present, it is not compulsory even for

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<sup>49</sup> Bíró A, Szabó-Morvai Á. *Hogyan befolyásolják a hírek az oltási hajlandóságot?* KRTK Blog, 2021. május 29. <https://www.portfolio.hu/krtk/20210529/hogyan-befolyasoljak-a-hirek-az-oltasi-hajlandosagot-485170> (Accessed 2021.08.3.)

<sup>50</sup> *Az oltásellenes mozgalom érvei és a valódi válaszok - Tévhitek és tények.* [https://www.webbeteg.hu/cikkek/fertozo\\_betegseg/17762/tenyek-es-tevhitek-az-oltasokrol](https://www.webbeteg.hu/cikkek/fertozo_betegseg/17762/tenyek-es-tevhitek-az-oltasokrol) (Accessed 2021.08.3.)

<sup>51</sup> Németh Á. *Az oltásellenesség tévhitei.* euronews 23/11/2020. <https://hu.euronews.com/2020/11/23/az-oltasellenesseg-tevhitei> (Accessed 2021.08.3.)

<sup>52</sup> Fabók B. „*Nem oltatjuk be magunkat, kerüljön ez bármibe*” – erős az oltásellenesség a fizikai dolgozóknál. G7, 2021. április 13. <https://g7.hu/vallalat/20210413/nem-oltatjuk-be-magunkat-keruljon-ez-barmibe-eros-az-oltasellenesseg-a-fizikai-dolgozoknal/> (Accessed 2021.08.3.)

<sup>53</sup> *Tombol az oltásellenesség a tiszaaburai romák körében.* 2021. június 12. [https://www.youtube.com/watch?v=CNqO9vOeN\\_Y](https://www.youtube.com/watch?v=CNqO9vOeN_Y) (Accessed 2021.08.3.)

<sup>54</sup> *Corona: Warum lassen sich viele nicht impfen?* <https://www.dw.com/de/corona-warum-lassen-sich-viele-nicht-impfen/a-58189549> (Accessed 2021.08.3.)

<sup>55</sup> Kolozsi Á. *Alig élttem, és közben azt láttam a neten, hogy nincs is vírus.* telex, 2021. március 19. <https://telex.hu/koronavirus/2021/03/19/alig-eltem-es-kozben-az-lattam-a-neten-hogy-nincs-is-jarvany-epp-az-oltastol-lesz-birkanep-a-magyar> (Accessed 2021.08.3.)

<sup>56</sup> *COSMO Befragung.* Erhebung vom 29./30.06.2021. <https://projekte.uni-erfurt.de/cosmo2020/web/summary/46/> (Accessed 2021.08.3.)

adults except for health care workers.<sup>57</sup> German policymakers are not planning on making vaccination compulsory for a broad section of the population, so the above-mentioned finding of 67% of people supporting full vaccination as the ultimate solution to the problem is rather intriguing. It is plausible that a central order may not be necessary and individual solidarity and proactivity will be sufficient, just like it occurred in Sweden with voluntary quarantine.

The immunisation of those who are planning to get pregnant, are expecting or breastfeeding is a very important aspect of medical ethics: the protection of foetuses and pregnant women is of utmost importance in every society. As there are no findings from long-term impact studies yet, the most feasible solution is considering the risk-benefit ratio. Hungarian recommendations state that Covid-19 does not cause miscarriage or foetal damage and it is not necessary to delay pregnancy after recovering from the infection. The guidelines recommend the use of Moderna or Pfizer vaccines in pregnancy.<sup>58</sup>

## VII. Conclusions

The countries considered “model laboratories” may have served as examples to follow, but they probably focused on operative prevention, scheduling restrictions, and easing, as well as on handling practical problems. My study aimed to describe other fields where the German and Austrian examples should be followed, considering this recent challenging period. Hungary would need further position papers in the field of ethics to assist laypeople in this situation, which is full of dilemmas. Highlighting these moral-ethical issues and including them in social discussions would be beneficial should we need to handle further waves of Covid or if we need to prepare for similar pandemics. The compilation of a post-covid strategy and a medium-term national pandemic plan is already scheduled<sup>59</sup>. This plan is supposed to analyse the information gained from the pandemic systematically focusing on the protection of health, society and economy<sup>60</sup>. Besides classifying and prioritising the diverse recommendations, it would be worth including a section specifically highlighting ethical aspects. Focusing on the ethical norm of individual responsibility (getting vaccinated, voluntary quarantine) would be more understandable in an ethical context. We would need open communication of minimal moral standards not confined to end-of-life decisions, which is the only topic dealt with in the guidelines of the Hungarian Medical Chamber. In addition,

<sup>57</sup> Czenkli D. "Jobb lett volna, ha a 12-15 éveseket még a nyári szünet előtt beoltják". MN, 2021.06.29. <https://magyararancs.hu/katasztrofa/jobb-lett-volna-ha-a-12-15-eveseket-meg-a-nyari-szunen-elott-beoltjak-239502> (Accessed 2021.08.3.)

<sup>58</sup> Dr. Toldi G. *COVID-19 és várandósság, szoptatás, csecsemőkori*. MTA Orvosi Tudományok Osztálya. 5. hírlevél | Covid-19. 2021. Április. [https://mta.hu/data/dokumentumok/egyeb\\_dokumentumok/2021/Orvosi\\_hirlevel-2021-5\\_02.pdf](https://mta.hu/data/dokumentumok/egyeb_dokumentumok/2021/Orvosi_hirlevel-2021-5_02.pdf) (Accessed 2021.08.3.)

<sup>59</sup> *A tudománynak számos fontos feladata lesz a járvány utáni időszakban*. hirado.hu, 2021. 03. 29. <https://hirado.hu/koronavirus/cikk/2021/03/29/a-tudomany-nak-szamos-fontos-feladata-lesz-a-jarvany-utani-idoszakban#> (Accessed 2021.08.13.)

<sup>60</sup> Veres LI. „Nemzeti szintű együttműködés kell nagy feladataink elvégzéséhez”. <https://magyarnemzet.hu/belfold/2021/03/nemzeti-szintu-egyuttmukodes-kell-nagy-feladataink-elvezesehez> (Accessed 2021.08.13.)

transparent and reasonably justified decisions in medical ethical issues could support social solidarity, thereby indirectly facilitating the prevention of the further spread of antivaccination ideology and increasing the appreciation and mental stability of healthcare workers.

It would also be necessary to clarify the role of telemedicine further and analyse online doctor-patient relationships. The more accurate consideration of the risk-benefit ratio of the latter would be salutary in both pandemic-related and spontaneous situations. It would be worthwhile to define the situations in which it cannot be applied, or to lay down as a rule that, although it supports medical activity, it can never replace that. The German Federal Medical Chamber has already made recommendations on the role of telemedicine: the medical community should be actively involved in setting the boundaries of telemedicine, as the inviolability of medical principles present ab ovo should be preserved even if future techniques support this special relationship as part of the doctor-patient relationship spectrum.<sup>61,62</sup>

Another important aspect is that the health, mental and psychological condition of the healthcare staff has a direct impact on patient care and the healing work itself. As a result, it would be essential to spend more time preparing residents, medical students and volunteers and also to develop more precise professional protocols.

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<sup>61</sup> Telemedizin. <https://www.bundesaerztekammer.de/aerzte/telematiktelemedizin/telemedizin/> (Accessed 2021.08.13.)

<sup>62</sup> Deutscher Ärztetag, *Entscheidung*, „Voraussetzungen für gute Telemedizin“. Dresden, 11. - 14.05.2010. [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/Telemedizin\\_Telematik/Telemedizin/V-03\\_Entscheidung\\_Telemedizin.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Telemedizin_Telematik/Telemedizin/V-03_Entscheidung_Telemedizin.pdf) (Accessed 2021.08.13.)

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