

## **Intercultural dialogues in times of global pandemics: The Confucian ethics of relations and social organization in Sinic societies**

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### **Abstract**

Since COVID-19 is a global-scale pandemic, it can only be solved on the global level. In this context, intercultural dialogues are of utmost importance. Indeed, different models of traditional ethics might be of assistance in constructing a new, global ethics that could help us confront the present predicament and prepare for other possible global crises that might await us in the future. The explosive, pandemic spread of COVID-19 in 2020 clearly demonstrated that in general, one of the most effective tools for containment of the epidemics is precisely human and interpersonal solidarity, which must also be accompanied by a certain degree of autonomous self-discipline. The present paper follows the presumption that these types of personal and interpersonal attitudes are—inter alia—culturally conditioned and hence influenced by different traditional models of social ethics. In light of the fact that East-Asian or Sinic societies were more successful and effective in the process of containing and eliminating the virus compared to the strategies of the Euro-American regions, I will first question the widespread assumption that this effectiveness is linked to the authoritarian political traditions of the Sinic East and Southeast Asian areas. Then, I will critically introduce the Confucian ethics of relations, which in various ways has influenced the social structures of these regions, and clarify the question of whether and in which way the relics of this ethics had an actual effect on the crisis resolution measurements. The crucial aim of this paper is to contribute to the construction of theoretical groundworks for a new, transculturally grounded global ethics, which is more needed today than ever before.

**Keywords:** global pandemic, COVID-19, intercultural exchanges, Confucianism, structure of Sinic societies

### **Introduction**

In this paper I will address the problems of global pandemic situations through the lens of transcultural studies. The primary motive for writing this study was to gain general insight into the various culturally conditioned practices that were observed during the COVID-19 crisis and to acquire common knowledge about the cultural backgrounds of various methods, procedures, and measures that were used to deal with the crisis.

As a sinologist working on Chinese intellectual history, I will focus in this context on the Chinese experience and in particular, as the title of this paper suggests, on Confucian philosophy and ethics. In this regard, I will mainly deal with the so-called Sinic region. This is a cultural and linguistic area that overlaps geographically with most East-Asian regions, as well as certain regions in Southeast Asia, such as, for instance, Vietnam and partly even Singapore. The term applies to all areas that have traditionally used Chinese writing and were historically strongly influenced by certain elements of Chinese culture, particularly by Confucianism, but also by Chan Buddhism and some other ideational systems that originated in China.<sup>2</sup>

My primary motivation to investigate the problem of premodern and traditional ethical models in the Sinic region dates back to the year 2020, to the time of the initial spread of the COVID-19 pandemic. As a Sinologist I cannot let go of the fact that the novel coronavirus, which leads to a respiratory illness with a high rate of contagiousness and mortality, first appeared in China, and thus in the cultural and linguistic area that comprises the core of my personal and professional interests, and therefore the fundamental focus of my academic work. But already in spring 2020, as the pandemic progressed, it also quickly became clear that Sinic societies (including China) were much more efficient at containing its spread than societies in the geopolitical realms of Europe and the United States.

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<sup>2</sup> For the example of Korea, see for instance Maldonado (2020, pp. 129–130).

Many authors attributed the social reasons behind the high level of cooperation required for this to the populace's general sense of obedience and collectivism (Escobar, 2020b, p. 3), which is supposedly related to the autocratic organization of traditional Sinic societies and is part of the common political thought tradition of East Asian societies based on Confucianism. However, such a position is superficial and generalizing, especially considering that the most effective measures against the spread of coronavirus were taken in those East Asian countries that are not autocratic but have a democratic social order, such as Taiwan or South Korea. In order to refute such superficial and unfounded assumptions, which are not only based on popular prejudices but also feed and reinforce them, we will first take a closer (and more substantiated) look at the thesis of alleged Asian authoritarianism. Then, I will proceed from the presumption that the reasons for this efficiency are rather connected to patterns of interpersonal behavior that originated in traditional and classical Sinic ethics, and particularly in Confucian moral philosophy. In the following, I will critically introduce the main paradigms of classical and traditional Confucian ethics, which is a type of deontological ethics, founded on the importance of interpersonal relations. On this basis, I will illuminate some crucial problems regarding the theoretical groundworks of a possible transcultural global ethics,<sup>3</sup> which might help us solve the present and possible future crises of our common world.

### **The thesis of immanent authoritarianism**

Let us first examine the background and underpinnings of widespread claims, according to which the reasons for the Sinic efficiency in containing the spread of the coronavirus were linked to the "Confucian autocratic traditions", which allegedly historically prevailed in the region (see for instance Han, 2020a, p. 4; Oviedo, 2020, p. 4; Escobar, 2020a, p. 2). In the next part of this section, I will show why such claims proceed from a latently Eurocentric and Orientalist position.

Some scholars, like the contemporary Berlin-based philosopher of Korean descent Byung-Chul Han, see the reasons for the faster establishment of measures to stop the spread of the pandemic in East Asia in the region's autocratic traditions. Han writes:

What advantages in the fight against the pandemic, compared to Europe, can we find in the Asian system? Asian countries like Japan, Korea, China, Hong Kong, Taiwan and Singapore have an authoritarian mindset, originating from their cultural tradition (Confucianism). People are less rebellious and more obedient than in Europe (Han, 2020, p. 2).

As indicated above, such claims are populist, generalising, and lacking in scientifically verifiable evidence. To begin with, the thesis of the alleged "all-around obedience" of people throughout the Sinic region, as compared to Europe and America, where people are supposed to be more critical and less compliant (as the above statement implicitly implies), is completely unfounded. Instead, it is based on the widespread assumption that Confucianism is a conservative normative ethic that advocates gerontocracy and the suppression of the individual for the good of the state. Few of the people who blindly advocate such theses actually have any real knowledge of the subject under discussion, and even fewer of them are aware that the ethics

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<sup>3</sup> Transcultural global ethics cannot be confused with universal ethics, even though the system is based on certain general premises that are common for all humanity. It is a dynamic and continuously changing unity of ideas, standards, and values, composed of different ethical paradigms and normative regulations, which originate in various cultures. Such an ethical system should answer the topical requirements of the current globalized world in a process of transcultural sublation, that is, a process that transcends the orthodox static formulation of culture and thus opens up the possibilities for the formation of new, transculturally conditioned horizons that enable us to theorize contents that originally belonged to separate systems or categories.

of the original Confucianism were extremely progressive and critical of the social attitudes of the time for the era in which it arose.

The ethical system of original Confucianism is based on the premise of humaneness (*ren*), which is a kind of reciprocal empathy, and defined by placing a high value on the type of education that raises the younger generations into respectable and learned, but also critical and autonomous adults. The Confucian *Analects* are teeming with segments that undoubtedly argue for the type of education, such as: “Learning without thought is empty; thought without learning is perilous” (Lunyu, s.d., Wei zheng, 15).

A similar spirit springs from Confucian commentaries on Confucius’s classic *The Spring and Autumn Annals*, which often advocate critical and autonomous decision-making:

If the ruler says something is right, then everyone says it is right. And if he claims something is wrong, then everyone will claim the same thing. But that’s like watering down an already watery soup with more water—who would want to eat it? Or as if the instruments in an orchestra all played the same musical line—who would want to hear it? Such sameness is not good (Chunqiu Zuo zhuan, s.d., Shao Gong ershi nian, 2).

Even Xunzi, one of Confucius’s most famous successors, who was otherwise known as an advocate for a “harder” version of the pragmatic-rational Confucianism, unequivocally points out that the people have the right to dethrone an unsuitable, immoral, and despotic ruler: “The ruler is like a boat, the people are like water. The water can carry the boat, but can also overturn it” (Xunzi, s.d., Wang zhi, 5).

Original Confucian teaching were quite progressive for their time and they doubtless included many proto-democratic elements; in this regard, we should mention the idea of “people as the root” (*Min ben*) which represented a crucial foundation of Confucian political philosophy.

On the other hand, during the time of East Asian modernization, Confucianism was seen as a dogma that had outlived its usefulness, one that oppressed individuals and did not tolerate their free and autonomous choices. Such a Confucianism was of course seen as the complete opposite to the kind of modernization that was being “imported” from the West, and whose foundational premises were defined based on autonomy and the freedom of the individual subject, as well as their critical and innovative thinking and action. During the period of East Asian “Enlightenment,” Confucianism was seen as a reactionary enemy of all forward-looking people who were trying to lead East Asia on a path towards the formation of modern societies based on equality and democracy. It is of course true that the Confucianist system was, in the Sinic societies of this pre-modern era, most widespread in the form of a dogmatic normative ethics, drenched in gerontocracy and advocating scholastic models of education for the young, who were supposed to—exclusively through rote memorization—uncritically adopt the dogmas of the ruling elites. As such, this form of Confucianism also oppressed young people, women, and marginalized social groups.

Here it is important to consider the difference between Confucian philosophy and its ethical discourses (*Ru xue*) on the one hand, and Confucian state doctrine or dogmatic normative ethics (*Ru jiao*) on the other. As mentioned earlier, Confucianism in the pre-Qin period was a progressive ethics that sharply criticized the concept of hereditary monarchy and advocated instead a proto-republican system in which the ruler would be elected primarily on the basis of his wisdom and moral maturity. This meritocratic system was based on the cultivation of one’s personality and the discovery of the autonomous moral self within one’s own mind. Its ideational foundation was based on the concepts of the aforementioned empathic humaneness (*ren*), and situational righteousness or appropriateness (*yi*). At the same time, this was an ethics based on diversity. The harmony for which the original Confucians stood was the harmony of pluralism, not an equalizing alignment of all individuals within a society (Sernelj, 2020, p. 169). Of course, this diversity also meant that society was structurally ordered according to the

Confucian design, which involved a normative arrangement of relationships or roles for individuals in a society.

Although in institutionalized official Confucian state discourse, the prevailing view is that society is strictly hierarchically ordered, this is not at all true in original Confucian philosophy. In this context, let us examine the Confucian theory of the “five relations” (*wu lun*) in more detail. Indeed, the political theory of original Confucianism was based on these five relations, which originate in the family and have a paradigmatic character for all relationships within the broader community, including the state. Confucius’ successor Mencius defined these relationships as follows:

Father and son should love one another and the relationship between the ruler and their subject should be defined by appropriateness. Between husband and wife there should be difference. Between old and young, there should be a proper order, and between friends, trustworthiness (Mengzi, s.d., Teng Wen Gong I, 4).

Hierarchy in the sense of prioritizing the decisions of a superior can only be seen in the relationship between a ruler and a subject, and between members of the older and younger generations. In the first case, the nature of the relationship itself is hierarchical, meaning that the ruler is naturally his subjects’ superior. But, especially in Confucianism, this does not necessarily mean that the latter must be absolutely obedient to the former; on the contrary, the Confucian definition of this relationship requires the ruler to be proper and responsible to his subjects. In fact, the real authority, in the sense of hierarchical primacy, is present in the relationship between members of the older and younger generations, such a relationship being defined by the requirement of proper order (*xu*) based on the sequence or order of priorities in decision-making. Here we have the only type of relationship within the framework of Confucian relational ethics in which one of the two opposing poles has absolute authority and priority in decision-making, although even in this case the older generation shares responsibility for the younger’s welfare. On the other hand, this is undoubtedly an element from which gerontocracy later emerged as one of the most problematic elements of Sinic social systems; however, we must also not overlook the fact that even this view was quite progressive for the time in which Confucian teachings emerged; we must not forget that in a semi-agrarian society of that time, the practices of killing and neglecting the elderly still existed.

With regard to the context of this paper, this element of Confucianism is especially interesting in light of the fact that the elderly comprise over 90% of the victims of the COVID-19 pandemic, and even more so in light of the utilitarian calculations that were applied in some states facing a lack of medical equipment, and that were supposed to make it possible to define which human lives were worth saving at the cost of others that could be sacrificed. However, as we are going to deal with these issues in later chapters, I will for now return to the central question of the present chapter and focus on the problem of autocratic elements in Confucian political and ethical discourses.

During the period of the first unification of China under the auspices of the Qin Dynasty (221 BCE), Confucianism was, like most other intellectual currents of the pre-Qin period, banned. The only permitted thought in this totalitarian, but luckily short-lived dynasty, was the ideology of Legalism (*fǎ jiā*), a Machiavellian political doctrine that served the interests of the absolute ruler and was based on repressive legislation and control over individuals and all social groups.

It was only after the defeat of the Qin under the rule of the new Han Dynasty (206 BCE–220 CE) that the classical schools of philosophy were rehabilitated. And during the Han Dynasty period, a new state doctrine was also established. The court ideologue Dong Zhongshu used Confucianism as the basis of this new system of ideas, and at the same time managed to covertly incorporate a number of repressive and despotic Legalist elements into it. Thus, a new autocratic

state doctrine was formed from the originally democratic Confucianism. The Legalist elements of totalitarianism and oppression of the state over the individual are latently present in China to this day. Such Legalistic elements, which were thus seen as integral parts of Confucianism, include, for example, procedures such as the method of collective responsibility or the principle of denunciation.

If we try in a very short (and somewhat generalizing) way to review the basic differences between Confucianist doctrine and Confucian philosophy, we can say that the former represented an institutionalized form of state policy, while the latter represented a school of thought or a deontological ethics based on individual autonomy.

Confucianism received its institutionalized basis as a state doctrine primarily with the introduction of civil service examinations, which thereafter formed the intellectual basis of civil service until their abolition in 1905. The material that had to be learned in order to attain an official position (and thus political power) consisted mostly of the Confucian classics. The system of examinations, however, was completely at odds with the basic principles of Confucianism, as it required candidates to simply memorize the material (without the contemplation desired by Confucius), along with internalizing the formal rules of writing reports and essays. The clearest difference between Confucianist doctrine and Confucian philosophy, however, is the fact that state doctrine also included (explicitly unnamed) Legalist methods of control and oppression. Through such use (or rather misuse) of the original Confucian ethics, the five paradigmatic relationships then actually developed a hierarchical character. This was expressed not only within the state's bureaucratic institutions, but also in the strict normative social ethics that formed and spread among the people based on this new doctrine. This Confucianist doctrine—both in its institutional and popular forms—actually posed an obstacle to East Asia's modernization through its dogmatism and conservatism, although different regions solved this problem in different ways. Also, the majority of today's repressive measures as applied by the various authoritarian states in the Sinic, i.e. traditionally Confucian, regions, are still based on Legalist elements within Confucianism. This applies to arranged marriages, which are still widespread—especially in rural areas—as well as to the modern digitalized “social credit system,” which was introduced on a trial basis in China back in 2015 and came into general effect on January 1, 2020.

This, then, is the Confucianism that Byung-Chul Han discusses as the main reason for the effectiveness of anti-coronavirus measures in East Asia. This view may apply in part to the PRC, in some respects to Singapore, and almost certainly to North Korea, although we do not know much about the actual situation there. It is a fact that the PRC used digital surveillance to monitor its population in the fight against the pandemic. Its digital control was certainly accompanied by the state authorities' paternalistic attitude towards the population, as expressed through intimidation and sometimes even open repression.

However, this is not the only reason for the success of anti-coronavirus measures in East Asia. The governments of different “soft” East Asian democracies, for example Taiwan, South Korea, and post-colonial Hong Kong, used no repressive measures in dealing with the pandemic, but were still extremely successful in limiting the spread.<sup>4</sup> When explaining their success, the state representatives pointed out to quick reaction times in the early stages, transparent, continued and practically directed information campaigns about the spread of the disease, excellent health systems, and very good systems of organizing and coordinating the population,

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<sup>4</sup> Especially Taiwan was seen throughout the world almost as a kind of “role model” for effective containment of the virus. This slightly changed during the third wave, i.e. by the mid-2021, when the disease's spread began to increase. However, this worsening of the situation was not connected to the patterns of people's behavior or any other social and ethical elements, but rather to the fact that—due to political reasons—Taiwan could not gain access to the vaccines soon enough.

which also saw in the epidemic a common problem that could only be solved by society as a whole, and not exclusively by individuals.

This view of social phenomena is typical of the original Confucianism. In addition to the community's hierarchical and gerontocratic elements and possible pressures exerted on the individual, Confucianist ethics, on which most principles for ordering interpersonal relationships are still based today, also contains elements of original teachings that have nothing to do with oppression and totalitarianism. The relational ethic and understanding of the individual based on the complementary and mutually inseparable relationship between society and the people who are part of it has survived in East Asia to this day. In this framework, the human self is an inseparable part of an organic whole that every individual person forms together with the society to which it belongs and into which it grows. Therefore, we can refute the thesis of the immanently authoritarian organization of Sinic societies, as advocated, for example, in some classic works of European Orientalism (see, for example, Wittvogel), and offer instead a better grounded and more realistic image of Sinic Confucianism-based ethical and political systems.

For a better understanding of the differentiations described above, we will take a brief look below at the basic characteristics of such ethical systems that are based on discourses of the original Confucianism and can be grouped under the umbrella category of social or ethical relationism or relationality (*guanxizhuyi*, cf. Li, 2016).

### **Relationism and Confucian “Role Ethics”**

The Confucian model of ethics that traditionally prevailed in the Sinic region is based on the primary role of the community. Its basic premise is that no one can survive (or even come into existence!) without others, that is, that society is the existential condition of the individual. In this context, we should emphasize from the outset the fact that the Sinic Confucian model of the relationship between the primary community and the secondary individual is neither a kind of collectivist, nor a kind of communitarian model of social interactions.

But if we start from the hypothesis that the efficiency of the measures against the coronavirus is linked to the traditional relational ethics prevailing in Sinic societies, we must also ask ourselves whether the internal organization of a society whose order is based on such an ethics is not also responsible for the low value attached to individual freedom, intimacy, and privacy. Indeed, as I have shown elsewhere (Rošker, 2021), a low worth placed on these values might facilitate social control of individuals and certain social groups. But due to the space limitations of the present paper, we will here primarily focus upon those structures of interpersonal relations that are instrumental for the establishment of social solidarity.

Traditional relational social orders belong to paradigms of interpersonal and political relations that are fundamentally different from individualist models in which the individual plays the key role. Indeed, in individualism, the individual's interests are also primary in an axiological sense, as opposed to those of the community, which are considered secondary. In the Sinic model, this relationship is complementary and based on the fundamental position of society, without which there would be no individuals at all.

Another fundamental difference between the Western individualist model and the Sinic relational system is that, in the individualist model, the individuals who make up the primary part of the relationship between society and the individual are considered equal, whereas Confucian and Sinic relationism are based on a clear distinction between individuals who are different.

Relational social orders are structured as webs of relationships that connect individuals who perceive themselves not as isolated and independent entities but as so-called relational selves. This means that the life and social roles of people in such systems are mutually interconnected and that their identities are to a large extent defined by their social relations. Within such a

framework, the Self was always necessarily part of concrete situations; in Sinic culture, social positions were usually closely tied to Confucian traditions, in which conceptualizations of persons were usually centered on relationships. Of course, this also means that all of the individual's intentions, choices, successes, and failures must be understood in the context of their interactions with other people (Lai, 2018, p. 64). As Paul D'Ambrosio (2016, p. 720) points out, we can therefore view classical Confucianism as a form of moral interpretation of relationships as the fundamental components of human life and morality. In societies and cultures influenced by such a system of ethics, it is only within the framework of such relationality that people can experience what it means to be a human being endowed with morality, the values of humanity, and the analogical attitude towards one's life and one's social and natural environment.

Both Chinese and Sinological theorists usually interpret the Confucian model of the "five relations" described in the previous section of this paper as the foundations of interpersonal relations, ethical order, and mutual responsibility that are rationalized but also include human emotions (Li, 2016a, p. 1097). These basic relationships roughly define the way interpersonal interactions take place, as within the network each individual is assigned certain tasks and modes of behaviors. In Sinic societies, this model can often be seen as a nexus of basic interpersonal relationships within a civil society, as it encompasses familial relationships as well as relationships among friends and colleagues, and political and other social relationships. On the other hand, this also reflects the Confucian emphasis on the family as the basic cell of the state, as three of the five such model relationships have their origins in the family community. This basic organization of the five relationships is not only a description of our social relations, but also includes a set of concretely prescribed norms of behavior that order social interactions within such models, as each of the relationships included therein is tied to specific virtues (Wang, 2016, p. 194).

The central role in these morally defined interactions is occupied by the virtue of filial piety (*xiao*). This virtue, which is the constitutive element of children's love for their parents and grandparents, is one of the cardinal virtues of Confucian ethics. In concrete contexts, it usually means the fulfilment of a child's duty to their parents. In the context of Confucianism, filial piety is important primarily because the relationship between children and parents provides the earliest social environment in which a child learns to understand normativity within relationships and appropriate responses (Lai, 2016, p. 121). Thus, these virtues are initially formed within the family, that is, within boundaries that define an individual's duties and responsibilities. These are established based on different relationships between individual family members. Therefore, it is important for Confucian moral epistemology that family love is a priority and takes precedence over all other kinds of love.<sup>5</sup> In a broader social context, this principle implies the priority of what is close over what is distant. Fan Ruiping's research (2010, p. xii) has shown that the Confucian emphasis on filial piety is closely related to the position that it is in the family that the foundations of virtuous living and morality are to be learned. The existential dependence of young children on their parents and the emotional dependence of the latter on the former are said to establish the human disposition to love. Therefore, for Confucians, love between parents and children is at the same time the foundation of the basic human virtue of humanity (*ren*). The latter, in turn, is central to any society of peace and prosperity, since it is based on mutual aid, trust, and solidarity.

We can thus assert that Confucianism is an ethical doctrine based on the moral interpretation of relationships as the fundamental constituents of human life and morality. Morality is then

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<sup>5</sup> Here again we can observe one of the fundamental differences between Confucianism and Christianity that shapes the basic ideologies of Euro-American cultural thought, since before the Christian God all people are accorded equal love. For an excellent comparative analysis of these differences and their ethical implications, see Huang (2002, pp. 204–229).

rooted in harmonious interactions between different people defined by different social roles. Li Zehou called this model of society and social ethics, which is not based on individualism but rather on social roles and relationships, “relationism” (*guanxizhuyi*). Many scholars believe that such an understanding of reality is more correct and realistic than social theories based on the ideas of the abstract individual, since in the real world there is no such thing as an individual in the sense of an isolated and “pure” Self, separate from all interpersonal intentions, feelings, and relationships, since no one can survive without others (Rosemont & Ames, 2016, p. 9).

It is therefore not strange that numerous Chinese researchers are critically reexamining Western discourses and believe them to have a one-dimensional emphasis on individual autonomy and the idea of free choice. Such paradigms are in the end always based on the assumption that individuals can be separated and abstracted from social contexts, relationships, even from such elements of the human condition that are of actual vital importance for human life, such as, for example, the ability and the need for interpersonal relationships and mutual care (Fan, 2010, p. 13). Compared to such models, Confucian relationism is a model of relational being.

In relational social systems, individuals are not supposed to act as an independent moral agent, separate from their fellow people (Lai, 2018, p. 6). That is why judgements about the individual are never defined in relation to an idealized standard of an independent Self. In this kind of understanding of the Self, the actual relationships and environments define individual values, thoughts, motivations, behaviors, and actions in the first place. Moreover, relationships in this context are always marked by mutuality and reciprocal complementarity: “A good teacher and a good student can only emerge together, and your welfare and the welfare of your neighbor are coterminous and mutually entailing” (Rosemont & Ames, 2016, p. 12). Even though relationism contains unequal positions—since the ruler is an authority to the subject, like the mother is to the daughter and so on—both parties who are involved in a specific relation are complementary and equal to one another, both in the metaphysical and the moral sense, since together they form a part of the social whole made up of those interpersonal relations.

This view of social composition is especially important in times of crisis, including those of the COVID-19 pandemic. Indeed, such times doubtlessly reinforce the need for cooperation that bridges the gap between the uniqueness of the individual on the one hand and their socio-relational Self on the other. It also poses a challenge to the artificially established dichotomies between the Self and the Other or between the specific and the general, the particular and the universal. This understanding is rooted in the paradigm of contrastive complementarity, as the unrepeatability of the individual can be measured not only by his or her individual achievements, but also by their social influence. And the latter, in turn, can be measured by an individual’s position within their contextual environment and by their relations with other individuals (Lai, 2018, p. 88). From the perspective of ethics, such a relational network has several important implications, especially in comparison to frames that postulate a person’s independent stability.

This kind of ethics does not derive from the concept of normative justice, but from a tendency towards social harmony (*he*),<sup>6</sup> which appears in the relational network of interactions between individuals, whose individual identities are perceived as harmonies of different combinations of the unique, particular characteristics of each of them. The network of relationships is dynamic and diverse, since no one within it forms a fixed specific identity or entity. Everyone in it is the bearer of numerous roles, which are interwoven and which complement and perfect one another. Thus, I myself am, say, a mother, but also a daughter; I am a teacher, but also a researcher, which means that I learn from the work of others. I am also a consumer, a singer, a driver, a citizen, a worker, etc. Analogously, my relationships with

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<sup>6</sup> Of course, this concept of social harmony should not be mistaken for the kind of ideologically misused concept of harmony that manifests itself in the patriotic propaganda of the leadership of China. For a more detailed description of such ideological misuses see Rošker (2012).



people are multi-layered and changeable. Therefore, in the network of relationality, I am never simply a fixed and unchanging entity, defined by my role within the network.

As we have indicated before, Confucian relationism also contains a special type of virtue ethics, though not based on the concept of the isolated individual, but rather defined by relations, or relationships, which are in their essence emotional.<sup>7</sup> Nevertheless, many other authors point out that it is rational and even necessary in visions of social systems to include, cultivate, and socialize emotions, since these are rooted in biological instincts that need to be directed towards mechanisms of mutual help (see Li, 2016a, p. 1097).

Another characteristic of relationism, which is important for crisis situations, such as the COVID-19 pandemic, is the factor of age-based inequality, which is certainly connected to the inequality of what is near and what is further away, of external and internal persons,<sup>8</sup> and so on. Confucianism emphasizes familial relationships in which people are automatically unequal. That is why relationism contains both rational order and emotional identification within conditions that are always concrete, unrepeatable, and connected to sensations and feelings. In this context, specific obligations, responsibilities, and actions differ for every individual according to the concrete, changeable situation in which they are located.

As mentioned already, relationism begins in the relational individual self and is rooted in the family, developed outwards to the wider community and the natural environments in which people live. The ancient Confucian Mencius described this structure of society, explaining that “the basis of the world is the state, the basis of the state is the family, and the basis of the family is the individual” (Mengzi, s.d., Li Lou I: 5).<sup>9</sup>

The historical importance of the social system based on family clans is, of course, closely connected with the general importance of interpersonal relations. Thus, concrete relationships between different people formed a social network, which in time became a sociohistorical paradigm that was not limited to a simply regulated sequence of pairs, but assumed the socially and ethically important function of the basic element of systematized social interactions.

This discrepancy between the emphasis on the relationism on the one hand and individualism on the other can be seen as the basic difference between two types of ethics, which prevailed in Sinic and Western societies, respectively. The important foundation from which these differences emerge can be seen in the fact that the former is based on the combination of reason and feelings, while the latter is mostly connected to rational prescriptions. Besides, relationism is in no way a system that would wholly negate the individual or the individual’s significance. However, compared to liberalism it does not perceive the individual as primary and superior to society.

## Conclusion

Of course, relationism does not represent the perfect and best possible system of social organization, since it is rife with errors, dangers, and problems. Individualism, theoretically based on the equality of all people, allows—at least on a formal level—a general respect for all people and their points of view. Relationism, which is hierarchy-based at its very foundations,

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<sup>7</sup> It is here worth pointing out that all three types of ethics, which are seen as the basic categories of this discipline, namely virtue ethics, deontological ethics, and utilitarian ethics, are categories that were established in the context of Western philosophy. Because transferring concepts and categories from one historical and cultural area to another is a problematic procedure (Silius, 2020, p. 258), tied to different culturally conditioned frames of reference, we have to take into account the fact that none of the above three categorizations are wholly suitable for defining or describing the basic nature of Confucian ethics, which at the same time certainly also belongs to the field of deontological ethics (cf. for example Lee, 2017, p. 94).

<sup>8</sup> The concepts of the “external” and the “internal” in this context refer to positions of people that are “inside” or “outside” certain social groups to which the subject, who is connected to these people, belongs.

<sup>9</sup> 天下之本在國，國之本在家，家之本在身。

could never produce the kind of discourse ethics<sup>10</sup> proposed by Habermas. The second important problem of relationism is evident in its tendency to harmonize individual situations based on pre-existing achievements and values, but also based on existing power relations. Even though relationism emphasizes flexibility and contextual dynamics, its hierarchical structure is inherently conservative in the sense that it hardly allows for innovations that might challenge the framework of existing ideas and social interactions. This danger is also related to the predominant role of emotions that connect people within the relational system and that often constitute an obstacle to the undisturbed functioning of laws, regulations, and sanctions. Thus, it could be said that relationism's greatest benefits are also its greatest risks. Moreover, due to globalization, traditional relationism is disintegrating in Sinic societies, and therefore there is a growing need in many East Asian populations to change the system and adapt it to the conditions of the contemporary world.

In the context of seeking durable solutions to crises such as the COVID-19 pandemic, it is nevertheless important to note that the basic framework of relationality and its associated values may well offer alternative possibilities or methods and ways of approaching a model of a more caring society, in the sense of a community based on an awareness and recognition of our responsibility and obligation to care for each other, as well as an awareness of our human vulnerability and our inherent interdependence.

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<sup>10</sup> Discourse ethics is a theory whose central criterion is discourse (cf. Habermas, 1991). This means that the correctness or rationality of the ethical assumptions (prescriptive claims) it makes is tested by means of discourse, which is formed based on rational arguments. Discourse ethics contains a cognitive meta-ethics, since the community of all participants in the discourse can (ideally) determine what is right. Discourse ethics differs from individualistic ethics in that its results are obtained through the process of intersubjective interactions. Therefore, it is useful for solving problems that go beyond the sphere of the individual, such as problems that arise in politics and the global economy.

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## **Ethics of vaccination prioritization and compulsory vaccination: An integrative approach**

**Martin O'Malley,<sup>1</sup> Jürgen Zerth<sup>2</sup> & Nikolaus Knoepffler<sup>3</sup>**

### **Abstract**

Vaccine scarcity and availability distinguish two central ethics questions raised by the Covid-19 pandemic. First, in situations of scarcity, which groups of persons should receive priority? Second, in situations where safe and effective vaccines are available, what circumstances and reasons can support mandatory vaccination? Regarding the first question, normative approaches converge in prioritizing most-vulnerable groups. Though there is room for prudential judgement regarding which groups are most vulnerable, the human dignity principle is most relevant for prioritization consideration of both medical and non-medical issues. The second question concerning mandates is distinct from considerations about persons' individual moral duty to receive vaccines judged reasonably safe and critical for individual and public health. While there is consensus regarding the potential normative support for mandated vaccination, the paternalistic government intervention of vaccine mandates requires a high bar of demonstrated vaccine safety and public health risk. We discuss stronger and weaker forms of paternalism to deal with the Covid-19 pandemic from an “integrative” approach that integrates leading normative approaches. We argue against a population-wide compulsory vaccination and support prudential measures to 1) protect vulnerable groups; 2) focus upon incentivizing vaccine participation; 3) maintain maximum-possible individual freedoms, and 4) allow schools, organizations, and enterprises to implement vaccine requirements in local contexts.

**Keywords:** covid-19, vulnerable persons, prioritization, compulsory vaccination, dignity

### **Introduction**

When the Covid-19 vaccines were developed, approved, and then available for distribution in early 2021, each national and regional medical agency had undergone the difficult task of establishing priority regimens for administering still scarce vaccines. These strategies implemented decisions to prioritize groups of people who were particularly at risk from Covid-19 illness, who were in close contact with people at risk such as medical-health professionals and nursing-home care providers, and groups performing systems-relevant activities such as firefighters, police, and public service employees. For example, the US's National Academies published their recommendations after careful ethics review in a book-length work in October 2020 (NASEM 2020). Germany's recommendations outlining the ethical and legal principles for prioritization were likewise generated with the cooperation of the German Ethics Council, STIKO (Ständige Impfkommission), and the Robert Koch Institute in November 2020. Though the early indications of successful vaccine candidates were greeted with hope and relief, it was also evident that vaccines would remain a scarce resource. Nations engaged in competitive actions to secure vaccines with pre-orders from pharmaceutical companies that created clear beneficiaries and unfortunately disadvantaged regions. The EU, acting as a negotiating bloc for member nations, was relatively disadvantaged compared to the USA, Israel, and the United Kingdom. This is remarkable given that one of the vaccines (Pfizer-BioNTech's Comirnaty) was even developed and produced in Germany. In many developed countries there is now more vaccine than is needed, while less economically developed countries continue to experience vaccine scarcity.

Section one briefly describes integrative medical-ethics – an approach that additionally integrates aspects of health economic incentive logic. Section two explores the question of whether the actual distribution and the prioritization preferred in most countries is consistent

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with ethical standards and principles, and whether we should strive for different prioritization for future pandemics. Section three explores the question of compulsory vaccination – mandates – to promote community immunity to Covid-19 disease. How far should state paternalism go? To what extent can the individual's right to self-determination be restricted to limit dangers to the life and health of others?

### **Ethics approach: Integrative medical ethics (IME)**

Our ethics approach begins with the fundamental claims of the Universal Declaration of Human Rights (UDHR, 1948) as well as the traditions of ethics reasoning rooted in that consensus framework document. The integrative ethics approach (IME) thus respects the individual, the unique dignity of each patient, and their basic human rights. With a goal of integrating leading ethics approaches where they are presenting consensus recommendations, IME includes the well-established four principles of Beauchamp and Childress (2019): autonomy, non-maleficence, beneficence, and justice as fairness (Rawls, 1999; Daniels, 2008). Likewise deserving of attention and respect are the three fundamental values of Emanuel et al. (2020a, p. 1309): “benefiting people and limiting harm, prioritizing the disadvantaged, and equal moral concern”. IME also integrates efficiency and other practical insights from the business-ethics approach “ordo-responsibility”, which focuses on rule-finding processes that are fair, implementable, and optimally efficient in terms of limiting transactional burdens of regulatory systems (Pies, 2016; Knoepffler & O'Malley, 2016; Ranisch et al., 2020). Here, we can also refer to health economics approaches that highlight aspects of incentive schemes and individual responsibility and accountability to promote self-protection activities (Hall, 2011). Hence, incentives schemes are often combined with specific forms of regulation intended to reduce negative externalities due to the spread of infections (Laxminaryan & Malani, 2011). Like public health considerations, this article considers both single-actor and group decision-making processes of incentives and impacts to develop implementable rules that respect organizational structures and are consistent with long-range social goals of public health, well-being, and ethics goals.

### **Fair and implementable prioritization of vaccines**

Community disease outbreaks categorized as pandemics pose a world-wide existential risk that is grave evidence of both international human interdependence as well as the importance of international solidarity to adequately deal with such risk. Accordingly, the WHO (2021) uses a guiding principle that “No one is safe until everyone is safe” in its ethical framework. Unreserved national prioritization is thus not only ethically objectionable, but also practically unsupportable, especially when many countries are dealing with woeful shortages of basic medical infrastructure as well as intensive care beds and ventilators. The WHO (2020a) stresses the principle of “global equity” to “ensure that vaccine allocation considers the special epidemic risks and needs of all countries; particularly low-and middle-income countries.” This principle corresponds to the justice concept advocated by IME that considers equity principles together with teleological goals of achievable social improvement (Knoepffler, 2021, p. 77).

This approach is also close in many respects to the influential “Fair Priority Model” (FPM) outlined in Emanuel et al. (2020a) in the journal *Science* in September 2020.<sup>4</sup> When discussing fairness in medical prioritization, harm is understood in terms of reversibility, gravity, and potential for compensation. Three values are particularly relevant:

1. benefiting people and limiting harm,
2. prioritizing the disadvantaged, and
3. maintaining equity, thus, equal moral concern.

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<sup>4</sup> The following paragraphs include sections from Knoepffler (2021, pp. 300–303).

A person's death represents the greatest damage because it is at the same time irreversible and the deceased person cannot be compensated. Harms incurred from a recovered illness are often significant and difficult to compensate. And there are ancillary harms that include diminished education progress, economic damage, and lost opportunity costs.

For these reasons, Emanuel et al. (2020a) proposes the following measures of prioritization while avoiding problematic rationing logics. The IME approach more prominently emphasizes dignitarian ethics reasoning, but there is much overlap between the FPM and the IME. Especially important is the understanding of justice as fairness and the commitment to prioritization rather than rationing for life-threatening diseases. This raises questions regarding terminology.

Rationalization is the judicious and ethically obligated form of discerning the most efficient and effective medical management in a context of scarcity (cf. Knoepffler & Daumann, 2018, p. 107). Rationalization can be understood as a reasonable and therefore compelling approach that saves valuable resources in a scarcity context while providing basic and needed services and therapies according to evidence-based principles.

"Rationing is used, in contrast to rationalization, to describe medical decision-making reasoning in a scarcity context that limits services or therapies despite well-established medical need or evidence-based benefits, even though in principle, all persons have a right to that service or therapy" (Knoepffler, Zerth & O'Malley, 2019).

Prioritization, in distinction to rationing, describes "the systematically justified establishment of rankings - in healthcare, the drawing up of ranking lists, or league tables, of medical interventions" (Deutscher Ethikrat, 2011, p. 22). Prioritization indicates that certain treatment regimens are preferred to other treatment regimens. Here, a treatment regime is not rationed, i.e. only allocated to some, although others would also have the same entitlement, but the prioritization treats all comparably affected persons equally. This means that the treatment measures are the same for all "same" cases. In principle, Emanuel et al. (2020a), as well as the WHO and the German Ethics Council, are using this concept of prioritization with its embedded transnational perspective.

The FPM presents three phases for implementation where national priorities are legitimate to the degree that community infections can be prohibited from increasing. National partiality is ethically justified in situations of continuing disease acceleration. But once the domestic rate of transmission ( $R_t$  value) falls below 1, that means that a nation's infection levels are decreasing, national partiality is no longer justifiable, and fairness priority conditions (FPM) apply. The first phase indicates participating in an international distribution program giving priority to vaccinate persons who still have many years of life ahead of them. In this first phase, poorer countries with a high proportion of young people benefit. To provide a stable and transparent method of adjudicating priority, the FPM uses a matrix of "Standard Expected Years of Life Lost (SEYLL)," i.e., a reasonable expectation of expected years lost by infection. This distributive justice analysis is first relevant for distributing vaccines on the national levels and is not a matter of choosing which specific persons either receive or are denied vaccines. This distributive system provides policymakers with an equity-based decision-making logic to optimally protect against death and the harms caused by disease. Individual nations would have the responsibility to distribute vaccines to individuals using evidence-based analysis.

Phase one aims to reduce premature deaths using the SEYLL metric, which indicates that all other variables being equal, younger persons with more expected years to live have priority over older persons. This preference of the young over the old is justified with an argument that all persons, including the elderly, are considered equally and consistent with their human dignity. "It integrates the aims of limiting harm and of prioritizing the least advantaged... using a standard metric used in global burden-of-disease calculations" (Emanuel et al., 2020). Vaccine priorities do not deny persons their dignity, but rather gives priority to those in times

of scarcity who are most likely to have the greatest benefit on an individual level. And on a national level, it gives priority to most disadvantaged nations.

In the second distribution phase, vaccine prioritization considers economic and social deprivations as well as mortality. So, in addition to minimizing SEYLL, issues of poverty are included into the distribution logic. Only in the third phase is the aim of ending community spread of disease infection. The following distribution prioritization would then result:

Phase & Aim	Relevant Metric	Values	Prioritization
Phase 1: Reduction of premature deaths	SEYLL	Prevent harm; human life value; equity	Countries with highest potential SEYLL
Phase 2: Reduction of ancillary harms	Reduction of SEYLL, poverty, national economic well-being	Social Equity	Countries most poverty-impacted
Phase 3: Return to health	Ranking transmission rates	Prevent harm, dealing with worst-impacted	Countries with highest transmission rates

*Fair Priority Model (FPM) Table, derived from Emanuel et al., 2020a*

But who are the worst off when it comes to Covid-19? A look at the prioritization criteria as recommended by STIKO, German Ethics Council, & Leopoldina helps here:

- “Prevention of severe courses of Covid-19 (hospitalization) and deaths.
- Protection of persons with an especially high work-related risk of exposure to SARS-CoV-2 (occupational indication).
- Prevention of transmission and protection in environments with a high proportion of vulnerable individuals and in those with a high outbreak potential” (German Ethics Council & Leopoldina, 2020, p. 3).

FPM presents transnational responsibilities exclusively within a distributive justice frame, such that an available scarce resource (vaccine doses) ought to be divided among nations. In contrast, the IME concept of fairness integrates incentive considerations at the resource generation stage as well as distribution stage. Individual states have a responsibility to provide vaccines for their citizens, obviously. Emanuel et al. (2020a) argues that richer states should show extensive solidarity with poorer states by sending them a greater portion of scarce vaccines. These poorer nations are burdened by not only health impacts, but also by ancillary economic, social, and political harms. Richer countries, by contrast, have capacities to use alternative infection-avoiding measures. Both the FPM and IME regret that vaccination distribution in 2021 reflects marginal transnational solidarity. And IME would advocate creative national approaches of domestic partiality if that was linked with accelerated benefits for situations of poorer countries. With this “difference principle” logic, richer nations would be incentivized to accelerate vaccine development, production capacities, and patent negotiations in ways that more adequately reflect the global threat posed by not only the Covid 19 pandemic, but also future pandemic risks. Studies by the Rand Institute show how important transnational solidarity would be even if the richer states were acting in self-interest:

“Vaccine nationalism could lead to the unequal allocation of Covid-19 vaccines and cost the global economy up to \$ 1.2 trillion a year in GDP terms. Even if some countries manage to immunize their populations against the virus, if the virus is not under control in all regions of the world, there will continue to be a global economic cost associated with Covid-19. If the poorest countries cannot access vaccines the world would still lose about \$ 153 billion a year of GDP. The EU would lose about \$ 40 billion a year; the US could lose \$ 16 billion; and the UK between \$ 2 billion and \$ 10 billion” (Rand.org, 2020).

There is also another challenge: Although enough vaccine is available in some countries such as the USA or Germany, many people refuse to be vaccinated. Against this background,

what measures are ethically necessary to ensure that as many people as possible can be vaccinated? Should there be compulsory vaccination?

### **Compulsory vaccination**

The dispute as to whether there should be compulsory vaccination is not new. There was resistance already in 1807 when Bavaria promulgated its mandate for compulsory vaccination against smallpox. And it was not until 160 years later, in 1967, that international consensus backed the WHO's global program of vaccination to effectively eliminate smallpox disease. Wehrle (1980) notes the enormity and complexity of this effort, which required "administrative leadership and imaginative approaches" to stay a course based upon sound epidemiological principles. These international efforts were suspended in 1976 when smallpox no longer posed a threat.

There are important differences between the smallpox and Covid 19 pandemics – smallpox was more life-threatening and vaccine development is more reliable today – yet historical anti-vaccination arguments bear important similarities with the present situation (Bayerischer Rundfunk, 2021). There were conspiracy theories that cowpox would turn people into cows. There was talk of a "incineration of the blood" (Eckart, 2017, p. 169). Now, conspiracy theories claim that Covid-19 vaccinations would reduce fertility or that, along with this vaccination, people would be implanted with monitoring chips.

Serious concerns about vaccines, then as now, are about associated risks or side effects. Public figures and medical professionals should be able to dispel fears of very-low risks associated with today's vaccines. However, communication about risk is notoriously difficult and public health and government officials struggle to translate scientific analysis in ways that are understandable and convincing (NASEM, 2021). Given the significant number of persons who are not receiving available vaccines, and the enormous health and social costs associated with community infections among non-vaccinated populations, the question arises whether a Covid-19 vaccination should also be made compulsory, analogous to the previously mandatory smallpox vaccination. Only persons with reasonable medical justification would then be exempt from compulsory vaccination.

Economic analysis of opportunity costs offers insights into how we might understand the present public health situation. Opponents of vaccination reject the comparison between smallpox and Covid-19 because smallpox was much more dangerous than Covid-19. The mortality rate for untreated smallpox was roughly 30 percent for all population groups, largely regardless of age. For Covid-19, the mortality rate is closer to one percent, with older people having a much higher risk. Children and adolescents are at very low risk of dying from Covid-19. Opponents of vaccination argue using basic rights claims such as their right to self-determination over their own body – a normative argument. Opposition to vaccination also reflects health economic analysis that, from the perspective of some individual citizens, the risks of the pandemic are basically acceptable.

Economic models analyze individual and social incentives, as well as the impacts of individual and social actions. Vaccination willingness has expected costs on the individual as well as social level (on vaccination propensity, see Laxminarayan & Malani, 2011, p. 191f). The social effects of increasing vaccination coverage are compared with the individual "expense costs" from an ideal-typical, individual point of view. The perception of individual expected costs thus represents a decisive factor as to whether the social costs are underestimated in the expected benefits due to the positive externality of growing community ("herd") protection.

In other words: individuals assess the personal costs of their own vaccination against the expected benefit effects for themselves and for society. If individuals interpret vaccination as a probable personal net-loss in terms of risk costs, they are more likely to be skeptical or reject vaccination. With a view to preventive behavior, Cohen and Mooney use the distinction



between utility in use and utility in anticipation to describe this reality (Cohen & Mooney, 1984). Covid-19 vaccines are seen by people as offering a relatively minor personal preventative benefit, which involves an investment (cost) in time, minor disruptions from vaccination (arm pain, fever-like symptoms), and small risks of side effects. So, while there are practical benefits of vaccinations, people's expectations and priorities are culturally impacted and relevant to vaccination willingness (Zerth, 2014, p. 307f). In short, the expectation of an induced benefit from a prevention or vaccination must be justified by the directly effective assessments of the benefit situation or potential benefit restriction caused by the vaccination. Even if the side effects of vaccinations appear to be largely controlled, this ambiguity of benefit perspectives should not be ignored, at least when it comes to the question of the appropriate regulatory design.

Covid-19 vaccines have demonstrated effectiveness in building community immunity in real-world conditions according to the CDC in the USA, RKI in Germany, and national monitoring agencies worldwide. Analysis of risks associated with the vaccines is limited by the relatively short timeline of their use compared with previous vaccines with many years of safety histories (cf. Olliaro et al., 2021). Nevertheless, there is already sufficient data available to show that, for individuals, in situations of even minimal community infections, Covid-19 infection risks are significantly higher than risks associated with vaccination. The problem is that vaccination opponents overestimate their own personal costs, underestimate their personal risks, and generate social costs of expanding the size and endurance of the pandemic.

In addition to risk analysis, there are normative arguments for avoiding vaccines, often made using rights language and specifically with reference to self-determination. People who refuse vaccination for ideological reasons have an adverse effect on the community immunity that protects particularly vulnerable people, for example persons with compromised immune systems who cannot benefit from vaccines and are particularly impacted by disease. In addition to this harm to social welfare, they take advantage of social benefits in the event of illness. That is, they receive medical treatments and burden health systems without incurring financial cost. In addition, their behavior has knock-on impacts of increasing risk of further infections while diminishing available healthcare opportunities. Widespread infections and associated mitigation efforts impose dramatic social costs through mandated distance learning for young people, psychological harms from lockdowns, and economic disruptions. In terms of environmental and economic policy, one would say that their behavior creates external effects for which they do not accept responsibility. In other words: they exploit the solidarity of society.

This directs attention to the overriding questions of socially acceptable responsibility for individual actions and non-action (refusal to vaccinate) in the light of expected benefits and cost effects for the social level. An "emission model" of vaccination refusal, which can be classified as a phenotypical idea of a responsible behavior in appropriate contexts of actor-related, society-related externalities, challenges the question of the allocation conditions of individual and social responsibility. This discussion brings a clarifying focus to the perspective dilemma of "bonum personal" versus the "bonum commune". Public health policy must respect persons' perspectives, rights, and responsibilities while achieving common good aims.

The IME approach, as integrative, builds upon already well-established social and ethical foundations to not only consider normative principles and action-bounding rules, but also seeks to propose action scenarios and rule frameworks that optimally achieve social goals. Even when viewed from the perspective of personal cost/benefit analysis, an otherwise healthy person who refuses the Covid-19 vaccination violates the duty of care because they are exposing themselves to a dangerous disease. Condemning anti-social action may be warranted, but hardly helpful. So, the question is raised: Should the state introduce a compulsory Covid-19 vaccination analogous to the former smallpox vaccination? Turkmenistan was the first country in the world to implement compulsory vaccination against Covid-19 on July 7, 2021. Many countries' democratic forms of government might not permit following Turkmenistan's example.

Compulsory vaccination interventions in free constitutional states would stir public resistance and complaints of state paternalism – the father state knows better what is good for the individual than they do themselves.

Thus, we must consider efficiency potentials of various levels of government-mandated vaccination programs that might cause social disruption and thereby have marginal effect. It would be a political approach to internalizing external effects, but the approach directly raises questions of normative and political legitimacy: Who is responsible for these partial interventions that impact personal self-determination rights? And who can enforce these interventions? Some states have already made such an obligation for certain professional groups. For example, in February 2021, the Vatican State made vaccination compulsory for its 5000 employees by decree. Anyone not complying must expect employment termination. France announced similar measures for healthcare workers and public protests already show how difficult this measure is to implement.

A different approach avoids widespread government mandates, but carves out legal protection for schools, organizations, and enterprises to implement vaccine requirements in specific contexts that can respond to local needs. The practical logic of this approach is to allow individuals the freedom to either choose or refuse the vaccine, but to recognize, first, the need for safe community space and, second, the legitimacy of providing and enforcing conditions insuring that safe space. In principle, this is no different from the licensing authority exercised to insure safe automobile traffic on public roads. Persad and Emanuel argue that licenses “should be compared to the alternatives of enforcing strict public health restrictions for many months or permitting activities that could spread infection, both of which exacerbate inequalities and impose serious burdens” (Persad & Emanuel, 2020, p. 2241). Non-vaccinated persons pose a risk to others, and while prudence would council against the imposition of mandates, persons posing a risk to public health would have the burden to show that they are not presently Covid-19 infected.

Quite a few countries have introduced restriction rules that require certification of 1) vaccination; 2) Covid-19 recovery; or 3) a recent negative result from a Covid-19 infection test. In Germany, these “3G rules” are used by enterprises to insure safe public and workplace spaces. Some states are adopting stricter 2G rules requiring vaccination or timely tests. With such rules, reliable documentation of “risk-free status” gains importance for local and wider mobility. Vaccination “passports” make it possible for vaccinated persons to participate in life activities (school, work, leisure) among other persons who pose no elevated risk. The social perspective has priority over the individual perspective for determining rules regarding licensing to operate motor vehicles and wearing seatbelts. Individuals are not left to their own judgment regarding their risk status in public spaces. Likewise, the social perspective has priority for determining risk status of non-vaccinated persons. For such persons to enjoy unrestricted access to public spaces, they must demonstrate their non-risk status using publicly certified documentation. The financial and time costs for attaining documentation, through testing or whatever, could potentially be a burden that incentivizes pro-social outcomes (see Cassel & Ulrich, 2021, p. 5).

Another alternative is to give incentives for vaccination that are perhaps non-obvious. This form of softer paternalism is also referred to as “nudging” in behavioral economics (Thaler & Sunstein, 2011). For example, the former president of the Bayern Munich soccer club, Uli Hoeneß, invited people to an event where sausages were free of charge and there was also the option of vaccination. The possibility of boosting vaccination readiness through direct financial incentives may also be considered. Such experimentation is best left to local decision makers to exercise their prudence based upon specific cultural and community-infection conditions.

## Conclusion

The IME approach attempts to integrate leading ethics schools of thought in a way that respects legitimate worldview, philosophical, and religious differences, and which realizes that public health policies are most effective in meeting their goals when they conform to normative principles that demonstrably prioritize human dignity and enjoy public consensus. We argue against a wide-population compulsory vaccination and support prudential measures to 1) protect vulnerable groups; 2) focus upon incentivizing vaccine participation; 3) maintain maximum-possible individual freedoms; and 4) allow local contexts of schools, organizations, and enterprises to implement vaccine requirements in ways that are optimally designed for those contexts. While there is consensus regarding the potential normative support for mandated vaccination, the paternalistic government intervention of vaccine mandates requires a high bar of demonstrated vaccine safety, public health risk, and potential social acceptance.

Public health policies should be made at the most-local social level to be most fitting and effective for specific regional public health risks. This is a simple principle of practical reasoning or prudence. The present ethics analysis supports local decision makers by making it clear that it is ethically acceptable, in situations where vaccines are generally available and proven to be safe, to require non-vaccinated persons to not pose an avoidable risk to public health. It is ethically acceptable to require non-vaccinated persons to demonstrate that they are safe (not Covid-19 positive) in some minimally intrusive but reliable certification. And there is no moral reason – though there may be practical ones – for vaccinated persons to bear burdens created by other persons' non-compliance with public health recommendations. It is fair to frame individual cost-benefit incentives so that the benefit of getting vaccinated will be subjectively assessed higher than the assumed personal costs and disutilities. From a moral-philosophical point of view, the “realism” of incentive discussions is perhaps disappointing in presuming persons acting for selfish motives. The IME approach respects individual persons as moral subjects and bearers of human dignity, and the approach also respects the realities of subjective self-interest behavior within complex societies. The integrative approach does not treat persons as only homo economicus, but it respects the insights that such an approach brings to the public health rules we need to achieve reasonable goals of social flourishing.

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## Triage of the elderly in the period of the COVID-19 pandemic crisis as a bioethical process

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### Abstract

The paper discusses the problem of triaging the elderly in the period of the COVID-19 pandemic crisis by analyzing the triage process, caused by lack of resources, in Germany, Holland, the Czech Republic, and Slovakia. We apply inductive, deductive, and normative bioethical methods, comment on various recommendations for the indication of intensive care during a crisis, and discuss the utilitarianism of benefit maximization. As it follows from the evaluation of the elderly by the frailty parameter, medically inappropriate treatment, as a result of limited resources, is characterized by clinical and bioethical uncertainty. If the main bioethical objective of general bioethics for the COVID-19 pandemic is, in the case of limited resources, based on the non-utilitarian consequentialism paradigm, from the perspective of medical ethics, we face a borderline situation closely related to the topic of dying and death. Such a situation requires social, ethical, and professional reflection. An algorithm for intensive care indication in the situation of crisis and limited resources in the period of the pandemic requires a definition of criteria that identify an acceptable reason for abandoning the treatment in the context of the autonomy of the elderly and by respecting their human dignity and humanity. A global objective of general bioethics in the situation of the pandemic crisis should be based on the paradigm of social justice.

**Keywords:** bioethics, COVID-19, elderly, utilitarianism, frailty, medically inappropriate treatment

### Introduction

The World Health Organization classified COVID-19 caused by SARS-CoV-2 as a pandemic on 11<sup>th</sup> March 2020. The pandemic caused by the new-discovered SARS-CoV-2 coronavirus brings about professional and ethical dilemmas concerning limited medical resources all over the world. In crises, such as pandemic situations, the decision-making processes significantly change if health care resources are insufficient. National and international medical and bioethical institutions worked out recommendations for addressing the problem of insufficient resources for acute health care. Triage in crises concerns the selection of patients for medical treatment, which means that those who are not selected do not have to be provided with any useful treatment. Triage decisions in a crisis are usually based on the specification of medical urgency priorities, the ability to utilize available resources, evaluation of short-term vs. long-term prognoses, including the role of age and comorbidities as potential triage criteria. Consistent and fair decisions depend on the definition of clear and transparent criteria for maximizing the benefits in triage situations.

### Bioethics and the pandemic

The bioethical perspective of health care during a pandemic crisis requires an analysis of changes in medical ethics that are conditioned by the pandemic situation in a crisis due to the lack of scarce resources. If the fundamental change in the philosophical paradigm in the pandemic period stems from the requirement of maximum benefits in providing intensive health care, we are dealing with a utilitarian requirement. This is specified in relevant ethical considerations and recommendations of professional institutions. Utilitarianism refers to several possible interpretations related to the problem of dying and death. Philosophy seeks

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a solution for the main principle of benefit maximization in the non-utilitarian ethics of social consequences that also reflects the medicine of disasters (Gluchman, 2016). The population of the elderly (from the point of view of the age and frailty as well as potential incompetence and absence of information for various bio-psycho-social reasons) is an extremely endangered group whose autonomy, respect for human dignity and a human approach must also be observed in the pandemic period.

Bioethical principlism is completed and partially replaced with new, dominant ‘crisis principles’. Specific situations in which the patient’s autonomy is relevant must be well defined. The situation of a crisis or disaster cannot relativize the patient’s autonomy. We point out the internal dimension of autonomy. The significance of human dignity in the form of respect for a patient is highlighted in crisis situations. From the consequentialist perspective, equal treatment of patients may hamper the best possible results; from the deontological perspective, the maximization of benefits may result in discrimination or violation of a person’s rights. The basic ethical problem is how to combine both perspectives and respect a person’s rights. A consequent utilitarian approach based on the maximization of saved years of life is not convincing. It is important to save the greatest number of lives possible without violation of patients’ rights.

### **Medically inappropriate treatment in the pandemic period**

The basic communication tools that bridge professional and ethical pandemic dimensions are the content of professional terminology. This section deals with the notion of ‘medically inappropriate treatment’ because an expert-ethical analysis demonstrates the impossibility to preserve the patient’s autonomy in the case of a medical decision of medically inappropriate treatment. The paper demonstrates that autonomy cannot be relativized, its extent must be precisely applied to concrete clinical situations also in the case of reduced reasons for the patient’s autonomy in the period of disaster. European recommendations for health care triage in the COVID-19 pandemic situation for which there is no medical indication substantially vary in terms of the terminology used. Austrian and German recommendations employ the term ‘medical indication’, Italian recommendations use ‘clinical appropriateness’ and ‘proportionality’, and Belgian authors use the term ‘inadequate care’ meant for “patients with unfavourable long-term expectations.” According to Swiss recommendations, a doctor must first determine the necessity of intensive care which can be interpreted as a synonym to medical indication (Ehni, Wiesing & Ranisch, 2020).

In the period of a pandemic, in connection with lack of medical resources in the absence of health care, the indication of medically inappropriate treatment prevails, in the case of classification decisions in a situation of lack of resources, the prioritization criteria depend mainly on value systems. These are borderline processes (Šustek & Černý, 2021).

Futile treatment from the point of view of a patient’s benefit does not lead to saving a life, preserving health, or maintaining the quality of life. From an ethical point of view, medicine is not expected to provide futile treatment (Kuře, 2020). Futile treatment can be evaluated in terms of quantitative, qualitative, and physiological futility. Quantitative futility expresses the measure of the probability of a positive change in a patient’s condition as a result of treatment. The quantitative futility method does not authorize a doctor to decide on the success/failure probability degree that is meaningful/meaningless for the patient. Any effort to do so would contradict the patient’s autonomy. Qualitative futility is a treatment that does not meet its objectives or is incompatible with them and does not improve the patient’s quality of life. In qualitative futility, a doctor cannot estimate the degree of fulfillment of the patient’s objectives that still make sense for the patient. Physiological futility refers to the patient’s situation in which the condition of the physiological systems cannot be reversed by any available medical intervention. Unlike the former two futile treatments, physiologically futile treatment may be

exclusively determined by a doctor because he was trained to assess whether a proposed treatment may achieve physiological objectives. Compared to the ethical-expert assessment of treatment futility which also includes the patient's preferences, medically inappropriate treatment is assessed by a doctor owing to their relevant education. If a doctor evaluates the medical appropriateness, its adequacy refers to the disease, its extent, and/or symptoms; it does not refer to the therapeutical objective (Novotný, Novotná & Andraščíková, 2020).

The medical appropriateness for universal patient triage (not only the COVID-19 pandemic), should be determined as follows:

1. quantitative medical appropriateness should be considered on the basis of an organ system failure despite adequate treatment of the associated serious palliative diseases, or in the case of terminal condition.
2. qualitative medical appropriateness should be considered based on the clinical condition progression and worsened syndromology, which affects the quality of life (geriatric patient based on geriatric deterioration).
3. Physiological medical appropriateness should be considered based on the frailty index if the condition of the patient's physiological systems in the terminal stage of frailty cannot be reversed by any available medical intervention.

The proposed understanding of the concept of 'medically inappropriate treatment' excludes the patients' preferences and their quality of life from the criteria that are generally used as futile treatment criteria. If, in an acute condition, a doctor assesses the chronically ill patient's condition primarily based on the possibility of medical intervention without assessing the overall patient's condition (by reflecting the disease stage, disease extent, the severity of clinical symptoms) medically inappropriate treatment as a reason for discontinuation of treatment cannot be accepted. It may be assumed that triage scoring systems are more consistent compared to clinical judgments for the doctor's decision-making. The severity of acute disease should be determined by a combination of clinical and laboratory findings and by means of scoring indexes (Feinstein et al., 2020).

Two main principles underlie the normative basis for patient triage recommendations: fairness and benefit maximization. The fairness principle means that all patients with a comparable prognosis should be provided equal access to the necessary medical care in the period of crisis on the basis of medical and ethical criteria to be specified in advance. The benefit maximization principle in the condition of shortage may refer to various situations: saving as many people as possible, saving as many years of life as possible, saving as many years of life as possible in terms of the quality of life (QALY – Quality-AdjustedLife-Years). Resource allocation heavily depends on the criterion applied. The principle of the maximum number of years of life considers comorbidities, makes use of validated prognostic models, for example, frailty score and the comorbidity index modifications proposed by Charlson. Young people would benefit from saving as many years of life as possible; on the other hand, people capable of living a long, healthy, and independent life would benefit from the QALY maximization. The principle of maximization of the number of lives makes use of 'acute' indexes, primarily the SOFA index (Sequential Organ Failure Assessment). The evaluation of the possibility that a patient leaves a hospital alive takes into consideration the course of the COVID-19 disease as well as accompanying potentially adverse prognostic factors (White et al., 2009; White & Lo, 2020).

Age is a controversial factor in triage models. The question is whether elderly patients are unfairly disadvantaged. One of the arguments is that age is also used in frailty indexes. The concept of frailty is, however, related to biological age. It does not correlate with chronological age. Earlier research has proved that the clinical frailty score and chronological age are independent entities. High chronological age is in itself an independent predictor of a bad result



of intensive care for both COVID-19 patients and non-COVID-19 patients (White et al., 2009; White & Lo, 2020).

An ethical analysis of international recommendations for COVID-19 triage suggests that all documents agree on the fact that the age itself is not sufficient as a criterion for deciding on triage. The age must correlate with comorbidities and a prognosis. Most of the documents mention long-term prognoses as a decision-making criterion for triage. Inherent age and comorbidity are considered crucial factors. The frailty scale and the degree of comorbidities in elderly people are recommended as a tool for the determination of a prognosis by various national recommendations. The inclusion of comorbidities (through the frailty index) is not only more advantageous for younger patients compared to elderly patients but also for people without health problems compared to people suffering from health problems. Consequently, there is an unambiguous tension between the maximization of benefits and the focus on non-discrimination of those groups that are characterized by frailer health. This should be evaluated as a situation of bioethical uncertainty.

Fairness and maximization of benefits should be the core triage principles. The principle of fairness: non-discrimination by age, race, health problems, sexual orientation, religion, insurance, wealth, social status; adequate attention should be paid to vulnerable groups (the elderly, minorities, handicapped people).

The principle of maximization of benefits: We need an unambiguous definition of the maximization of benefits in various stages of deficiency. It is important to distinguish between first-order criteria (e.g., short-term survival) and second-order criteria (e.g., long-term survival). Recommendations concentrate on the maximization of benefits from “saved lives” or “saved years of life.” The quality of the saved years of life is not explicitly mentioned. Most of the recommendations specify parameters for short-term and long-term prognoses (Germany, UK, USA). All recommendation documents comprise health criteria for triage decisions. We need a comprehensive evaluation of short-term and/or long-term survival by medical criteria, tests, and validated prediction scoring systems. Various scores are recommended for the evaluation of death risk and estimation of survival probability of the acute condition. Some of the recommendations employ the SOFA score (Germany), others reject it because it was not validated for the SARS-CoV-2 pandemic (USA).

Principle of equality: Professional-ethical considerations of triage comprise all patients, both current and new ones, and both COVID-19 patients and all non-COVID-19 patients.

The principle of transparent decision-making, explicitly specified in the majority of recommendations, enables patients and their relatives to understand the process of clinical decision-making. Transparency is defined as providing information for public access. No recommendation proposes the specification of priorities based on merits or social status (Jöbges et al., 2020).

### **German recommendations for triage in the period of a pandemic crisis**

German decisions of intensive care resource allocation in connection with the COVID-19 pandemic are clinical and ethical recommendations. They were elaborated by a multidisciplinary group of authors supported by eight scientific medical societies. The recommendations were proposed by experts from clinical urgent medicine, intensive medicine, medical ethics, law, and other areas of science. The recommendations stress that medical decisions must always reflect the needs of a concrete patient. In addition to this patient-oriented approach, the determination of priorities in the situation of resource deficiency presupposes a super-individual perspective. Decisions of the allocation of limited resources must be taken analogically to triage decisions in the medicine of disasters. The specification of priorities does not explicitly pursue the objective of assessing the value of people or human lives. The specification of priorities should rather enable the maximum possible number of patients to

make use of (limited) medical resources in the conditions of a pandemic crisis. The determination of priorities regarding patients should therefore stem from the criterion of clinical chances for success. Patients with better chances to survive after intensive care should be prioritized (indexes SOFA, APACHE II – Acute Physiology and Chronic Health Evaluation II, CRB-65 – Score for Pneumonia Severity, ECOG – Eastern Cooperative Oncology Group, Performance Status). The principle of equality does not permit any priorities derived from calendar age, social characteristics, specific diseases, or handicaps. The specified diseases and conditions (seriousness of the main disease or injury and the stage of serious comorbidities that reduce the probability of surviving intensive treatment, overall health condition before the present disease, for example, according to the clinical frailty scale as a part of geriatric evaluation) are not exclusion criteria – in contrast to other triage protocols.

Overall evaluation should take into consideration all important factors that affect the chances for success (present disease, comorbidities, general health condition). Former diseases are relevant only if they influence the probability of survival concerning the present disease (Marckmann et al., 2020).

### **Dutch recommendations for triage in the period of a pandemic crisis**

As the first step towards a stricter triage protocol, the Dutch Intensive Care Society (Nederlandse Vereniging voor Intensive Care – NVIC) formulated various levels of medical criteria strictness for patients considered for intensive care (NVIC, 2020). The exclusion criteria were formulated in accordance with the CHEST consensus declaration (Christian et al., 2014) based on a low probability of survival and short life expectancy. The Dutch ethical recommendations for the COVID-19 intensive care protocol emphasize an early interaction between clinical and ethical expertise. Tailor-made ethical recommendations can and must be employed at the time of a crisis.

Every human being has an equal moral value. A justified triage objective at intensive care units is saving the greatest possible number of lives. Triage based on mental and physical disorders or indexes of the former life quality was rejected because every human being has the same moral value, and every life is worth saving. Medical criteria, such as the clinical frailty score (De Geer, Fredrikson & Tibblin, 2020), were used as a factor for the determination of the probability of survival in former triage steps, which means that there are no additional reasons for their use in deciding on scarce resource allocation. Age as a priority criterion is relevant for patients whose condition is worst. If it is not possible to save all lives, the position of young people is relatively worse than that of people who have been living their life longer (fair change). Age as such should not be a criterion. What matters is a sufficiently large difference between patients belonging to different intergeneration categories. This is best captured by the term ‘generations’ that can be used to refer to intergeneration solidarity. Many elderly Dutch citizens stated during the first weeks of the pandemic that they were ready to give up their claim to an ICU (Intensive Care Unit) bed if it could save the life of a younger person. Consultations with various groups of patients and elderly citizens showed that the ‘generation’ argument was positively accepted and considered as justified. Age is a relevant criterion in terms of intergeneration solidarity. Based on their age, people are classified as members of a generation. Younger generations have a higher priority than the older generations. Generations are defined as the following age groups: 0–20, 21–40, 41–60, 61–80, and 81+. Holland reached a social agreement on the fundamental idea of a fair change, which means that younger people are more authorized to life-saving intervention. The conception of a fair change cannot be considered as discrimination of elderly people.

Dutch bioethicists contributed to the rejection of the idea of using age (e.g., > 80 years or even > 70 years) as a criterion for absolute exclusion in triage. As a result, the score of clinical

frailty is not used for elderly people because it might lead to unfair discrimination of a person with former mental or physical disorders (Verweij et al., 2020).

### **Czech views and instructions for triage in the period of a pandemic crisis**

The Czech recommendations *Ethical and legal principles for making decisions on scarce resource allocation in providing health care during the COVID-19 pandemic* is based on, among others, the following tenets: Reference to the philosophy of utilitarianism; maximization of benefits by the number of saved lives; the principle of respect for autonomy is backgrounded at the period of crisis; ethics permits the making of decisions on the basis of age and to prioritize younger patients (death would be worse for them than for older patients); it is not age-based discrimination; age is not a triage criterion – it is a variable that determines the degree of evil caused by death (Černý, Doležal & Doležal, 2020).

Jedličková (2020) maintains that the above-mentioned document by Černý, Doležal & Doležal (2020) specifies four principles of scarce resource allocation. They are identical to the ethical aspects of decision-making included in the recommendations published by the World Health Organization (WHO, 2020). The document states that prioritization should be targeted at those at greatest risk of becoming infected and seriously ill who, however, have a real chance to survive or those who, in the case of death, would live a short life (young patients). She points out that the WHO recommendations do not mention priority-setting by age (Prioritize the worst off). On the contrary, the WHO documents unambiguously stress that since this pandemic most seriously affects elderly patients, the priority-setting in scarce resource allocation might lead to an inappropriate application of triage instructions based on age limits thus excluding elderly patients from treatment (WHO, 2020). The author concludes that the four proposed principles of scarce resource allocation should neither replace the four basic ethical principles of medical practice nor modify them. Some practical aspects could, if necessary, complement them in strict compliance with all legislation.

The Standpoint of the committee of the *Czech Society of Anaesthesiology and Intensive Care Medicine ČLS JEP (ČSARIM and ČSIM)* (ČSARIM, 2020) labeled as *Decision-making on intensive care patients in the situation of the lack of scarce resources* mentions bioethical principlism, individualizes the beneficence principle, selects the autonomy principle, and emphasizes the human dignity of patients. Any discrimination (disability, age, etc.) is unacceptable. The Standpoint identifies basic ethical principles of scarce resource allocation in crisis situations (fairness, maximum benefit, prioritization); the life expectancy criterion, in its view, contradicts the legal system of the Czech Republic. The benefit maximization is assessed on the basis of maximum medical benefit for the greatest number of patients possible. The decision of admitting a patient to an Intensive Care Unit (ICU) should be based on the principles specified in the Standpoint of the ČSARIM and ČSIM committee dated 2015. The reasons for non-admission to intensive care or the termination of intensive care should result from a comprehensive evaluation of the overall clinical context. An expert view cannot be replaced in this case with any scoring system or numerical parameter. Treatment can be terminated without comparison to any other patient if an expert assessment finds it the medically inappropriate (ČSARIM, 2015).

In the Czech Republic, the expert, (bio)ethical, and legal views of health care during the COVID-19 pandemic differ in terms of scarce resource allocation. No consensual recommendations of triage have been approved. Comments emphasize the legal and ethical uncertainty of doctors in this situation, this being an important aspect that is not accentuated in the recommendations of other countries (Šustek & Černý, 2021).

### **Slovak recommendations for triage in the period of a pandemic crisis**

Slovak recommendations were published as *Expert guidance of the Ministry of Health for intensive care indication in a crisis due to the COVID-19 pandemic* in March 2021. It was published in the periodical of the Ministry of Health (Ministry of Health of the Slovak Republic, 2020). The text is divided into paragraphs. Paragraph II specifies medical, ethical, and legal principles. It refers to the tables (Table 1: Terminological dictionary, Table 2: Principles of medical triage decision-making, Table 3: Ethical triage principles) that provide general medical and ethical principles. Paragraph IV specifies the triage procedure. The triage process should be preceded by an assessment of a patient's condition in terms of an intensive care indication. Table 4 specifies the intensive care indication. Diagram 1 is an aid for decisions on triage for intensive care indication. Table I concerns comorbidity, Table II frailty, and Table III provides the total score compiled from Tables I and II. The total score equal to or exceeding 8 indicates acute care (ICU or Anesthesiology and Intensive Care Unit); the total score of 9 and more indicates conservative care; the total score equal to or higher than 11 indicates palliative care. For illustration, Table II Frailty (defined as "a description preceding an acute condition") assigns 9 points to terminal patients approaching the end of life, which means, they are not expected to stay alive for more than six months even if they are not evidently frail.

The Terminological dictionary of the expert guidance (Table 1) defines the term 'unyielding treatment' (synonymous with futile, inadequate, medically non-indicated treatment). It should be noted that the term 'futile treatment' lacks a corresponding expert-ethical context in the case of a limited capacity for intensive care indications, and therefore, the term 'medically inappropriate treatment' is used for triage.

Medically inappropriate treatment concerns not only the decision on what will not be provided but also on what will be provided. Consequently, the governing decision-making principle is the objective of health care. A selected means is medically appropriate if the normative criterion for a change in the doctor's procedure is in harmony with the objectives of health care (teleologically, its harmony with the specified purpose) (Černý, Doležal & Doležal, 2020).

### **Tasks and objectives of a bioethical process and triage in the period of a pandemic crisis**

Contemporary bioethics is dominated by utilitarian theories stemming from the tradition of the British empiricism of Jeremy Bentham, John Stuart Mill, and Henry Sidgwick. The representatives of this theory maintain that evaluation of moral acceptability of a particular activity must take into consideration the options available at the time of selection and assess the consequences of all possible acts. The general form of utilitarianism consists of two components: on the one hand, it is consequentialism (the correctness of activity is exclusively assessed by its consequences); on the other hand, consequentialism is completed with the criterion of rightness: the rightness of the consequences of our acts is determined by their utility (hedonism) or fulfillment or failure to fulfil our desires. Consequentialism excludes more traditional normative factors, such as the intention of the actor. Consequentialists do not usually speak of human rights. In their view, the notion of dignity and the related respect for a human being does not provide clear criteria for drawing normative conclusions (Černý, 2018).

The ethical theory of preferential utilitarianism represented by the Australian philosopher Peter Singer seeks the criterion of rightness in maximization of preferences defined broadly to also cover the preferences of persons who are not gifted with the ability of higher cognitive functions. Singer distinguishes two meanings of the term 'human being': it can refer to a member of the biological species *Homo sapiens*; it can mean a being who is defined functionally rather than ontologically (i.e., what the being is). Singer assumes that there is no inherent moral difference between killing and allowing to die. Singer believes that active euthanasia is the only truly moral option (Černý, 2012).

We understand theoretical bioethical modeling as a comprehensive process that combines methods of general bioethics and an expert process of clinical bioethics. For a crisis/disaster situation, we prefer, from the perspective of general bioethics, the non-utilitarian model; medical ethics employs the ethics of uncertainty, situational, and nursing ethics. The main triage principles comprise maximization of benefits, justice, and autonomy, followed by equality and transparency. The main values are human dignity, multi-culture, and saved lives. Clinical bioethics employs an expert-ethical triage method. The global bioethical objective of general bioethics in the period of a pandemic crisis should be based on the paradigm of social solidarity and justice (fair change).

### **Bioethical comparison of the differences in the approach to intensive care indication in the situation of crisis and limited capacities in Germany, Holland, Czech Republic, and Slovakia (Conclusions)**

A) The objective of the German recommendations is not to assess the value of human life. Priority-setting should enable the greatest possible number of patients to use (limited) medical resources. Saving human lives is specified in the Dutch and Czech bioethical documents. Slovak guidelines define utility in general terms, on the basis of health criteria. The number of saved lives, years of life, and years of good quality life are mentioned as options.

B) Respect for human beings is mentioned in the German, Dutch, and Slovak recommendations. While the notion of human dignity is emphasized in the Czech Standpoint of the ČSARIM (2020), it is absent in the recommendations of Czech bioethicists (Černý, Doležal & Doležal, 2020).

C) Age as a criterion for denying intensive care is absent in the German and Slovak documents. It is proposed by Czech bioethicists (Černý, Doležal & Doležal, 2020), not by Standpoint of the ČSARIM (2020). The Dutch recommendations talk in this regard about the principle of intergeneration solidarity in the sense of fair change.

D) The geriatric frailty index is mentioned in the German guidelines in the context of overall health condition evaluation for a long-term prognosis without numerical expression. The Dutch guidelines use frailty in expert evaluation criteria for providing acute care; ethical guidelines explicitly exclude it. Czech expert recommendations explicitly exclude it, too. The expert guidelines of the Slovak Ministry of Health mention frailty in the triage process under the condition of prioritizing the physiological frailty (without defining it). Furthermore, it is pointed out that a special evaluation is needed for an existing stabilized condition that affects the physical and other activities of a patient, and thus inappropriately influences the total score. For the process of triage, frailty is evaluated numerically according to the scale of serious diseases. The total score determines the selection of an acute, conservative, or palliative treatment.

1) The differences in the German, Dutch, Czech, and Slovak expert-ethical recommendations for intensive care indication in a crisis stem from the specific social-cultural environments, and are projected onto the particular legal systems and health care.

2) Triage-related decisions concerning the medically inappropriate treatment of the elderly based on a numerical evaluation (frailty index) would correspond with the functionalist definition of human being primarily not defined ontologically; intensive care indication would overlap with utilitarian preferences. Moreover, the decision of the medically inappropriate treatment of the elderly based on numerically defined frailty would violate the principles of equality and justice. Bioethics would assess it as a borderline situation overlapping with the utilitarian attitude to human dignity, human rights, and a 'good' death. We propose non-utilitarian ethics of social consequences as a solution to and illustration of a philosophical theory for medical bioethics in the situation of a disaster. The primary values of this ethics are humanity, human dignity, and moral rights. The secondary values comprise justice,

responsibility, moral duty, and tolerance. Their task and purpose follow from their capacity to help in reaching and implementing the moral good (Gluchman, 2016).

Compared to preferential utilitarianism, non-utilitarian ethics compensates for the requirement of maximizing the benefits and non-discrimination of endangered groups of patients in the period of crisis and, therefore, reduces bioethical uncertainty.

3) The application of strict medical criteria for triage decisions for the sake of optimal effects can mean that some groups of patients lose any chances to save their life. This can be viewed as unfair: belonging to a high-risk group does not imply depriving a patient of intensive care. Full concentration on medical reasons for effective utilization of resources might increase health care inequality (Verweij et al., 2020).

Medical expert processes should define the criteria for the evaluation of patients based on the definition of a medically inappropriate treatment in which case the parameter of frailty is a part of a long-term prognosis, depending on limited or scarce resources.

4) A selected medical expert procedure must be followed by a bioethical process of consensual evaluation of the intensive care indication in the situation of a crisis and limited capacity. Neither age nor the parameter of frailty should be included in the bioethical triage process for the elderly. Age can be considered on the basis of intergeneration solidarity as a fair change. The legal situation in a crisis period cannot reflect the existing situation. Therefore, expert-ethical guidelines should be commented on by relevant professional organizations and institutions. In Slovakia, it is the Health Care Supervision Office. In an ideal case, the triage protocol should be an outcome of a politically legitimate process. The triage of patients in a pandemic crisis requires nationwide discussion.

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## Pandemic challenges and models of democracy

Leszek Koczanowicz<sup>1</sup>

### Abstract

This article examines the impact of a pandemic on democratic societies. The central research question is the extent to which a pandemic can alter the trajectory of social and ethical democratic development nationally and internationally. Therefore, the article examines contemporary controversies in democratic society in the aftermath of a pandemic. The leading hypothesis is that the pandemic should reinforce the need for social solidarity, but it is unclear what political form this need will take: populism or deliberative/nonconsensual democracy.

**Keywords:** pandemic, democracy, ethics of democracy, populism, deliberative democracy

### Pandemic and politics

For a year now, the world has struggled with the rising tide of infections caused by SARS-Cov2. The scale of the problem is best illustrated by numbers: on the 25<sup>th</sup> of November 2020, a cumulative count of 62 153 458 confirmed cases was registered with a death toll of 1 443 300, and on that day, there were 486 545 confirmed cases and 6907 deaths (JHU, 30 Nov 2020). At the same time, however, it is stressed that not all countries have been equally severely affected by the pandemic. According to data provided by John Hopkins University Coronavirus Resource Centre, the highest death tolls have been registered in the US, Brazil, India, Mexico, and the UK (JHU, 30 Nov 2020).

These shocking statistics revealing the scale of the problem indicate that the pandemic is not only a matter of purely technical actions of the healthcare system and medical services, although, admittedly, it is now extremely important to assess their operation, but above all, it is a social, political, and cultural phenomenon which, evidently, can have far-reaching effects on societies. The great Black Death epidemic that decimated the population of Europe in the 14<sup>th</sup> century affected the economy of that period, and indirectly, its politics. Historical data show that although during the plague social inequalities in terms of income decreased, the situation swiftly came back to the norm and even increased (Scheidel, 2018). Evidently, the plague, enhanced and accelerated pre-existing tendencies rather than created new social or political mechanisms. The COVID-19 pandemic, however, shows specific traits whose political impact should be analyzed before we can assess its far-reaching consequences.

The pandemic exposes both the weaknesses and strengths of science. In this respect, it is “scientifically” constructed. Without access to pandemic statistics and mathematical propagation equations, it could have been easily overlooked or taken for a new strand of flu. Nevertheless, the influence of these indicators can be deemed ambivalent. Warnings were often ignored or lost in the information overload, as they referred to previous epidemics which, despite initial concerns, were limited in scope. This led to the underestimation of the threat at the onset of the virus before scientific research provided adequate data and, first of all, proper extrapolations which forced governments to take suitable action. The power of science was sufficient to construct the pandemic, but insufficient to contain it. Sophisticated methods of science, such as genetic tests, biochemical analyses on the one hand, and elaborate techniques of mathematical modelling on the other, are harnessed to implement the most basic and time-tested methods, such as quarantine and isolation. Obviously, these ancient measures are complemented with state-of-the-art methods of social modelling, but they have been unaltered

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at their core and their application is basically intuitive as is shown by the differences in scope and strictness of the implemented measures in particular countries. We are thus presented with a paradox here. In many cases, the effects of the pandemic are not clearly visible in “the world of everyday experience” (Lebenswelt); they appear as dry numbers of new cases in media reports. Simultaneously, epidemiologic data and modelling methods based on elaborate statistics show that we are confronted with a lethal threat.

This specific nature of the pandemic obviously affects its reception in everyday life due to the fact that its visibility is limited, or, so to speak, secondary. What most of us can see are empty streets and precautionary measures such as face masks, disinfectants, protective gloves, social distancing, etc. We see much more through the media: the pandemic is probably the first health crisis that is so widely, globally broadcast and discussed in real time. The discordancy between the direct perception of the pandemic and the necessary- as scientists and governments insist on restrictions changing everyday life - brings about a constant tension which has not yet been alleviated in any pandemic-stricken countries. Due to this discrepancy, a cognitive gap is created through which all sorts of fantasies squeeze in, starting from conspiracy theories, through dusted-off religious preaching of the penalty for sins and related millenarism, to visions of the new world emerging after the pandemic has been eradicated.

### **Ethics of democracy**

In this paper, I understand democracy not as a set of institutions, rules, and procedures but more as a form of life, to use Wittgenstein’s category: “‘So you are saying that human agreement decides what is true and what is false?’ – It is what human beings say that is true and false; and they agree in the *language* they use, That is not agreement in opinions but in form of life” (Wittgenstein, 1999, §241). For this reason, the most important thing for the functioning of democracy is the ethical engagement of citizens, which grows out of the form of political life and at the same time constitutes this form.

In political philosophy this ethical concept of democracy can be illustrated by two apparently different traditions. The first tradition is of French political philosophy where I see a special place for the works of Claude Lefort. The second is that of American pragmatism, especially John Dewey’s concept of democracy. I think that what is also common for them is the concept of the dynamic of the democratic system. They believe that democracy doesn’t necessarily mean consensus but on the other hand they do not think that any antagonism has to lead to rejection of liberal democracy. As Claude Lefort states, if we are aware of these setbacks of democracy then we can protect it from the temptations of totalitarianism. Democracy is a system of constant internal struggle because it differs from other political forms in that that it is organized around “empty space”. As an expert on Lefort writes:

[W]ithin a democracy, the source of legitimate power is ‘the people’ but who is to speak in the name of people? According to Lefort, political life on modern democracy is a continual debate on just this question. No-one claim can to be authorized *a priori* to speak in the people’s name; each person’s claim must be discursively validated and every claim is always subject to challenge. The legitimate spokesperson for the people cannot be established with certainty; it is always ‘up for grabs’ and as such it engenders an anxiety. The political anxiety which is endemic to democracy is experienced most intensely in times of crisis; it has its ‘object’ the possibility that the symbolically empty space will become *really* empty, which is to say, no one will be able to establish legitimacy and this would mean that the symbolic place of power would fall into [the] real (Flynn, 2005, pp. xxv–xxvi).

Thus, the struggle to legitimize the definition of “the people” is built into the system. Antagonism is thus the essence of democracy, and at the same time a threat to democratic society

and a source of its strength. Democracy must constantly define itself and is a system that requires constant change. On the other hand, it is also in constant danger of falling into totalitarianism, where the empty space is filled by a clear definition of “the people”. The moral for democratic theory is that since the threat of totalitarianism is endemic to democracy, the only way to protect that system is for the people to actively participate in its defense. However, one must think of democracy not in terms of a system or institution, but in terms of habits and moral commitment. Democracy is from this point of view both an ideal and a form of life.

For Dewey, democracy is a kind of inquiry that is directed toward facilitating the social life of the individual. “[...] organization is never an end in itself. It is a means of promoting association of multiplying effective points of contact between persons, directing their intercourse into the modes of greatest fruitfulness” (Dewey, 1950, pp. 160–161). This assumes, of course, that Dewey accepts at least a weak version of the social ideal of democracy. This ideal can be understood precisely as an idea that guides or regulates the development of society and the individual. The individual may, of course, enjoy more or less freedom in a given society, depending on historical conditions, but this does not mean that progress is impossible. It is measured by the development of all the abilities of the individual through an appropriate relationship with others.

Democracy is thus a system that operates in constant ethical tension, this tension can be represented in the form of a triangle: ideals (values) – action (customs, practices of democracy) - institutions. Relating to each side of this triangle requires ethical sensitivity and a critical relationship to ideals, practices, and institutions. Ideals challenge democracy as a promise that, even if impossible to fulfill, must be activated and reactivated so that the practice of democracy does not fall into a daily routine of small institutional actions that cannot be translated into a broader perspective.

The practice must, in turn, create a conscious context for engaging in democracy and defending its principles against the anomie of legitimacy and the totalitarianism that emerges from this anomie, against the temptation to replace democratic heterogeneity with the totalitarian unity of “the people”. The institutional dimension of democracy must be constantly challenged in the sense that democracy, in order to survive, requires the coexistence of competing social and political projects. It is therefore crucial and vital for democracies to be imaginative and creative in their design. The pandemic is a challenge to democratic politics and, at the same time, a test of the efficiency of a democracy that can survive even the worst conditions. Because the pandemic involves not only institutions but also people’s daily lives, it must reconfigure the democratic triangle I mentioned above.

### **The Pandemic and the controversies of democratic society**

The specific nature of the current pandemic and the entirety of experience gained while responding to this crisis may significantly change the form of democratic societies. It is noteworthy that the pandemic has set off certain contradictory tendencies and, at present, it is difficult to predict the drift of events. Moreover, similarly to the previous great plagues, the COVID-19 pandemic is a sort of an amplifier of preexisting social and political trends. It can be assumed that some trends will be enhanced while others will be rejected or reduced. Let me point to some of the major areas in which such trends may occur or have already occurred.

One such area is undoubtedly globalization and, to be more precise, the question is whether the effect of dealing with the pandemic will be to strengthen international cooperation or whether the opposite trend towards national autonomy will prevail.

The pandemic is a global phenomenon and thus it should be dealt with globally. It is reflected at numerous levels. Chinese scientists, by making the virus genome accessible, helped accelerate timelines for development and rolling out new vaccines. Sharing information on the virus altered the trajectories of scientific publications and helped create platforms for instant,

cost-free sharing of findings. International cooperation is essential for development, allocation, and deployment of new vaccines. Similarly, close cooperation is required to alleviate the economic losses caused by the pandemic. A clear example is the EU's initiative to set up a fund for the compensation of economic losses incurred due to the pandemic.

At the same time, as is generally known, the governments of Poland and Hungary highlight the sovereignty and autonomy of the national state. Although their attitude is evidently related to certain internal policy issues, nevertheless it signifies a deeper problem. The pandemic, while enforcing cooperation, at the same time strengthens the sentiments for an autonomous national state. The pandemic response has never been agreed upon by states, on the contrary, each country implemented their own strategy. Obviously, these strategies showed some common elements, but they were the result of common conditions rather than the consequence of intentional cooperation. Moreover, the national strategies of pandemic response seem to reflect the political system and culture of a given country rather than general pandemic factors. A comparison between China and Sweden provides a clear illustration of this characteristic. The former resorted to radical control of citizens' behavior while the latter implemented appeals and democratic debates on applied restrictions. The separatist trends in national states may also be reinforced by so called 'vaccine nationalism' i.e., the efforts of particular countries to acquire and distribute the vaccines as quickly as possible. This attitude seems understandable as the effectiveness shown in such an important area can, to a large extent, translate into favorable results in the post-pandemic-elections. This strategy is not only instrumental in character; the national divisions into 'us' and 'them' still play a key role as governments try to fight for their "own" citizens. Such an attitude, however, leads to enhanced entrenchment in nationalist positions.

In this case the pandemic enhances the preexisting controversy between tendencies to form supranational institutions and organizations and to return to the well-known forms and institutions of national state. It should be assumed that the COVID-19 epidemic favors the latter trend, at least in the sense that the state is more trusted than distant, transnational forms of power. This is due to the fact that, according to the laws of social psychology and sociology, in crisis situations there is a tendency to close in well-known cognitive structures. There is also a tendency to simplify the situation to find quick solutions. So, it seems that, at least in the near future, democratic forces will come under pressure from supporters of a return to the greatest possible powers of the national state and extreme isolationism. It is a dangerous trend because even the eradication of this pandemic will not safeguard us against new strains which may threaten the world. According to many scholars, our ways of producing food, but also social habits will promote the propagation and spread of new strains of the virus. Such a new strain has already appeared in the UK during the holiday week. Fortunately, it seems that newly developed vaccines will also be effective in this case, but worse case scenarios cannot be ruled out in the future. Moreover, other global challenges, such as climate issues, which require the cooperation of many countries, have not disappeared.

### **Democracy of expertise or democracy of sovereignty: the media and "fake news"**

The pandemic is an extremely complex phenomenon whose understanding, as I wrote above, requires considerable scientific knowledge as well as knowledge how to combat it. Pandemic decisions are made by politicians on the basis of the expertise of scholars or, strictly speaking, are often a compromise between policy requirements and science-based guidelines. For example, when epidemiologists recommend a strict closure and politicians choose a softer variant for the sake of economy or to adjust it to citizens' habits. Despite such compromises, the authority of experts has become significant. Scientists often endorse decisions and take responsibility for them. Thus, the pandemic enhances tendencies whose origins can be traced back to the beginnings of liberal democracy and which have been on the increase since the

beginning of the 19<sup>th</sup> century - leaving key decisions in the hands of experts. It is not surprising as modern societies are complex organisms whose functioning depends on the cooperation of many elements. To be able to see these interdependences requires knowledge which is, obviously, not equally accessible to everyone, hence the role of experts. However, this knowledge has been contested and questioned as often as it was used. A great debate on the role of experts swept through all the countries affected by the 2007–2009 financial crisis when economy professionals took up the reins of power and dictated the measures for alleviating the crisis. An additional issue is the erosion of trust in science caused by the fact that expert opinions are often deemed contradictory and inconclusive, which leads to all kinds of disinformation taking the form of “fake news”, especially widespread on social media. Therefore, even if we were to assume, following the early 20<sup>th</sup> century pioneer of media science, Walter Lippman, that expert authority is a necessity, its rationality would still be threatened by information overload on social media. Unfortunately, the pandemic has enhanced a tendency to undermine the role of scientific experts, even though surveys show that 61% of Poles still trusts scientists and the healthcare system the most, only 21% trusts the government and 26% trusts the media (Wróblewski, Meler & Afeltowicz, 2020). The pandemic has become a testing ground for spreading chaos and information hype into social media (Anwar, Malik, Raees et al., 2020).

The opposite of expert democracy is popular sovereignty democracy where the voice of the majority is decisive in all matters. This concept is generally referred to by populist movements whose ideologists claim that most decisions are made by experts or court verdicts based, after all, on expert opinions. Resisting such a state of affairs is, according to many experts, one of the mechanisms which fuels populism. It coincides with the difficulty experienced by a growing number of people, to understand complex rules and procedures governing modern, democratic society. As noted by the prominent political psychologist, Shawn Rosenberg, liberal democracy has fallen victim to its own success. People’s cognitive powers are not developed enough to cope with the complexity of democratic politics (Rosenberg, 2021). If his diagnosis is correct, the challenges facing democracy are not incidental, but they lie at the core of its functioning. Undoubtedly, if we adopt this perspective, the pandemic may be instrumental in the failure of liberal democracy system. The reason is obvious, further restrictions and regulations, in many cases incomprehensible to most people, increase the complexity of the system. The justifications for implementing new rules are convoluted and the procedures themselves are often ambiguous. Therefore, it is not surprising, that in many countries, there are trends which oppose such conjuncture. They are generally politically marginal, but it seems reasonable to presume that they will leave their mark on people’s mentality, evoke mistrust in democracy and shift public sentiment toward populism. An additional effect may be a growing distrust in science which manifests in COVID-19 vaccination resistance.

The pandemic, even when it is over, will make its mark on democratic societies. It may significantly reduce trust in science, and, consequently, reduce the level of rationality in political debates and decisions. Obviously, politics is never fully rational, but a “healthy” democratic policy requires a certain balance between a scientific approach to social issues, and emotions. The pandemic has undermined this balance and, as a consequence, the increase of populist sentiment may take place. It can be reduced, to some extent, by a rapid economic recovery, but it seems unlikely that simply improving the economy will be sufficient. There is a need to restore trust in science which must, however, be achieved by incorporating scientific data into social discourse. This strategy is necessary, not only in post-pandemic situations but also because of other global challenges facing humanity. If we fail to persuade the general public to the rational response to such an immediate threat as the pandemic, it will be even more difficult to convince them of proper action in response to climate change which also requires change in deep-rooted habits and reduction of consumption. It is, therefore, necessary

to consider the implementation of policy that would allow for an open debate on expert-proposed solutions. However, this, in turn, requires clearing the forefront of incorrect information and fake news. The EU-adopted directive of the 3<sup>rd</sup> of December 2020 “On the European democracy action plan” (The Commission, 2020) gives clear guidelines on how to proceed in case of disinformation generated by both domestic organizations which contest the state policy, such as the anti-vaccine movement and by foreign powers which are interested in weakening democratic states in the EU. Implementation of the directive is a necessary step in the process of incorporation of science into democratic discourse.

### **The pandemic and the models of democratic societies**

The consequences of the pandemic have a significant influence on the present-day debate on democracy. This impact can be considered in two aspects:

Firstly, the lessons learned from the pandemic make it possible to predict the paths of development of different models of a democratic society, at least in the sense that we now know that certain opportunities have been blocked for a long time. As I wrote above, after the end of the Black Death in the 14<sup>th</sup> century, the inequalities that had been eliminated for a moment returned with renewed strength.

In any case, the prevalence of communal thinking can be expected in the near future. The plague brought a significant change in this respect, namely, in the dispute between communitarians and liberals, it has tipped the balance in favor of the first option. During the pandemic, people seek to identify with a group, a community, and the obvious choice for such identification is nation and/or religion. This identification may be superficial to a large extent, since a community which is thus created is, first of all, a community of suffering, but political ideologies translate it into accessible, easily articulated values, such as the nation or a particular religion.

Community involvement also entails a particular paradox. The sense of belonging to a community is combined with behaviors of individualistic character. People in isolation are alienated individuals who are, in a way, connected by restrictions imposed by law. Therefore, it can be said that they are a paradigmatic example of the most fundamentalist liberal theory. However, the situation is at least partially broken by the use of new media, especially, social media. All in all, it can be said that the mechanism driving communal thinking is fear, both of the pandemic and of its economic and social consequences. The vast majority of people in closure-affected countries realize that only joint effort can mitigate the impact of the pandemic.

On a political level, the intensified sense of belonging to communities can manifest in a number of ways, which fall under various parts of the political spectrum. On an economic level, it is certain that massive state intervention in the economy will be unavoidable. It seems that extremely popular, neoliberal, economic recipes have lost their power. David Harvey points out that the pandemic even forces capitalist economy to adopt more pro-social solutions.

It applies specifically to the sphere of distribution and redistribution of goods (Harvey, 2020). At present, it is difficult to imagine radical free-market capitalism with minimal state intervention. The pandemic can therefore have similar effects to those which WWII had on the European economy when the war experience gave rise to the welfare state. It was founded on a public consensus to alleviate the inequalities through transfers from the wealthy to the lower earners (Piketty, 2014). Undoubtedly, evident neglect in the public sectors, especially in healthcare which came to light during the pandemic, will have to be more than compensated. Biopolitics will combine with social policy. Public healthcare has to be connected with actions aiming at equalizing opportunities and alleviating inequalities. The consequence of the pandemic should therefore be favoring solidarity solutions, at least in terms of the economy. Nevertheless, this is only the first step in the analysis of the effect of the pandemic on democratic models. Each of the models below is, at its core, a certain spectrum of possible

political solutions, and as such, has to be analyzed separately. Moreover, solidarity/social solutions in an economy can involve entirely different political strategies, ranging from authoritarianism to dialogue.

Secondly, an important aspect is the internal analysis of various models of democratic society. For the sake of analysis, I chose the following options: (1) representative parliamentary democracy (classic liberal model of democracy), (2) populism, (3) deliberative democracy, (4) hegemonic model of democracy, (5) non-consensual democracy, whose outline I presented in my book (Koczanowicz, 2016).

Representative parliamentary democracy (classic democracy model) has been in permanent crisis for many years now, which has been repeatedly diagnosed and described (Mounk, 2018; Zielonka, 2017). The fundamental problem in this model is its hybrid character; it is a combination of two separate projects: inalienable individual rights (human rights) and majority rule. Both parts were consonant with each other for nearly 200 years, though obviously not without some friction. However, in the last two decades, there has been a distinct imbalance between them. The common point is that key decisions affecting people's lives are made by courts or experts and implemented through complicated and incomprehensible procedures. In public perception, the most important issues and decisions that affect people's lives are made behind people's backs although they should be the subjects of democracy. The course of the pandemic so far indicates that the situation of liberal democracy has declined. Although, according to Freedom House reports, authoritarian regimes are restricting human rights during the pandemic the most, democratic countries also have troubles with realizing the fundamental principles of the democratic system. In 88 countries, a partial retreat from democratic rules can be observed (Repucci & Slipowitz, 2020). Obviously, the question to what degree will these negative changes affect democracy remains open, but it can be expected that liberal democracy will be weakened in many countries.<sup>2</sup>

Populism is currently the main adversary of liberal democracy. Numerous studies give various definitions of it, but distrust of the ruling elites and the tendency to introduce clear "us" versus "them" divisions come to the fore (Mudde & Kaltwasser, 2017). The second characteristic of populism may be the term "non-liberal" democracy", because out of the two pillars of liberal democracy I mentioned above, populism, at least declaratively, would like to leave just one, i.e., direct rule of the people (Zakaria, 2003). This strategy is closely related to an anti-elitist attitude; populist movements seek to present themselves as the "vox populi", stigmatizing elites for being out of touch with social realities. In the majority of the literature on populism, it is widely debated whether such a general attitude can turn into a specific political agenda, all the more so because the program spectrum of populism is extremely broad.

The issue becomes pressing when groups which preach such slogans (voice of the people, anti-elitism) come to power either alone or as part of a governing coalition, as in the case of Poland and Hungary. Current experience shows that such system shows a tendency to strengthen executive power at the expense of other elements of the democratic system, which may be a prelude to authoritarianism. Anti-elitist and anti-procedural attitudes of populism predispose it to take a skeptical or even hostile stance on anti-COVID-19 measures. Cultural populism is coupled with anti-vaccination and, generally, anti-medical movements. However, political analyses indicate that political populism is rather cautious in this matter. A report by the *Tony Blair Institute for Social Change* found that out of the 19 populist leaders analyzed, only 5 were skeptical about the pandemic (Meyer, 2020). This is probably due to the fear of losing support in the face of the noticeable effects of a healthcare crisis.<sup>3</sup> Nevertheless, it seems

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<sup>2</sup> This is what 65% of experts surveyed in the study cited above expect. Poland is quoted as a country where: "Politicians make a statement unsupported by facts".

<sup>3</sup> It can be assumed that Donald Trump's ambivalent attitude towards the pandemic contributed to his election defeat (cf. Paz, 2020).

obvious that populist or quasi-populist countries (Hungary, Poland, the US during the Trump era, and the UK during Boris Johnson's rule) have regarded the pandemic as a useful tool in the political game, highlighting the threat at times when it brings tangible political benefits. A key moment in the discussions on democracy will certainly be the introduction of vaccines and the convincing of people to get vaccinated. If this means the end of the pandemic, liberal democracy, with its attitude towards rational discussion, should be strengthened. However, when the whole operation fails and the pandemic continues to be a threat, it will fuel populism. An additional problem is the anticipated economic crisis resulting from the pandemic. It is clear that it will fuel the popularity of populist movements unless it is relatively quickly reduced through extensive state intervention.

Alternative models of democracy include deliberative, hegemonic, non-consensual and it is known that the problems of liberal democracy were already noticed in the late 1970s and 1980s and then certain models of democracy appeared that were supposed to be improvements of the classic model. I am thinking here about deliberative democracy and hegemonic (radical) democracy. These two models come from different premises. In the case of deliberative democracy, they were the concepts by J. Habermas and J. Rawls who claimed that a rational consensus can always be achieved provided that certain political requirements are met. Improving democracy would mean that democratic debate cannot be reduced to just making choices from a specific pool of proposals put forward by the parties, but it must take so long that the various positions and arguments behind them can be presented. Then the choice will be truly conscious and rational. Hegemonic democracy, on the other hand, assumes that conflict is an inevitable feature of a democratic society and, as such, should not be avoided but rather "tamed" through turning opponents into adversaries, and antagonism into agonism. Then, the democratic vote gives hegemony to the winning side, but at the same time, the losing side can work on a rematch in the next election. The concept of non-consensual democracy emphasizes understanding which is supposed to be the middle way between the above-mentioned concepts. According to it, the aim of democratic dialogue is, first and foremost, to understand, not to agree. Deliberation, even if it does not lead to the consensus, paves the way to better mutual understanding among the sides of a conflict. I am discussing these three concepts together despite their significant differences, as they largely remain experiments of some kind, although they take on a new meaning in the face of popular belief that the classic model of liberal democracy needs to be changed.

Actually, finding ways to improve the classic model is now a matter of survival of democratic society. A report by the Bennet Institute for Foreign Policy, and the Cambridge University based on surveys of nearly 5 million respondents from 160 countries between 1973 and 2019, shows a disturbing, but ambiguous trend. In general, every subsequent generation, starting with the first post-war generation, has become increasingly disillusioned with democracy. The "millennials" are the most disillusioned with democracy of all generations. However, the report's authors observed an interesting phenomenon; in countries where populist leaders (both left and right) came to power, young people's support for democracy increased. Nevertheless, conclude the authors, it is uncertain what will happen if populists are in power for longer than one term. There are reasons to believe that then the support for democracy may diminish (Foa, Klassen, Wenger et al., 2020).

Everything that has been said above indicates that, to a large extent, the future of the democratic system will depend on how national authorities, but also transnational organizations (the European Union is an obvious example here) can cope with the pandemic. The question is not only whether they will be able to effectively eradicate the epidemic, but also what means they will use and, above all, to what extent they will be authoritarian decisions, and to what extent they will have wider public support. It is certain that the pandemic will accelerate the transformation of classic, liberal democracy. It must be enriched with elements of social



solidarity at an economic level and should possess greater co-decision possibilities. This should foster deliberative or participatory democracy, although it can be assumed that new forms of communication and political decisions can be established using new social media. If it is defeated in the fight for public support and fundamental decisions are made authoritatively, the populist movement, which contains elements of the hegemonic concept of democracy, but without its most important part, namely allowing all social voices into discourse, will gain the upper hand. Social media will then serve to build an information monopoly.

### Final conclusions

The pandemic is a multi-aspect phenomenon of medical, social, cultural, ethical as well as political dimensions. Politically, it acts as a catalyst of certain trends that existed prior to its occurrence. It strengthens certain tendencies while reducing others. At present, during the pandemic, we can identify the areas where its impact is most significant, but, on the whole, we are not yet able to determine the direction of this impact. However, it is now clear that, as a consequence of the pandemic, political and ethical ideas that promote social solidarity will come to the fore, at least in the sphere of distribution. The pandemic has therefore enhanced a current of ethical criticism of the free-market capitalism (neoliberalism), already existing in the public sphere, together with its political and legal superstructure. It is not clear, however, what political solutions will emerge as the consequences of this critique. (Re)distributive actions may be based on a broad public discourse, but they may also be arbitrary actions by governments strengthening their authority.

The pandemic is one of many global crises, and similar threats may occur in the future. The settled, authoritarian response patterns to these issues, and the belief that they are the only way to resolve them will pose a serious threat to the survival of democratic societies.

The pandemic has clearly demonstrated that democracy must be radically reformed in order to survive such crises. The reforms should aim at increasing the scope of participation and deliberation, also through the use of social media. In the long run, transparent mechanisms need to be put in place for the relations between science (experts) and policy decision-making, which, combined with information policy, should reduce the effects of disinformation in the media, especially social media. Political education is absolutely crucial to ensure universal participation in decision-making as it guarantees better understanding of democratic procedures.

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## **Equitable global COVID-19 vaccine allocation and distribution: Obstacles, contrasting moral perspectives, ethical framework and current standpoints**

**Georgios Kalaitzidis<sup>1</sup>**

### **Abstract**

Accelerated COVID-19 vaccine development represents an important accomplishment and a milestone in the history of vaccine evolution. However, the vaccine's scarcity made its equitable global allocation and distribution ambiguous. Despite the initial pledges from wealthy countries for fairness and inclusivity towards the poorer ones, the policies followed diverged significantly. Wealthy countries have vastly superior access to vaccines in a reality likened to an ethical disaster. This paper calls for the need for fair global vaccine allocation and distribution and examines the barriers that were met along the way, originating from different points, such as the nationalistic approach on the matter that most wealthy countries have adopted or the inability of poor countries to purchase or manufacture vaccines. Further, a suggestion regarding the ethical principles and values that ought to guide global vaccine allocation and distribution is provided with a higher priority given to helping the worst-off, saving the most lives, protecting people in high risk, such as frontline healthcare professionals, and minimising social gaps, along with an ethical theoretical background for each prioritisation. It is not too late for wealthy countries to realise that vaccine inequity prolongs pandemics, so that they change their policies in favour of the global common good that will not only provide immediate universal benefits but will also serve as a guide for future pandemic crises.

**Keywords:** COVID-19, vaccines, access, global, equity

### **Introduction**

With coronavirus (COVID-19) affecting an increasing amount of the global population, vaccines have emerged as a powerful weapon in the arsenal of public health policies. The lives of millions of people are in danger with more than a million deaths from the virus worldwide, and national economies suffering deep downturns. This situation serves as the latest demonstration of how detrimental infectious diseases can be in the absence of an effective vaccine (IMF, 2020). In 1918, an influenza outbreak (Spanish Flu) killed more than 50 million people globally and had devastating socioeconomic impacts (Martini et al., 2019). In another case of different geographical and socio-economic backgrounds, over the course of 2 years (2014–2016) the Ebola virus was responsible for the death of approximately 11,000 people in West Africa due to rapid viral spread across several countries (Brown, Mephram & Shorten, 2017).

Most nations are attempting to secure adequate access to an effective and safe vaccine, which combined with other public health measures, including masks, social distancing and extensive testing may help to limit the spread of the disease (McNeil Jr., 2020). Therefore, there is a general belief that a COVID-19 vaccine could put an end to the current pandemic, re-enable free movement, drastically decrease the number of deaths, help economies recover, and improve the physical and mental welfare of people. However, this is only partly accurate. Even in the presence of a potential vaccine, COVID-19 will stop posing a threat only if enough people (more than 60–70% of the global population) are consenting and given the opportunity to get vaccinated (Aschwanden, 2021). This matter raises several compelling ethical issues regarding vaccination strategies and policies. Vaccination decisions and programs to a certain extent impact both vaccinated and non-vaccinated individuals as well as the wider community and therefore should be considered as ethical decisions.

Currently, due to efforts from the global scientific community, unparalleled in speed, resource allocation and scientific focus, there are at least 308 vaccine candidates, of which 16

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have reached late-stage development.<sup>2</sup> At the time of drafting this report, the Moderna and Janssen vaccines have been approved for emergency use against COVID-19 virus by the European Medicines Agency (EMA) and the Food and Drug Administration (FDA). Notably, the Pfizer-BioNTec vaccine received full approval by the FDA and emergency use approval by the EMA. Additionally, there is a contingent marketing authorisation for the Oxford-AstraZeneca vaccine provided by the EMA (Chakraborty et al., 2021; Waxman et al., 2021; Forni & Mantovani, 2021; Peiffer-Smadja et al., 2021; FDA, 2021). They can potentially prevent thousands of deaths and shield vulnerable individuals, but it seems ambiguous whether the obstacles associated with their vast production and equitable distribution can be overcome.

The cooperation between the World Health Organization (WHO), humanitarian and private sector companies, combined with their Access to COVID-19 Tools Accelerator, led to the declaration of 24<sup>th</sup> April 2020, supposedly ensuring just, global access to “safe, quality, effective, and affordable COVID-19 diagnostics, therapeutics and vaccines” (WHO, 2020). Most countries have already started materialising their pledges (Miller, Shields & Farge, 2021).<sup>3</sup> (Miller, Shields & Farge, 2021). Moreover, in 2000 the Global Alliance for Vaccines and Immunisation (GAVI) was created which has secured billions in donations from public and private organisations to aid vaccination in low-income countries where vaccination normally faces various barriers, such as inability to afford vaccines and supplies, insufficient healthcare structures and resources to vaccinate (Zerhouni, 2019). Importantly, a multiparty alliance between GAVI, the Coalition for Epidemic Preparedness Innovations (CEPI), and the WHO created COVAX to set up the framework for equitable access to vaccines globally, with the promise to cover the vaccination need of 92 middle and low income countries (MLICs) and immunise 20% of their population within 2021 (Loembe & Enkegason, 2021). Nevertheless, the global scarcity of vaccines, high costs, and exacerbating injustice and disparity observed during pandemics likely aggravate the vaccination barriers that low-income countries continually face (Torres et al., 2021; Bong et al., 2020). Therefore, it remains extremely unlikely that donations and interventions from developed countries will ensure fair distribution of vaccines against COVID-19 without the existence of a concrete, well-defined ethical framework for allocation adopted by everyone.

The real challenge is identifying the most efficient and ethical approach that would achieve equitable global vaccine allocation and distribution. One approach examines the issue through a more consequentialist or utilitarian scope, advocating that the outcomes or consequences of an action or adopted policy determine its moral justification. In practice, when a particular result is defined as good then the action that allows its maximisation is the ethical one. A second approach, based on a more deontological perspective, proposes allocating COVID-19 vaccines according to good principles or standards. According to this perspective, equity and fairness are the two fundamental values that should govern vaccine allocation, even if it means that sometimes it compromises efficiency. This way, vaccination can lead to decreased suffering, reimbursement of the people who were exposed to high risk during the pandemic and even enhance post-pandemic equity. However, such an approach has to deal more with complex and compelling ethical questions, such as identification of the most vulnerable or evaluating who was affected the most. An ideal approach would be an amalgamation of both these perspectives. In my view, embedding the consequentialist reasoning (e.g., maximising benefit, limiting harm) within a deontological framework (e.g., prioritising the socially disadvantaged, equal concern) would fit current COVID-19 vaccine allocation needs.

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<sup>2</sup> All these vaccines differ in physiological response to varied dose, effectiveness and supply network demands.

<sup>3</sup> Including United States which initially refused to support it.

### **Vaccine as a Global Public Good**

For the purpose of this paper, I will refer to all COVID-19 vaccines as “the vaccine”. As the COVID-19 vaccine was initially approved for emergency use there were several voices advocating for its declaration as a Global Public Good (GPG), that would influence its fair global allocation and distribution (UNESCO, 2021; UN, 2021; Yunus, Donaldson & Perron, 2020). Therefore, it would be beneficial to briefly define this concept. Originating from classical liberal economics, the concept of Global Public Goods has been utilised to subsidise equitable global distribution of social aid, such as health services. Public goods are goods that fulfil the two requirements of being non-excludable and non-rivalrous in nature. A good is non-rivalrous when its utilisation by one does not stop others from utilising it and non-excludable when every individual benefits from it despite how many other individuals do (Samuelson, 1954). Innately, they raise specific ethical questions regarding fairness and free-riding. The contribution from an individual is not compulsory in order to benefit themselves, or others, from it; therefore, the problem of free-riders occurs. The existence of free-riding is unethical, and sometimes even illegal, because it compromises fairness (Giubilini, 2021).

Multiparty negotiations were held to decide whether the vaccine should be declared as ‘global public good’.<sup>4</sup> However, it was finally decided to declare ‘herd immunity’ acquired by the vaccine as GPG instead (WHA, 2020). ‘Herd immunity’ is the situation when the majority of a population is immune to an infectious disease, providing indirect protection to those not immunised against the disease. For instance, immunising 80 % of a population against a virus means that four out five people who come across someone with the disease will not become ill or transmit the disease. The herd immunity threshold of any disease depends on how infectious the pathogen is and the efficacy of the potential vaccine (Fine, Eames & Heymann, 2011). From an ethical perspective, herd immunity is a public good and raises the already mentioned ethical questions regarding fairness and free-riding since not all people need to get vaccinated in order to achieve it (Lim, Zhang, 2020). According to certain sources, an individual’s denial to contribute to herd immunity because it is immaterial, is a contravention against fairness (Giubilini, 2019).

An emerging question is whether herd immunity specifically for COVID-19 is still an achievable goal. The answer is positive, but does not mean the immunity level in society will soon be at such a degree as with other infectious diseases, such as measles or mumps, that would allow us to say that the crisis has disappeared. The world will have to get used to the idea of coexisting with the virus for several years due to various reasons. One reason is the difficulty to get people vaccinated against COVID-19 globally. Unlike measles vaccination, many people have been significantly sceptical towards the COVID-19 vaccines, even if we already know that they are safe and provide protection against the virus, including the dominant B.1.617.2 (delta) variant. Secondly, children are still not widely qualified for vaccination and until that happens there will be a continuous COVID-19 circulation among children, who will subsequently infect mainly unvaccinated adults. Thirdly, the uneven COVID-19 vaccine roll-out is significantly hampering the global goal of herd immunity for COVID-19. “No one is safe until everyone is safe” became the global slogan for COVID-19 pandemic for a good reason. Fourth, even though COVID-19 vaccines are extremely efficacious and decrease the risk of infection, this risk is not completely eradicated. Vaccinated people or people with natural immunity against COVID-19 can still become infected. As a result, an increased vaccination rate is required in order to achieve the desirable herd immunity. Since complete elimination of COVID-19 virus is unlikely, it might continue circulating in the population until a large portion of the population is exposed to it. Further, vaccinated people have significantly less probability of infection and in case they do become infected, they experience a milder version of COVID-

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<sup>4</sup> Approximately 100 participating member countries suggested it to be part of a World Health Assembly resolution in response to COVID-19.

19 and are protected against its most severe complications. Hence, the goal of herd immunity for COVID-19 is different than herd immunity for other infectious diseases. In the case of COVID-19, the desirable goal is to achieve an immunity level within the community that will render the COVID-19 outcomes controllable (D'Souza & Dowdy, 2021; Klass & Ratner, 2021; Yigit, Ozkaya-Parlakay & Senel, 2021; Dong, He & Deng, 2021).

### **The need of global vaccine allocation, obstacles and different moral approaches**

Despite initial pledges from developed countries regarding equitable global access to vaccination against COVID-19, the reality resembles an ethical catastrophe. At the time of writing, approximately 3.73 billion people have received at least one dose of the vaccine globally, with 1.03 billion people being fully vaccinated. However, it is highly concerning that only 1.1 % of people in low-income countries have received at least one dose (Mathieu et al., 2021). The significant discrepancy regarding COVID-19 vaccination among different income groups is expressed even more by the fact that an important level of protection is out of reach for low-income countries until at least 2023 and that vaccination rates must increase nineteen times in order to reach 40% immunisation of their populations (Padma, 2021). This discrepancy brings into light the first primary element governing global distribution which is a country's purchasing power. The majority of the world's vaccines are produced by five international companies who negotiate with governments and private organisations for buying (McLean et al., 2016). Furthermore, during the COVID-19 pandemic, a very small number of countries possess the technological means and capacity to produce vaccines against the virus which represents the ability to develop. This is the second primary element determining global distribution. Vast technology transfer between countries is essential to accelerate global vaccine production capacity (Gates & Gates, 2020; WHO, 2021). Nonetheless, low-income countries contribute in drug development and testing in different ways, e.g., providing virological samples or participants for clinical trials (Alemayehu, Mitchell & Nikles 2018; Fidler, 2008). This behaviour should be rewarded fairly with priority post-trial access to medications in order to improve equitable distribution through a reciprocal system.

Consequently, insufficient global efforts to fairly distribute vaccines, are already establishing citizenship as the most important factor deciding vaccine distribution. In a nationalistic approach that favours unethical and inequitable allocation, these nationalistic interests of wealthy nations, such as the United States of America, have been expressed in various ways, e.g. the United States' initial refusal to join COVAX claiming potential self-sufficiency or by high-income countries purchasing 85% of the COVID-19 vaccine doses distributed up to date and vaccinating 12-year old children with low-risk of a severe infection instead of donating to the vulnerable populations of low-income countries (Rauhala & Abutaleb, 2020; Cohen & Kupferschmidt, 2021; Yamey, 2021).

During a pandemic, governments have a wide array of duties, such as cross-border responsibilities, since viruses do not recognise countries or borders (Lee et al., 2020). Therefore, the argument for equitable global allocation could be supported even on a strict nationalistic frame. Failure of a country to contain a virus within its borders exposes populations everywhere to a threat. Moreover, considering that many inhabitants of middle or low-income countries will most likely remain unvaccinated until 2023 and therefore uneven global vaccine distribution will continue, the potential consequences will be devastating (Ekstrom et al., 2021). The COVID-19 virus might mutate into variants which could render some of the vaccines ineffective, prolonging the pandemic and thus allowing more potential severe infections and deaths (WHO, 2021). Hence, a perspicacious government would allow distribution of the vaccine outside their borders, after vaccinating the required part of its population.

Contrasting ethical perspectives buttress discussions regarding national versus global vaccine distribution. The main idea behind vaccine nationalists is moral nationalism, the ethical

perspective that an individual has a special concern and duty for people with whom they share the same nationality and citizenship (Tan, 2004). On the contrary, moral cosmopolitanism is the rival of moral nationalism and the main idea behind those who support global vaccine allocation and distribution. Throughout history, moral cosmopolitanism has been given several different interpretations. For example, for the Stoics, human beings are not seen as members of provincial political societies but as citizens of the world. According to Kant, the community of moral argument is where all human beings belong and are a part of, an understanding that expresses the universality of the position of moral argument. More recently, the term has been adopted to describe a broad range of cultural, political or legal perspectives. Nonetheless, the most prominent contemporary perception is connected to none of these perspectives and it better relates to our comprehension of the virtuous state of human individuals. According to the latter, there are three common elements in all cosmopolitan interpretations. First is individualism, meaning that human beings or individuals are the ultimate unit of moral concern rather than states, nations, family bonds, religious, political, legal, or cultural associations, which can be units of moral concern merely indirectly as a result of their individual human beings. The second element is universality, advocating that each living human individual, irrespective to the subgroup where they might belong, such as men or nobles, is equally entitled to the status of the ultimate unit of moral concern. Thirdly, generality renders the power of this exceptional status universal, meaning that every human being is the ultimate unit of moral concern not solely for their fellow compatriots or people with whom they share a common religious, political or suchlike idea, but without exception to everyone (Held & Maffettone, 2017; Pogge, 1992). Interestingly, we can observe that both perspectives share a common characteristic. They both recognise that the need for duties to ‘compatriot’ or ‘foreign’ individuals might arise for distinct reasons, such as the need for efficiency or the goal of the optimal benefit (Tan, 2004; Pavel, 2009). In addition to moral cosmopolitanism, cultural cosmopolitanism depicts a particular perspective and represents another idea that favours global vaccine allocation and distribution. For cultural cosmopolitanism, an individual’s welfare is irrespective of their belonging to a specific culture and therefore supports cultural diversity, blending and the fluidity of an individual’s distinctive identity (Scheffler, 2002). However, a moral nationalist might claim that all forms of cosmopolitanism are a tool for poor countries to receive aid from the wealthy ones.

There is a growing belief that wealthy countries have a moral obligation and ought to do much more to help low-income countries, particularly to ensure their access to the advantages of modern medicine and state-of-the-art technology. Many experts have indicated the responsibility of wealthy nations to provide greater assistance to developing countries to counteract the HIV/AIDS epidemic in Africa (Nelson, 2002). This belief is the intersection point of various justice concepts debating distributive principles often applied to healthcare prioritisation. For instance, according to sufficientarian justice, the question whether a society is fair depends on whether each individual has the opportunity to secure enough goods to lead a minimally satisfactory life (Shields, 2020). Luck egalitarianism separates inequalities in two categories: fair inequalities, resulting from individuals’ intentional and fully knowledgable decisions (option luck) and unfair inequalities, resulting from decisions over which individuals have no control (brute luck). Inequalities ensuing from brute luck ought to be corrected since a person should not have less currency of goods or any metric than anyone else due to brute luck (Dworkin, 1981). Next, prioritarianism advocates the idea that it is more important to improve the well-being of people and especially of those who are the worst-off. It is distinct from egalitarianism in the sense that it finds higher intrinsic morality in benefiting worse-off people than better-off people and that the concern for benefiting the worse-off is irrespective of the benefit’s outcome (e.g., if the comparative welfare level difference between them and the better-off individuals elevates) (Nielsen, 2021). Lastly, utilitarian justice places more weight

on the equal promotion of everyone's well-being. All these justice principles align with moral cosmopolitanism and diverge from moral nationalism. Importantly, all of them place extra weight on the importance of human life and consider the duty to improve the life of the less-fortunate, regardless of their place of origin, fundamental in a humanitarian approach, that I believe if adopted, would define vaccines as essential goods for the preservation of health and life globally.

### **The ethics that should guide global vaccine allocation and distribution**

This failure of the developed world to establish and follow a well-defined and structured ethical framework for a global up to date COVID-19 vaccine allocation and distribution, has resulted in vaccine inequity that aside from prolonging the COVID-19 pandemic, has various consequential implications, such as hampering nations' financial recovery and the further spreading of the virus (WHO, 2021; Padma, 2021). Assuming that there is still time for governments to change the allocation and distribution pathway that they follow, setting the ethical principles that should govern this pathway is essential in order to make easier the decision-making and determining which policies should be adopted.

### **Prioritising people with the most urgent need**

The populations of poor and developing countries, which can be seen as the worst-off, need to be among the first priorities in global COVID-19 vaccine allocation and distribution. Prioritarianism, that has already been slightly referred to above, is a generally plausible and broadly shared distributive value that fits properly the needs of the COVID-19 vaccine priority setting. According to prioritarians, benefiting the worst-off has a bigger intrinsic moral weight than benefiting the better-off people, that distinguishes prioritarian weighting from utilitarianism or egalitarianism, which would prioritise the worst-off following a different rationale based on reducing marginal utility or improving inequalities. Practically, this means that we ought to benefit the worst-off individuals, irrespective of the utility-related or inequality reducing outcomes that this action will yield. Further, a second distinct principle of prioritarianism, advocates that benefiting the worst-off is based on their absolute (not comparative) level of wellness, and could be favoured irrelevant of the fact that the comparative difference between them and the better-off might increase as a result (Parfit, 1997).

One interpretation of the general prioritarian concept is the social justice prioritarianism. This theory suggests that the priority principle should condition the distribution of resources, such as the COVID-19 vaccine, and opportunities in the society, with the principle of benefiting the worst-off, having a higher moral intrinsic value. A justice principle that takes into special consideration the worst-off individuals is the right one to adopt since every rational and logical human-being recognises that the inequalities of these unfortunate groups are uneven. On the other hand, if we were deciding the values that ought to govern the vaccine allocation unaware of our own situation, a principle that would prioritise the worst-off should again be preferred. Therefore, I conclude that social justice prioritarianism can be defended on both consequentialist and contractualist grounds (Adler, 2012; Holtug, 2010; Rawls, 1971; Scanlon, 1998).

Social health factors shape health deficiency and vulnerability. However, this occurrence spotlights not only the wide social gap between the rich and the poor, but the existence of a constant universal health social gradient within society. Socially disadvantaged populations are more susceptible to health hazards, have a shorter lifespan and a lower quality of life compared to socially privileged populations. This is a result of different determinants, such as high population density, lack of clean water or food, poor housing conditions that increase the possibility of infection, low socioeconomic status, insufficient sanitation, limited access to healthcare, and significantly higher risk of poor outcomes. Further, limited, or even absent,



healthcare access establishes vaccinations as the most important preventive intervention, (Sadmi et al., 2020). All these factors highlight the socially unequal distribution of health risks and the urgent necessity to receive the vaccine. Consequently, these populations have the most urgent healthcare needs (Acheson, 1978).<sup>5</sup> Nonetheless, health needs should not be confused with healthcare needs (Wright, 1998).<sup>6</sup> Pandemic distributional outcomes place additional and disproportional weight mainly on the socially unprivileged and we have strong prioritarian reasons to protect the worst-off against the COVID-19 pandemic and ask healthcare systems to alleviate these unfair harms by giving them priority access to the COVID-19 vaccine.

At the top of prioritised groups in every country should be older adults who belong to the worst-off population groups. This is mainly due to their urgent healthcare needs, their high susceptibility to a severe COVID-19 infection and subsequent death, and their high benefit from preventative measures against the disease, such as face masks and social distancing. It is a moral duty to protect the elderly and, by giving them the vaccine, the possibility of infection is significantly decreased, and thus the social duty is carried out (Mallapaty, 2020; WHO, 2020). A high mortality rate due to COVID-19 is connected to advanced age worldwide. For instance, in the early stages of the epidemic in Italy, advanced age was associated with increased mortality, particularly around 80 % of deaths occurred in patients over 70 years old, while in South Korea the mortality rate was higher in patients over 60 years old (Kang & Jung, 2020; Amore et al., 2021). It is important to mention though that prioritising the elderly opposes the view of age-weight prioritarianism according to which the younger an individual is, the more important it is to save them. (Tsuchiya, 2000; Bognar, 2008).<sup>7</sup> Nonetheless, I believe that this perspective is not congruent with needs of COVID-19 vaccine allocation because it does not take into consideration the important duty of prioritising socially underprivileged populations and focuses strictly on the augmentation of life years based on age.

Another interpretation of the prioritarian idea is severity prioritarianism that views treating the most severely sick as fundamental. However, it can be argued that severity can be viewed as a multivariate idea, calling on urgency, fairness, and saving lives amongst others. Hence, protecting the individuals most prone to severe illness ought to be considered a profound duty as well. In practice, one possible explanation of severity prioritarianism can be provided by setting health deficiency as the base for the strict definition of the worst-off. Consequently, the most severely sick individuals or those with a higher risk of developing the most severe disease are considered as the relevant worst-off. The application of a prioritarian scope, suffering severely from COVID-19, that always includes the possibility of death, most likely establishes suffering people as worst-off compared to other individuals over the course of a life. According to this rationale, groups that should be given high priority include individuals with immunodeficiencies and patients with various underlying diseases, especially ones associated with a higher mortality rate due to COVID-19, such as hypertension, diabetes and obesity. All these groups are significantly susceptible to severe illness and society should not just recognise and list the predicaments of each group, but acknowledge the way that each predicament contributes to poor outcomes.

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<sup>5</sup> A healthcare need is defined as a need that requires medical care services and represents a humanitarian perspective since it implies that when human suffering occurs, clinical intervention is required to alleviate it.

<sup>6</sup> In the case of a health need, the potential benefit does not come strictly from a medical service but also from a wider set of factors, such as environmental or social variables.

<sup>7</sup> This theory advocates that an untreated disorder at an early stage of human life will make life harder than an untreated disorder at a later stage in the course of a lifetime and indicates the injustice of a younger person being deprived of the opportunities that an older person has already enjoyed in life.

### **Saving as many lives as possible**

The value of saving the most lives represents another principle that ought to govern global vaccine allocation and distribution, meaning that the most worthy action is saving lives and can be understood as a way of benefit maximisation. However, it can be defended from both a utilitarian moral perspective that focuses more on population consequences and a non-utilitarian scope that highlights the supreme worth of each human life (Kerstein, 2017). Practically, this value could be implemented to determine how many lives would be saved if equitable global COVID-19 vaccine allocation was promoted or not. For this purpose, the following variables should be examined:

1) Probability: Let us hypothesise that the implementation of equitable global vaccine allocation would result in saving 2,000,000 lives and inequitable allocation 500,000 lives. In this case, promoting equitable global vaccine allocation would be the right option since 1,500,000 more people would be saved and hence the benefit will be maximised with justice served equitably (Savulescu & Wilkinson, 2020).

2) Nature of the resource: While allocating and distributing scarce resources, the fact that resources equal to number of lives should be considered seriously. In particular, for COVID-19 vaccine allocation, this fact is even more important since the vaccine will not only increase the receiver's possibilities of a severe infection and subsequent health complications, such as death, but will also decrease significantly transmission to others. Therefore, the benefits to society are maximised both directly and indirectly, in the short-term and long-term.

Maximising lives saved is the main principle behind standard hospital triage implementation during a disaster, such as during the early stages of the COVID-19 pandemic in Europe, aiming to save the most lives by giving priority to patients sick enough to benefit from the potential resource and unlikely to survive without it (Maves et al., 2020). Operationalising the fundamental value of maximising benefits, in allocation and distribution of scarce resources, such as ventilators, during a pandemic relies on the prioritisation of sick patients with a higher chance of not just surviving (higher possibility of being discharged) but surviving for longer with the resource over sick patients with low possibility to survive even with the resource or with a high probability to recover without it. This is contrary to the current allocation needs where the vaccine, as a scarce resource, is most likely to save more lives when distributed to people with a high risk of serious complications or death in case of infection and to old individuals (Persad, Wertheimer & Emanuel, 2009; Zucker et al., 2015). The current COVID-19 vaccine allocation needs are served from a utilitarian perspective since in order to maximise the vaccine's utility and, thus, the benefits, it must reach those people who rely on it the most.

Throughout history, resource allocation during a public health emergency has been shaped by the utilitarian goal of maximising net benefit which can be translated as saving the most lives. Further, it is the most common bioethical approach when trying to address resource allocation during a public health crisis (Bayer et al., 2011). In 2021, Goldstein et al., concluded that vaccinating the elderly with a higher priority not only saves the most lives but also the most years of life (Goldstein, Cassidy & Wachter, 2021). In support of this finding, Emanuel et al. recommended that, since COVID-19 has more devastating results on older individuals or people with chronic conditions, they should be prioritised over young patients, in a strategy attempting to save the most lives. On the other hand, it was suggested that younger patients should only receive priority if there is scientific proof that it would benefit public health through reduced viral spread and risk of infection (Emanuel et al., 2020).

### **Quality of life**

For utilitarianism, it is highly significant that the maximisation of lives saved is accompanied by a good level of well-being through the course of each life. Therefore, the quality of life is considered fundamental. However, there is a lot of controversy regarding how to define quality

of life and what it really means, in an attempt to at least set a minimum quality of life threshold. In general, quality of life is either described directly in terms of the wellbeing acquired from goods or indirectly in relation to the wellbeing acquired from the goods' characteristics. In a non-utilitarian approach, quality of life might be linked to the intrinsic characteristics of people, such as genetic predisposition of health, their relative deprivation irrespective of total commodity consumption or the features of those commodities, their moral value and meritoriousness. Furthermore, it might relate to the nature of relationships among people, such as quality of friendship, community provision for the worst-off and social seclusion, or alterations to their statuses, such as becoming a widow/er or getting divorced. Nonetheless, the most conventional approach is the welfarist one. According to this, not just the quality of life, but also the standard of living, effective social dispositions and distributive justice, are all measured in relation to the utilities of the people involved. The utilitarian ethical value, that the total or average utility must be maximized, characterises this form of welfarism (Culyer, 2012).

In order for an individual to be able to have access, achieve and enjoy an adequate level of life quality, a fundamental requirement ought to be fulfilled. Arora et al. stated that 'unconsciousness or severe disorders of consciousness, such as minimally conscious state' as a permanent result of intensive care would pass below the minimum life quality threshold (Arora et al., 2016). However, in COVID-19 vaccine allocation and distribution, the cause of an unconscious state should be irrelevant, for example, it might be the result of intensive care due to severe COVID-19 complications or due to a car accident or a progressive mental illness. To explain it thoroughly, I will formulate an extreme example. Unconsciousness is the final result of dementia. Imagine that we have two patients, both over 70 years old and candidates to get the COVID-19 vaccine. The first patient has a functioning level of consciousness and the second patient has end-point level of dementia. In the case that we could not administer both with the vaccine, utilitarianism would prioritise the first patient over the second. The second patient would receive no benefit from being protected and kept alive in an unconscious condition. Concerning minor levels of cognitive impairment or disabilities, from a utilitarian scope, if they affect the well-being of an individual they should also be assessed when deciding allocation policies.

Nonetheless, comparing the overall wellness of different individuals can be a deceitful and complex task. It cannot be taken for granted that someone with a disability would have a lower level of wellness and would benefit less from a scarce resource, such as the COVID-19 vaccine, than someone with no disability. For example, someone with a 50% loss of vision in the right eye will not necessarily have a worse level of wellbeing than someone with normal vision. One of the most intense ethical questions is which factors define a person's life as good or which are the elements of wellness and has been a philosophical topic of debate for centuries. Potential answers to this question include a person's overall happiness, satisfaction of desires, being autonomous and independent, and having strong and meaningful interpersonal relationships (Parfit, 1984; Griffin, 1988).

### **The multiplier effect**

During the COVID-19 pandemic, the implementation of further selection criteria to guide vaccine allocation and distribution is crucial. According to utilitarianism, all actions have consequences, direct and indirect, short-term, and long-term, and they are all associated with decisions. Therefore, it would be useful to contemplate not only the benefit for a person affected by an action but also the benefit that this action might have for others.<sup>8</sup> I propose that on a global scale, frontline healthcare professionals with increased exposure to the virus due to their workplace should be highly prioritised for vaccination in an attempt to maximise the utility.

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<sup>8</sup> Social worth or social benefit.

This category includes not only physicians, nurses and clinical pharmacists but also respiratory technicians or any other category of worker providing important benefits to others. Prioritising frontline healthcare professionals can be ethically justified using three main arguments. Firstly, by giving them priority, a society benefits not only themselves but also all the people that they take care of in hospitals or clinics during the pandemic, creating the multiplier effect that increases benefits. The multiplier effect, also known as “narrow social utility” is a value advocating that certain occupations should be prioritised due to their short-term value to the community during a public health emergency or crisis. This short-term value is measured in terms of saving lives, keeping the critical infrastructure operating or prevent societal disintegration through the practice of certain professions.<sup>9</sup> Therefore, front-line healthcare professionals and individuals who care for ill patients ought to be treated with the highest priority since they are essential for the smooth and efficient operation of the critical healthcare system and/or their protection is beneficial for the society’s common good (Childress, 2003; Emanuelson et al., 2020; Winsor et al., 2014).

A narrow social utility example occurred in World War II when penicillin was considered a scarce resource and was firstly administered to soldiers who were suffering from syphilis but were able to make a full recovery and go back to fight rather than to soldiers with severe injuries unable to return to battle (Beecher & Dorr, 1970). During a pandemic, there might exist a sufficient number of ventilators but a shortage of expert personnel able to handle them. Therefore, vaccinating the healthcare providers may prevent them from getting sick or recover fast enough so that they can continue saving lives. This assumption, however, relies both on the duration of the COVID-19 pandemic and the speed of the recovery so that the individual can return to work.

The second argument for prioritization of frontline healthcare professionals relies on the nature of their profession that includes the possibility of harm during the practice of their profession and the subsequent service to society (infected while caring for others). A way to better analyse it is by using the social contract metaphor which advocates that the agreement of healthcare professionals to put themselves at risk while serving society by treating the ill, is rewarded by society with advantages and powers. As part of this agreement, the society ought to protect healthcare professionals from getting sick or care for them in case they do (Cruess & Cruess, 2010). A third and final argument, calls on society’s moral duty to benefit those who benefit society, which constitutes the value of reciprocity which assigns duties not only on the side of healthcare workers but also on the side of governments and other private individuals (Becker, 1990)

An important arising question is what happens about the social worth of others. Should other population groups such as immigrants, prisoners, lab scientists, pregnant women, dependent children, parents, and athletes have lower or higher priority access to scarce resources, such as the COVID-19 vaccine? The complexity of developing rules for assessing social worth is very high from both an ethical and epistemic perspective and critical level utilitarianism would most likely not support such prioritisation, except of essential frontline healthcare professionals or people with serious health comorbidities, such as diabetes, since they have a high degree of clarity, is easy to apply and has broad social approval. Notably, operationalised utilitarian values are prone to potential misuse. Hence, when the risk of value misuse is identified, it should be assessed to determine whether to operationalise the value or not. For instance, the argument of advantage is used by the mighty to misuse social worth.

Another important objection is dealing with the appearance of favouritism created by the decision to prioritise frontline healthcare professionals. Giving priority to this group should not be received as a form of favouritism due to their higher societal value but solely because, at this

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<sup>9</sup> Further, this short-term value is what distinguishes narrow social utility from broad social utility, which judges the collective individual’s value to society.

particular instant, they are the most suitable people to keep society operating and prevent its collapse, manifesting their short-term value to society. This selection has been strictly based on maximising utility and thus the benefit and is reflected in my proposal to include, in the frontline healthcare professionals group, not only strictly physicians, nurses and clinical pharmacists but also any other individual providing important services to benefit other people. Nonetheless, I consider the narrow social utility approach a little problematic in the current COVID-19 pandemic, if applied blindly and unanimously worldwide without taking into consideration various other parameters, such as the estimated duration of the crisis at the national level, and geosocioeconomic factors, such as origin, age group, socio-economic background and comorbidities that could affect recovery speed, the susceptibility to infection and the severity of a potential infection. All these parameters could influence the ethical rationale for such prioritisation. To explain it properly, I will present an example. We hypothesise that the duration of a COVID-19 wave crisis in Greece is three to four months. On one hand we have Nikos, who is a 26 year-old pharmacist at a Greek hospital and has no underlying conditions, such as diabetes, obesity or hypertension. He is mainly responsible for inventory control of drugs that plays a pivotal role in hospital management. However, due to the nature of his position, his contact with physicians (most of them have already been vaccinated and thus they have a significantly small transmission rate) within the hospital is small and he rarely enters rooms where infected people have been placed. On the other hand, we have Kostas, a 55 year-old Greek postman, who is a heavy smoker and has diabetes mellitus type 2 and chronic obstructive pulmonary disease (COPD). He comes in daily contact with various people (we cannot know the vaccination rate among them) while delivering their letters and parcels. If we cannot give the vaccine to both of them, prioritising Nikos over Kostas strictly because he is a frontline healthcare professional might not be the ideal solution. Kostas most likely has a higher risk of severe infection, due to many factors, from COVID-19 and serious subsequent health complications, such as the need for intensive care or even death and thus by giving him the vaccine, we maximise the utility and the net benefit. Moreover, even if Nikos gets infected, the condition of his health and his age are likely such that will most likely allow him to recover fast enough and return to work before the end of the crisis even without the help of the vaccine. Therefore, a more personalised evaluation, even if more complex and time consuming, would be a step in the right direction.

### **The booster controversy**

Several wealthy countries, such as Israel and Germany, have announced plans to begin booster-shot administration in August 2021 in an attempt to further safeguard their populations against COVID-19 infections. The third dose administration is based mainly on the fear of the dominant delta variant that emerged from poorer countries, without clear definite evidence that would justify this revaccination need. The WHO recognises the need for an additional vaccination for specific reasons, such as decreased protection from severe infection due to weakening immunity, lower protection against emerging serious variants that render the existing vaccination insufficient and ineffective protection from the currently recommended vaccination regimen for some risk groups. According to the WHO, though the logic underlying booster doses may vary according to vaccine manufacturer, epidemiological setting, risk group and vaccination coverage rate. A booster is an additional mRNA-based vaccine shot on top of the previous ones, that increases the level of antibodies against the pathogen after the drop that occurs approximately 2 to 3 months post complete vaccination. The level of antibodies will decrease once again but the collection of memory B-cells, that protect the organism from future infections by this pathogen, will be significantly larger than before. Nonetheless, this decision of wealthy countries has been highly criticised by activists and non-profit organisations around the world, such as Doctors Without Borders (DWB), on the grounds of worsening the already

unfair global vaccine allocation and distribution and exacerbating social gaps, and the WHO called for a moratorium to be applied on booster shots at least until the end of September 2021 in favour of unvaccinated people who represent the majority of the world. Further, global-health researchers assert that each booster administered equals a vaccine that could be given to a citizen of a middle or low-income country where the majority of the population is unprotected and subsequently serious COVID-19 variants might emerge (Maxmen, 2021; The Lancet Infectious Diseases, 2021; Callaway, 2021; UCL, 2021; WHO, 2021). Considering the fact that access to healthcare, such as vaccination, is probably the most fundamental social primary good since diseases and health disorders can damage a society's overall happiness and satisfaction, seriously affecting self-confidence and self-esteem, the equitable provision of this good should be made available equitably to all people universally. Depriving poor countries from the vaccine, and instead providing it again to citizens of wealthy countries where more than half of their populations have received the primary series of the vaccine and all consenting essential workers and adults have been immunised, would be highly questionable for utilitarians who would rather prioritise those at a higher risk of infection from the virus and subsequent serious health complications. The utilitarian position takes these vulnerable populations into consideration and by giving them priority relieves not only the increased social stress during this time but also the increased stress at hospitals.

The rationale for booster-shots might be justified in terms of protecting public health and fighting the virus but the timing and ethical background of this decision is problematic. With wealthy countries having been able to administer 100 shots per 100 citizens and poor countries only 1.5 shots per 100 citizens, the booster dose policy will worsen inequities and injustice since it will increase the consumption of scarce resources by wealthy nations while at the same time even priority groups of poor countries have not been able to receive the vaccine's primary series (WHO, 2021). This injustice is highlighted even more by the fact that citizens of LICs have a higher vaccination acceptance rate than citizens of HICs, such as United States (Solis-Arce et al., 2021). Prioritising the vaccination of poor countries instead of booster doses for wealthy ones at this moment would be in the best interest for all parties involved from either a nationalistic or cosmopolitan perspective since it will diminish the threat of potential novel emerging variants in poor countries which would spread worldwide and inevitably affect everyone (UN, 2021).

Through a more consequentialist scope, someone could claim that if global herd immunity, as a collective good, is the primary goal and desirable outcome, prioritising the vaccination of poor country populations instead of administering booster-jabs to citizens of wealthy nations, who already have a sufficient coverage, would be the right decision in order to achieve it and maximise benefits. If wealthy populations get the booster, it might protect them from the danger of harm from viral infection in the short-term, but in the long term they will worsen the devastating consequences of unfair COVID-19 vaccine allocation and distribution. Most likely new variants of the virus will emerge in countries where the majority of the population would still remain unvaccinated, which will inevitably spread universally and cause the existing vaccinations to once again become insufficient and hence the need for more boosters will emerge in a never-ending vicious cycle. I can conclude that, this action's negative social consequences will prevail over the positive ones and therefore I consider it ethically unsuitable.

Another possible way to examine the issue is through the principle of the least restrictive scenario, which represents a utilitarian principle and is a key principle in public health ethics, but first we need to define its proper formulation (Childress et al., 2002). For the purpose of this paper, I will utilise this principle to determine the adoption of the right vaccination policy to achieve the goal of global herd immunity, taking into account the criterion of the least violation of personal rights as well (Gostin, 2008). However, an interpretation of what might be leaning towards restrictiveness can possibly emphasise more the potential harm arising from

particular policies, rather than intrusion of rights and freedoms (Pugh & Douglas, 2016). Hence, if a policy poses more risks for people, it can be considered more restrictive compared to the alternative ones irrespective of whether it infringes on freedoms or not. Applying this rationale on the booster issue, I tend to believe that the least restrictive alternative would be the alternative that carries the lowest threat of harm for the global population, in agreement with the desirable goal of herd immunity. Therefore, the implementation of the booster-shot policy for wealthy countries' populations rather than the distribution of these vaccines to poor countries where the majority of people remain unvaccinated, would be highly controversial since it will most likely prolong the COVID-19 pandemic, act against the universal goal of herd immunity and cause more harm in a global scale through the subsequent consequences of this action, such as potential new serious variants of the virus or further lockdowns and in-house isolation globally that could be seen as a violation of human freedom and autonomy.<sup>10</sup>

### Conclusion

The COVID-19 pandemic brought again into light the issue of even, equitable allocation and distribution of scarce resources, such as the novel COVID-19 vaccine. It still remains controversial whether a country should distribute doses to its own citizens or if distribution should occur at a global scale and which principles or values should govern each scenario. I support global vaccine distribution with higher priority given to populations of poor and developing countries in an attempt to help the worst-off individuals with the most urgent needs. Globally, older individuals and front-line healthcare professionals (under certain criteria) should be prioritised along with people with a higher risk of severe infection and subsequent death. Ethical values such as benefiting the neediest people, decreasing social gaps, saving as many lives as possible and keeping society operating ought to be reflected in our prioritisation for even allocation and distribution. Equitable global vaccine allocation can be accomplished even at this point if wealthy countries, which now have a good level of coverage against the virus, allow the redistribution of surplus doses to those who have been deprived of them, through the COVAX initiative which can guarantee fairness and equity for every country in the world.

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<sup>10</sup> However, utilitarianism liberties and rights are important as far as they protect welfare, which is all that matters.

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## Moral bioenhancements and the future of utilitarianism

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### Abstract

Utilitarianism has been able to respond to many of the objections raised against it by undertaking a major revision of its theory. Basically, this consisted of recognising that its early normative propositions were only viable for agents very different from flesh-and-blood humans. They then deduced that, given human limitations, it was most useful for everyone if moral agents did not behave as utilitarians and habitually followed certain rules. Important recent advances in neurotechnology suggest that some of these human limitations can be overcome. In this article, after presenting some possible neuro-enhancements, we seek to answer the questions, first, of whether they should be accepted by a utilitarian ethic and, second, if accepted, to what extent they would invalidate the revision that allowed them to escape the objections.

**Keywords:** moral bioenhancement, human enhancement, utilitarianism

Utilitarianism has survived in part because it has revised its postulates with the intention of presenting itself as a realist theory. To demand strictly the best for all was to expect human beings to behave like moral saints. Thus, the utilitarians eventually came to believe that the theory should accommodate flesh-and-blood agents, who would do what was right in consequentialist terms, but within their cognitive and motivational limitations. Recognition of these limitations led them to maintain, paradoxically, that it is often in everyone's best interest for the agent not to behave like a utilitarian agent. Instead, they prescribed following deontological rules. This allowed them to respond to much of the strong criticism that had previously been levelled at them for their demanding and counter-intuitive prescriptions and, in so doing, to keep the theory afloat.

But, in the near future, this theoretical resource of utilitarianism may cease to be an effective life vest. Current neurological and biotechnological advances may make biological interventions that enhance our capacities, including those related to morality, a reality. At that point, human beings could no longer be blamed for those limitations that prevented them from fully meeting the demands of utilitarianism. If such "moral bioenhancements" were one day feasible, would they not require a thorough revision of utilitarianism to bring it back into line with an (updated) realist conception of human nature? And if that nature were to be less limited, shouldn't the theory now demand, based on its commitment to the optimum, that the agent forget the rules and do in each situation what has the best consequences for everyone? Wouldn't this entail the obligation to behave "monstrously" in the search for the common good, forgetting, if necessary, about personal rights and obligations? These are the questions I pose in this article. To do so, first, I will show how in the structural revisions of utilitarian theory the recourse to certain limitations or weaknesses of the human being has been crucial and how this has allowed the theory to survive the strong criticism that has been levelled at it. In the second section, I will review the current possibilities of using biotechnology to avoid or alleviate those human limitations that prevented the utilitarian agent from fully applying the principles of the theory. In the last section I will argue for some basic requirements that bioenhancement interventions should meet in order to be considered ethically acceptable, I will test whether the interventions necessary to enhance the utilitarian agent meet them and, if so, whether this would strip the utilitarian theory of its hitherto fruitful remedy.

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### **Ought implies can: Human limitations as a theoretical resource**

At first sight, there is something strange in an ethical theory that starts from the criterion that what is right consists of always seeking what is useful, when morality is usually conceived as a sphere of behavioural regulation in accordance with non-negotiable principles, whose fulfilment should be alien to consequential considerations. This initial impression of strangeness has been accompanied, in the academic sphere, by strong criticism of the theory, arguing that from the utilitarian conception of what is right it is impossible to respect, to an adequate degree, both personal autonomy and duties, as well as individual rights.

On the one hand, the consequentialist scheme that underlies this utilitarian conception of what is right,<sup>2</sup> due to its neutral and global perspective, in which there is no place for what is permissible because everything that is not optimal is forbidden, prevents us from assigning preference to our commitments, projects and loved ones. Devoting time and resources to oneself or one's kin at the expense of the general good would constitute an unacceptable licence for any consequentialist agent (Williams, 1973, pp. 116–117; Railton, 1984). On the other hand, if the ultimate goal is to achieve the best outcomes, any action that allows us to do so would be justified, including those that do not respect important individual rights. At the time, this possibility aroused the most gruesome imagination of some critics. Utilitarians were accused of allowing, because of their consequentialist theory of rightness, such heinous and ruthless actions as falsely incriminating an innocent person in order to prevent riots and lynchings (McCloskey, 1957; Foot, 1967; Nielsen, 1972); blowing up the obese person blocking the mouth of the cave as the only way to prevent his companions from drowning when the tide comes in (Nielsen, 1972); persuading a frightened old woman by twisting her grandson's arm to hand over car keys to take injured people to hospital (Nagel, 1986, p. 176); or even dismembering someone in order to save several sick people with their organs (Foot, 1967; Thomson, 1976).<sup>3</sup>

It is not surprising, then, that this consequentialist conception of moral obligation as something empirical and relative and the consequent criticism of the counter-intuitiveness of its normative implications led to predictions about the short future of the theory. Thus, Bernard Williams (1973, p. 150), for example, already maintained in the early seventies that the day could not be far off when we would no longer hear of utilitarianism.

But such predictions have not been accurate. The extensive literature and specialised community to which utilitarianism has given rise shows that it continues to be one of the protagonists of the current ethical debate.<sup>4</sup> What is the reason for this survival of utilitarianism, contrary to the understandable predictions?

A first explanation could come from the same consequentialist scheme that was used by many to criticise it. If everything is a question of achieving the best results, any morally difficult or dilemmatic situation can be resolved by doing the least bad thing. To the attraction, for some, of this pragmatism, we must add the fact that the theory incites, more than others, activism and social conscience. In contrast to deontology, which is based on what is prohibited, consequentialism opts for what is obligatory, for a broad conception of moral responsibility, for which all kinds of consequences (immediate and long-term, direct and indirect) deriving from both actions and omissions count.

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<sup>2</sup> Utilitarianism is basically composed of two theoretical components. A welfare conception of what is good and a consequentialist conception of what is right. Thus, if for the latter, our obligation is to do that which brings about the best results for all, considered impersonally, for its conception of the good, the value of the results must be measured in terms of welfare.

<sup>3</sup> On utilitarianism's inability to take individual rights seriously, see also Fried (1978, pp. 81–105), Glover (1977, pp. 73–75), McCloskey (1957) and Williams (1973, pp. 97–100).

<sup>4</sup> Proof of this are the expert societies to which this theory has given rise, among which the International Society for Utilitarian Studies and the Ibero-American Society for Utilitarian Studies stand out. In addition, these societies publish the specialised journals *Utilitas* and *Telos*, respectively.

However, it is evident that this resolute and mobilising character of consequentialism does not explain by itself the survival of utilitarianism, since, as I said above, the criticism of utilitarianism is derived from it as well. What will allow utilitarianism to really free itself from criticism are certain structural modifications in its theory. The most significant of these is a differentiation between the criterion of moral correctness and the decision-making procedure we derive from it. This allows one, in principle, to maintain that, even when the criterion of correctness tells us that the right thing to do is to behave optimally, this does not mean that we always have to decide what to do by calculating the consequences of possible actions.<sup>5</sup>

Now, in order not to depart from the consequentialist scheme, this permission not to calculate at all times must have an empirical foundation, it must be justified by virtue of the limitations. One of these limitations is purely cognitive because it is often not within our reach to know what the consequences of our choices will be. But there are also motivational limitations. It is common for us to interpret data in a self-interested way. Thus, for example, we are prone to believe, contrary to available information, that acting in our own interest, or in accordance with some cultural prejudice, coincides with what is best overall. In other cases, emotions prevent us from appreciating what is right or weaken our will to be governed by it.

Therefore, if by our limited nature, we cannot behave as agents who always choose the optimal action, it makes no sense to defend strict consequentialism as a decision-making procedure, even if our normative criterion is still to do what is optimal. It will often be best for the agent to be guided by consequentialist evaluations not of the particular action options before him, but of the general patterns of behaviour - rules, predispositions, virtues, institutions, etc. - to which those behavioural options would be subsumed. Thus, if one considers that, for example, predispositions or virtues are the factor to be evaluated in terms of consequences, one should not calculate at each moment which particular action has the best results; one should only perform that action which conforms to that character trait (loyalty, honesty, aversion to inflicting pain, gratitude, spontaneity, etc.) which, if regularly followed by all, produces the best results (Driver, 2001; Hurka, 2001; Jamieson, 2007; Bradley, 2005).

This strategy of deciding by evaluating the consequences of general behavioural patterns, however, poses the difficult challenge of articulating the regular following of such patterns with the consequentialist spirit that must infuse them. How can we harmonise the defence of non-contingency that comes with following internalised rules or predispositions without considering the consequences of doing so in each situation, with the consequentialist non-complacency that demands always being attentive to changing circumstances in order to achieve the optimum? What about those situations in which, considering all relevant aspects, we very reliably believe that we will get the best result by doing the opposite of what our rules and predispositions prescribe?

The most successful way to meet this challenge to consequentialism is by resorting to a two-level ethical theory of deliberation. On one basic level, the agent would be governed by these general guidelines of conduct, considered as if they were unrenounceable; and on the other, critical, the agent would consequentially justify both the existence of such guidelines and the possible exceptions to following them (Hare, 1981). Thanks to this theoretical resource, it can be argued that, even if we normally behave according to general guidelines, we do not lose coherence by accepting that such guidelines cannot always govern our decision about what we

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<sup>5</sup> This differentiation of functions can, in principle, be defended by any normative ethics that seeks to implement its abstract principles. See Feldman (2012, p. 151). However, it has been the utilitarians who have explored this avenue the most, especially since Bales (1971). This has been done, for example, by Adams (1976), Ellis (1981), Railton (1984, pp. 100–106, 113–117), Parfit (1984, pp. 24–29), and Pettit (1986, p. 194). It should be noted, however, that even in a less explicit way, this differentiation of functions has been present in the utilitarian tradition since its origins. See, for example, Bentham (1789), chap. IV, sect. VI, Mill (1861, p. 64), and Sidgwick (1907, p. 413).

should do. And they will not govern it in exceptional situations where, either because of some control of the main decisional factors, or because of the very bad conditions, we can, in consequentialist terms and with probable success, resolve conflicts between guidelines or choose new guidelines for new stages. In such situations we would be making decisions from the critical level.

With this modification of the theory, utilitarian consequentialism can now respond to criticism. On the one hand, it can justify special obligations towards relatives by pointing out the best consequences of not calculating at all times whether or not to respect them. For example, it can appeal to the happiness and lower psychological cost of normatively directing people according to a predisposition, in line with the natural inclination of parents to put the interests of their children before the general welfare (Hare, 1981, pp. 136–137). Moreover, if they are not required to constantly calculate their relationships with relatives, it will be easier to maintain a socially beneficial institution, the family. It would be difficult to maintain ties, for example, between parents and children if the latter realised that the former were caring for them purely in the general interest, not because they felt a predilection for them.

The same would be true of respect for individual rights. Internalising this respect has better consequences than constantly calculating its desirability. Firstly, because due to our cognitive limitations, one can hardly be sure that one is in that exceptional situation in which it would really be advantageous to violate rights. For in order to undertake something normally as harmful as, for example, killing, torturing or enslaving an innocent person, one has to have very strong, and unusual, evidence that doing so will ultimately be more advantageous.

Therefore, in the face of that usual lack of certainty, it will almost always be better to do what is usually in everyone's interest, in this case, to respect rights. And it is usually best for all because, in addition to protecting its direct beneficiaries, the prescription of such respect would allow for sufficient trust among agents to enable cooperation and, ultimately, the very existence of society (Harsanyi, 1977, pp. 12–16; Hodgson, 1967, c. 2; Brandt, 1979, pp. 271–277; Johnson, 1991, c. 3, 4, 9; Pettit, 1986, pp. 450–451; 1988, pp. 51–53). Only if rights, such as to life or property, are guaranteed outright, is it in the interest of agents to covenant with others and to honour the covenant, despite the personal sacrifices that the covenant entails.

In short, there are consequential reasons to demand not to calculate normally but to respect obligations and rights, and even for these rules to be internalised in such a way that people are reluctant to violate them, except in exceptional situations. But these consequentialist reasons for not behaving as a consequentialist are only grounded by virtue of the aforementioned cognitive limitations and that natural tendency to bias, which leads agents to put their own self-interest and sentiment before the common good. It is the recognition of these limitations and their normative implications that has allowed utilitarianism to be revised in order to survive. But what would happen if advances in neuroscience and biotechnology were to overcome these limitations, and should utilitarianism demand that such advances be used to morally improve human beings? Would the theory then be forced to return to its original defence of an extremely calculating moral agent?

### **Possible bioenhancements of the utilitarian agent**

The first thing to do would be to ask about those biotechnological advances that could modify individuals to make them better consequentialist agents. To do so, I will elaborate on the limitations that served to justify the well-worn two-level theory, and then outline the neurological interventions available to us now or in the short term to address these limitations.

#### *Enhancing our ability to foresee the consequences of our actions*

In principle, utilitarianism, because of its consequentialist conception of what is right, is a more fallible theory than others. Although we can sometimes anticipate the effects of our actions, we



will never be certain of them. Moreover, the more distant and global the effects, the less certain. Thus, an act that seems to lead to good results can always lead to disaster. It is true that, after all, life is full of risks and uncertainties and, even so, we do not stand still, we do things on the basis of more or less reasonable forecasts. But such forecasts based on uncertain calculations, which may serve to make prudential decisions, will be of little help to a behavioural domain in which the right thing is intended. Can someone be said to have done the right thing when doing what *seems* optimal produces lousy results? From a consequentialist perspective, can this be said of the individual who, in 1938, threw himself into the river to save a stranger who later turned out to be Adolf Hitler? (Smart, 1973, p. 59).

The above-mentioned distinction between the criterion of moral rightness and the decision-making procedure is also very useful to get out of this impasse. For, even if the right thing to do is still only that action whose consequences *actually* maximise the good, the way of deciding may be designed in accordance with human limitations to require only that action which conforms to *the probable expected consequences, in the short or medium term*. In the words of Ingmar Persson (2008), it would be something like distinguishing between what we should do, maximising actual value, and what we should try to do, maximising expected value.<sup>6</sup>

Even so, this does not exempt the agent from *trying* to maximise expected value by acquiring as much certainty as possible about the consequences of his choices, using all the means at his disposal. He must therefore make a mental effort and inform himself “externally” as much as he can; but if he can improve himself “internally” to improve the degree of certainty of his deliberations, he should do so as well. What does biotechnology offer today for this purpose?

Among the smart drugs or nootropics, Modafinil (Provigil) stands out, as it appears to have neither side effects nor chemical addiction (Myrick et al., 2004). It is a neurostimulant commonly used for sleep disorders and attention deficits and has recently been shown to improve working memory by inhibiting rapid adaptive response. It allows for an equally rapid, but much deeper response due to better use of certain areas of memory (Sanderg, 2011, p. 74). This tremendous mental functionality and its effects in costlessly extending wakefulness and attention make this drug an ideal tool for making better consequential decisions in complicated situations that require sustained concentration and, at the same time, lucidity in the use of memorised information. An alternative technology that is also showing good results in terms of possible cognitive enhancement with respect to consequential foresight is brain stimulation. Studies show how transcranial magnetic stimulation, in particular, could increase or decrease the excitability of the cortex, thus changing its plasticity levels, and thus improving, among other things, working memory (Fregni et al., 2005).

### *Strengthening the will with greater impulse control*

Doing what one believes to be right is not always easy. This phenomenon was known to ancient philosophers as weakness of the will (*akrasia*). This human limitation was also among those that were adduced to justify why human beings cannot be asked to behave as strictly consequentialist agents. However, insofar as this limitation sometimes has a biological origin, it could be partly rectifiable. The weakness of the will often responds to a dysfunction similar to that suffered by people suffering from some kind of addiction. I refer to the inability to delay gratification. When these people find immediate incentives to perform an action, they lose sight of the reasons, supported by indirect and long-term incentives, against performing that action. Recently this thesis has been confirmed by physiological studies of even more impulsive

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<sup>6</sup> This possible solution to the fallibility problem of consequentialism, integrating actual and probable outcomes, would settle a long-standing internal debate between those who, following Mill and Bentham, favoured a probabilistic or subjective consequentialism (Hudson, 1989; Jackson, 1991; Howard-Snyder, 2005), and those who thought that what is right is what, in fact, objectively, produces the best outcomes (Bales, 1971; Brink, 1986; Railton, 1984; Smith, 1988).

individuals, such as psychopaths. They show both increased activity in the ventral striatum region of the brain, which is responsible for our inclination towards immediate rewards, and a reduced connection of this area with the prefrontal cortex, which is associated with future-focused decisions (Hosking et al., 2017). But impulses may have a deeper physiological cause, which in addition to explaining addictive or unrestrainable behaviour, better accounts for weakness of will. They may be due to an inadequate functioning of the serotonergic transmission system. When this happens, the orbitofrontal cortex of the brain, the area where emotions are regulated, receives inadequate doses of serotonin and, as a consequence, impulses can sometimes not be controlled, nor emotional reactions to provocation or temptation regulated. Therefore, if a person with this dysfunction were to take a selective serotonin reuptake inhibitor (SSRI), a substance used to combat certain psychological disorders, they could slow down the uptake of serotonin (also balancing dopamine and noradrenaline) and thus control their impulses and strengthen their will to act according to those intentions and reasons that are more consistent with their values and the relevant data (Stahl, 2006).

### *Counteracting the tendency towards self-interest*

Many actors do not pursue the best consequences for all concerned because this entails a significant personal effort and/or a sacrifice of self-interest for the common good. But this could also be remedied, in part, by neurology; in particular, by the discoveries made about the intervention in the nervous system of the oxytocin, a hormone that also functions as a neurotransmitter and is partly responsible for the predisposition of some mammals to mate bonding and offspring care (Hasting et al., 2014). It has been artificially synthesised and has been shown to enhance certain empathic abilities important for perspective-taking in humans when administered nasally or intravenously. Thus, for example, it facilitates the identification of emotional states when looking at photos that only show the surroundings of the eyes (Domes et al., 2007), makes the subject look more closely into the eyes of the other (Guastella et al., 2008), improves the recognition of positive emotional expressions (Marsh et al., 2010), or helps autistic people to better understand affective language (Hollander et al., 2007). Furthermore, scientific evidence shows that the involvement of this substance in neural systems can explain the altruistic motivation to avoid the suffering of others (Bartels et al., 2004; Insel & Fernald, 2004; Dolen et al., 2013), and that when administered to humans, they sacrifice more for others and become more trusting, reciprocal and generous (Kosfeld et al. 2005; Reyes & Mateo, 2008; Morhenn et al., 2008; Rodrigues et al., 2009; Barraza 2010; Zak et al., 2004; 2005; 2007). In enhancing sociability and promoting cooperation, it has been shown that SSRIs, by increasing serotonin levels, may also have an important effect (Wood et al., 2006; Tse & Bond, 2002).

### **Ethical requirements for bioenhancements**

It follows from the above that we already have biotechnological resources to alleviate, in part, the biological limitations that prevented individuals from behaving as full utilitarian agents. But does that mean that we should use such resources? I will argue in what follows that, from an ethical point of view in general, and from a utilitarian point of view in particular, at least the following two requirements should be met to answer this question in the affirmative.

#### *1. The principle of security*

Despite the theoretically positive effects of the above interventions, they could be risky for health because of possible side effects. It should be borne in mind that most of the neurotransmitters or brain areas affected by the stimulation substances or techniques normally serve many functions. Thus, for example, serotonin, in addition to having effects on social behaviour, is involved in other processes such as learning, vision, sexual behaviour, sleep, appetite, pain or memory, and may cause unintended changes (Crockett, 2014).

In addition, other adverse effects may occur if we are not able to modulate its application according to differences between individuals and different application contexts. Thus, oxytocin has been shown to have positive effects on empathy only in certain contexts (Akitsuki & Decety, 2009; Bartz et al., 2011; Bos et al., 2012). Thus, for example, such effects would occur when the individual needs to interact with acquaintances, trusted ones, or family members, but would seldom appear in situations of competition (Shamay-Tsoory et al., 2009), uncertainty (Declerck et al., 2010), institutional inefficiency (Zak, 2008) and interaction with strangers (De Dreu et al., 2010). Similarly, the empathic effectiveness of oxytocin appears to depend heavily on the peculiarities of the individual. Thus, its effects would be meagre or negative in the social sphere for those who have less ability to put themselves in the place of others (Abu-Akel et al., 2015); for those who, whether for genetic reasons (Rodrigues et al., 2009) or for manifested behaviour (Barraza, 2010) are less willing to show empathy; for those who are the most socially adept (Bartz et al., 2010); for those who have been brought up with less parental care (Carter, 2003); for persons with aggressive tendencies (DeWall et al., 2013); or simply for men rather than women (Hurlemann et al., 2010).

Given these difficulties in implementing biotechnological interventions in humans and the possible negative welfare implications of not taking them into account, it should be a first ethical-utilitarian criterion that bioenhancements should not be implemented until there is a high degree of certainty about their efficiency and safety.

## 2. *The requirement of open intervention*

But it is not enough for biotechnological interventions to be safe. They should also be “open” in the sense that they aim to directly modify moral skills, but not character traits, motivations or behavioural patterns (Shaw, 2014; Schaefer, 2015; Earp et al., 2018). In other words, changes in the nature of the agent cannot involve imposing substantive values on the subject by inducing ways of thinking and feeling that are clearly determined by those values. On the contrary, they should only aim at giving the subject mental tools with which to critically determine his or her own values.

What are the basic reasons for requiring bioenhancements to be open? First of all, it is a matter of simple operationality. A “closed” bioenhancement, in which the aim is to modify directly, and in isolation, certain aspects of the moral personality of human beings, is very unlikely to increase their morality. There would be no point in changing certain values or attitudes if these are not controlled or modulated by higher-order, usually deliberative, capacities that allow the agent to flexibly apply such tendencies in response to relevant reasons and the context in which they are used (Earp et al., 2018). This is similar to what Focquert and Schermer (2015) argue, for whom it is not enough to improve the emotions that lead to better actions if this does not correspond to a proper functioning of moral reasoning. Harris (2011) gives an example to show how biotechnologically diminishing aggression might not be morally desirable. He asks us to imagine the situation of an individual attacking a terrorist who is about to bomb a plane. If that individual had previously undergone an SSRI intervention to reduce his aggression, he would probably not have been able to save the passengers. With this example, Harris wants to underline that true moral behaviour is a complex phenomenon that must prepare you to act correctly in different scenarios and that for this to happen, it is important to be able to reason morally. Thus, pretending for its own sake to reduce the force of our impulses, as we suggested he could do with an agent in order to make him more strictly consequentialist, might incapacitate the agent to act decisively, and even unreflectively, in situations that (rationally) demand such a course of action. The same would be true of empathy, which, as we saw above, is context- and individual-related and, to be morally effective, would also require modulation in its use (Earp et al., 2018, pp. 169–171).

But it is not only a question of interventions that aim to directly modify behaviour and attitudes being unsuccessful for moral enhancement. They are also inconsistent with their objective. That is, a bioenhancement that claims to be moral cannot be closed. Even if it were ultimately successful, making the enhanced individual's behaviour conform to moral standards, the intervention would be more an example of social control than a moral enhancement in the strict sense of the word, because it would be carried out with the aim of directly changing their behaviour and not their capabilities. We would have made individuals behave better morally, but not because they had chosen to do so, but because someone or something, the enhancer or the technology in question, has made them behave that way. The mistake would be in pretending to morally enhance individuals by short-circuiting something that is essential to morality: freedom and behaviour in accordance with self-assumed reasons (Schaefer, 2015; Focquaert & Schermer, 2015, pp. 145ff).

Moreover, closed enhancements would also go against this autonomous and critical conception of morality because they would undermine a crucial element for the development of personal autonomy: dissent. If closed enhancements are based on the assumption that certain attitudes or behavioural patterns, together with the values that underlie them, are morally correct, it is to be expected that these same attitudes and patterns will be the ones that are tried to be implanted in all the subjects to be enhanced. This would lead to a homogenisation of people (Schaefer, 2015) and a consequent lack of reference points for individuals to contrast their views, thus making moral progress, understood in fundamentally critical terms, considerably more difficult.

These reasons for preferring that interventions should always be open are compatible with a certain type of utilitarianism. The origin of this would be in J. S. Mill's (1859; 1861) defence of the ideal utilitarian agent, who, from the greatest possible autonomy, ends up identifying the collective good with his personal good. In its more modern version, utilitarianism is interested in personal autonomy from a conception of well-being dependent on human freedom to choose. The ultimate good cannot consist, for this perspective, in mere pleasurable enjoyment or in a satisfaction of interests conditioned by an imposed situation. The subjective or experiential aspects of the subject must be complemented by the demand for objective capacities to autonomously choose one's own way of life (Sen, 1985; 2009).

In short, I believe that there are important reasons, even from a utilitarian perspective, to demand that moral enhancement interventions should only be carried out if, in addition to being safe, they do not infringe on the autonomous capacity to deliberate. We must now ask ourselves whether the aforementioned bioenhancement interventions, which could alleviate those human deficiencies that led to the revision of utilitarianism, would fulfil this requirement.

On the one hand, enhancing cognitive capacities to increase the degree of certainty about the probable consequences of our actions could be defended as an open intervention. The more efficient use of our memory does not in itself entail a change of personal identity in any particular direction. It is simply a matter of enhancing skills with which to make better judgements when making moral decisions in which the interests of all concerned are at stake.

The other two possible bioenhancements would, however, be more controversial. Changes in impulsivity and, above all, in a person's capacity for empathy could be seen as closed enhancements. They could lead to a substantive change in the values, identity traits and thus motivational disposition of the person being treated. For a person who is intervened to be less impulsive, or another who is treated to be more empathetic, is likely to end up being something he or she was not before: more calculating or more altruistic, respectively.

However, changes in such attitudes could also be directed so that the agent changes certain skills that, having much to do with morality, affect understanding rather than motivation. Thus, by increasing the subject's willpower so that, by not allowing himself to be so easily led by temptations, he can be consistent in his actions with his consequential reasons, what we would

ultimately achieve is to make him more autonomous. The intervention would then be understood as an aid so that, by controlling his emotions, the agent can harmonise more what he feels with what he thinks, so that, in short, he can be freer and more reflective in his behaviour. In short, he would be freed from his subjection to the arbitrariness of emotions.

On the other hand, if by enhancing empathy, we give the agent the option of better perceiving the harm that his actions would cause, either by putting himself in the place of the other or by seeing him from a position of fairness, we would be making it easier for him to judge the consequences of our decisions on the well-being of all.<sup>7</sup>

The decisive question would then be whether it is possible to establish any criteria to differentiate when these bioenhancements in impulsivity and empathy involve a substantive change in values or motivation (closed intervention) and when they only increase the capacities for understanding and deliberation (open intervention). Vincent (2011) does not believe that this is possible. He suspects that such bioenhancements, in one way or another, ultimately always involve some modification of personal identity, of what is authentically constitutive of a person. However, Vincents scepticism only makes sense if we start from an essentialist conception of identity. It is possible, however, to understand personal authenticity as something under construction or self-discovery. If we understand it in this way, the reduction of impulsivity, for example, could be seen as a liberation from impediments to becoming more authentic. Indeed, as Bolt and Schermer (2009) have shown, it is this sense of liberation and personal authenticity that is experienced by ADHD patients taking Ritalin. Similarly, it can be assumed that the increased empathy would allow modified individuals to have important information to redirect their own lives. By making it easier to put ourselves in the shoes of others, we could learn more about how others see us and, with this information, enhance our understanding of ourselves, which is essential for discovering or building our authentic selves.

However, this does not mean that some of these interventions cannot be an attack on personal identity, even when, in line with the defence of autonomy postulated here, we understand it as self-discovery or self-creation. It is a matter of degree. A constant and/or profound influence on impulsivity or empathy could be the cause of a motivational or attitudinal change that is not, in itself, open to different values or ways of life; it could mean, ultimately, the imposition of an identity not determined by the agent himself. It seems to me that the key here is to keep in mind a distinction between two tiers in the human deliberation. In the first would be the desires, interests, knowledge or predispositions that one has before one has meditated on them. These elements are then interpreted, in a second tier, with flexibility and rationality, with the agent conforming to them, or not, according to reasons based on their contextual applicability, but also on prudential or constitutive aspects of the agent's own personality.

Bearing this distinction of deliberative tiers in mind, the determining factor for ethical approval of a bioenhancement will be the degree to which the values of the first instance are modified. If the modification is so constant or profound that it alters the idiosyncratic principles of the agent, we would be limiting or even annulling this second tier of reflection, which is so decisive for personal autonomy and critical spirit. In this case, the intervention would be unethical because we would be imposing on the subject an evaluative perspective in the assimilation of which he or she has not participated.

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<sup>7</sup> In the field of human enhancement, there are positions that seek to change the capacities of human beings to the point of placing them on a higher ontological plane. In one of the most recent critiques of these transhumanist positions, S.B. Levin (2021) calls for a non-biotechnological progress of the human being based on the acquisition of a holistic and virtuous perspective of the good life. The requirement of open intervention would, however, imply a commitment to a non-transhumanist justification of moral bioenhancements. It would be a guarantee that these interventions never exceed the limits imposed by our basic conception of human nature. Indeed, bioenhancement might even enhance human nature. It would make us more autonomous and thus more disposed to the holistic and virtuous vision claimed by Levin.

### **Towards a new revision of utilitarianism?**

It follows from the above that the three bioenhancement interventions considered, provided they are safe, could, in principle, be open and therefore acceptable from an ethical, as well as utilitarian, point of view. Even those more related to motivation, such as impulse control or empathy, can be carried out to a degree in which personal autonomy and integrity are enhanced. We must now ask whether these acceptable bioenhancement interventions would invalidate the appeal to human limitations that led utilitarianism to a two-level decisional theory and thus to escape the strong criticism levelled against it.

Presumably they would not invalidate it. For two reasons. First, because ethically permissible enhancements would not turn the enhancing agent into a “moral saint”, excellently calculating what is right and behaving accordingly. And, secondly, as a consequence of the first, because the theory, not having excellent moral agents as targets, has no other structural option than the two-level decisional theory. Let us look at it.

Why do I argue, on the one hand, that the so-called bioenhancements will not turn humans into excellent consequentialist moral agents? First, because the cognitive enhancements, although significant, would be insufficient. The intervened individual would have an enhanced knowledge of the consequences of his possible acts, but he would not have it all his own way. His progress would be in terms of a more versatile and extensive memory, less intellectual fatigue and increased concentration. It is true that this would allow him to increase his degree of prediction of the consequences of his actions, but he would still be far from omniscient. Not having a crystal ball, there will still be unintended consequences that can turn your claim to do the right thing into an unexpectedly negative event.

Second, enhancing agents would not be moral saints because requiring enhancements to be overt would not allow for such a significant alteration of motivation as to ensure that the agent identifies with the utilitarian agenda. For example, the impulse control achieved could not, by itself, in any case, amount to a substantive alteration of identity. Therefore, for those who are emotionally determined in their way of being, after the intervention, there would still be the possibility that, having to choose between what they know to be right and what they desire, they would let themselves be led by the latter. They would progress with this and other open interventions in that they would have a greater (consequential and cognitively empathic) knowledge of what is right and that their final decision would not be driven by strong impulses or blind immediate gratification. However, there will always be the possibility that individuals will put their own interests before those of all concerned.

On the other hand, why would these partial advances in moral agency not be sufficient to dispense with the decisional levels theory of utilitarianism revisited? Why would it still be in everyone’s best interest for consequentialist agents to behave as if the (useful) behavioural patterns had no exceptions (even though they know that the patterns may have exceptions if they switch to the other level)? I understand that this would still be a necessity because the target agent of the theory, though morally enhanced, remains incapable of knowing and wanting to do what, *at any given moment*, has the best consequences for all. It is true that the enhanced agent, in comparison with the non-enhanced agent, can design their behavioural patterns in a way that is more consistent with consequentialism, introducing more exceptions in those patterns, with more possible situations in which they have the licence to change at the critical level. Their greater knowledge of consequences will allow them to do this without much psychological cost. But this greater agential versatility will also have its significant limits. It will remain true that for agents to learn and use behavioural guidelines easily, these cannot contain so many exceptions in their formulation, nor be so open to revision. Moreover, keep in mind that such guidelines, in order to be followed with conviction as if they admit of no exceptions, should be assumed by the enhanced agent as defining his or her personality, even

to the point of generating remorse in case of non-compliance. To this end, these must be firm and general, without being habitually open to revision.

In conclusion, given these persistent human limitations, it is foreseeable that, from a utilitarian perspective, it is still better that new utilitarian agents, enhanced by safe and open interventions, behave according to a two-level decisional scheme. Presumably, however, bioenhancements would allow for a higher frequency of occasions when pattern revision should be considered and a higher rate of success, from a consequentialist perspective, both in such revisions and in resolving conflict between patterns.

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## Epistemic and ethical responsibility during the pandemic

Andrea Klimková<sup>1</sup>

### Abstract

Intellectual (specialised) knowledge is omnipresent in human lives and decisions. We are constantly trying to make good and correct decisions. However, responsible decision-making is characterised by rather difficult epistemic conditions. It applies all the more during the pandemic when decisions require not only specialised knowledge in a number of disciplines, scientific consensus, and participants from different fields, but also responsibility and respect for moral principles in order to ensure that the human rights of all groups are observed. Pandemic measures are created by politicians, healthcare policy-makers, and epidemiologists. However, what is the role of ethics as a moral philosophy and experts in ethics? Experts in ethics and philosophy are carefully scrutinising political decisions. Levy and Savulescu (2020) have claimed that Ethicists and philosophers are not epistemically arrogant if they question policy responses. They played an important role in the creation of a reliable consensus. This study analyses epistemic and moral responsibility, their similarities, analogies, and differences. Are they interconnected? What is their relationship and how can they be filled with actual content during the pandemic?

**Keywords:** epistemic responsibility, moral responsibility, epistemic communities, knowledge during the pandemic

### Introductory notes and outline of the issue

The urgent need to address the theoretical as well as practical aspects of human decision-making and actions in terms of ethics and morals has gained even more importance during the COVID-19 pandemic. Ethicists and philosophers are not epistemically arrogant if they question policy responses (Levy & Savulescu, 2020). They play an important role in the creation of a reliable consensus. During the pandemic, many experts in ethics and philosophy have focused on clinical medicine and public healthcare dilemmas (justice, fair access to resources and healthcare, patient care, obligation to provide healthcare, clinical demand, allocation of resources, human rights, ethical aspects of vaccination, etc.), and the attention paid to these issues is undoubtedly deserved. However, there are other ethical and moral questions related specifically to knowledge. Research and knowledge, whether they relate to diagnostics, treatment, prevention, transmission, containing the Coronavirus COVID-19 (SARS COV 2) as well as the social impact of the pandemic, are of key importance. Delays in preventive, diagnostic, or therapeutic interventions may lead to major damage and even casualties (the greatest burden a person or society can carry is the burden of death). All this creates enormous pressure on scientists and scientific communities, but also research as such. The processes are often expected to speed up, which may affect the quality of research, and has to do with epistemic and moral responsibility.

The main goal of this study is to reflect the moving limits of moral responsibility in research and knowledge during the pandemic, examine and analyse the basic attributes of epistemic responsibility held by scientists and experts in ethics, and last but not least, present the concept of epistemic responsibility proposed by Lorraine Code as one of the approaches to epistemic (intellectual) responsibility. The text analyses the basis and some consequences of Lorraine Code's approach, which can be seen as a model of epistemic responsibility tailored for times when the social dimension and social context need addressing.

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Neil Levy and Julian Savulescu refer to an epistemic storm in their publication entitled *Epistemic responsibility in the face of a pandemic* (2020).<sup>2</sup> The question is whether lay persons should rely solely on epidemiology in an epistemic situation, which resembles a storm. In other words, many questions remain unsolved while others still lack a scientific consensus. There is a discourse (conflict) between those who advocate far-reaching interventions and those who insist on waiting for more data. This discourse addresses epistemic obligations and responsibility (Levy & Savulescu, 2020). Policy makers are also affected by this discourse and many of them choose to be rather careful about their decisions.<sup>3</sup> However, many authors have pointed out that research cannot be stopped and the hypotheses cannot remain untested: the decisions cannot be delayed during the pandemic – right now, there is no time to wait. Decision-making takes place even during times of epistemic insecurity, during times referred to as an “epistemic storm” by Levy and Savulescu.

Human knowledge is fallible, which requires constant creation of opportunities for critical discussion to ensure that our (actual) beliefs are justified; it can also help us avoid errors and reveal possible gaps in our convictions and opinions. A single viewpoint cannot justify these convictions at a time when scientific hypotheses are tested under enormous pressure and sped up. There are many other questions related to science and research, which require consideration of the epistemic and moral responsibility held by scientists, epistemic communities, policy makers, but also experts in ethics and philosophy who assess and evaluate the decisions made by the former group during the pandemic, i.e. an emergency situation. The title of the paper clearly and explicitly states that the issues arising from the current pandemic period are related to knowledge and science (not only epidemiology) and research (not only biomedical) as well as policy makers’ decisions. Epistemic or intellectual responsibility of scientists represents an important aspect of knowledge acquisition. The examples presented in the introduction (coping with the burden of the pandemic and the evaluation of its consequences in terms of life, death, and welfare) show that responsibility related to knowledge<sup>4</sup>, actual scientific knowledge as a product of reliable and strict testing, comprises both epistemic (intellectual) and moral responsibility of the scientists. I study and think epistemic and moral responsibility during a pandemic from an ethical point of view (not epistemology).

### **The moving limits of responsibility**

Science is a critical activity. Science has neither reached a reliable consensus, nor answered all the difficult questions about our survival of the pandemic, which makes the questions of epistemic and moral responsibility even more relevant. A moral agent’s (e.g., a scientist, an expert in ethics) knowledge and beliefs are considered epistemically responsible if they are justified, and irresponsible if they are unjustified. Cintora (2011) has further explained that if the agent believes in something they cannot justify with evidence, it is epistemically irresponsible. Popper (2012) has claimed that objective knowledge is closely related to the social aspect of the scientific method: scientific objectivity does not result from individual

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<sup>2</sup> The focus on the social dimension of knowledge and emphasis on the social context are not new, they can be traced back to J. S. Mill. There has been a return of discussions about the consensus theory of truth, scientific consensus, and also internalism vs. externalism in the philosophy of science. Most current (analytically oriented) epistemologists consider the intentions of the so-called tripartite definition of knowledge, according to which knowledge corresponds to a belief that is both true and substantiated (Démuth, 2009, pp. 19–21).

<sup>3</sup> The principle can be simplified as follows: if we have to decide between alternatives, we should always avoid the one that may cause serious harm (Clarke, 2005; Vladyková, 2015) or negative consequences.

<sup>4</sup> The term “knowledge” is used based on Démuth’s analysis in the first chapter of his book entitled *Poznanie, vedenie alebo interpretácia* (2009). The author has defined knowledge as well as semantically related epistemic terms to distinguish them. A tripartite definition of knowledge calls for truthfulness, (correct) belief, and justification (Démuth, 2009).

scientists' effort to be "objective". Scientific objectivity is not an individual matter, it is a social one and draws exclusively from criticism – scientists criticising one another (Popper, 1992).<sup>5</sup> Tense discussions between scientists and politicians should inspire us to search for the "correct" interpretation. However, in terms of epistemic responsibility, the tested and verified hypotheses, hard facts (expert opinions, research, records), and justification influence clinical decision-making. This knowledge permeates the broader social and political environment. Knowledge in the form of concepts is (re)formulated in the social environment and interpreted by both media and political discourse. Scientific concepts represent the objective criteria and norms in terms of decision-making during this pandemic calling for responsibility as an objective value or causal relationship (responsibility for something). In the search for an objective viewpoint for evaluating decision-related responsibility, the fact that the healthcare system and its participants do not exist in a world of abstract rules or an imaginary vacuum outside of social discourse, political and social narratives, and expectations is sometimes forgotten.

The difficult task of searching for clear ethical criteria distinguishing good and bad decisions is in the hands of philosophers and experts in ethics. During the pandemic period, it is their obligation to evaluate the recommendations formulated by scientists as well as political decisions. To construct an ethical framework, it is necessary to realise that assigning responsibility is inevitably a political act. It is an act performed from a specific position, therefore it is inherently subjective.

In ethical reflection, moral responsibility as a form of social relationship carries a variety of semantic components: "the subject is responsible for its actions as well as the actions of others, i.e. it exceeds their objective responsibility" (Smreková & Palovičová, 2009, p. 8). Max Weber (1965) has claimed that a responsible person accepts the burden of the unpredictable consequences resulting from their own actions. However, responsibility can be perceived from different viewpoints, for example, as the ability to provide a guarantee (the guarantor is held accountable). The act of assigning responsibility presupposes a clear formal and informal system of ethical rules providing a normative framework to determine whether any rules have been broken, which rules and who has broken them. Biomedical (and epidemiological) research as well as clinical practice follow the rules set out in international documents, national legislative frameworks, and professional codes. Despite this, the role of experts in philosophy and ethics remains difficult. Assigning responsibility for incorrect decisions is often a vague process. The impact of the aforementioned concepts on the formulation and interpretation of ethical criteria or norms in care provision during the pandemic will be illustrated using the recent decision made by a renowned Slovak expert in bioethics and member of the National Ethical Committee, Peter Sýkora. From 2005 to 2021, he was a member of the Ethical Committee at the Ministry of Health of the Slovak Republic. As of 1 March 2021, he resigned from the Committee because he believed the national vaccination strategy was unethical.

### **Moral responsibility in the pandemic times and public health**

Knowledge is related to epistemic responsibility for information as well as the way it is obtained, i.e. whether it has been obtained from an authority in the field (epistemic authority). Decision-making is related to epistemic as well as moral responsibility for the decisions and actions. An authority in the field (epistemic authority) should have good education, significant achievements, good reputation in the scientific and epistemic communities, and a good position in a scientific or research institution. "Good" as a term can be defined as correct, appropriate, or acceptable when referring to a phenomenon or state. In ethics, this term can be used in two

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<sup>5</sup> In the published work *Kritický racionalizmus a metóda falzifikácie* (2019), Miloš Taliga defends the opinion that Popper's critical rationalism deserves attention even today. As he states, it is precisely "that is why scientists engage in critical testing of theories" (Taliga, 2019, p. 27).

ways: instrumental when referring to a function or attributive when referring to a person who can act in a good way (Tugendhat, 1993, pp. 55–56).

Philosophers usually recognize two necessary individual and sufficient conditions upon which a person is morally responsible for their actions. The first condition is freedom while the second one is an epistemic state referred to as knowing. The first condition refers to the degree of freedom or control moral participants have over their actions; the second condition refers to the epistemic or cognitive state of the moral participants, i.e. whether they can be held responsible for their actions and their consequences.

While the first condition prompts us to ask “was this person acting *freely* when she did A?”, the second condition prompts us to ask “was this person *aware* of what she was doing (of its consequences, moral significance, etc.)?” (Stanford Encyclopedia of Philosophy, 2021).

Epistemic and moral responsibility applies not only to scientists and scholars, but also the politicians and policy makers who are currently under enormous pressure. On the one hand, this pressure is created by those scientists who call for necessary, legitimate pandemic measures (vaccination, face masks, limited movement, etc.). On the other hand, a part of the public protests (demonstrates) against these measures arguing that they violate their freedom and human rights. Politicians are even attacked by some experts (doctors, lawyers) who claim to protect autonomy and freedom, but mainly try to get more followers on social media. When their arguments are not supported by the scientific consensus, it can be evaluated as epistemically irresponsible.

When the emphasis is on the public good, decisions in the public interest as well as political ethics are called for, but it does not happen in a vacuum as the problems are real. Nevertheless, political decisions are often inconsistent, inconsequential, inflexible and deviate from the opinions of experts not only in epidemiology, but also ethics and philosophy. Can such decisions be labelled as morally irresponsible if they relate to responsibility for public health? If a politician faces an important decision during the pandemic and epistemic storm and has to decide between ethics & scientific consensus vs. personal interest, what do they choose? Will they act in a morally responsible way or prefer their personal interest to please the public? Peter Singer refers to the choice between ethics and personal interest as “the ultimate choice” (Singer, 1997, p. 4). Singer perceives this decision as a choice between two ways of life: the first choice is determined by one’s personal interest, while the other is guided by morals or certain balance between morals and personal interest (e. g. re-election). The principle of responsibility in politics has been justified and emphasized by a number of theoreticians (e.g. Weber, 1965; Jonas, 1984).<sup>6</sup> The responsibility for survival or, in other words, future generations is a part of political responsibility. It bears three attributes: (1) totality – while a politician holds the office or power, they bear responsibility for the citizens’ lives and public well-being; (2) continuity – responsibility lasts while the person holds the office; (3) future – responsibility goes beyond the immediate presence and applies to future consequences as well (Jonas, 1984). Dagmar Smreková (2000) has explained that the principle of responsibility “is mainly spatial and represents the legal, allowed actions (everything which is not forbidden by the law is allowed). Its relevance increases when the rules of the game have not been specified *a priori* and the responsibility itself cannot be reduced exclusively to the evaluation of rule observation”

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<sup>6</sup> In his lecture entitled *Politics as a vocation* (1990), the German sociologist Max Weber considers responsibility as an integral personality attribute along with passion and the ability to estimate. A politician’s passion means their devotion to a cause, but “mere passion, however genuinely felt, is not enough. It does not make a politician, unless passion as devotion to a ‘cause’ also makes responsibility to this cause [...]” (Weber, 1965, p. 60).

(Smreková, 2000, p. 631). It is the policy area that is characterized by the fact that the consequences of political decisions are not visible here and now, but go beyond the present.

The importance of measures at the point when the number of persons contracting the SARS-CoV 2 virus is rapidly rising again is easier to understand if we suppress the individual perspective and see ourselves as a part of society in terms of public health. As the term itself indicates, the ethics of social consequences evaluates the correctness of human thinking, decision-making, and actions based on the consequences, although such formulation is quite simplified. Nevertheless, the need to address the practical aspects of human decision-making, actions, and behaviour in terms of ethics and morals is a part of our everyday life (Gluchman, 1995), and in pandemic conditions, it grows. Evaluating the consequences of the decisions made by scientists and politicians (or secondarily, their main motives and intentions, which can result in negative social consequences) is a serious matter. The point is that not only those who contract the virus and suffer from serious symptoms are at risk. There are other patients whose treatment will be postponed due to the situation, potential collapse of the health care system due to the number of patients, loss of employment, isolation, rise of domestic violence, economic decline, and many other negative social consequences. Positive social consequences “help to satisfy the necessity of moral agent, social community or society as such” (Gluchman, 1994, p. 19) although they are not prioritised. Vasil Gluchman (2008, p. 77) has explained that “the core values of ethics of social consequences are: humanity, human dignity and moral right”, they interact with the value of positive social consequences. During the pandemic, responsibility can be analysed in the context of knowledge, freedom, autonomy, or even the way it is ascribed. The moral responsibility held by politicians undoubtedly applies to making decisions related to humanity and human dignity (patients, seniors, Roma, homeless, incomplete families, the unemployed, or citizens in general). Ethics of social consequences shows that these values can be analysed in terms of consequentialist theories, they are not reserved for deontological ethics. In terms of methodology, the specific situation represents the starting point to identify the positive social consequences. According to the author of this concept, the situational approach is a feasible method because positive social consequences can be filled with different content, even ambivalent at first sight (Gluchman, 1996). To summarise, the consequences of a situation can be evaluated if all the facts, factors, and morally relevant circumstances are known. Ethics of social consequences avoids the principle of maximisation and utility; therefore, it can be categorised as non-utilitarian consequentialism.

As for specific decisions made by the politicians, mainly those related to compulsory face masks, lock-down, and vaccination are being challenged. Can the state legitimately require the citizens to comply? Freedom should be restricted as little as possible, but in this situation, it is necessary to consider not only the justification of the aforementioned decisions, but also their consequences. These decisions can be perceived as interfering with individual freedom and rights, but people are individual as well as social beings: we live in society. Social prosperity and well-being are determined by the (health) condition of society. During the current SARS-CoV-2 pandemic, the goals of society are to save lives, reduce the spread of the disease, prevent the healthcare system from collapsing, and minimise the social consequences of the pandemic. These goals are legitimate and so are the political decisions as far as they follow these goals and are epistemically and morally responsible. This paper does not focus on humanity, dignity, and moral rights (and their violation) from the viewpoint of ethics of social consequences. It examines whether ethics of social consequences can provide any evaluation criteria that could be useful in the evaluation of pandemic political decisions. Can it be used to evaluate whether a decision has been morally responsible (in terms of positive social consequences, humanity, human dignity, and moral rights) or not? As of today, there is no clear answer. These decisions are still being made and it is impossible to evaluate the consequences – there is no reliable scientific consensus on the relevant questions so far. However, I am inclined to justify that yes.

We must evaluate every decision in politics in the light of its social consequences. As it was claimed in the introduction, experts in philosophy and ethics are not epistemically arrogant if they challenge political decisions. They play an important role in the creation of a reliable consensus.

Levy and Savulescu (2020) have stated that:

there are many different approaches non-epidemiologists—decision-makers and experts in other fields alike—might take, the following three seem to be the most widely advocated: (i) Attempt to adjudicate the debate between the experts; (ii) Attempt to split the difference between experts; (iii) Attempt to identify which of the competing experts is more likely to be reliable. None of these options is very acceptable, but some are more irresponsible than others (Levy & Savulescu, 2020).

### **Epistemic responsibility (Lorraine code)**

The philosopher Lorraine Code seems to be right when she claims that a person cannot understand human actions if they are separated from life, history, contexts, and stories. Therefore, concepts such as knowledge, virtue, or integrity can only be understood if their complexity and different angles are taken into consideration. In her book entitled *Epistemic responsibility* (2020), Code has explained that having adequate knowledge about the world is not only a matter of survival, but also an obligation. If we are to take the right actions, we need to read the world correctly. Philosophers refers to this obligation to “know well” as “epistemic responsibility.” Code (2020) has defined knowing as a creative process ruled by the imperatives of epistemic responsibility, i. e. good and correct knowledge is necessary for taking good and correct actions.

Before the model of epistemic responsibility proposed by Code is presented, it is necessary to point out that in terms of mainstream epistemology, this project is atypical. As explained at the beginning, the generally acceptable definition specifies knowledge as a true and justified belief. “Knowledge is a true claim or belief but it also comprises the ability to provide evidence about its own truthfulness” (Démuth, 2009, p. 22). Such definitions are in line with the classical analytical tradition as well as common language intuition related to epistemic terms – “only true propositions (statements) can be known, we must believe our knowledge, and our belief must be evidence-based. There has to be a reason why we have this belief, i. e. this belief itself has to be justified by a belief” (Szapuová, 2003, p. 267). However, the dominant approach to knowledge is often criticised due to its “high level of abstraction and idealisation as well as certain ignorance toward the actual conditions of knowledge” (Szapuová, 2003, p. 269) as well as the fact that certain models and standards of justification apply to ideal conditions and ideal cognitive participants.

Code’s alternative to the mainstream line of thinking in epistemology and the traditional tripartite model is based on the idea that the actual conditions for knowing and justification are not only epistemic but also moral. Responsibility for knowing involves three assumptions: (1) knowledge and the effort to know are a part of human life and result from the interaction between cognitive participants, their communities, and the world; (2) there is no knowing without scientists and no knowledge without the context; (3) people have access to knowledge and shape its contents and structure (Code, 2020). Code suggests looking at human cognitive activity in another way and asking different questions. A different perspective allows for looking for the missing complement to foundationalist and coherentist theories. Code deals with good cognitive activity in a way the foundationalist or coherentist approaches do not (Code, 2020). Her intention is to show that some varieties of epistemic proceedings are better and more responsible than others. “Knowing well, being epistemically responsible, have implications for people’s individual, social, and political lives” (Code, 2020, p. 41).



She uses the example of Phillip Gosse, Sr. (Father and Son: A case study) to illustrate an epistemological crisis faced by a scientist, which arose due to his internal intellectual conflict involving two antagonistic beliefs. Gosse tried to harmonise his fundamentalist Christian belief with the knowledge he has gained as a marine zoologist structured by new biology and the theory of evolution (Darwin, Lyell, etc.). Code analysed his epistemic responsibility when he ultimately chose Creationism and the story of Genesis – this conflict prevented him from holding responsibility for his further work.

“A ‘responsibilist’ approach to epistemology, for which epistemic responsibility is a pivotal normative concept, says that the nature of the knower and of his/her environment and epistemic community are epistemologically relevant, for they act as enabling and/or constraining factors in the growth of knowledge, both for individuals and for communities” (Code, 2020, p. 57). Code has explained that the “integrity of your source is a crucial component in my decision about whether or not to accept what you say, or even whether to consider it seriously. My estimation of your reliability in relaying testimony is equally important.” A person’s actions can be evaluated by taking into account their character, moral integrity, and reliability. Their cognitive activity can also be evaluated: in the context of the epistemic reliability of science. Thus arises the question: who can we trust and why? The author suggests that if we apply the aforementioned to evaluate one’s intellectual activity (knowing), we examine intellectual virtues and appeal to the social criteria of virtuous intellectual behaviour. In other words, an epistemological evaluation focuses not only on individual actions, but also acceptable social practice. Code has further claimed that epistemic responsibility “is a central virtue from which other virtues radiate. This is analogous to the way in which, for hedonists, happiness is the central good, for Kant, good will is the only good in itself, from which all other goods derive” (Code, 2020, p. 77).

Her approach focuses on the social context of knowing and knowledge, and the fact that they are anchored in a network of social relationships as well as cultural and historical meanings. Bruno Latour and Steve Woolgar have explained that although research itself takes place behind the closed laboratory door, human beings are a part of society – they are social, and their intellectual activity takes place in *Lebenswelt* anyway (Laboratory Life, 1979). Everything that will be perceived and accepted as a suitable method, strategy, procedure, or result is a product of social negotiation and communication. It might be useful to remind the reader that while social epistemology reflects the results of inquiry, it studies the social dimension of knowledge, “which involves not only the institutions creating knowledge, but also interpersonal experience and communication of the participants” (Szapuová, 2003, p. 271).

### Conclusion

During the current pandemic, mainstream discourse (specialised and political) involves experts who advocate far-reaching interventions and restrictions versus those who insist that the decisions (on measures, lock-down, medication, child vaccination, etc.) must be postponed until there is sufficient evidence. This discourse addresses the epistemic and moral responsibility of scientists as well as politicians. Governments rely on science and selected experts; as there is no time to wait for more evidence, such policy can be considered epistemically and morally responsible. Epistemic responsibility is achieved by following the advice provided by experts (not only epidemiologists, but also other scientists and scholars e. g. in ethics). According to L. Code, a scientist’s (thinker’s) character determines whether we take their claims seriously. Therefore renowned, trustworthy scientists with good reputations are selected.

Ethicists and philosophers are not epistemically arrogant if they challenge political decisions. They play an important role in the creation of a reliable consensus in the time of epistemic storm as Levy & Savulescu (2020) writes about. When decisions are a matter of survival and coping with a pandemic, they involve consequences in terms of life, death, and

welfare, therefore it is our moral obligation to evaluate them. Epistemic and moral responsibility held by experts in ethics involves challenging political decisions. They carry the burden of responsibility; therefore they cannot stop evaluating and pointing out incorrect, unacceptable, and irresponsible decisions. An expert in bioethics Sýkora, analysed the Slovak vaccination strategy as well as data about infected people and casualties and claimed that “the record number of deaths is a consequence of incorrect strategy”. Although he has admitted that it is too soon to evaluate the pandemic, he has criticised the Slovak vaccination strategy, claiming that “we have sacrificed the seniors” (Horák, 2021). It can be stated that during the initial period of vaccination (March – June 2021), the vaccination strategy could not be considered acceptable in terms of epistemic and moral responsibility in relation to seniors as the most vulnerable group.

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## **Ethical implications of procedural or protocol adjustments to clinical research involving the participation of human subjects during the COVID-19 pandemic**

**Anetta Jedličková<sup>1</sup>**

### **Abstract**

The current coronavirus disease 2019 (COVID-19) pandemic has led to essential adjustments in clinical research involving human subjects. The pandemic is substantially affecting most procedures of ongoing, as well as new clinical trials related to diseases other than COVID-19. Procedural changes and study protocol modifications may significantly impact ethically salient fundamentals, such as the risk-benefit profile and safety of clinical trial participants, which raise key ethical challenges the subject-matter experts must face. This article aims to acquaint a wide audience of clinical research professionals, ethicists, as well as the general public interested in this topic with the legal, ethical and practical considerations in the field of clinical trials during the COVID-19 pandemic and to support the clinical researchers and study sponsors to fulfil their responsibilities in conducting clinical trials in a professional way that does not conflict with any legal or ethical obligations.

**Keywords:** clinical research, clinical trials, COVID-19, ethics, medical ethics, regulatory adjustments, research ethics, risk management

### **Introduction**

Clinical research professionals are generally well aware of applicable regulatory guidelines, scientific standards and ethical principles (i.e., beneficence, nonmaleficence, respect for autonomy and justice), and they are used to conduct clinical trials in compliance with all pertinent requirements. Neither study sponsors<sup>2</sup> nor clinical investigators were prepared for the disruption triggered by the current COVID-19 pandemic that was caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2 virus), which significantly impacted the conduct of clinical trials globally. The necessity for strict social distancing to impede transmission of the coronavirus, as well as the scarcity of research resources affected clinical researchers' ability to successfully continue or complete clinical trials, they were conducting prior to the current pandemic. According to a project supported by the National Center for Advancing Translational Sciences and National Institutes of Health, the COVID-19 pandemic had an indisputable impact on the number of completed clinical trials in 2020. The project assessed the impact of the COVID-19 pandemic on the number of both, submitted and completed interventional clinical trials by analysing 117,000 clinical trials across different regions and sectors that had been registered on the ClinicalTrials.gov database. Data from the December 1, 2019 to the December 1, 2020 was compared. For given regions (United States, Asia and Europe) and sectors (pharmaceutical and academic clinical research), the COVID-19 pandemic had a stronger impact on the number of completed clinical trials in 2020 with a decrease ranging from 13% to 23% depending on the region, sector and whether COVID-19 related clinical trials were included (Hawila & Berg, 2021).

General considerations that led to modifications of the clinical trials conduct should have been based on a risk assessment in order to address prioritization of the safety, confidentiality and privacy of clinical trial participants, as well as to prevent, reduce or minimize missing data, and thus, to ensure data integrity and reliability. According to the Guideline for good clinical practice E6(R2), study sponsors “should implement a system to manage quality throughout all

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<sup>2</sup> Sponsor means “an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial” (EMA, 2014, p. 12).

stages of the trial process. Sponsors should focus on trial activities essential to ensuring human subject protection and the reliability of trial results. Quality management includes the design of efficient clinical trial protocols and tools and procedures for data collection and processing, as well as the collection of information that is essential to decision making” (EMA, 2016, p. 30).

### **Ethical frameworks for clinical research**

Ethical concerns play a significant role in establishing the processes and procedures for conducting clinical trials in a way that protects human subjects and minimizes risks while still advancing the public interest and enhancing benefits to individuals and society. Ongoing attention to the ethical concerns is crucial to ensure that clinical trials remain moral, and the research results will be valid.

Essential ethical frameworks are included in the following influential documents, and provide ethical guidance for clinical research ethics: The Nuremberg Code (1947) was based on universal principles of natural law and human rights, and established the fundamental principle that the participation in research requires the voluntary informed consent of the participating subject. The Declaration of Helsinki is an official policy of the World Medical Association (WMA) that was adopted for the first time in 1964 and has since undergone a number of revisions. The declaration established the first official set of guidelines for maintaining ethical standards in clinical research and emphasized the need to protect the health and interests of research participants. The Belmont Report, that was published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, is known for establishing a framework of basic ethical principles – respect for persons, beneficence, and justice – which should assist scientists, subjects and reviewers to understand the ethical issues inherent in research involving human subjects.<sup>3</sup> In 1993 the Council for International Organizations of Medical Sciences (CIOMS) published the International Ethical Guidelines for Biomedical Research Involving Human Subjects which superseded Proposed Ethical Guidelines (1982).<sup>4</sup> There are also many further guidelines provided by the directives of the Council of Europe and the European Commission, and last but not least by the regulatory authorities of individual states (Nardini, 2014). Since each of these guidelines emphasizes certain ethical requirements while eliding others, there were specified the following seven general ethical requirements that provide a systematic framework for determining whether clinical research is ethical: social or scientific value, scientific validity, fair subject selection, favourable risk-benefit ratio, independent review, informed consent, and respect for potential and enrolled subjects (Emanuel et al., 2000).

In 2018 a team of multinational subject-matter experts consisted of ethicists, methodologists, health system leaders, regulators, research ethics committees, research funders and community members initiated a new project in order to identify ethical issues in clinical research and based on their analysis to develop a new ethical guidance document rooted in internationally accepted ethical principles. The guidance will facilitate the conduct of research important to patients, clinicians, and the healthcare system, while upholding the highest ethical standards in research (Taljaard et al., 2018). In 2019 the team reported that new ethical issues were detected that need to be addressed, and that there is a need to discuss ethical topics in new ways. The substantive areas of discussion were consistent with topics in the clinical trials literature, including risk assessments, informed consents, the governance of research activities, the selection of clinical trials participants, the roles and responsibilities of different stakeholders, and the publication and reporting transparency of clinical trials. Their findings suggested that, despite existing guidance on minimal risk and consent approaches (Office for Human Research Protections, 2015), there is a need to develop practically applicable frameworks for the risk

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<sup>3</sup> For more information see Department of Health, Education, and Welfare (1979).

<sup>4</sup> For information about the revision process see Delden (2016).

assessment in clinical trials, as well as the guidance with respect to alternative informed consent approaches. The team also stated that addressing the highlighted ethical issues and developing ethical guidance will require multidisciplinary input within a broader and more comprehensive analysis (Nicholls et al., 2019).

### **Regulatory adjustments to clinical research during the COVID-19 pandemic**

Shortly after a public health emergency related to COVID-19 had been declared, regulatory authorities in almost all countries recognized that the public health emergency might seriously impact the conduct of clinical trials. During the COVID-19 public health emergency, clinical trial participants might not be able to travel to a clinical trial site location for study visits and study-specific research procedures or to receive the treatment that should be dispensed on a recurring prescription.

Not only travel limitations affecting clinical trial participants, but also quarantines, other urgent work commitments of clinical site staff, clinical trial site restrictions or closures, interruptions to the supply chain for investigational medicinal products (IMP),<sup>5</sup> or the risk of an exposure to or acquiring COVID-19 infections of clinical trial participants or health care professionals, are a few examples of unprecedented situations that have arisen numerous new challenges. These challenges led to difficulties in meeting clinical trial procedures, including dispensing, administering or using the investigational medicinal products, in adhering to protocol-mandated study visits, conducting key safety assessments or laboratory and diagnostic testing, which could have an impact on the safety and well-being of human subjects<sup>6</sup> (Akacha et al., 2020). Therefore, regulatory authorities that are responsible for regulation of clinical trials acknowledged that substantial study protocol modifications could be required and they promptly issued relevant guidance documents which addressed the COVID-19 public health emergency with the aim to support response efforts to the pandemic and to ensure human subjects protection, as well as the reliability of clinical trials results (FDA, 2020, pp. 1–3).

### **Regulatory adjustments of the European Medicines Agency**

Due to the impact of the COVID-19 pandemic on the health care systems and society, as well as the impact it might have on conducting clinical trials and the safety and welfare of clinical trial participants, the European Medicines Agency (EMA) in cooperation with other working groups<sup>7</sup> issued the guidance document entitled as ‘Guidance on the management of clinical trials during the COVID-19 (Coronavirus) pandemic’. The purpose of the recommendations specified in the guidance was to protect the safety and well-being of clinical trial participants and to maintain the integrity of the clinical trials data (EMA, 2021, p. 3).

Key recommendations of the guidance covered the following aspects:

- Conversion of physical study visits into telephone or video study visits, alternatively postponement, reducing frequency or complete cancellation of study visits;
- A temporary halt of clinical trials at some or all clinical sites;

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<sup>5</sup> Investigational medicinal product means “a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use” (EMA, 2016, p. 11).

<sup>6</sup> Subject means “an individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control” (EMA, 2014, p. 13).

<sup>7</sup> Such as Good Clinical Practice Inspectors Working Group, the Clinical Trials Facilitation and Coordination Group, a working group of the Heads of Medicines Agency, the Clinical Trials Expert Group, a working group of the European Commission representing Ethics Committees and National Competent Authorities and the European Commission (EMA, 2021, p. 3).

- Interruption or slowing down of recruitment and enrolment of new clinical trial participants;
- Extension of the duration of clinical trials;
- Postponement of clinical trials or of activation of clinical sites that have not been initiated;
- Clinical site closures if it was not feasible for a clinical site to continue participation in a clinical trial. Site closures should be performed without compromising the rights, safety and well-being of clinical trial participants and data validity;
- If unavoidable (based on the risk-benefit assessment for clinical trial participants), transfer of clinical trial participants to clinical sites away from risk areas, or closer to their home could occur;
- In case there was a need for any critical laboratory tests, imaging procedures or other diagnostic tests to be performed for the clinical trial participant's safety or integrity of the clinical trial (e.g., blood specimens, radiographic images, biopsies, ultrasonography, etc.), however, the clinical trial participant could not visit the clinical site, it was acceptable that laboratory, imaging or other diagnostic tests were done at an accredited local laboratory or relevant authorised and certified clinical facilities.
- If shipment of blood samples or other clinical specimens to a central laboratory could not be maintained, analysis should be performed locally and then assessed and properly reported in the clinical study report (EMA, 2021, pp. 4–5).
- In case of a need to re-consent enrolled clinical trial participants, it should be avoided that they visited clinical sites for the sole purpose of obtaining re-consent. If re-consent was necessary for the implementation of new urgent changes in the clinical trial conduct for reasons related to the COVID-19 public health emergency or important safety issues, alternative ways of obtaining the re-consent should be considered. These could comprise contacting the clinical trial participants via telephone or video-calls and obtaining verbal consents. Approved updated patient information sheets and informed consent forms should be provided to clinical trial participants by e-mail, mail or courier before the re-consent is obtained. Alternative ways of obtaining the re-consent should be documented in the clinical trial participants' medical records and supplemented with e-mail confirmation. At the earliest opportunity when the clinical trial participants are able to visit clinical sites for the regular study visits, the re-consents obtained by means of alternative methods need to be confirmed by way of usual consent procedures (EMA, 2021, p. 11).
- Alternative distribution methods for investigational medicinal products to clinical trial participants to avoid treatment interruptions were acceptable. Larger amounts of IMP could be provided to the clinical trial participants than normally provided during regular on-site study visits. Alternatively, the IMP might be delivered to the clinical trial participants by a distributor. The guidance specified conditions of the alternative means, such as a contract between the study sponsor and the distributor should be in place, an agreement with the investigator should be signed, and an appropriate consent of clinical trial participants should be obtained. The consent should be documented in the clinical trial participant's medical records. It should be noted that the distributor should not store any personal data of the clinical trial participant (the participant's name, address and contact details) for a longer period than is required for the purpose of dispatching the IMP. The clinical trial participants' personal data should never be provided to the study sponsor, and the distributor should not have access to the clinical trial participants' health information (EMA, 2021, pp. 11–13).
- As part of the risk assessment, a risk-based approach to monitoring should be taken, focusing on certain clinical sites, data points and processes that are critical to ensure the rights, safety and well-being of clinical trial participants, as well as the integrity of the clinical trial and clinical trial data. As cancelling or postponing of on-site monitoring visits and extending of the period between monitoring visits were necessary, the role of centralised monitoring had an increasing importance during the public health emergency.

Additional off-site monitoring activities included phone calls, video visits, e-mails or other online tools in order to discuss the clinical trial progress with clinical investigators and site staff (EMA, 2021, pp. 14–15).

- Remote source data verification should focus on the quality control of critical data collected in the course of the clinical trial, such as primary efficacy data and safety data. Remote source data verification should only be carried out if adequate data protection, including data security and protection of personal data is ensured (EMA, 2021, pp. 16–17). According to the EMA guidance, “data subject to remote source data verification are likely to require re-monitoring, in particular if it was based on pseudonymised documents, which cannot be considered as source documents, and considering that remote monitoring is expected to only have focused on the most critical information” (EMA, 2021, p. 15).

EU member states were encouraged to implement the harmonised guidance to the maximum possible extent to mitigate the disruption of clinical research during the COVID-19 public health emergency. They should complement the EMA guidance to create additional clarity on specific national legal requirements (EMA, 2021, p. 3). Based on this recommendation of EMA, regulatory authorities of EU member states have swiftly released their own national guidance documents on clinical trial management during the COVID-19 pandemic.<sup>8</sup>

### **Adjustments of the regulatory authority in the US**

The United States Food and Drug Administration (FDA)<sup>9</sup> issued a guidance document for industry, investigators, and Institutional Review Boards entitled ‘Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency’,<sup>10</sup> which provided general considerations to assist study sponsors in assuring the safety of clinical trial participants, in maintaining compliance with good clinical practice (GCP),<sup>11</sup> and in minimizing risks to the clinical trial integrity for the duration of the COVID-19 public health emergency. The guidance was implemented immediately, even without prior public comments, as the FDA determined that prior public participation for this guidance was not feasible (FDA, 2020, pp. 1–2). As large numbers of clinical investigators at European clinical trial sites signed the Statement of Investigators, so-called Form FDA 1572,<sup>12</sup> they also have to follow pertinent FDA regulations. For this reason, the general considerations for study sponsors and clinical investigators specified in the FDA guidance are also included in this paper.

The FDA pointed out that any decision should be based on ensuring that the safety of clinical trial participants can be maintained. Thus, the safety of clinical trial participants was of the utmost importance in determining if and what changes in the clinical trial conduct were needed. Study sponsors, in consultation with clinical investigators and relevant Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs), should assess whether the protection

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<sup>8</sup> National guidance documents can be found here: [https://www.hma.eu/fileadmin/dateien/Human\\_Medicines/01-About\\_HMA/Working\\_Groups/CTFG/2020\\_03\\_CTFG\\_Link\\_to\\_National\\_guidance\\_on\\_CT\\_management\\_during\\_the\\_COVID-19\\_pandemia.pdf](https://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2020_03_CTFG_Link_to_National_guidance_on_CT_management_during_the_COVID-19_pandemia.pdf)

<sup>9</sup> The FDA is a federal government agency in the United States responsible for protecting the public health by ensuring the safety, effectiveness and security of human drugs, vaccines and other biological products for human use, as well as of medical devices.

<sup>10</sup> The document was issued in March 2020. Up to now, the FDA provided several updates to the guidance.

<sup>11</sup> Definition of GCP: “Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible” (EMA, 2016, p. 6).

<sup>12</sup> The Statement of Investigator, Form FDA 1572, is “an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic” (FDA, 2010, pp. 4–5).



of participants' safety, welfare, and rights might be best served by continuing clinical trial participants in the clinical trial as per the study protocol, or by discontinuing the administration or use of the investigational medicinal product, or even by discontinuing their participation in the clinical trial. Such decisions should depend on specific circumstances, including the ability to conduct appropriate safety monitoring, the nature of the investigational medicinal product, the potential impact on the investigational medicinal product supply chain, the nature and the seriousness of the disease or condition being treated, and the risks involved in switching to an alternative treatment of the disease (FDA, 2020, p. 3). Study sponsors should carefully consider the following aspects of the subsequent clinical trial conduct when deciding on any procedural changes or study protocol modifications:

- Assessing whether the limitations imposed by the COVID-19 public health emergency on protocol implementation pose new safety risks to trial participants, and whether it is feasible to mitigate these risks by amending study processes and procedures.
- Assessing the continued availability of the clinical investigator/sub-investigators to provide oversight of the trial and properly assess and manage safety issues that may emerge.
- Assessing whether there will be sufficient clinical trial support staff given the evolving COVID-19 situation and its impact on staff availability. Are there appropriately trained staff that could be available to handle the expected tasks? Is there adequate equipment and materials for clinical trial support staff?
- Assessing whether clinical investigator sites will remain open to trial participants for required in-person assessments or whether the clinical investigator has the ability to provide required in-person assessments at an acceptable alternate location(s), or whether such protocol-specified, in-person assessments can instead be conducted virtually.
- Assessing the continued availability of clinical trial supplies and continued operations of vendors, especially related to supply of the investigational product and/or to clinical trial supplies that are essential for maintaining appropriate safety monitoring or other key trial procedures. This should include consideration of product stability (shelf life) if the treatment schedule is revised, or if the clinical site is unable to properly store the product for the needed duration.
- Assessing the continued availability of, and support for, information technology systems and any other technological tools needed to support the trial (FDA, 2020, p. 8).

Modifications to study protocols and clinical trial related procedures should address the impact on the informed consent process, protocol-mandated study visits and procedures, data collection, processing and interpretation, clinical trial monitoring, adverse event reporting, and changes in clinical investigators, site staff, or monitors (FDA, 2020, p. 5). As emphasized in the FDA guidance: "In all cases, it is critical that trial participants are kept informed of changes to the study and monitoring plans that could impact them" (FDA, 2020, p. 3).

### **Adjustments to the study protocol and study-specific research procedures and their ethical implications**

During the COVID-19 public health emergency study sponsors had to carefully consider how to mitigate safety risks to clinical trial participants and, therefore, they might need to modify protocol-specified procedures. Clinical investigators should meet all legal and ethical requirements, including all new study protocol or procedural adjustments. Modifications were made to protect the life, safety or well-being of clinical trial participants, however, from another perspective, some changes in study protocols and subsequently in clinical trial procedures had potentially effects on the ethics of conducting clinical trials. The impact of modifications on the clinical trial conduct may have numerous ethical implications that can be categorized into those

that are more related to the risk-benefit profile of clinical trial participants and, thus, to their safety, and those that are more related to the study sponsors and may affect the clinical trial integrity, data interpretability and scientific validity of the clinical trial results.

Although regulatory authorities in numerous countries worldwide published applicable guidelines to support study sponsors and clinical investigators in their decision-making process, it should be emphasized that determining the risk-benefit ratio remains the responsibility of the clinical investigators and study sponsors. This needs to be performed in compliance with the ethical principles of beneficence, nonmaleficence, respect for autonomy and justice (Beauchamp & Childress, 2019) that serve as a basic justification for ethical evaluations in clinical research, as well as in compliance with the seven ethical requirements mentioned above.

### **Ethical implications related to clinical trial participants and their safety**

A clinical trial's risk-benefit profile for each individual clinical trial participant might significantly change during the COVID-19 pandemic. In case clinical trial participants were not able to come to the clinical trial site for protocol-mandated study visits, then such visits were done by telephone or video contact, and thus, study-specific procedures and assessments were either not conducted at all (e.g., vital signs measurements, blood samples collection), or performed by other means (e.g., by using alternative arrangements, laboratories or imaging centres). Reducing visit frequency was also a common study protocol modification during the COVID-19 public health emergency. Such significant protocol adjustments could have substantial impacts on the clinical trial participants safety.

Other ethical concerns and, therefore, risks related to the clinical trial participants safety may be caused by the following aspects:

- Waiting for postponed study-specific research procedures;
- Treatment discontinuation due to supply chain management issues during the COVID-19 public health emergency;
- Assessing investigational medicinal products' responses not performed by a responsible clinical investigator on a regular basis when clinical trial participants were unable to come to the clinical trial sites;
- Prohibited concomitant medication not detected in time;
- Clinical significance of out-of-range laboratory findings not determined when the procedures described in a clinical trial laboratory manual were not followed if clinical specimens' collection and handling were performed in local laboratories;
- Physical examination findings and/or their progression not identified in time;
- Disease progression not determined in a timely manner;
- Clinically relevant changes in health status not identified in time;
- Belated detection of serious adverse events (SAEs);
- Late determination of potential causal relationships of SAEs to the investigational medicinal products;
- Postponed follow-up of clinically significant adverse events and impossibility to perform follow-up until a medical condition stabilizes or is no longer clinically significant;
- Significant difficulties and subsequent risks could also arise from the informed consent interview and discussion conducted by telephone and if the informed consent was obtained by means of an alternative method. Investigators are obliged to discuss all new and important information influencing the clinical trial participants' consent and their willingness to continue to participate in the clinical trial with already enrolled participants. Accordingly, updated informed consent forms need to be provided to the participants and

their re-consent should be obtained before the investigator may conduct any clinical trial specific procedures. It is important to emphasize that in compliance with the ethical requirement of respect for autonomy, clinical trial participants are free to withdraw from the clinical trial treatment and/or the clinical trial for any reason and at any time without giving reason for doing so and without penalty or prejudice. In any case, investigators should allow clinical trial participants to assess the potential risks and to make their own decision about their continued clinical trial participation and provide them ample time and opportunity to inquire about details.<sup>13</sup> It is questionable whether one telephone call enables enough time for such a decision.

- Last but not least, the risk of exposure to COVID-19 during the engagement in clinical trial-related activities, e.g., during study protocol-specified procedures or protocol-mandated study visits. Other risks with serious safety implications may also be caused by concomitant medication intakes due to the treatment of COVID-19 symptoms.<sup>14</sup>

Although not all of these individual risks may have the potential to modify the clinical trial's overall risk-benefit profile, all of them are important aspects to consider what study protocol modifications need to be implemented during the COVID-19 pandemic in order to avoid safety hazards to clinical trial participants and ethical implications they may have. All the ethical concerns listed above are based on experience emerged from the remote GCP audits carried out during the COVID-19 public health emergency by the author of this paper, who also acts as a clinical and research Quality Assurance consultant and auditor. The nature and significance of the concerns were discussed with clinical trial teams and responsible personnel of pharmaceutical companies in order to determine whether there is a risk of a potential ethical issue, to prevent ethical implications or to find ways how to solve situations when ethical impacts have already occurred. It is worth emphasizing that clinical investigators are crucial in identifying any changes in medical conditions of clinical trial participants that are potentially ethically consequential, as well as that the investigators are responsible for protecting the safety of clinical trial participants under the investigators' care and for the control of investigational medicinal products.<sup>15</sup>

### **Ethical implications related to study sponsors**

FDA as well as EMA regulations allow modifications made to a study protocol without a prior review or approval by regulatory authorities, if the changes are intended to eliminate an apparent immediate hazard or to protect the life and well-being of trial participants.<sup>16</sup> Therefore, changes in the clinical trial conduct that are necessary to assure the clinical trial participants safety can be immediately implemented with the subsequent submission of the study protocol amendment, its review and approval by IRBs/IECs and regulatory authorities. However, until the study protocol amendment is approved, all such changes are considered protocol deviations and need to be transparently documented. Protocol amendments that are not required to prevent imminent safety risks to clinical trial participants can be implemented after they were submitted to IRBs/IECs and regulatory authorities and their approval has occurred.<sup>17</sup> Clinical investigators and study sponsors should therefore document as protocol deviations any modifications to study protocol-specified procedures that have occurred prior to the approval of the study protocol amendment implementing the modifications (FDA, 2020, p. 4; EMA, 2021, p. 8).<sup>18</sup>

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<sup>13</sup> See EMA (2016, p. 25).

<sup>14</sup> All listed ethical concerns are based on personal experience of the author of this paper.

<sup>15</sup> See Code of Federal Regulations (CFR): 21 CFR 312.60.

<sup>16</sup> See 21 CFR 56.108(a)(4), 312.30(b)(2)(ii).

<sup>17</sup> See 21 CFR 312.30(b)(2).

<sup>18</sup> See 21 CFR 312.62.

The main challenging areas that have a significant impact on the ethical conduct of clinical trials for study sponsors are as follows:

- Safety of clinical trial participants and of investigational medicinal products.  
The study sponsor is always responsible for monitoring the safety of investigational medicinal products, for evaluating all accumulating safety data, as well as for a sufficient oversight of required reporting of serious adverse events that occur in the course of clinical trials (including submission of expedited safety reports to the regulatory authorities, as necessary, e.g., reporting of suspected unexpected serious adverse reactions, known as SUSARs). However, adjustments that resulted from challenges related to the COVID-19 public health emergency could significantly limit safety monitoring, which represents a new potential risk associated with investigational medicinal products, particularly, if there is a reasonable suspected causal relationship between the IMP and the occurred SAE. This, without any doubt, may potentially affect the risks-benefit profile and the clinical trial's scientific integrity. According to the EMA guidance, study sponsors should continue to follow the safety monitoring and reporting requirements in adherence to EU and national legal frameworks. "When per protocol physical study visits were reduced or postponed, it is important that the investigators continue collecting adverse events from the clinical trial participant through alternative means, e.g., by phone calls or telemedicine visits, as appropriate" (EMA, 2021, p. 6).
- Likewise, belated primary endpoints assessments, as well as important secondary or safety endpoints assessments due to COVID-19 restrictions may affect the clinical trial's scientific integrity.
- Another important challenge that raises the ethical implications for study sponsors is limited or even no on-site monitoring, since monitors may not be able to access clinical trial sites to perform standard monitoring activities, which may result in delayed identification of GCP non-compliances.  
Sponsors tried to arrange alternative methods how to maintain monitoring of the clinical trial participants safety and the clinical trial data integrity, such as telephone contacts with the clinical trial team to assess modified clinical trial procedures at clinical sites, or monitoring through video conferencing, alternatively remote monitoring. Compared to the FDA guidance, most regulatory authorities in Europe did not allow to conduct remote source data verification. This could significantly affect risk management processes. It is worth mentioning that study sponsors should document if monitors were unable to access a clinical trial site or if monitoring was postponed, and they should carefully consider further strategy execution.
- Supply chain complications pose another substantial risk and subsequent significant impacts on the safety of clinical trial participants. The public health emergency could affect the feasibility of delivery of investigational medicinal products to clinical sites and subsequently to clinical trial participants. The interruptions might cause problems, which may jeopardize or even harm the clinical trial participants, as well as they may compromise the integrity and interpretability of clinical trial data.
- A key component prior to any implementation of study protocol modifications is a thorough consideration of the consequences to the statistical analysis. Some adjustments may raise important statistical issues that may substantially affect clinical trial results on efficacy and safety of an investigational medicinal product and validity of the data collected during the conduct of the clinical investigation during the COVID-19 public health emergency. Study sponsors should carefully evaluate the extent of missing data as this could lead to a significant loss of important information. Unforeseen intercurrent events raise statistical concerns as they could lead to serious issues and, thus, need additional thorough

considerations. “Some of the unforeseen intercurrent events may even result in the need to change certain endpoints, if the ones originally specified cannot be collected or assessed as planned. Therefore, appropriate missing data handling approaches aligned with the estimand<sup>19</sup> of interest and plausible sensitivity analyses need to be specified” (Akacha et al., 2020). Deaths due to COVID-19 infections could also raise statistical concerns on clinical trial data integrity and the interpretation of clinical trial results.

The ethical interpretation of clinical trial results is essential to ensure the reliability of new knowledge on efficacy and adverse events of any medical interventions for regulatory authorities, as well as for physicians and subsequently for their patients in routine medical practice. Failure to adhere to ethical principles may have serious safety implications for patients caused by overestimation of benefits or underestimation of risks and harms.

- And last but not least, we cannot omit potential issues related to data collected from clinical trial participants by electronic methods using the electronic Patient Reported Outcome (ePRO) systems, i.e., electronic patient diaries and questionnaires. These hand-held devices are designed to be used for symptoms or vital signs reporting on a daily basis and should be completed by the clinical trial participants at home. However, if there was no regular review of data entered into the ePRO devices during the COVID-19 public health emergency, this could represent a new potential safety risk.<sup>20</sup>

Study sponsors should identify emerging risks or trends, recognize all potential concerns about the safety of clinical trial participants and the integrity of data collected, consider how to mitigate the risks and take appropriate measures to comply with applicable regulatory requirements and guidelines, as well as with the ethical principles. The safety of the clinical trial participants is of primary importance, and risks of involvement in the clinical trial, in particular with additional challenges due to the COVID-19 pandemic, should be weighed against anticipated benefits for the clinical trial participants and society. As mentioned above, according to the EMA guidance, the sponsor should implement a system to manage quality during all stages of the clinical trial process,<sup>21</sup> and all decisions to modify the clinical trial conduct should be based on a risk assessment. All identified risks should be reassessed as necessary. During the current pandemic, it is expected that study sponsors perform a thorough risk assessment of each ongoing clinical trial, as well as clinical investigators perform a risk assessment of each individual clinical trial participant. The measures that prioritize the clinical trial participant safety and clinical trial data validity should systematically be implemented. It must be noted that in case these two aspects conflict, the clinical trial participant safety is always a matter of greatest importance (EMA, 2021, pp. 6–7).

The above listed ethical concerns may significantly affect the integrity of collected or generated scientific data and the scientific validity and reliability of clinical trial results. Therefore, there is a strong ethical necessity of a regular independent examination of clinical trial related activities and documents<sup>22</sup> so as to identify potential ethical missteps and to avoid any non-compliance with regulatory requirements and ethical principles. It is the responsibility of study sponsors to develop evidence-driven strategies to ensure the safety of clinical trial participants and scientific integrity of clinical trials.

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<sup>19</sup> An estimand is “a precise description of the treatment effect reflecting the clinical question posed by a given clinical trial objective. It summarises at a population level what the outcomes would be in the same patients under different treatment conditions being compared. The targets of estimation are to be defined in advance of a clinical trial” (EMA, 2020, p. 6).

<sup>20</sup> All listed ethical concerns are based on personal experience of the author.

<sup>21</sup> See EMA (2016, p. 30).

<sup>22</sup> Such as independent remote GCP audits.

### **Practical aspects: GCP audits during the public health emergency related to COVID-19**

A primary purpose of GCP audits<sup>23</sup> is to evaluate the clinical trial team<sup>24</sup> compliance with a study protocol and relevant regulations and guidelines, to verify that the rights and welfare of clinical trial participants have been adequately protected, to assure the integrity of scientific data reported to the sponsor, to verify that the investigational medicinal products have been maintained and used in accordance with the study protocol, and last but not least, to verify the clinical trial has been adequately monitored. In addition to the above stated purposes of GCP audits, the auditor's assessment of the impacts of modifications of the clinical trial conduct is during the COVID-19 pandemic crucial. Therefore, GCP audits are an effective way to verify and substantiate the compliance with study documents, and legal or ethical requirements.

Particularly in the case of none or very limited on-site monitoring activities during the public health emergency related to COVID-19, there are serious concerns about delayed identification of GCP non-compliance, including protocol deviations not caused due to the impact of the COVID-19 related adjustments. Based on experience raised in the course of remote GCP audits carried out during the public health emergency it can be confirmed that numerous ethical challenges were examined. Some of them led to major, in several cases even to critical nonconformances. Examples of observations, identified by the author of this paper, included, but were not limited to:

- Violation of adherence to GCP standards was observed in the following areas:
  1. Lack of a sponsor's oversight and inadequate management of the study
  2. Principle investigator oversight was inadequate
  3. Inadequate study management by the contract research organization (e.g., Failure to escalate issues)
  4. Lack of accuracy and completeness of data collected:
    - Multiple inconsistencies between source data and electronic case report forms (eCRFs)<sup>25</sup> inputs were observed
    - Lack of source data to support eCRFs entries
    - Investigators or another site designee did not review electronic patient diaries/questionnaires data on the applicable website to confirm the correct data entry procedures and ensure that all entries were clear, complete, timely and plausible
  5. Backdating of essential documents
  6. Insufficient informed consent process: No evidence was present that subjects were re-consented as required and that the re-consents were obtained verbally, or if the subjects signed and dated the revised version of the informed consent form with all new information related to study protocol adjustments
- Failure to adhere to study protocol discontinuation criteria
- Failure to report safety information: Numbers of SAEs were not reported to the sponsor and not followed up properly
- Lack of source documents and/or source data to substantiate eligibility criteria
- Critical eligibility protocol deviations were found: Protocol excluded subjects were

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<sup>23</sup> GCP audit is "a systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s)" (EMA, 2016, p. 7).

<sup>24</sup> Clinical trial team is usually comprised of a principal investigator, sub-investigators, study nurses, pharmacists, laboratory technicians and study coordinators.

Principal investigator is "the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site" (EMA, 2014, p. 13).

<sup>25</sup> Case report form is "a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject" (EMA, 2016, p. 8).

randomized although they were not fully eligible per several inclusion and/or exclusion criteria

- Laboratory results outside of the reference range were assessed as clinically significant, however, no appropriate action was taken
- Failure to comply with study protocol adjustments
- Lack of procedural compliance
- A significant backlog in entering data into the eCRFs<sup>26</sup>

This is not intended to be an exhaustive list of nonconformances observed during remote GCP audits. Rather, it serves as an overview of some of the serious issues all responsible personnel should be aware of. Most of the major and critical findings were related to monitoring, study management and data management, source documentation/source data, the informed consent process and study protocol compliance. There were also cases of fraud detected during the remote GCP audits. Remote GCP audits have shown that the incidence of fraud in conducting clinical trials is approximately the same as it was prior to the current pandemic. According to research on fraud in clinical trials, there were 13.1% cases of fraud in the total number of GCP audits carried out in 22 European countries during a research period of six years (Jedličková, 2015, p. 135). As these cases of fraud were detected only in clinical trials during on-site GCP audits, it is likely that there could be additional undetected cases of fraud in clinical trials that were not audited. On the basis of data and the experience gained during the further GCP audits conducted by the same clinical GCP auditor, it can be confirmed that the incidence of fraud was slightly increasing after the research had been finished and published.

Clinical research performed in developing countries poses another challenge and raises ethical concerns that might cause significant ethical implications as there are very limited reasonable means to assess compliance of clinical sites during the COVID-19 pandemic. Remote GCP audits are currently the only efficient method to mitigate risks to clinical trial participants and to ensure that vulnerable local research ethics is protected and applicable ethical principles are also respected in developing countries. Particularly, when according to the repeated experience of the author of this paper, as well as the experience of other authors (Tsutsumi et al., 2021), there were no additional observations identified at the subsequent on-site audits carried out at the clinical sites audited remotely.

Although EMA recommended not to perform on-site GCP audits during the public health emergency, or to postpone them, the seriousness of observations identified during remote GCP audits proves that a systematic examination of clinical trial related activities is necessary. The nonconformances observed during remote GCP audits have resulted in multiple safety and ethical risks and, furthermore, raise concerns about the overall accuracy of collected and reported clinical trial data during the public health emergency. Given the number and severity of the audit observations, it was evident that monitoring procedures using alternative approaches were not sufficient. It is therefore recommended that efficient monitoring activities (e.g., remote source data verification)<sup>27</sup> should continue during the COVID-19 pandemic to assure confidence that the clinical site's processes of source documentation/data and study protocol compliance are adequate, as well as to ensure issues at clinical sites are identified and/or escalated in a timely manner to allow for prompt corrective actions.

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<sup>26</sup> All listed examples are based on the compilation of observations emerged from the remote GCP audits carried out during the COVID-19 public health emergency by the author of this paper, who also acts as a clinical and research Quality Assurance consultant and auditor.

<sup>27</sup> Remote source data verification was, however, not permissible during the public health emergency related to COVID-19 by majority of regulatory authorities in Europe due to data privacy and data protection regulations (e.g., GDPR).

The nonconformances may seriously impact the accuracy and completeness of the data collected and, therefore, pose a significant risk for the clinical trial participants safety and data quality or integrity. Critical or major nonconformances should be urgently addressed to minimize potential safety, regulatory or business risks. Since ethical implications could be serious, responsible professionals must be held accountable for all critical nonconformances with all potential consequences during the public health emergency as well. Therefore, it is without any doubt that regular independent auditing is essential not only to assure the safety and data quality or integrity, but also to prevent the potential loss of the data collected, particularly during the COVID-19 pandemic.

Given the current insights into the ethical issues, study sponsors have the indisputable responsibility to conduct regular quality assurance activities, such as on-site GCP audits, alternatively remote GCP audits if on-site audits are unfeasible, in order to protect the safety of clinical trial participants, as well as to ensure validity of the clinical trials data. Postponed GCP audits, as recommended by EMA,<sup>28</sup> may cause numerous serious nonconformances not identified in time, which may raise significant ethical issues. This leads to ethical dilemmas whether not to carry out any GCP audits during the public health emergency with all the above listed risks (including serious safety risks not detected or assessed in a timely manner), or, whether to conduct remote GCP audits, with all the limitations they may have. There is a clear evidence that remote audits undoubtedly represent an effective mean of performing a compliance assessment of a clinical site and, therefore, they may play an important role in mitigating risks to clinical trial participants. It should be noted that although some aspects of GCP audits cannot be analysed remotely and should be verified on-site, e.g., the evaluation of facilities or specialized techniques, remote GCP audits are considered as a valuable alternative (Geijo, 2020). This was also confirmed by verification experiments of remote auditing in Japan where the remote auditing model was found as feasible and useful as conventional on-site audits and can provide the same level of auditing in terms of the number of observations. In the verification experiments facility tours were conducted with direct viewing via combination of Information and Communication Technology (ICT) tools, e.g. smart glasses (Tsutsumi et al., 2021). Based on the experience gained it can be concluded that remote GCP audits as part of a sponsor's risk-based approach have added value on the quality of clinical trials and on the level of confidence in the GCP compliance status of clinical sites.

### **Conclusion**

It is anticipated that the COVID-19 related adjustments to clinical research that we experienced during last months could be relevant for any other public health emergencies in the future and the current experience may serve as an important precedent. Regulatory authorities, study sponsors and clinical trial teams now have appropriate sets of guiding principles and instructions that can be used in a similar situation and together with the practical experience from the current pandemic may facilitate clinical research preparedness for future public health emergencies.

Due to the significant challenges quality improvement experts and safety professionals are being faced with, study sponsors should identify and realize all effects that the current COVID-19 pandemic may have on the conduct and quality of clinical trials, and how to deal with those challenges. It is highly recommended that study sponsors and contract research organizations have along with a risk management plan also a crisis management plan in place. For example a business continuity plan or a business contingency plan, which is designed to keep a business running in the event of any unexpected disaster. The crisis management plan should minimize

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<sup>28</sup> According to the EMA guidance, during the COVID-19 pandemic on-site GCP audits, as well as remote GCP audits can be considered only for critical trials. Nevertheless, it was not specified further what clinical trials should be considered as critical trials (EMA, 2021, p. 17).



any potential disruptions and should specify critical items and procedures on how to implement an efficient disaster recovery strategy.

In the light of the acquired experience, it is without any doubt that research ethics continues to play a key role to address effects of the COVID-19 pandemic on clinical trials integrity. All responsible personnel should keep in mind that there is an urgent ethical imperative to conduct only reasonable and meaningful clinical research with the primacy of respect for the clinical trial participants' safety, rights, dignity, humanity and wellbeing. Only such approaches can be effective in efficient clinical trial management and can ensure that the clinical research professionals are well prepared to handle potential ethical issues in order to avoid any negative ethical implications. It is important to develop professional ethical reflection on research ethics in the context of the new unprecedented circumstances in conducting clinical trials. Based on such hindsight and reflections, there should be a wider discussion within subject-matter experts to address each area of concern, and to ensure ethical and scientific quality standards for designing and conducting clinical trials, including efficient methods of monitoring and auditing, as well as for the collection, processing, analysis and interpretation of the clinical trial data generated in the course of the clinical trials during any other public health emergencies. This is a way how to advance the ethical practice of clinical research, to strengthen its credibility, as well as the reliability and validity of clinical trial results, and to create the safe future of clinical research.

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## On the safety and danger of ‘viral’ information from the perspective of the epistemological subject

Peter Gurský<sup>1</sup>

### Abstract

The present paper addresses the formal perspective of information with the focus on ‘untrue’ information presented as dangerous. Grounded in perspectivism, the epistemic subject is understood as decisive in informational transfer. In this context, ethics should focus on how the epistemic subject receives information. Regarding wide-spread information, the notions of danger and safety, the latter being a reaction to the former, essentially result from the fear mechanism of affective neural systems in higher mammals. The practice of attaining safety by eliminating danger is analyzed through the Nietzschean metaphor of the Apollonian and the Dionysian and the concept of resentment. Focusing on the individual, the paper presents a critique of systemized authoritative management of speech content, intensified by the emergence of social media. It is asserted that, by reacting to danger through the systematization of prevention and regulation of speech, it not only affirms fear but also decreases the faculties of an individual to deal with danger and fear itself. The paper argues that the only way to overcome danger and fear is through the individual’s exposure to it, which allows for the strengthening of one’s faculties, thus fulfilling one’s potential in freedom.

**Keywords:** authority, COVID-19, danger, epistemology, information, Nietzsche, perspectivism safety, speech, subject

### Introduction

“Scientists have discovered an accessible drug for COVID, according to the study, it reduces the risk of death by 80%” (Zem & Vek, 2021). The headlined article was published in January 2021 and contains the testimony of a Slovak physician of a promising COVID-19 patient treatment by zinc, vitamin C, aspirin, calcitriol, and ivermectin. Towards the end of the article, there is a notice that most of the scientific community is skeptical about the effect of ivermectin on COVID-19 patients and expects further research. At the very end, it is claimed that “[i]t is clear why the scientific community funded by the pharma lobby is questioning a cheap drug, since the vaccine will bring incalculable profits” (Zem & Vek, 2021). In February 2021, the Slovak Ministry of Health informed the public about the approval of a significant increase of ivermectin supply to Slovak pharmacies (Ministry of Health of the Slovak Republic, 2021a; 2021b). In March, the European Medicines Agency advised “against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials” (European Medicines Agency, 2021). In July, the findings of the original research concluding the positive effectiveness of ivermectin on COVID-19 patients (Elgazzar et al., 2020/2021) were disputed and the study was retracted (MedPage Today, 2021). In those and following months, there was a significant growth in the number of patients suffering from ivermectin side-effects or ivermectin overdose (TV Markíza, 2021), among which is sterility in men (Idonije et al., 2011),<sup>2</sup> coma, and death (The Centers for Disease Control and Prevention, 2021).

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<sup>2</sup> The claim about the sterilization effect of ivermectin in men is, however, undergoing discussion regarding the validity of the methods used. USA Today rates the study as “false” (USA Today, 2021).

In the last, approximately, 10 years, so-called new media experienced a rapid growth in their user databases.<sup>3</sup> During those years, these platforms became the standard means of communication (both peer-to-peer and via institutional representative pages, including legacy media) which meant the expansion of user-created content to such a degree that it escaped the state of controllability. This phenomenon became unsettling to the controlling powers (mainly at government level) since the reach of an average user's speech became significantly more impactful. The reason for this was that the potential danger exceeded what was previously understood as the danger of 'free speech'.

In 2005, the Slovak government passed the law in which it became forbidden for a citizen to spread such information that is *untrue* and as such causes danger for and/or agitation of the part of the public. The subsequent paragraph of the law extends the definition during a national (state) crisis also to the act (of speech) in *negligence* (Zákon č. 300/2005; § 361–362). Whether the law was defined effectively or not, it did not anticipate the complex situation of speech entering online, corporate-owned ground. After the 'boom' of these platforms, governments started to generate pressure on those companies with the goal of improving control over online speech. In doing so and with the acknowledgment that the governments cannot control speech on private grounds directly, it led to an increase in private control over their content. Every registered user of any social media grants consent to the platform's policies. Those policies, although ordinarily including the policy of abiding to the legislation of the country of origin of the user's online action, are set by the company with no strict correlations with the law of the company's country. However, in connection with recent data leaks and Facebook Papers (2021), the governments of multiple countries increased the pressure put on social platforms to assume more responsibility for the content. It should be obvious that the before-mentioned growth of user count created a kind of a content bandwidth that is at least as difficult to control as it is to deal with 'offline' criminal activity. The increase in the number of employees dealing with content control, AI bots seeking banned content, or even allowing users to report content that does not follow a given platform's policies, helped control over the content only to some extent,<sup>4</sup> however, such a motion made private subjects more powerful in respect to the control of online speech than European governments. The war of private and public sectors over online speech control has changed its narrative during the last 10 years, which could be represented by the carefully-thought utterance by the European vice president for the digital single market, Andrus Ansip: "We need to find a balanced approach between the [sic] freedom of expression, media pluralism and a citizen's right to access diverse and reliable information [...] All the relevant players like online platforms or news media should play a part in the solution" (European Commission, 2017). It could be concluded that there is an empirically traceable trend that some politically influential European governments having a problem controlling online speech prefer to make private companies more powerful over speech than to have no control at all. This would imply that the need to control speech can be as valuable as is the son to his rightful mother in the Judgement of Solomon. However, why would it be so valuable?

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<sup>3</sup> In 2011, Facebook surpassed 500 million monthly active users, Twitter and the Russian social network VKontakte reached 100 million. In the years 2009–2011 many other social media entered the market including Pinterest, Instagram, Quora, Snapchat, and Twitch, representing some of today's most used platforms.

<sup>4</sup> See Howard (2020) and Constine (2017).

The European Commission justifies the development of EU initiatives<sup>5</sup> to generate activity towards better control of information by the notion that disinformation – “verifiably false or misleading information created, presented and disseminated for economic gain or to intentionally deceive the public” (European Commission, 2021) – can lead to “threatening our democracies, polarising debates, and putting the health, security and environment of EU citizens at risk” (European Commission, 2021). Setting the morality of the act of creating a ‘disinformation’ aside, the (re)action towards speech control is set in motion by an (acute or potential) awareness of danger. It could (and should) be examined, in another paper, how adequate the fear of the danger is and to what extent the presumption of the possible danger is adequate, but for now, let us focus on the formal side of the phenomenon.

### Information

Firstly, let us base our investigation on the supposition that existence *is*. As such, existence must be comprised of everything that exists. Everything in existence for it to *be* must exist in a certain way and not another. Therefore, for existence itself to *be*, it must exist in a certain way and not another. The *way* existence *is*, is the formation of things. Let us call this formation *information*. If the nature of existing things is defined by *how* they are in existence, then existing things themselves are information. Everything that exists is therefore information. In this way, things as information are in relation to information as such in the same way as the existing things are in relation to existence as such. Information has, in this way, a co-dependent relationship with existence, which means that every piece of information pertains only to existence and nothing else. For this reason, when considering any piece of information, the answer to the question of the described *existence* in the piece of information is always positive, therefore the question is invalid. To examine information, existence is a necessary presupposition and not in question, but the *manner* in which the existence related to the examined piece of information exists is decisive for our further evaluations regarding the relationship between a certain piece of information and a certain existence.

Now, let us consider a recipient of information – the epistemic *subject*. If the epistemic subject exists, he must exist in a certain way. It also follows that the epistemic subject, being in existence but not being existence as such, is also a sum of certain kinds of information, but not information as such, which means that the limitedness of epistémé (ἐπιστήμη) is a necessity, and in this way, the epistemic subject has a limited access to information due to his very nature. Let us focus more on the nature of the epistemic subject. The uniqueness of the subject as a thing in existence is identical to its information. The specificity of the epistemic subject constitutes the manner in which information (in this context epistémé) is obtained. This specificity can be understood as a concrete *subjectivity*, i.e., a quality of epistemic means by which a set of information obtains new information. In this way, the epistemic subject obtains only information about the information of existing things. If the epistemic subject wills to obtain true information about existence, he must tailor his epistemic means in such a manner that allows such obtainment. In any way, the epistemic subject carries information due to his nature; this set of information correlates with (/is adequate to) either the information about the existence of things or the subject as a set of information. In making claims, we refer to information of some existence. However, since subjectivity carries a specific set of information due to the nature of the epistemological subject, in dealing with such

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<sup>5</sup> Code of Practice on Disinformation (2018), European Digital Media Observatory (2018), Tackling online disinformation: a European approach (2018), European Democracy Action Plan, COVID-19 disinformation monitoring and reporting programme (2020), and other.

information we must always take the factor of subjectivity into consideration. The extra value of subjectivity regarding information is *perspective*. Existence is objective, but the epistemic subject carries information in perspectives, ergo is subjective. The perspective of epistemic subject consists of information about information, i.e., a mode in which information of existence exists in a subjective mode, ergo a concrete mind. For a concrete perspective to be true not only to a concrete subjectivity, but also to the existence, it must be in congruence with information of existence. For this reason, the main ethical interest should be in exploration and correction of the manner in which the subject *receives* information from the existence, in other words, the main epistemological and ethical issue lies in formation of the information of information of existence, i.e., the subjective (secondary) level of obtaining information.

In this context, let us consider the following propositions of epistemological perspectivism: 1) there is a world outside the mind that can be seen in different perspectives; 2) perspectives reveal the world; 3) all views occur in some perspective;<sup>6</sup> 4) perspectives qualitatively differ in validity since we are able to compare perspectives to one another (Miner, 2017, p. 64).<sup>7</sup> The first two claims about the world outside the mind are compatible with the views provided by this study, and as such, they provide the validity dimension towards the (objective) world. The third proposition is a manifestation of the limitedness of the epistemic subject, since all information is accessible to the epistemic subject only as information about information, as argued before. The fourth proposition presents us with factors by which a perspective can be assessed, but only in comparison to another. Perspectives can be compared through the perspective of coherency, logic, aesthetics, capacity, utility, effects, etc. In this way, in order to gain *reliable* knowledge, a piece of information must be viewed in relation to other information, or as Nietzsche puts it: “[a]n isolated judgment is never ‘true’, never knowledge; only in the connection and relation of many judgments is there any surety” (Nietzsche, 1968, p. 287; WP 530).<sup>8</sup>

### Untrue information

Now, let us look at some of the most used concepts in contemporary discussions on the possible danger of information. There is an ongoing tendency to view meaning through the prism of *intentionality*, with the bases in the theory of mind (Brentano, 2015; Crane, 1998; 2009; Perry, 1994), particularly through the theory of consciousness (Dennett, 1987), philosophical psychology (Premack & Woodruff, 1978), phenomenology (Bayne & Montague, 2011), epistemology (Loewer, 1987; Zalta, 1988), and ethics (Anscombe, 2000). In the context of semantics, P. Grice (1957) demonstrated that in ordinary language we use *meaning* in two senses: natural meaning and non-natural meaning. The latter, being of his primary focus, is in what was later called intention-based semantics explained from the perspective of intentionality (Grice, 1957; 1975). S. O. Sørensen, following Grice’s research, presents three kinds of non-natural information: intentionally non-misleading *information*; unintentionally misleading information – *misinformation*; intentionally misleading information – *disinformation* (Sørensen, 2019). In this way, the factors of the perspective are intent and verity. We find general acceptance in a definition of disinformation that includes an intention to deceive.<sup>9</sup> Zimmerman and Kohring, however, claim that we can condition the

<sup>6</sup> “[...] facts is [sic] precisely what there is not, only interpretations” (Nietzsche, 1968, p. 267; WP 481).

<sup>7</sup> Miner, as paraphrased, provides the components of perspectivism as inversions of the claims provided by Leiter (1994, p. 344).

<sup>8</sup> See also another passage: “There is *only* a perspective seeing, *only* a perspective “knowing”; and the *more* affects we allow to speak about one thing, the *more* eyes, *different* eyes, we can use to observe one thing, the more complete will our “concept” of this thing, our “objectivity,” be” (Nietzsche, 1967, p. 119; GM III/12).

<sup>9</sup> See the discourse analysis by Jaster & Lanius (2021); see also Fallis (2015).

definition of disinformation either by intention to deceive or by *disregard* for truth (Zimmerman & Kohring, 2018). Such a definition of disinformation is criticized as “highly idiosyncratic” (Jaster & Lanius, 2021, p. 35), since the *bullshit* dimension (Frankfurt, 2005) is generally ascribed to misinformation (Søe, 2019; Pritchard, 2021), and the *intent* to deceive is attributed to disinformation (Fallis, 2015; Fallis & Stokke, 2017) and fake news (Dentith, 2016; Rini, 2017; Jaster & Lanius, 2021; Gelfert, 2021; Zimmermann & Kohring, 2021).

We can find a similar problem of definition within the discussion about the above-mentioned fake news. By a small meta-analysis of fake news definitions provided by Jaster & Lanius (2021) we find that most of the theorists subjected to the analysis agree on the *truth*, *deception*, and *bullshit* dimensions in defining fake news, which means that in pursuit of *consensus* in defining fake news we would have to take into account that fake news is untrue and misleading and/or is intended to deceive and/or that distributors of fake news are indifferent to the truth (Jaster & Lanius, 2021). Fake news viewed in these terms overlaps with both misinformation and disinformation, as categorized by Søe, although the sum of both does not constitute fake news itself, since it would be identical to untrue information. In this context, Jaster & Lanius (2021) point out that in journalism, it is becoming more common to use the term disinformation instead of fake news. It is often overlooked, however, that the truth dimension itself is not necessarily decisive for a piece of information to be fake news, since some effective forms of fake news do not contain an explicit untruth, but they omit some relevant contexts (Gelfert, 2018; 2021; Pritchard, 2021).

From the previously stated, it should be clear that the conceptual set in the discussion about possible danger of information is not clear at all. A first set of problems arises from the understanding of intentionality. From the semantic point of view, intentionality is a presupposition of sense of any given sentence. A sentence is a representation of its reference (a thing in existence), but not the reference itself (neither the thing nor existence themselves). Without the intention dimension, a sentence could be read only through means of linguistics in a restricted sense (i.e., syntax and morphology). Although, to presuppose the intention of a sentence, i.e., that the sentence has a meaning at the sentence level, allows for understanding of what the sentence means, i.e., in what *way* the sentence is to be understood. In this way, every unit of morpheme, word, phrase, clause, and sentence carries a specific meaning, different at every level. From the semantic point of view, a proposition itself cannot carry the intent to deceive, since the intent of the proposition is expected and necessary to be known for the intended understanding – understanding presupposes intention. It means that no proposition can be deceitful in itself, since if the proposition is understood as intended, the deception perishes.

When we talk about the intent to *deceive*, then we talk about a psychological-ethical state of mind, where the intent to deceive represents a motive of the moral agent regarding the intent of the meaning of the expressed proposition. The intent to deceive on ethical grounds means the intent to lie, i.e., a possibility not to allow access to a given piece/set of information to other recipients of information (i.e., other minds), upon which the moral agent is willing to act, via means of information. A moral intent to deceive thus represents a non-identical relationship between the semantic meaning of a given proposition and the information carried by the originator of the proposition. Vice versa, an endeavor to establish an identical relationship between meaning and knowledge represents an intent to be honest.

The dimensions of intent to deceive and disregard the truth arise from an omniscient perspective which presupposes certain kinds of knowledge that are obtainable only by an extra set of information apart from the original evaluated piece of information. To see this, let us consider a subjectivistic perspective. When a subject is presented with *a piece* of information, the intent to deceive and disregard for truth become one category – the unknown. There is no reliable method

of gaining knowledge about the content of the motives and relationships to the truth of originators of any information. We can make claims about the verity of given information, which are as good as our epistemological abilities are, but to ascribe certain qualities to motives and relations, which are by nature truly transcendent to the subject (when it comes to other subjects), is nothing but our limited judgement based on the present effects of our subjective set of information, i.e., on *us*, with the questionable presupposition of existence of given moral *facts* in the world.

It is not clear in what ways the intent to deceive and disregard for truth are treated as epistemological dimensions. The above-mentioned connections of epistemological and ethical dimensions of certain kinds of perspectives on information present a specific set of problems. When confronted with a piece of information we later evaluate as untrue, the information about the untruth of the piece of information tells us nothing about the motive or the relationship to the truth of the originator. However, what is more important is that, even if we could reliably assess the un/intentionality of spreading untrue information, it tells us absolutely nothing about the *morality* of the action, since it would require a presupposition of existence of the moral *fact* that to lie is always morally bad/wrong. In considering the verity dimension, by acknowledging the subjective character of our epistemological judgements about information from other subjects, we must acknowledge the complexity of subjectivity of the originator of a given piece of information.

For these reasons, the paper will not focus on the *intent* and *bullshit* dimension, since the true knowledge about both intent and verity is obscured by the requirement for an extra set of knowledge. To avoid the terminological confusion described earlier, the paper will, for the subjectivistic perspective, use the term information in the sense of language claims that carry meaning in correspondence with a set of shared language rules and about which we have no knowledge of verity, intent, and relation to the truth of the originator, and the terms untrue and dangerous information, which we consider not true and dangerous by a subjective judgement.

### **On the notion of control and safety**

The need to control (other people and their actions) comes both from affects of the mind (in this case by fear) and rationality (as a reaction to the affect). The unpleasant affect triggers the mind to identify the unpleasant affect as a problem that is as such categorized as a problem for rationality, shifting the energy from a passive feeling to *action* based on the passive feeling.<sup>10</sup> One of the most basic reactions to fear (other than flight) is to *eliminate* the source (i.e., object, or stimulus) of the fear.<sup>11</sup> Since a living human agent is essentially in control of the self (and only to a variably limited extent) and learns to only indirectly ‘control’ the behavior of other people through social learning (albeit this too varies greatly), the aim to ‘control’ other people is to regulate the social environment in such a manner that it reduces the actual or potential danger that could decrease the chance of experiencing an affected mind. Although an undoubtedly useful mechanism that (among others) secured the survival of the human species, the fear mechanism describes the formal aspect of an affective process manifested as an actual experience of the affect of fear which is in fact itself the immediate source of the mind being bound by an affect and thus not being ‘free’. An experience of intense emotions, such as fear, anger, stress or anxiety, can activate the so-called amygdala hijack, which triggers a fight-or-flight response and disables the frontal lobe, which is associated mainly with cognitive functions (Goleman, 2005). The aim of removing the fear stimuli is fundamentally the aim of removing the unpleasant affect; the removal of the fear stimuli is, from

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<sup>10</sup> For a detailed description of affective mechanisms and the affected mind see the forthcoming monograph of Petrufová Joppová: *Od patetiky k etike [From pathetics to ethics]* (2022).

<sup>11</sup> See footnote 20.



the perspective of the mind (not rationality), a mere byproduct. By killing a spider, an arachnophobe does not stop being fearful of spiders; by ‘killing’ potentially ‘dangerous’ information in the social ether one does not stop being fearful of the potential danger of ‘dangerous’ information.

The reasoning is this: the mind, conscious of its potential (i.e., of freedom, to a limited extent), ‘feels’ unfree being bound by an ongoing affect since then it becomes its subject – this unfreedom is an active resistance of the mind (using those abilities that are momentarily ‘available’, e.g., rationality) which leads to an action with two aims: the elimination of all fear *stimuli* or the elimination of all *fear*. It is important, however, not to forget that the process of resistance is in fact a part of the process of fear mechanism – there is no resistance (the need to control) without fear itself. It may be safe to say that neither of those aims is achievable, although in politics we tend to focus on eliminating the stimuli rather than fear itself. On the other hand, thanks to some great anthropological studies and recent neuroscience, we understand the role of fear mechanism to such an extent that we could rationally conclude that the removal of fear (mechanism) would endanger the proper regulation of the body and its being in the physical world, and as such is *good* for the survival of the body.<sup>12</sup>

If the notion that the need for social control arises from the need to control fear is true, then the question ‘What is the desired (and perhaps good) proportion between fear and safety?’ is in place. If we act on fear, our urge is to escape the object of fear or to destroy it. If we act on rationality, we act on ratio evaluating the object (ratio being motivated by the affect). The process of elimination of the affect by recognizing the object is a common method in current psychotherapy. However, it was never the objective of psychotherapy to affirm fear to such an extent that the whole procedure would aim to eliminate all fear. It is a result of the assumption that there is a ‘normal’ (‘healthy’) level of the fear mechanism functions and an ‘unhealthy’ level of fear reactions (the reaction level would be either too high or too low and would limit the subject in his ordinary life to a significant extent).

### **Danger and fear**

At the political level, the notion of safety is a part of what is expected of a democratic state and its leaders. The citizen acknowledges the responsibility of the state for safety in the government-controlled area as its innate function. Governments regulate weapon, drug, and service markets for this purpose. The more the authority limits the citizen’s means of self-preservation and self-protection, the more it takes the responsibility for these natural faculties. When danger emerges, the citizens of a state rightfully expect the authority to eliminate it. The effect of the responsibility shift is that citizens, not being expected to resolve danger in the areas that the authority took over, are also shielded from a large number of dangerous stimuli, which leads to a lesser concern (fear) from citizens over given areas that could be of no interest to them when not being exposed to them – the ‘acute’ fear from natural stimuli is veiled.

As we already established that a certain amount of fear to certain (dangerous) stimuli contributes to human self-preservation and that acting on the affect of fear does not lead to freeing the mind but rather affirms the affect, it should be obvious that the solution to this is not to eliminate fear but to overcome it. For this reason, Aristotle defines courage (ἀνδρεία) as a midpoint (or an equilibrium) between fear (δειλός) and recklessness (θράσος): to be courageous is to know what to fear and what not to fear (Aristotle, 2004, pp. 48–54; NE III/6–9). The archetype of the devouring mother (Jung, 2004) could be an appropriate warning of what the relationship between the

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<sup>12</sup> See footnote 20.

individual and the authority can become. The devouring mother acts on her rationally constructed idea of her love instead of acting in such a manner so that the child matures through a series of attempts to orient itself in the world, many of which are a success and many a failure. The devouring mother as an overprotective mother tries to eliminate all possible dangers to ensure absolute safety in which the child never matures. The child of the *devouring mother*, not being exposed to fear stimuli, never understands fear and how to process it, so it never becomes courageous. The child remains weak and dependent on the mother who fought every danger instead of the child. Although the world is too complex to fit the metaphor perfectly, it speaks a simple truth: overprotection does harm. To seek refuge in safety at all costs means to find the weakness. To seek danger at all costs, however, often leads to death. So, the true strength of an individual can be only forged through the individual overcoming of actual fear. This is why F. Nietzsche utters: “*From life’s school of war. – What doesn’t kill me makes me stronger*” (Nietzsche, 2005, p. 157; TI Maxims/8).

While the questions of what kind of dangers we are willing to be confronted with and what kind we are willing to entrust the authority to deal with in an ideal state should be discussed, it should be remembered that we, both as individuals and as humankind, become defenseless before the abandoned danger in the course of time. The ability of an authority to deal with a given set of areas is based on experience and is passed on through state institutions (e.g., laws or bodies). The main problem is that while the authority ‘disarms’ its citizens with the promise to resolve certain kinds of danger, it never truly succeeds so that it could prevent the given danger not to endanger a disarmed citizen. If this sounds innocuous, it describes the situation of dealing with untrue information accurately.

In the context of untrue information in the social sphere, Rini claims that “individual people typically act reasonably when they grant greater credibility to fellow partisans, even if this sometimes leads to the acquisition of false beliefs” (Rini, 2017), so that this transmission of untrue information often can be reasonable at the individual level. Although Rini does not claim that epistemic partisanship is good in itself, she takes a pessimistic stance in what an individual can control in the given sphere. Thus, Rini sees the solution to the problem of fake news not by “focusing on individual epistemic virtue”, but in an “institutional change” (Rini, 2017), i.e., in expecting more control by institutions, e.g., of social media, over spreading ‘untrue’ information. Arguably, we can find that political-epistemic partisanship and trust, a major determinant of relationships between social subjects, can be reasonable, since we always accept and carry a certain sum of information that is given to us by others. However, trust often becomes ideological gullibility when it comes to politics. The epistemic demands on the individual to successfully orient himself mainly in the social world are increasing with the growing mass of accessible information, and together with advancing democratization they require a change in the epistemic habits of the individual towards a higher suspiciousness when confronting a new piece of information.

Let us suppose that the political-epistemic partisanship can be *reasonable*, given the shared normative value commitments and a lack of knowledge of the receiving partisan (Rini, 2017). Reasonability itself, however, is an insufficient reason for it to be a *moral* value, i.e., something worth pursuing while following the good, unless we identify *the good* solely with rationality, but not with truth. Since the information gained and accepted by a partisan often leads to sharing untrue and manipulative information, it cannot be perceived as good at the ethical level and reliable at the epistemological level. On the other hand, the same issue can also be brought up in individualistic epistemology, if we presuppose a broad, actual, and reliable approach of each epistemic individual consistent with the individual’s cognitive functions. *Reductio ad absurdum*, if we expect by a theory that the individual knows everything, we will certainly fail. However, if we presuppose by

a theory knowledge dependent on the individual's cognitive functions (and all knowledge we dispose of depends on them), then, I believe, it can fulfil the requirement of knowledge, while we can focus on how to perfect cognitive functions in the epistemological sense while following the good.

The notion that “[t]he advent of widespread and rapid disinformation increases the number of deaths through the proliferation of hoaxes and epistemological confusion” (Palomo, 2021) can itself create epistemological confusion when used as cliché – “[...] disinformation kills” (Palomo, 2021) or “Covid misinformation on Facebook is killing people” (BBC, 2021; US President J. Biden) – it makes a sweeping statement, leaves out the true agent, and makes it a ‘statistic’. M. Palomo indicates the role of the individual mainly in his ‘epistemological motivation’: “This confusion occurs when individuals are incapable of maintaining high-quality criteria of truthfulness once they have received informative elements of an ideological nature. Epistemological confusion is manifested by people granting truthfulness mainly to what they want to be true [...]” (Palomo, 2021). The end of the quote indirectly exposes the fact that the nature of the problem is fundamentally *ethical* and therefore should be treated as such. At the political level, the diversion of the problem to the epistemological ground leads to the above-mentioned mechanism: information represents a potential danger, an individual fears the danger of other people acting on ‘dangerous’ information, an individual has no power over other people but through the authority (public or private), the authority assumes the notion of responsibility and acts upon it;<sup>13</sup> if it succeeds it minimizes the occurrence of the danger which then only rarely meets the individual, if it fails, the individual is on his own. In the political context, the debate over the control of *untrue* speech quickly leads to the question of ‘Who has the authority over what is true and what is not?’ and provokes standard liberal issues. Information itself does not carry an innate danger or moral evil. The debate should withdraw from the metaphor and return to ethics.

The identification of the danger of information is a projection of previous experience of causal identification of a given piece of information and the perception of a situation that causes an unpleasant affect in the perceiver, of which the problem is two-fold: the causal link, where we essentially speak of consequences, is strongly at risk of being a mere disguised correlation and by the projection itself, which is fundamentally assigning the given information a moral attribute, the true causal agent is obscured. If the Ministry of Health *considered* the information about ivermectin to be *true*, does it make the Ministry in any way morally less responsible?

In general, neurally-based affective mechanisms in mammals follow a simple aim: the affective systems allow the organism to orient itself in its environment by reacting to it which ultimately leads to the increased chance of survival of the organism. An object identified as an external cause of an ongoing affect (e.g., ‘I fear the wolf in my immediate proximity since the wolf *in my knowledge* represents the human experience of wolves violently hunting down prey. The wolf is thus dangerous.’) is added a certain surplus value with a specific relevance. The difference (one of many) between affective systems and rationality, of which a healthy adult human is a carrier, is their effective span. While rationality raised humankind from the wilderness to civilizations through planning, organization, and exploring the environment (e.g., through science), the affective systems prepare and compel the affected body to react immediately. Although rationality ‘acts’ on a set of data that is ‘prepared’ by the affective systems through the added surplus value of relevance, thus being the ‘problem-solver’ for affects, it should seem convincing that to rely solely on affective information in long-term decisions is contra-productive in the context of the survival of

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<sup>13</sup> Speaking of European countries, the state authority depends on popular will (through voting system). The trend in European countries is for a government to usually accept the responsibility to regulate any new area possible.

the organism and/or species. To overcome the compulsion of affects to act on them, one must be confronted with a given affect (i.e., be affected) in a certain dosage.<sup>14</sup> If the stimulus raises an affect that is overly ‘strong’, the subject is *unfree* not to act upon it. A manageable dose of exposure of a given stimulus (thus of an affect) is at such a rate that allows the subject to be free not to act upon it. A challenging dose is at such a rate that allows the subject not to act upon the affect while it pressures the subject to do so. If the urge is strong and yet it is not affirmed by acting on it, the challenge is overcome and the subject is stronger and more free. To be strong and to be free (due to the nature of a given organism, i.e., to be free is to fulfill one’s potential) is the ultimate aim of *any* living organism. Upon this goal, we create a society to secure human enhancement through creating optimal conditions. As Nietzsche puts it: “[...] everything evil, terrible, tyrannical, predatory, and snakelike in humanity serves just as well as its opposite to enhance the species ‘humanity’” (Nietzsche, 2002, p. 41; BGE I/44).

The notion of security can therefore be treacherous: absolute security means absolute elimination of danger. Human enhancement requires a challenge so that by overcoming one enhances himself in accordance to his nature. A challenge requires such stimuli that make the overcoming possible. Perhaps paradoxically, the elimination of danger does not suppress the affective systems – rationality removes the stimuli causing fear and the fear *seeks* stimuli of what to be feared. By elimination of all sorts of natural danger, the character of the object of fear has shifted to a significant extent to the social sphere. The most danger a European citizen encounters is represented by the object of ‘others’. By achieving a state of safety, the affected polis is heading to become weaker. A strong (free) individual is condemned to be surrounded by danger: “That is the yielding of the greatest: it is hazard and danger and casting dice for death” (Nietzsche, 1978, p. 115; Z II).<sup>15</sup> If the desire of a human/humankind to become ‘stronger’ is valid then safety is of secondary importance.

Arguably, if those patients, who were voluntarily treated by ivermectin in prevention of or during COVID-19, were prevented from the obtainment of the information mentioned in the introduction of the paper (if it was possible), they would not endanger their health as a consequence. However, the subjects, represented by the patients, will remain susceptible to similar instances of exposure to ‘dangerous’ information, i.e., they remain weak. This is *not* to say that one should act based on a random set of information. On the contrary, one should act on information only if he/she considers the perspective in which the given set of information is manifested to be the most *valid*, while acting on ethical-epistemological obligation *to obtain* more perspectives (i.e., aim for wisdom, strength), which was explained in the introduction to the paper.

### **The Apollonian and the Dionysian**

The philosophical concepts of the Apollonian and the Dionysian represent the duality of order, clarity, and individuation, on the side of Apollo, and chaos, emotion, and unity, on the side of

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<sup>14</sup> The human particularity allows himself to handle fear (or any affect for that matter) not only actively (i.e., being affected) but also (and perhaps mainly) through the forms (ideas) of affects. I argue that while being able to *think* of a given affect, there is no need (or possibility) to counteract the affect since it is in its formal ‘stage’. The formal thought allows the mind to prepare for the effect of the affect (to a limited extent), but the overcoming itself must take place while being affected.

<sup>15</sup> See also Nietzsche (1968, pp. 501–503; WP 957). For a more detailed study on danger in Nietzsche’s ethics see Kuehne (2018).

Dionysus.<sup>16</sup> Being the two fundamental forces (or ‘drives’), their influence is mutually dependent.<sup>17</sup> In *The Birth of Tragedy*, Nietzsche criticizes the shift in the Ancient Greek art from equilibrious fusion of the Apollonian and the Dionysian to the side of the Apollonian (Nietzsche, 2000; BT). The primary affective reaction to the unknown is fear and it can be argued that fear of the unknown is a/the fundamental fear, or even that the unknown is the fundament of fear.<sup>18</sup> Apollo fears the chaotic unknown of Dionysus (who as unindividualized is not *in-form*ation) and reacts to the fear by the ‘light’ of order and clarity. A state of things biased in favor of Apollo heads to an absolute organization and elimination of chaos. In an absolute Apollonian state, the only dynamics left is the process of individuation which could be seen as the process of an infinite division. Apollo’s end is in endless stagnation and the end of Dionysus is in absolute chaos.

In 2005, the World Health Organization published *International Health Regulations*, and in 2013, the *Official Journal of the European Union* released *Decision No 1082/2013/EU*, which called on EU states to develop national plans for pandemic management.<sup>19</sup> In 2019/2020, most European states abandoned these procedures and started to prepare new ones, more suitable and relevant to the situation of COVID-19 pandemics. The endeavor to contain all danger, be it immediate or even potential, as this shows, through order and safety, expresses the Apollonian will not to be ‘controlled’ by chaos (Dionysus). However well the plans were prepared, being created under a projection of possible (imaginary) danger they could not anticipate the reality. This only shows that the Apollonian force cannot possibly cover the complexity of reality (i.e., chaos, in the epistemological sense) and therefore is *not* an exclusively reliable approach to danger.

Nietzschean *ressentiment*, in short, means the process of externalization (projection) of one’s weakness into an external enemy, who is in essence imaginary, for the purpose of freeing ego from the burden of self-conscience. An unpleasant affect emerging from a sense of inferiority (weakness) seeks its object outside the subject. It is the inverting of values as a consequence of vengeful reaction of those who realize they are not masters (Nietzsche, 2009, pp. 53–59; GM II/8–11). Fear, as any negative affect, can and does produce *ressentiment* in various shapes, one of which is the need to surrender the unpleasant affect (fear of danger) into the hands of authority. The goal is a *feeling* of ‘safety’, undisturbedness – pleasure (Nietzsche, 2002, pp. 40–42; BGE 44). In this sense, both ‘irrational’ distrust of authorities (scientific or political) which we are dealing with today in the context of vaccination, and ‘rational’ endeavor of order are products of reaction to fear, i.e., they arise from fear as a rationalized affect – *ressentiment*.

The current pandemic, comprising every affected field of human life, amplified the flaws of the social-political setup. The significance of the individual made another step towards the background in favor of society as a whole in the name of ‘public good’. The shift is lubricated by transferring the focus of the popular narrative from the agent to ‘information’. In this focus, no particular individuals endangered their health, but *information*, and as such is perceived as dangerous. The individual in this scenario is a passive carrier and actor of dangerous information.

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<sup>16</sup> See Nietzsche (2000; 2013); Schopenhauer (2016) (especially the third book: *The World as Presentation – The Platonic Idea: The Object of Art*). See also Nussbaum (1999); Soll (2013); Thornton (2018).

<sup>17</sup> Nietzsche described the concepts variously as drives, forces, impulses, and powers. The substantial ontological force for Nietzsche is the will to power. The concepts of the Apollonian and the Dionysian should therefore be understood as epistemological foundations rather than ontological ones, i.e., they are ‘higher’ drives that one submits himself to. They do not constitute affects; they rather represent kinds of *knowledge*.

<sup>18</sup> See Carleton (2016); Panksepp (1998; especially chapter 11: The Sources of Fear and Anxiety in the Brain); Panksepp & Biven (2012; especially chapter 5: The Ancestral Roots of FEAR).

<sup>19</sup> See World Health Organization (2016) and The European Parliament and the Council of the European Union (2013). For a critique of the documents see Speakman, Burris & Coker (2017).

Paralyzed by the notion of safety, the individual becomes a ‘child’ dependent on the ‘mother’. By weakening the individual through responsibility transfer, we gamble with the strength of humankind which can and will cost us our future. To be prepared for another catastrophe does not mean eliminating potential danger in the name of Apollo but becoming and being strong as individuals. Hardly anyone would argue that the law or ‘plans’ are more flexible and reliable than the faculties of the human mind. This crisis derides the calculated social ‘preparedness’ and mercifully warns us before the Apollonian path we have taken.

### Conclusion

Information about the efficacy and danger of ivermectin, vaccines, masks, tests, and many other similar phenomena emerging due to the current pandemic tend to be considered as causal agents of undesired effects that emerge, e.g., human suffering or death. It attracts the attention of mainstream social discourse, which tends to aim for simple solutions. The current discourse on the danger of information in epistemology and ethics makes effort to cope with both the public mainstream discourse and the phenomena emerging from the current situation.

Based on the study of the relationship between existence and information, it was demonstrated that the epistemic subject is epistemologically limited. This limitation appears not only in the quantity of information the epistemological can dispose of, but also, and mainly, that the epistemic subject has only a secondary access to the world. For assessment of validity of information, it is necessary to view a given piece of information in the perspective of inter-related information. Although it is not possible for the epistemic subject to assess the validity of a given perspective in relation to existence as such, it is possible to compare a perspective to another. In this way, it can be viewed as epistemologically and ethically *good* to aim for obtaining perspectives of high quality.

Based on our study regarding information and epistemic subject, the notions of misinformation, disinformation, and fake news have been examined with the focus on intent to deceive and disregard for truth, by which the terms tend to be defined. If we look for solutions, we should understand that we are unable to obtain true knowledge about moral intentions and the relationship to the truth of the originators of a given set of information. For this reason, the paper focused on how one *receives* information.

It has been argued that to be strong means to fulfill one’s potential (especially of the mind), i.e., to become free. To grow in strength requires being exposed to challenges. Overcoming challenges (i.e., courage) demands the full engagement of the body and the mind of the exposed individual (i.e., strength). Freedom, not understood as mere chaos (Dionysus), requires both an idea of unfreedom, which fundamentally constitutes ‘anxiety’ (or ‘angst’), and a certitude of one’s self in his own faculties (i.e., wisdom). Courageous wisdom is thus a fulfillment of one’s potential and there is nothing more active, reliable, and complete the human mind can achieve. Fear, a natural and useful neural reaction to environment’s stimuli, should be treated with a cautious distance. There is an evident gap between the fear reaction and the moral notions of what is desired in the social sphere. To *act* upon the unpleasant affect of fear is to evade experiencing pain through resentment by relinquishing the faculties of dealing with danger. By surrendering the danger into the hands of authority, one does not avoid danger and fear of danger but rather substitutes the character of the kinds of danger one encounters. The notion of authoritative security is therefore not only a misanthropic stance fundamentally based on fear of others, but more importantly, it limits the individual’s natural potential to grow stronger. This warning should challenge our vision of an ideal social-political state of things in which we desire to realize our lives.

Undoubtedly, the ivermectin boom, downplaying coronavirus, and untrue information spread about vaccination and treatment can represent a kind of informational danger. With the focus on

the content of information and motives of its creation, it is fundamentally the problem of untruthfulness. Lies and deception represent a danger older than human languages. However, the giant leap towards the control of speech as such indicates a rather naive view both of humans and truth. In a sterile and safe world, where only truth is allowed to be spoken, the strongest are those who lie. If we took a step back from the ‘unquestionable’ call to action, it would allow us to see the motives of *our* action. Not the fact that we fear *fear*, but that we *fear* fear shows us that we cannot escape fear while acting upon fear itself. By affirming fear through fear of fear, we not only stagnate in it, but we actively expand its ‘tentacles’. Even more, by successfully eliminating any given danger – neither danger as such nor fear as such diminishes. Whether we take on the Sisyphean curse of establishing safety or not, this should be understood: the *only* possible means of truly overcoming danger posited by information is through the mind of an individual, and the *only* authority of truth is reality.

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## Healthy people and biochemical enhancement: A new paradigmatic approach to the enhancement of human beings?

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### Abstract

The authors analyse a new paradigmatic approach to the enhancement of human beings proposed in transhumanist visions. Transhumanist authors promote the biochemical enhancement of healthy people via the concepts of bio-happiness and bio-love (love drugs). The paper is based on an assessment of the value attributed to the lives of disabled people vis-à-vis those of healthy people. The value imbalance in the transhumanist conception is criticized on the grounds that it is an incorrect response to the posthuman urge to redefine human beings. The authors' final standpoint is that the value of human beings should be derived primarily from our naturalness and that artificiality (which is indisputably a part of people) should be subordinate to this.

**Keywords:** transhumanism, biochemical enhancement, disability, value assessment, bio-happiness, bio-love

### Introduction

Enhancement has been part of the history of man from the very beginning. And not just in the history of the human race itself but in the history of life as well. It is a crucial part of evolution. The aim to improve is what Charles Darwin called *natural selection*, the constant process of ensuring variation between even the most inconsequential things, rejecting the bad and preserving the good, or even perfecting things. He believed that we subconsciously do this whenever and wherever the opportunity presents itself; all organic beings seek to improve themselves concerning the organic and inorganic conditions of life. Unfortunately, we remain unaware of these changes owing to our short life span (Darwin, 1859, p. 84).

Whether we realize it or not, we enhance ourselves, and have always done so as a natural part of our existence. We may not have always used natural tools, but that too can be considered characteristic of our human nature. This is what the German philosopher Helmuth Plessner describes as the law of *natural artificiality* (Plessner, 1975, pp. 309–321). In short, humans have a constant longing to build their own place in this world and using artificial means to do so is part of our nature.

Besides evolving biologically, we also evolve culturally and that determines how we enhance ourselves. We moved out of huts and into skyscrapers, we swapped our spears for pistols, we replaced horses with cars and shamans with hospitals. The ways in which we enhance ourselves have developed hand in hand with science and technology, as part of our cultural evolution, which is in many ways now overtaking our biological evolution. But the progress in our cultural development is more easily observed than the natural selection described by Darwin. Indeed, we can see that it is accelerating exponentially, which is prompting ethical concerns.

In this paper, we will discuss the new approaches to human enhancement that raise moral questions about the possible adverse consequences. Specifically, we will focus on the visions of biochemical enhancement that have no medical purpose, but are aimed at perfectly healthy people who face some kind of life challenge. This, we believe, is the new paradigm of human enhancement. Never before in human history have there been such realistic visions of how chemicals can be used to change the lives of healthy people in profound biological ways; and yet, there are still many diseases and medical problems that require solutions. Our *natural artificiality* is advancing very quickly and requires us to engage in some deep philosophical and

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ethical thinking. Historically, there have been numerous paradigmatic turns in the approach towards human enhancement, but the one now standing before us is of a different kind and so should be the subject of philosophical inquiry and investigation in other anthropological disciplines too. Our critical thinking on this topic follows the premise that our biological nature takes priority over our artificiality. We attempt to argue this premise using the example of disabled people.

### **Biochemical enhancement of human beings – background**

People's lives have changed dramatically in the last few centuries. Science and technological innovations mean that we live longer and are smarter and extremely powerful. Biochemical enhancement is not destined for the cyborgs; most of us are already enhancing our bodies beyond their natural potential. For modern humans, these biochemical advantages are a routine part of our existence; yet our grandparents would have considered them supernatural. The most significant modern innovation insofar as the topic of this paper is concerned is *pills*. The question is how did herbs end up as pills? American science historian Thomas Hager explains that it all started more than 150 years ago when the first pharmacists and herbalists extracted drugs from barrels of dried plants. The word drug was originally the name of these barrels used for keeping herbs in. The first pharmacists were the first suppliers of effective natural medicines to doctors in the 18<sup>th</sup> century seeking to help their patients. Today we have more than ten thousand, targeted and increasingly powerful medicines that can “treat and often cure conditions that have confounded healers for thousands of years” (Hager, 2019, p. 7).

When technology became advanced enough for us to put all the effort and hard work originally needed for healing into one small powerful pill, it changed our paradigmatic understanding of the human power to enhance. It was a long journey from having absolutely no understanding of, or power over, disease to decoding human DNA and being able to treat or at least understand almost all diseases. We are now on the verge of the next paradigmatic change – biochemical enhancement has progressed so far that we are considering using it not simply to eliminate diseases but to enhance ordinary life and ease the psychological challenges associated with it.

When fighting illnesses in the past, the options people could choose from were limited. In prehistoric times even resting could be considered enhancement since it was the first (and very often the only) means of fighting the disease. Those who did have the luxury of long-term convalescence without starving to death could enhance their life conditions to above average. We may not realize it in the current era of paid sick leave but our ancestors did not have the opportunity to get time off work and rest while being supplied with all the necessities of life. The urge to hunt for food to feed the individual as well as the family was much stronger then than it is today. The first global pandemic in the modern era – Covid-19 – is illustrative of the social change that has occurred over time. While most people living in previous centuries had to grow their own food, nowadays, thanks to innovations in food production and distribution, most people are unaware of the time and seasonal pressures connected with agricultural production.<sup>3</sup> Obviously, there are other types of pressures that force us to work despite being ill, but the research shows we often tackle these by taking over-the-counter painkillers such as paracetamol or ibuprofen (Simundic et al., 2020). This is another example of the paradigmatic shift. Whereas rest was previously considered a costly way of healing and the enhancement was simply resting without the negative consequences, nowadays the answer lies in pills bought in a store that are capable of suppressing the symptoms of sickness and fatigue.

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<sup>3</sup> Far fewer farmers are needed to feed many more people thanks to food production innovations. According to the United Nation's Food & Agriculture Organization the world's farmers can now produce enough food to provide every person with more than 2,700 calories per day. That means we could even feed an additional billion people (United Nations Food & Agriculture Organization, 2010).

The distinction between over-the-counter (OTC) medications and prescription medications represents an important step towards the current transhumanist visions of biochemical enhancement, which are the outcome of these paradigmatic shifts. Initially, most drugs were available without a prescription because there were only a few of them and they were quite simple, although little was known about them. With further advances in medicine and the expansion of drug use for medical purposes, clear guidelines were issued as to which drugs could be sold by prescription only and which could be sold over the counter. Prescription drugs were defined as compounds that could be unsafe, except when used under a doctor's supervision. Anything else could be sold over the counter. But questions remain as to whether some OTC drugs should be accessible without regulation. This applies especially to paracetamol or ibuprofen and the potential for misuse (Frei et al., 2010). A less discussed issue concerning OTC drugs is that their overuse and misuse has become socially acceptable and normalized. The risks of the potential side effects are underestimated, which is connected to the weak vigilance towards this kind of biochemical enhancement. The above-mentioned historian Thomas Hager suggested that we should perhaps rename our species *Homo pharmacum*, the species that makes and takes drugs. He said, "we are the People of the Pill" (Hager, 2019, p. 6).

This brief explanation of the background to the current paradigmatic turn in what we understand by human biochemical enhancement began at a time when there was no biochemical enhancement at all, proceeded through the period when herbs were used to treat common diseases and ended with the present era of biochemical treatments for lifestyle diseases. What is the next step? Medications are regularly misused and overused as we strive to keep up with our hectic lifestyles, and chemical substances have become a permanent part of our social habits. It is not surprising therefore to find that there are transhumanist visions of the human future in which chemicals are not used simply to fight disease or treat other medical problems but to artificially enhance healthy people.

### **Transhumanist visions of the biochemical enhancement of human beings**

Transhumanism is a relatively new philosophical, cultural and scientific movement that arose in the late 1980s and early 1990s. Francesca Ferrando from New York University explains that the transhumanism movement:

...problematizes the current understanding of the human not necessarily through its past and present legacies, but through the possibilities inscribed within its possible biological and technological evolutions (Ferrando, 2013, p. 27).

Ferrando points out that transhumanism<sup>4</sup> is a response to the urgent need for an integral redefinition of the notion of the human being in the evolving environment of interconnected existence that is related to the onto-epistemological developments of the twentieth and twenty-first centuries (Ferrando, 2013, p. 32). It is what we call an onto-epistemological crisis and presents a challenge to us all. The interconnected existence is linked to the current info-era that began in tandem with the advances in information technologies. Unfortunately, this interconnected existence comes at the expense of the personal existence of human beings. The epistemological ability to understand the world in which we humans live is hampered by the enormous increase in the availability and quantity of information from countless resources.<sup>5</sup>

<sup>4</sup> Ferrando used the notion of transhumanism that comes under the term of posthumanism. The distinction between transhumanism and posthumanism lies in the difference in emphasis on science and technology. In posthumanism technology is not the main focus, whereas in transhumanism science and technology are the main subjects of interest insofar as the redefinition and enhancement of human beings is concerned.

<sup>5</sup> More about the epistemological issues discussed here can be found in a special issue of *the Journal of Futures Studies*, "The internet, epistemological crisis and the realities of the future: An introduction to this special" (Ramos & Nycyk, 2020).

Since most crucial pieces of information are globally interconnected and the certainty of any of them is regularly questioned, it is very difficult for individuals to create their own worldview and to anchor their comprehension of the ontological aspects of their existence. The epistemological and ontological questions in human life are moving apart and it is increasingly harder to find the harmony between them in seizing one's existence. Transhumanism is a response to this onto-epistemological crisis, but it puts the emphasis entirely on science and technology. Within that we can identify two main fields: bio-engineering and techno-cybernetic enhancement. Biochemical enhancement comes under bio-engineering.

These are the transhumanist visions of biochemical enhancement that represent the current paradigmatic change in our understanding of humans. They are closely related to two of the most important components of existence: *happiness* and *love*.<sup>6</sup>

The vision of enhanced happiness is a complex socio-political and philosophical theory. It consists of the idea that everybody living in a democratic state should have free access to happiness pills. These pills would contain two main active substances – serotonin and dopamine. It is believed, and the scientific research shows, that these two hormones are responsible for the feelings of happiness induced in our brain. The main advocate of this vision is Mark Walker, who bases it on studies that show a correlation between the level of happiness and the level of pro-social behaviour (Walker, 2007, pp. 201–203). The idea is that taking these happiness pills would both benefit those who take them and they in turn would then promote positive values in society. Happy-people-pills are supposed to address the root problem of humanity – the lack of goodwill – and, in theory, enhancing our biologically determined happiness should boost the fight for greater social justice.<sup>7</sup>

Consuming different kinds of food, drink, herbs or chemicals to generate good feelings is not a new concept, but doing it so we act better is. People have always tried to make life easier by consuming different things. Coffee is a good example. It does us no harm and, moreover, it has positive effects on our health and we drink it to get a daily energy boost. The proponents of bio-happiness (biochemically induced happiness) believe that the happy-people-pills would pose no higher risk than drinking a cup of coffee, but would have more significant and useful effects at the same time.

A similar example is the use of cannabidiol (CBD), which has already become reality with the granting of legal approval in many countries. It is similar to the transhumanist vision of bio-happiness. The long discussions about the legal use of the cannabis plant (marijuana) have ended in consensual agreement. CBD or cannabidiol is the second most active ingredient in cannabis, but most importantly it is not psychedelic nor psychotropic. The World Health Organization confirmed that CBD has “no effects indicative of any abuse or dependence potential” (World Health Organization, 2017, p. 5). Many studies have confirmed that it has a positive impact on physical and mental health (for example Maroon & Bost, 2018 or Morales & Reggio, 2019) and it is now legal in many countries for clinical use at least, with free use being regulated to varying degrees. It has become a new hit among managers with high-stress jobs. *Eos Scientific* conducted national representative research across a sample of more than 2,000 British adults to examine how job-related stress levels affect our health. One finding was that 38% of workers in high-stress careers would consider using CBD to treat their mental

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<sup>6</sup> Our deeper research into the biochemical enhancement of love and happiness can be found in our previous works (Plašienková & Farbák, 2020; Plašienková & Farbák, 2021) in which we (among other things) critically consider the transhumanist vision of the chemical future of relationships induced by *Love drugs* as proposed by Brian D. Earp and Julian Savulescu (Earp & Savulescu, 2020) and the vision of *Happy-People-Pills for All*, the term created by Mark Walker in his manifesto of the biochemical enhancement of happiness (Walker, 2013).

<sup>7</sup> It would be interesting to analyse Walker's conception in relation to the ethics of social consequences that was developed by Vasil Gluchman. In this context, his paper about Moore's contributions to the development of the theory of moral/right action may prove inspirational in the analysis of ethical problems (Gluchman, 2017, p. 62).

health and many of them already do.<sup>8</sup> Are we just a few steps away from governments distributing happy-people-pills to citizens to induce pro-social behaviour, as Mark Walker envisioned (Walker, 2007)?

Another transhumanist vision of how humans can be biochemically enhanced is to be found in *Love drugs*. Brian D. Earp and Julian Savulescu, the authors of the book *Love drugs – the chemical future of relationships* (Earp & Savulescu, 2020), suggest that chemical substances should be used in psychological therapy for couples dealing with a relationship crisis. They specifically mention the chemical compound MDMA<sup>9</sup> and the hormone Oxytocin. Earp and Savulescu propose a vision in which couples faced with the loss of mutual love emotions and passion, so-called “grey relationships”, could undergo specialist-directed pair therapy and take low doses of these drugs. When properly directed the effects of such drugs could help couples rediscover the initial spark between them (Earp & Savulescu, 2020, p. 81).

Both of these visions are based on a similar understanding of ontological and existential phenomena such as happiness and love – that they are genetically and biologically determined (Hughes, 2004, p. 48) and so can be enhanced or induced through various external interventions. We believe that if we are to understand the role of *happiness* and *love* in human life we cannot ignore their ontological essence and importance in answering existential questions. The experience of having a loving and intimate relationship or being happy is integral to people as relationship-based beings within the complexity of their biological, psychological, socio-cultural and spiritual structure. We have a natural ability to relate to ourselves, to others and to the whole world in which we realise our existence. This ability allows us to keep our distance and to unlock our potential to understand ourselves, others and the world. In this process, we maintain our sense of the continuity of life and integrity. Hand in hand with authenticity we continuously form our personal integrity by gradual overcoming life’s challenges. This personal integrity is also constituted (sometimes exclusively) in situations that cause us pain and suffering (Plašienková, 2015, p. 37). But these issues are not addressed in the works of transhumanist visionaries.

Science has already changed our perception of the use of chemicals to enhance our lives. We automatically seek help in a pill when we have a headache, when we cannot sleep or when we want to prevent car sickness. We have extensively pushed the boundaries between *naturalness* and *artificiality* in the last decades, and although this is done under strict medical research into the possible biological impacts on our bodies and brains, we lack answers to our ontological questions. As we said at the beginning, we believe that enhancement is an indelible part of human life, but that there is a need for deeper philosophical-ethical and critical reflection so we can find the right balance of naturalness and artificiality.

### **Enhancing healthy people: Why not?**

We have been examining the biochemical enhancement of healthy people and the correct balance between naturalness and artificiality. But to explain why it can be considered a new paradigmatic approach in human enhancement we will compare the transhumanist assessments of disabled and healthy people.

In the transhumanist vision of the ideal future world, there will be no disease or disabilities (but at what price?). Anything connected to suffering is to be eradicated with the help of science and technology (not just through biochemical enhancement) and transhumanists believe this

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<sup>8</sup> The full title of the research is *Brits in high-stress careers would consider CBD oil for mental health* (Open Access Government, 2020).

<sup>9</sup> 3,4-methylenedioxymethamphetamine (commonly known as ecstasy, E, X, or Molly). MDMA was synthesized by a German pharmaceutical company in 1912 during research into new haemostatic (blood-clotting) agents. Chemists later investigated the compound’s pharmacological potential. Since this research did not reveal anything of particular interest, MDMA was not developed for clinical use, but was later discovered as a party drug (Meyer, 2013, pp. 83–84).

will become possible at some point if we allow the artificial evolution of humans. According to this value assessment of suffering, the lives of disabled people are less valuable because of the inconveniences associated with being disabled and so it is better to either prevent the birth of such people or not prolong their life. To demonstrate our case, we can refer to the academic polemic between Peter Singer and Harriet McBryde Johnson. Their discussion started after Singer gave a lecture on *Rethinking Life and Death* at the College of Charleston in 2001. Singer defended a position that was met with vehement opposition. He defended the position of physicians who routinely withdraw life support from severely disabled newborns.<sup>10</sup> He argued that:

This is not very different from allowing parents to decide, in consultation with their doctors, to end the life of a baby when the child has disabilities so serious that the family believes this will be best for the child or for the family as a whole (Singer, 2016, p. 205).

He was opposed by Johnson, a supporter of *Not dead yet*, a disability rights organization, who had neuromuscular disease and was severely disabled herself. She argued that if her parents had been permitted to end her life support after she was born, she would not have become an attorney and, more importantly, a person who enjoyed life. She claimed that it would be a mistake to believe that having a disability makes life less worth living and she developed this idea in her personal memoir *Too late to die young* (Johnson, 2005). The reasoning behind the value assessment informing Singer's opinion may seem correct, but Johnson opposed it on the grounds that it was controversial decision-making about human value.

Our concern is that transhumanism does not attach a fixed moral value to a human person.<sup>11</sup> The value is assigned to the person's life conditions rather than their existence, and that is problematic because it could lead to extreme outcomes in a politically unstable world. The comparison in this paper between the transhumanist approaches to disability and the biochemical enhancement of healthy people is illustrative of the paradigmatic turn we mentioned. The role science and technology can play to the benefit of disabled newborns is underestimated; some would rather end such lives without giving them a chance. Yet they would use scientific and technological achievements to help perfectly healthy people overcome common difficulties that people have been dealing with for centuries. This discrepancy originates in the new paradigmatic understanding of human value and it may be very wrong.

John Harris from the University of Manchester defends the same standpoint as Peter Singer on withdrawing life support from severely disabled newborns (Harris, 2001, p. 383). His critics, led by Tom Koch from the University of British Columbia, have argued strongly against such a standpoint. Koch's arguments can be summarized in the statements below, and we consider them to be correct:

- 1) The elimination of persons with disabilities – especially those with genetic distinctions (Motor Neuron disease, Huntington's, etc.) – would deprive society of important members (for example Stephen Hawking).
- 2) Physically distinguishable conditions of disabled people may provide the impetus for a rich life. The "harm" of life under the burden of disability is balanced, and in some cases outweighed, by the resulting "benefit".
- 3) Disability can act as a catalyst for positive social change, which can have a great impact on society (Koch, 2002, p. 203).

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<sup>10</sup> Singer's approach to death in cases involving brain death differs in that he follows the evidence that clearly shows that brain death is not equivalent to the death of the human organism but equivalent to a human irreversibly losing consciousness (Singer, 2018, p. 163).

<sup>11</sup> Another good example in support of this statement is the concept of *procreative beneficence* defended by Julian Savulescu (Savulescu, 2007), which was heavily criticized by Rebecca Bennett (Bennett, 2009).



Harris' view was also criticized by professor of bioethics Rebecca Bennett, who said:

If we have a moral obligation to choose against individuals with disability, not because of concern for their own welfare but because a world without disability is a morally preferable place, then this inevitably places a lower value on those living with disabilities (Bennett, 2014, p. 30).

Harris responded to his critics by formulating one principle and three fallacies, of which he was then accused of making. The principle concerns the equality of all people and Harris agreed with it. All persons are equal and no one is less equal than others. No disability – slight or severe – implies a lesser ethical status, worth or value.

The three fallacies Harris was accused of (Harris, 2001, p. 383) can be reformulated like this:

- 1) Choosing not to repair damage or dysfunction or not to enhance the functioning of a disabled person implies either that their state is incompatible with life or that the person in that state is of lesser value, or it indicates that the individual has a life that is not worth living.
- 2) The aim to artificially produce children who will be either less damaged or diseased, or more healthy, or who will have enhanced capacities, violates the principle of equality.
- 3) Disability or impairment should not be defined relative to normal species functioning or species-typical functioning.

Even though Harris disagreed with the accusation, we believe (together with his critics) that these fallacies appear in his conception as well as in transhumanist visions of human enhancement.

### **Conclusions**

In this paper, we have discussed what we call a new paradigmatic approach to the enhancement of humans. It is embodied in the attempts of transhumanist authors to enhance healthy people via the visions of bio-happiness and bio-love (love drugs), even though it is not necessary for their survival and may even have adverse consequences for their existence. The example given here of people with disabilities who are able to embrace their lives with love and happiness, and fill them with meaning (for instance Harriet McBryde Johnson or Stephen Hawking) gives us a clearer sense of why the paradigmatic approach of transhumanist visions that seek to biochemically enhance healthy people is unacceptable. In such a paradigm, the hierarchy of life values changes completely. The value of life's conditions, such as suffering, is not understood properly and this means that the transhumanist vision has unrealistic outcomes. It proposes that scientific and technological achievements should serve not severely disabled humans but rather perfectly healthy people. Our final standpoint is that the value of human beings should be derived primarily from our naturalness and that artificiality (which is indisputably a part of us) should be subordinate to that. Our critical assessment is that the value imbalance in the transhumanist conception provides the wrong answer to the current onto-epistemological crisis and redefines the notion of humans and their place in the future world. It misunderstands the scientific and bio-technological developments of the twentieth and twenty-first centuries.

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## Editorial

Josef Kuře<sup>1</sup>

The ongoing COVID-19 pandemic, caused by SARS-CoV-2, is a unique phenomenon in modern history. It represents the deadliest respiratory virus pandemic since the Spanish flu, affecting all areas of social and individual life of the global population and, in many respects, bringing unprecedented challenges. From the epistemological point of view, this pandemic raises questions about information, misinformation, hoaxes, manipulation, dealing with scientific facts, etc. It affects many aspects of social life such as social distancing, loneliness, patterns of social behaviour, quality of social life, ostracism, discrimination, vulnerability, protection of the vulnerable, social coherence and social justice. The COVID-19 pandemic creates an enormous load for health care systems, challenging access to health care and its fair distribution in a situation of limited resources, including issues such as triage, transparency, or vaccination. On the level of administration and governance, it not only questions epidemiological approaches, policies and the moral responsibility of different actors, but also significantly influences politics (e.g. populism), economies (the costs of diverse measures, including lock-down) and the basic understanding of democracy.

This special issue of the *Ethics & Bioethics (in Central Europe)* brings a collection of papers devoted to ethical reflection on this global phenomenon.

Andrea Klimková departs from the general assumption that any good decision requires good knowledge and correct understanding. She applies those general epistemic conditions to the current pandemic, analysing epistemic and moral responsibility of relevant actors, including scientists and politicians. Ethicists and philosophers can challenge political decisions, without being necessary epistemically arrogant. The contribution of Peter Gurský addresses the issue of the safety and danger of ‘viral’ information. He focuses on how the epistemic subject receives information which is decisive for any information transfer. He argues that the only way to overcome danger and the fear of misinformation and disinformation is exposure of the mind of an individual in a comparative (and critical) perspective. In this way, one also fulfils their potential to become free.

Rudolf Novotný and his colleagues discuss triage of the elderly during the COVID-19 pandemic. Triage, as a consequence of the lack of resources in health care, is analysed and exemplified on the cases of Germany, the Netherlands, the Czech Republic and Slovakia. Martin O’Malley, Jürgen Zerth and Nikolaus Knoepffler in their ethics of vaccination against COVID-19 propose an integrative approach towards vaccination prioritization and compulsory vaccination. Georgios Kalaitzidis addresses the COVID-19 vaccine’s scarcity and its equitable global allocation and distribution. His paper calls for the need for fair vaccine allocation and distribution. Anetta Jedličková deals with the ethical implications of protocol adjustments of clinical trials during the COVID-19 pandemic – as procedural changes and protocol modifications are necessary during the current pandemic, however those adjustments may impact the risk (and benefit) and safety of clinical trial participants.

Leszek Koczanowicz examines, in his paper, the impact of the pandemic on democratic societies, paying attention to the question to what extent a pandemic, as one of the many global crises, can alter the trajectory of democratic development.

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The paper by Jana S. Rožker provides an intercultural perspective on the global pandemic, using traditional Confucian ethics and its tools such as interpersonal solidarity or autonomous self-discipline. She also demonstrates that those attitudes based on Confucian ethics and applied in Southeast Asian countries were more successful and effective in elimination of the epidemic in comparison with the strategies of Euro-American regions.

In the COVID-19 discourse, primarily in triage discussions and in some vaccination debates, classical utilitarian arguments have been presented. Francisco Lara in his paper asks the question whether some possible neuro-enhancements should be accepted by utilitarian ethics. Zlatica Plašienková and Martin Farbák, discussing a new paradigmatic approach to human enhancement proposed by transhumanists, criticize the value imbalance in the transhumanist conception of enhancement.

Despite all previous efforts and measures such as vaccination or lockdown, the COVID-19 pandemic has reached a new and intense wave recently. The papers of this issue of *the Ethics & Bioethics (in Central Europe)* hopefully contribute to the reflection on this significant global phenomenon.