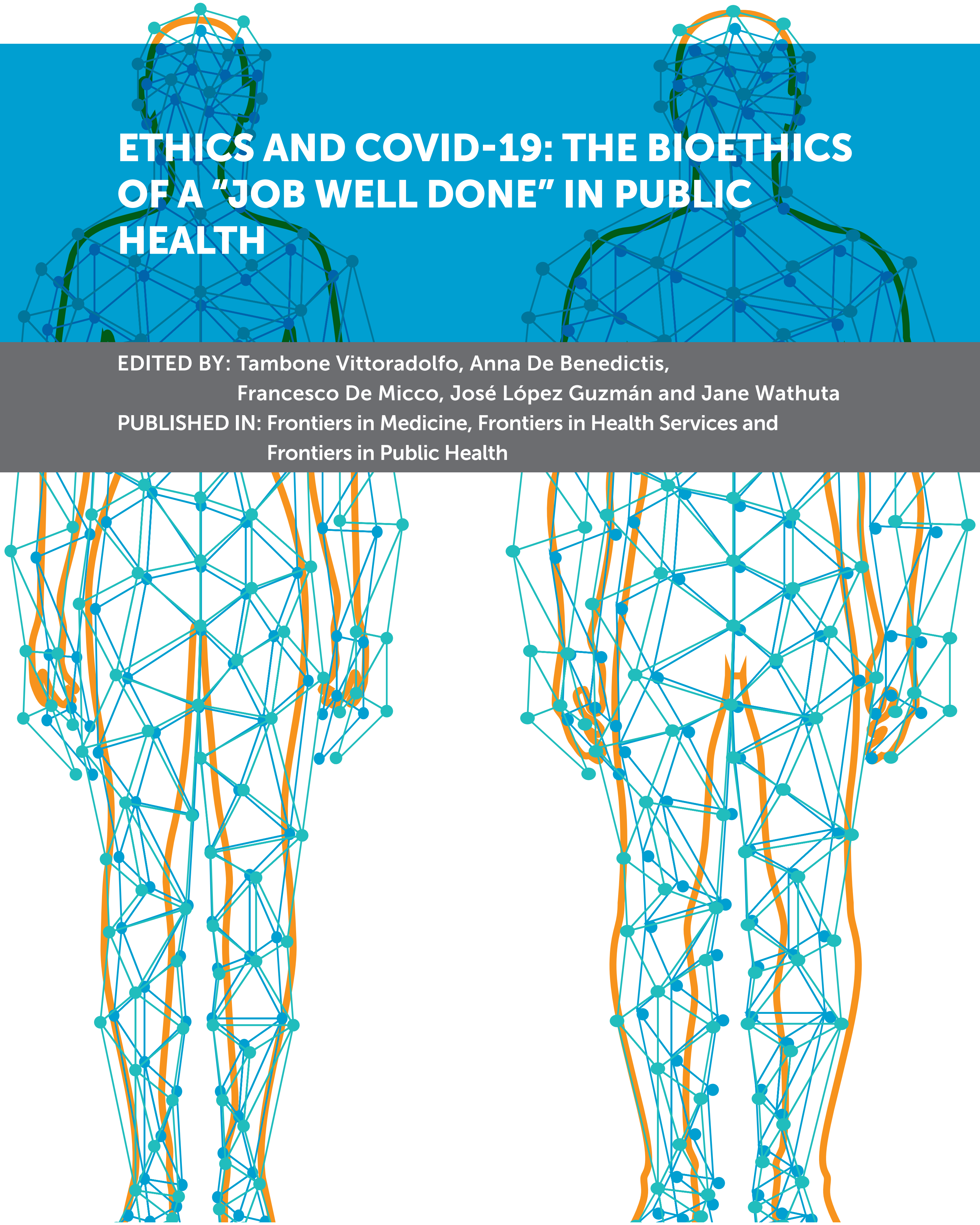

ETHICS AND COVID-19: THE BIOETHICS OF A "JOB WELL DONE" IN PUBLIC HEALTH

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ETHICS AND COVID-19: THE BIOETHICS OF A “JOB WELL DONE” IN PUBLIC HEALTH

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Editorial: Ethics and COVID-19: The bioethics of a "job well done" in public health

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COVID-19, job well done, public health ethics, clinical risk management, policy and practice

Editorial on the Research Topic
Ethics and COVID-19: The bioethics of a "job well done" in public health

The COVID-19 pandemic has tested the capacities of health care systems and raised new challenges related to ethical, medical humanity, communication, psychological, patient safety, and clinical risk management issues. In addition, the COVID-19 pandemic revealed that it is no longer possible to make medicine from medicine alone, but that every reality with which humans are confronted can have an effect on health, showing a systemic dimension of medicine (1), in which the ethics of a "job well done" is the foundation and effect of an integrated collaboration between health professionals.

The ethics of a "job well done" has, as its theoretical objective, the enhancement of the moral object of the Human Act which, in public health, provides the main content of best practice and of the care gold standard. The aim of this Research Topic is to highlight the ethical issues that emerged during the pandemic and how these were addressed according to an approach consistent with the definition of a "job well done."

COVID-19 has shown how interactions between biological and social factors can negatively influence the prognosis and treatment of a disease, supporting the reasoning of those who consider COVID-19 not as a pandemic, but rather a syndemic phenomenon (1). A syndemic approach provides an important orientation for clinical medicine because it reveals how socio-biological interaction can affect the course of a disease. Similarly, the syndemic assessment of a biological phenomenon provides methodological support to public health to guide health policy choices (2).

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For this reason, we argue that the WHO has promoted a syndemic approach for the next decade to improve the quality of healthcare and ensure patient safety. The WHO has encouraged multi-disciplinary approaches based on the implementation of protective legislative measures, health systems characterized by good governance, transparency and a no-blame culture, patient and family engagement, identification of centers of excellence in patient safety education, and training and development of multi-sectoral and multinational synergies (3).

Governments and health systems around the world have experienced unprecedented stress: globally, there have been more than 300 million confirmed cases of COVID-19, including more than 5 million deaths (4, 5).

The pandemic emergency has also raised important bio-political, bioethical, and bio-juridical questions (6), which also emerge from this collection. In particular, original papers published in the special issue address the main themes detailed below.

First, the patients' access to care in conditions of limited health resources, and the related search for appropriate criteria to determine the ceiling of care (Bhattarai et al.; D'Errico et al.) represents one of the main challenges for governments and healthcare facilities, together with the need to address ethical and legal issues of telemedicine (De Micco et al.) and new risks and benefits due to the increased use of digital tools in health care (Oliva et al.) (7, 8).

In addition, some of the most relevant questions faced during the pandemic include the safety and protection of frontline healthcare professionals (Piredda et al.; Zhao et al.) while ensuring the best possible person-centered care for all patients (De Benedictis et al.), the consideration of ethical implications of the social determinants of health (Valera et al.), and the need to include the voices of patients in research, development, and care activities (Mirpuri et al.). The international debate also focused on the need to prevent the dissemination of inaccurate information from unreliable sources, while guaranteeing freedom of expression (Bakuri et al.).

Moreover, the legal and bioethical issues of vaccination which emerged from the pandemic should be addressed from different points of view (Inoue). Some of the most debated questions concern the vaccine hesitancy phenomenon (Raballo et al.) and the ethical and legal questions of compulsory COVID-19 vaccination (Gibelli et al.). At the same time, it is necessary to reflect on people's acceptance of vaccination, with a focus on different setting and low-resource settings (Maccaro et al.), and to shed new light on questions related to vaccinations for vulnerable groups of people (Scendoni et al.).

According to UNESCO's International Bioethics Committee (IBC) and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), the impact of the COVID-19 pandemic on public health requires a global bioethics reflection and response (9).

We believe that the most advanced vision of bioethics is that which creates, together with medicine, a true co-working relationship. This methodological perspective certainly has its roots in the choice of an ethics of the first person quite distinct from ethical proceduralism of a utilitarian type (10). Scientific action (like any human action) is first of all a *Human Act* carried out by a *subject* together with other human beings, within a specific ecosystem and with a broad political dimension.

Thanks to the theory of complexity and systemic thinking (11, 12), the concept of "medicine made only within medicine" is outdated. Nowadays, talking about public health implies being aware of the impact that nutrition, industrial production, communication, and many other areas of human action have on the health of everyone (13). For example, the Covid-19 pandemic affected the education of young people (14), and it has also changed the economy of entire countries (15), in addition to the increased risk of violence against women (16).

On the other hand, the awareness of the systemic dimension of human existence and, consequently, the decisive importance of co-working as a "job well done," brings the model of human work back from the individualistic dimension to that of conscious cooperation (17).

The main features of an approach to work based on the bioethics of a "job well done" are the following (14):

(a) interdisciplinary co-design in relation to complexity theory and systemic thinking;
(b) realistic knowledge that always starts from experience and leads to the search for scientific truth as the basis for one's choices;
(c) maintaining the purpose of medicine by going beyond the temptation to reduce it to a "business model," instead moving toward a "Living Company Model" capable of developing a management model that is useful for the motivational involvement of all the components involved;
(d) awareness that every medical act is a free and responsible *Human Act* with an intrinsic ethical value;
(e) recovery of the political dimension of work well done, whereby professional excellence becomes a means of serving society and the common good;
(f) capacity for radical procedural innovation and not just implementation of correct procedures;
(g) putting the person at the center of work, always starting with the best evidence available.

The ethics of a "job well done" develops and justifies specific and concrete professional characteristics to improve effectiveness and efficiency, while ensuring sustainability. The pandemic emergency poses the ancient and ever new challenge described in one of the most influential frameworks for quality assessment in healthcare put forth by the Institute of Medicine (IOM), that is, caring for patients in a safe, effective, person-centered, efficient, equitable, and timely way.

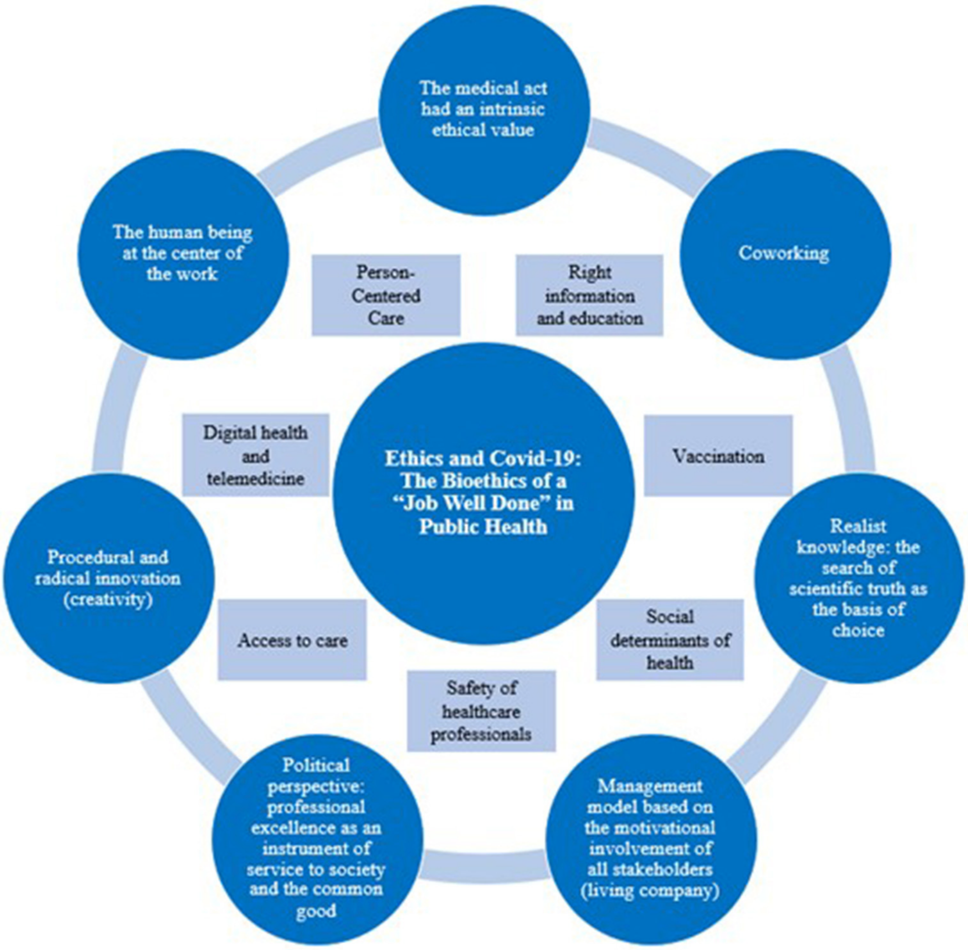

FIGURE 1
The main themes that emerged from the Research Topic with respect to the "Ethics of Job Well Done framework" (De Micco et al., modified).

This framework is aimed at avoiding injuries to patients; providing evidence-based healthcare services that respond to individual preferences, needs and values; reducing waiting times and sometimes detrimental delays; avoiding waste; and, providing the best care for all (18, 19). A new paradigm of doing medicine is the way to achieve these goals for individual and public health.

Professionals at all levels over the course of the pandemic experienced the power of interprofessional and interdisciplinary collaboration in providing the best possible care for all patients, within highly interdependent healthcare environments (20).

At the same time, new patient needs emerged and health professionals are faced with an extraordinary challenge of treating fragile patient categories, while also ensuring their safety and aspirations for the best possible treatment in a person-centered way (De Benedictis et al.). In this new scenario, public health should be guided by new drivers, including the voices of patients, frontline professionals and caregivers and their ever increasing involvement in research, development, and care activities (Mirpuri et al.) (21, 22).

For this reason, it seemed necessary to propose a special issue that would observe the same clinical reality from many different points of view. The main objective was to provide "raw material" to those who want to independently compose the "puzzle" of a more systemic proposal for the governance of COVID-19 (Figure 1), based on the "Ethics of job well done framework" (De Micco et al.). We are still learning how to deal with a pathology that has a variety of novel characteristics and we are discovering many unexpected things by observation of the evidence. We are yet to fully understand what exactly has happened and is still going on, but what is clear is that we need to take care of people "all together" in a vision that moves from a regional Public Health to a Systemic Public Health (3).

Author contributions

VT wrote the first version of the manuscript. All authors made a significant contribution to this paper and have read and approved the final version of the manuscript.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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References

1. Horton R. Offline: COVID-19 is not a pandemic. *Lancet.* (2020) 396:874. doi: 10.1016/S0140-6736(20)32000-6

2. Singer M, Bulled N, Ostrach B, Mendenhall E. Syndemics and the biosocial conception of health. *Lancet.* (2017) 389:941–50. doi: 10.1016/S0140-6736(17)30003-X

3. De Micco F, De Benedictis A, Fineschi V, Frati P, Ciccozzi M, Pecchia L, et al. From syndemic lesson after Covid 19 pandemic to a "Systemic Clinical Risk Management" proposal in the perspective of the ethics of job well done. *Int J Environ Res Public Health.* (2021) 19:15. doi: 10.3390/ijerph19010015

4. WHO. *WHO Coronavirus (COVID-19) Dashboard.* Available online at: https://covid19.who.int/ (accessed January 5, 2021).

5. WHO, UN, UNICEF, UNDP, UNESCO, UNAIDS, et al. Managing the COVID-19 infodemic: promoting healthy behaviours and mitigating the harm from misinformation and disinformation. Available online at: https://www.who.int/news/item/23-09-2020-managing-the-covid-19-infodemic-promoting-healthy-behaviours-and-mitigating-the-harm-from-misinformation-and-disinformation (accessed January 5, 2021).

6. Tambone V, Boudreau D, Ciccozzi M, Sanders K, Campanozzi LL, Wathuta J, et al. Ethical criteria for the admission and management of patients in the icu under conditions of limited medical resources: a shared international proposal in view of the COVID-19 pandemic. *Front Public Health.* (2020) 8:284. doi: 10.3389/fpubh.2020.00284

7. Gasser U, Ienca M, Scheibner J, Sleigh J, Vayena E. Digital tools against COVID-19: taxonomy, ethical challenges, and navigation aid. *Lancet Digit Health.* (2020) 2:e425–34. doi: 10.1016/S2589-7500(20)30137-0

8. Whitelaw S, Mamas MA, Topol E, Van Spall HGC. Applications of digital technology in COVID-19 pandemic planning and response. Erratum in: Lancet Digit Health. (2021) 3(3):e147. *Lancet Digit Health.* (2020) 2:e435–40. doi: 10.1016/S2589-7500(20)30142-4

9. UNESCO. *Statement on Covid-19: Ethical Considerations From a Global Perspective.* Available online at: https://en.unesco.org/inclusivepolicylab/e-teams/ethical-considerations-covid-19-responses-and-recovery/documents/unesco-ibc-comest-statement (accessed January 5, 2021).

10. Tambone V, Ghilardi G. *Philosophy and Deontology of Medical Practice. Ethics of the Job Well Done in Bio-medical Sciences.* Rome: Società Editrice Universo (2020).

11. Von Bertalanffy L. General system theory. In: *Foundations, Development, Applications.* London: Penguin (1968).

12. Gallon L. Systemic thinking. In: Leal Filho W, Azul AM, Brandli l, Gökcin Özuyar P, Wall T, editors. *Quality Education.* Cham: Springer (2019), 830–40.

13. Wernli D, Clausin M, Antulov-Fantulin N, Berezowski J, Biller-Andorno N, Blanchet K, et al. Building a multisystemic understanding of societal resilience to the COVID-19 pandemic. *BMJ Glob Health.* (2021) 6:e006794. doi: 10.1136/bmjgh-2021-006794

14. Quintiliani L, Sisto A, Vicinanza F, Curcio G, Tambone V. Resilience and psychological impact on Italian university students during COVID-19 pandemic. Distance learning and health. *Psychol Health Med.* (2022) 27:69–80. doi: 10.1080/13548506.2021.1891266

15. Cavallo A, Godwin C. *The Coronavirus (COVID-19) Pandemic and the Global Economy (A). Harvard Business School Case* 720–031 (2020).

16. The European Institute for Gender Equality. *COVID-19 Wave of Violence Against Women.* Available online at: https://www.consilium.europa.eu/en/documents-publications/library/library-blog/posts/covid-19-wave-of-violence-against-women/?filters=1490 (accessed January 5, 2021).

17. McIntyre A. *Dependent Rational Animals: Why Human Beings Need the Virtues.* London: Duckworth (2009).

18. *Agency for Healthcare Research and Quality.* (2021) Available online at: https://www.ahrq.gov/talkingquality/measures/six-domains.html (accessed January 5, 2021).

19. Institute of Medicine (IOM). *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, D.C: National Academy Press (2001).

20. Fernandez R, Lord H, Halcomb E, Moxham L, Middleton R, Alananzeh I, et al. Implications for COVID-19: a systematic review of nurses' experiences of working in acute care hospital settings during a respiratory pandemic. *Int J Nurs Stud.* (2020) 111:103637. doi: 10.1016/j.ijnurstu.2020.103637

21. Elkin E, Viele C, Schumacher K, Boberg M, Cunningham M, Liu L, et al. A COVID-19 screening tool for oncology telephone triage. *Support Care Cancer.* (2021) 29:2057–62. doi: 10.1007/s00520-020-05713-5

22. Curnow E, Tyagi V, Salisbury L, Stuart K, Melville-Jóhannesson B, Nicol K, et al. Person-centered healthcare practice in a pandemic context: an exploration of people's experience of seeking healthcare support. *Frontiers Rehabilit.* (2021) 36:726210. doi: 10.3389/fresc.2021.726210

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Supporting Decision Making in Intensive Care: Ethical Principles for Managing Access to Care During the COVID-19 Pandemic

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The pandemic from COVID-19 causes a health threat for many countries and requires an internationally coordinated response due to the high spread of the infection. The current local and international situation gives rise to logistical and ethical considerations regarding the imbalance between needs for assistance and availability of health resources in the continuation of the emergency. A shortage condition will require healthcare professionals to choose between patients who will have access to respiratory support and those who will have to continue without. The sharing of criteria for the introduction of patients to the different therapeutic paths is fundamental to prevent the onset of ethical issues. The present paper analyzes the critical issues related to the scarcity of healthcare resources and the limitation of access to intensive care with the aim of proposing ethically sustainable principles for the management of the current pandemic situation.

Keywords: COVID-19 pandemic, global health emergency, access to care, intensive care, ethics

INTRODUCTION

The declaration of pandemic from COVID-19 released by the World Health Organization (WHO) on March 11, 2020 sanctioned the beginning of a public health emergency of international concern (PHEIC). This state of emergency causes a health threat for many countries and requires an internationally coordinated response due to the high spread of the infection (1).

The increase in contagions has forced different governments to adopt drastic containment measures. In the Italian context, the emergency response implied the total closure of all non-essential activities and the prohibition on all people to move except for proven work needs, absolute urgency or for health reasons.

The current local and international situation gives rise to logistical and ethical considerations regarding the imbalance between needs for assistance and availability of health resources in the continuation of the emergency. In fact, the outbreak of the novel Coronavirus (nCoV) engaged human and material resources far beyond the tolerance limits of health systems, producing conditions of extraordinary lack of care (2).

The management of ethical disputes in the emergency period requires advance planning that provides specific guidelines to hospital management and healthcare professionals. Among the challenges to be addressed, limiting access to intensive care represents the main and most discouraging issue. The severity and duration of respiratory problems due to COVID-19 is able to saturate the intensive care system in a very short time (3). A shortage condition requires healthcare professionals to choose between patients who will have access to respiratory support and those who will have to continue the therapeutic course without.

The sharing of criteria for the introduction of patients to the different therapeutic paths is fundamental precisely to prevent the onset of ethical issues when the time for evaluating alternatives will necessarily be scarce (4).

The present paper analyzes the critical issues related to the scarcity of healthcare resources and the limitation of access to intensive care with the aim of proposing ethically sustainable principles for the management of the current pandemic situation.

ISSUES IN ACCESS TO INTENSIVE CARE

The current pandemic scenario has led to a serious shortage of respiratory support machines requiring a rapid "arms race" for crisis management. According to previous estimates, a pandemic may require tripling the availability of mechanical ventilators (5).

System overload is made it impossible to provide respiratory support to patients with respiratory failure who need mechanical ventilation to survive. The deficiency status raised unprecedented allocation dilemmas that imposed the subordination of any decision to public health goals (6). As well as beds and drug therapies, respiratory support should be considered a resource to be rationed and assigned based on criteria established in the interest of public health rather than decisions of individual doctors and patients (7). The formulation of guidelines for the allocation of medical resources in a condition of scarcity requires multiple interventions characterized by different levels of specificity. At a more general level, national health policies must express a social agreement on the need to link the decisions of individual doctors and patients to public health needs during the emergency phase. At a specific level, regarding decisions on clinical care, hospitals, and healthcare professionals must share criteria for managing access to intensive care when demand significantly exceeds supply. Finally, the professionals in the front line must have clear guidelines for the implementation of the triage process and the decision between the different care paths in specific cases (8). In principle, for the optimization of care and the reduction of deaths during an emergency, priority should be given to patients who need mechanical ventilation but who are very likely to survive after a few days of respiratory support.

Under normal conditions, the lack of resources for intensive care constitutes a sporadic event that can be resolved through an assignment based on the "first come, first served" principle. Sporadic shortages generally lead to the development of short-term measures to increase the availability of intensive care. Among other things, it is important to divert patients to other hospitals, cancel elective surgery, use post-operative rooms as temporary Intensive Care Unit (ICU) beds. Furthermore, it is possible to accelerate the transfer to the ward of patients weaning from intensive care to maximize the availability of ventilators. It is absolutely clear how such measures cannot be feasible during the present health emergency precisely because of the severity and duration of the current coronavirus disease.

The emergency context requires instead to review the general principles for the allocation of scarce resources with a view to maximizing health outcomes, giving priority to patients who can be treated more efficiently (9). Although in general the ethical line to follow is to help the neediest patients by maximizing the number of lives saved, in a restriction period there may be a contradiction with the principles of allocation (10). Therefore, it is essential to establish an agreement on the principles to be applied for the management of resources in the emergency phase (11).

The first ethical issue concerns the possibility that the goal of maximizing the number of lives saved could take over the patient's autonomy. Public health officials, clinical experts, and political representatives should agree on criteria for establishing the care priorities that individual healthcare professionals and patients should follow.

Secondly, it is not disputed that patients with a high probability of survival after a few days of intensive care should receive the highest priority. However, the characterization of such a group of patients is extremely difficult since the evidence is currently scarce and incomplete (12); in fact, for example, there is no data to predict the duration of intensive care (13). The scarcity of evidence requires reaching a consensus based on the discussion of available data and expert opinion.

The third issue is related to equity and perception of equality during a public health emergency. The population is more inclined to subordinate personal interest to the common good if the constant application of the same criteria is evident. Specifically, people are less likely to accept mandatory emergency measures and to sacrifice for the community if apparently some are receiving special consideration or favoritism (14).

Finally, the fourth problem concerns the obligation to ensure transparency during the emergency phase. The priorities and policies of triage should be accessible in order to make the methods for allocating resources known to the population and prepare the community for any individual discussions on access to care (15).

Although there is a broad consensus on the use of triage to minimize loss of life during a pandemic, hospitals, and healthcare professionals are forced to face heterogeneous situations and make difficult decisions in specific cases (16).

The complexity of the problem is increased by the need to re-evaluate patients who have already had access to intensive care. In fact, patients receiving respiratory support may have a worse prognosis than new patients with respiratory failure. The continuation of intensive care in patients with poor prognosis and low expectations of maintaining the state of health determines a limitation of access for patients who instead, despite being able to benefit from respiratory support, are directed toward other care paths.

Therefore, the non-inclusion of patients already admitted to intensive treatment in the triage process can lead to a decrease in the total number of lives saved. On the other hand, discontinuing intensive care for patients with poor prospects for improvement would violate the ethical rules that the physician should be loyal to patients and act in their best interest. Although the choice to stop treatment is emotionally difficult for healthcare professionals and the patient, logically there is no difference between the interruption and the initial exclusion if in both cases the justification complies with the emergency rules and has been discussed between the subjects involved.

With a view to profitable crisis management, it may be useful to separate the roles of triage and care to allow doctors to keep the patient's interests a priority. An out-of-care physician in the intensive care unit can be appointed to make triage decisions so that the doctors involved in care are not obliged to decide to maintain or stop mechanical ventilation. Such an approach creates a situation in which the triage doctor can make decisions based on the overall results for the population, while the attending physician is free to serve the patient's best interest.

If the shortage of means for intensive care persists after the application of the probability of survival and short-term need for mechanical ventilation criteria, several other criteria may be considered for the assignment of respiratory support. These criteria could include life expectancy and likely quality of life after treatment. However, the use of such criteria should be limited or even avoided in emergency conditions due to the physician's evaluative subjectivity, possible disagreements with the patient and concerns about injustice.

Unfortunately, patients with respiratory failure who do not have access to ventilatory support can experience death. Therefore, such patients should be candidates for respectful and compassionate palliative care pathways, including at home (17). Death from respiratory failure can be extremely distressing because of the feelings of drowning and air hunger to which it is related. The administration of sedatives and analgesics is to be considered ethically and clinically appropriate in such situations, even at doses capable of causing loss of consciousness if lower doses fail to alleviate the symptoms. Although palliative sedation has a strong ethical justification, not all healthcare professionals are trained in palliative sedation and the reduction of hospital supplies can cause a shortage of the drugs needed to alleviate the symptoms.

POSITION STATEMENT

The response of health systems to the pandemic emergency imposes medical, scientific, moral, and ethical considerations on the political and health authorities involved (**Figure 1**). The review of existing triage procedures to meet the overwhelming demand for intensive care requires the responsible application of the principles of equity, justice, usefulness, efficiency, transparency, and participation.

Preliminarily it is essential to establish that the scope of the guidelines for the selection of access to intensive care must be universally limited to contexts in which there is an effective scarcity of health resources. In fact, the aprioristic application of the triage procedures would be in clear contradiction with the previously mentioned principles.

Governments and healthcare systems must provide hospitals and healthcare professionals with explicit criteria for assessing patients with respiratory failure under conditions of limited access to intensive care. Similarly, it is essential to prepare guidelines for the practical management of critical issues during the implementation of triage procedures.

For a correct allocation of resources, it is essential to aim at maximizing therapeutic successes and safeguarding public health by prioritizing patients who can be treated in a more profitable and efficient way. In this perspective, it is important to plan health care according to the integration between home and hospital care through the formulation of shared operational protocols; in this way, it would be possible to identify patients manageable at home avoiding the excess of requests for hospitalization. Such an objective presupposes the implementation of territorial systems through the recruitment of health professionals and specific training.

Triage procedures should be conducted by professionals not directly involved in patient care. Based on the criticality of the conditions at the local level, the triage procedure should be extended by re-evaluating the subjects already admitted to intensive care.

In view of the objective difficulties weighing on the prognostic evaluation of patients, the recommendations should be promptly updated based on the evidence on COVID-19.

Nonetheless, the regulatory obligation to inform patients on decision-making criteria emerges to foster trust in care relationships. Particular attention must be paid to fragile individuals who may be at risk of family and social isolation at the time of need for assistance. Sharing the established criteria with public opinion is fundamental in order to promote acceptance of the sacrifice for the benefit of public health and limit discussions during the management of concrete cases.

Of course, given the impossibility of guaranteeing access to intensive care for all patients, it is necessary to plan paths for the provision of respectful and compassionate palliative care. The administration of analgesic and sedative drugs should however be carried out maintaining the objective of alleviating suffering and avoiding active euthanasia practices.

DISCUSSION

The outbreak and rapid evolution of the COVID-19 pandemic forced national health systems to redefine the priorities for access to care due to the increased need for assistance and the scarcity of resources. The present discussion has outlined the general principles that should be considered in the management of the current pandemic emergency for the protection of public health.

The main question in a pandemic situation concerns compatibility between the restrictions imposed by the need to allocate health resources and the assistance obligations of health systems. Specifically, it is necessary to establish whether in a context of rationing it is necessary to review the ethical principles underlying medical care. Obviously, ethical foundations of care must change in consideration of the dramatic increase in health care loads imposed by the pandemic (18).

Certainly, the ordinary "first come, first served" criterion must deal with the critical issues related to the scarcity of resources

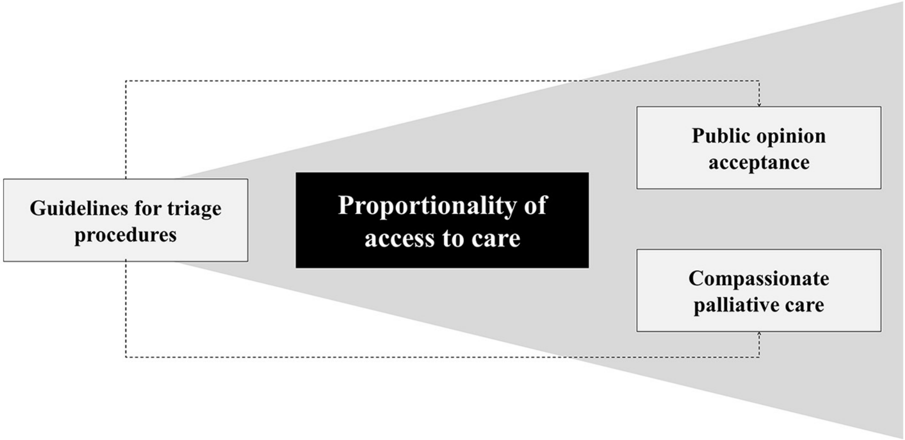

FIGURE 1 | Position statement on proportionality of access to care during pandemic.

making it necessary to adopt practical choices (19). Therefore, any evaluation should be carried out considering the probabilities of benefit, the possibilities of improving the quality of life, the expected effectiveness of the measures taken, the critical condition of the patient, as well as—secondly—the resources required for the success of the treatment (20).

The extraordinary nature of the pandemic scenario, especially in the acute phases of the different waves, cannot lead to the overcoming of fundamental ethical values. The COVID-19 health emergency highlighted the importance of promoting macro-allocation policies capable of guaranteeing the protection of the individual even in exceptional conditions. In other words, the implementation of health policies aimed at investments in preparation is fundamental so that, in the emergency state, one should not be forced to choose which individuals to treat. What happened during the pandemic must lead to a reflection on the protection of the individual and on the need for maximum inclusion in care pathways so that the rationing or scarcity of available resources should not lead to the identification of criteria for selecting the value of human life. Ultimately, it is crucial to avoid "loosening of the mesh," even if only temporary, of the protection network of the fragile individual to avoid the risk of marginalization, discrimination, and disproportionality in access to care, even outside the emergency. The goal of health systems must be to ensure the greatest number of lives saved, guarantee life expectancy and aim to improve the quality of life. In this perspective, it is necessary to ask whether the health professional can independently be a resource allocator and whether he can alone make choices that penalize the most vulnerable people (21).

Considering that the right to health is universally thought fundamental, inalienable, and essential for the dignity of life, the need to support health professionals in the emergency context is evident, making sure that the individual is not forced to decide for himself which patient to sacrifice.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

All authors contributed equally to manuscript drafting, critical discussion, and approved the final version.

REFERENCES

1. Remuzzi A, Remuzzi G. COVID-19 and Italy: what next? *Lancet*. (2020) 395: 1225–8. doi: 10.1016/S0140-6736(20)30627-9
2. Ji Y, Ma Z, Peppelenbosch MP, Pan Q. Potential association between COVID-19 mortality and health-care resource availability. *Lancet Glob Health*. (2020) 8:e480. doi: 10.1016/S2214-109X(20)30068-1
3. Spina S, Marrazzo F, Migliari M, Stucchi R, Sforza A, Fumagalli R. The response of Milan's Emergency Medical System to the COVID-19 outbreak in Italy. *Lancet.* (2020) 395:e49–50. doi: 10.1016/S0140-6736(20)30493-1
4. Persad G, Wertheimer A, Emanuel EJ. Principles for allocation of scarce medical interventions. *Lancet.* (2009) 373:423–31. doi: 10.1016/S0140-6736(09)60137-9
5. Kandel N, Chungong S, Omaar A, Xing, J. Health security capacities in the context of COVID-19 outbreak: an analysis of International Health Regulations annual report data from 182 countries. *Lancet.* (2020) 395:1047–53. doi: 10.1016/S0140-6736(20)30553-5
6. Heymann DL, Shindo N, WHO Scientific and Technical Advisory Group for Infectious Hazards. COVID-19: what is next for public health? *Lancet.* (2020) 395:542–5. doi: 10.1016/S0140-6736(20)30374-3
7. Cook TM, El-Boghdadly K, McGuire B, McNarry AF, Patel A, Higgs A. Consensus guidelines for managing the airway in patients with COVID-19: guidelines from the difficult airway society, the association of anaesthetists the intensive care society, the Faculty of Intensive Care Medicine and the Royal College of Anaesthetists. *Anaesthesia.* (2020) 75:785–99. doi: 10.1111/anae.15054

8. Christian MD, Sprung CL, King MA, Dichter JR, Kissoon N, Devereaux AV, et al. Triage: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. *Chest.* (2014) 146(Suppl. 4):e61S−74S. doi: 10.1378/chest.14-0736
9. Hick JL, Biddinger PD. Novel coronavirus and old lessons - preparing the health system for the pandemic. *N Engl J Med.* (2020) 146(Suppl. 4):e145S−55. doi: 10.1056/NEJMp2005118
10. Biddison LD, Berkowitz KA, Courtney B, De Jong CM, Devereaux AV, Kissoon N, et al. Ethical considerations: care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. *Chest.* (2014) 146(Suppl. 4):e145S−55. doi: 10.1378/chest.14-0742
11. Gostin LO, Hodge JG Jr. US emergency legal responses to novel coronavirus: balancing public health and civil liberties. *JAMA*. (2020) 323:1131–2. doi: 10.1001/jama.2020.2025
12. Fauci AS, Lane HC, Redfield RR. COVID-19 - navigating the uncharted. *N Engl J Med.* (2020) 382:1268–9. doi: 10.1056/NEJMe2002387
13. Yang X, Yu Y, Xu J, Shu H, Xia J, Liu H, et al. Clinical course and outcomes of critically ill patients with SARS-CoV-2 pneumonia in Wuhan, China: a single-centered, retrospective, observational study. *Lancet Respir Med.* (2020) 8:475–81. doi: 10.1016/S2213-2600(20)30079-5
14. Gould CC. Solidarity and the problem of structural injustice in healthcare. *Bioethics.* (2018) 32:541–52. doi: 10.1111/bioe.12474
15. Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. *Implement Sci.* (2016) 11:114. doi: 10.1186/s13012-016-0480-9
16. Swiss Academy of Medical Sciences. COVID-19 pandemic: triage for intensive-care treatment under resource scarcity. *Swiss Med Wkly.* (2020) 150:w20229. doi: 10.4414/smw.2020.20229
17. Maddocks M, Lovell N, Booth S, Man WD, Higginson IJ. Palliative care and management of troublesome symptoms for people with chronic obstructive pulmonary disease. *Lancet.* (2017) 390:988–1002. doi: 10.1016/S0140-6736(17)32127-X
18. Emanuel EJ, Persad G, Upshur R, Thome B, Parker M, Glickman A, et al. Fair allocation of scarce medical resources in the time of covid-19. *N Engl J Med.* (2020) 382:2049–55. doi: 10.1056/NEJMsb2005114
19. Levin PD, Sprung CL. The process of intensive care triage. *Intensive Care Med.* (2001) 27:1441–5. doi: 10.1007/s001340101042
20. Kerstein SJ. Dignity, disability, and lifespan. *J Appl Philos.* (2017) 34:635–50. doi: 10.1111/japp.12158
21. Tambone V, Boudreau D, Ciccozzi M, Sanders K, Campanozzi LL, Wathuta J, et al. Ethical criteria for the admission and management of patients in the ICU under conditions of limited medical resources: a shared international proposal in view of the COVID-19 pandemic. *Front Public Health.* (2020) 8:284. doi: 10.3389/fpubh.2020.00284

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REVIEW
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Management of Medico-Legal Risks in Digital Health Era: A Scoping Review

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Artificial intelligence needs big data to develop reliable predictions. Therefore, storing and processing health data is essential for the new diagnostic and decisional technologies but, at the same time, represents a risk for privacy protection. This scoping review is aimed at underlying the medico-legal and ethical implications of the main artificial intelligence applications to healthcare, also focusing on the issues of the COVID-19 era. Starting from a summary of the United States (US) and European Union (EU) regulatory frameworks, the current medico-legal and ethical challenges are discussed in general terms before focusing on the specific issues regarding informed consent, medical malpractice/cognitive biases, automation and interconnectedness of medical devices, diagnostic algorithms and telemedicine. We aim at underlying that education of physicians on the management of this (new) kind of clinical risks can enhance compliance with regulations and avoid legal risks for the healthcare professionals and institutions.

Keywords: privacy, artificial intelligence, big data, risk management, COVID-19

INTRODUCTION

Digital revolution is changing and will radically change the way healthcare is conceived (1). Currently, several artificial intelligence (AI) products have been developed, covering all aspects of healthcare, like the prediction of the risk of acute or chronic disease (e.g., cardiovascular risk, gastrointestinal bleeding, glaucoma), the prediction of risk of cancer/cancer recurrence and the survival likelihood in oncologic patients, the management of common chronic conditions (e.g., optimization of insulin dose in type-1 diabetes), the organization of clinical, surgical and anesthesiologic services, and the discovery of new drugs (2–13). AI can work and evolve only if personal health information is collected in datasets. Currently, in healthcare enormous amounts of data are normally collected—not only descriptive information (e.g., name, occupation, physical and mental conditions, genetic profile) but also data acquired by ambient sensors, images (obtained through endoscopy, radiologic techniques or dermoscopic mapping) and molecular/genetic data (5, 8, 14–16). Moreover, there are portable/wearable/implanted medical and non-medical devices that regularly collect data that can be used for predictions useful for preserving and improving the health of both individuals and the entire community (17). Health and genetic data are the most sensible personal information and their misuse can be extremely harmful and discriminatory.

Globally, there are different regulatory approaches intended for privacy protection, but the European Union (EU) regulatory framework is often considered the broadest (6, 18). Moreover, in Europe privacy protection is a right guaranteed both by the European Charter of Human Rights and by some national constitutions (for example in Spain) (6, 18). However, from a legal point of view privacy is never an "absolute" right, but it has many trade-offs, that must always be carefully considered to decide what right should prevail in the specific situation (16).

This scoping review is aimed at underlying the medico-legal and ethical implications of the main artificial intelligence applications to healthcare. Starting from a summary of the United States (US) and European Union (EU) regulatory frameworks, the current medico-legal and ethical challenges are discussed in general terms before focusing on the specific issues regarding informed consent, errors/cognitive biases, diagnostic algorithms and telemedicine.

METHODS

The review question was "what are the main medico-legal and ethical issues of general interest concerning artificial intelligence applied to healthcare?" Since the question is very broad, the targets are very diverse and the aim is to describe an overview of the available research evidence, a systematic review approach was not chosen. Two investigators searched published studies through the electronic database MEDLINE via PubMed. They combined three classes of search terms (the classes were connected through the Boolean operator AND, while the items of each class were combined through the Boolean operator OR): (1) artificial intelligence, algorithms, personal data processing; (2) COVID-19, informed consent, medical malpractice, cognitive bias, automation, interconnectedness, robot, telemedicine; (3) medico-legal issues, ethical issues, medico-legal implications, ethical implications, medico-legal risks. The eligibility criteria were the language (only papers written in English were considered), the publication date (between January 1, 2015 and June 30, 2021) and the publications status (only papers that had been fully published online were selected). Search was not filtered by article type. The 41 papers considered for the review were selected on the basis of their relevance according to the review question.

US AND EU REGULATORY FRAMEWORKS

In the US, **Table 1** AI products must be approved by the Food and Drug Administration (FDA, that classifies them as "software as a medical device"), while the collection, storage and disclosure of personal health information is regulated mainly by the 1996 Health Insurance Portability and Accountability Act (HIPAA) (19). Personal health information (individually identifiable health information, a category that also includes genetic data) can be lawfully disclosed, for example, to the individual upon his legitimate request or to public authorities (e.g., if the disclosure is allowed/required by an applicable law, for public health activities and purposes, and for judicial and administrative proceedings). In general, when individually identifiable health information is used or disclosed, the minimum necessary standard must be adopted. A HIPAA authorization written in plain language (patient consent) is generally required, for example, for the use or disclosure of psychotherapy notes or of personal health information for research or marketing purposes. In most of the circumstances, the patient can restrict or prohibit some or all of the uses or disclosures of his personal health data (when he can't express his will - for example, because of emergency conditions - the disclosure of his data can be allowed if it is consistent with his prior expressed preference and pursues his best interests). However, HIPAA regards only individually identifiable health information and covered entities (healthcare provides, health plans—like health insurance companies—and healthcare clearinghouses). Therefore, this law doesn't apply to deidentified data (that can be freely used, for example, for research) and non-covered entities (e.g., private firms) (16, 20). In other words, most health apps are not covered by HIPAA (21). Deidentification is an articulate process: HIPAA sets a list of 18 personal identifiers (e.g., name, address, medical record number) that must be removed for the lawful use/disclosure of data (safe harbor method) (16). Alternatively, an expert must assess a very small risk of re-identification applying a rigorous and transparent scientific and statistical methodology. Finally, in the US a broader protection of anonymized data can be given by statal laws, like the California Consumer Privacy Act (defined the "little sister of GDPR"), that covers also data that can be indirectly identified (e.g., through IP address) (21, 22).

EU has several peculiarities from a legal point of view. First, there is a significant heterogeneity among EU countries in terms of digital health funding, readiness and use (23). Moreover, in EU, there is no common regulatory framework for medical liability, since, despite some common legal principles, there are enormous legal differences among the juridical cultures of the Member States (e.g., in Italy medical errors can also be criminally persecuted) (24). That being said, privacy protection is guaranteed by the General Data Protection Regulation (GDPR), that applies when personal data are processed by a processor or controller in the context of the activities of its establishment in EU. GDPR is usually considered broader than US laws (16, 20). In particular, the GDPR definition of health data is extensive, regarding even the data that can reveal the health status or risk of patient only if combined with other information (25). Data can be processed lawfully and in a transparent manner only for "specified, explicit and legitimate purposes" and must be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed" (principle of minimization) (Art. 5). Data can be stored for longer period than that necessary for the purposes of their processing only under particular circumstances (e.g., archiving purposes in public interest or scientific research), and the controller is always accountable for their protection (Art. 5). The explicit consent of the data subject can be waived, for example, for compliance with a legal obligation, for reasons of substantial public interest or for scientific research. In this latter case, for instance, according to articles 9 and 89 of the GDPR, there must be appropriate safeguards (specified by Union or Member State laws), among

TABLE 1 | Main differences between US and EU regulations regarding data processing.

	HIPAA privacy rule	General data protection regulation
Country	United States	European Union
Protected data	Protected health information = individually identifiable health information	Personal data = any information (physical, physiological, genetic, mental, economic, cultural or social data) relating to an identified or identifiable natural person
Covered entities	Health plans, clearinghouses, health care providers (and their business associates)	Companies and entities which process personal data as part of their activities
De-identification methods	Assessment of a very small risk of re-identification performed by an expert or reversible (e.g., encoded)/irreversible removal of 18 identifiers (like name, personal dates and biometric identifiers) [45 CFR Subtitle A (10–1–02 Edition) § 164.514]	[Recommended] anonymization (irreversible removal of personal identifiers) or pseudonymization (reversible removal of personal identifiers) [Art. 9, Art. 89]

which the GDPR indicates a reversible form of anonymization called pseudonymisation. However, up to date many Member States have not approved laws of this kind yet (26). Moreover, Malgieri et al. underlined a significant disparity between private and public universities in terms of legal/ethical standards for data processing, since private institutions must comply with much stricter criteria (they must prove the so-called "legitimate interest") (26). Regarding international law aspects, a US health institution, physician or geneticist could be liable under GDPR if its/his patients are EU citizens (16).

CURRENT MEDICO-LEGAL AND ETHICAL CHALLENGES

Grande et al. identified five medico-legal and ethical issues regarding personal data processing: invisibility (patients don't know how their data are processed), inaccuracy of the collected data, immortality (no timeline for the data storage), marketability and identifiability (even when data are anonymized, it is often possible to reidentify the patient) (27). These issues concern both the data that the patients agree to send to the provider of a service and those that are involuntarily left as "digital health footprints" when a digital device is used (27). From a medico-legal perspective, the main risk is that of re-identification (16). Indeed, personal health information can be used for unlawful purposes (for instance, a genetic predisposition to a disease can be used to increase the cost of the insurance coverage) or to obtain more sensible information (e.g., some genetic markers can be used to predict externally visible characteristics of the individual like the skin tone and the color of the eyes).

Data protection has become even more critical since the beginning of the pandemic: the processing of big data was (and is) used to enhance the COVID-19 control measures (e.g., through contact tracing, risk prediction algorithms), adopting two different approaches: some nations adopted the data-first approach (in which storage and communication to health and research institutions of the data represent the priority) and some others chose the privacy-first approach (in which health authorities do not know individual movements and interactions) (28, 29). In any case, each country is storing an unprecedented amount of population data of every kind (e.g., health data, individual movements and interactions), that, if not properly processed, could lead to catastrophic outcomes (28). Therefore, cybersecurity should still represent a priority. Morley et al. observed that an application for tracking and tracing of COVID-19 cases can be considered ethically justifiable only if it complies with "high-level principles" (necessity, proportionality, scientific soundness, and time-boundedness) and "enabling factors" (e.g., the use of the application is voluntary, a consent is requested, stored data can be erased upon users request, its purpose is defined and limited) (30).

Besides the risk of data misuse, AI systems are vulnerable to both software and hardware faults, that can be extremely harmful for patients. For instance, inadequate training data or wrong design choices can cause abnormal system behavior (31). These errors can be due to the users rather than to the developers: for instance, an AI system can make wrong (and potentially harmful) decisions if it is not used in the original design context (31). Moreover, logic, memory or communication components of the devices can be affected by permanent or transient hardware failures (like the transient failures—also called "soft errors"—represented by bit flips due to radiation particles) (31).

For these reasons, AI products designed for healthcare are considered by EU Commission as "high-risk" and, before they can be put on the market, have to meet these requirements: adequate risk assessment and mitigation systems, high-quality datasets, logging of activity, detailed documentation to prove the compliance with legal requirements, clear and adequate information to the user, appropriate human oversight measures and high level of robustness, security and accuracy (https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1682).

CONSENT

AI can also be used to do clerical work on behalf of physicians, who then would have more time to communicate to patients (6). In digital health, the central role of communication and informed consent is threatened by the fact that artificial intelligence softwares are often not transparent. This is a serious legal issue, since patients should give their consent without fully understanding how their data will be processed. Moreover, many patients lack the level of technological literacy necessary for fully understanding the pros and the cons of digital health (32). This issue undermines the patients' engagement and can impede to obtain affirmative, unambiguous, and conscious decisions required in current medicine (32). On the other side, the access to some data (e.g., glucose blood levels reported by a microinfusor) can empower patients with a more direct and efficacious role in prevention (e.g., the diabetic person could better understand what behavior increases the glucose blood levels) and can reduce the information asymmetry between them and physicians/geneticists. Empowering patients would also mean to reduce the uncertainty regarding the causes of adverse outcomes: if a device can record all the inputs and the outputs, this "black box" can be used for both improving patient education and, after an adverse event occurred, reconstruct what was its cause. In this way, physicians, healthcare institutions and device manufacturers could not be considered wrongly liable for adverse events who the patients mainly caused (e.g., if a poor diabetes control is proved to be due to an abnormal intake of food). Regarding consent, specific principles must be applied to children. Generally, the relatives are entitled for giving consent to process data of their siblings, but the minor should be still heard (this principle has been expressed, among the others, by United Nations General Assembly in 1989 and in some countries, like Italy, it is regulated by national laws). Moreover, when data of a minor must be processed, the proof that the best interests of the child are pursued is needed to go forward (in Europe this duty is guaranteed by the 2007 European Convention of Human Rights, the 2012 Charter of Fundamental Rights of the European Union and the 2013 United Nations Committee on the Rights of the Child) (33).

COGNITIVE BIAS AND RISK OF MEDICAL MALPRACTICE

AI can strongly influence healthcare professionals, changing the approach to their profession. In particular, AI is associated with the risk of deskilling (the physician outsources his tasks to the software, losing his technical and non-technical skills) and overfaith (the physician relies on the results obtained by the algorithm, not critically evaluating/considering the possibility of errors) (6, 34–36). Passively accepting AI outputs is called automation bias and represents a source of important medico-legal risks, since AI can be wrong (because of an operation error or of an operation on wrong data). For instance, Bond et al. found that the diagnostic accuracy of the interpreters of ECGs, especially if not specialized in cardiology, nearly halved when the automated diagnosis software missed the correct diagnosis (37). Adopting the proper approach to AI, the physicians would not lose their technical skills - but their skills could improve on one side and worsen on another side. For instance, Carter et al. observed that if normal mammograms are triaged out by AI radiologists would improve their skills in interpreting pathological images but could lose their skill to recognize normal images (36). For these reasons, proper and updated medical education is needed: for instance, in Italy less than a fourth of young physicians has a proper knowledge of artificial intelligence and big data, and this could be cause scarce engagement and higher risk of deskilling (38). However, even in case of proper education, the issue of the interpretability/explainability of AI results remains. Some authors distinguish two models of interpretability (i.e., the interpretation of the general behavior of the AI system) from inference interpretability (i.e., the interpretation of the instance-specific decisional process of the AI system), but in any case physicians/geneticists can't be out of the loop and must always be able to explain and—in case of adverse outcome—justify the logical process behind a diagnosis or a treatment choice (11, 32). Indeed, as observed by Reddy, "trust in clinicians encompasses trust in the clinical tools they choose to use, and in the selection of those tools, including AI-based tools" (19). The first issue regarding interpretability and transparence of the process is represented by the fact that the outputs of an algorithms and the algorithms themselves are often a "black box" (5, 6). In particular, artificial intelligence produces a prediction but cannot explain its results and it is not capable of causal inference. For instance, Verghese et al. reported the case of an algorithm developed for crime forecasting that assigned a significantly higher risk of reoffence to black individuals than to white persons without a clear statistical reason (39). Many of the most accurate algorithms are not particularly transparent, and this could create a trade-off between accuracy, intellectual property protection and explainability (36, 40). A second issue is represented by the fact that the direct output of AI tools is often represented by raw results (e.g., those produced by an implantable cardiac defibrillator), that can be hardly understandable for both patients and physicians (11). Finally, artificial intelligence can be adaptive, evolving through a process of continual learning, and AI devices can autoupdate (19, 41). Rapid regulatory obsolescence is a critical issue, since it can create regulatory gaps that can represent a serious hazard for data protection (40).

MEDICO-LEGAL ISSUES OF DIAGNOSTIC ALGORITHMS

Machine learning is a technology that, working on a dataset (training data), can develop predictions through algorithms (a process also known as "generalization"). It is modeled on human brain and can operate through supervised or unsupervised algorithms (6, 42). Supervised algorithms identify patterns in well-organized databases, in which each entry is correctly labeled (43). Supervised algorithms are subdivided into classification and regression algorithms. The latter work on continuous data and are aimed at reliably predicting an output variable, while classification algorithms process discrete data and divide the dataset into different classes, predicting to which class an input variable belongs. On the other side, unsupervised algorithms try to deduce a "natural" pattern evaluating the relationships among unlabeled data (for example, through the individuation of similarities and differences among data) (6, 43). Sometimes, the term "semi-supervised" is used to define the algorithms that use incomplete input information (44, 45). Unsupervised algorithms are complex and mainly used for data mining (44). Currently, the on-demand access to graphical processing units technology needed to process data is also provided by cloud-computing platforms, and thus softwares for health/genetic data can be relatively easy to use (43).

Quantity and quality of data are core factors for AI and are factors of great medico-legal interest (because a low-quality algorithm must be considered unreliable and thus cannot be adopted). Indeed, when there are few data (and/or the algorithm is too much complex), there is the risk of overfitting: the prediction is valid for the dataset but it could prove to be unreliable if other data are added (43, 46). There are some strategies to reduce the risk of overfitting (e.g., metaanalyses of different algorithms applied to the same dataset; data augmentation: for example, considering an image from different perspectives in order to obtain more data from the same image) (43). The big quantity of data (big data) needed for AI to properly function is frequently expressed with the term "data hungriness" (11). Data hungriness is related to substantial medico-legal issues, since a single institution often does not have enough data to develop reliable predictions and in complex (multifactorial) diseases (like cancer) it is frequently necessary to combine more kinds of big data (e.g., familiarity, behavior, diet, genetic profile) coming from different sources (47). Therefore, data are frequently transferred and shared. Over the last years several EU and non-EU countries transferred large amounts of deidentified personal health information to private companies (in order to develop AI softwares) (36). In these cases, the main legal problem is the risk of re-identification of anonymized data, an operation that can be performed both by hackers and the private companies that receive the big data (36, 48). This issue is particularly important if it is considered that many producers of health-related AI (e.g., Google) also detain many non-health data that could be used in combination to re-identify the specific individuals (36). Therefore, data transfer, even when it occurs legally, can still represent a serious risk for privacy.

MEDICO-LEGAL ISSUES LINKED TO AUTOMATION AND INTERCONNECTEDNESS

As said, when most of the crucial decisions are made by AI, especially when AI is not transparent and when there are multiple interconnected devices, causal inference probably is the main issue from a medico-legal point of view (49). Indeed, in these cases, causal processes are often very complex and the provability of individual responsibility is often difficult. The commonest liability rule is the so-called negligence (or fault-based) liability: the plaintiff is compensated if his damage ant the breach of a duty are proven and the responsible entities are identified (46). In 2021, Zech noted that strict liability can be more adequate for errors committed by AI systems than the negligence liability (49). Under this rule, the plaintiff is compensated simply if he proves to have been damaged (regardless of the proof of the breach of a duty). In particular, Zech underlined that social first party insurances could compensate patients without an individual attribution of responsibility (49). However, as noted by the author, incentives for risk control created by liability rules could be lost if the developers and users of AI cannot be held liable (49).

Causal inference and individual attribution of responsibility are extremely complex issues in robotic surgery: in these cases, it can be difficult to determine whether the surgeon or the software committed the error. For this reason, some authors proposed to install into the robots devices that record any input and output (similarly to flight recorders), while in EU a recent (2017) Resolution advocates creating a specific legal status for robots in order to make them liable for their errors (48). However, the error rate in robotic surgery tends to be lower than in traditional surgery (48). This fact represents a serious issue (from a medico-legal and economic point of view) in legal systems in which the compliance with best practices is mandatory (e.g., in Italy).

Robots are also linked to specific ethical issues, like: the replacement of human operators, the risk of dual use (harmful use—use for warfare or terrorism—of AI systems developed for civilian purposes), the anthropomorphisation of the robots (that can cause social and psychological issues to the users), the social and ethnic gaps (a fair and equal access to new technologies) and the environmental impact of robots (50, 51). At this regard, Campanozzi et al. underlined the importance of building trust in social robotics: developing acceptable and sustainable robots that meet people's needs, values and attitudes, adverse events due to overtrust or undetrust in AI products could be avoided (52).

MEDICO-LEGAL ISSUES OF TELEMEDICINE

Telemedicine is having a significant impact on healthcare services like preventive medicine and follow-up of chronic conditions (24). In general, it is considered beneficial for both the healthcare institutions (that can offer their services also to distant people or to elder/physically impaired/sedentary persons who normally don't go to hospitals for non-urgent conditions) and for the patients (who can save more than 100 min per visit) (24, 53). The main medico-legal issue of telemedicine is the so-called de-coupling: the physician and patient are in different locations or even in different states (32). Therefore, since different states usually have different regulations, in case of claimed medical malpractice, it can be controversial what law is applicable.

A particular kind of telemedicine is mobile health: digital applications can, for instance, enhance the compliance with programs of primary or secondary prevention and permit to perform "domestic triage" (i.e., symptom checkers applications used to stratify the risk, reducing the number of avoidable hospitalizations) (18). Moreover, during COVID-19, both public and private entities developed applications for contact tracing, movements tracking, enforcing quarantine compliance and symptom checking (18, 54). The specific legal and medico-legal issues of mobile health are related to the risk of "digital health footprints," left when a digital device is used (27). Grande et al. observed that US laws don't adequately protect patients privacy, discussing five issues regarding digital health footprints: invisibility (patients don't know how their data are processed), inaccuracy of the collected data, immortality (no timeline for the data storage), marketability and identifiability (even when data are anonymized, it is often possible to reidentify the patient through the combination of digital footprints) (27).

CONCLUSION

Healthcare is radically being changed by the introduction of artificial intelligence. Despite each country has its own regulatory framework on data processing and protection, some principles are shared by Western countries, like the possibility of processing de-identified information for research even without the patient consent. Storing and processing big (health and genetic) data is the only way to develop reliable predictions in both clinical and genetic fields but, at the same time, represents a serious threat for privacy protection. Data controller can be considered accountable for data breach and/or failure to comply with regulatory standards. Therefore, since data sharing is essential to allow the full development of artificial intelligence, it is fundamental that physicians learn how to fully comply with regulations.

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REFERENCES

1. The Lancet Digital Health. Walking the tightrope of artificial intelligence guidelines in clinical practice. *Lancet Digital Health.* (2019) 1:e100. doi: 10.1016/S2589-7500(19)30063-9
2. Fantasia KL, Stockman MC, Ju Z, Ortega P, Crable EL, Drainoni ML, et al. Professional continuous glucose monitoring and endocrinology eConsult for adults with type 2 diabetes in primary care: results of a clinical pilot program. *J Clin Transl Endocrinol.* (2021) 24:254. doi: 10.1016/j.jcte.2021.100254
3. Tyler NS, Mosquera-Lopez CM, Wilson LM, Dodier RH, Branigan DL, Gabo VB, et al. An artificial intelligence decision support system for the management of type 1 diabetes. *Nat Metab.* (2020) 2:612–9. doi: 10.1038/s42255-020-0212-y
4. Nimri R, Battelino T, Laffel LM, Slover RH, Schatz D, Weinzimer SA, et al. Insulin dose optimization using an automated artificial intelligence-based decision support system in youths with type 1 diabetes. *Nat Med.* (2020) 26:1380–4. doi: 10.1038/s41591-020-1045-7
5. Hashimoto DA, Witkowski E, Gao L, Meireles O, Rosman G. Artificial intelligence in anesthesiology: current techniques, clinical applications, and limitations. *Anesthesiology.* (2020) 379–94. doi: 10.1097/ALN.0000000000002960
6. Dorado-Díaz PI, Sampedro-Gómez J, Vicente-Palacios V, Sánchez PL. Applications of artificial intelligence in cardiology. The future is already here. *Rev Española Cardiol.* (2019) 72:1065–75. doi: 10.1016/j.rec.2019.05.014
7. Kwon JM, Lee Y, Lee Y, Lee S, Park J. An algorithm based on deep learning for predicting in-hospital cardiac arrest. *J Am Heart Assoc.* (2018) 7:e008678: doi: 10.1161/JAHA.118.008678
8. Yang YJ, Bang CS. Application of artificial intelligence in gastroenterology. *World J Gastroenterol.* (2019) 25:1666–83. doi: 10.3748/wjg.v25.i14.1666
9. Kimber TB, Chen Y, Volkamer A. Deep learning in virtual screening: recent applications and developments. *Int J Mol Sci.* (2021) 22:4435. doi: 10.3390/ijms22094435
10. Devalla SK, Liang Z, Pham TH, Boote C, Strouthidis NG, Thiery AH, et al. Glaucoma management in the era of artificial intelligence. *Br J Ophthalmol.* (2020) 104:301–11. doi: 10.1136/bjophthalmol-2019-315016
11. Banegas-Luna AJ, Peña-García J, Iftene A, Guadagni F, Ferroni P, Scarpato N, et al. Towards the interpretability of machine learning predictions for medical applications targeting personalised therapies: a cancer case survey. *Int J Mol Sci.* (2021) 22:4394. doi: 10.3390/ijms22094394
12. Mitsala A, Tsalikidis C, Pitiakoudis M, Simopoulos C, Tsaroucha AK. Artificial intelligence in colorectal cancer screening, diagnosis and treatment. A new era. *Curr Oncol.* (2021) 28:1581–607. doi: 10.3390/curroncol28030149
13. Murphy AC, Farouque O, Yeo B, Dick R, Koshy AN, Roccisano L, et al. SMARTphone based cardiovascular risk reduction in BREAST cancer patients (SMART-BREAST): a randomised controlled trial protocol. *Heart Lung Circ.* (2021) 30:1314–9. doi: 10.1016/j.hlc.2021.03.271
14. Saba L, Biswas M, Kuppili V, Cuadrado Godia E, Suri HS, Edla DR, et al. The present and future of deep learning in radiology. *Eur J Radiol.* (2019) 114:14–24. doi: 10.1016/j.ejrad.2019.02.038
15. Aquila I, Sacco MA, Abenavoli L, Malara N, Arena V, Grassi S, et al. Severe acute respiratory syndrome coronavirus 2 pandemic. *Arch Pathol Lab Med.* (2020) 144:1048–56. doi: 10.5858/arpa.2020-0165-SA
16. Martinez-Martin N, Luo Z, Kaushal A, Adeli E, Haque A, Kelly SS, et al. Ethical issues in using ambient intelligence in health-care settings. *Lancet Digital Health.* (2021) 3:e115–23. doi: 10.1016/S2589-7500(20)30275-2
17. The Lancet Digital Health. Wearable technology and lifestyle management: the fight against obesity and diabetes. *Lancet Digital Health.* (2019) 1:e243. doi: 10.1016/S2589-7500(19)30135-9
18. Gasser U, Ienca M, Scheibner J, Sleigh J, Vayena E. Digital tools against COVID-19: taxonomy, ethical challenges, and navigation aid. *Lancet Digital Health.* (2020) 2:e425–34. doi: 10.1016/S2589-7500(20)30137-0
19. Reddy S, Allan S, Coghlan S, Cooper P. A governance model for the application of AI in health care. *J Am Med Inform Assoc.* (2020) 27:491–7. doi: 10.1093/jamia/ocz192
20. Gostin LO, Halabi SF, Wilson K. Health data and privacy in the digital era. *J Am Med Assoc.* (2018) 320:233–4. doi: 10.1001/jama.2018.8374
21. McGraw D, Mandl KD. Privacy protections to encourage use of health-relevant digital data in a learning health system. *npj Digital Med.* (2021) 4:2. doi: 10.1038/s41746-020-00362-8
22. Cohen IG, Gerke S, Kramer DB. Ethical and legal implications of remote monitoring of medical devices. *Milbank Q.* (2020) 98:1257–89. doi: 10.1111/1468-0009.12481
23. Beckmann M, Dittmer K, Jaschke J, Karbach U, Köberlein-Neu J, Nocon M, et al. Electronic patient record and its effects on social aspects of interprofessional collaboration and clinical workflows in hospitals (eCoCo): a mixed methods study protocol. *BMC Health Serv Res.* (2021) 21:377. doi: 10.1186/s12913-021-06377-5
24. Vera Lúcia Raposo. Telemedicine: The legal framework (or the lack of it) in Europe. *GMS Health Technol Assess.* (2016) 12:3. doi: 10.3205/hta000126
25. Hordern V. Data protection compliance in the age of digital health. *Eur J Health Law.* (2016) 23:248–64. doi: 10.1163/15718093-12341393
26. Malgieri G. Data protection and research: A vital challenge in the era of COVID-19 pandemic. *Comp Law Sec Rev.* (2020) 37:105431. doi: 10.1016/j.clsr.2020.105431
27. Grande D, Luna Marti X, Feuerstein-Simon R, Merchant RM, Asch DA, Lewson A, et al. Health policy and privacy challenges associated with digital technology. *JAMA Netw Open.* (2020) 3:e208285. doi: 10.1001/jamanetworkopen.2020.8285
28. Fahey RA, Hino A. COVID-19, digital privacy, and the social limits on data-focused public health responses. *Int J Inf Manag.* (2020) 55:102181. doi: 10.1016/j.ijinfomgt.2020.102181

29. Whitelaw S, Mamas MA, Topol E, van Spall HGC. Applications of digital technology in COVID-19 pandemic planning and response. *Lancet Digital Health.* (2020) 2:e435–40. doi: 10.1016/S2589-7500(20)30142-4
30. Morley J, Cowls J, Taddeo M, Floridi L. Ethical guidelines for SARS-CoV-2 digital tracking and tracing systems. *SSRN Electron J.* (2020). doi: 10.2139/ssrn.3582550
31. Athavale J, Baldovin A, Graefe R, Paulitsch M, Rosales R. AI and reliability trends in safety-critical autonomous systems on ground and air. In: *2020 50th Annual IEEE/IFIP International Conference on Dependable Systems and Networks Workshops (DSN-W)*. Valencia: IEEE (2020). p. 74–7.
32. Morley J, Machado CCV, Burr C, Cowls J, Joshi I, Taddeo M, et al. The ethics of AI in health care: a mapping review. *Soc Sci Med.* (2020) 260:113172. doi: 10.1016/j.socscimed.2020.113172
33. Beauvais MJS, Knoppers BM. Coming out to play: privacy, data protection, children's health, and COVID-19 research. *Front Genet.* (2021) 12:659027. doi: 10.3389/fgene.2021.659027
34. Recht MP, Dewey M, Dreyer K, Langlotz C, Niessen W, Prainsack B, et al. Integrating artificial intelligence into the clinical practice of radiology: challenges and recommendations. *Eur Radiol.* (2020) 30:3576–84. doi: 10.1007/s00330-020-06672-5
35. Séroussi B, Hollis KF, Soualmia LF. Transparency of health informatics processes as the condition of healthcare professionals' and patients' trust and adoption: the rise of ethical requirements. *Yearbook Med Inform.* (2020) 29:7–10. doi: 10.1055/s-0040-1702029
36. Carter SM, Rogers W, Win KT, Frazer H, Richards B, Houssami N. The ethical, legal and social implications of using artificial intelligence systems in breast cancer care. *Breast.* (2020) 49:25–32. doi: 10.1016/j.breast.2019.10.001
37. Bond RR, Novotny T, Andrsova I, Koc L, Sisakova M, Finlay D, et al. Automation bias in medicine: the influence of automated diagnoses on interpreter accuracy and uncertainty when reading electrocardiograms. *J Electrocardiol.* (2018) 51:S6–11. doi: 10.1016/j.jelectrocard.2018.08.007
38. Casà C, Marotta C, di Pumpo M, Cozzolino A, D'Aviero A, Frisicale EM, et al. COVID-19 and digital competencies among young physicians: are we (really) ready for the new era? A national survey of the Italian Young Medical Doctors Association. *Ann Istituto Superiore Sanita.* (2021) 57:1–6. doi: 10.4415/ANN_21_01_01
39. Verghese A, Shah NH, Harrington RA. What this computer needs is a physician humanism and artificial intelligence. *J Am Med Assoc.* (2018) 319:19–20. doi: 10.1001/jama.2017.19198
40. Cohen IG, Evgeniou T, Gerke S, Minssen T. The European artificial intelligence strategy: implications and challenges for digital health. *Lancet Digital Health.* (2020) 2:e376–9. doi: 10.1016/S2589-7500(20)30112-6
41. Vokinger KN, Feuerriegel S, Kesselheim AS. Continual learning in medical devices: FDA's action plan and beyond. *Lancet Digital Health.* (2021) 3:e337–8. doi: 10.1016/S2589-7500(21)00076-5
42. Hamet P, Tremblay J. Artificial intelligence in medicine. *Metab Clin Exp.* (2017) 69:S36–40. doi: 10.1016/j.metabol.2017.01.011
43. Krittanawong C, Johnson KW, Rosenson RS, Wang Z, Aydar M, Baber U, et al. Deep learning for cardiovascularmedicine: a practical primer. *Eur Heart J.* (2019) 40:2058–69C. doi: 10.1093/eurheartj/ehz056
44. Mooney SJ, Pejaver V. Big data in public health: terminology, machine learning, and privacy. *Ann Rev Public Health.* (2018) 39:95–112. doi: 10.1146/annurev-publhealth-040617-014208
45. Zou J, Huss M, Abid A, Mohammadi P, Torkamani A, Telenti A. A primer on deep learning in genomics. *Nat Genet.* (2019) 51:12–8. doi: 10.1038/s41588-018-0295-5
46. Car J, Sheikh A, Wicks P, Williams MS. Beyond the hype of big data and artificial intelligence: building foundations for knowledge and wisdom. *BMC Med.* (2019) 17:143. doi: 10.1186/s12916-019-1382-x
47. Cesario A, D'oria M, Calvani R, Picca A, Pietragalla A, Lorusso D, et al. The role of artificial intelligence in managing multimorbidity and cancer. *J Person Med.* (2021) 11:314. doi: 10.3390/jpm11040314
48. O'Sullivan S, Nevejans N, Allen C, Blyth A, Leonard S, Pagallo U, et al. Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery. *Int J Med Robot Comp Assist Surg.* (2019) 15:e196. doi: 10.1002/rcs.1968
49. Zech H. Liability for AI: public policy considerations. *ERA Forum.* (2021) 22:147–58. doi: 10.1007/s12027-020-00648-0
50. Aicardi C, Akintoye S, Fothergill BT, Guerrero M, Klinker G, Knight W, et al. Ethical and social aspects of neurorobotics. *Sci Eng Ethics.* (2020) 26:2533–46. doi: 10.1007/s11948-020-00248-8
51. Esperto F, Prata F, Antonelli A, Alloni R, Campanozzi L, Cataldo R, et al. Bioethical implications of robotic surgery in urology: a narrative review. *Miner Urol Nephrol.* (2021) 7:1. doi: 10.23736/S2724-6051.21.04240-3
52. Campanozzi LL, Guglielmelli E, Cella E, Ghilardi G, Michilli M, Molina A, et al. Building trust in social robotics: a pilot survey. *IEEE Technol Soc Mag.* (2019) 38:45–54. doi: 10.1109/MTS.2019.2948440
53. Kichloo A, Albosta M, Dettloff K, Wani F, El-Amir Z, Singh J, et al. Telemedicine, the current COVID-19 pandemic and the future: a narrative review and perspectives moving forward in the USA. *Fam Med Commun Health.* (2020) 8:530. doi: 10.1136/fmch-2020-000530
54. Kuntsman A, Miyake E, Martin S. Re-thinking digital health: data, appisation and the (im)possibility of 'Opting out.' *Digital Health.* (2019) 5:1–16. doi: 10.1177/2055207619880671

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COVID-19 Compulsory Vaccination: Legal and Bioethical Controversies

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The imposition of compulsory health treatments has always been a subject of animated legal and bioethical debate. What is at stake are two opposing interests that are in their own way protected by international treaties and constitutional provisions: the right to individual self-determination and the duty to defend and preserve collective safety. The global health crisis related to the COVID-19 pandemic has placed the issue of the legitimacy of imposing compulsory vaccination at the center of the multifaceted debate on pandemic health policies. Indonesia, Tajikistan, Turkmenistan, and the Federated States of Micronesia are currently the only four countries in the world where the COVID-19 vaccine is mandatory for all citizens. Italy was the first country in the European Union to introduce this obligation, effective from 8 January 2022 by virtue of the decree-law approved on 5 January 2022, which imposed vaccination compulsory for everyone over the age of 50. Similar paths have been undertaken by Greece and Austria, where the obligation will start respectively on 16 January 2022 (for citizens aged over 60) and 1 February 2022 (for citizens of all ages). However, in many civilized countries, "selective" forms of compulsory vaccination, i.e., aimed at specific categories of individuals, especially healthcare professionals, are already provided for. The present work aims to offer a concise and as much as possible exhaustive overview of the main ethical and legal issues related to compulsory COVID-19 vaccination, with reference to both the Italian and the international context, mainly European.

Keywords: vaccinations, consent, obligations, autonomy, public health

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INTRODUCTION

On 4 November 2021, the World Health Organization officially declared the entry into the fourth pandemic wave, identifying Europe as the epicenter of the new epidemic phase.

Although the proportion of the population fully vaccinated against COVID-19 is encouraging in industrialized countries (70% of the population in the US and Canada, 67% in South America, 64% in Asia and 62% in Europe have received at least one dose) (1), the impact of COVID-19 vaccination hesitancy could be a major hindrance to this delicate phase of the pandemic fight.

The international epidemiological trend has brought the issue of compulsory vaccination, temporarily neglected during the summer break, back to the attention of national institutions.

COVID-19 vaccination is already compulsory in many countries for specific categories of workers, mostly healthcare professionals, but a mandatory vaccination extended indiscriminately to the entire population is still largely unprecedented.

There are currently four countries in the world where COVID-19 vaccine is mandatory for all citizens: Indonesia, Tajikistan, Turkmenistan, and the Federated States of Micronesia.

On 5 January 2022, the Italian government approved a decree-law imposing compulsory vaccination for all citizens over the age of 50, which came into force on 8 January 2022. Italy was thus the first European country to adopt a form of compulsory vaccination extended to the entire population (albeit with a fixed age limit).

On November 19, 2021, Austrian Chancellor Alexander Schallenberg announced that in Austria the COVID-19 vaccine will be mandatory for all citizens from February 2022.

On 30 November 2021, Greek Prime Minister Kyriakos Mitsotakis declared that vaccination against COVID-19 will be compulsory in Greece from 16 January 2022 for all citizens over the age of 60.

Although the subject of hundreds of years of jurisprudential and bioethical reflection, the issue of the imposition of compulsory health treatment is still, in 2021, very far from seeing an unambiguous and shared key to interpretation.

Striking a fair balance between the protection of individual autonomy and the protection of collective health is in fact extraordinarily complex, especially when set in the peculiar epidemiological and scientific context of the COVID-19 pandemic.

This is because the COVID-19 vaccine has completely new features, from the technology used to make it to the particular way in which it combats the disease. This unique profile makes the discussion on compulsory vaccination particularly intriguing and raises legal and bioethical issues that have never before been addressed.

AT THE DAWN OF COMPULSORY VACCINATION: THE FIGHT AGAINST SMALLPOX

The first compulsory vaccination policy in history dates back to the late 18th century, during the American Revolutionary War, when General George Washington required his troops to be inoculated with the smallpox virus in 1777 (2).

Of all the diseases affecting the continental army, smallpox was one of the most fearsome threats, as it had a mortality rate of 10 to 60% in non-immune hosts.

According to historians' estimates, at the end of the 7-year war, nine times as many soldiers died of the disease consequences (63,000) as died in battle (7,000) (3).

Washington had the merit of recognizing the seriousness of the disease early on and devising an effective immunization strategy for his army, which gave his troops a significant physical and psychological advantage over their opponents.

A few years later, in 1796, English physician and naturalist Edward Jenner officially tested the first vaccine against smallpox by injecting a child's arm with a small amount of pus taken from the bumps of a woman suffering from cowpox, a form of smallpox that affects cows and, to a lesser extent, humans.

Jenner concluded that cowpox inoculation was a safe alternative to human smallpox virus inoculation and equally effective in terms of protection against smallpox disease (4).

After the scientific community recognized the efficacy and safety of the vaccine, the practice of smallpox vaccination spread widely in Europe, and several countries introduced mandatory vaccination requirements for their citizens, such as Norway in 1811, Russia in 1812 and Sweden in 1816 (5).

The first western nation to introduce free, universal, and compulsory smallpox vaccination was England with the Vaccination Acts of 1840, 1853 and 1867 (6).

The 1840 text provided for the smallpox vaccine to be free of charge and prohibited the variolation procedure, i.e., the inoculation of the subject to be immunized with human smallpox virus taken from an infected subject (the immunization technique practiced before Jenner's smallpox vaccine was developed).

The 1856 Act made vaccination compulsory for all children up to 3 months and established penalties for non-compliance.

The 1867 text tightened up the penalties for those who refused to vaccinate their children and introduced imprisonment for practicing variolation (7).

In the following decades, the outbreak of new smallpox epidemics triggered by the Franco-Prussian war prompted many European states to introduce compulsory vaccination.

In the United States of America, in 1905 the Supreme Federal Court issued a landmark judgement that legitimized the authority of states to "reasonably" violate personal liberties during a public health crisis by fining those who refused vaccination (8).

In the late 1960s, the World Health Assembly (WHA) initiated a strategic plan for the definitive eradication of the smallpox virus, which led to Resolution 11.54, adopted in 1958 by the Eleventh World Health Assembly (9).

On 1 January 1967, the World Health Organization launched the smallpox eradication programme, which led to the eradication of the virus in 1980.

The worldwide effort to combat the disease made it possible to eradicate a virus that was responsible for 500 million deaths between the XIX and XX centuries (10), mainly through compulsory vaccination.

COMPULSORY VACCINATION IN THE EUROPEAN REGULATORY CONTEXT

The primary legal reference for the protection of fundamental human rights in the European regulatory context is the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR), signed in Rome in 1950, in force since 1953, and adopted by the 47 member states of the Council of Europe (11).

Article 8 ("Right to respect for private and family life") states that "*1. Everyone has the right to respect for his private and family life, his home and his correspondence. 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public* *safety or the economic wellbeing of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others"*.

According to the Convention, therefore, forms of interference with the right to individual privacy are permitted whenever necessary to protect the public health of a democratic society.

This principle found a recent practical application in judgement no. 116/2021 of 8 April 2021 (Vavřička and others v. Czech Republic) by the European Court of Human Rights (ECtHR), which rejected the appeal of the parents of some Czech minors against national legislation prohibiting non-vaccinated children from enrolling in nursery school (12).

The Strasbourg Court interpreted the imposition of compulsory vaccination against the 10 vaccine-preventable childhood infectious diseases (diphtheria, tetanus, whooping cough, Haemophilus influenzae type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella and–for children with specified health indications–pneumococcal infections) for admission to nursery school as a means of protecting public health, and as such not violating Article 8 of the ECHR.

The judgement sets out in detail the seven requirements that justify the interference in private life by national legislation:

1. The primary objective of compulsory vaccination must be to protect public health.
2. The imposition of compulsory vaccination must be based on a *"pressing social need"*, e.g., due to a low rate of spontaneous vaccination against a specific disease that could threaten public health.
3. *"Relevant and sufficient reasons"* are needed to impose mandatory vaccination.
4. The safety level of vaccines must be carefully evaluated in relation to scientific evidence.
5. The obligation cannot apply to persons with contraindications to the administration of the vaccine.
6. The obligation must be enforced through penalties for non-compliance, and may not provide for the forced administration of the vaccine.
7. The possibility for persons contesting penalties arising from non-compliance with the obligation to initiate appeals should be guaranteed.

Another important normative reference is represented by the Charter of Fundamental Rights of the European Union, signed in Nice in 2000 and legally binding for the European institutions and member states with the entry into force of the Treaty of Lisbon in 2007.

Article 1 (Human dignity) states: *"Human dignity is inviolable. It must be respected and protected"*.

Article 3 (Right to the integrity of the person) establishes: *"Everyone has the right to respect for his or her physical and mental integrity. In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law; the prohibition of eugenic practices, in particular those aiming at the selection of persons; the prohibition on making the human body and its parts as such a source of financial gain; the prohibition of the reproductive cloning of human beings"* (13).

The concept of free and informed consent expressed in Article 3 is borrowed from the Convention on Human Rights and Biomedicine (Oviedo Convention), the first international treaty on bioethics, signed in Oviedo (Spain) on April 4, 1997, and entered into force on December 1, 1999, following ratification by the first five member states of the European Union.

Article 5 of the Oviedo Convention states: *"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks"* (14).

THE LEGAL BASES OF COMPULSORY VACCINATION IN THE ITALIAN LEGAL SYSTEM

In the Italian legal system, the right to health is enshrined in the Constitution, which in Article 32 states that *"The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. No one may be obliged to undergo any health treatment except under the provisions of the law. Under any circumstances, the law may not violate the limits imposed by respect for the human person"* (15).

Therefore, health is not only a *"fundamental right of the individual"* but also a *"collective interest"*.

The Italian Constitution aims on the one hand to protect the individual's right to self-determination, and on the other to guarantee the health of the community.

The protection of public health may entail the imposition of compulsory health treatments, which would not be permitted under normal conditions, but which becomes legitimate if provided for by specific laws.

The Italian Constitutional Court, the main constitutional guarantee body, which is called upon to verify the conformity of state and regional laws and acts having the force of law with the Constitution, fully illustrated the concept of balancing the protection of the right to individual self-determination and the safeguarding of public health in judgement no. 307 of 22 June 1990, concerning the constitutional legitimacy of compulsory polio vaccination for children within the first year of life: *"… the law imposing a medical treatment is not incompatible with article 32 of the Constitution if the treatment is aimed at improving or preserving the state of health of those subject to it, but also at preserving the state of health of others, since it is precisely this further purpose, pertaining to health as an interest of the community, which justifies the compression of that self-determination of man which is inherent in the right of everyone to health as a fundamental right"* (16).

Similarly, in 1994, the same Court held that the protection of collective health *"implies and includes the duty of the individual not to damage or endanger the health of others through his or* *her own behavior, in observance of the general principle that each person's right is limited by mutual recognition and equal protection of the coexisting rights of others"* (17).

In that judgment, no. 218 of 2 June 1994, the Court declared unconstitutional Article 5 of Law no. 135 of 5 June 1990 on AIDS (18), which provided that no one could be tested for HIV infection without his or her consent except on the grounds of clinical necessity in his or her own interest.

In fact, the judges considered that the provision represented a prejudice to collective health, since *"Article 32 of the Constitution [...] implies [...] the duty to protect the right of third parties who come into necessary contact with the person for activities involving a serious risk, not voluntarily assumed, of contagion"* (17).

Another recent confirmation of the non-incompatibility of the imposition of compulsory vaccination with Article 32 of the Constitution came again from the Italian Constitutional Court in 2018.

With judgement no. 5 of January 18, 2018, the Italian Constitutional Court declared partly inadmissible and partly unfounded the question of constitutional illegitimacy raised by the Veneto region in relation to the vaccination requirement introduced by Law 119/2017 (transition from 4 to 10 mandatory vaccines for children from 0 to 16 years of age) (19).

The reasons for the judgement state: *"The law imposing a health treatment is not incompatible with Art. 32 Cost. This is the case if the treatment is intended not only to improve or preserve the state of health of the person undergoing it, but also to preserve the state of health of others; if it is provided that it does not adversely affect the state of health of the person who is obliged to undergo it, except only for those consequences that appear normal and, therefore, tolerable; and if, in the hypothesis of further damage, the payment of an equitable indemnity in favor of the damaged party is provided for, and this regardless of the parallel protection of compensation … "* (20).

Regarding the last sentence of the judgment extract, the reference is to Law 210/1992 ("Economic indemnity for persons affected by irreversible pathological impairment following compulsory vaccinations, transfusions, and administration of hemoderivatives"), which protects victims of permanent damage deriving from compulsory health treatments, offering them the possibility of receiving adequate financial compensation after an appropriate medical-legal evaluation (21).

Another constitutional principle of central importance in qualifying the imposition of compulsory health treatments is that set out in Article 2: *"The Republic recognizes and guarantees the inviolable rights of the person, both as an individual and in the social groups where human personality is expressed. The Republic expects that the fundamental duties of political, economic and social solidarity be fulfilled"* (15).

Article 2 enshrines the principle of social solidarity between the individual and the community, according to which the citizen, as a member of a community, is called upon to act not only for his own personal interests, but also to protect collective interests.

Thus, the combined provisions of Articles 32 and 2 of the Italian Constitution make the legitimacy of compulsory vaccination conditional on an appropriate balance between protecting the health of the individual and the community.

In the near future (since the official publication of the decree-law passed on 5 January 2022), the vaccine will be compulsory in Italy for all citizens over the age of 50.

Until 31 December 2021, the COVID-19 vaccine was compulsory in Italy for all healthcare professions and workers, pursuant to Article 4 of Decree-Law no. 44/2021 (22).

This was, in fact, a "selective" vaccination requirement, in that it was intended for a specific category of workers, and a "temporary" one, operating until 31 December 2021.

According to the provisions of the law, failure to comply with the vaccination requirement by those who *"carry out their activities in public or private health, social and health care and social assistance structures, in pharmacies or parapharmacies and professional offices"* results in the suspension of the right to perform services or tasks involving interpersonal contacts.

As a matter of fact, SARS-CoV-2 is classified as a human pathogenic agent of risk group 3) according to Art. 267 of Legislative Decree no. 81/2008 (the so-called "Unified Text on Occupational Safety and Health"), i.e., the category that *"includes pathogenic microorganisms that can cause disease in humans and pose a serious risk to workers; they can spread in the community but effective prophylactic or therapeutic measures are usually available"* (23).

In line with this principle, EU Directive 2020/739 of 3 June 2020 also included SARS-CoV2 among the biological agents against which protection in the workplace is mandatory (24).

On the basis of the combined provisions of Article 267 of Legislative Decree 81/2008 and Article 2087 of the Civil Code (which states that the employer is obliged to protect the physical integrity of employees), on 19 March 2021 the Court of Belluno issued an ordinance declaring legitimate the conduct of the management of a nursing home that had deemed unfit for duty and forced to take leave 10 healthcare workers who had refused to undergo the COVID-19 vaccine (25).

The ordinance, therefore, rejected the appeal filed by the claimants, who argued the constitutional illegitimacy of Article 4 of Decree-Law no. 44/2021 insofar as it obliged healthcare workers to vaccinate. The Court held that the question was manifestly unfounded, since the imposition of medical treatment aimed at protecting the health of others is entirely compatible with the Italian Constitution, provided that the subject is guaranteed fair compensation in the event of damage beyond normal foreseeability.

MANDATORY COVID-19 VACCINE: THE REASONS FOR CONTROVERSY

The vast majority of civilized countries require their citizens to undergo a series of compulsory vaccinations starting from childhood.

In Italy, for example, all minors between zero and 16 years of age and unaccompanied foreign minors must undergo 10 vaccinations.

Children who are not up to date with vaccinations cannot access school services (19).

The imposition of compulsory health treatments such as childhood vaccinations was always accompanied by a lively bioethics debate, which however never reached even remotely the proportions of the dispute regarding the compulsory vaccine against COVID-19.

This is because COVID-19 vaccines have characteristics that make their mandatory imposition particularly controversial, chief among them the lack of final approval by regulators in many countries.

With particular reference to the European context, any pharmaceutical company wishing to market a drug within the European Union must first apply for marketing authorization by submitting an application to the European Medicines Agency (EMA).

Based on recommendations provided by the EMA, which carefully evaluates the drug efficacy and safety profiles, the European Commission can issue 3 types of authorization: emergency use authorization (EUA), conditional marketing authorization (CMA), and standard marketing authorization (SMA) (26, 27).

So far, the European Commission has granted four conditional marketing authorizations for vaccines developed by BioNTech and Pfizer, Moderna, AstraZeneca and Janssen Pharmaceutica NV, after the EMA gave a positive assessment of their safety and efficacy. The other vaccines are at different stages of evaluation.

Conditional marketing authorization is granted in cases where not all the clinical data for a drug required for standard authorization are available, but the benefit of placing the drug on the market immediately is considered to outweigh the risks related to the temporary incompleteness of the data.

Conditional marketing authorization is granted when 4 requirements are simultaneously met: there is a favorable benefit-risk ratio for the drug; all conditions are in place to believe that the pharmaceutical company will be able to provide complete data after authorization; the medicine meets an unmet medical need; and the benefit of the drug's immediate availability to patients outweighs the risk inherent in the fact that additional data are still needed.

Conditional marketing authorization is valid for 1 year and may be renewed.

The conditional marketing authorization imposes several obligations on the authorization holder that must be fulfilled within defined time frames, such as collecting additional data to demonstrate that the drug is effective and safe.

The marketing authorization can be converted to a standard marketing authorization once the marketing authorization holder meets the imposed obligations and complete data confirm that the drug's benefits continue to outweigh the risks.

The procedure for authorizing the marketing of a drug under the American regulatory authority, the FDA (Food and Drug Administration), has similar characteristics, but is carried out more quickly due to the implementation of streamlined procedures such as "fast track", "priority review", and "accelerated approval".

This procedural simplification enabled the US FDA to grant final approval of the mRNA vaccine developed by BioNTech and Pfizer on 23 August 2021 for everyone over 16.

Until then, commercialization of the vaccine in the United States had been granted by virtue of an emergency use authorization dated 11 December 2020 (28).

The vaccines developed by Moderna and Janssen Pharmaceutica NV are still marketed in the US due to an emergency authorization issued by the FDA on 18 December 2020 and 27 February 2021, respectively.

The relatively unknown nature of the etiological agent responsible for the COVID-19 disease and the development of vaccines in an extraordinarily short timeframe make the described criticalities in the path to final approval of vaccines quite natural.

In any case, it should be noted that, regardless of the marketing approval process, the COVID-19 vaccine is the first drug in history to have benefited from a "real-life" test of exceptional proportions, having been administered to over 5.5 billion people and having shown absolutely satisfactory efficacy and safety profiles.

Regarding safety, according to EMA data, as of 28 October 2021, 412,571 adverse effects have been reported in 428,000,000 doses of Comirnaty vaccine administered to European citizens (0.09%), 214,528 in 68,800,000 doses of Vaxzevria (0.31%), 94,636 in 61,600,000 doses of Spikevax (0.15%) and 28,244 in 16,300,000 doses of Janssen (0.17%).

The vast majority of recorded adverse effects were mild or moderate (29).

Regarding efficacy, although COVID-19 vaccines show relatively modest effectiveness in preventing the contraction of viral infection (30, 31), their overall ability to control the onset of serious illness requiring hospitalization and intensive care has been proven by the world's most authoritative clinical studies (32–35).

Important decisions on compulsory vaccination against COVID-19 have been taken within the European institutions.

The Council of Europe, the main international organization committed to protecting human rights, separate and independent from the European Union, signed Resolution no. 2361 on 27 January 2021 ("Covid-19 vaccines: ethical, legal and practical considerations").

The text clearly rules out the possibility of individual states making the COVID-19 vaccine compulsory and prohibits its use as a means of discrimination.

In points 7.3.1 and 7.3.2, the Resolution requires member states to: "*… ensure that citizens are informed that the vaccination is not mandatory and that no one is under political, social or other pressure to be vaccinated if they do not wish to do so; ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated*" (36).

However, this Resolution, being issued by the Parliamentary Assembly of the Council of Europe, is not a source of law, and is therefore neither binding nor mandatory for individual member states.

A possible conflict between the domestic law of one of the European States and the Council of Europe Resolution never implies illegality of the national rules.

This is not the case for the judgments of the European Court of Human Rights, which is called upon to check whether national laws comply with the principles laid down in the European Convention for the Protection of Human Rights and Fundamental Freedoms.

The Strasbourg Court has so far ruled on cases related to the COVID-19 pandemic on three occasions.

In the first case (Le Mailloux v. France, 5 November 2020, declaration of inadmissibility), concerning a French citizen who claimed that national legislation had failed to comply with the positive obligations to protect life and health of persons enshrined in Article 2 ECHR by not providing citizens with adequate means of defense against the spread of the virus (masks and tests), the Court dismissed the application because the applicant did not have "victim" status (37).

The second case concerns a Romanian citizen's appeal against the imposition of lockdown, which allegedly violated Article 5 of the ECHR, protecting personal freedom (Terheș v. Romania, 13 April 2021, declaration of inadmissibility).

The Court dismissed the appeal because the lockdown does not impose restrictions that can be regarded as a "deprivation of liberty" within the meaning of Article 5 ECHR (38).

The third case concerns an application for provisional measures made by 672 French firefighters, who invoking Articles 2 and 8 of the ECHR asked the Strasbourg Court to suspend as an interim measure the provisions of the French law no. 2021–1040 of 5 August 2021 imposing on their category the vaccination requirement to work (Abgrall and 671 Others v. France, 24 August 2021, rejection of requests for interim measures).

The Court rejected the appeal of the 672 firefighters as being outside the scope of Article 39 of the Rules of Court, which governs the conditions for adopting interim measures (39).

Indeed, the Court stated that granting interim measures is possible only in exceptional circumstances, when the applicants would otherwise face "a real risk of irreversible harm".

However, it must be emphasized that this judgment excludes the existence of conditions suitable for the adoption of emergency protective measures, and in no way precludes the possibility that the Court may subsequently declare the admissibility of the firemen's action concerning the compatibility of the French legislation with the principles of the ECHR.

In summary, therefore, in none of the three decisions of inadmissibility the Strasbourg Court tackled head-on the question of the legitimacy of compulsory vaccination.

HOW TO ENFORCE A POTENTIAL OBLIGATION?

Another central issue regarding the actual applicability of a direct vaccination obligation to all nation citizens concerns how this obligation would be enforced.

Basically, two compulsory vaccination policies are conceivable.

The first consists of a highly coercive strategy, a "hard" compulsory vaccination, whereby the drug is administered against the individual's will through the intervention of law enforcement.

The second, decidedly softer, option is to bar people who have not been vaccinated from participating in social and working life by adopting a vaccination passport.

The policy of forced inoculation presents countless critical elements in its hypothetical application and must therefore be considered as merely abstract.

On the other hand, the vaccine passport strategy is far more feasible and is in fact already partially applied in EU countries.

The application is "partial" because not only vaccinated citizens, but also citizens who have recovered or tested negative to a molecular swab carried out within the last 72 h can obtain the EU digital COVID certificate.

Shifting from a partial application of the digital COVID certificate to an extensive application, i.e., a vaccination passport granted only to those who have been vaccinated, would in fact represent the imposition of a vaccination obligation.

However, according to this provision, there would be a thorny new issue to be addressed, that of the actual usefulness of vaccinating people who have recovered from COVID-19, and are therefore naturally immunized.

Scientific evidence suggests that healed individuals with adequate antibody levels are more protected from reinfection than vaccinated people (40, 41).

Vaccination against COVID in recovered individuals may even be burdened with a higher probability of adverse effects (42, 43).

In accordance with these scientific data, it would not be unreasonable to grant vaccination passports not only to those who have been vaccinated, but also to those who can prove that they have recovered from the infection, as is the case in Switzerland (44).

However, it should be noted that the introduction of a vaccine passport as a prerequisite for access to social and working life would have a paradoxical effect, i.e., it would exacerbate restrictions on the personal freedom of the population instead of restoring the freedoms of all (the primary objective of vaccination).

In the light of this reflection, the choice of basing the compulsory vaccination policy on the immunity passport would therefore be counterproductive.

This would open up a third way in which the compulsory vaccination could be enforced: the imposition of fines on individuals who do not wish to be vaccinated.

The idea of creating a specific offense and the related criminal consequences (arrest and imprisonment) to punish those who do not intend to undergo vaccination is to be discarded, for the simple reason that no judicial system would be able to withstand the impact of such a measure. Italy, for example, had around 5.5 million unvaccinated people at the beginning of 2022, for which an equal number of criminal prosecutions should be initiated.

A financial penalty for those who do not comply with the vaccination requirement would be much more feasible.

This fine, however, to fulfill the task at hand, should be of such a magnitude as to have a substantial impact on the person's economic status.

In other words, a system of economic penalties that provides for monetary sanctions commensurate with the income of the person sanctioned would be effective, as is already the case in some countries (Switzerland and Finland).

In Italy, the size of economic sanctions is not related to the financial resources of the individual, and the definition of a fixed monetary amount as a fine to be paid in case of non-compliance with the vaccination obligation would lead to an obvious social inequity, with rich people willing to pay in order to preserve their non-vaccinated status and poor people forced to comply with the legal obligation.

CONCLUSION

The alarming rate of progression of the fourth wave of the COVID-19 pandemic, particularly in Europe, has placed the issue of compulsory vaccination at the center of the international legal and bioethical debate.

As shown by the brief collection of principles enshrined in international treaties and jurisprudential pronouncements proposed, the right to individual self-determination is not configurable as intangible, being subordinate to the duty to ensure public safety.

In this sense, in accordance with the legal guidelines outlined above, we consider the legal bases for imposing a generalized vaccination obligation to be sufficiently sound.

Obviously, such an obligation must be based on reliable scientific data attesting to the absolute safety and efficacy of the COVID-19 vaccine.

Although authorisations for these vaccines are still largely conditional (only in the United States has one vaccine obtained final approval), it cannot be forgotten that more than 2 years after the pandemic broke out, SARS-CoV2 is putting even the most advanced health systems in serious difficulty.

Vaccines have proved to be an extraordinarily effective tool in containing the spread of the infection and limiting hospitalisations and deaths.

Their safety and efficacy have been widely proven in studies carried out all over the world.

These safety and efficacy profiles have enabled these drugs to obtain conditional approvals from the major regulatory agencies. These authorisations, although "conditional", were granted after a thorough and scrupulous process of verifying the existence of a benefit-risk balance in favor of the benefits.

As for adverse events, although their existence is undeniably documented, it is absolutely impossible to imagine that a worldwide vaccination campaign could result in an absolute absence of undesirable effects.

Although it may therefore seem anomalous to impose a compulsory requirement for drugs that have not yet been definitively approved, in our opinion the extraordinary and exceptional nature of the pandemic situation makes it fully justifiable.

In our view, waiting for the final authorisations to be granted before imposing compulsory vaccination would pose a serious danger of delay in the fight against the fourth pandemic wave.

AUTHOR CONTRIBUTIONS

FG: conceptualization and writing original draft. GR, AS, and DD: writing, reviewing, and editing. All authors contributed to the article and approved the submitted version.

REFERENCES

1. The New York Times. *World Vaccination Tracker*. Available online at: https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html (accessed November 22, 2021)
2. Cantey JB. Smallpox variolation during the revolutionary war. *Pediatr Infect Dis J.* (2011) 30:821. doi: 10.1097/INF.0b013e318227759a
3. Liebowitz D. Smallpox vaccination: an early start of modern medicine in America. *J Community Hosp Intern Med Perspect.* (2017) 7:61–3. doi: 10.1080/20009666.2016.1273611
4. Riedel S. Edward Jenner and the history of smallpox and vaccination. In: *Baylor University Medical Center Proceedings*. Taylor and Francis (2005). p. 21–5.
5. Sköld P. From inoculation to vaccination: smallpox in Sweden in the eighteenth and nineteenth centuries. *Population Studies.* (1996) 50:247–62. doi: 10.1080/0032472031000149336
6. The Vaccination Acts. *Nature*. (1903) 67:274. doi: 10.1038/067274a0
7. Tafuri S, Martinelli D, Germinario C, Prato R. History of compulsory immunization. *Igiene e Sanità Pubblica.* (2011) 67:659–72.
8. Jacobson v Massachussets, 197 US 11 (1905). doi: 10.1159/000189401
9. World Health Assembly, 11. *Eleventh World Health Assembly, Minneapolis, 28 May-13 June 1958: Resolutions and Decisions: Plenary Meetings: Verbatim Records: Committees: Minutes and Reports: Annexes*. Geneva: World Health Organization (1958). p. 524. Available online at: https://apps.who.int/iris/handle/10665/85706
10. Kennedy RB, Ovsyannikova I, Poland GA. Smallpox vaccines for biodefense. *Vaccine.* (2009) 27:D73–9. doi: 10.1016/j.vaccine.2009.07.103
11. Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5. Available online at: https://www.refworld.org/docid/3ae6b3b04.html (accessed November 18, 2021).
12. ECtHR, judgement no. 116 of 8 April 2021, Grand Chamber, App. nos. 47621/13 (Vavrička v. the Czech Republic), 3867/14 (Novotná v. the Czech Republic), 73094/14 (Hornych v. the Czech Republic), 19306 and 19298/15 (Brožík v. the Czech Republic and Dubsky v. the Czech Republic), 43883/15 *(Roleček v. the Czech Republic)*. Available online at: http://hudoc.echr.coe.int/fre?i=001-209039 (accessed November 18, 2021)
13. *European Union, Charter of Fundamental Rights of the European Union, 26 October 2012, 2012/C 326/02*. Available online at: https://www.europarl.europa.eu/charter/pdf/text_en.pdf (accessed November 19, 2021).
14. Council OE. *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. Oviedo: COE (1997). Available online at: https://rm.coe.int/168007cf98 (accessed November 19, 2021).

15. *Constitution of Italy, 22 December 1947*. Available online at: https://www.senato.it/documenti/repository/istituzione/costituzione_inglese.pdf (accessed November 18, 2021).
16. *Italian Constitutional Court, judgement no. 307 of 22 June 1990*. Available online at: https://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=1990andnumero=307 (accessed November 18, 2021).
17. *Italian Constitutional Court, judgement no. 218 of 2 June 1994*. Available online at: https://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=1994andnumero=218 (accessed November 18, 2021).
18. Law 5 June 1990, no. 135. *Programme of urgent action to prevent and combat AIDS*. Official Gazette of the Italian Republic, General Series no. 132 of 8 June 1990.
19. Law 31 July 2017, no. 119. *Conversion into law, with amendments, of Decree-Law no. 73 of June 7, 2017, containing urgent provisions on vaccine prevention*. (17G00132). Official Gazette of the Italian Republic, General Series no. 182 of 5 August 2017. Available online at: https://www.gazzettaufficiale.it/eli/id/2017/08/5/17G00132/sg (accessed November 19, 2021).
20. *Italian Constitutional Court, judgement no. 5 of 18 January 2018*. Available online at: https://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2018andnumero=5 (accessed November 19, 2021).
21. Law no. 210 of February 25, 1992. *Economic indemnity for persons affected by irreversible pathological impairment following compulsory vaccinations, transfusions, and administration of hemoderivatives*. Gazzetta Ufficiale della Repubblica Italiana (1992). p. 4–5.
22. Law Decree no. 44 of 1 April 2021. Urgent measures for the containment of the COVID-19 epidemic, SARS-CoV-2 vaccinations, justice and public competitions. Official Gazette, General Series no. 79 of 1 April 2021.
23. Legislative Decree no. 81 of 9 April 2008. Implementation of Article 1 of Law no. 123 of 3 August 2007 on health and safety at work. Official Gazette, General Series no. 101 of 30 April 2008-Ordinary Supplement no. 108.
24. Commission Directive (EU) 2020/739 of 3 June 2020 amending Annex III to Directive 2000/54/EC of the European Parliament and of the Council as regards the inclusion of SARS-CoV-2 in the list of biological agents known to infect humans and amending Commission Directive (EU) 2019/1833.
25. Court of Belluno, 19 March 2021, Ordinance no. 12. Refusal of vaccination by ten health workers of a nursing home: "unfitness for duty" and forced holidays. Available online at: https://agens.it/wp-content/uploads/2021/03/Trib._Belluno-ord.-n.-12-2021.pdf (accessed November 22, 2021).
26. Regulation (EC) no. 726/2004. Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. *Official Journal of the European Union*. (2004) 136:1–33.
27. Regulation (EC) no. 507/2006. Regulation (EC) 726/2004 of the European Parliament and of the Council of 29 March 2006 on the conditional marketing authorization for medicinal products for human use falling within the scope of Regulation (EC) no. 726/2004 of the European Parliament and of the Council. *Official Journal of the European Union.* (2006) 50:6–9.
28. Tanne JH. Covid-19: FDA approves Pfizer-BioNTech vaccine in record time. *BMJ.* (2021) 374:n2096. doi: 10.1136/bmj.n2096
29. European Medicine Agency website. *Coronavirus disease (COVID-19). Vaccines for COVID-19. Safety of COVID-19 vaccines*. Available online at: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/safety-covid-19-vaccines#latest-safety-information-section (accessed November 22, 2021).
30. Bleier BS, Ramanathan M Jr, Lane AP. COVID-19 vaccines may not prevent nasal SARS-CoV-2 infection and asymptomatic transmission. *Otolaryngol Head Neck Surg.* (2021) 164:305–7. doi: 10.1177/0194599820982633
31. Swan DA, Bracis C, Janes H, Moore M, Matrajt L, Reeves DB, et al. COVID-19 vaccines that reduce symptoms but do not block infection need higher coverage and faster rollout to achieve population impact. *Sci Rep.* (2021)11:1–9. doi: 10.1038/s41598-021-94719-y
32. Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. *N Engl J Med.* (2020) 383:27. doi: 10.1056/NEJMoa2034577
33. Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. *N Engl J Med.* (2021) 384:403–16. doi: 10.1056/NEJMoa2035389
34. Voysey M, Clemens SAC, Madhi SA, Weckx LY, Folegatti PM, Aley PK, et al. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. *Lancet.* (2021) 397:99–111. doi: 10.1016/S0140-6736(20)32661-1
35. Logunov DY, Dolzhikova IV, Zubkova OV, Tukhvatullin AI, Shcheblyakov DV, Dzharullaeva AS, et al. Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia. *Lancet.* (2020) 396:887–97. doi: 10.1016/S0140-6736(20)31866-3
36. Council of Europe, Parliamentary Assembly. Resolution 2361 of 27 January 2021. "Covid-19 vaccines: ethical, legal and practical considerations". Available online at: https://pace.coe.int/en/files/29004/html (accessed November 21, 2021).
37. ECtHR, Decision of 5 November 2020, Fifth Section, App. no. 18108/20 (Le Mailloux v. France). Available online at: http://hudoc.echr.coe.int/eng?i=001-206611 (accessed November 21, 2021).
38. ECtHR, Decision of 13 April 2021, Fourth Section, App. no. 49933/20 (Terheş v. Romania). Available online at: http://hudoc.echr.coe.int/eng?i=001-210026 (accessed November 21, 2021).
39. ECtHR, Judgement of 24 August 2021, App. no. 41950/20 (Abgrall and 671 Others v. France).
40. Kojima N, Klausner JD. Protective immunity after recovery from SARS-CoV-2 infection. *Lancet Infect Dis.* (2021) 22:12–4. doi: 10.1016/S1473-3099(21)00676-9
41. Qureshi AI, Baskett WI, Huang W, Lobanova I, Naqvi SH, Shyu CR. Reinfection with SARS-CoV-2 in patients undergoing serial laboratory testing. *Clin Infect Dis.* (2021) 22:12–4. doi: 10.1093/cid/ciab345
42. Shrestha NK, Burke PC, Nowacki AS, Terpeluk P, Gordon SM. Necessity of COVID-19 vaccination in previously infected individuals. *medRxiv*. (2021) (preprint). doi: 10.1101/2021.06.01.21258176
43. Raw RK, Kelly C, Rees J, Wroe C, Chadwick D. Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination. *J Infect*. (2021). doi: 10.1016/j.jinf.2021.05.035
44. Schengen Visa Info. Switzerland plans to extend COVID certificate requirement until mid-November (2021). Available online at: https://www.schengenvisainfo.com/news/switzerland-plans-to-extend-covid-certificate-requirement-until-mid-november/ (accessed November 23, 2021).

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Bioethics and COVID-19: Considering the Social Determinants of Health

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In this paper, we focus on a novel bioethical approach concerning the ethical implications of the Social Determinants of Health (SDs) in the time of COVID-19, offering a fresh interpretation of our agency and responsibility in the current pandemic era. Our interpretation is grounded on the idea that our health basically depends on factors that go beyond our organism. In this sense, we stress the radical importance of circumstances to ethically assess an action, in the current pandemic context. Moreover, due the centrality of the SDs in our bioethical assessments—that implies that our health does not exclusively depend on our choices, behaviors, and lifestyle—we can affirm that we are not entirely responsible for our wellness or diseases. As health depends on economic, social, cultural, and environmental factors, we argue that the analysis of personal responsibility facing personal health status should receive further consideration. In this sense, following the "social connection model," we stress the importance of the concept of "shared responsibility" in collective decisions: if we make many decisions collectively, we are also collectively responsible of these decisions. Furthermore, to responsibly tackle the social inequalities that are the underlying cause of disparities in health outcomes, we propose two main strategies based on the Capability Approach: 1. empowering the individuals, especially the most vulnerable ones; and 2. designing preventive policies and interventions that provides an opportunity to address the disparities moving forward. This will help us going beyond the "individualistic medical ethics paradigm" and integrating our concept of health with social factors (e.g., the SDs), based on a more relational and interdependent anthropological thought.

Keywords: bioethics, social determinants of health, public health ethics, shared agency, shared responsibility, vulnerability

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INTRODUCTION

The COVID-19 pandemic has highlighted, on the one hand, the fragility of our health systems, of our way of conceiving medicine and, therefore, of our way of interpreting our social coexistence. On the other, it has emphasized the need to rethink basic anthropological issues, such as our interdependence, vulnerability, and finitude. These considerations are the result of the global reflections that have been carried out over the last 2 years. An important role, in this sense, has been played by philosophy, and, more specifically, by public health ethics and bioethics. Numerous experts have contributed to the public debate with the aim of offering interpretations and considerations on the condition of human beings in times of pandemic [e.g., (1, 2)], in order to propose principles and ethical guidelines with reference to the use of the limited medical resources available [e.g., (3, 4)] and to help in the development of policies to address the health crisis [e.g., (5, 6)].

In this regard, although the topic of justice has been at the center of the public debate, it seems to us that, when thinking at possible policies and ethical guidelines, little thought has been given to the ethical centrality of the Social Determinants of health (SDs). Although the issue of arbitrary discrimination in relation to the scarce resources available in times of pandemic has been largely addressed (5, 7), little thought has been given to the importance of rethinking ethical evaluations based on these socioeconomic factors, which are usually known as SDs. In this sense, we agree with Churchill et al. (8), when they state: "Bioethics has gone too small: it has focused primarily on bedside issues. The consequence is that it has paid scant attention to societal-level macro-issues such as the social determinants of illness and health, the structural racism that magnifies the burden of disease for people of color, and the effects of dismantling the infrastructure for public health." In this paper we specifically focus on this novel approach with regards to the ethical implications of SDs in the time of COVID-19, offering a fresh interpretation of our agency and responsibility in the current pandemic era.

CONSIDERING SDS FOR A MORE ADEQUATE CLINICAL INTERPRETATION

It is not only a matter of making a proper ethical (or bioethical) assessment, but also of correctly considering all the factors that influence people's health. Indeed, the recent pandemic has shown us how a different model of "health" is emerging, one that goes far beyond the simple absence of disease or the functionality of certain organs (or the whole organism). Now, it must be acknowledged that health is not only the result of individual behavior, personal predisposition, and health care provision, but also economic, social, cultural, and environmental factors (9). At the same time, a broader comprehension of the main factors that directly or indirectly affects human health—as the Systemic Clinical Risk Management (SCRM) suggests—may help the physicians to "develop a proactive approach to patient safety" (10).

In this sense, the end of the "biomedical paradigm of health" may be declared—a paradigm which is essentially individualistic and with a "pathological" approach. Conversely, emerges a more complex, systemic, multidimensional, and relational idea of human health. As Engel (11) correctly points out: "The scientific approach to disease began by focusing in a fractional-analytic way on biological (somatic) processes and ignoring the behavioral and psychosocial." Indeed, this emerging idea of health (and, consequently, of disease) would imply a non-mechanistic interpretation of the world (and, more specifically, of the human body), inspired by von Bertalanffy's General System Theory. This paradigm would replace the biomedical one, given the evident lacks and inability to properly explain the human condition in the current era of the latter. Again Engel (11) states: "The existing biomedical model does not suffice. To provide a basis for understanding the determinants of disease and arriving at rational treatments and patterns of health care, a medical model must also take into account the patient, the social context in which he leaves, and the complementary system devised by society. [...] This requires a biopsychosocial model." This is exactly what the pandemic has shown us: we need a broader anthropological interpretation in order to understand human health.

In this regard, the COVID-19 pandemics has even shown that there is a "strong associations between crowding and airway infections, and there is reason to believe that COVID-19 is no exception" (12). Moreover, many other social factors have been related to COVID-19 outcomes, such as "poverty, physical environment (e.g., smoke exposure, homelessness), and race or ethnicity" (13). This is why a strong focus on socioeconomic status is more urgent than ever (14): our health basically depends on factors that go beyond our organism. Or better: our organism could not be isolated from its context and socioeconomic environment, as human ecology clearly highlighted (15). A significant part of this environment is: income and wealth; conditions of employment; access to health services; conditions of housing; food environment; environmental conditions; education; and safety (16–18). These are precisely the SDs, which may be understood as "the conditions in which people live their daily lives and the structural influence on these conditions that ultimately reflect the distribution of power and resources" (19). These lead to "differences in health between groups—identified by measures of socioeconomic position, occupation, education, geographical place of residence, sex, race and ethnicity, disability and intersections between groups (such as socioeconomic position and sex)" (19).

The medical and clinical relevance of these factors has been particularly evident in the current pandemic scenario, where "physical distancing measures, which are necessary to prevent the spread of COVID-19, are substantially more difficult for those with adverse social determinants and might contribute to both short-term and long-term morbidity. School closures increase food insecurity for children living in poverty who participate in school lunch programmes. Malnutrition causes substantial risk to both the physical and mental health of these children, including lowering immune response, which has the potential to increase the risk of infectious disease transmission. People or families who are homeless are at higher risk of infection during physical lockdowns especially if public spaces are closed, resulting in physical crowding that is thought to increase viral transmission and reduce access to care. Being able to physically distance has been dubbed an issue of privilege that is simply not accessible in some communities" (13). This is a faithful description of the current situation of millions of people all around the world. Obviously, this fatal scenario mostly affects certain world regions where health inequalities have been historically present: Latin-America is one of the most affected regions (2).

Nevertheless, despite the strong evidence showing the relevance of SDs in health outcomes, increased due to the current pandemic, the causal mechanisms involved are not fully elucidated, yet. Different models have been proposed, ranging from linear (20) to more complex in structure (21), including those considering geographical and temporal variables (22). Considering SDs in designing and implementing public health policies, thus, is essential to increase the effectiveness of them, as "standard compartmental epidemiological models do not adequately consider the various social determinants of health that have a direct impact on the inequalities of health outcomes and the ability of populations to effectively comply with NPIs [Non-Pharmaceutical Interventions]" (18).

ETHICAL FACTORS AND SDS

The role of SDs in health outcomes is important not only for health care practitioners and policy makers, but it is also relevant for bioethicists. As Prah Ruger (23) points out, "alongside this practical debate exists a parallel debate at the philosophical level." In this sense, through this chapter we want to face this philosophical debate, basically focusing on the ethical implications of the new idea of health presented above.

On the one hand, as health is not only the result of individual behavior, personal predisposition, and healthcare, but it also depends on economic, social, cultural, and environmental factors, the analysis of personal responsibility facing personal health status should receive further consideration. The classical case of people requiring liver transplant due to alcoholism could be considered, then, not only as someone voluntarily engaging in an unhealthy behavior, but also as someone suffering from social conditions that render him/her prone to addictions, diminishing his/her own responsibility. The possible implications regarding other aspects, however, deserves careful consideration. "The COVID-19 pandemic has demonstrated, in profound ways, that all sectors of society and all members of society are interlinked and interdependent" (16) and this issue has not been properly explored in Western bioethical literature, yet. Our traditional attention is devoted to high-tech treatments and relies on personal autonomy as one of the most important values (together with classical "principles"), whereas African bioethicists claims that "bioethical questions related to urban poverty, drug use, immigration, occupational hazards in the workplace or environmental injustice make only rare appearances in peer-reviewed bioethics journals, course syllabi, and conferences" (24).

Even though these issues haven't been largely explored in "traditional" medical ethics, it cannot be said that this is something "absolutely new." Just think at the "classical ethical paradigm" (25, 26). The "ordinary means or treatments" basically depend on geographical and temporal factors, cultural conditions, financial status, psychological condition of the patient, and so forth (27). Or, when ethically assessing an action, it is known that the circumstances constitute a relevant criterion to define the morality of the act itself. In this regard, the SDs may be considered as the "circumstances" in the classical ethics tradition. However, it is also illusory to claim that these aspects were of extreme importance in "classical" ethics, to the extent that we should consider, for example, that cultural circumstances can change our judgment about an action. On the other hand, it seems to us that the pandemic is inviting us to consider the radical importance of circumstances—along with the other factors that determine the morality of the human act—when ethically assessing an action. These considerations do not necessarily imply forms of "circumstantialism," casuistry, or relativism, evidently, but only invite us to more comprehensive moral evaluations.

A broader ethical consideration of health is more than urgent nowadays, indeed. On the one hand, if our health does not exclusively depend on our choices, behaviors, and lifestyle, we can affirm that we are not entirely responsible for our wellness or diseases. On the other, if we are interdependent and mutually vulnerable—the new paradigm of "One Health" (28) basically expresses this fact—our health choices may affect other lifestyles and health. Some lessons can be learned from geriatric approaches that have considered factors beyond clinical issues, including social and environmental, to assess complex constructs, such as frailty (29). A good example of this multidimensional approach is the treatment of illnesses associated to loneliness in elderly people. Indeed, investigations argue that this phenomenon may predict functional decline and death in elderly population (30, 31). In this regard, a successful public health initiative should reduce social disconnection (29) by "facilitating participation in community activities, thereby protecting against the development of affective disorders" (32).

These considerations imply a different form of responsibility: where does our responsibility begin and end? Does it still make sense to speak simply of individual responsibility or is it better to reframe it as "shared responsibility"? As we said, as health is not only the result of individual behavior, personal predisposition, and healthcare, but also depends on economic, social, cultural, and environmental factors, the analysis of personal responsibility facing personal health status should receive further consideration. In this regard, the "social connection model" proposed by Young (33) may provide interesting insights to analyze individual and social responsibility facing collectively determined facts. She argues: "Our responsibility derives from belonging together with others in a system of interdependent processes of cooperation and competition through which we seek benefits and aim to realize projects" (33). This fact doesn't imply the inexistence or irrelevance of personal responsibility, though. It is just a different kind of approach to the issue of responsibility and agency: it focuses on humanity as a moral agent, from which a new sense of responsibility may emerge, as suggested by Jonas (34). In this sense, the concept of "shared responsibility" in collective decisions (35) is the counterpart of the idea of "shared agency" (36, 37): if we make –implicitly or not—many decisions collectively, we are also collectively responsible of these decisions.

Obviously, the degree of responsibility of the individual in collective decisions is quite distinct from that of individual decisions. In fact, the two types of actions have practical effects (even at the level of evaluation) on distinct areas of life: if individual actions concern the "moral" life of the individual (and ethics is the discipline that evaluates them), collective actions relate to the "public" life of persons (and public policies are its test bench). This last consideration about shared responsibility allows us, therefore, to examine and address public health policies in times of pandemic, with particular attention to SDs.

WHAT SHOULD WE DO? MORALITY AND POLICIES

The aforementioned issues for clinical practice and philosophy revealed by the COVID-19 pandemic constitute a call for action. As Burström and Tao (12) claim, "an important starting point is increasing knowledge and awareness of the underlying mechanisms; studies are needed to understand how the disease strikes and by which pathways it impacts certain population groups more adversely—taking lessons from previous disease outbreaks." This information will provide us with the required knowledge to design and implement policies that would effectively decrease health disparities, as those shown by COVID-19 (13). Additionally, healthcare access has been shown to be a determinant on explaining these disparities and it has become urgent to implement "laws and policies to ensure access to healthcare services is based on medical need rather than on ability to pay or social status and that services are tailored to recipients' cultural, linguistic, and religious requirements" (38). Echoing the statement by Takian et al. (39), we argue that "viruses do not discriminate, nor should health systems."

Following our previous consideration, anyway, in order to face this problem our actions should go beyond health sector and involve the society as a whole. Social inequalities are the underlying cause of disparities in health outcomes. Therefore, "the pandemic has highlighted the unequal distribution of power and resources, and people are also using this moment to challenge these inequalities anew" (38).

A suitable framework to address this challenge, then, could be represented by the Capability Approach (CA), proposed by Amartya Sen. This perspective "emphasizes the importance of human agency—i.e., people's ability to live a life they value. It underscores that agency is essential for both individual and collective action and is critical for changing policy, norms, and social commitments. Reducing social inequalities in health therefore requires more than 'flattening the socioeconomic gradient"' (23). CA, then, calls for new forms of social commitment, understanding democracy as something more than representative governments where citizens have the right to vote, but a society in which empowered persons have multiple ways to participate in public deliberation and decision making (40). This may be a daunting challenge, however, "interventions to tackle systematically reproduced conditions of vulnerability would contribute toward a fairer and more sustainable world" (38). To do so, we may follow two main strategies: 1. Empowering the individuals, especially the most vulnerable ones (23)—e.g., developing, effective communication (41); and 2. Designing preventive policies and interventions that provides an opportunity to address the disparities moving forward (13), starting from an increasing knowledge and awareness of the underlying mechanisms of health inequalities (12). In this regard, bioethics can provide arguments to challenge traditional development assessment approaches, such as the Gross Domestic Product (GDP), and pay attention to multidimensional and more comprehensive strategies, such as the Human Development Index. While the second strategy is more common and more frequently addressed by the public discourse, the first one is less used and applied, since it represents a long-range challenge. This first strategy may represent the new educational challenge emerging from this time of pandemic that can drive changes to future national and international policies and guidelines.

These two strategies are not mutually exclusive, obviously. Furthermore, we may state that they are complementary since they address the same problems and concerns (the emerging of SDs and the pandemic) but starting from different points of view (i.e., top-down and bottom-up). These two have same aim: to improve the conditions "under which individuals are free to choose healthier life strategies and conditions for themselves and for future generations" (23). The CA has a preeminent role, thus: it focuses on "the empowerment of individuals to be active agents of change in their own terms –both at the individual and collective level" (23).

CONCLUSIONS: BIOETHICS MAY GO FAR

The time of pandemic is, basically, a time of changes. We changed our behaviors, our lifestyle, our worldview, our perception of the future, our concept of health and illness, and so forth. We may add: it is time to change our bioethical view, too.

It is time to integrate our "classical" view of ethics with the new evidence that are currently emerging. In this sense, the history of bioethics may help us. The classic contention (42–44) between Wisconsin (i.e., Potter's global bioethics) and Georgetown (i.e., Hellegers and Callahan's medical ethics) doesn't make sense anymore. It is time to go beyond the "individualistic medical ethics paradigm" to develop theoretical bridges toward public health ethics, environmental ethics, and global policies issues (45). This may help us integrating our concept of health as a "biological issue" with social factors (e.g., the SDs), based on a more relational and interdependent anthropological thought. This is an urgent step we should take in bioethical inquiries, in addition to assume an active role in policy making, advocating for a fair balance between social interdependence and individual autonomy.

On the one side, thus, we may think, together with Churchill et al. (8), that "bioethics has gone too small," if we consider only the Georgetown paradigm (46), which seems to be too narrow for current pandemic concerns. On the other, redeeming Potter's (47) idea of bioethics, this novel form of considering SDs as the circumstances of the action may help developing the bridge between public health ethics, bioethics, and environmental ethics (45). In brief, a bridge to the future. Bioethics may, thus, go far.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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REFERENCES

1. Vineis P. *Salute Senza Confini. Le epidemie Della Globalizzazione*. Torino: Codice Edizioni (2020).
2. Sánchez I, López R, Valera L. COVID-19 and ethics: a Latin-American perspective. *Asia Pac J Public Health.* (2020) 32:8. doi: 10.1177/1010539520957814
3. Tambone V, Boudreau D, Ciccozzi M, Sanders K, Campanozzi LL, Wathuta J, et al. Ethical criteria for the admission and management of patients in the ICU under conditions of limited medical resources: a shared international proposal in view of the COVID-19 pandemic. *Front Public Health.* (2020) 8:284. doi: 10.3389/fpubh.2020.00284
4. Valera L, Carrasco MA, López R, Ramos P, von Bernhardi R, Bedregal P, et al. Orientaciones éticas para la toma de decisiones médicas en el contexto de la pandemia de COVID-19 en Chile. *Rev Med Chile.* (2020) 148:393–8. doi: 10.4067/S0034-98872020000300393
5. Emanuel EJ, Persad G, Upshur R, Thome B, Parker M, Glickman A, et al. Fair allocation of scarce medical resources in the time of covid-19. *NEJM.* (2020) 382:2049–55. doi: 10.1056/NEJMsb2005114
6. Wax RS, Christian MD. Practical recommendations for critical care and anesthesiology teams caring for novel coronavirus (2019-nCoV) patients. *Can J Anaesth.* (2020) 67:568–76. doi: 10.1007/s12630-020-01591-x
7. Sokol D. *The Life and Death Decisions of COVID-19*. The BMJ Opinion. Available online at: https://blogs.bmj.com/bmj/2020/03/20/daniel-sokol-the-life-and-deathdecisions-of-covid-19/ (accessed September 13, 2021).
8. Churchill LR, King NMP, Henderson GE. The future of bioethics: it shouldn't take a pandemic. *Hastings Cent Rep.* (2020) 50:54–56. doi: 10.1002/hast.1133
9. Schroeder SA. We can do better -improving the health of the American people. *NEJM.* (2007) 357:1221–28. doi: 10.1056/NEJMsa073350
10. De Micco F, De Benedictis A, Fineschi V, Frati P, Ciccozzi M, Pecchia L, et al. From syndemic lesson after COVID-19 pandemic to a "systemic clinical risk management" proposal in the perspective of the ethics of job well done. *Int J Environ Res Public Health.* (2022) 19:15. doi: 10.3390/ijerph19010015
11. Engel GL. The need for a new medical model: a challenge for biomedicine. *Science.* (1977) 196:129–36. doi: 10.1126/science.847460
12. Burström B, Tao W. Social determinants of health and inequalities in COVID-19. *Eur J Public Health.* (2020) 30:617–8. doi: 10.1093/eurpub/ckaa095
13. Abrams EM, Szefler SJ. COVID-19 and the impact of social determinants of health. *Lancet Respir Med.* (2020) 8:659–71. doi: 10.1016/S2213-2600(20)30234-4
14. Rollston R, Galea S. COVID-19 and the social determinants of health. *Am J Health Promot.* (2020) 34:687–9. doi: 10.1177/0890117120930536b
15. Marten GG. *Human Ecology. Basic Concepts for Sustainable Development.* Sterling: Earthscan Publications Ltd. London. (2003).
16. Xafis V. What is inconvenient for you is life-saving for me: how health inequities are playing out during the COVID-19 pandemic. *Asian Bioeth Rev.* (2020) 12:223–34. doi: 10.1007/s41649-020-00119-1
17. Singu S, Acharya A, Challagundla K, Byrareddy SN. Impact of social determinants of health on the emerging COVID-19 pandemic in the United States. *Front Public Health.* (2020) 8:406. doi: 10.3389/fpubh.2020.00406
18. Galanis G, Hanieh A. Incorporating social determinants of health into modelling of COVID-19 and other infectious diseases: a baseline socio-economic compartmental model. *Soc Sci Med.* (2021) 274:113794. doi: 10.1016/j.socscimed.2021.113794
19. World Health Organization. *Addressing the Social Determinants of Health: The Urban Dimension and the Role of Local Government.* (2012). Denmark: WHO -Regional Office for Europe. Available online at: https://www.euro.who.int/__data/assets/pdf_file/0005/166136/UrbanDimensions.pdf (accessed November 12, 2021).
20. Mosley WH, Chen LC. An analytical framework for the study of child survival in developing countries. *Popul Dev Rev.* (1984) 10:25–5. doi: 10.2307/2807954
21. Kim D, Saada A. The social determinants of infant mortality and birth outcomes in western developed nations: a cross-country systematic review. *Int J Environ Res Public Health.* (2013) 10:2296–335. doi: 10.3390/ijerph10062296
22. Marmot M. *Strategic Review of Health Inequalities in England Post-2010: Fair Society, Healthy Lives*. London: The Marmot Review (2010).
23. Prah Ruger J. Ethics of the social determinants of health. *Lancet.* (2004) 364:1092–7. doi: 10.1016/S0140-6736(04)17067-0
24. Rennie S, Mupenda B. Living apart together: reflections on bioethics, global inequality and social justice. *Philos Ethics Humanit Med.* (2008) 3:25. doi: 10.1186/1747-5341-3-25
25. Jansen LA, Sulmasy DP. Proportionality, terminal suffering and the restorative goals of medicine. *Theor Med Bioeth.* (2002) 23:321–37. doi: 10.1023/A:1021209706566
26. Sullivan SM. The development and nature of the ordinary/extraordinary means distinction in the Roman Catholic tradition. *Bioethics.* (2007) 21:386–97. doi: 10.1111/j.1467-8519.2007.00567.x
27. Valera L, Carrasco MA, Castro R. Fallacy of the last bed dilemma. *J Med Ethics.* (2021). doi: 10.1136/medethics-2021-107333. [Epub ahead of print].
28. Zinsstag J, Schelling E, Waltner-Toews D, Tanner M. From "One Medicine" to "One Health" and systemic approaches to health and well-being. *Prev Vet Med.* (2011) 101:148–56. doi: 10.1016/j.prevetmed.2010.07.003
29. Newman MG, Zainal NH. The value of maintaining social connections for mental health in older people. *Lancet Pub Health.* (2020) 5:e12–e3. doi: 10.1016/S2468-2667(19)30253-1
30. Perissinotto CM, Stijacic Cenzer I, Covinsky KE. Loneliness in older persons: a predictor of functional decline and death. *Arch Intern Med.* (2012) 172:1078–83. doi: 10.1001/archinternmed.2012.1993
31. Gerst-Emerson K, Jayawardhana J. Loneliness as a public health issue: the impact of loneliness on health care utilization among older adults. *Am J Public Health.* (2015) 105:1013–9. doi: 10.2105/AJPH.2014.302427
32. Santini ZI, Jose PE, Cornwell EY, Koyanagi A, Nielsen L, Hinrichsen C, et al. Social disconnectedness, perceived isolation, and symptoms of depression and anxiety among older Americans (NSHAP): a longitudinal mediation analysis. *Lancet Public Health.* (2020) 5:e62–e70. doi: 10.1016/S2468-2667(19)30230-0
33. Young IM. Responsibility and global justice: a social connection model. *Soc Philos Policy.* (2006) 23:102–30. doi: 10.1017/S0265052506060043
34. Jonas H. *The Imperative of Responsibility. In Search of an Ethics for the Technological Age*. Chicago; London: The University of Chicago Press (1984).
35. El Zein M, Bahrami B, Hertwig R. Shared responsibility in collective decisions. *Nat Hum Behav.* (2019) 22:554–9. doi: 10.1038/s41562-019-0596-4
36. Bratman M. Shared cooperative activity. *Philos Rev.* (1992) 101:327–41. doi: 10.2307/2185537
37. Bratman M. *Shared Agency: A Planning Theory of Acting Together.* Oxford: Oxford University Press (2014).
38. Paremoer L, Nandi S, Serag H, Baum F. COVID-19 pandemic and the social determinants of health. *BMJ.* (2021) 372:129. doi: 10.1136/bmj.n129
39. Takian A, Kiani MM, Khanjankhani K. COVID-19 and the need to prioritize health equity and social determinants of health. *Int J Public Health.* (2020) 65:521–3. doi: 10.1007/s00038-020-01398-z
40. Anderson E. *The Imperative of Integration*. Princeton: Princeton University Press (2010).
41. Ataguba OA, Ataguba JE. Social determinants of health: the role of effective communication in the COVID-19 pandemic in developing countries. *Glob Health Action.* (2020) 13:1788263. doi: 10.1080/16549716.2020.1788263
42. Reich WT. The word "bioethics": its birth and the legacies of those who shaped it. *Kennedy Inst Ethics J.* (1994) 4:319–35. doi: 10.1353/ken.0.0126
43. Cascais AF. Bioethics: history, scope, object. *Global Bioethics.* (1997) 10:9–24. doi: 10.1080/11287462.1997.10800712

44. Dawson A. The future of bioethics: three dogmas and a cup of hemlock. *Bioethics.* (2010) 24:218–25. doi: 10.1111/j.1467-8519.2010.01814.x
45. Lee LM. A bridge back to the future: public health ethics, bioethics, environmental ethics. *Am J Bioeth.* (2017) 17:5–12. doi: 10.1080/15265161.2017.1353164
46. Callahan D. Bioethics as a discipline. *Stud Hastings Cent.* (1973) 1:66–73. doi: 10.2307/3527474
47. Potter VR. *Global Bioethics*. *Building on the Leopold legacy*. East Lansing: Michigan State University Press (1988).

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BRIEF RESEARCH REPORT
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Relationship Between High Organ Donation Rates and COVID-19 Vaccination Coverage

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Background: Besides attaining the goal of self-protection, the rollout of vaccination programs also encourages altruistic practices. Therefore, the progress in vaccination against coronavirus disease (COVID-19) in each country may be related to the prevalence of cooperative and altruistic practices in health care. I hypothesized that in countries where organ donation is popular, individuals would exhibit a greater tendency to become vaccinated.

Methods: I examined the correlation between the level of progress of COVID-19 vaccination and the status of organ donation just before the pandemic in Organization for Economic Co-operation and Development (OECD) countries. Publicly available statistical information on the progress of immunization and organ donation was used. Univariate and multivariate analyses were conducted to examine common drivers of immunization and organ donation.

Results: In OECD countries, progress in vaccination was found to be significantly correlated with the status of organ donation in each country. This relationship was stable after the summer (September 1: Pearson's $r = 0.442$, October 1: 0.457, November 1: 0.366). The results of the univariate and multivariate analyses showed that high trust in medical professionals was significantly correlated with both the "progress of vaccinations" and "organ donations."

Conclusions: Progress in COVID-19 vaccination and organ donation status for transplantation have similar trends, and both may involve people's trust in medical personnel and public health systems. Similar to the efforts to obtain organ donors, governments around the world need to take further steps to ensure that vaccination programs are supported by people's trust and sense of solidarity.

Keywords: vaccination, COVID-19, organ donation, trust, social capital, medical professionals, solidarity, OECD countries

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INTRODUCTION

By the end of October 2021, coronavirus disease (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), had infected over 200 million individuals and caused more than 5 million deaths; however, there is still no end in sight to the pandemic (1). Nevertheless, in 2021, in addition to pre-existing restrictions, several types of vaccines that may control the spread of infection to a certain degree were introduced. Although there are concerns about the persistence of efficacy (2) and the need to be vigilant regarding new viral mutations, there are high hopes for the effectiveness of these vaccines in controlling infection.

Many developed nations of the world have made great progress in vaccinating their populations against SARS-CoV-2. However, a detailed examination of worldwide data, even when limited to data of the Organization for Economic Co-operation and Development (OECD) member nations, shows that there are major differences in the progress of vaccination programs in each country. For example, according to statistics published in "COVID-19 Data Explorer" (Our World in Data) as of May 2021 (3), Israel (59.9%), followed by the United Kingdom (UK, 45.9%), Chile (36.2%), and the United States of America (USA, 33.1%) were the countries with the highest percentage of people who had received at least one COVID-19 vaccine dose. However, as the summer passed, many of these countries were overtaken by other countries (mainly European countries) that had increased their vaccination efforts. As of October 1, 2021, Portugal was in the lead (88.2%), followed by Iceland (82.1%), Chile (81.1%), and Spain (81.7%) (**Table 1**).

What certainly lies in the background of the progress made by these countries is each country's independent initiatives to obtain and supply the vaccine, but I believe that this cannot fully explain their success. Given that there was little experience and high risks associated with the vaccine, people were not vaccinated simply because their government encouraged them to do so (4). Thus, there is a need to consider why people in these countries responded to their governments' calls to get vaccinated.

Besides attaining the goal of self-protection, the rollout of vaccination programs also encourages altruistic practices—e.g., lowering the risk of infection in vulnerable populations or maintaining the functioning of the healthcare system. According to Pywell, among altruistic medical practices, the tense relationship between individuals' self-determination and social interests tends to surface, especially in relation to vaccination and organ donation programs (5). When considering COVID-19 vaccination, vaccination progress may be smoother in countries that have successfully coordinated the relationship between the two. Thus, I hypothesized that in countries where organ donation is popular, individuals would exhibit a tendency to get vaccinated. To the best of my knowledge, there are no reports focusing on a predilection toward organ donation when considering the progress in COVID-19 vaccination.

MATERIALS AND METHODS

Using publicly available statistical information, I examined the correlation between progress in immunization against SARS-CoV-2 infection and the status of organ donation for transplantation just before the pandemic in OECD countries.

The progress in vaccination was based on data from the COVID-19 Data Explorer (Our World in Data), as mentioned above. Individuals who were fully or partly vaccinated against COVID-19 were included in the study. Donated organ transplant data were obtained from The Global Observatory on Donation and Transplantation (http://www.transplant-observatory.org/). The number of transplants per one million population in all countries in 2019, just before the pandemic, was used in the analysis.

Univariate (Pearson's correlation coefficients) and multivariate analyses (multiple linear regression) were conducted to examine organ donation and common drivers of immunization, using publicly available data ["trust in medical professionals" (6), "trust in the government" (7), "social solidarity" (8), "GDP" (9)]. All analyses were conducted using SPSS Statistics version 27.0 (IBM Corp., Armonk, NY, USA).

RESULTS

I compared the progress in COVID-19 vaccination with the actual number of donated organ transplants in 38 OECD countries. **Figure 1** shows the relationship between the number of organ donations (number of donations per million population) and the progress in COVID-19 vaccination (percentage of people vaccinated in the population). The correlation was loose, but significant, and it persisted during the summer and fall of 2021 when the vaccination program was in full swing among developed countries (September 1: Pearson's $r = 0.442$, October 1: 0.457, November 1: 0.366). Spain and France are typical cases where organ donation has been relatively active and vaccination has proceeded well. In contrast, both organ donation and vaccination have been sluggish in Greece. Meanwhile, the United States, has had a sluggish vaccination rollout compared to its thriving organ donation program. Iceland, Chile, and Japan, conversely, are experiencing a slump in organ donation, but are doing relatively well in vaccination.

Both the number of organ donations (Pearson's $r = 0.438$, $p < 0.01$) and the prevalence of COVID-19 vaccination (Pearson's $r = 0.592$, $p < 0.01$) in these OECD member nations showed a loose correlation with trust in medical professionals (see **Supplementary Table 1A**). The results of the multivariate analysis also showed that high trust in medical professionals was significantly correlated with both the "progress of vaccinations" and "organ donations" (see **Supplementary Table 1B**).

In this study, other factors that have been considered to have a significant association with the progress in COVID-19 vaccination were also examined. The results of the univariate analysis replicated these relationships. With the exception of trust in the government, these factors also showed significant relationships with the progress in COVID-19 vaccination. However, multivariate analysis did not reproduce these relationships (see **Supplementary Table 1B**).

It is also worth noting that in the univariate analysis, many of the factors found to be associated with the progress in COVID-19 vaccination also showed significant relationships with willingness to donate organs. However, these factors, with the exception of trust in the medical profession, did not show significant relationships in multivariate analysis.

The value of the adjusted coefficient of determination (adjusted R-squared) was mild, which indicates that factors other than those examined in this study may also have a significant impact. Nevertheless, the consistently high level of trust in health

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Abbreviations: COVID-19, coronavirus disease 2019; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; OECD, Organization for Economic Co-operation and Development.

TABLE 1 | The percentage (%) prevalence of COVID-19 vaccination (top eight OECD member nations).

	April 2021	June 2021	August 2021	September 2021	October 2021
1	Israel (59.9)	Israel (62.2)	Iceland (78.4)	Portugal (85.6)	Portugal (88.2)
2	United Kingdom (45.9)	Canada (58.1)	Denmark (72.2)	Iceland (81.4)	Iceland (82.1)
3	Chile (36.2)	United Kingdom (58.0)	Chile (72.1)	Spain (78.3)	Chile (81.1)
4	United States (33.1)	Chile (56.6)	The Netherlands (71.5)	Denmark (75.7)	Spain (80.7)
5	Hungary (22.4)	Hungary (54.1)	Canada (71.2)	Chile (75.1)	South Korea (77.2)
6	Finland (16.8)	United States (51.9)	Portugal (70.1)	Ireland (74.4)	Denmark (76.6)
7	Estonia (15.9)	Iceland (51.7)	Belgium (69.5)	Canada (73.4)	Canada (76.5)
8	Iceland (14.4)	Finland (44.6)	Spain (68.8)	The Netherlands (73.2)	Norway (76.4)

OECD, Organization for Economic Co-operation and Development; COVID-19, coronavirus disease; N.B. People who were fully or partly vaccinated against COVID-19 in the population were included in the study.
Data source: Our World in Data (Available online at: https://ourworldindata.org/covid-vaccinations) "Share of people vaccinated against COVID-19".

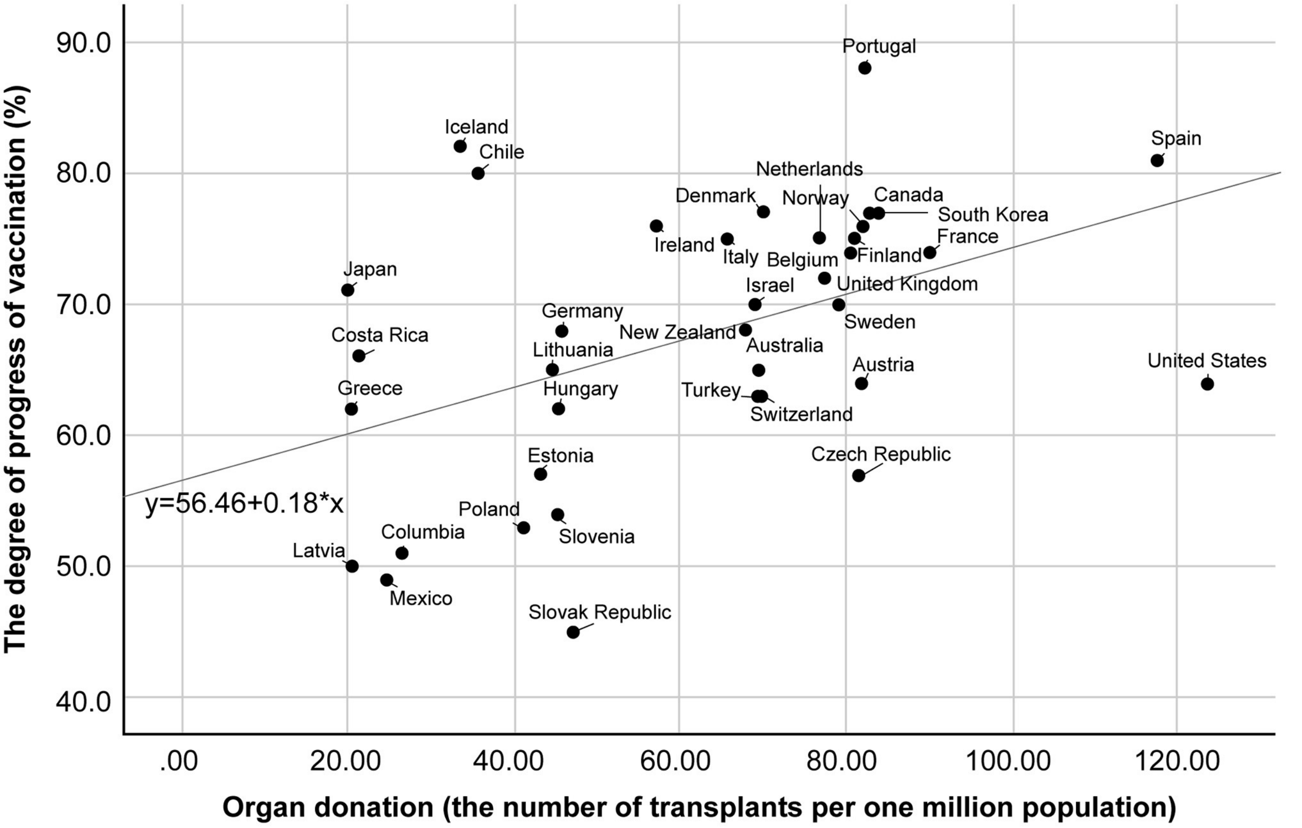

FIGURE 1 | Correlation between COVID-19 vaccination progress and the number of organ donations. COVID-19, coronavirus disease.

care providers was stable and deserves mention as a strong candidate for a common factor deeply related to the progress in COVID-19 vaccination and organ donation.

DISCUSSION

Several investigations regarding the factors promoting COVID-19 vaccinations have been conducted. The following factors have been reported to have an effect on the progress in COVID-19 vaccination: educational background and gender (10, 11); old age (10–12); country income level (13); transparency of government activities (14); numbers of infected and deceased individuals (15); degree of vaccine acceptance (16) [e.g., use of the seasonal influenza vaccine (17, 18)]; digital infrastructure (19); and trust in governments (11, 15, 18, 20), physicians (18), and scientists (21, 22).

Although conducting a detailed investigation of the correlation between COVID-19 vaccinations and the number of organ donations is not straightforward, I believe that the two share common facilitating factors. However, whether there is a cause-and-effect relationship is unclear.

One hypothesis is that trust in specialists plays an important role in both activities. The results of the analysis showed that high trust in medical professionals was significantly correlated with both the "progress of vaccinations" and "organ donations."

Medical professionals have advanced medical knowledge and skills, use the latest medical techniques, and are simultaneously in positions in which they spread knowledge and use these skills and techniques. If trust in medical professionals is low, it is unlikely that the number of people who are willing to receive the novel vaccines will increase. In addition, those who appreciate their country's health care system will be more likely to get vaccinated, if they understand that COVID-19 places an enormous burden on the system.

Another hypothesis is that this can be explained by shared understanding of the role of the individual in public health. Organ donations and vaccinations are activities groups engage in, and they test the strength of the links between trust in existing governing institutions and the degree of group consciousness (23, 24). If a sense of solidarity is awakened in times of crisis (25), then societies that are more supportive of organ donation may tend to be more united in the face of public health disasters. Naturally, as mentioned above, the fact that medical professionals enjoy a high degree of trust in the community can be a factor that contributes greatly to community participation in vaccination programs and to the expressed desire of many in the community to donate organs. Moreover, based on the correlation between univariates, the development of vaccinations is related to a high degree of trust in governments (Pearson's $r = 0.451$, $p < 0.01$). At the same time, organ donation is associated with a strong sense of solidarity in society (Pearson's $r = 0.497$, $p < 0.05$) (see **Supplementary Table 1A**). However, probably due to the small sample size and the correlation between variables, there was no clear relationship between the two in the multivariate analysis. More detailed studies are required in the future (see **Supplementary Table 1B**).

The above discussion is based on the premise that organ donation and vaccination have much in common as public health efforts. However, I also have to consider that there are meaningful differences between organ donations and vaccinations. For example, vaccination is mainly intended for healthy people, and individuals are expected to act on their own initiative. On the other hand, in the case of organ donation, especially post-mortem, the actions of others and institutional efforts are essential. Regarding organ donation situations, many countries have adopted so-called "opt-out" mechanisms in which the individual does not necessarily give explicit consent (26). Past studies have indicated that social factors, such as relationships with family members (27) and active intervention involving the community (28, 29), can relate to the progress in organ donation. Whereas, individual concerns about vaccination are about the risk and efficacy of the vaccine, concerns about the fairness and the sustainability of the system are likely to come to the fore in the case of organ donation (30). Despite these differences, there remains an important commonality between vaccination and organ donation; they are essentially public health issues that cannot be addressed by one person alone, and the role entrusted to health care providers and the health care system is of great importance. I have not found any issues that conflict with our results, and this understanding deserves consideration as a noteworthy finding.

This study had several limitations. Although the study scope was limited to OECD member nations, cultural and social backgrounds surrounding transplantation medicine, and the timing of securing vaccinations were different for each country. In addition, some statistical analyses were limited by the small sample size. Furthermore, other factors that strongly influence both COVID-19 vaccination and organ donations may not have been fully considered. Nevertheless, it is noteworthy that there are clear differences in the speed of COVID-19 vaccination between countries, and these differences may be related to fundamental public health and medical care factors.

Currently, COVID-19 vaccination programs are progressing around the world. However, in many countries, vaccination numbers are decreasing after reaching a peak in the summer. Particularly, in countries that were among the first to introduce vaccination programs (e.g., USA, Israel, UK), ∼30% of their populations remain unvaccinated and the number of people receiving vaccinations has not increased since the summer. An important issue is how to approach those who refuse to be vaccinated. One subject of debate is whether to make COVID-19 vaccination obligatory. Additionally, given that a lot is expected from medical professionals, it is recommended that they get vaccinated. Naturally, consideration must be paid to the concerns of individual medical professionals, but if their vaccination will be effective in increasing appreciation for, and trust in, COVID-19 vaccines, then it may serve as an incentive for the general public to consider getting vaccinated.

Because of concerns regarding the sustainability of the effectiveness of COVID-19 vaccinations, even in countries where large numbers of people have already been vaccinated, there is a perceived need for COVID-19 booster vaccinations. In the interests of community and public health, it is important that booster vaccination programs are undertaken. Even in such cases, the presence of medical professionals who are attentive to people's concerns and interests will be critical.

To conclude, progress in vaccination against COVID-19 infections in OECD countries in 2021 is significantly associated with people's trust in medical personnel and public health systems, common to organ donation. Although there is no end to the pandemic in sight, people's sense of cooperation and high level of interest are not necessarily endless. Similar to the efforts to obtain organ donors, governments around the world need to laud and show appreciation for the cooperation people have shown so far, and to take further steps to ensure that vaccination programs are supported by people's trust and sense of solidarity. There is also a need to consider and address anxiety and distrust of medical professionals not only in terms of individual physician–patient relationships, but also as a public health issue.

DATA AVAILABILITY STATEMENT

Publicly available datasets were analyzed in this study. This data can be found here: All data used in this paper are publicly available only. All sources of these data have been acknowledged in the text and in the **Supplementary File**.

AUTHOR CONTRIBUTIONS

YI conceptualized the original study and prepared the article draft.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.855051/full#supplementary-material

REFERENCES

1. World Health Organization. *WHO Coronavirus (COVID-19) Dashboard.* (2020). Available online at: https://covid19.who.int/ (accessed January 4, 2022).
2. Centers for Disease Control and Prevention. *COVID-19.* (2020). Available online at: https://www.cdc.gov/coronavirus/2019-nCoV/index.html (accessed January 4, 2022).
3. Our World in Data: share of people vaccinated against COVID-19. *Global Change Data Lab, United Kingdom.* (2020). Available online at: https://ourworldindata.org/covid-vaccinations (accessed January 4, 2022).
4. Machingaidze S, Wiysonge CS. Understanding COVID-19 vaccine hesitancy. *Nat Med.* (2021) 27:1338–9. doi: 10.1038/s41591-021-01459-7
5. Pywell S. Vaccination and other altruistic medical treatments: should autonomy or communitarianism prevail? *Med Law Int.* (2000) 4:223–43. doi: 10.1177/096853320000400405
6. Gallup. *Confidence and Trust in Health Professionals and Hospitals (Chart 3.6 & Q11E in Appendix D: Dataset and Crosstabs for All Countries).* Wellcome Global Monitor 2018. Available online at: https://wellcome.org/reports/wellcome-global-monitor/2018 (accessed January 4, 2022).
7. OECD. *Trust in Government (10. Core Government Results).* (2019). Government at a Glance (accessed January 4, 2022).
8. Sanz García M, Caselles A, Micó Ruiz JC, Soler Fernández D. Development of the Happiness Index in a country (Table 5. Solidarity Index by Country). *Syst Des Beyond Processes Thinking.* (2016) 807–18. doi: 10.4995/IFDP.2016.3096
9. International Monetary Fund. GDP (nominal) per capita. *World Econ Outlook Database.* (2021) (accessed January 4, 2022).
10. Wong LP, Alias H, Danaee M, Ahmed J, Lachyan A, Cai CZ, et al. COVID-19 vaccination intention and vaccine characteristics influencing vaccination acceptance: a global survey of 17 countries. *Infect Dis Poverty.* (2021) 10:122. doi: 10.1186/s40249-021-00900-w
11. de Figueiredo A, Larson HJ. Exploratory study of the global intent to accept COVID-19 vaccinations. *Commun Med.* (2021) 1:30. doi: 10.1038/s43856-021-00027-x
12. Whiteman A, Wang A, McCain K, Gunnels B, Toblin R, Lee JT, et al. Demographic and social factors associated with COVID-19 vaccination initiation among adults aged ≥65 years — United States, December 14, 2020–April 10, 2021. *MMWR Morb Mortal Wkly Rep.* (2021) 70:725–30. doi: 10.15585/mmwr.mm7019e4
13. Duan Y, Shi J, Wang Z, Zhou S, Jin Y, Zheng ZJ. Disparities in COVID-19 vaccination among low-, middle-, and high-income countries: the mediating role of vaccination policy. *Vaccines.* (2021) 9:905. doi: 10.3390/vaccines9080905
14. Petersen MB, Bor A, Jørgensen F, Lindholt MF. Transparent communication about negative features of COVID-19 vaccines decreases acceptance but increases trust. *Proc Natl Acad Sci USA.* (2021) 118:e2024597118. doi: 10.1073/pnas.2024597118
15. Lazarus JV, Ratzan SC, Palayew A, Gostin LO, Larson HJ, Rabin K, et al. A global survey of potential acceptance of a COVID-19 vaccine. *Nat Med.* (2021) 27:225–8. doi: 10.1038/s41591-020-1124-9
16. Castillo C, Villalobos Dintrans PV, Maddaleno M. The successful COVID-19 vaccine rollout in Chile: factors and challenges. *Vaccin X.* (2021) 9:100114. doi: 10.1016/j.jvacx.2021.100114
17. El-Elimat T, AbuAlSamen MM, Almomani BA, Al-Sawalha NA, Alali FQ. Acceptance and attitudes toward COVID-19 vaccines: a cross-sectional study from Jordan. *PLoS ONE.* (2021) 16:e0250555. doi: 10.1371/journal.pone.0250555
18. Joshi A, Kaur M, Kaur R, Grover A, Nash D, El-Mohandes A. Predictors of COVID-19 vaccine acceptance, intention, and hesitancy: a scoping review. *Front Public Health.* (2021) 9:698111. doi: 10.3389/fpubh.2021.698111
19. KPMG. *Israel's COVID Vaccination Success.* (2021). Available online at: https://home.kpmg/xx/en/home/insights/2021/04/israel-covid-vaccination-success.html (accessed January 4, 2022).
20. Pilichowski E, Scarpetta S, Brezzi M, Colombo F, Lopert R, Wenzl M, et al. Enhancing public trust in COVID-19 vaccination: the role of governments. *OECD Proc.* (2021) 3–27.
21. Sturgis P, Brunton-Smith I, Jackson J. Trust in science, social consensus and vaccine confidence. *Nat Hum Behav.* (2021) 5:1528–34. doi: 10.1038/s41562-021-01115-7
22. Anonymous. Why national attitudes about science matter for vaccine acceptance. *Nature.* (2021) 593:481. doi: 10.1038/d41586-021-01334-y
23. Ladin K, Wang R, Fleishman A, Boger M, Rodrigue JR. Does social capital explain community-level differences in organ donor designation? *Milbank Q.* (2015) 93:609–41. doi: 10.1111/1468-0009.12139
24. Sharp C, Randhawa G. The potential role of social capital in the willingness to be a deceased organ donor: a case study of UK Polish migrants. *Transplant Proc.* (2016) 48:680–8. doi: 10.1016/j.transproceed.2015.10.063
25. Petersen MB. COVID lesson: trust the public with hard truths. *Nature.* (2021) 598:237. doi: 10.1038/d41586-021-02758-2
26. Ahmad MU, Hanna A, Mohamed AZ, Schlindwein A, Pley C, Bahner I, et al. A systematic review of Opt-out Versus Opt-in consent on deceased organ donation and transplantation (2006-2016). *World J Surg.* (2019) 43:3161–71. doi: 10.1007/s00268-019-05118-4
27. Knox K, Parkinson J, Pang B, Fujihira H, David P, Rundle-Thiele S. A systematic literature review and research agenda for organ donation decision communication. *Prog Transplant.* (2017) 27:309–20. doi: 10.1177/1526924817715459
28. Costa-Font J, Rudisill C, Salcher-Konrad M. 'Relative Consent' or 'Presumed Consent'? Organ donation attitudes and behaviour. *Eur J Health Econ.* (2021) 22:5–16. doi: 10.1007/s10198-020-01214-8

29. Li AT, Wong G, Irving M, Jan S, Tong A, Ralph AF, et al. Community-based interventions and individuals' willingness to be a deceased organ donor: systematic review and meta-analysis. *Transplantation.* (2015) 99:2634–43. doi: 10.1097/TP.0000000000000897
30. The Lancet (Editorial). Organ donation depends on trust. *Lancet.* (2016) 387:2575. doi: 10.1016/S0140-6736(16)30886-8

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OPINION
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Vaccine Hesitancy, Anti-Vax, COVID-Conspirationism: From Subcultural Convergence to Public Health and Bioethical Problems

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INTRODUCTION

Vaccine hesitancy is not in itself a novel social and individual phenomenon, yet the ongoing COVID-19 pandemic is associated to increasing degrees of widespread sociopolitical weaponization of such attitude, becoming a major threat to the progress and success of vaccination campaigns (1–3).

Behavioral vaccine-hesitancy might be due to heterogeneous motivations. The majority of people simply adhere to an over-cautious "wait-and-see" attitude, due to presumed, possible unforeseeable long-term effects of fast-authorized novel vaccines; a minority of people adhere to an anti-vaccine activism (usually labeled as Anti-Vax), which proactively opposes vaccinations denying the existence of COVID-19 or ascribing bizarre, deliberately malignant biopsychosocial effects to current vaccines (4–6) and boosting trust in fake and irrational beliefs[1].

PUBLIC HEALTH CONSEQUENCES AT GROUP- AND INDIVIDUAL LEVELS

On a public health perspective, the most extreme, impermeable side of the Anti-Vax spectrum is posing a plateau to the vaccination rate and allegedly retarding the reach of a possible herd immunity (7). At the same time, Anti-Vax activists are often publicly blamed as infectors being the major cause of infective surges, thereby becoming the new, transnational political scapegoat for cumulative public health inefficiencies and related socio-economic shock-waves.

Moreover, at the individual level, there is increasing reporting of another phenomenon that warrants further reflection: although not yet quantified by focused surveys, there is reporting of hospitalized unvaccinated COVID-19-deniers that refuse the best therapies and even intensive care treatment if needed[2,3]. This phenomenon has recently led the Italian Society of Anesthesiology, Analgesia, Resuscitation and Intensive Care to officially discuss the ethical issues raised by

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[1] Available online at: https://www.telegraph.co.uk/global-health/science-and-disease/vaccines-carry-tiny-knives-cut-veins-inside-romanias-toxic-anti/

[2] Available online at: https://www.kwch.com/2021/09/29/patients-refusal-treatment-creates-new-challenge-hospitals/

[3] Available online at: https://www.timesofisrael.com/1500-said-to-refuse-covid-antibody-treatment-leading-to-preventable-deaths/

this hazardous self-threatening behavior, given that, in some cases, this has led to the death of the hospitalized patient[4], with additional psychological burden in already overwhelmed healthcare workers.

This potentially lethal, self-threatening behavior is apparently expressed without manifest signs of suicidal intention or documented psychopathology. Such para-suicidal behavior in COVID-19 deniers evokes some features of faith-based (e.g., Peoples Temple in Guyana, Order of the Solar Temple in Switzerland, France and Canada, Heaven's Gate in Santa Fe, USA) (8) and ideologically-based suicides (e.g., suicidal terrorism) (9), since it is enacted on the background of shared, specific worldviews. However, while these latter suicidal behaviors are explicitly based on an envisioned, post-mortem scenario of eternal glory, salvation or political revolution, the acceptance of a serious, life-endangering risk due to the refusal of suitable therapies for an illness whose existence is denied is far less comprehensible. Indeed, shifting from a proclivity to entertain conspiracy beliefs to the point of refusing appropriate therapy is a significant psycho-behavioral step. Concretely, it means to explicitly enact a life-threatening behavior on the ideological basis of Anti-Vax/COVID-denialist narrative.

One plausible explanation is that these patients really mistrust the existence of COVID-19 and therefore do not realize that they could die if not adequately treated. This hypothesis presupposes a weakening of the reality testing and an ongoing para-delusional thinking which is not amenable to change in light of massive conflicting evidence as own's physical symptoms requiring hospitalizations, treatment indications of the medical staff, presence of other hospitalized patients with similar health conditions, ongoing societal measures to contain the pandemic; indeed, if these features could be neglected through the echo-chamber phenomenon (10) while healthy and at home, they are more difficult to ignore when ill and hospitalized.

This agrees with the alleged importance of maladaptive personality features (such as schizotypal odd beliefs) and poorer reality testing in determining a higher proneness to entertain conspiracy beliefs (11–13). This suggests that individual psychotic-like features (e.g., odd beliefs, poor reality testing, biased thinking not amenable to change in light of conflicting or disconfirmatory evidence) are likely to contribute to the enactment of COVID-related conspiracy beliefs to their utmost consequences (including self-threatening therapeutic refusal).

BIOETHICAL DILEMMA: ILLNESS DENIAL AND INFORMED CONSENT

Overall, the contiguity of a fixed belief which is incorrigible despite massive, surrounding disconfirmatory evidence with a psychotic-like mental state, is particularly critical, given that even the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM-5) as well as the International Classifications of Diseases 11th Revision (ICD-11) emphasize the distinction between delusional and culturally-grounded beliefs, assuming that delusions generally involve beliefs not ordinarily accepted by other members of the person's culture or subculture. Yet, the high prevalence of some type of COVID-denialism among a significant worldwide minority of the population (14) makes it *de facto* a culturally-grounded belief. Nonetheless, if people who deny the existence of COVID-19 decline urgent, non-deferrable lifesaving interventions because they are in a delusional-like mental state (i.e., a psychotic state of mind), compulsory treatment might be legitimately applied because the individual's ability to make decisions about medical treatment is significantly impaired.

Indeed, mental illness is one of the main obstacle to medical decision making, and psychiatrists are usually involved in evaluating decisional capacity in hospitalized patients refusing medical therapies.

Therefore, compulsory treatment of COVID-19 deniers would of course count as a condition of exemption from the otherwise central jurisprudential principle of freedom of choice in the bioethical matter of medical treatment (15), whose driving concept (informed consent of the patient) is challenged by illness denial.

CONCLUSIONS

Extreme societal reaction to COVID-19 pandemic included also denialism and conspiracy interpretations. Besides its mediatic, more or less instrumentally amplified impact[5], such extreme reactions have clear public health effects at the societal level (e.g., reducing vaccination rate and delaying the reach of a possible herd immunity) as well as critical reverberations at individual level when infected patients refuse urgent lifesaving treatments for an illness they do not believe to exist.

While still not precisely quantified this phenomenon deserves an appropriate bioethical discussion which could be helpful not only along the current pandemic but also for possible future similar situations of societal and/or individual illness-denialism. In this perspective, bioethicists as well as psychiatrists must be aware of the challenge that the Anti-Vax movement is posing to the evaluation of extreme cultural beliefs, whose widespread diffusion may be enhanced by social media in current globalized and connected western society, especially when they harbor a clear potential for a huge impact in terms of public safety and individual decision-making (16).

Given the consequences that the involvement of a psychiatric assessment could have in the decision

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[4] Available online at: https://www.siaarti.it/news/622309

[5] Available online at: https://www.wsj.com/articles/russian-disinformation-campaign-aims-to-undermine-confidence-in-pfizer-other-covid-19-vaccines-u-s-officials-say-11615129200

about involuntary treatment of hospitalized COVID-19 deniers in need of urgent, life-saving intervention, it is desirable to formalize such decision at political-administrative level after due ethical, medical and public health debate. Political authorities might decide about vaccine obligation while maintaining freedom of choice in end-of-life decisions.

AUTHOR CONTRIBUTIONS

All authors equally conceived the paper, analyzed the current situation and wrote the first draft, revised it and contributed to the final manuscript, and agreed on the final version of the manuscript.

REFERENCES

1. Khubchandani J, Sharma S, Price JH, Wiblishauser MJ, Sharma M, Webb FJ. COVID-19 vaccination hesitancy in the United States: a rapid national assessment. *J Community Health.* (2021) 46:270–7. doi: 10.1007/s10900-020-00958-x
2. Sallam M. COVID-19 vaccine hesitancy worldwide: a concise systematic review of vaccine acceptance rates. *Vaccines.* (2021) 9:160. doi: 10.3390/vaccines9020160
3. Solís Arce JS, Warren SS, Meriggi NF, Scacco A, McMurry N, Voors M, et al. COVID-19 vaccine acceptance and hesitancy in low- and middle-income countries. *Nat Med.* (2021) 27:1385–94. doi: 10.1101/2021.03.11.21253419
4. Ball P, Maxmen A. The epic battle against coronavirus misinformation and conspiracy theories. *Nature.* (2020) 581:371–4. doi: 10.1038/d41586-020-01452-z
5. Allington D, McAndrew S, Moxham-Hall V, Duffy B. Coronavirus conspiracy suspicions, general vaccine attitudes, trust and coronavirus information source as predictors of vaccine hesitancy among UK residents during the COVID-19 pandemic. *Psychol Med.* (2021) 12:1–12. doi: 10.1017/S0033291721001434
6. Jennings W, Stoker G, Bunting H, Valgarð*sson VO, Gaskell J, Devine D, et al. Lack of trust, conspiracy beliefs, and social media use predict COVID-19 vaccine hesitancy. *Vaccines.* (2021) 9:593. doi: 10.3390/vaccines9060593
7. Fontanet A, Cauchemez S. COVID-19 herd immunity: where are we? *Nat Rev Immunol.* (2020) 20:583–4. doi: 10.1038/s41577-020-00451-5
8. Dein S, Littlewood R. Apocalyptic suicide: from a pathological to an eschatological interpretation. *Int J Soc Psychiatry.* (2005) 51:198–210. doi: 10.1177/0020764005056762
9. Pape RA. The strategic logic of suicide terrorism. *Am Pol Sci Rev.* (2003) 97:343–61. doi: 10.1017/S000305540300073X
10. Cinelli M, De Francisci Morales G, Galeazzi A, Quattrociocchi W, Starnini M. The echo chamber effect on social media. *Proc Natl Acad Sci U S A.* (2021) 118:2023301118. doi: 10.1073/pnas.2023301118
11. Dyrendal A, Ottesen Kennair LE, Bendixen M. Predictors of belief in conspiracy theory: the role of individual differences in schizotypal traits, paranormal beliefs, social dominance orientation, right wing authoritarianism and conspiracy mentality. *Personality Indiv Diff.* (2021) 73:110645. doi: 10.1016/j.paid.2021.110645
12. Drinkwater K, Dagnall N, Parker A. Reality testing, conspiracy theories and paranormal beliefs. *J Parapsychol.* (2012) 76:57–77.
13. Furnham A, Grover S. Do you have to be mad to believe in conspiracy theories? Personality disorders and conspiracy theories. *Int J Soc Psychiatry.* (2021) 9:207640211031614. doi: 10.1177/00207640211031614
14. Roozenbeek J, Schneider CR, Dryhurst S, Kerr J, Freeman ALJ, Recchia G, et al. Susceptibility to misinformation about COVID-19 around the world. *R Soc Open Sci.* (2020) 7:201199. doi: 10.1098/rsos.201199
15. Beauchamp TL, Childress JF. Principles of biomedical ethics. 7Th ed. New York, Oxford University Press (2013).
16. Schneider PL, Bramstedt KA. When psychiatry and bioethics disagree about patient decision making capacity (DMC). *J Med Ethics.* (2006) 32:90–3. doi: 10.1136/jme.2005.013136

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Social Engagement in the Fight Against COVID-19 in the Urban and Peri-Urban Areas of Cotonou (Benin, Sub-saharan Africa): Acceptability of the Vaccination and Tracking Program

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Introduction: This article aims at investigating social engagement in the fight against the COVID-19 pandemic in low-resource settings (LRSs). In particular, it focuses on Benin (Sub-Saharan Africa), and reports the results of a field study that investigated the local people's acceptance of the vaccine and the tracking program.

Methods: This project is the product of a collaboration between the ABSPIE (Applied Biomedical and Signal Processing E-Health) Lab of the University of Warwick (UK) and the LAMA (Laboratoire d'Antropologie Medical Appliqué) of the University of Abomey Calavi (Benin). This international multidisciplinary collaboration brought together engineers, sociologists, anthropologists, and bioethicists. In light of the aims of the project, a qualitative methodology was deemed appropriate. The research team prepared two questionnaires that provided the basis for semi-structured interviews that took place between June and August 2021.

Results: The research team interviewed 34 Beninese respondents, comprising people aged 60+ (with multiple comorbidities), who were primarily healthcare workers and/or traditional therapists. The results of this work highlight the fact that there is widespread reticence about the vaccination program in Benin, both due to local beliefs and uncertainty about governmental management. In this study, we uncovered several local reasons interfering with the involvement of the population in the vaccination campaign against COVID-19, e.g., the existence of traditional medical practices considered as valid alternatives to vaccines, and many beliefs showing a fear of neo-colonialism hidden in the pandemic threat. Yet, another hindrance can be traced to shortcomings in the management of the vaccination campaign which resulted in obstacles to the implementation of the program.

Conclusions: This work does not intend to denounce any governmental effort or foster a regressive mindset, but shows how the overall confusion (defined by the World Health Organization as infodemic) linked to the pandemic and its management has caused even more dramatic consequences in LRSs. In addition, the paper proposes a specific framework for the interpretation and management of bioethical and biomedical issues in LRSs that the authors are validating in their current research.

Keywords: COVID-19, vaccine, acceptance, tracking, social engagement, pandemic management, Benin, Sub-Saharan Africa

INTRODUCTION

The COVID-19 pandemic constitutes the most important public health challenge of our times. Globally, for the past 2 years, health systems have been facing a great strain due to the lack of means and resources [e.g., priority medical devices (MDs), intensive care unit (ICU) beds, COVID-19 tests and vaccines], as well as personnel and specialized knowledge. Consequently, even high income countries experienced a situation typical of LRSs (1–3). As of January 2022, the world experienced the third wave of the COVID-19 healthcare crisis, which was heavily influenced by the appearance of five variants of the SARS-COV-2 virus (4, 5). The most effective solution identified was mass vaccination. For this reason, many companies promptly started working on vaccine development and testing. The genetic sequence of SARS-COV-2 was published on January 1[1], 2020 and the first COVID-19 vaccine candidate entered human clinical testing with an unprecedented celerity on 16 March 2020.

To this end, the scientific community joined forces to develop the most promising vaccine candidates. Out of several vaccines developed on different technology platforms (6), only seven obtained the authorization for human administration (see footnote 1). Currently, more than 9 billion vaccine doses have been administered[2] worldwide. However, a great gap in coverage still exists between countries such that while some are already administering the third or fourth dose (e.g., more than 60% fully vaccinated persons in the US), others are barely covered by the first dose[3]. Specifically, in high-income and upper-middle income countries respectively, 71 and 73% of the population completed the vaccination cycle (as of January 17, 2022). Contrarily, in low- and lower-middle income countries respectively, only 4.9 and 36% of the population received the vaccine. Overall, only 50.15% of the population completed the vaccination cycle[4].

Unfortunately, inequalities and differences among countries are exacerbated by the cost of vaccines. However, cost is evidently not the only reason why vaccine deployment is unequitable among different countries. Other reasons include governmental preparedness, poor transport links and inability to maintain a cold chain, which is vital for preserving some vaccines. This situation resulted in governments, scientific institutions, and healthcare professionals embarking on unprecedented collaborations to promote equitable access to COVID-19 vaccines through speedy deployment and distribution in low- and middle-income countries (LMICs). This materialized in the COVAX initiative, co-led by the Gavi Alliance, the Coalition for Innovations in Epidemic Preparedness (CEPI) and the WHO[5] The vaccine distribution strategy references an ethical framework established by the WHO's Strategic Advisory Group of Experts' on Immunization (SAGE) (7–9). Nevertheless, these efforts did not automatically translate into popular support for COVID-19 vaccines worldwide (10), and particularly in LMICs (11, 12).

One of the main reasons for hesitation in relation to vaccination is the lack of clear information from the government and scientific institutions, exacerbated by the circulation of inaccurate news through social media and the internet (13). This phenomenon, referred to by the WHO as "infodemics"[6] (14–16) or "disinfodemic" (17), has particular repercussions in LMICs, where it feeds widespread negationism (18). Despite the COVAX target to provide up to 600 million COVID-19 doses by the end of 2021, and the fact that 52 African countries received almost 177 million doses (19) of vaccines as of January 2022, the vaccination target for Africa was not reached. The authors of this paper believe that this may not be linked to a lack of supply chain, but rather, to the local culture and pessimistic approach relative to the vaccines.

This study was limited to Benin since it is inhabited by a melting pot of ethnic groups, is considered the "cradle" of the Vodun religion and an exemplar for the traditional culture dominant in Sub-Saharan Africa, and is also enrolled in the COVAX initiative that saw the deployment of a specific National Vaccination Plan[7,8]. A total of 26,036 confirmed COVID-19 cases with 162 deaths were reported to the WHO in Benin from January 3, 2020 to January 13, 2022, while no less than 1,897,214

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[1] The Pfizer/BioNTech Comirnaty, 31 December 2020. The SII/COVISHIELD and AstraZeneca/AZD1222 vaccines, 16 February 2021. The Janssen/Ad26.COV 2.S developed by Johnson & Johnson, 12 March 2021. The Moderna COVID-19 vaccine (mRNA 1273), 30 April 2021.The Sinopharm COVID-19 vaccine, 7 May 2021. The Sinovac-CoronaVac, 1 June 2021. The Bharat Biotech BBV152 COVAXIN vaccine, 3 November 2021.

[2] https://covid19.who.int/

[3] https://covid19.who.int/table

[4] https://ourworldindata.org/covid-vaccinations globally

[5] https://www.who.int/initiatives/act-accelerator/covax

[6] https://www.who.int/news/item/23-09-2020-managing-the-covid-19-infodemic-promoting-healthy-behaviours-and-mitigating-the-harm-from-misinformation-and-disinformation

[7] https://unsdg.un.org/latest/stories/benin-national-covid-19-vaccination-campaign-has-launched

[8] https://www.gouv.bj/coronavirus/#documents

vaccine doses had been administered as of January 3, 2022. This means that 11% of the population completed the vaccination cycle, and 15% received at least one dose[9]. Interestingly, according to available literature (20, 21), Benin is one of the countries with the lowest COVID-19 vaccine acceptance rate. In general, the reported data related to the spread of COVID-19 in Africa are strictly dependent on tracking systems, which are evidently problematic in LMICs due to institutional and technical under-preparedness (22, 23). Therefore, an in-depth analysis of the social reasons for these phenomena is essential to understanding the underlying problems in order to favor a better vaccine rollout and acceptance. It is important to note that the COVID-19 vaccine was introduced pari passu with the rich tradition of healthcare treatments that offered alternative herbal-based therapies (EB + anti-COVID-19, Api-COVID-19, etc.), which were well received by the population (24–26).

This work presents the results of a multidisciplinary collaboration, which focused on the analysis and critical appraisal of the perceptions of the Beninese population and the novel challenges brought about by the COVID-19 pandemic. It relies on a previously created *hermeneutic heuristic framework* that combines the theoretical structure of intercultural bioethics and the empirical, inductive and contextualized approach (by design) of the sciences (in this case biomedical engineering), thus proposing solutions inspired by the concept of "frugality" that takes account of the particularism of each context, while tending toward a model of universalism. Part of this framework relating to the frugal design of medical devices is already published (27), while the other part is currently under consideration. Our research goals included capturing popular perceptions about COVID-19 and strategies put in place for fighting the pandemic (i.e., test and trace, vaccines), investigating the main reasons behind the emerging local perspectives, highlighting the main local reactions, and understanding the differences between the perspectives and reactions of the inhabitants of urban and peri-urban areas. Given this background, the results of the study will be a proxy to understanding the overall level of commitment in the fight against COVID-19, and to support community engagement for the future of public health management in LMICs.

MATERIALS AND METHODS

This article is the outcome of an international multidisciplinary collaboration between the ABSPIE Lab of the University of Warwick (UK) and the LAMA of the University of Abomey Calavi (Benin) that brought together engineers, sociologists, anthropologists and bioethicists, with the common goal of bringing key interdisciplinary issues that affect LRSs to the attention of the world. The project was divided into three phases, mainly; (a) the hermeneutical (interpretative) phase—conducted as a field study by the researchers of the University of Abomey-Calavi, (b) the analytical phase, and (c) the synthetical phase. The last two phases were led by researchers at the University of Warwick.

TABLE 1 | Description of the characteristics of the interviewees.

Average age	48.76 (29–89 years old)
Gender	61.8% Male; 38.2% Female
Category distribution	17.65% Caregivers
	29.41% with co-morbidity
	20.59% over 60 years old
	32.35% traditherapeutes

In light of the aims of the project, a qualitative methodology and inductive approach were deemed appropriate and selected for the first phase. The research methodology was structured around data collection methods (semi-structured interviews and focus groups), with experts drawn from groups specified in the criteria contained in the government's vaccination strategy as dictated by the COVAX initiative, i.e., the healthcare sector, traditional local medicine practitioners (*traditherapeutes*), as well as representatives of the local people, in particular, carriers of comorbidities, people aged 60 and above, and vaccinated subjects. The research team prepared the layout of two questionnaires (attached in the **Supplementary Materials**), which formed the basis for semi-structured interviews (held either in French or in Fon) that took place between June and August 2021[10], while also taking into account the writing of the concept note, interviews, translation and transcription of data, and thematic sorting. The fieldwork was conducted by two researchers who assumed responsibility for data transcription and thematic sorting.

Survey populations were selected using the reasoned choice and snowball techniques. Reasoned choice provides that the sample is chosen in a way that represents the studied population as accurately as possible. For this reason, all the groups involved in the vaccination campaign were captured. The sample size was determined by the saturation threshold, i.e., the number of interviewees was stopped when no new codes or themes emerged from the interviews, rather, the same ones started recurring (28, 29). The final sample size was 34, including nine co-morbidity carriers, six health care workers, eleven *traditherapeutes*, and eight people over 60 years old. Particular attention was paid to the gender dimension in the conduct of the interviews to make sure that it was as balanced as possible. Overall, we believe that this mixed-background population could be a good representative sample of the Beninese population. **Table 1** reports the characteristics of the interviewees.

Finally, the survey data was recorded and then transcribed for the second stage of thematic sorting. When necessary, the transcription was preceded by translation for interviews and passages conducted in local languages (especially French and the Fon dialect). In addition to the interviews conducted, direct observation was chosen as an additional technique for collecting data that could not be captured by speech. The research site was initially identified as Cotonou, but was later expanded to Abomey-Calavi and Seme-Pkodji—two dormitory cities adjoining Cotonou. This choice is justified by the fact that the latter two are affected, in the same way as Cotonou, in terms of

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[9] https://covid19.who.int/region/afro/country/bj

[10] The study received full ethical approval from the University of Abomey-Calavi Comitè d'Ethique de la Recherche CER-ISBA (No. 131).

the prevalence of COVID-19, in addition to being part of the "red zone" of the pandemic. These choices thus reflected the social urban perception of vaccination, more so because Cotonou and its peripheral towns (Abomey-Calavi and Seme-Pkodji) have 38 vaccination sites out of 78, totaling almost half for the whole country (76 cities).

In the second phase of the project, the results of the field study was analyzed by the University of Warwick team using thematic analysis, triangulation of data collection sources, and content analysis techniques, which was corroborated with a broad literature review. The last (synthetical) phase, in the Hegelian sense, involved combining the results of the first two phases, thus using the framework for proposing strategies and solutions for addressing the identified problems. The framework aims at bringing to public attention the problems identified and interpreted in a pluriprospectic way, and this paper is one of the results and part of the ongoing dissemination strategy.

RESULTS

The conducted interviews revealed many elements worthy of interest related to the social engagement of the Beninese population in the fight against COVID-19. The use of the hermeneutical framework made it possible to identify four macro-areas: (a) governmental and technical aspects; (b) social aspects; (c) traditional care aspects; (d) ethical aspects. It was from these four areas that crucial elements emerged. **Figure 1** represents a tree diagram summarizing the main themes pinpointed during the coding of the interviews.

a) Governmental and technical aspects.

The interviewees were requested to give their opinion on the governmental management of the COVID-19 pandemic, including the vaccine delivery mechanism system. The respondents report that the vaccination system followed in Benin is in line with the protocols established by the WHO (30), which registered a good system of vaccine conservation and hygiene in the administration and disposal of waste. However, two accounts were opposed to an overall good opinion of the mechanisms put in place. An interviewee declared his concerns about the hygiene and procedure followed.

> "The biomedical devices in place do not always meet the technical needs of the vaccination sites. Here at the National University Hospital Centre, for example, it is not possible to observe the distance in case of turnout. Also, there is no observation room to allow those who feel ill after vaccination to rest (...). The second part I have doubts about is the vaccinator. I don't know if he or she follows the precautions. In principle, after a vaccination, the vaccinator must change gloves before vaccinating another person. But I'm not sure if he respects this standard because they don't have enough gloves. After four or five vaccinations, the vaccinator uses hydro-alcoholic gel. So, they get up from time to time to wash their hands. (Caregiver, male, 54, Cotonou, 09/08/2021)."

Another respondent expressed concerns that temperatures to keep vaccines viable may be subject to fluctuations.

> "So, the question is, do we have all the equipment we need to respond? That's the question that came up. I'm already telling you that we don't have a refrigerator in the infirmary and that we put the vaccines in the cooler in the morning until maybe 3 p.m. before vaccinating people, maybe that's a guess, that's my point of view. So, in terms of safety, maybe we're breaking the cold chain a bit. (Health worker, 44 years old, Cotonou, 23/07/2021)."

Most respondents report that they are aware of the system of registration of vaccinations that passes through a national digital system that releases a QR code and is connected to a mobile app[11]. However, some people are unaware of this and report on some procedures that are still paper-based and should be followed by subsequent online data entries.

Ultimately, the Beninese government's handling of the pandemic is perceived in a controversial way. Those who appreciate technical health management are pleased with the government's agenda and attribute its merits to the WHO, while those who are more critical, instead, look favorably on the experiences of other states that have used traditional medicine in the fight against COVID-19 (31) (e.g., the Malagasy president). Moreover, the interviewees show many doubts about the Beninese local government's ability in overcoming the resistance to the vaccination drive due to accusations of corruption (e.g., collusion for economic reasons with the "whites", poor commitment to the recognition of local traditional medicine, faking the vaccination procedure) and lack of clarity and disinterest in the real involvement of the population.

> "Before proceeding to vaccination, the leaders must seek public opinion on the ins and outs of the vaccine and in relation to the rumors that are circulating about the vaccine. Today, Africans have a very high level of awareness and no longer want to submit to the yoke of white imperialism. (...). On the other hand, if it were with our plants and barks, I know that such and such a plant cures such and such a disease, and thus I will be able to submit to the indicated treatment". (Person over 60, Female, 89, Cotonou, 27/07/2021).
>
> "Now our leaders are being vaccinated to set an example. What is being inoculated into their bodies? We are not doctors to know. What is to be administered to the rest of us as well, we have no idea. Sincerely, they have love for their citizens, let them not be baited by money to feed us." (Person over 60, Female, 89, Cotonou, 27/07/2021).
>
> "The lack of information means that few people are currently vaccinated. Only intellectuals who have to travel and those who are among the targets listed by the government do so. I can say that the communication around vaccination is not going well. There is no mobilization. Apart from media releases, there is no other form of social mobilization." (Caregiver, male, 55 years old, Cotonou, 06/07/2021).

b) Social Aspects.

The interviews sought to highlight the position of the population in relation to the COVID-19 pandemic and the reasons that justified them. There is clearly a misconception of the true nature of COVID-19, which gives rise to an overall rejection

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[11] https://www.afro.who.int/news/benin-goes-digital-offensive-against-covid-19

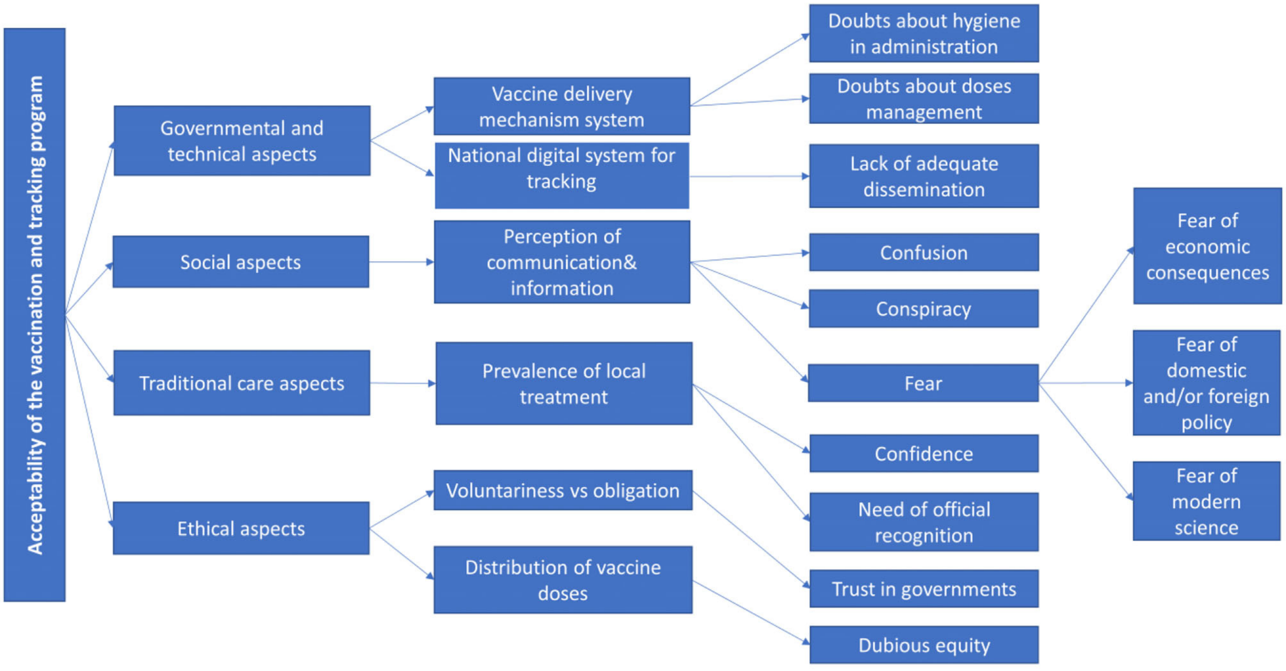

FIGURE 1 | Tree diagram highlighting the main themes surfacing from the interviews.

of the vaccine. Conspiracy theories are very common, and conspiracy against the population is foreseen and explained with the tradition of *zangbeto*, in the local culture the victim par excellence[12].

> "This story talks about the zangbeto that is caught in a mouse trap. In this story of the COVID-19 pandemic, there is something fishy going on; something is being plotted to harm 'Man'. Something is being hidden from us. We are not being told the truth". (Person over 60, Female, 85, Cotonou, 28/06/2021).

The emotion that is recorded in a more recurrent way is the *fear* that feeds the denial of COVID-19 and the rejection of the vaccine.

> "Some people say that if you get the vaccine, you will die in two years. Maybe that's why people refuse to get vaccinated. Who wants to die? So, people are suspicious. This is the feeling that drives the population; they are afraid. People doubt who is telling the truth and who is not. And so, they decide not to be vaccinated and to remain as they are" (Co-morbidity carrier, Female, 58, Abomey-Calavi, 23/07/2021).

The *confusing information* bombarding the population through communication networks and social media (about post-injection manifestations, the doubts of the government about the age requirements for the vaccination) is the main cause for fear. Social media builds up a real "mobilization strategy" made of WhatsApp messages that are spread by unknown numbers through message chains or forums on the internet. Because this information source is not controlled and/or censored by the authorities, they are considered to be confidential and, therefore, more reliable.

> "At the moment, I am not willing to do the vaccination. I am willing to do it if it will protect my health. But, with the rumors on social networks and the alerts on TV channels, and with what is recorded here and there after injections—the illnesses that it causes afterwards, I am not tempted to do it immediately". (Comorbidity carrier, male, 32, Cotonou, 22/06/2021).

The declared fear can be traced back to three major issues: (a) fear of economic consequences, (b) fear of politics, and (c) fear of modern science.

- *Fear of economic consequences.* This appears to be the major reason for denying the existence of the virus, especially in rural areas that are mostly affected by the restrictions (such as the ban on having markets).

> "I have a brother in the village who has a cough. He suffers from a stubborn cough and he is a prominent gentleman in the community who enjoys a certain socio-economic prestige. Eventually, at the local health center, he was found to be a carrier of the COVID-19 virus and had to restrict himself to quarantine requirements. He saw all his activities interrupted, the health

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[12] The zangbeto is the composition of two phonemes: "zan" meaning "night" and "gbeto" meaning "hunter", i.e., night hunter. The zangbeto is, from a social point of view, the traditional night watchman and a secret society of masks in southern Benin. When he goes out, the zangbeto, being masked, is accompanied by zanvi (followers of the zangbeto) and if he is caught by a mouse trap, it means that he is a victim of a trap. Otherwise, the people are victims of a conspiracy.

> center that took care of him is closed to users and the village itself is stigmatized with the adverse effects of poor sales for traders of doughnuts, and especially mustard and Akassa ball, which the locality is known for because of its quality of production." (Co-morbidity carrier, Female, 55, Cotonou, 29/06/2021).

- *Fear of domestic and/or foreign policy.* As anticipated, the population revealed that they have no trust in the government, based on claims of corruption, and are therefore fearful of any government action. In addition, the fear of politics is also relevant in the international context, and traces its roots to the colonial experience in the past centuries: it is believed that COVID-19 would allow foreign rule to return, thus controlling African populations, or even decimating them in order to limit any anticipated danger that could arise from the increasing population size.

> "The anti-COVID-19 vaccine is being introduced in our countries in Africa to shorten the lifespan of the population. The great powers of this world consider that we are overpopulated, there are more people than we need in the world and therefore we have to find a way to reduce the world population size, especially in Africa, to a given threshold. I suppose that we must be 6 billion in the world and here we are at 10 billion! the surplus is thus to be removed". (Person over 60, Male, 67, Cotonou, 19/07/2021).

- *Fear of modern science.* The population adduces a number of reasons to justify the fear of modern science, coupled with politics. They feel this is another cornerstone of the above-mentioned "anti-African" plot. In particular, some interviewees underline the small number of known COVID-19 infections in Benin and the high temperatures in Africa, from which they deduce that it is a disease that does not particularly develop at such climates and does not particularly affect the Africans' genetics. In addition, with regard to the fight against COVID-19, the population is suspicious of the speed at which vaccines were trialed and believes that this could compromise its effectiveness and safety. In this regard, other respondents reinforce the hypothesis that it is a political-economic expedient because they are dubious about the reasons for the speed behind vaccine production and spread in spite of the fact that other more common diseases in Africa are still waiting for a cure (e.g., malaria or AIDS). This also brings up the suspicion that the African population is being used as "guinea pigs" to test certain types of vaccines. All these reasons reinforce the general rejection of not only the COVID-19 vaccine, but also other vaccines that were accepted in the past.

> "COVID-19 is not in our country. It is the white people who brought it". (Tradithérapeute, Male, 35, Cotonou, 16/06/2021).
>
> "The whites do not like blacks. With the number of deaths caused by COVID-19, they do not take action to save themselves and they want to save us. This way of acting should make black people think. AIDS has been around for years without a vaccine, and it's COVID-19 that they have found a vaccine for. I don't want this vaccine!". (*Tradithérapeute*, Male, 35, Cotonou, 16/06/2021).
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> "In the face of every disease, Africans are used as test drivers. They use us as test subjects to improve their products. It is true that the whites have already started taking the vaccine. But the drugs they use are different from the ones they send to us in Africa. The quality of the pharmaceutical products is not the same. That's why our Heads of State go abroad for treatment when they are ill". (*Tradithérapeute*, Female, 33, Cotonou, 16/06/2021).
>
> "As a result, I have had to dismiss the polio vaccinators who go to households door-to-door because we don't really know any more if they are polio vaccinators or if it is the COVID-19 vaccine". (*Tradithérapeute*, male, 35 years old, Cotonou, 16/06/2021).

These convictions nourishing the social perception of the ongoing pandemic are extremely acute in the peri-urban and rural areas where there is a widespread belief that the virus is fictitious. Also, the distance from the vaccination mechanism, which is concentrated in urban areas, and the government's disregard in respect of the control of compliance with safety measures contribute to these beliefs.

> "The disease is not in our villages. The villagers ask us to be careful. They ask us not to come and contaminate them. Because the disease is not in the village. It's all fabrications when they tell us that there are cases of COVID-19 in the villages". (*Tradithérapeute*, male, 34, Cotonou, 16/06/2021).
>
> "In the villages, compliance with these rules was lower. But in our urban areas, the police will arrest you if you don't respect the barriers". (*Tradithérapeute*, Male, 34, Cotonou, 16/06/2021).
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> "It is in Cotonou that we can say that people are more or less aware of COVID-19 restrictions, but when they leave Cotonou, it is not so evident. (...) In Cotonou, you can't go into a pharmacy without a mask, but in Parakou, for example, you can go into a pharmacy without a mask, which reduces the motivation to get vaccinated". (Comorbidity carrier, male, 43 years old, Sémé-Podji, 26/07/2021).

c) Traditional care aspects.

In Benin, there exists a rich context of traditional medicine based on the use of plants for self-medication and the multiplicity of traditional healers (i.e., *traditherapeutes*), many of whom are recognized by the health care system, while others are considered charlatans. The main problem of traditional medicine is that there are no scientific studies that establish doses and confirm full alternatives to modern treatments. Nevertheless, there is a great engagement of the population (including medical doctors) in this type of treatment. The interviewees reveal the strong belief that traditional medicine is a valuable preventive prophylaxis tool against COVID-19, and think it is better than any other modern treatment.

> "We have strengths in traditional medicine that can help us prevent and cure even COVID. These are the recipes and I believe in them. We are told that COVID-19 is like the flu that chloroquine can cure. But we also have drugs that play the role of chloroquine and Azithromycin. So the problem is solved traditionally." (Caregiver, male, 54, Cotonou, 09/08/2021).
>
> "Do you see in the West, despite the development in their health systems, that their populations have suffered a hecatomb?

> Have you not asked yourself why not here? It is precisely because of our food and pharmacological habits based on plants! These people, we must not give in to ignorance and simply follow them. They will simply kill us. No, in Africa we have everything we need to cure all kinds of diseases". (*Tradithérapeute*, Male, 66, Abomey-Calavi, 23/07/2021).

The respondents are aware that studies of traditional medicines require time and investment of money. Respondents report that some local products are licensed, while others have been banned. This gives rise to the fear of government repercussions against the traditional healers. In fact, based on some reports, the government tried to involve traditional healers in the management of the pandemic by creating a group of experts in traditional medicine. This however did not give them the opportunity to take initiatives. In reality, local governments are acting very cautiously with respect to local medical traditions, fearing international repercussions (as in the case of Madagascar, where the president sponsored local treatment against COVID-19, but later withdrew the regulations following pressures from the international community).

> "The problem of complementarity is primarily a political and geostrategic issue of the great powers. To date, no blacks have been allowed in the circle of researchers conducting research on COVID-19. Without protection, we cannot exhibit our products against COVID-19 because we will be fought. The case of the Malagasy President is an example. The second example is that of Dr. Agon Valentin. Burkina Faso had accepted his product, API-VIRIL, as a remedy against COVID-19. However, when the 'Whites' got involved in the dance, his product was banned from use against COVID-19, and was withdrawn from the Burkinabe market and banned from sale in his country, Benin." (*Tradithérapeute*, Female, 37, Cotonou, 16/06/2021).
>
> "In fact, there are many problems at this level. First of all, there is the problem of the non-complementarity of the biomedical and endogenous offer. Moreover, the promising endogenous physicians have difficulty in getting together to produce quality medicines. The quest for individual recognition leads them to evolve in a scattered manner. As an example, to face the COVID-19 pandemic, the Beninese government has set up a committee of experts. This committee met with the traditional medicine actors that we are. It asked us to organize ourselves to make proposals for a remedy against the pandemic. Instead of uniting to produce something of quality, each healer went to the committee of experts with their product. It was so disorganized that the expert committee has not made a decision to this day yet. So, it's an internal problem for us." (*Tradithérapeute*, Male, 34, Cotonou, 16/06/2021).

Fear recurs as the dominant theme in the interviews, and one of the remedies to fear is considered to be traditional medicine. In fact, some respondents report that before vaccination against COVID-19, some people had undergone a spiritual purification and made specific sacrifices to local deities, or consulted the oracle of local geomancy. This represents another side of traditional medicine, not necessarily related to herbal treatments.

> "There are some who are vaccinated and have not had any effects. But when I approached them, they told me that they prepared themselves psychologically, medically and spiritually by giving themselves to God to become immune to COVID-19. They too were afraid and took steps to overcome the fear. A few days before taking their doses, they took chloroquine and azithromycin to fight against the virus and paracetamol to prevent fever, as is done for children during vaccination. They also prayed a lot and did not want their husbands and wives to follow suit. The others did it first to see what it would do". (Caregiver, woman, 45, Cotonou, 12/08/2021).
>
> "There is also that deity 'Sapkata[13]'. Let us not forget it. It is 'Sapkata' who governs all diseases. If one makes the required sacrifices to her, she protects and prevents the population from falling ill". (*Tradithérapeute*, Male, 34, Cotonou, 16/06/2021).
>
> "All illness comes from a spiritual imbalance that negatively impacts the physical condition. Therefore, if we can regulate all spiritual imbalances, no one will fall sick because illness is a spirit. It is enough to make Soudjo conjure the spirits responsible for the disease so that they do not come into our environment." (*Tradithérapeute*, Male, 34, Cotonou, 16/06/2021).
>
> "Moreover, we had consulted the Fa oracle about the origin of COVID-19. [...] The Fâ was clear and precise. He even said that young people will not be victims of this disease. Following these revelations, we made sacrifices. Only charlatans paid money to make the sacrifice against COVID-19. We should then do the ritual called tokplopklo. But due to lack of funds, this has not yet been done. The tokplopklo[14] is done by several people. The government itself has to give money. But it refuses to provide the necessary means. This is proof that our leaders do not love their country." (*Tradithérapeute*, Male, 66, Abomey-Calavi, 23/07/2021).
>
> "In addition, we have other methods to send the disease away from our lives. These include taking adjanouhlahoun and zozoman. When you take a bath with the potion of these two leaves, any disease stays away for a good period of time." (*Tradithérapeute*, Male, 34, Cotonou, 16/06/2021).

Ultimately, it emerges that the population feels more represented by traditional medicine than by modern medicine and would very much appreciate the formalization of the former. It is also evident that an official involvement of traditional medicine in the fight against the pandemic would lead to a stronger popular engagement.

> "But I think the authorities need to approach our traditional healers to learn about the recipes they use, test them scientifically before accepting or rejecting their use. If not, we will lose. Besides, we are used to losing. Because our old people are dying every day with their recipes. The best strategy would be to accept these traditional plants, study them scientifically and make them available to the population. Researchers are there for that. Our governments must change their positions. They know full well that traditional medicine is full of qualities. So we should not

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[13] Sapkata is a deity of southern Benin, of Yoruba origin, reputed to be one of the dominant figures of the Vodun pantheon. It is considered as the regent on earth and the God of eruptive diseases. It is usually the beneficiary of expiatory rites in cases of epidemic.

[14] Soudjo and Tokplopklo are expiatory rites literally known as baths of purification for the community life to ostracize the evil from the socio-linguistic group.

> categorically refuse without experimenting." (Caregiver, Male, 55, Cotonou, 06/07/2021).

d) Ethical aspects.

In Benin, vaccination is voluntary. In the first phase, it was limited to some categories (i.e., health professionals, people with serious comorbidities, over 60 years), but now, it is open to people aged 18+. A specific section of the interviews was dedicated to asking how the population considered the theme of mandatory health treatments, and if the vaccine against COVID-19 was perceived as an obligation. We discovered that many health care workers were also opposed to vaccination, although they were not obliged to get it done at that time.

> "So far, nothing! I thought that if someone doesn't get vaccinated, they won't be able to do their job, that they will be fired, but so far there is no such pressure. Vaccination is not mandatory for health care workers. But if it were compulsory, I would make one condition: I have a medical certificate describing my state of health and I would write to the authorities that it's against my will and that I'm getting vaccinated to save my job." (Caregiver, female, 45, Cotonou, 12/08/2021).

As regards the COVID-19 passport, the population is opposed to it and considers it as a form of oppression.

> "It is wrong to talk about the COVID-19 vaccination passport. But we are not going to let it happen. However, it's a pity". (*Tradithérapeute*, male, 34, Cotonou, 16/06/2021).

Finally, the interviewees underlined the lack of equitability in the distribution of vaccine doses: the sharp difference between areas of the world prevents a global community vision.

> "What did not work was the international community. It does not have that kind of solidarity. If everyone is affected, everyone should benefit equally from the vaccine doses. But today we see that the Westerners give priority to themselves first, and then send us a few drops. That didn't work. The mobilization of resources has not worked. I'm sure that the resources that countries have received and mobilized have not allowed them to do much. (Co-morbidity carrier, male, 43 years old, Cotonou).

DISCUSSION

The fight against COVID-19 will be successful only if it will build on a complete engagement of the population. As shown in some of the reported interviews, the latter is strictly connected to many sociocultural aspects. The first aspect is the net gap between the population and politics, which often relies on contradictory and unclear communication strategies for the population, thereby fomenting conspiracy theories and negationism. Overall, it seems that local policy is geared more toward complying with international standards rather than to assessing and tackling what is happening in the country.

Firstly, Benin is carefully trying to follow the WHO protocols of conservation, administration and disposal of waste, but does not deal with the very serious risks that could result from blackouts or unstable electrical supply to the refrigerators containing vaccines. The cold chain (i.e., cold storage during the delivery and storage at the provider's facility up until the administration to the patient) is required by some vaccines to maintain their potency and effectiveness. This may be very difficult to maintain in a LRS such as Benin, which has an electrification rate of 43% and a quality of electricity rated as 2.06/7 (as a comparison, Italy has a 100% electrification rate, and a quality of 5.91/7). The quality of the electricity is compromised by frequent blackouts, sags and swells, and the frequent unavailability/breakdown of generators, as also reported in previous studies (32, 33). The more general concern is that for politics, economics, and in the present case, also health, there are established International Standards, which although have the benefit of standardizing practices and facilitating trade between countries, are in fact limited by not considering the variety of specific contexts and situations. The alleged universality of standards is often generic and risky because, as in the case of the storage temperature of vaccines, it could call into question the effectiveness and safety of health technologies and, consequently, the health and rights of patients.

The second evidence of the policy's distance from the population is that there is lower control over distancing measures and spread of vaccination and its tracking mechanism, particularly as observed in the Beninese rural areas. This significantly affects popular engagement, which is clearly more limited in those areas and feeds the denial. Emerging from the interviews are many reasons given for the denial of COVID-19 and vaccine refusal, including alleged environmental or genetic reasons and the so-called "neo-colonialism". In fact, the population believes that more than as a health emergency, this pandemic could be better described as a political alarmism with economic aims. This latter motivation finds its roots in the centuries of colonialism that still persist in the memory of the population so vividly; mainly that some people believe and spread conspiracy theories against the African population. One of the most interesting supported theories is that the low prevalence of the disease does not justify preventive prophylaxis compared to many other more common diseases with much higher mortality rates that have long deserved the search for a vaccine or cure. It would seem that a common belief is that the world wants to vaccinate Africa to protect itself, and that if the pandemic is not eradicated globally, there will always be the danger of its comeback, possibly in the form of even newer variants (two of the most recent ones were already firstly identified in Africa). On closer inspection however, it is clear from the interviews that local people do not want to fight a battle which is being disputed elsewhere, i.e., a disease that is not of concern in their own country. Even more so, local people are suspicious and angry about the underlying faulty mechanism behind it all (e.g., the COVID-19 vaccine discovery and testing in such short times), which did not consider as priority other epidemics or diseases mainly affecting Africa.

For these reasons, one of the most obvious lessons learnt from the pandemic is the urgent need to reflect once again on the *priorities*, that is, the ethical criteria that drive the progress of science, globally. Generally, the interviews highlighted the belief that third parties (international and/or local politicians, pharmaceutical companies, "whites") for various reasons (economic, political, and experimental) are conspiring against the population (i.e., *zangbeto* metaphor). These fears reveal once again a clear gap between the people and the politicians, creating a situation where the populace fear the behavior of elected individuals who, in a democratic government, should represent them. This evident crisis of democracy motivates the attachment to popular beliefs concerning political charlatans, or those spread *via* social media, or by conventional wisdom.

As mentioned earlier, the most recurrent feeling interwoven with the interviews is that of fear. Fear has always been a philosophical, as well as a psychological concept on which many contemporary theorists have developed important reflections: from the heuristics of fear, theorized by Hans Jonas, for which profiling a terrifying future picture of the consequences of one's actions could favor the "principle of responsibility" (34), capable of promoting responsible actions to protect future generations, up to the reflections of the American philosopher Martha Nussbaum, a theorist of the social democracy based on skills and capabilities, who also modernly argues about the "monarchy of fear" (35), according to which fear is no longer part of an emotional dimension of the private sphere, but is part of a wider public sphere, affecting mass behaviors, just as it happened during the so-called "COVID-19 era".

In the case of Benin, the fear of oppression, linked to historical resentment toward the West, has led to the habit of identifying external culprits, thus fueling undemocratic attitudes. In this respect, Nussbaum argues that the wrath-blame mechanism is typical of fear. On closer inspection, however, fear is a primitive, narcissistic, and asocial emotion that is still causing more serious consequences in some countries than the spread of the virus itself. The fear of the vaccine is not a new thing for animist cultures. According to general belief, inoculation introduces pathogens that cause "something sick and evil", a situation which most would interpret in a spiritual sense (36). Currently, the traditional fear of the vaccine is intensified, evidenced by the refusal of the COVID-19 vaccine, with the implication that people might begin to reject vaccinations for other diseases too. Nonetheless, this should not lead us to think that the population rejects the COVID-19 vaccine for religious reasons, though it is a phenomenon common to several religions, which verified the compliance of vaccine serums with their religious dietary requirements. Islam and Judaism, for example, prohibit the intake of pork and its derivatives, while the Hindu religion prohibits the intake of cattle derivatives (37).

On the contrary, in Benin, the extraordinary tradition of traditional medicine, cloaked in its dual spiritual and phyto-therapeutic nature, is readily available for searching causes and remedies related to the pandemic. Unfortunately, the government appears to distance itself from what represents very valuable local knowledge, even for primary health care. In fact, not only has the government refused to do an in-depth study of traditional medicines by assessing their effects and establishing their correct dosages, but also withdrew some herbal remedies that were either being used against COVID-19 or for strengthening the immune system from the open market (e.g., artemisia). This disposition again shows the government's detachment from a confused and frightened population left to act alone and in secret. Certainly, in times of emergency, it is expensive and tedious to undertake studies parallel to official ones on alternative remedies to COVID-19, but it is also true that traditional medicine experts could support research and, at the same time, represent a reliable reference for the community to facilitate the engagement of the population (38). Notably, an attempt to officially appoint a group of traditional medicine experts to provide a solution to COVID-19 was made, but was unsuccessful due to a lack of organization and capacity for initiative.

Overall, as we have seen, there are many reasons behind the rejection of the COVID-19 vaccine. Among all, social engagement should be considered a priority. When considering feedback from the interviews, it would seem that social engagement poses a greater challenge than the much-debated issue of the unfairness in the distribution of vaccines. Even if there were the availability of free and universal vaccination coverage, the popular rejection of vaccination would yet remain an obstacle to global health.

The aforementioned document of the Beninese government announcing the opening of the vaccination campaign states "Vaccination against COVID-19 is effective, safe, voluntary and free. Get vaccinated to protect yourself and others"[15]. Voluntariness corresponds to the ethical principle of *autonomy* that ascribes to the individual the balance between *risks* and *benefits*. According to the interviews, it would seem that the population is particularly frightened by the risks (including post-injection complications, scams made by governments, and the fear of dying). The benefit of vaccination, that is, individual and mass immunization, is underestimated because, from the personal point of view expressed by most interviewees, it is believed that other diseases are more widespread in those places (39) and there is no urgent need for this specific vaccine. The prospect of achieving global health should instead be mindful of historical heritage since the local belief is that the population is being used as "guinea pigs" to test health solutions for the sake of others.

Since people would be naturally more inclined to choose personal interests over collective ones, it is highly imperative that they are properly educated in making the right choices, especially as this improves the fight against possible pandemics and their behavior in times of emergency. Moreover, it is not possible to predict whether in the future the countries which are now relatively unaffected by the pandemic will witness an increase in infections, resulting in even more disastrous technical and medical consequences. This is why the Beninese government has not followed the risk-benefit balance, but rather, the *precautionary principle* in promoting mass vaccination of the population. However, considering the low record of population engagement in the fight against COVID-19, if the Beninese government wants to pursue the immunization goal, the question to ask is; should it give up the *autonomy principle*? From a

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[15] https://www.gouv.bj/coronavirus/#documents

theoretical point of view, it should be pointed out here that the *principle of autonomy*, which is at the basis of informed consent and dissent, is exercised when a competent individual, i.e., someone made clearly aware of the health framework, makes a decision in accordance with their moral perspective. However, in the present case of COVID-19, and taking infodemics into consideration, it would seem that the lucid and genuine self-determination of the individual has been seriously compromised. This is well linked to the ethical principle of *trust*, which is not built on authority, but on the relationship, involvement and genuine inclusion of the population in scientific and political healthcare management. Trust should be built with clarity and honesty, and with sufficient explanations on any eventual limit or uncertainty of science (40). As of now, the emergence of rapid publication of information has called into question the accuracy of the information being circulated (41, 42). This phenomenon can be stopped by appealing first to scientists and researchers to be responsible and conscientious in their work, before even reaching out to those responsible for the circulation of information on communication networks and/or social media.

One of the first steps to clearer management of the pandemic would be to follow the infections more strictly with more capillary testing and digital tracking mechanisms (43). Many countries have followed this path, starting from the "immunity passport" (44) (which certifies whether a person has received the COVID-19 vaccine or has recently tested negative[16]). These passports permit holders to return to some of their normal activities, such as traveling more freely and returning to work (45). An immunity certification program could complement population or community-based strategies to ease restrictive measures, as well as secure societal and individual freedom and wellbeing.

Leaving aside the non-negligible issue of limited access to technologies (such as smartphones) and internet coverage, which could be the first obstacle to full deployment of the procedure, Benin has put in place an online portal hosting an app that can be used by vaccinated people to download and show a QR code as a proof of their status. Moreover, due to the limited number of people who accepted the vaccine, the government is prevented from limiting access to certain activities to only the vaccinated people, as well as from returning to severe containment measures such as lockdowns. Certainly, the immunity certification should never be used as the main strategy for reducing the effects of the COVID-19 pandemic, but could be used as a part of a plan that provides for a decrease in the number of people subject to highly restrictive measures (46, 47). As it is now, the immunity certification is an intermediate management strategy between mere recommendation and obligation, with related sanitation measures for whistleblowers—a balance between autonomy and public health.

The trust of the population must be built based on the recognition of local actors as community leaders, or even *traditherapeutes* that can facilitate popular engagement in the vaccination program (48, 49). This is related to the ethical principle of *equal moral respect,* which is particularly interesting in relation to our study. This principle provides that "the interests of all be taken into equal account" and also requires "being sensitive to cultural diversity and plurality", which in turn requires a willingness to engage in dialogue and deliberation in terms of equal standing and recognition. In practice, this means ensuring that potential participants are empowered to reach their own decision regarding whether they would like to participate, ensuring that consent is sought in a culturally appropriate manner, and addressing participants' perspectives or concerns about the research, including information about how their data and samples will be handled, and so forth" (7). This could be achieved by an adequate study of local medicines and traditional therapeutic practices that can go hand in hand with the development of modern medicine.

This brings us back to the ethical principle of *equity*, which is not only related to a fair distribution of resources, but also to a consideration of specific popular needs: "for people to be treated equitably, they should be able to exert at least some influence over the decision-making process as well as the decision itself, i.e., procedural fairness"[17]. Beyond this, including individuals and communities means maximizing the social value of science and politics (50). All points mentioned beforehand respond to the ethical principle of *solidarity* (51), which encompasses the respect of the pluralism of cultures and human rights. In the present case, human rights pertaining to health initiatives are individual and at the same time global, and go hand in hand with the right to enjoy the benefits of science and its results (in this case COVID-19 vaccines), all in respect of an individual's right to cultural identity. Furthermore, the latter point should be related to the right to having an adequate education, which puts a person in a position to clearly understand what is happening so as to exercise autonomous choices responsibly.

CONCLUSION

The world shares a collective responsibility in fighting the present pandemic; therefore, the reluctance of many local populations to accept the vaccine or their hesitancy toward tracking COVID-19 cases highlighted the urgent need for a study on social engagement in the fight against COVID-19. In particular, this paper shows the example of Benin, a Sub-Saharan country characterized by multiple endogen differences and a rich cultural tradition of animism and traditional medicine. With this interdisciplinary study, we explored the popular perspectives and beliefs on the pandemic from a sociological, ethical, political and scientific point of view. In order to be able to use a multi-level angle view and engage in multi-level discussions, an interdisciplinary framework was used. This framework, which makes use of multiple methodologies, allows schematization

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[16] Although this second option gives very limited freedom as the obtained pass lasts only a few days.

[17] Ivi, p. 129.

within a broad question and a number of issues, and provides tools to facilitate discussions at different levels. Moving away from a top-down approach and favoring a bottom-up one is considered an important way for multi-directional learning and for shaping an effective response informed by values.

The outputs emerging from the interviews, however, suggest a clear separation between the public and private sphere, and the distance of politics from the population, especially in peri-urban and rural areas, where negative perceptions and feelings of being ostracized prevail. The objective of this framework is to bring to public attention particularistic perspectives and how these suffer from the imposition of universal standards and procedures, i.e., in this case, the protocols of vaccine administration and tracking. The framework proposes flexible solutions to address these gaps (e.g., social mobilization strategy through the involvement of local medical expertise) because social engagement is vital to engage an effective immunization process. Current researchers should understand which modalities of public engagement are most effective. This study illustrates the urgent need for connecting clinical practice, public health, and social policy decision tables with broader community concerns, while also relying on bioethics. For the future, one of the lessons that should remain from the pandemic is that public perception should be considered a priority in the future management of health care emergencies, thus delivering the stamp of a "job well done" to posterity. One might argue that one of the limitations of this study is the limited sample size, which may not be representative of the whole Beninese populations. However, both the fact that our sample includes people with different cultural and socio-economic backgrounds, and our use of the aforementioned saturation threshold to capture all the possible themes, make this limitation negligible. Nonetheless, further comparative ethnography studies could focus on other populations of Sub-Saharan Africa to see whether similar beliefs and perceptions are shared within wider communities.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethical Committee of the University of Abomey-Calavi. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AM wrote the main manuscript text. MV and AG conducted the field study. AM, DP, and IO analyzed and reviewed the results. AM, DP, and MV prepared all the **Supplementary Materials**. AM, LP, and RH contributed to the conceptualization. IO and DP involved in supervision and editing. LP involved in funding acquisition. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2022.857890/full#supplementary-material

REFERENCES

1. Pecchia L, Piaggio D, Maccaro A, Formisano C, Adanza E. Thenadequacy of regulatory frameworks in time of crisis and in low-resource settings: personal protective equipment and COVID-19. *Heal Technol*. (2020) 10:1375–83. doi: 10.1007/s12553-020-00429-2
2. Maccaro A, Piaggio D, Pagliara S, Pecchia L. The role of ethics in science: a systematic literature review from the first wave of COVID-19. *Heal Technol.* (2021) 11:1063–71. doi: 10.1007/s12553-021-00570-6
3. Maccaro A, Piaggio D, Dodaro CA, Pecchia L. Biomedical engineering and ethics: reflections on medical devices and PPE during the first wave of COVID-19. *BMC Med Ethics*. (2021) 22:130. doi: 10.1186/s12910-021-00697-1
4. European Centre for Disease Prevention and Control. *SARS-CoV-2 Variants of Concern as of 13 January 2022*. European Centre for Disease Prevention and Control. Available online at: https://www.ecdc.europa.eu/en/covid-19/variants-concern (accessed January 17, 2022).
5. World Health Organization and Tracking SARS-Co V-2 Variants. Available online at: https://www.who.int/emergencies/what-we-do/tracking-SARS-CoV-2-variants (accessed January 17, 2022).
6. Le TT, Andreadakis Z, Kumar A, Roman RG, Tollefsen S, Saville M, et al. The COVID-19 vaccine development landscape. *Nat Rev Drug Discov.* (2020) 19:305–6. doi: 10.1038/d41573-020-00073-5
7. Dawson A, Emanuel EJ, Parker M, Smith MJ, Voo TC. Key ethical concepts and their applicationo COVID-19 research. *Public Health Ethics.* (2020) 13:phaa017. doi: 10.1093/phe/phaa017
8. Faden R, Saad O, Kochhar S, Kaslow D, Pallas S, Olayinka F, et al. *WHO SAGE Values Framework Forhe Allocation and Prioritization of COVID-19 Vaccination*. (2020). Available online at: https://apps.who.int/iris/handle/10665/334299 (accessed January 1 8, 2022).
9. WHO. *Microsoft Power BI: Africa COVID-19 Vaccination Update*. (2021). Available online at: https://app.powerbi.com/view?r=eyJrIjoiZmMwYzJiZjktZWE5MS00ZjlkLThkZjItZjlkNWNiZjc5OTc1IiwidCI6ImY2MTBjMGI3LWJkMjQtNGIzOS04MTBiLTNkYzI4MGFmYjU5MCIsImMiOjh9 (accessed January 19, 2022).
10. Troiano G, Nardi A. Vaccine hesitancy in the era of COVID-19. *Public Health.* (2021) 194:245–51. doi: 10.1016/j.puhe.2021.02.025
11. Machingaidze S, Wiysonge CS. Understanding COVID-19 vaccine hesitancy. *Nat Med.* (2021) 27:1338–9. doi: 10.1038/s41591-021-01459-7

12. Solís Arce JS, Warren SS, Meriggi NF, Scacco A, McMurry N, Voors M, et al. *COVID-19 Vaccine Acceptance and Hesitancy in Low and Middlencome Countries, andmplications for Messaging*. (2021). Available online at: http://medrxiv.org/lookup/doi/10.1101/2021.03.11.21253419 (accessed January 17, 2022).
13. van der Linden S, Dixon G, Clarke C, Cook J. Noculating against COVID-19 vaccine misinformation. *EClinicalMedicine.* (2021) 33:100772. doi: 10.1016/j.eclinm.2021.100772
14. Infodemic. Available online at: https://www.who.int/westernpacific/health-topics/infodemic (accessed Januaruy 17, 2022).
15. Zarocostas J. Howo fight an infodemic. *Lancet.* (2020) 395:676. doi: 10.1016/S0140-6736(20)30461-X
16. WHO. *An ad hoc WHO Echnical Consultation Managinghe COVID-19 Infodemic: Call for Action Infodemic Management*. (2020). Available online at: https://apps.who.int/iris/bitstream/handle/10665/334287/9789240010314-eng.pdf?sequence=1andisAllowed=y (accessed January 18, 2022).
17. UNESCO. *DISINFODEMIC: Deciphering COVID-19 Disinformation*. (2021). Available online at: https://en.unesco.org/covid19/disinfodemic/brief1 (accessed January 18, 2022).
18. Bhopal S, Nielsen M. Vaccine hesitancy in low- and middle-income countries: potential implications for the COVID-19 response. *Arch Dis Child.* (2021) 106:113–4. doi: 10.1136/archdischild-2020-318988
19. WHO. *WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines Inhe Context of Limited Supply: An Approacho Inform Planning and Subsequentecommendations Based Onpidemiological Setting and Vaccine Supply Scenarios*. (2021). p. 1–24. Available online at: https://apps.who.int/iris/handle/10665/342917 (accessed April 26, 2022).
20. Ackah BBB, Woo M, Ukah UV, Fazal ZA, Stallwood L, Okpani A, et al. *COVID-19 Vaccine Hesitancy in Africa: A Scopingeview*. (2021). Available online at: https://www.researchsquare.com/article/rs-759005/v1 (accessed January 17, 2022).
21. Bono SA, de Moura Villela E, Siau CS, Chen WS, Pengpid S, Hasan MT, et al. Factors affecting COVID-19 vaccine acceptance: annternational survey among low- and middle-income countries. *Vaccines.* (2021) 9:515. doi: 10.3390/vaccines9050515
22. Arakpogun EO, Elsahn Z, Prime KS, Gerli P, Olan F. Digital contact-tracing and pandemics:nstitutional andechnological preparedness in Africa. *World Dev.* (2020) 136:105105. doi: 10.1016/j.worlddev.2020.105105
23. Adebisi YA, Oke GI, Ademola PS, Chinemelum G, Ogunkola O, Lucero-Prisno DE, II. SARS-CoV-2 diagnostic testing in Africa: needs and challenges. *Pan Afr Med J.* (2020) 35(Supp. 2):703. doi: 10.11604/pamj.2020.35.4.22703
24. Onebunne JI, Okechukwu S, Okoye BC. African ecophilosophy and COVID-19. In: Kanu A, editor. *Trends and Advances in Education and Management in Africa*. Maryland (2021). p. 199–219. Available online at: https://www.researchgate.net/publication/356377633 (accessed January 19, 2022).
25. Onebunne J, Okechukwu S, Okoye B. COVID-19 and African environmental/herbal based remedies. In: Kanu A, editor. *African Eco-Philosophy: Cosmology, Consciousness and the Environment.* Maryland: Association for the Promotion of African Studies (2021). p. 275–96.
26. Akubor EO. The African forests inhe face ofhe coronavirus (COVID 19) pandemic. In: Kanu A, editor. *African Ecological Spirituality: Perspectives in Anthroposophy and Environmentalism a Hybrid of Approaches.* Maryland: Association for the Promotion of African Studies (2021). p. 151–205.
27. Piaggio D, Castaldo R, Cinelli M, Cinelli S, Maccaro A, Pecchia L. A framework for designing medical devices resiliento low-resource settings. *Global Health.* (2021) 17:1–13. doi: 10.1186/s12992-021-00718-z
28. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant.*(2018) 52:1893. doi: 10.1007/s11135-017-0574-8
29. Baker SE, Edwards R. *How Many Qualitative Interviews Isnough? Expert Voices and Early Career Reflections on Sampling and Cases in Qualitative Research*. Southampton, GB: National Centre for Research Methods (2012).
30. WHO. *WHO's Infection Prevention and Control Department*. (2022). Available online at: https://www.who.int/teams/integrated-health-services/infection-prevention-control (accessed January 19, 2022).
31. Nordling L. Unproven herbal remedy against COVID-19 could fuel drug-resistant malaria, scientists warn. *Science*. (2020) doi: 10.1126/science.abc6665. [Epub ahead of print].
32. Di Pietro L, Piaggio D, Oronti I, Maccaro A, Houessouvo RC, Medenou D, et al. A framework for assessing healthcare facilities in low-resource settings: field studies in Benin and Uganda. *J Med Biol Eng*. (2020) 40:526–34. doi: 10.1007/s40846-020-00546-3
33. Piaggio D, Medenou D, Houessouvo RC, Pecchia L. Donation of medical devices in low-income countries: preliminary results from field studie. In: Badnjevic A, Škrbić R, Gurbeta Pokvić L, editors. *{CMBEBIH} 2019*. Cham: Springernternational Publishing (2020). p. 423–7. Available online at: http://link.springer.com/10.1007/978-3-030-17971-7_64 (accessed January 17, 2022).
34. Jonas H. *Themperative of Responsibility:n Search of an Ethics forhe Technological Age*. University of Chicago Press (1984). Available online at: https://philpapers.org/rec/JONTIO-4 (accessed January 19, 2022).
35. Nussbaum MC. *The Monarchy of Fear: A Philosopher Looks at Our Political Crisis*. Simon and Schuster (2019). Available online at: https://doi.org/10.1057/s41296-018-00305-9 (accessed January 19, 2022).
36. Fourn L, Haddad S, Fournier P, Gansey R. Determinants of parents' reticence toward vaccination in urban areas in Benin (West Africa). *BMCnt Heal Hum Rights.* (2009) 9:S14. doi: 10.1186/1472-698X-9-S1-S14
37. Williams JTB, Fisher MP, Bayliss EA, Morris MA, O'Leary ST. Clergy attitudesoward vaccines and vaccine advocacy: a qualitative study. *Hum Vacc Immunother.* (2020) 16:2800–8. doi: 10.1080/21645515.2020.1736451
38. Maccaro A. Beninese therapeutic pluralism. Historical roots and bioethical issues. *J Theor Appl Vasc Res.* (2018) 3:19–24. doi: 10.24019/jtavr.53
39. Smith MJ, Upshur REG. Learning lessons from COVID-19 requires recognizing moral failures. *Bioethicalnq.* (2020) 17:563–6. doi: 10.1007/s11673-020-10019-6
40. Giubilini A, Douglas T, Savulescu J. The moral obligationo be vaccinated: utilitarianism, contractualism, and collectiveasyescue. *Med Heal Care Philos.* (2018) 21:547–60. doi: 10.1007/s11019-018-9829-y
41. Smith MJ, Upshur REG, Emanuel EJ. Publication ethics during public health emergencies such as the COVID-19 Pandemic. *Am J Public Heal.* (2020) 110:947–8. doi: 10.2105/AJPH.2020.305686
42. Smith MJ, Ahmad A, Arawi T, Dawson A, Emanuel EJ, Garani-Papadatos T, et al. Top five ethical lessons of COVID-19 that the world must learn. *Wellcome Open Res.* (2021) 6:17. doi: 10.12688/wellcomeopenres.16568.1
43. WHO. *Ethical Considerations to Guide the Use of Digital Proximity Tracking Technologies for COVID-19 Contact Tracingn Terim Guidance*. (2020). Available online at: https://apps.who.int/iris/bitstream/handle/10665/332200/WHO-2019-nCoV-Ethics_Contact_tracing_apps-2020.1-eng.pdf (accessed January 19, 2022).
44. Persad G, Emanuel EJ. The Ethics of COVID-19 immunity-based licenses ("immunity passports"). *JAMA*. (2020) 323:2241. doi: 10.1001/jama.2020.8102
45. Brown RCH, Savulescu J, Williams B, Wilkinson D. Passporto freedom? Immunity passports for COVID-19. *J Med Ethics*. (2020) 46:652–9. doi: 10.1136/medethics-2020-106365
46. WHO. *"Immunity Passports" in the Context of COVID-19*. Geneva (2020). Available online at: https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19 (accessed January 18, 2022).
47. Voo TC, Reis AA, Thomé B, Ho CWL, Tam CC, Kelly-Cirino C, et al. Immunity certification for COVID-19:thical considerations. *Bull World Heal Organ*. (2021) 99:155–61. doi: 10.2471/BLT.20.280701
48. Faye SLB, Diouf W, Cisse PN, Quach A, Sylla MM, Koita MM, et al. Engager (avec) les communautés dans unssai vaccinaln contexte post-Ebola (Guinée Conakry) : un modèle basé sur les ≪ champions ≫. *Sci Actions Soc*. (2018) 10:112–41. doi: 10.3917/sas.010.0112

49. Sarradon A, Egrot M, Blanc M-A, Faure M. Approche anthropologique des déterminants de l'observance dans leraitement de l'hypertension artérielle. *HAL Open Sci*. (2008) 39:11.
50. Jalloh MF, Wilhelm E, Abad N, Prybylski D. Mobilizeo vaccinate: lessons learned from social mobilization for immunization in low and middle-income countries. *Hum Vaccines Immunother*. (2020) 16:1208–14. doi: 10.1080/21645515.2019.1661206
51. Bruce L. Global solidarity in COVID-19 vaccine distribution. *BioLaw J Riv di BioDiritto*. (2021) 1:5.

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Back to the Roots of Nursing: Qualitative Study on the Experience of Nurses in the Front Line During the COVID-19 Pandemic

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The COVID-19 emergency has led many health facilities to reorganize themselves in a very short time to meet the urgent needs for intensive, semi-intensive or ordinary care of SARS-CoV-2 patients. In this pandemic, characterized by speed of transmission and severity of respiratory symptoms, care has been affected by the increase in volume and clinical complexity of patients, the sudden and unpredictable staff decrease and the lack of support from family members / caregivers. At the same time, experience in the field has shown how "informal" resources have been activated, which enabled to treat the highest possible number of patients above the real availability of resources. The purpose of this study was to explore the experiences of nurses involved in frontline care (COVID Centers) during the pandemic with a particular focus on professional motivation and on the development of technical-professional and personal skills. A study with a qualitative research design using focus group technique was conducted. Two focus groups were held with nine nurses. Data were analyzed with inductive content analysis. The findings can be summarized in five main categories: professional identity; motivation and sense of mission; development of professional and personal skills; spirituality; person-centered care; uniqueness of the lived experience. These findings shed new light on the correlation between motivation, professional identity and value, sense of duty and sense of belonging to the professional group. Moreover, the experience in the COVID Centers represented a valuable opportunity for participants to rediscover some specific issues related to nursing professional identity and to develop new personal and technical-professional skills in a very short time. Finally, nurses experienced once again how the nurse-patient relationship and basic care are essential to provide effective and excellent care, even and especially for patients in critical conditions. Nurses re-discovered, in a careful body care and basic care, irreplaceable elements to give back to patients, often dying, their own dignity, and all the needed closeness and attention necessary also to compensate the absence of the loved ones. These elements represent a way to concretely and deeply express the ethics of a job well done in nursing.

Keywords: COVID-19, nursing, person centered care, job well done, quality management

INTRODUCTION

The COVID-19 emergency has led many health facilities to reorganize themselves in a very short time to cope with the urgent needs for intensive, semi-intensive or ordinary care of SARS-CoV-2 patients. In this pandemic, characterized by the speed of transmission and severity of respiratory symptoms, patient care has been affected by the pressure of some variables, including the increase in the volume and complexity of patient care, the sudden and unpredictable decrease in staff and the lack of support from family members / caregivers. At the same time, "informal" resources have been activated to treat the highest possible number of patients above the real possibility (1–6).

Recent studies have shown that working experience in emergency situations can have a strong impact on the motivation of the personnel involved. In fact, despite significant efforts, professionals during emergencies show greater resilience, dedication and active cooperation to overcome difficulties and save more lives (3). In many cases, this phenomenon can represent an important lever for change and growth (4). A strong motivation can affect the improvement of performances, and the experience of a health emergency may also have a strong impact on the development of professional and personal skills. Work pressure during an health emergency may push nurses to improve their soft skills, bringing significant collective growth (5) and strengthening their professional identity and value (7). Many of the nurses involved in caring for SARS-CoV-2 patients reported a unique experience in terms of sharing work with other team members and managing new and complex clinical and organizational situations (8, 9). Numerous studies have been carried out to explore the experience of nurses involved in the frontline during the SARS-CoV-2 emergency, but there is still limited literature referring to the possible impact of the pandemic on nurses' motivation, as well as on the development of new skills (9).

MATERIALS AND METHODS

Aims and Objectives

This study aimed to explore the experience of nurses involved in the care of inpatients in a COVID Center of an Italian University Hospital during the first period of pandemic emergency. The main study's objectives were to explore whether and how the pandemic has affected nurses involved in frontline care with a particular focus on professional motivation, on the willingness to care for COVID-19 patients, and in the growth in personal and professional skills.

Research Design

According with the descriptive aims of the study, a qualitative research design was used (10). Focus group technique was selected as data collection method as it allows generating rich information, also and especially thanks to the interaction between the participants, to understand the experience of nurses during the pandemic era with respect to the research questions (11, 12). Indeed, this technique tends to be more advantageous for the early stages of a research study, as in the case of the study conducted, and it allows to collect more information also through observation and interaction between participants.

Another secondary rationale for choosing the focus group technique is that, at the time of the study, the nurses were still very emotionally impacted by their experience in the COVID centers, and it was thought that the opportunity to share their experiences with other colleagues who had had the same experience-rather than face-to-face with the researchers-might help them express their opinions better and more easily.

Setting and Timing

The study was carried out at a 380-beds University Hospital in Rome (Italy), which during the first period of the pandemic had two COVID centers with a total availability of 94 beds for COVID-19 patients, including intensive and semi-intensive areas. The study was conducted in the period between December 2020 and June 2021.

Sampling, Recruitment and Participants

The study participants were nurses who worked in the COVID Centers of the Hospital, they were approached by mail. Purposive sampling was conducted guided by the research questions, in order to obtain the saturation of the topics under study (13, 14). An over recruitment was performed to allow for potential drop out. The initial sample consisted of 20 nurses, 10 from each focus group, but at the time of the study some nurses were unable to participate. It is important to consider that the study was conducted during the pandemic, with all the resulting critical issues related to the need to cover shifts.

Ethics Issues

The study was approved by the General Management of the University Hospital on November 2020 and by the University Ethics Board on December 2020 (Prot. 106.20 OSS ComEt CBM). Participants were informed about the study aims and procedures, and they were asked to sign informed consent for participation in the study before each focus group. Participant personal data were treated as confidential.

Data Collection and Analysis

The focus groups were moderated by two facilitators, one of which was a Research Nurse; she also was the principal investigator of the study and acted as the group leader, as recommended (15, 16). The other researcher worked as co-facilitator ensuring that discussions were tape-recorded and observed participants' non-verbal behavior and group dynamics utilizing a specific observation grid.

Opening instructions were provided before starting each discussion. Both groups developed lively, open and spontaneous discussions, sharing a wide range of personal experiences, feelings and opinions. A multidisciplinary panel, composed of middle managers, nursing coordinators and nurses not involved in the focus groups, defined the topic guide including specific questions to guide the discussion (17) (**Table 1**). A non-directive approach to moderation was adopted. The discussions were tape-recorded and the recordings transcribed verbatim. The two facilitators debriefed immediately after each focus group to share

TABLE 1 | Topic guide.

1	Did your professional and personal motivation and the motivation of your colleagues change during the COVID-19 pandemic? If so, how? If so, what do you think is the reason for the change?
2	What is your experience with respect to the attention at the "person centered care" during the COVID-19 pandemic?
3	Has the experience of the COVID-19 pandemic had an impact on your personal and professional skills? If so, how? If so, why?
4	Can you tell me about your work experience as a nurse in a COVID Center?
5	Can you tell me about the main areas for improvement emerging during the COVID-19 pandemic? Could you tell me what you have learned from this experience?

TABLE 2 | Themes and sub-themes.

N.	Themes	Sub-themes
1	Motivation and sense of mission	Professional identity, professional value and sense of duty Desire to participate in the battle against COVID-19 Voluntary choice Camaraderie and sense of belonging to the professional group
2	Development of professional and personal skills	Teamwork and unity Personal growth and humility New skills acquisition
3	Spirituality, feelings and emotions	Prayer and God Mixed feelings Tiredness and fatigue
4	Person-centered care	Relationship between nurses and patients and patient-centered care Basic care and body care Centrality of professionals and role of hospital management
5	Uniqueness of the lived experience	Indescribable experience and a sense of isolation Inhumane experience for patients and families Like in a war

their observations and to facilitate the recording of important details (18). One of the moderators and another researcher then transcribed and analyzed the data. The transcripts returned to participants for comment and/or correction, and participants provided feedback on the findings. The researchers discussed data saturation. Inductive content analysis of data was used (19). Each focus group transcript was considered as a unit of analysis. The analysis process included: open coding, category creation and abstraction phase. Two researchers independently read the transcripts and defined codes, categories and subcategories. A researcher expert in qualitative analysis confirmed the codes and categories.

RESULTS

Two focus groups were carried out, with a total of nine participants, including eight staff nurses and one nurse manager. Nurses' ages ranged from 28 to 46 years (mean age: 35.4 years; SD: 5.6); seven were female and two male. They worked in different wards before the experience in the COVID Center. Each focus group lasted from 60 to 80 min. None of the nurses had ever participated in a focus group. Participants were pleased to share their experience as front-line nurses in COVID Centers, and they were grateful for this opportunity, seen as an important moment to re-elaborate and reflect on their own lived. The discussions were characterized by empathy, involvement and respect for the experiences and opinions of other participants.

The findings can be summarized in five main categories: motivation and sense of mission; development of professional and personal skills; spirituality, feelings and emotions; person-centered care; uniqueness of the lived experience (**Table 2**).

Theme 1: Motivation and Sense of Mission

Professional Identity, Professional Value and Sense of Duty

Many of the nurses involved expressed a motivation also driven by a strong sense of mission linked to their professional identity, sense of duty and the desire to participate with their own weapons in the battle against COVID: *"The sense of duty has pushed me..." [N3]; "This war is not fought with weapons, the classic ones, it is fought with health care, so as a health worker it seemed normal to me... to offer my availability to try to help" [N3]; "… It's like having been called to enlist" [N3].*

Together with a strong civic sense: *"... when it was proposed to me [to work in the COVID Center], a sense of duty prevailed, with respect of my profession, but also as a citizen and also in front of my children" [N2].* This motivation also led to an explicit identity and professional pride, as a nurse said: *"Oh God, now I'm a nurse, now it's mine … I felt involved and called. [N4]".*

Desire to Participate in the Battle Against COVID-19

Participants unanimously demonstrated a strengthening of professional motivation during the pandemic. For example, a nurse said: *"I was very determined to offer my availability because there was a need for nurses and I am a nurse, I am proud of being nurse and therefore it was right to try to do it." [N3].* This desire to participate has not faded over time: *"In my opinion, motivation has never been lacking … " [N1]*; *"I never thought of giving up." [N8].* Other words that emphasize the strong will that has characterized the nurses: *"One cannot fail to be in this moment." [N4].*

Voluntary Choice

The work of the nurses involved in the COVID Centers was characterized by the freedom of choice. The nurses were called, on a voluntary basis, to work with COVID patients, and the response was immediate: *"Immediately by instinct" [N3]*, *"I immediately decided to get off [in the COVID ward]".* According to some of them: *"… the main motivation was the same that led me, years ago, to make this career choice." [N1]*, representing a confirmation of the professional choice, which is also motivated by the desire to take care of persons. A nurse said: *"I chose a profession that somehow it was oriented to do something for others as well." [N1]*. The issue of determination in the voluntary choice emerges several times by different nurses: *"My request." [N7]*; *"It was my choice." [N2]*; *"Voluntarily ..." [N4]; "I asked to be moved to the COVID ICU." [N8]*; *"I had no doubts, I'm going!" [N3]*. Those who were unable to participate in some moments even felt deprived of this possibility: *"I felt a little deprived of this great opportunity." [N9]; "I resigned [from my previous job] to be able to work in the COVID Center." [N8]*. From the words of the participants it is clear how the motivation remained stable: *"I have never lost motivation." [N1]*, *"I never thought of giving up ..." [N5]*, and even in some cases it seems to have increased: *"Motivation is back." [N1]*. A nurse said: *"If today they asked me 'there is another COVID center to open, there is another moment of pandemic, would you start again?' I would say yes again. It was one of the most professionally stimulating experiences." [N3]*.

Camaraderie and Sense of Belonging to the Professional Group

A common theme noted by all participants was a particular sense of belonging to the professional group and the climate of continuous mutual support, so much that they noted: *"You become a family" [N7]*. These represent some of the main levers of motivation, as some nurses reported: *"We said: - oh thank goodness we come to work! Because we are among us, we are fine, there was a lot of complicity." [N8]; "There was fear but there was also the energy and happiness of being in a good group." [N7]; "The help of the group, because they were really close, they did a great job, together we did it." [N1]*. This sense of belonging also had impact on personal lives of professionals. Nurses report experiencing a sense of belonging and *"That strange feeling of camaraderie ..." [N8]* that made the work environment like a family: *"It wasn't a family, it wasn't a work group, it wasn't... it's something that goes beyond everything." [N3]*. On the other side, a certain difficulty emerged in the relationships outside of work, as a sort of fear of not being included, in contrast to the workplace that becomes the comfort zone, the safe space in which to feel understood, despite the risks linked to the possibility of contagion. As claimed by a nurse: *"... now that you start meeting people who have a role outside... friends, relatives, who have nothing to do with your work, you don't feel comfortable with them ..." [N7]*. Other participants shared: *"The others live it [this situation] just differently." [N7]*; "*Colleagues are the only people who understand you." [N7]; "Instead, your colleagues know what you are facing." [N2]*; *"I only trust you ..." [N1]*. Nurses seem to have more confidence, and feel more comfortable with the people with whom they have shared the COVID period, so much so as to lead a nurse to say: "*But ... you know, maybe I will miss all this." [N8].*

Theme 2: Development of Professional and Personal Skills

The participants considered their experience in the COVID Center as a *"great opportunity to get involved ..." [N8]* as it was lived as *"... a professional and personal growth, first of all." [N3]*. They shared that *"We all came out of there with an important training experience." [N7]* and that *"The whole group has grown a lot." [N5]*. Other representative statements are for instance: *"I really feel like another person." [N6]* and *"An improvement of everything ... everything." [N1].*

Teamwork and Unity

An experience of a great teamwork emerged from the discussions: *"Supporting each other ... for me this was fundamental because not everyone can do everything. But not on a technical level ... on a technical and practical level we are all capable... I mean ... on a personal and emotional level." [N6]*. The support concerns both, the technical-professional field, and the collaboration to address fear, fatigue, weight and difficulties characterizing the work in the COVID Centers.

A nurse said: *"There you reset everything ... and everyone has brought their own contribution." [N1]*. It is worth dwelling on the latter expression; indeed, many nurses found themselves working in new wards and with a type of patients never attended before. Everyone has used their skills to better cope with the emergency, as expressed by a nurse: *"Because we helped each other in everything..." [N4],* an "everything" that goes from monitoring critical patients to managing of death or communication with patients and their family. They worked so that everyone put their skills at the service with the willingness to learn. As they noted: *"There was no one great, neither new, nor old, nor experienced, nor without experience, it was as if we all started from scratch." [N3]*; and also: *"We were all like in our first work experience." [N1].*

Personal Growth and Humility

Some nurses often used the terms *Humbleness* and *Teamwork* to explain the professional experience lived in the COVID Centers. One of them said *"... and humility ... that if sometimes you have forgotten it, here it comes back strongly, and it is crucial as a person and as a professional" [N3];* another *One* stated that it was normal to say: *"Teach me because I don't know how to do it ..." [N3]* or *"Guys, I can't do it with this patient now, come with me or do it for me, because I can't ..." [N6].* A nurse told the experienced atmosphere: *"COVID made us make a single team... we helped each other in everything." [N7]*; *"They were really close to me ..." [N2]*; *"We just couldn't do it alone." [N7]*. A common theme emerging from participants was the great trust established in a very short time among colleagues who did not know each other before or had never worked together, accompanied by a growth in *"... a great self-confidence." [N1].*

New Skills Acquisition

In addition to the specific skills related to the use of Personal Protective Equipment (PPE), participants focused on the growth in advanced skills for critical care, such as: *"... positioning a non-invasive mechanical ventilation ..." [N7]*. A nurse expert in the critical area, who guided less experienced staff, explained that *"At the beginning it was difficult, now they have learned to be quick, to receive instructions, to put them into practice and certainly also to make proposals, to feel part of that department." [N3]*. Participants also reported the growth in problem solving and decision making skills, given the need to find and propose solutions quickly. It was common to "*… make decisions quickly." [N1]* or "*… to manage situations you have never experienced before …" [N2]* as "*You had to face something that no one knew." [N7]*. A nurse said: "*We have learned to be fast". [N1].*

Theme 3: Spirituality, Feelings and Emotions

Prayer and God

Some nurses reported having rediscovered the meaning and the need to pray, as one of them said: *"I think I have never prayed as much as since I'm in the COVID Center." [N6]*, and prayer has been a constant, thanks also to the presence of a Priest completely dedicated to COVID-19 patients and staff.

Mixed Feelings

It turned out that nurses often experienced mixed feelings. In fact, despite the tragic situation, they showed gratitude for the lived experience and for how it was managed: *"We were lucky." [N8]*, *"It was joy… You know that you really did everything you could." [N8]*; *"It was gratifying... Like those who manages to reach the top [of the mountain]." [N2]*; *"We are happy to have succeeded and I thank you for that time there." [N3]*. At the same time, feelings of joy alternate with *"Uncertainty"*, *"Pessimism" [N2]* and *"Sadness" [N5]*, along with fear and anger. Fear is linked above all to the fear of contagion, for oneself but above all for the loved ones: *"You were afraid of having the virus... but the fear was mainly linked to the family." [N1]*; *"I'm afraid... afraid of infecting someone." [N9]*; *"I lived the first few days with fear… fear of being able to infect some relatives." [N5]*, *"Fear to make a mistake … fear of hurting the people around you." [N6]*.

Tiredness and Fatigue

Physical and emotional fatigue linked to the situation and also to the need to work with the PPE emerged from all the participants: *"In my opinion we almost feel a depression." [N8]*; *"It really tested me on a psychological level." [N3]*; *"It's been a terrible month." [N2]*; *"It's no small thing to be in there." [N6]*; *"You can't go to the bathroom, take a shower because you have the anxiety that they call you." [N8]*. Some nurses said that in some moments they would have wanted to escape: *"I couldn't wait to go away…" [N5]* and *"Maybe it's the case that I get out of this place…" [N6]*; *"It takes away a lot of energy." [N4]*; *"You were exhausted." [N9]*. At the same time it emerged that, although nurses could ask to be moved, they did not; some of them stated that: *"The operator hardly says he is tired… it would be a bit like betraying other colleagues." [N4]*.. Fatigue has also often been related to the use of PPE, as reported by some nurses: *"Obviously, fatigue increases because you have to do everything with PPE." [N7]*.; *"You stay... hours inside the PPE… Completely foggy…" [N1]*.

Theme 4: Person-Centered Care

One of the biggest challenges was, on the one hand, the communication between healthcare professionals and patients/family members, on the other hand the commitment to do as much as possible to foster communication between patients and their families, and to accompany the patients in such a difficult moment of their life also characterized by the absence of the affection and closeness of relatives.

Nurses-Patient Relationship and Patient-Centered Care

Despite the complexity of care, nurses rediscovered the importance and effective of some elements and behaviors of caring. Difficulties in the relationship due to the critical clinical conditions of patients, the presence of the PPE, and the absence of relatives, favored the establishment of highly significant relationships with patients in which even small gestures, acts of closeness and listening were rediscovered as an important part of care: *"The patient-centered care was one of the things on which... we worked a lot." [N5]*; *"Patients also needs a chat, a word … a word of comfort." [N1]*; *"We do things that maybe we didn't do before... more care also in terms of appearance... pay attention to these things, to the beard, to fix it... a caress every now and then..." [N7]*; *"A lot, but really a lot of attention …" [N7]*. Some nurses affirmed that they felt like the patient's family: "*The centrality of patients... as far as we operators are concerned, we also act as relatives …" [N9]*, another sums it up as follows: *"So you really put him at the center, in everything... We have put the patient at the center of everything" [N4]*. A nurse remembers the words of a patient: *"Ok, I trust you, you are my wife that I cannot have around." [N6]*. Another said: *"At that moment you are objectively the only person next to them" [N5]*. All of the participants experienced significant care relationships with the patients and the development of a deep feeling of empathy: *"I think that I have never had a relationship like this with patients before …" [N6]*, which also concerned for example: *"giving some extra attention to a person who... maybe needed to be motivated..." [N8]*, *"… [giving] an extra caress every now, when you can, when you can't - almost never - but when you can you do it" [N8]*. On the one hand, it was like rediscovering some patients' needs, such as that of esteem and belonging, which in ordinary conditions of care might remain in the shade. For example, a nurse noted that *"… you are objectively the only person next to them … if the patient asks for help for a video call with his relatives and you can't because of the workload, you realize that a video call for patient is a very important …, that does it matter, and you think: this patient is asking for a video call and I have too much to do to help him!" [N4]*.

Basic Care and Body Care

The nurses said they rediscovered the importance and effectiveness of basic care: *"It becomes important to cut patients' hair or shampoo them, which are things you can't do every day in the ordinary wards... Take a lot of care of patients' hygiene and body care." [N3]*. Speaking about the patients' death, it emerged that *"The moment of death, yes it is hard …" [N6]*, "*You think that relatives will never see it … you see patients terrified … That is one of the particular moments that not everyone [nurses] are able to cope" [N6]*, and "*… an extreme personal care is needed... even in that extreme moment …" [N4]*. Speaking abut the feeling of helplessness associated with seeing patients to die alone, within the team they found the solution to give each dying patient as much as possible in basic care, to better prepare them for the moment of death: *"At a certain point... with my group...*

we talked... and we started a little to anticipate situations. When you know that the situation evolves in that way, then... in the end we hurry more to do things, which can be to wash that person well, take better care of their body, because you know that you have to... 'send them away' like this... the feeling was somehow we lacked the dignity of the person... because the relatives will never see it... but you... you really did everything and... in short, we discussed among us and we found this solution." [N1].

Centrality of Professionals and Role of Hospital Management

The nurses felt protected and cared for by the continuous and timely communications, provided by the hospital management, and by the resources provided to prevent the risk of contagion (PPE, availability of room and board for those who wished, protected paths for hygiene staff after the shift, etc.). Nurses reported that: *"Our hospital has also put us nurses and doctors, in short, all the staff who worked in COVID at the center of attention ... " [N9]*; *"In terms of centrality of person, I did not feel abandoned" [N5]*; *"I don't know how many hospitals have given this opportunity and have treated their staff as we have been treated ... we have been very supported ... nothing has ever been lacking here" [N5]; "There was too much attention for us at the COVID Center." [N1].*

Theme 6: Uniqueness of the Lived Experience

Indescribable Experience and Sense of Isolation

The uniqueness and indescribability of the lived experience was a common experience, together with the feeling of being understood only by those who have lived the same experience: *"Only those who have lived it can know" [N1]*; *"But am I only experiencing all this?" [N1]*. For some participants *"...there were no words to describe..." [N4]* and they experienced the common feeling of *"... managing something bigger than me" [N5]*. The sense of isolation also emerges, also described as *"... giving up a bit of normal life..."*, because *"You could not see friends, you avoided the family for fear..." [N8]*; *"...you avoid going to lunch, dinner, sharing your free time with others" [N2]*.

Inhumane Experience for Patients and Families

One of the themes perceived as more terrible and inhumane of the experience in the COVID Centers was seeing patients dying without the possibility of seeing family members, as a nurse shared: *"The fact of [absence of] the relatives, in my opinion, is against nature... because you think it is inhuman... It is not human for the patient and for those who stay at home waiting for the phone call once a day... It is not human that a daughter, a wife, cannot assist her husband, father or cannot see him for weeks or months" [N8].* Another nurse stated that *"The lack of a relative is devastating for them" [N6]*, and it was moving to know that family members *"recorded the phone call to listen to it again to understand better." [N8].*

Like in a War

Participants expressed a shared idea, which was like experiencing a war: *"A feeling like being in a war" [N3]*. At the same time some nurses said that the experience was so unique that this war will probably miss them: *"Like the soldiers after the war, who are depressed because in the end they miss some of the war." [N8].*

DISCUSSION

This study aimed to explore the experience of nurses involved on the front line during the first period of pandemic. The main objective of the study was to explore whether and how caring for COVID patients had impacted nurses with a particular focus on professional motivation and the development of professional and personal skills. However, other important issues have emerged that are worth of discussion. The main themes found are: professional identity; motivation and sense of mission; development of professional and personal skills; spirituality, feelings and emotions; person-centered care; uniqueness of the lived experience. They shed new light on the correlation between motivation, professional identity, professional value, sense of duty and sense of belonging to the professional group; at the same time the experience on the front line in the COVID Centers represented a valuable opportunity for all the participants to rediscover specific aspects of nursing professional identity and to develop personal and technical-professional skills in a very short time.

A recent study (20) correlated the motivation of nurses engaged in the COVID emergency to the sense of duty and their career choice, and it reported how the pandemic has strengthened professional value. Nurses felt called into question, it was their moment, a mission for them, and they responded with courage, sense of responsibility and great sense of freedom, a freedom that is the ability to choose the good (21). Attention to emerging needs and the desire to contribute to the common good characterized the choice of nurses, which was immediate and voluntary. In line with other recent studies (9), the COVID experience made it possible to create strong and close-knit teams in a short time, and this had repercussions on professional motivation, and on the ability to deal with difficult situations, new work environments and need to learn advanced skills in a short time.

At the same time, the sense of belonging to the professional group, experienced as camaraderie, led nurses to a sort of self-isolation, whereby the reality in which they felt comfortable was precisely the workplace that became like his own family (22, 23). Nurses experienced the desire to be with their colleagues, by whom they felt understood, more than with relatives and friends outside the workplace.

Working conditions and the characteristics of the workplace strongly influence motivation (24). The sense of belonging to a team, a good working climate and support from colleagues have constituted a motivational drive to start the 'adventure' in the COVID Center, and also to stay there as long as necessary (25). Nurses' professional motivation is therefore the result of the interaction between individuals, the workplace and the social context (26), and is above all intrinsic, an internal force that influences the person's behavior (27); in fact, none of the professionals related his motivation to external factors.

Nurses' experience with regard to the development of personal and technical-professional skills is very interesting. One of main findings is the great teamwork and the climate of union and continuous collaboration between everyone, regardless of the role held. Most nurses found themselves working in a new field and with colleagues they did not know, or with whom they had never worked before. It would be a great result to be able to bring back the lessons learned on teamwork within the COVID Centers even in ordinary care contexts. More experienced nurses joined less experienced ones; nurses with many years of experience were guided by younger nurses to learn how to manage critical patients. Everyone experienced and talked about humility and trust as virtues rediscovered and much appreciated through this experience.

Already the Framework of Disaster Nursing Competencies (28) highlighted the role that teamwork has in patient care in an emergency setting. Catania (29) in his study also highlighted the advantages of a good teamwork on the quality of care and on the well-being and mutual support of the staff involved on the front line. The study also confirms a growth in learning of skills such as problem solving and decision making, typical in situations of urgency and emergency. Consistent with recent studies (3, 5, 30, 31), the findings highlights that work-related factors impact positively on the development of fatigue, physical and psychological stress of nurses, often related to the use of PPE and to the increased workload. At the same time, the experience of conflicting and coexisting feelings emerges. In fact, despite the tragic situation, the nurses showed gratitude for the lived experience and for how it was managed, saying that "*… maybe we will miss all of this …* ". At the same time they experienced fear, anger and helplessness. In particular, similar to the findings of a recent studies (8, 32) fear among nurses has been mainly related and aggravated by being a possible carrier for family members.

An important result is the re-discovery by the nurses of the importance of some attitudes and behaviors which are essential part of caring, but which are sometimes overshadowed in ordinary care. In fact, the increasing difficulties in the relationship linked to the critical conditions of patients, the presence of the PPE, and the absence of family members, has led nurses to devote more time to relationships with patients. Small gestures, closeness, support in a video call, body care and listening have become an irreplaceable part of caring and have been rediscovered as such in all their value (33, 34); or to give more support than usual to other healthcare professionals, for example in communicating with a frail patient or his family, to obtain valid informed consent (35, 36). Nurses discovered in careful basic and body care the best way to provide dying patients all the necessary attention, and to be able to make up for the absence of loved ones as much as possible. At the same time, these attitudes have been a way for nurses to overcome the sense of helplessness experienced in numerous critical situations. Consistent with previous studies (8) our findings reported worries among nurses related to care provision. Sadness and worries are mainly attributed to witnessing patients' suffering and to the absence of their family (3, 32). Indeed, witnessing patients' sufferings, especially the end of a patient' life is one of the main sources of psychological pressure among nurses (37). In particular, during the pandemic, the absence of family of dying patients lead nurses to live this experience as 'inhuman'. Being able to be cared for by those one loves is part of the dignity of the human person, and the nurses on the front line tried to take the place of the patients' families to give them the affection and dignity that every person deserves. For this reason it is important to promote the creation of systems and technologies that allow the family members to keep contact with the patients (38). Moreover, nurses can feel guilty because they can provide only limited care compared to usual care, for example due to the time required to wear PPE before contact with patients. These negative consequences can be associated with burnout, compassion fatigue and reduced well-being of nurses (39, 40). Improving psychological resilience is essential to cope with these issues (41, 42), and psychological counseling for nurses is recommended (32). Nurses' experience showed the key role of the hospital management in the protection and care of health workers, placing them at the center of the numerous and not easy decisions and policies taken during a pandemic (8).

Some limitations of our study should be acknowledged. Although generalizability is not a goal for qualitative studies, this was a single-center study conducted with a small number of participants who may not be representative of all nurses who worked in the COVID Centers during the COVID-19 pandemic.

CONCLUSIONS

This qualitative study sheds new light on the experience of frontline nurses during the first period of SARS-CoV-2 pandemic. The findings are relevant for governments, managers, policy makers, nursing associations and healthcare organizations, in order to achieve continuous improvement in quality of patient care and in well-being and satisfaction of health professionals, even in ordinary situations.

The results underline the key role played by the work environment and by the group of colleagues in motivating and coping with physical and psychological fatigue due to care for patients in the COVID Centers (43). An effective support network includes the accompaniment, support and protection received by management, peers and co-workers in finding internal and external resources *"to take care of those who take care"*. An interesting relationship emerges between professional identity, sense of justice, basic care and professional well-being, and the importance of these elements for the delivering of excellent and effective care. Nurses rediscovered in careful body care and basic care-also and above all in critical area setting-an irreplaceable asset to restore dignity and to give the necessary closeness and attention to the often dying patient, also filling the absence of their familiars. These elements represent a way to concretely and deeply express the ethics of a Job Well Done. The study highlights how the need for esteem and belonging are essential elements of care, and that only love and benevolence are suitable and valid attitudes toward each person. For this reason, there is the need to actively engage new research, strategies and innovative technological tools, so that, even in situations similar to that experienced during the COVID-19 pandemic, a relationship can be maintained between patients and their loved ones.

Starting from the emerging findings, further studies are needed to deepen the main themes found involving a larger sample of nurses. In addition, performing a second study post-pandemic, and with a greater emotional distance from such a powerful experience, might lead to additional and novel findings.

Future research is needed more than ever to prepare healthcare for the future in similar situations, and a person-centered approach guided by an ethics of a Job Well Done will be the key to success.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary materials, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

ADB: study design, writing, data curation, and analysis. RG and CP: revision. SS, AM, GF, AP, CD, and ID: data curation and analysis. MP: data curation, analysis and writing revision. FD, RA, and DT: conceptualization. All authors contributed to the article and approved the submitted version.

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REFERENCES

1. Hoogendoorn ME, Brinkman S, Bosman RJ, Haringman J, de Keizer NF, Spijkstra JJ. The impact of COVID-19 on nursing workload and planning of nursing staff on the intensive care: a prospective descriptive multicenter study. *Int J Nurs Stud.* (2021) 21:104005. doi: 10.1016/j.ijnurstu.2021.104005
2. World Health Organisation. Coronavirus desease (COVID-19) (2022). Available online at: https://www.who.int/health-topics/coronavirus#tab=tab_1 (accessed March 10, 2022).
3. Liu Q, Luo D, Haase JE, Guo Q, Wang XQ, Liu S, et al. The experiences of health-care providers during the COVID-19 crisis in China: a qualitative study. *Lancet Glob Health*. (2020) 8:e790–8. doi: 10.1016/S2214-109X(20)30204-7
4. Eftekhar Ardebili M, Naserbakht M, Bernstein C, Alazmani-Noodeh F, Hakimi H, Ranjbar H. Healthcare providers experience of working during the COVID-19 pandemic: a qualitative study. *Am J Infect Control.* (2020) 1−8. doi: 10.1016/j.ajic.2020.10.001
5. Sun N, Shi S, Jiao D, Song R, Ma L, Wang H, et al. A qualitative study on the psychological experience of caregivers of COVID-19 patients. *Am J Infect Control.* (2020) 48:592–8. doi: 10.1016/j.ajic.2020.03.018
6. Gualandi R and De Benedictis A. Taking advantage of coronavirus disease 2019 (COVID-19) to improve hospital models of care: are we moving in the right direction? *Infect Control Hosp Epid.* (2021) 1−2. doi: 10.1017/ice.2021.210
7. He Q, Li T, Su Y, Luan Y. Instructive messages and lessons from chinese countermarching nurses of caring for COVID-19 patients: a qualitative study. *J Transcult Nurs.* (2020) 32:96–102. doi: 10.1177/1043659620950447
8. Rathnayake S, Dasanayake D, Maithreepala SD, Ekanayake R, Basnayake PL. Nurses' perspectives of taking care of patients with coronavirus desease 2019: a phenomenological study. *PLoS ONE.* (2021) 16:e0257064. doi: 10.1371/journal.pone.0257064
9. Fernandez R, Lord H, Halcomb E, Moxham L, Middleton R, Alananzeh I, et al. Implications for COVID-19: a systematic review of nurses' experiences of working in acute care hospital settings during a respiratory pandemic. *Int J Nurs Stud*. (2020) 111. doi: 10.1016/j.ijnurstu.2020.103637
10. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care.* (2007) 19:349–57. doi: 10.1093/intqhc/mzm042
11. Merton RK, Marjorie Fiske, Kendall PL. *The Focused Interview*. London: The Free Press (1956).
12. Morgan D. *Focus Group as Qualitative Research*. London: Sage Publications (1988).
13. Bryman A. *Social Research Methods*. Oxford: Oxford University Press (2001).
14. Patton MQ. *Qualitative Research and Evaluation Methods, 3rd edn*. Thousand Oaks, CA: Sage (2002).
15. Asbury JE. Overview of focus group research. *Qual Health Res.* (1995) 5:414–20. doi: 10.1177/104973239500500402
16. Robinson N. The use of focus group methodology—with selected examples from sexual health research. *J Adv Nurs.* (1999) 29:905–13. doi: 10.1046/j.1365-2648.1999.00966.x
17. Arthur S and Nazroo J. Designing fieldwork strategies and materials. In: Ritchie J, Lewis J, editors. *Qualitative Research Practice*. London: Sage. p. 109–37.
18. Carey MA. Comment: concerns in the analysis of focus group data. *Qual Health Res.* (1995) 5:487–95. doi: 10.1177/104973239500500409
19. Elo S and Kyngäs H. The qualitative content analysis process. *J Adv Nurs 62.* (2008) 107–15. doi: 10.1111/j.1365-2648.2007.04569.x
20. Ji E-J. New nurses' experience of caring for COVID-19 patients in South Korea. *Int J Environ Res Public Health.* (2021) 18:9471. doi: 10.3390/ijerph18189471
21. LoGiudice JA and Bartos S. Experiences of nurses during the COVID-19 pandemic: a mixed-methods study. *AACN Adv Crit Care.* (2021) 32:14–25. doi: 10.4037/aacnacc2021816
22. Kim Y. Nurses' experiences of care for patients with Middle East respiratory syndrome-coronavirus in South Korea. *Am J Infect Control.* (2018) 46:781–7. doi: 10.1016/j.ajic.2018.01.012
23. Villar RC, Nashwan AJ, Mathew RG, Mohamed AS, Munirathinam S, Abujaber AA, et al. The lived experiences of frontline nurses during the coronavirus disease 2019 (COVID-19) pandemic in Qatar: a qualitative study. *Nurs Open.* (2021) 8:3516–26. doi: 10.1002/nop2.901
24. Zaghini F, Fiorini J, Piredda M, Fida R, Sili A. The relationship between nurse managers' leadership style and patients' perception of the quality of the care provided by nurses: cross sectional survey. *Int J Nurs Stud.* (2020) 101:103446. doi: 10.1016/j.ijnurstu.2019.103446
25. Lee N and Lee H. South Korean nurses' experiences with patient care at a COVID-19-designated hospital: growth after the frontline battle against an infectious disease pandemic. *Int J Environ Res Public Health.* (2020) 17:9015. doi: 10.3390/ijerph17239015
26. Franco LM, Bennett S, Kanfer R. Health sector reform and public sector health worker motivation: a conceptual framework. *Soc Sci Med.* (2002) 54:1255–66. doi: 10.1016/S0277-9536(01)00094-6
27. Marquis BL and Huston CJ. *Leadership Rules and Management Functions in Nursing: Theory and Application*. Philadelphia, PA: Lippincott Williams and Wilkins (2012).
28. International Council of Nurses. *Core Competencies in Disaster Nursing. Version 2.0*. Geneva, Switzerland (2019). Available online at: https://www.icn.ch/sites/default/files/inline-files/ICN_Disaster-Comp-Report_WEB.pdf (accessed March 10, 2022).
29. Catania G, Zanini M, Hayter M, Timmins F, Dasso N, Ottonello G, et al. Lessons from Italian front-line nurses' experiences during the COVID-19 pandemic: a qualitative descriptive study. *J Nurs Manag.* (2021) 29:404–11. doi: 10.1111/jonm.13194
30. Yin X and Zeng L. A study on the psychological needs of nurses caring for patients with coronavirus disease 2019 from the perspective of the existence, relatedness, and growth theory. *Int J Nurs Sci.* (2020). doi: 10.1016/j.ijnss.2020.04.002
31. World Health Organisation. WHO calls for healthy, safe and decent working conditions for all health workers, amidst COVID-19 pandemic (2020). Available online at: https://www.who.int/news/item/28-04-2020-who-calls-

for-healthy-safe-and-decent-working-conditions-for-all-health-workers-amidst-covid-19-pandemic (accessed March 10, 2022).
32. Galedar N, Toulabi T, Kamran A, Heydari H. Exploring nurses' perception of taking care of patients with coronavirus disease (COVID-19): a qualitative study. *Nursing Open*. (2020) 19:119. doi: 10.1186/s12912-020-00516-9
33. Marchetti A, Piredda M, De Marinis MG. Centrality of body and embodiment in nursing care: a scoping study of Italian literature. *J Nurs Scholarship*. (2016) 48:31–8. doi: 10.1111/jnu.12178
34. Marchetti A, Piredda M, Facchinetti G, Virgolesi M, Garrino L, Dimonte V, et al. Nurses' experience of body nursing care: a qualitative study. *Holist Nurs Pract*. (2019) 33:80–9. doi: 10.1097/HNP.0000000000000314
35. Cannovo N, Scendoni R, Fede MM, Siotto F, Fedeli P, Cingolani M. Nursing home and vaccination consent: the Italian perspective. *Vaccines*. (2021) 9:429. doi: 10.3390/vaccines9050429
36. Cuthbert R, Ferguson D, Kayani B, Haque S, Ali A, Parkar A, et al. Evidence-based approach to providing informed consent for hip fracture surgery during the COVID-19 era. *World J Orthop*. (2021) 12:386–94. doi: 10.5312/wjo.v12.i6.386
37. Huang L, Lei W, Xu F, Liu H, Yu L. Emotional responses and coping strategies in nurses and nursing students during Covid-19 outbreak: a comparative study. *PLoS ONE*. (2020) 15:e0237303. doi: 10.1371/journal.pone.0237303
38. Gualandi R, De Benedictis A, De Marinis MG, Tartaglini D. Managing the journey of patients under chemotherapy in a pandemic era: a nursing perspective. *Chemotherapy*. (2020) 65:115–8. doi: 10.1159/000513140
39. Duarte J and Pinto-Gouveia J. Empathy and feelings of guilt experienced by nurses: a cross-sectional study of their role in burnout and compassion fatigue symptoms. *Appl Nurs Res*. (2017) 35:42–7. doi: 10.1016/j.apnr.2017.02.006
40. Karimi Z, Fereidouni Z, Behnammoghadam M, Alimohammadi N, Mousavizadeh A, Salehi T, et al. The lived experience of nurses caring for patients with COVID-19 in Iran: a phenomenological study. *Risk Manag Healthc Policy*. (2020) 13:1271–8. doi: 10.2147/RMHP.S258785
41. Maben J and Bridges J. Covid-19: supporting nurses' psychological and mental health. *J Clin Nurs*. (2020) 29:2742–50. doi: 10.1111/jocn.15307
42. Duncan DL. What the COVID-19 pandemic tells us about the need to develop resilience in the nursing workforce. *Nursing Management*. (2020) 27:22–7. doi: 10.7748/nm.2020.e1933
43. Jang Y, You M, Lee S, Lee W. Factors associated with the work intention of hospital workers' in South Korea during the early stages of the COVID-19 outbreak. *Disaster Med Public Health Prep*. (2021) 15:e23–30. doi: 10.1017/dmp.2020.221

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From COVID-19 Pandemic to Patient Safety: A New "Spring" for Telemedicine or a Boomerang Effect?

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During the Covid-19 health emergency, telemedicine was an essential asset through which health systems strengthened their response during the critical phase of the pandemic. According to the post-pandemic economic reform plans of many countries, telemedicine will not be limited to a tool for responding to an emergency condition but it will become a structural resource that will contribute to the reorganization of Healthcare Systems and enable the transfer of part of health care from the hospital to the home-based care. However, scientific evidences have shown that health care delivered through telemedicine can be burdened by numerous ethical and legal issues. Although there is an emerging discussion on patient safety issues related to the use of telemedicine, there is a lack of reseraches specifically designed to investigate patient safety. On the contrary, it would be necessary to determine standards and specific application rules in order to ensure safety. This paper examines the telemedicine-risk profiles and proposes a position statement for clinical risk management to support continuous improvement in the safety of health care delivered through telemedicine.

Keywords: telemedicine, Healthcare risk Management, patient safety, quality of care (QoC), systemic clinical risk management, clinical governance (CG), Ethics of Job Well Done

INTRODUCTION

Telemedicine enables medical care in situations where distance is a critical factor by using information and communication technologies (ICT) to exchange information for the diagnosis, treatment and prevention of disease and trauma, for research and evaluation and for the continuing education of health professionals in the interests of individual and community health (1).

Compared with traditional health care, telemedicine may represent (a) a diagnostic and/or therapeutic alternative, (b) a supportive health care activity that increases efficiency and distributive equity, (c) an integrative health care intervention, (d) a health care activity able to completely replace the usual health care intervention (2).

Prior to the pandemic, telemedicine was adopted by Health Systems in various regions/countries, although in different and uneven ways (3) and it was supported by legislation and policy documents (4–7).

However, the Covid-19 health emergency greatly increased the use of telemedicine both to provide health care to Covid-19 patients with mild symptoms and to ensure that diagnostic and therapeutic health care activities were carried out while respecting the physical distance between people (8–10). For this reason, the World Health Organization (WHO) and the Organization for Economic Co-operation and Development (OECD) considered telemedicine an essential asset through which health systems strengthened their response during the critical phase of pandemic management (11, 12). In the near future, telemedicine will not only be a tool for responding to an emergency situation. Telemedicine will become a structural tool for Healthcare Systems to provide diagnostic and therapeutic services, also thanks to integration with robotics and artificial intelligence (13).

The ambitious EU4Health 2021–2027 investment programme promoted activities to enhance telemedicine and supported optimal use of telemedicine (14). Telemedicine is a cornerstone for strengthening health care and improving standards of treatment for citizens in the reform and investment plans presented by Italy, Germany and France to access Next Generation EU funds (15–17).

In the United States, the Telehealth Extension and Evaluation Act will establish an extension of telemedicine services by ensuring a thorough evaluation of these services prior to future permanent action (18).

Telemedicine can therefore contribute to a reorganization of Healthcare Services, allowing the shift of health care from the hospital to the home-based care, through innovative citizen-centered care models and facilitating access to Health Services. Therefore, telemedicine is a great resource that makes possible new approaches to care and new ways of continuity of care between hospital and home-based care (19, 20).

However, the spread of telemedicine presents Health Systems around the world with new challenges, one of the most important being patient safety. The use of digital technologies can expand risk factors.

Healthcare Risk Management is defined by the clinical and administrative activities performed to identify, assess and reduce the risk of injury to patients, staff and visitors and the risk of loss to the organization itself (21).

The aim of Clinical Risk Management (CRM) is to improve the quality and safety of health care activities by identifying and preventing conditions that could put a patient at risk of an adverse event (22).

Concerning telemedicine: have clinical risk control models been established with the aim of preventing the occurrence of an adverse event or error and limiting its consequences? Have training programmes for health workers, patients, formal caregivers and family members on risk management been set up? Has an incident reporting system been established? Have systems been established to measure risks, adverse events and all factors affecting risk?

It was pointed out that telemedicine is burdened by numerous ethical and legal issues, and that standards and specific guidelines for its application should be drawn up (23).

A literature review conducted to identify patient safety risks associated with the use of telemedicine showed that although there is an emerging discussion of patient safety issues related to the use of telemedicine, there is a lack of researches specifically designed to investigate patient safety (24).

However, evidence suggests that attention to patient safety should be an important feature to ensure integrity in the design, implementation and operation of telemedicine services (25). This topic is eminent while "digital therapies" and "digital trials" are now proposed and accepted, even by regulatory agencies.

Existing global documents frame telemedicine as part of the process of computerization and digitalization of the health system, but they do not provide a comprehensive and up-to-date framework for the new needs that have emerged. However, the definition of evidence-based eHealth standards and rules is required to ensure safety (26).

In a changing healthcare scenario characterized by the expansion of healthcare technology, hospitals are developing proactive Clinical Risk Management plans based on a much broader perspective of the entire healthcare ecosystem (27). In fact, according to the American Society for Healthcare Risk Management (ASHRM), Clinical Risk Management encompasses eight risk domains: operational, clinical and patient safety, strategic, financial, human capital, legal and regulatory, technological, environmental and infrastructure (28).

An efficient clinical risk management ensures effective planning, high standards of performance, efficient and effective resource allocation, improved competitive capacity and organizational innovation.

Like any free and responsible human act, health risk management has an intrinsic ethical value (29). Therefore, clinical risk management activities should protect healthcare organizations by fulfilling their mission, i.e., promoting and protecting the health of patients (30). The health risk management professional is responsible for helping to promote the overall quality of life, dignity, safety, and wellbeing of every individual in need of health services (31).

After analyzing the risk profiles related to the use of telemedicine, this paper aims to propose an ethical-based position paper for clinical risk management to support continuous improvement of safety in telemedicine.

TELEMEDICINE RISK-RELATED

In healthcare institutions, recognition of the full spectrum of activities performed by clinical and non-clinical staff has allowed the development of standards to improve activities and reduce the risks associated with process variability (21).

Risk assessment in telemedicine requires consideration of the professional and non-professional stakeholders involved in the process of care, as well as the particular setting in which the health care takes place. Patient safety in home-based care is related to the variables

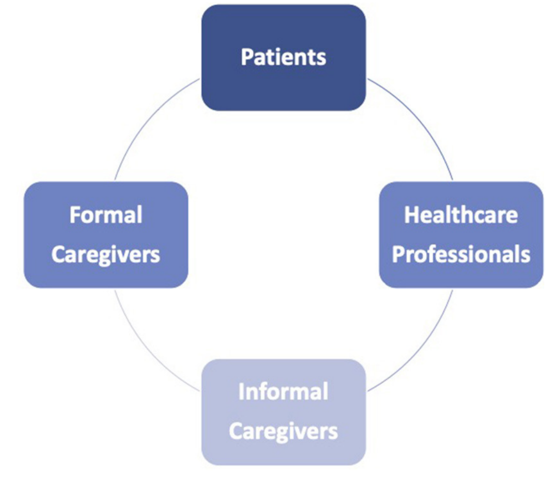

FIGURE 1 | Relationships between patients, professional and non-professional stakeholders in telemedicine health care provision.

of the relationships between patients, healthcare workers (HWs), informal and formal caregivers (24, 32) (**Figure 1**).

HUMAN FACTORS

"To err is human" (33). Considering the operational framework of medical care in telemedicine it is evident that, as in hospital care, a first source of potential risk for patient safety is the human factor. Such is the relevance of the human factor that Human Factors and Ergonomics (HFE) is recognized by the leadership of health care institutions as a scientific discipline capable of producing knowledge to redesign Healthcare Systems and processes and improve patient safety and quality of care (34).

In telemedicine, therefore, some adverse events are entirely comparable to those that occur in any health care organization, such as deaths or injuries resulting from incorrect drug therapy or deaths or injuries due to the patient falling down. Compared to hospital care there is a significant difference. Unlike health care personnel, informal caregivers are not bound by standards and can make non-evidence-based decisions (35). However, "the conscientious, explicit and judicious use of the best current evidence in making decisions about the care of individual patients" is the main paradigm on which health care is based (36) and improving evidence-based practice is also one of the main goals for improving patient safety (37).

Therefore, the systematic inclusion in the health care process of caregivers who are not constrained by guidelines or standards of good clinical practice may significantly increase the risk level of telemedicine. Caregivers often cannot give accurate information because of miscommunication, misunderstandings or poor memory (38) and have been identified as contributors to several adverse events (39). Canadian retrospective study shows that caregivers of home care patients contribute to 20.4% of adverse events (40).

Fortunately, telemedicine itself could mitigate this "health care bias." An intelligent telecare system could monitor whether caregivers are on time for scheduled visits, monitor their response time, whether they respond to a traditional alarm call, how long they stay for each visit, the total number of visits and the type of care provided at each visit (32). Monitoring the type and timeliness of care provided through telemedicine has a limitation because it is a quantitative assessment and cannot offer any information on "the application of medical science and technology in a manner that maximizes its benefit to health without correspondingly increasing the risk" (41). A "telemedicine-tailored" organization, a modified staff management and the identification of specific competences and responsibilities may contribute to a further attenuation of caregiver-related risks. Patient safety in telemedicine could be implemented by research and application of health care work system models such as SEIPS (34, 42), the patient-centered medical home model (43) or the work system of the patient-centered medical home (44).

Assessing the human factors issues in telemedicine is a challenge that must be taken up decisively in order to develop telemedicine-specific risk management strategies to both prevent avoidable errors and contain their possible harmful effects.

PATIENT-PHYSICIAN RELATIONSHIPS

A second potential patient safety risk concerns the physician-patient relationship.

The impact of verbal and non-verbal communication in building an empathic relationship in the processes of diagnosis, treatment and rehabilitation has been proven (45–47). Above all, communication errors are the cause of the vast majority of unexpected adverse events in patients (48).

For this reason, improving the effectiveness of communication is one of the International Patient Safety Goals (IPSG) developed by Joint Commission International (JCI) (49). Communication plays a key-role in the etiology, exacerbation and reduction of adverse events in health care.

However, digital technologies in health care could depersonalize and negatively influence the healthcare relationship (45, 50, 51), leading to poor communication and limited data transmission which can expose the patient to a clinical risk in many situations (52).

It has been shown that during a telemedicine health care service compared to an in-person health care provision, patients are more likely to ask for repeat information (53), receive less information and the specialist physician interacts more with the primary care provider (54).

These studies show some important critical issues in the physician-patient relationship during a telemedicine health care provision. However, a potential cause of risk to patient safety is that we do not currently fully understand the nature and content of the communication process (55).

Even if the matter is largely unexplored (56), a clinical risk assessment and management in telemedicine cannot disregard the high number of adverse events, or near misses, which occur due to poor or insufficient communication and which may concern both communication between HWs (internal communication) and communication between HWs and the patient or his/her caregivers (external communication) (57).

On the contrary, no matter how a health care provision is made, effective, timely, targeted, comprehensive, unambiguous and easily understood communication is mandated to reduce errors and improve patient safety.

In this regard, the World Medical Association (WMA) has recommended that telemedicine should be limited to situations where a physician cannot be physically present within a safe and acceptable period of time, or it should be used in the management of chronic conditions or in follow-up after initial treatment, if its safety and effectiveness have been demonstrated (58).

Therefore, in a priority area for the application of telemedicine models for promoting continuity of care such as the follow-up of chronic diseases, adequate physician-patient interaction is required, giving consideration to how information can be stored and accessed for future episodes of treatment in line with patients' preferences (or the decisions of their relatives or caregivers) and how the information will be transmitted to the patient's general practitioner or other physicians caring for the patient (59). It is therefore essential to identify the Primary Care Physician (PCP) as the physician responsible for the treatment and coordination of the patient with the remote medical team (58). The role of healthcare professional in the web-based interrelationship, besides a specific training and certification of knowledge, should be properly defined to assure the correct and appropriate connection, considering also the present possible modifications of professional involvement, generally named "task shifting," owing to even decrease of medical doctors, especially in some Countries and in same specialties (60).

Given that communication between doctors and patients is fundamental for patient safety, continuous, effective and high-quality communication must be guaranteed in telemedicine (61) considering not only the doctor-patient interaction but also the participation in the care process of formal and informal caregivers.

INFORMED CONSENT

Related to the different configuration of the physician-patient relationship and to the critical communication and information issues, a third source of potential risk to patient safety concerns the lack of protection of the patient's right to autonomy, which is expressed mainly through informed consent (62). Informed consent is an essential feature of patient-centered health care and remains central to patient safety (63).

Information and consent in telemedicine, in addition to guaranteeing the rights and duties provided for any health care treatment, should also consider the specific risks of providing healthcare using ICTs (64).

Indeed, if it is fair to say that consent to health care treatment is particularly crucial for "high risk" procedures, it is also fair to say that the use of ICTs or the "distance factor" may push routine health care treatments into a higher risk category. An incorrect or delayed diagnosis due to errors in the transmission of health documentation (medical records, X-rays and medical device printouts) or an inaccurate assessment of the patient's condition due to an incomplete physical examination because of the "distance factor" are just a few examples of adverse events in telemedicine (65).

In addition, the involvement of relatives and caregivers may be necessary in the management of disabling or chronic illnesses. This is a far from remote event, given that public health policies have generally identified telemedicine as a target for development because of its potential to treat and manage patients with chronic diseases at their homes rather than in hospital.

It is therefore necessary for the physician to customize the informed consent procedure to provide patients and their caregivers with the necessary information on the distinctive features of telemedicine (58, 59).

The information should include how the confidentiality of personal data is protected, how patient personal data are documented and stored, how medications are prescribed, how to interact with other medical specialists, procedures for activating an emergency plan, conditions under which the telemedicine health care may be interrupted and the patient referred to in-person health care, potential technical failures, etc. (66). At the same time, patients and their caregivers should be aware of the potential, limitations and modalities of telemedicine and what is expected of patients when using these technologies (58, 59).

Nevertheless, it should be considered that the patient's decision-making autonomy might be compromised when choice is limited by access or pressures from family and community (51) and also the limitations of electronic informed consent especially for that target population with insufficient IT background or low trust toward health technologies (67).

Lack of or insufficient informed consent is an important source of medical malpractice cases (68). In the near future, an increasingly large population will be treated through telemedicine, so Clinical Risk Managers in healthcare organizations should seriously consider the critical issues related to inadequate information and uninformed consent from the perspective of both patient safety and medical malpractice.

PATIENT IDENTIFICATION

A fourth potential risk to patient safety concerns patient misidentification.

Patient identification is a crucial step in ensuring the safety of treatment and healthcare, both because it is necessary to reliably identify the person receiving the healthcare service and to verify that the healthcare provided corresponds to that individual patient (49).

Currently, most telemedicine does not allow for strong and compliant verification of patient identity (69) and it is also possible for identity theft to occur (70).

Thus, critical issues in patient identification may have important implications not only on patient safety but may also offer new fraud activities with negative economic and trust repercussions for National health systems.

In addition, patient misidentification may have as a direct consequence the transmission of sensitive data to third parties and the violation of privacy. Protection of privacy, access to data, interoperability and quality of recorded data have ethical, legal and social implications in telemedicine with major implications (45, 50, 51).

For this reason, it is necessary to ensure that personal data obtained during a telemedicine consultation must be protected by appropriate security measures and the electronic transmission of information must be safeguarded against unauthorized access (58).

However, there is a lack of standardization regarding security in telemedicine, and much research does not consider the possibility of having to diversify data security systems according to the type of population targeted by the telemedicine service. For example, a data integrity security system may be efficient in an elderly population but may fail in cognitively impaired adults (71).

One thing is certain, trust in telemedicine could be undermined if the risks to patient privacy and safety are not seriously addressed (72). Such concerns are much more urgent considering a significant growth in cybercrime attacks, during the pandemic time for Covid 19, especially against healthcare facilities (73).

STRUCTURAL AND TECHNOLOGICAL FACTORS

In healthcare, to define the level of risk, it is also necessary to consider the safety and logistics of environments, the operation, maintenance and renewal of equipment and instruments and the critical issues of infrastructure, networks, digitalization and automation. In this scenario, particular attention should also be paid to the assessment, introduction and use of equipment and technology on the patient by non-specifically trained staff (74).

The development and implementation of ICT are creating new and different ways of doing medicine (58). Regarding patient safety, already at the beginning of the 21st century, the Institute of Medicine (IOM) argued that the use of medical technology by non-HWs would become increasingly important as healthcare shifted to the outpatient and home setting (33).

Therefore, we can consider structural and technological factors as the fifth potential risk to patient safety.

The development process and performance of these devices are influenced by an infinite number of variables that are not always considered and whose effects are not always predicted (75).

A review of the risks to patient safety in telemedicine showed that the main critical issues relate to the poor technical quality of the systems, poor usability of the technology, poor reliability, changes in staff workload and changes associated with staff roles and responsibilities (24).

Poor usability of medical devices in particular is recognized as a major issue for patient health (76) and it is related to adverse events, patient injuries and readmission to hospital (77). Collaboration between physicians and experts in Human Factors and Ergonomics (HFE) is desirable for the design of medical devices to benefit not only patients but also HWs, formal and informal caregivers. However, at present, unfortunately there is no methodological uniformity among studies on the usability of medical devices because often the rapid and continuous evolution of medical devices exceeds the development goals covered by rules and standards (75).

To correct for poor reliability, a telecare system should be flexible enough to automatically detect fault conditions, notify the patient and the local intelligence unit of fault conditions, and be fail-safe (32).

Remote monitoring is an additional tool for implementing reliability in telemedicine. Evidence supported the benefits of remote monitoring in reducing hospitalization/re-hospitalization, improving patient drug compliance and improving health outcomes (66), and also during pre-hospitalization, i.e., preparatory procedures before hospital medical or surgical treatment, and after discharge, particularly for collecting Patient reported Outcome Measurements, which are now entering in the standardized evaluation of follow-up of the patient, to measure the improvement of quality of life linked to the medical treatment (78). The digital medicine should really improve the patient journey, decreasing economical and social costs of patient transfers, clearly evident and increasing in modern medicine, owing to centralization of some specialized treatments and technology.

Incident Reporting Systems (IRS) are a cornerstone of patient safety improvement (79). However, a recent review showed that patient safety initiatives in Health Information Technology (HIT) mainly concern software. Instead, more standardization and supervision is needed to ensure security throughout the lifecycle and initiatives should cover both software and hardware (80). Although the application of such patient safety initiatives in home care is a complex challenge (81, 82), reporting of adverse events should become mandatory as well as for medical devices.

In assessing the critical patient safety issues related to digitisation and automation, it is necessary to consider the enhancement of telemedicine through artificial intelligence (AI). AI will increasingly integrate with telemedicine (13) it will facilitate the use of telemedicine as a tool for the shift from hospital to home-based care (83).

At the same time, an integrated telemedicine-AI system will also incorporate the critical issues of AI: "black box" problem and unclear definition of liability for AI-related errors and damages.

The latest machine learning models are like "black boxes," i.e., they have such a complex structure that users cannot understand how an AI system converts data into decisions-making (84). However, human-computer interaction forms an Integrated Cognitive System in which the human operator remains at the top of the system and can take over when a specific situation requires it (85, 86).

Uncontrolled and incorrect decision-making by an algorithm can cause serious and irreparable damage. This is a risk that no health care activity can afford. Certainly not telemedicine where human supervision in accordance with an Integrated Cognitive System may be limited as the HWs and the patient are not in the same location.

Another issue concerns the liability in the event that the operation or malfunction of an AI system causes harm to a human being.

A recent resolution of the European Parliament stated that a human being, and not a robot, should be responsible at the moment. The resolution specified that the greater the learning capacity or autonomy of a robot and the longer the duration of a robot’s training, the greater should be the responsibility of its trainer. However, in determining actual liability for the damage caused, the skills resulting from the ’training’ of a robot should not be confused with skills that depend strictly on its self-learning abilities. It was therefore proposed that the most sophisticated autonomous robots could be considered as electronic persons responsible for compensating any damage caused by them (87).

The European Economic and Social Committee (EESC) is opposed to the introduction of legal personality for robots or AI systems, as this would nullify the preventive function of correcting behavior once civil liability no longer falls on the manufacturer because it has been transferred to the robot or AI system (88).

For criminal law, the liability of artificial intelligence systems is still very much unexplored territory, but it is not without interest. It has been argued that intelligent autonomous agents with cognitive and machine-learning capabilities should not be considered as mere devices (89).

The increasing integration of AI in telemedicine requires absolute transparency between physicians and patients, between physicians and healthcare organizations and between healthcare organizations and the community because it is essential for quality, safety, accountability and informed decision-making (90).

Patients are increasingly willing to adopt telemedicine systems but their compliance with existing regulations needs to be implemented and responsibilities for all parties involved need to be better defined (91). In addition, a standardization or almost a homogenization of processes used in telemedicine should be defined a priori, through the classical and universally accepted scientific approach and validation, i.e., case-control and/or randomized studies and/or health technology assessment, to assure quality and efficacy of the web-based procedures. In fact, the procedures admitted and applied are widely different, although contained in a “digital area,” considering also different cognitive involvement of the patient and different technological equipment; the evidences of efficacy of telemedicine, are still few, despite the wide practical use of this approach, just for example in tele-rehabilitation after orthopedic surgery (92).

Finally, another structural factor must be added to these variables, namely that healthcare is not provided in a hospital but at the patient’s home through the use of digital technologies. There are no standards concerning the physical environment in which home care services are provided, in stark contrast to the requirements for healthcare institutions (35).

However, this peculiar kind of health care requires a human-systems approach to understand the interactions between people, equipment/technology, tasks and environments (93). In this perspective, promoting specific improvements in the area of patient safety for telemedicine would require the home to be considered as a complex working system in which different human, technological and environmental factors interact to influence the health care process (24).

POSITION STATEMENT

The critical issues related to the use and diffusion of telemedicine call for a wide-ranging reflection on medical, legal, ethical and organizational principles in order to provide safe health and social care.

Clinical Risk Management aims to improve the safety of care by identifying and preventing circumstances that could expose a patient to the risk of an adverse event.

Intrinsic ethical implications are present throughout the clinical risk management process, i.e., in the assessment, management and communication of clinical risk. Indeed, from an ethical point of view, risks can be approached from different perspectives (utilitarian, contractual, subjective, sociobiological and personalistic) (74).

A literature review showed that the ethical aspects of specific telemedicine applications are a neglected area, with only a few empirical studies (94). However, there are many ethical issues related to telemedicine, many of which are addressed in this paper: the protection of patient autonomy and the right to express informed consent to the proposed treatment; the appropriateness of telemedicine in relation to the specific clinical case; the proper identification of the patient; the guarantee of equal access to treatment and quality care; the definition of professional duties and responsibilities; the preservation and integrity of confidential patient data; the dehumanization of healthcare (95). Ethical principles are experienced differently by telecare providers and patients: providers consider that telemedicine provides better care than patients; patients feel that telemedicine may place a greater share of costs and burdens on them, reducing equity (96).

The World Medical Association and the American Medical Association have endorsed the need to create an ethically-based system that safeguards the interest of patients and reduces the risks of non-compliance and compromised effectiveness (58, 59).

For this reason, let us first define our perspective. The ethical framework we refer to is the Ethics of Job Well Done, which is part of ethical personalism (29). According to the Ethics of Job Well Done, health care in telemedicine should be characterized by: (a) an awareness that every medical act is a free and responsible Human Act with an intrinsic ethical value; (b) an interdisciplinary co-design in relation to complexity theory and systemic thinking; (c) a realistic knowledge that always starts from experience and leads to the search for scientific truth as the basis for one’s choices; (d) a management model useful for the motivational involvement of all the components involved; (e) a recovery of the political dimension of Job Well Done, i.e., professional excellence as a means of serving society and the common good; (f) the capacity for radical procedural innovation;

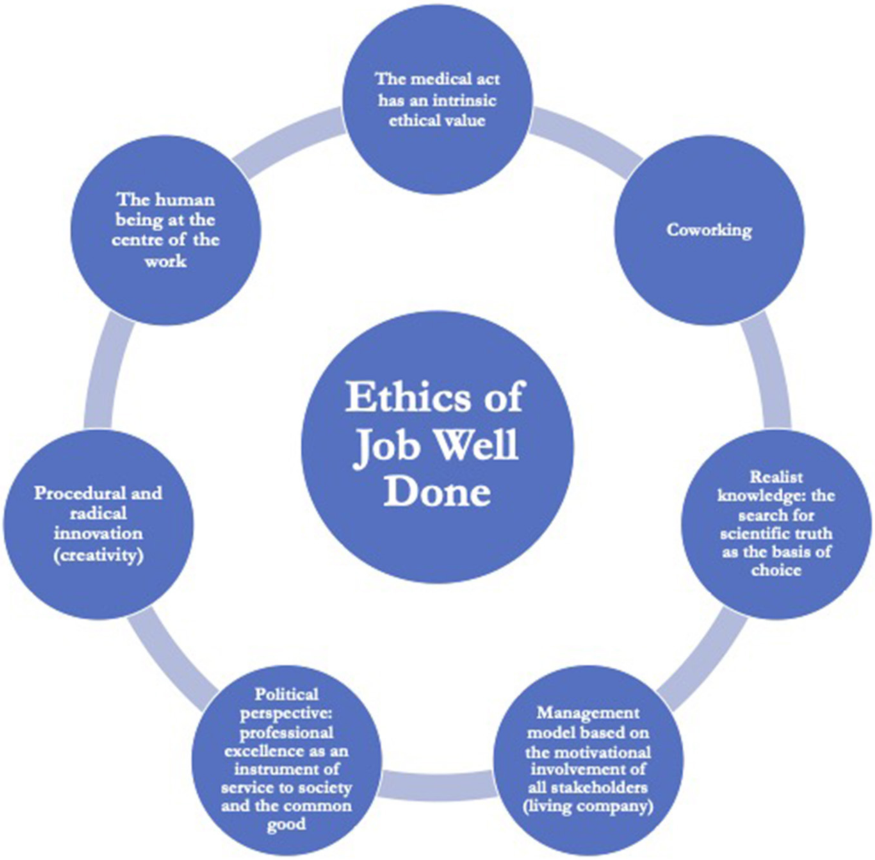

FIGURE 2 | Ethics of Job Well Done framework.

(g) putting people at the center of work, improving effectiveness and efficiency and ensuring sustainability (**Figure 2**).

Based on the Ethics of Job Well Done, we propose the following lines of action:

1. The telemedicine service should be integrated in a "Hub and Spoke" organizational model, where the hospital is the Hub and the patient's home is the Spoke. This would make it possible to identify, assess and eliminate current and potential risks in the healthcare process carried out through telemedicine in order to ensure the quality and safety of care services (**Figure 3**).
2. As an integral part of healthcare (Hub and Spoke), HWs, formal and informal caregivers should have an incident reporting system in place to collect information about the occurrence of adverse events, near misses or sentinel events.
3. CRM should be based on a systems approach. Systemic Clinical Risk Management (SCRM) is a proactive CRM approach in which patient safety is the result of the acquisition and processing of multifactorial quantitative e-tech data and qualitative data such as the human-animal-environment interface, lifestyle behaviors, social factors, political and socio-economic conditions and globalization processes (97). The systemic approach to patient safety should be fostered by the increasing implementation and integration of AI systems and telemedicine.
4. HWs, formal and informal caregivers should receive specific training on critical telemedicine issues regarding risk management in telemedicine, communication processes and critical topics such as confidentiality, security, privacy, storage and integrity of sensitive data. The aim is to implement a culture of safety and to achieve an adequate and specific level of competence for each of the players involved in the healthcare procedure.
5. Patients should be selected carefully. It would be necessary to verify the correspondence between the patient's health needs and the possibility of delivering the service *via* telemedicine. The aim is to pursue appropriateness of provision (supporting, supplementing or replacing telemedicine) by also using tools for remote detection and monitoring of biological parameters and clinical surveillance.
6. Health care through telemedicine should only be started after an initial in-person medical consultation, except for specific needs determined by the physician and for situations that

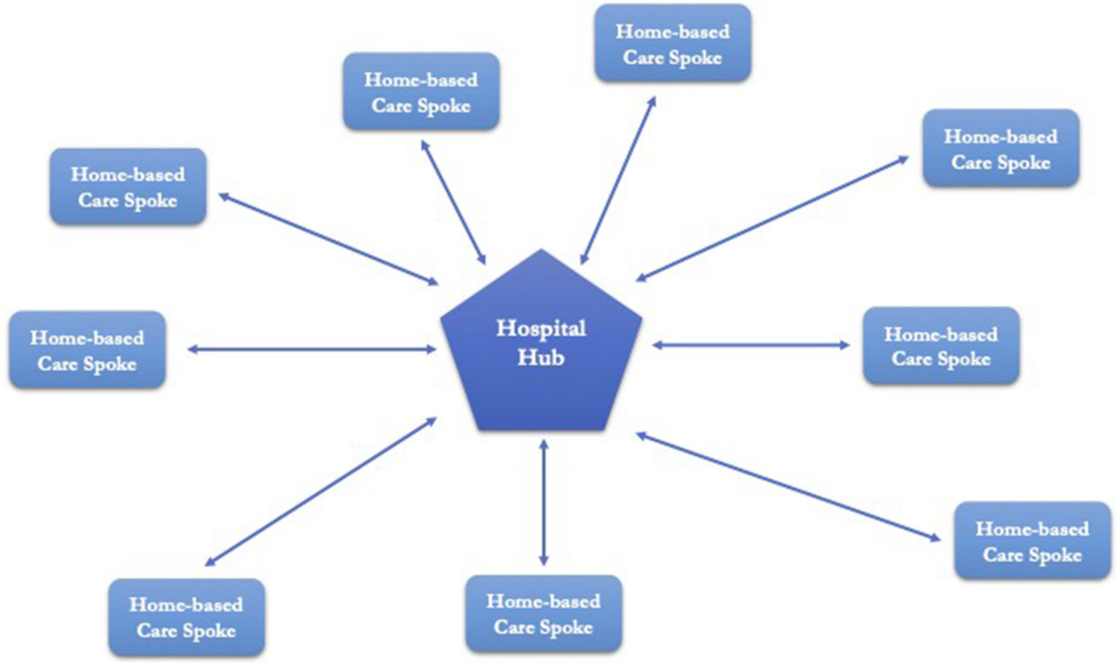

FIGURE 3 | "Hub and Spoke" organizational model.

make the patient's presence in a health facility particularly difficult (mobility problems, impossibility of finding an accompanying person, etc.).

7. Each patient should have a medical *case manager* to refer to.
8. The patient should be able to check and communicate to the *case manager* the degree of satisfaction and should be able to communicate any need or desire for change.
9. Healthcare organizations should identify an appropriate catchment area, clinical pathways, structural and organizational arrangements, and rules regarding transfers from hospital/hub to home-based care/Spoke and vice versa in case of need.
10. Informed consent should fully explain the process of treatment through telemedicine, expected outcomes, non-treatment outcomes, complications, treatment alternatives, impact on family life, organizational, structural and instrumental needs, impact and risks to privacy. The language should be comprehensible, simple and clear, appropriate to the age, capacity and health, psychological, cultural and linguistic status of the patient. The aim is to provide the patient with as much information as possible so that the choice to be assisted by telemedicine is a free and informed one and not an obligation without an alternative. In this way, the principle of autonomy would not conflict with the principle of health protection.
11. The implementation in medical practice of telemedicine procedures should be defined by the evaluation and validation of efficacy obtained from specific studies performed following classical scientific schemes and also by metanalyses and health technology assessment.
12. Patients' organizations, especially disabled and vulnerable ones, should participate in decision-making processes and they should help healthcare organizations to monitor the long-term effects of telemedicine.
13. Information and Communication Technologies (ICT) must guarantee authentication, safety, security, integrity, confidentiality and availability of data.

These lines of action can help stakeholders involved in safety promotion to manage telemedicine risk-related, i.e., patients and their relatives, formal and informal caregivers, patients' organizations, policy-makers, healthcare governance, healthcare workers (HWs), providers and insurance providers.

CONCLUSION

During the pandemic, telemedicine was the tool through which many Health Systems ensured health care for Covid-19 patients with mild symptoms and for patients who needed diagnosis and treatment but had to respect physical distancing (8–12).

Because of its recognized effectiveness, many countries have planned economic and regulatory interventions (15–18) to enhance telemedicine even after the pandemic with the aim of moving healthcare from the hospital to the territory, strengthening healthcare and improving standards of patient care.

Nevertheless, telemedicine is not a new healthcare tool. A 1997 paper paradigmatically titled "Telemedicine: new technology = new questions = new exposures" (98).

Simply the Covid-19 pandemic has emphasized its usefulness. Telemedicine is experiencing a new springtime. The hope is that telemedicine does not fall into oblivion or, worse still, become a boomerang for the health and safety of patients, the safety of all professionals and others, the expectations of family members, and also for the budgets of health systems worldwide.

For this not to happen, we need to put into practice some "alerts" already sounded in the pre-Covid-19 era.

In 2004, the Commission of the European Communities argued that e-Health should be supported by a wide diffusion of best practices including quality impact and accountability assessments in telemedicine services and accreditation procedures (99). Eight years later, for professionals (health and scientific communities) the focus will be on developing evidence-based clinical practice guidelines for telemedicine services with particular emphasis on nursing and social care workers (100).

In 2005, the WHO supported the need to diffuse experiences and best practices regarding telemedicine, to promote standards through the diffusion of guidelines and to train HWs to strengthen the quality and safety of healthcare (26).

In 2018, the WMA's position steatment encouraged the development of ethical standards, practice guidelines, national legislation and international agreements on topics related to the practice of telemedicine, protecting the patient-physician relationship, confidentiality and quality of medical care (58).

The American Medical Association (AMA) has supported the continuous improvement of telehealth/telemedicine technologies, and the development and implementation of clinical and technical standards to ensure safety and quality of care (59).

Telemedicine is a major challenge for all healthcare organizations wishing to offer telemedicine programmes to patients. Telemedicine programmes are positioned within larger health organizations and do not operate in a vacuum. In turn, each organization operates within a wider environment, which is often limited by fiscal, geographical and personnel factors. All these factors could influence the introduction of telemedicine (101).

This enormous task requires new knowledge which, if not recognized, could see telemedicine projects continue to founder (102).

With this position paper we have accepted the challenge and wanted to make our own contribution. We are convinced that the sustainable development of telemedicine can only be achieved by increasing citizens' confidence in telemedicine. To do so, healthcare organizations will have to offer quality, technologically advanced and safe healthcare for patients, professional and non-professional stakeholders involved in the process of care.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary materials, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

FD, LP, and ER: writing. VF: supervision. GB, AO, GC, and RA: revision. PF and TP: writing revision. GT: data curation. MP: visualization. AD and VT: conceptualization. All authors contributed to the article and approved the submitted version.

REFERENCES

1. World Health Organization. *A Health Telematics Policy in Support of WHO's Health-For-All Strategy for Global Health Development: Report of the WHO Group Consultation on Health Telematics*. (1998). Available online at: https://apps.who.int/iris/handle/10665/63857 (accessed March 15, 2022).
2. Ferorelli D, Nardelli L, Spagnolo L, Corradi S, Silvestre M, Misceo F, et al. Medical legal aspects of telemedicine in Italy: application fields, professional liability and focus on care services during the COVID-19 health emergency. *J Prim Care Community Health.* (2020) 11:2150132720985055. doi: 10.1177/2150132720985055
3. Bhaskar S, Bradley S, Chattu VK, Adisesh A, Nurtazina A, Kyrykbayeva S, et al. Telemedicine across the globe-position paper from the COVID-19 pandemic health system resilience PROGRAM (REPROGRAM) international consortium (part 1). *Front Public Health.* (2020) 8:556720. doi: 10.3389/fpubh.2020.556720
4. Commission of the European Communities. *Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Telemedicine for the Benefit of Patients, Healthcare Systems and Society*. (2008). Available online at: https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2008)689&lang=it (accessed March 15, 2022).
5. European Commission. *Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Digital Agenda for Europe.* (2010). Available online at: https://eufordigital.eu/wp-content/uploads/2019/10/COMMUNICATION-FROM-THE-COMMISSION-TO-THE-EUROP EAN-PARLIAMENT.pdf (accessed March 15, 2022).
6. European Commission. *Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Enabling the Digital Transformation of Health and Care in the Digital Single Market; Empowering Citizens and Building a Healthier Society*. (2018). Available online at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0233&from=EN (accessed March 15, 2022).
7. Hyder MA, Razzak J. Telemedicine in the United States: an introduction for students and residents. *J Med Internet Res.* (2020) 22:e20839. doi: 10.2196/20839
8. Monaghesh E, Hajizadeh A. The role of telehealth during COVID-19 outbreak: a systematic review based on current evidence. *BMC Public Health.* (2020) 20:1193. doi: 10.1186/s12889-020-09301-4
9. Bhaskar S, Bradley S, Chattu VK, Adisesh A, Nurtazina A, Kyrykbayeva S, et al. Telemedicine as the new outpatient clinic gone digital: position paper from the pandemic health system REsilience PROGRAM (REPROGRAM) international consortium (part 2). *Front Public Health.* (2020) 8:410. doi: 10.3389/fpubh.2020.00410
10. Bhaskar S, Nurtazina A, Mittoo S, Banach M, Weissert R. Editorial: telemedicine during and beyond COVID-19. *Front Public Health.* (2021) 9:662617. doi: 10.3389/fpubh.2021.662617
11. World Health Organization. *Regional Office for Europe, Strengthening the Health Systems Response to COVID-19: Policy Brief: Recommendations for the WHO European Region.* (2020). Available online at: https://apps.who.int/iris/handle/10665/333072 (accessed March 15, 2022).

12. The Organisation for Economic Co-operation and Development (OECD). *Beyond Containment: Health Systems Responses to COVID-19 in the OECD*. (2020). Available online at: https://www.oecd.org/coronavirus/policy-responses/beyond-containment-health-systems-respon ses-to-covid-19-in-the-oecd-6ab740c0/#blocknotes-d7e786 (accessed March 15, 2022).
13. Bhaskar S, Bradley S, Sakhamuri S, Moguilner S, Chattu VK, Pandya S, et al. Designing futuristic telemedicine using artificial intelligence and robotics in the COVID-19 era. *Front Public Health.* (2020) 8:556789. doi: 10.3389/fpubh.2020.556789
14. European Union. *Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 Establishing a Programme for the Union's Action in the Field of Health ('EU4Health Programme') for the Period 2021-2027, and Repealing Regulation (EU) No 282/2014*. (2021). Available online at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.107.01.0001.01.ENG (accessed March 15, 2022).
15. Governo italiano. *Piano Nazionale di Ripresa e Resilienza*. (2021). Available online at: https://www.governo.it/sites/governo.it/files/PNRR.pdf (accessed March 15, 2022).
16. Gouvernement français. *Plan National de Relance et de Résilience*. (2021). Available online at: https://www.economie.gouv.fr/plan-national-de-relance-et-de-resilience-pnrr (accessed March 15, 2022).
17. Bunderministerium der Finanzen. *Deutscher Aufbau-und Resilienzplan*. (2021). Available online at: https://www.bundesfinanzministerium.de /Content/DE/Standardartikel/ Themen/ Europa/ DARP/deutscher-aufbau-und-resilienzplan.html (accessed March 15, 2022).
18. The United States Congress. *Telehealth Extension and Evaluation Act*. (2022). Available online at: https://www.cortezmasto.senate.gov/imo/media/doc/GOE22074.pdf (accessed March 15, 2022).
19. Aly DM, Erickson LA, Hancock H, Apperson JW, Gaddis M, Shirali G, et al. Ability of video telemetry to predict unplanned hospital admissions for single ventricle infants. *J Am Heart Assoc.* (2021) 10:e020851. doi: 10.1161/JAHA.121.020851
20. Insulander P, Carnlöf C, Schenck-Gustafsson K, Jensen-Urstad M. Device profile of the Coala Heart Monitor for remote monitoring of the heart rhythm: overview of its efficacy. *Expert Rev Med Devices.* (2020) 17:159–65. doi: 10.1080/17434440.2020.1732814
21. The Joint Commission releases improving America's hospitals: the Joint Commission's annual report on quality and safety 2007. *Jnt Comm Perspect.* (2007) 27:1–3.
22. World Health Organization. *Patient Safety Curriculum Guide: Multi-Professional Edition*. (2011). Available online at: https://www.who.int/patientsafety/education/curriculum/who_mc_topic-6.pdf (accessed March 15, 2022).
23. Solimini R, Busardò FP, Gibelli F, Sirignano A, Ricci G. Ethical and legal challenges of telemedicine in the era of the COVID-19 pandemic. *Medicina.* (2021) 30:1314. doi: 10.3390/medicina57121314
24. Guise V, Anderson J, Wiig S. Patient safety risks associated with telecare: a systematic review and narrative synthesis of the literature. *BMC Health Serv Res.* (2014) 14:588. doi: 10.1186/s12913-014-0588-z
25. Darkins A. Patient safety considerations in developing large telehealth networks. *Clin Risk.* (2012) 18:90–4. doi: 10.1258/cr.2012.012006
26. World Health Organization. *Resolutions and Decisions - WHA58.28 on eHealth*. (2005). Available online at: https://www.who.int/healthacademy/media/WHA58-28-en.pdf (accessed March 15, 2022).
27. NEJM Catalyst. *What Is Risk Management in Healthcare?* (2018). Available online at: https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0197 (accessed May 10, 2022).
28. American Society for Health Care Risk Management. *Enterprise Risk Management*. (2021). Available online at: https://www.ashrm.org/system/files?file=media/file/2019/06/ERM-Tool_final.pdf (accessed May 10, 2022).
29. Quintiliani L, Sisto A, Vicinanza F, Curcio G, Tambone V. Resilience and psychological impact on Italian university students during COVID-19 pandemic. Distance learning and health. *Psychol Health Med.* (2022) 27:69–80. doi: 10.1080/13548506.2021.1891266
30. Card AJ. What is ethically informed risk management? *AMA J Ethics.* (2020) 22:E965–75. doi: 10.1001/amajethics.2020.965
31. American Society for Health Care Risk Management. *Health Care Risk Management Code of Professional Responsibility*. (2013). Available online at: https://www.ashrm.org/sites/default/files/ashrm/Code_of_Conduct_2013.pdf (accessed May 10, 2022).
32. Williams G, Doughty K, Bradley DA. Safety and risk issues in using telecare. *J Telemed Telecare.* (2000) 6:249–62. doi: 10.1258/1357633001935833
33. Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn LT, Corrigan JM, Donaldson MS, editors. *To Err is Human: Building a Safer Health System*. Washington, DC: National Academies Press (2000).
34. Carayon P, Wetterneck TB, Rivera-Rodriguez AJ, Hundt AS, Hoonakker P, Holden R, et al. Human factors systems approach to healthcare quality and patient safety. *Appl Ergon.* (2014) 45:14–25. doi: 10.1016/j.apergo.2013.04.023
35. Lang A, Edwards N, Fleiszer A. Safety in home care: a broadened perspective of patient safety. *Int J Qual Health Care.* (2008) 20:130–5. doi: 10.1093/intqhc/mzm068
36. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ.* (1996) 13:71–2. doi: 10.1136/bmj.312.7023.71
37. Karsh BT, Holden RJ, Alper SJ, Or CK. A human factors engineering paradigm for patient safety: designing to support the performance of the healthcare professional. *Qual Saf Health Care.* (2006) 15:i59–65. doi: 10.1136/qshc.2005.015974
38. Romagnoli KM, Handler SM, Hochheiser H. Home care: more than just a visiting nurse. *BMJ Qual Saf.* (2013) 22:972–4. doi: 10.1136/bmjqs-2013-002339
39. Johnson KG. Adverse events among Winnipeg home care clients. *Healthc Q.* (2006) 9:127–34. doi: 10.12927/hcq.2013.18377
40. Blais R, Sears NA, Doran D, Baker GR, Macdonald M, Mitchell L, et al. Assessing adverse events among home care clients in three Canadian provinces using chart review. *BMJ Qual Saf.* (2013) 22:989–97. doi: 10.1136/bmjqs-2013-002039
41. Donabedian A. *Explorations in Quality Assessment and Monitoring: The Definition of Quality and Approaches to its Assessment*. Ann Arbor: Michigan Health Administration Press (1980).
42. Carayon P, Schoofs Hundt A, Karsh BT, Gurses AP, Alvarado CJ, Smith M, et al. Work system design for patient safety: the SEIPS model. *Qual Saf Health Care.* (2006) 15:i50–8. doi: 10.1136/qshc.2005.015842
43. Stange KC, Nutting PA, Miller WL, Jaén CR, Crabtree BF, Flocke SA, et al. Defining and measuring the patient-centered medical home. *J Gen Intern Med.* (2010) 25:601–12. doi: 10.1007/s11606-010-1291-3
44. Wetterneck TB, Lapin JA, Karsh BT, Beasley JW. Human factors and ergonomics in primary care. In: Carayon P, editor. *Handbook of Human Factors and Ergonomics in Health Care and Patient Safety*. Boca Raton, FL: Taylor and& Francis Group (2012) p. 763–74.
45. Botrugno C. Towards an ethics for telehealth. *Nurs Ethics.* (2019) 26:357–67. doi: 10.1177/0969733017705004
46. Marcinowicz L, Konstantynowicz J, Godlewski C. Patients' perceptions of GP non-verbal communication: a qualitative study. *Br J Gen Pract.* (2010) 60:83–7. doi: 10.3399/bjgp10X483111
47. Pinto RZ, Ferreira ML, Oliveira VC, Franco MR, Adams R, Maher CG, et al. Patient-centred communication is associated with positive therapeutic alliance: a systematic review. *J Physiother.* (2012) 58:77–87. doi: 10.1016/S1836-9553(12)70087-5
48. Leonard M, Graham S, Bonacum D. The human factor: the critical importance of effective teamwork and communication in providing safe care. *Qual Saf Health Care.* (2004) 13:i85–90. doi: 10.1136/qshc.2004.010033
49. Ciccozzi M, Menga R, Ricci G, Vitali MA, Angeletti S, Sirignano A, et al. Critical review of sham surgery clinical trials: Confounding factors analysis. *Ann Med Surg (Lond).* (2016) 12:21–6. doi: 10.1016/j.amsu.2016.10.007
50. Nittari G, Khuman R, Baldoni S, Pallotta G, Battineni G, Sirignano A, et al. Telemedicine practice: review of the current ethical and legal challenges. *Telemed J E Health.* (2020) 26:1427–37. doi: 10.1089/tmj.2019.0158
51. Kaplan B. Revisiting health information technology ethical, legal, and social issues and evaluation: telehealth/telemedicine and COVID-19. *Int J Med Inform.* (2020) 143:104239. doi: 10.1016/j.ijmedinf.2020.104239
52. O'Daniel M, Rosenstein AH. Professional Communication and Team Collaboration. In: Hughes RG, editor. *Patient Safety and Quality: An*

Evidence-Based Handbook for Nurses. Rockville, MD: Agency for Healthcare Research and Quality (2008).

53. Agha Z, Roter DL, Schapira RM. An evaluation of patient-physician communication style during telemedicine consultations. *J Med Internet Res.* (2009) 11:e36. doi: 10.2196/jmir.1193
54. Street R, Wheeler J, McCaughan W. Specialist-primary care provider-patient communication in telemedical consultations. *Telemed J.* (2000) 6:45–54. doi: 10.1089/107830200311842
55. Miller EA. Telemedicine and doctor-patient communication: an analytical survey of the literature. *J Telemed Telecare.* (2001) 7:1–17. doi: 10.1258/1357633011936075
56. Morony S, Weir K, Duncan G, Biggs J, Nutbeam D, Mccaffery KJ. Enhancing communication skills for telehealth: development and implementation of a Teach-Back intervention for a national maternal and child health helpline in Australia. *BMC Health Serv Res.* (2018) 7:162. doi: 10.1186/s12913-018-2956-6
57. Le cure primarie PD. In: Tartaglia R, Vannucci A, editors. *Prevenire gli eventi avversi in medicina*, Milano: Springer-Verlag Italia (2013).p. 241–54.
58. World Medical Association. *WMA Statement on The Ethics of Telemedicine*. (2018). Available online at: https://www.wma.net/policies-post/wma-statement-on-the-ethics-of-telemedicine/ (accessed March 15, 2022).
59. American Medical Association. *Ethical Practice in Telemedicine*. Available online at: https://www-ama--assn-org.translate.goog/delivering-care/ethics/ethical-practice-telemedicine? _x_tr_sl=en&_x_tr_tl=it&_x_tr_hl=it&_x_tr_pto=wapp (accessed March 15, 2022).
60. European Commission. *Task Shifting and Health System Design Report of the Expert Panel on Effective Ways of Investing in Health (EXPH)*. (2019). Available online at: https://ec.europa.eu/health/system/files/2019-11/023_taskshifting_en_0.pdf (accessed March 15, 2022).
61. Bittner-Fagan H, Davis J, Savoy M. Improving patient safety: improving communication. *FP Essent.* (2017) 463:27–33.
62. De Micco F, Martino F, Campobasso CP. Ethical issues in age assessment by the third molar development. *Aust J Forensic Sci.* (2020) 54:88–99. doi: 10.1080/00450618.2020.1789220
63. The Joint Commission International. *Informed Consent: More Than Getting a Signature*. (2016). Available online at: https://www.jointcommission.org/-/media/tjc/documents/newsletters/ quick_safety_issue _twenty-one_february_ 2016pdf.pdf (accessed March 15, 2022).
64. MedPro Group. *Risk Management Strategies for Informed Consent*. (2020). Available online at: https://www.medpro.com/documents/10502/2837997/Guideline_Risk$+$Management$+$Strategies$+$for$+$Informed$+$Consent.pdf (accessed March 15, 2022).
65. Green BE. *Proactively Approaching Telehealth Informed Consent*. (2013). Available online at: https://www.lexology.com /library/detail.aspx?g=a90e1cd6-8090-481b-90c0-7b19407a70a0 (accessed March 15, 2022).
66. Gough F, Budhrani S, Cohn E, Dappen A, Leenknecht C, Lewis B, et al. ATA practice guidelines for live, on-demand primary and urgent care. *Telemed J E Health.* (2015) 21:233–41. doi: 10.1089/tmj.2015.0008
67. Simon CM, Schartz HA, Rosenthal GE, Eisenstein EL, Klein DW. Perspectives on electronic informed consent from patients underrepresented in research in the United States: a focus group study. *J Empir Res Hum Res Ethics.* (2018) 13:338–48. doi: 10.1177/1556264618773883
68. Grauberger J, Kerezoudis P, Choudhry AJ, Alvi MA, Nassr A, Currier B, et al. Allegations of failure to obtain informed consent in spinal surgery medical malpractice claims. *JAMA Surg.* (2017) 152:e170544. doi: 10.1001/jamasurg.2017.0544
69. Raval T. *Fighting Telemedicine Fraud: Why Robust Verification is Needed*. (2020). Available online at: https://www.forbes.com/sites/ forbestechcouncil/2020/08/25/fighting-telemedicine-fraud-why-robust-verification-is-needed/?sh=4422b8ed1f6f (accessed March 15, 2022).
70. Terry M. Medical identity theft and telemedicine security. *Telemed J E Health.* (2009) 15:928–32. doi: 10.1089/tmj.2009.9932
71. Garg V, Brewer J. Telemedicine security: a systematic review. *J Diabetes Sci Technol.* (2011) 5:768–77. doi: 10.1177/193229681100500331
72. Hall JL, McGraw D. For telehealth to succeed, privacy and security risks must be identified and addressed. *Health Aff.* (2014) 33:216–21. doi: 10.1377/hlthaff.2013.0997
73. Travaini G, Caruso P, Merzagora I. Crime in Italy at the time of pandemic. *Acta Biomedica.* (2020) 91:199. doi: 10.23750/abm.v91i2.9596
74. Ministero della Salute. *Sicurezza dei pazienti e gestione del rischio clinico: Manuale per la formazione degli operatori sanitari*. (2007). Available online at: https://www.salute.gov.it/imgs/C_17_pubblicazioni_640_allegato.pdf (accessed March 15, 2022).
75. Ranzani F, Parlangeli O. Digital technology and usability and ergonomics of medical devices. In: Donaldson L, Ricciardi W, Sheridan S, Tartaglia R, editors. *Textbook of Patient Safety and Clinical Risk Management*. Cham (2021). p. 455–64.
76. U.S. Food and Drug Administration. *Draft Guidance for Industry and Food and Drug Administration Staff – Applying Human Factors and Usability Engineering to Optimize Medical Device Design*. (2011). Available online at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm 259748.htm (accessed March 15, 2022).
77. Reed TL, Kaufman-Rivi D. FDA adverse event problem codes: standardizing the classification of device and patient problems associated with medical device use. *Biomed Instrum Technol.* (2010) 44:248–56. doi: 10.2345/0899-8205-44.3.248
78. Cabitza F, Dui LG. Collecting patient reported outcomes in the wild: opportunities and challenges. *Stud Health Technol Inform.* (2018) 247:36–40.
79. Pham JC, Gianci S, Battles J, Beard P, Clarke JR, Coates H, et al. Establishing a global learning community for incident-reporting systems. *Qual Saf Health Care.* (2010) 19:446–51. doi: 10.1136/qshc.2009.037739
80. Magrabi F, Aarts J, Nohr C, Baker M, Harrison S, Pelayo S, et al. A comparative review of patient safety initiatives for national health information technology. *Int J Med Inform.* (2013) 82:139–48. doi: 10.1016/j.ijmedinf.2012.11.014
81. Goodman KW, Berner ES, Dente MA, Kaplan B, Koppel R, Rucker D, et al. Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: a report of an AMIA special task force. *J Am Med Inform Assoc.* (2011) 18:77–81. doi: 10.1136/jamia.2010.008946
82. Fu M, Weick-Brady M, Tanno E. Medical devices in the home: a unique challenge for the FDA. *Work.* (2012) 41:361–5. doi: 10.3233/WOR-2012-1305
83. World Health Organization. *Ethics and Governance of Artificial Intelligence for Health: WHO guidance*. (2021). Available online at: https://www.who.int/publications/i/item/9789240029200 (accessed March 15, 2022).
84. Habli I, Lawton T, Porter Z. Artificial intelligence in health care: accountability and safety. *Bull World Health Organ.* (2020) 98:251–6. doi: 10.2471/BLT.19.237487
85. Hollnagel E. *Cognitive Reliability and Error Analysis Method (CREAM)*. Amsterdam, NL: Elsevier (1998).
86. Sheridan T. Human supervisory control of robot systems. In: *Proceedings IEEE International Conference on Robotics and Automation*. San Francisco, CA: IEEE (1986). p. 808–12.
87. European Parliament. *Civil Law Rules on Robotics*. (2017). Available online at: https://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html (accessed March 15, 2022).
88. European Economic and Social Committee. *Opinion of the European Economic and Social Committee on "Artificial Intelligence-The Consequences of Artificial Intelligence on the (Digital) Single Market, Production, Consumption, Employment and Society"*. (2017). Available online at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri= CELEX:52016IE5369&from=CS (accessed March 15, 2022).
89. Hallevy G. The criminal liability of artificial intelligence entities - from science fiction to legal social control. *Akron Law J.* (2010) 4:171–201. doi: 10.2139/ssrn.1564096
90. Kaplan GS. *Building a Culture of Transparency in Health Care*. (2018). Available online at: https://hbr.Org/2018/11/building-a-culture-of-transparency-in-health-care (accessed March 15, 2022).
91. Parimbelli E, Bottalico B, Losiouk E, Tomasi M, Santosuosso A, Lanzola G, et al. Trusting telemedicine: a discussion on risks, safety, legal implications

and liability of involved stakeholders. *Int J Med Inform.* (2018) 112:90–8. doi: 10.1016/j.ijmedinf.2018.01.012

92. Wang Q, Lee RL, Hunter S, Chan SW. The effectiveness of internet-based telerehabilitation among patients after total joint arthroplasty: a systematic review and meta-analysis of randomised controlled trials. *J Telemed Telecare.* (2021). doi: 10.1177/1357633X20980291. [Epub ahead of print].
93. Beer JM, McBride SE, Mitzner TL, Rogers WA. Understanding challenges in the front lines of home health care: a human-systems approach. *Appl Ergon.* (2014) 45:1687–99. doi: 10.1016/j.apergo.2014.05.019
94. MethoTelemed project. *The MAST Manual*. Available online at: https://joinup.ec.europa.eu/sites/default/files/document/2014-12/The%20Model%20for%20Assessment%20of%20Telemedicine%20%28MAST%29%20Manual.pdf (accessed May 10, 2022).
95. Cordeiro JV. Digital technologies and data science as health enablers: an outline of appealing promises and compelling ethical, legal, and social challenges. *Front Med.* (2021) 8:647897. doi: 10.3389/fmed.2021.647897
96. Keenan AJ, Tsourtos G, Tieman J. Promise and peril-defining ethical telehealth practice from the clinician and patient perspective: a qualitative study. *Digit Health.* (2022) 8:1–17. doi: 10.1177/20552076211070394
97. De Micco F, De Benedictis A, Fineschi V, Frati P, Ciccozzi M, Pecchia L, et al. From syndemic lesson after COVID-19 pandemic to a "systemic clinical risk management" proposal in the perspective of the ethics of job well done. *Int J Environ Res Public Health.* (2021) 19:15. doi: 10.3390/ijerph19010015
98. Abke A, Mouse-Young D. Telemedicine: new technology = new questions = new exposures. *J Healthc Risk Manag.* (1997) 17:3–6. doi: 10.1002/jhrm.5600170402
99. Commission of the European Communities. *Communication From the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions e-Health - Making Healthcare Better for European Citizens: An Action Plan for a European e-Health Area*. (2004). Available online at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF (accessed March 15, 2022).
100. Commission of the European Communities. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. eHealth Action Plan 2012-2020 - Innovative Healthcare for the 21st Century*. (2012). Available online at: https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2012)736&lang=it (accessed March 15, 2022).
101. Whitten P, Adams I. Success and failure: a case study of two rural telemedicine projects. *J Telemed Telecare.* (2003) 9:125–9. doi: 10.1258/135763303767149906
102. Mort M, May CR, Williams T. Remote doctors and absent patients: acting at a distance in telemedicine? *Sci Technol Human Values.* (2003) 28:274–95. doi: 10.1177/0162243902250907

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Characterization of Factors Predicting a Favorable Opinion of Research Applications Submitted for an Ethical Review Process

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Introduction: In Spain, biomedical research applications must receive a positive ethical opinion from Research Ethics Committees (RECs) before being executed. There is limited information on how to optimize the ethical review process to reduce delays. This study was performed to characterize variables predicting favorable opinions at the first ethical review performed by a REC.

Material and Methods: The study assessed all research applications revised by a REC in 2019–2020. Data was extracted from REC's database of La Rioja, Spain. Variables collected covered three areas: (i) principal investigator's profile; (ii) study design; and (iii) ethical review process. A model based on multiple logistic regression analysis was created to identify variables explaining favorable opinions in first rounds of ethical review processes.

Results: The sample included 125 applications (41 submitted in 2019, and 84 in 2020). At the first review, nine (7%) applications were rejected, 56 (45%) were approved, and the remaining 60 (48%) required at least two reviews prior to approval. When comparing both years, a 2-fold increase in the number of applications submitted, and a difference in the ratio of applications with a favorable vs. non-favorable opinion were observed. Furthermore, a model predicted 71% of probability of obtaining a favorable opinion in the first ethical review. Three variables appeared as being explanatory: if the principal investigator is either the group leader or the department's head (OR = 17.39; $p < 0.001$), and if the informed consent (OR = 11.79; $p = 0.01$), and methods and procedures (OR = 34.15; $p < 0.001$) are well done.

Conclusions: These findings confirm an increase in the number of submissions and a difference in the ratio of applications approved by year. Findings observed also confirm deficiencies in "informed consent" and in "methods and procedures" are the

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two main causes of delay for favorable ethical opinions. Additionally, findings highlight the need that group leaders and heads of departments should be more involved in guiding and supervising their research teams, especially when research applications are led by less experienced researchers. Based on these findings, it is suggested that an adequate mentoring and targeted training in research could derive in more robust research applications and in smoother ethical review processes.

Keywords: Research Ethics Committee (REC), research applications, predictors, informed consent, leadership and mentoring, research methodology and ethics, COVID-19, Spain

INTRODUCTION

Patients play an essential role in biomedical research, either as study subjects or as source of clinical data. Hence, it is expected that all professionals actively involved in biomedical research – in addition to the necessary technical, clinical and scientific knowledge – should have an individual commitment with professionalism in order to work in consonance with the ethical and legal frames that accompany their research activities (1). This professionalism is synonym of a "job well done" placing a high value of doing a good job, as well as respecting the autonomy of the patients and acting with integrity.

Research Ethics Committees as Guarantors of Professionalism in Biomedical Research

The main responsibility of a Research Ethics Committee (REC) is to guarantee that a biomedical research application meets the standards of scientific, ethical and legal rigor prior to its experimental execution (2). This obligation, in Spain, has been regulated within the framework of the Organic Law (*Ley Orgánica*, LO) LO 3/2018 (3), both on the protection of personal data; the LO 41/2002, on patient autonomy and obligations regarding information and clinical documentation (4); the SCO/362/2008, on good clinical practice (5); and the Royal Decree (*Real Decreto*, RD) RD 1090/2015, on clinical trials with drugs (6). Therefore, shortcomings in any aspect related to methods, procedures, ethics or legal frame could lead to a reevaluation, or even rejection by the REC responsible to review a given research application. Nevertheless, reaching this goal implies that the REC must be composed by a robust structure capable to address issues coming from different disciplines (7).

Despite the existence of different national normatives, there are certain coincidences in common aspects of the RECs' activity that could be improved. For example, McNeill (8), Beshir (9), and Wagner and colleagues (10) agree that the REC's administrative work involves a slow bureaucratic process, which has been sometimes criticized as costly or at least making the review process laborious. Others have criticized that inflexible requirements for adherence to narrow literal interpretations of certain normative can lead to a system that is more concerned with "legalism" than the protection of human research participants (2, 11). Furthermore, some authors (12, 13) have highlighted the inconsistencies across different committees, even though they were following the same national normative. In this regard, Edwards and colleagues (14) argue that those inconsistencies are negative only when they derive from a lack of expertise in identifying ethical issues in the research applications that are revised. In addition, Beshir (9) remarks that it is crucial for a REC to ensure that researchers have sufficient research experience and qualifications or alternatively are collaborating with experienced colleagues in the field of their research. This is especially important in two circumstances: when research procedures imply risk for researchers, participants or the environment; and when sensitive aspects related to the privacy and patients' identity can be exposed. In both cases, it is a duty of RECs to minimize the risk of any harm. Finally, some authors have suggested to reassess the role of RECs in order to ensure their purpose is fulfilled to encourage the scientific development maintaining an acceptable ethical framework (7). However, in practice, reaching this goal does not look feasible due to the implicit nature of the ethics and the deliberative methodology followed by the RECs.

The situation above described became more stressful in the last 2 years due to the rapid expansion of the SARS-CoV-2 pandemic and the extremely high number of SARS-CoV-2 infections (COVID-19). The pandemic not only tested the capacity of the scientific community for finding therapeutic and preventive responses to contain and mitigate the disease, but also derived in a greater effort for RECs to guarantee that the increasing number of research applications in different areas were in accordance with scientific, ethical and legal standards. Aware of this situation, the World Commission on the Ethics of Scientific Knowledge and Technology (COMTEST), and the International Bioethics Committee (IBC) signed a joint Ethical Declaration entitled "Ethical considerations from a global perspective", 2 months after the pandemics was declared (15). The aforementioned document has been received from the research ethics committees as an important exhortation to establish actions in order to facilitate a rapid scientific and technological development, but without neglecting the ethical standards that should always frame any research activity involving human subjects (16). In consonance with this, the Bioethics Committee of Spain (*Comité de Bioética de España*, CBE) prepared a Report with ethical and legal guidelines that researchers working with health data and biological samples should fulfill during the pandemic (17). In addition, the Spanish Agency of Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios*, AEMPS) elaborated a special core of guidelines for research activities involving either patients infected with COVID-19 or clinical data from these patients (18). As receptor of these guidelines, each REC was in charge of conciliate practical needs with ethical principles in an extraordinary socio-sanitary context with new research projects increasing rapidly in time.

Study Purpose

Evidence of the effect that the pandemic situation has had and in still having on the RECs is scarce. In Spain, there is only one study performed by the REC of the Autonomous Community of Galicia (19). Bugarin-Gonzalez and colleagues, authors of the aforementioned study, reported that the vast majority of research applications submitted to their REC met the ethical requirements necessary for their approval. However, more than a third of them included deficiencies either in methodological aspects or in the informed consent. According to them, these deficiencies could be associated with a lack of knowledge in the normative, training gaps related to management in biomedical research, and a poor communication and interdisciplinary collaboration in the research teams, especially with more experienced professionals. These deficiencies derived not only in delays in the start of research activities, but also implied a work overload in the REC that was forced to dedicate more than one round of revisions for the same application prior to giving a final approval.

Based on the situation described above, this study was designed with the purpose of confirming the following hypothesis: Research group leaders and department heads are usually the most experienced researchers in their groups. In consequence, they play an important role in the success of research applications performed by their teams as first guarantors of a "job well done." This involvement can be reflected in a favorable opinion of a REC, once those applications are submitted for a first ethical review. With this purpose, four research objectives were pursued:

To collect information of the research applications submitted for an ethical review process based on three areas: profile of the researcher who led the study (principal investigator, PI), aspects related to the study design, and aspects related to the ethical review process.

To identify the ratio of research applications that obtained a favorable opinion in the first ethical review and to confirm whether this ratio was different in the 1st year of pandemic in comparison with the year before the initiation of the pandemic.

To analyse which of the aforementioned variables showed statistical association with a favorable opinion in the first ethical review.

To characterize which of the variables with statistical association appear as predictors of a favorable opinion in the first ethical review.

MATERIALS AND METHODS

Study Sample

This study covered the 125 research applications submitted to the Research Ethics Committee of La Rioja (*Comité Ético de Investigación con medicamentos de La Rioja*, CEImLAR), between January 1st, 2019 and December 31st, 2020. Only applications referred to biomedical research projects were included. Other types of projects, such as clinical trials with previous ethical favorable opinion from another REC (REC of Reference), and informative post-authorization studies, were not included in this study. According to the Royal Decree 1090/2015, which regulates clinical trials with medicines, the Ethics Committees of Drug Research and the Spanish Registry of Clinical Studies, clinical trials following a multicentre study design only require the ethical evaluation of one REC, which will be the REC of Reference.

The CEImLAR was initially established as CEICLAR (*Comité Ético de Investigación de La Rioja*) in 1995 by Order 10/1995, March 2nd of the Autonomous Community of La Rioja. This Order was updated in 2005 (Order 71/2005, December 2nd). In 2018, the CEICLAR received a certification from the Regional Ministry of Health of La Rioja as a Research Ethics Committee with drugs (CEImLAR). Following the current Spanish normative, the main objective of the CEImLAR is to guarantee the protection of human rights, safety, and well-being of participants and the society as a whole in the framework of activities related to the clinical research, health and scientific advances in La Rioja. Thirteen members, including a permanent secretariat with voice but not vote, currently comprise the CEImLAR. Nine of these members are healthcare professionals (including specialists on clinical and primary care pharmacology, pharmacy, medicine, and nursing), two members are professionals from other disciplines different from medicine (including a lawyer with specialization in data protection, and an economist), a member from a patients' association, and a member with specialization in bioethics. In addition, different regional public health organizations must be represented in the committee's structure. Similar as others RECs, the current activity of the CEImLAR is focused in the evaluation of the methodological, ethical and legal issues of any biomedical research intended to be performed in La Rioja, according to the evaluation criteria stablished by the national normative.

Main Measures

Variables collected were distributed in three groups. Variables composing the first group included information related to the characteristics of the principal investigator (PI), defined as the researcher who led the study and submitted the application. These variables were: identity and academic background of the PI, if the PI was alone or had a research team, if the PI was a professional-in-training (in those cases where the application was part of a post-graduate training program and the PI had a mentor or tutor), and position of the PI in his/her research group, department or unit. The second group of variables referred to different aspects related to the study design. These variables included: the type of study (observational or interventional), the research design (retrospective or prospective), the methodology applied (quantitative, qualitative, or both), participants recruited (minors, adults, or both), and usage of an informed consent form. Finally, aspects related to the ethical review process were collected in a third group of variables. These variables were: dates of first and final ethical revision, time-span (days) between the first and the final opinion of the REC, first and final opinion, number of clarifications required, and type of deficiencies reported in the first ethical review process. Since such deficiencies were not classified in the reports performed by the REC, six categories were created: "informed consent," "objectives and/or hypotheses," "methods and/or procedures," "legal aspects," "conflict of interests," and "economic aspects." Examples of deficiencies reported in the "informed consent" category were applications with informed consent forms in poor writing, with confusing information, or with missing sensitive information. Category "objectives and/or hypotheses" referred to following type of deficiencies: applications with poor writing or confusing research objectives or hypotheses, or applications where those aspects were not connected with the procedures or methodological aspects previously described. Poor writing procedures or procedures missing sensitive aspects related to the process of participants' recruitment, data manipulation, or techniques planned for application in the research protocol, were examples of deficiencies reported in "methods and/or procedures" category. Examples of deficiencies included into the "legal aspects" category were applications not using updated normative or that were not in accordance with the current normative. Applications with financial or other personal considerations that the REC considered could compromise (or had the appearance of compromising) the research purpose and were not reported by the principal investigator, were included in the "conflict of interest" category. Finally, applications requiring clarifications in relation to the sources of financial support, or applications inquired to bring information related to the budget or financial source, were included in the "economic aspects" category.

Procedures and Ethical Approval

Data were extracted from the main database of the CEImLAR. This preliminary search covered all research applications presented in 2019 and 2020 based on the inclusion/exclusion criteria and in the pre-defined categories mentioned above. Three researchers, who are members of the CEImLAR (EMM, LGA, and MTAG), extracted the information and created a preliminary dataset. The identity of the PIs was collected in order to search for two indicators of scientific productivity (articles published and h-index) from SCOPUS. Identities of the PIs were extracted in a second dataset after the preliminary dataset was pseudonymized with alphanumeric codes. Another researcher (BBC), who was not a member of the CEImLAR, completed a second dataset with the information collected from SCOPUS. Finally, both datasets were merged. This procedure was performed with the purpose of keeping anonymous the identity of the PIs. The Research Ethics Committee of the Foral Community of Navarra, an independent Research Ethics Committee, approved the aforementioned procedure prior to be executed (Ref. PI 2021/57).

Statistical Analysis

The opinion submitted by the REC after a first ethical review was used as dependent variable. This variable was categorical and included four possible answers: "application rejected," "application requiring clarifications," "application approved with minor clarifications," and "application approved." For analysis purposes, this variable was recoded into a new binary one with two possible outcomes: zero ("failure"), when the application was rejected or required clarifications after the first ethical review was finished; and one ("successful"), when the application was approved with or without minor clarifications. All the other elements collected were treated as independent variables.

Chi-square test for nominal independent variables and the Mann–Whitney *U* test for quantitative independent variables were applied in bivariate analyses. Then, in a binary logistic regression model, the magnitude of association of the independent variables that showed a significant relationship in the previous bivariate analysis was determined. In order to measure the power of explanation of the logistic regression model obtained, the Nagelkerke's R squared was calculated. Finally, the weight of association between the dependent variable and its predictors was calculated by the measurement of the Odds ratio.

All analyses were done in the R language and programming environment for statistical and graphical analysis, version 3.6.2 for Windows and with the help of the statistical analysis packages *fmsb* (20), *nortest* (21), *rstatix* (22), and *OddsPlotty* (23).

RESULTS

The first objective was to collect information related to the PI, the research application, and the ethical review process. Analysis of SCOPUS database showed a range of publications between zero to 316 (M = 44; Mdn = 5; *SD* = 87.79). In the entire sample, 33 PIs did not have any article published in a peer-review journal, while the other 92 researchers had at least one article published. In relation to h-index, analysis showed a range of scores between zero to 40 (M = 9; Mdn = 1; *SD*=13.63). In the entire sample, 52 PIs had an h-index equal to zero, while the other 72 had h-indexes equal or higher than one. Also, analysis of the CEImLAR records showed that the time-span of the entire ethical review processes (from the 1st submission until the final opinion) ranged from zero to 550 days (M = 51; Mdn = 5; *SD* = 118.08). Distribution of the other characteristics related to the PIs, the research applications, and the ethical review process are summarized in the **Table 1**.

The second objective was to identify the ratio of research applications with a favorable opinion in the first ethical review; and whether this ratio changed in 2020 in comparison with 2019. From the 125 applications analyzed, nine (7%) were rejected at the first ethical review, 60 (48%) required clarifications, nine (7%) were approved with minor clarifications, and 47 (38%) obtained an approval. Based on these findings, 56 (45%) research applications with approval or approval with minor clarifications were recoded as "successful," while the other 69 (55%) were recoded as "failure." The analysis of the entire review process showed that seven applications initially rejected, and other 55 applications requiring clarifications obtained a final approval after further reviews. Only five applications requiring clarifications were abandoned by their PIs without answering the queries performed. A comparative analysis by year showed, in one hand, a two-fold increase in the total number of

TABLE 1 | Sample characteristics of categorical variables ($n = 125$).

Variables	No (%)	Yes (%)
Principal investigator		
Was a professional-in-training (the application was part of his/her training)	105 (84%)	20 (16%)
With research as his/her principal working activity	107 (86%)	18 (14%)
Discipline: medicine	37 (30%)[a]	88 (70%)
Academic degree: Doctoral or PhD	77 (62%)[b]	48 (38%)
Gender: male	65 (52%)	60 (48%)
With previous experience submitting a research application	61 (50%)	61 (50%)
Was the group leader or chief of his/her department	90 (73%)	33 (27%)
Was working alone	97 (81%)[c]	23 (19%)
The study		
Study type: observational	23 (19%)[d]	100 (81%)
Design: prospective	47 (38%)[e]	76 (62%)
Methodology: quantitative	13 (11%)[f]	110 (89%)
Required the use of an informed consent form	34 (27%)	90 (73%)
Participants: only adults	15 (12%)[g]	109 (88%)[h]
Deficiencies reported at the first ethical review process		
Documentation incomplete	105 (84%)	20 (16%)
Informed consent form	104 (83%)	21 (17%)
Hypothesis and/or research objectives	113 (90%)	12 (10%)
Methods and/or procedures sections	62 (50%)	63 (50%)
Legal aspects	106 (85%)	19 (15%)
Funding and economic report	110 (88%)	15 (12%)
Conflict of interest	125 (100%)	0 (0%)

[a] *Nursing (18), biology (5), biochemistry (2), chemistry (6), biotechnology (4), and pharmacy (2).*

[b] *Master (21), Medical specialty (33), and Bachelor (23).*

[c] *Research teams ranged between two to 10 members (IP included).*

[d] *Interventional studies using a technical dispositive (3), a substance (4), and studies without using neither a dispositive or a substance (16).*

[e] *Retrospective studies.*

[f] *Studies based on a qualitative methodology.*

[g] *Studies with only minors (5), and with minors and adults (10) as participants.*

[h] *Studies with patients (80), with healthcare professionals (10), and general public (19) as participants.*

TABLE 2 | Frequency table of the REC's opinion in the first ethical review by variables collected.

Variables	FO	NFO	χ^2
Principal investigator			
With research as his/her principal professional activity	12	6	4.07*
No	44	63	
Academic degree: Doctoral or PhD	29	19	7.68**
No	27	50	
Gender: male	33	27	4.85*
Female	23	42	
With previous experience submitting a research application	36	25	10.77**
Without previous experience	18	43	
Was the group leader or head of his/her department	28	5	29.39***
No	27	63	
Deficiencies reported at the first ethical review process			
Documentation incomplete	0	20	19.32***
No	56	49	
Informed consent	2	19	12.70***
No	54	50	
Hypothesis and/or objectives	0	12	10.78**
No	56	57	
Methods and/or procedures	6	57	63.92***
No	50	12	
Legal aspects	1	18	14.16***
No	55	51	
Economic aspects	1	14	10.02**
No	55	55	

FO, favorable opinion; NFO, non-favorable opinion; χ^2*, Chi-squared coefficient;* $^{*}p < 0.05$; $^{**}p < 0.01$; $^{***}p < 0.001$.

applications submitted from 2019 to 2020. While in the 1st year 41 applications were submitted, 84 were submitted in the 2nd year. On the other hand, statistical differences appear in the ratio of applications with a favorable opinion over those with non-favorable opinion by year ($\chi^2 = 4.23$; $p = 0.04$). While this ratio was 0.46 in 2019, it changed into 1.05 in 2020.

The third objective was to determine whether a favorable opinion and each variable studied were statistically associated. Chi-squared tests confirmed a significant relationship between a favorable opinion and each of the following variables: PI with research as his/her principal working activity, PI with a Doctoral degree, being a male, PI with previous experience submitting a research application, and PI who is the group leader or the chief of his/her department. In addition, each variable related to different type of deficiencies reported in the first ethical review showed a statistical relationship with the judgement of the REC in the first ethical review. A summary is presented in **Table 2**. This relationship was not confirmed in the following cases: PI is a professional-in-training (and the application is part of his/her training), PI is a physician, and PI is working alone. Moreover, none of the second group of variables referred to aspects related to the study design were associated with a favorable ethical opinion. In addition, Mann–Whitney U tests confirmed that research applications with a favorable opinion were submitted by PIs with a higher number of publications ($p < 0.001$), and a greater h-index ($p < 0.001$).

Finally, the fourth objective was to characterize which of the variables identified in the previous objective played a role as predictors of a favorable opinion. An analysis based on logistic multiple regression allowed to create a model predicting 71% of probability of obtaining a favorable opinion in the first ethical review (Nagelkerke $R^2 = 0.71$). Three variables appeared as being explanatory in this model: if "methods and/or procedures" were complete ($p < 0.001$); if "the PI was the group leader or the head of his/her department" ($p < 0.001$), and if "informed consent" was well done ($p = 0.01$). A complete summary of these findings is reported in **Table 3**. From the analysis of the reports emerged the following common deficiencies in relation to "methods and/or procedures": methods or procedures that

TABLE 3 | Multiple logistic regression model.

	β	*SE*	95% CI	OR	*p*
Deficiencies in methods and/or procedures sections	+3.53	0.63	10.9–136	34.15	<0.001
The PI is the group leader or head of the department	+2.86	0.84	3.85–111	17.39	<0.001
Deficiencies in the informed consent	+2.47	1.00	2.06–121	11.79	0.01

β, *logistic regression coefficient; SE, standard error; CI, confidence interval; OR, Odds ratio; p, probability.*
Nagelkerke $R^2 = 0.71$.

were either poor writing or confusing, lack of information of participants' recruitment process, and ambiguous or missing information of data manipulation process. Regarding "informed consent," three main types of deficiencies were observed: lack of informed consent form (due to researchers considered not necessary), contact information of the PI not included in the inform consent form, informed consents form with obsolete normative or normative not applicable to the study. In addition, a few informed consent forms either presented information overload, or were poor writing (text confusing, very technical or difficult to understand for the patient).

DISCUSSION

One of the aims of this study was to compare the number of applications submitted for an ethical review process in the 1st year of the pandemic and the ones submitted in the previous year. The findings observed confirm an increase in the number of submissions, and in the ratio of applications approved each year. Findings related to an increasing number of applications submitted are in accordance with the ones previously reported by the REC of Galicia (19). The difference reported in the ratio of approvals observed in this study can be explained by a certain grade of flexibility in the criteria followed by the REC in the ethical review process once the pandemic started. This flexibility is consequence of following the recommendations suggested by the AEMPS (18) under the extraordinary circumstances being suffered at the beginning of the pandemic.

Another aim was to identify which of the three group of variables collected (those related to the principal investigator's profile, aspects related to the study design, and aspects related to the ethical review process) were individually associated with a favorable opinion in the first ethical review. Findings observed in binary analyses confirmed a higher ratio of success when either the PI has research as his/her main professional activity, has previous experience preparing a research applications, is a male, or when there is a coincidence in which the PI is also the research group leader or the head of the department. Findings reported in this study indicate that neither having a doctoral or PhD degree (which should imply certain research experience), having a professional background different from medicine, nor preparing a research application in collaboration with other colleagues, were associated with a favorable opinion in the first ethical review. In addition, none of all variables related to the scientific and technical parameters of the studies referred in the research applications evaluated were associated with a higher ratio of obtaining a successful ethical review. These findings indicate that a favorable opinion was not dependent on the characteristics of the study. However, the findings confirm an association between deficiencies in sensitive aspects of the research application, such as documentation submitted, informed consent, research objectives and hypotheses, methods and procedures, legal, and economic reports, and a non-favorable opinion in the first ethical review process. On one hand, these findings indicating deficiencies in the applications are in consonance with previous studies in which similar outcomes have been reported, such as: incomplete documentation (24), legal and ethical aspects inappropriately addressed (2, 25), informed consents not properly written (2, 19, 26), and an insufficient description of sensitive aspects related to the objectives, methods or procedures (2, 19). In addition, some of the aforementioned aspects have been associated either with a non-favorable opinion or with delays in the ethical review process (25). On the other hand, findings reported in relation with the PI's profile indicate some important aspects that require a separate consideration. Having research as a main professional activity and having previous experience submitting research applications appear associated with a greater chance of obtaining a positive opinion in the review process. These evidences confirm the importance that targeted training and experience have in the preparation of research applications with a high scientific quality. Unfortunately, information such as the PI's age or years of professional experience were not collected in this study. This type of information could allow a deeper analysis of this matter. However, the higher ratio of successful observed in applications written by PIs with a leadership working position (PIs who are research group leaders or heads of department), offers evidence supporting the positive impact that having experience and being trained has for researchers who assume the role of a PI. In addition, being a male also appear as a variable associated with a higher success rate. This finding, more than an indication of a difference related to gender, should be interpreted as a direct consequence of the fact that most leadership positions are occupied by male researchers, this being confirmed in the logistic multivariable analysis in which this variable was dismissed. Neither being a professional-in-training (which implies having the support of a supervisor or a mentor), having a doctoral or PhD degree, being a clinician, nor working in collaboration with other colleagues were associated with a higher success ratio. These findings bring more evidence supporting the important role that targeted training and research experience have in the preparation of a robust research application. However, these findings are also in consonance with the need that a researcher who leads a research application should have sufficient research experience and qualification or alternatively collaborate with more experienced colleagues in the field of his/her research, as has been recently stated by Beshir (9). In fact, the lack of training and experience of the research group has been described as one of the main causes of failures in research applications submitted for a review process in other European countries (2, 24).

The last aim of this study was to determine which of the aforementioned variables with statistical association appeared as predictors of a favorable opinion at the first ethical review. A multiple logistic regression confirmed that only three variables appeared as predictors in a model explaining 71% of the probability of obtaining a favorable opinion. Two of these variables are associated with sensitive aspects of the research application, such as having an informed consent and methods and procedures properly written and adequately explained. These findings are in accordance with the majority of the evidence reported, where both elements are described as the most frequently cause of rejections and delays in ethical review processes (2, 19, 25, 26). Having a leadership position appears in the aforementioned model as the third predictor of a favorable opinion in the first ethical review process confirming the main hypothesis of this study. This finding not only brings new evidence supporting the important role that a targeted training and experience in research play in this matter, which is in accordance with the opinion of other authors and the evidence reported (2, 9). This finding also provides strong evidence supporting the importance that leadership and mentoring have in interdisciplinary teams performing research activities. In particular, this finding focuses on the specific role of the senior researcher who holds a leadership position in their group or department where these research activities are carried out. This is consistent with the contribution made by other authors (27–29) establishing a direct relationship between leadership and mentoring performed by the most experienced researchers and the improvement in indicators of scientific productivity in their teams. Those indicators include, for example, research projects with high quality, publications, or the consolidation of the scientific careers of less experienced researchers. In the context of professionalism as a paradigm of "job well done" in biomedical research, it is desirable that this third predictor disappeared in the future. Because it suggests, in worst case scenarios, the existence of research groups with very hierarchical compositions, where high experienced group leaders are not transmitting their knowledge and experience to less experienced researchers. In this frame, the reinforcement of lifelong learning and inter-professional collaborative abilities could be two successful strategies for addressing this gap.

Limitations

This study included a heterogeneous group of studies with different methodologies, study designs, and researchers from different academic and professional backgrounds and profiles. In addition, the study covered only studies submitted to one Research Ethics Committee for an ethical review. Due to the nature of the Autonomous Community of La Rioja, the majority of the studies submitted corresponded to only one healthcare institution, the University Hospital San Pedro of La Rioja. Considering the complexity of the phenomenon analyzed, it is recommended that other two aspects should be included in further studies, such as the age of the PIs or their years of research experience. Unfortunately, both aspects were not collected in this study. However, findings reported in this study bring novel evidence that can help our understanding of elements influencing in a favorable opinion in the review process. Future lines of research could focus in a deep analysis of some of the factors described in this study.

In conclusion, in the wide context of a "job well-done" the aforementioned findings bring new evidence supporting the importance that professionalism plays in biomedical research. In the specific case of biomedical research studies involving human subjects, it implies preparing research applications fulfilling adequate scientific, methodological, legal and ethical standards of quality. In this sense, Research Ethics Committees play an important role as guarantors that such standards are complied before they are executed. Therefore, research applications with deficiencies in some of these aspects are in risk of receiving a non-favorable opinion once they are submitted for a first ethical review or of having delays in obtaining a favorable opinion. Researchers in charge of the preparation of research applications should pay attention to bringing a complete information of the study design, methods and procedures according to the applicable normative in order to ensure a favorable review process. In this frame, more-experienced researchers holding leadership positions in their research groups play a fundamental role during the preparation of new research proposals. Based on the evidence reported in this study, it is recommendable that research group leaders enhance the improvement of lifelong learning and inter-professional collaborative abilities in their teams in order to reduce training gaps.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Research Ethics Committee of the Foral Community of Navarra (Ref. PI 2021/57). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

LV was in charge of the study's overall design. EM, LG-A, MTA-G and BB were in charge of data collection. LV and MS-M performed the statistical process of the data. LV, EM and RCDB prepared the draft manuscript. All authors contributed to the present work, participated in the interpretation and processing of results, and reviewed and approved the final manuscript.

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REFERENCES

1. Vivanco L, Delgado-Bolton R. "Professionalism," in *Encyclopedia of Global Bioethics*. Cham: Springer International Publishing (2015) 1–9. doi: 10.1007/978-3-319-05544-2_353-1
2. Russ H, Busta S, Jost B, Bethke TD. Evaluation of clinical trials by Ethics Committees in Germany–results and a comparison of two surveys performed among members of the German Association of Research-Based Pharmaceutical Companies (vfa). *Ger Med Sci.* (2015) 13:Doc02. doi: 10.3205/000206
3. España J del E. Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales (BOE-A-2018-16673). *Bol Of del Estado.* (2018) Available online at: https://www.boe.es/buscar/doc.php?id=BOE-A-2018-16673 (accessed February 16, 2022).
4. España J del E. Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica (BOE-A-2002-22188). *Bol Of del Estado.* (2002)40126–40132. Available online at: https://www.boe.es/buscar/doc.php?id=BOE-A-2002-22188 (accessed February 13, 2022).
5. España J del E. Orden SCO/362/2008, de 4 de febrero, por la que se modifica la Orden SCO/256/2007, de 5 de febrero, por la que se establecen los principios y las directrices detalladas de buena práctica clínica y los requisitos para autorizar la fabricación o importación. *Bol Of del Estado.* (2008)8738–8739. Available online at: https://www.boe.es/diario_boe/txt.php?id=BOE-A-2008-2827 (accessed February 15, 2022).
6. España J del E. Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos (BOE-A-2015-14082). *Bol Of del Estado.* (2015) Available online at: https://www.boe.es/eli/es/rd/2015/12/04/1090 (accessed February 13, 2022).
7. Page SA, Nyeboer J. Improving the process of research ethics review. *Res Integr peer Rev.* (2017) 2:14. doi: 10.1186/s41073-017-0038-7
8. McNeill PM. Research ethics review and the bureaucracy. *Monash Bioeth Rev.* (2002) 21:S72–3. doi: 10.1007/BF03351280
9. Beshir L. Research Ethics Committees in Laboratory Medicine. *EJIFCC.* (2020) 31:282–291. Available online at: /pmc/articles/PMC7745300/ (accessed February 7, 2022).
10. Wagner TH, Murray C, Goldberg J, Adler JM, Abrams J. Costs and benefits of the national cancer institute central institutional review board. *J Clin Oncol.* (2010) 28:662–6. doi: 10.1200/JCO.2009.23.2470
11. Kolstoe SE, Carpenter D. Research approvals iceberg: helping it melt away. *BMC Med Ethics.* (2019) 20:100. doi: 10.1186/s12910-019-0434-2
12. Abbott L, Grady C, A. systematic review of the empirical literature evaluating IRBs: what we know and what we still need to learn. *J Empir Res Hum Res Ethics.* (2011) 6:3–19. doi: 10.1525/jer.2011.6.1.3
13. McWilliams R, Hoover-Fong J, Hamosh A, Beck S, Beaty T, Cutting G. Problematic variation in local institutional review of a multicenter genetic epidemiology study. *JAMA.* (2003) 290:360–6. doi: 10.1001/jama.290.3.360
14. Edwards SJL, Ashcroft R, Kirchin S. Research ethics committees: differences and moral judgement. *Bioethics.* (2004) 18:408–27. doi: 10.1111/j.1467-8519.2004.00407.x
15. UNESCO International Bioethics Committee, UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). Statement on COVID-19: ethical considerations from a global perspective. París (2020). Available onlne at: https://unesdoc.unesco.org/ark:/48223/pf0000373115 (accessed December 16, 2021).
16. Vivanco L, UNESCO. sobre el COVID-19: Directrices Éticas para una Respuesta Global. *Cuad Bioet.* (2020) 31:269–73. doi: 10.30444/CB.69
17. de Montalvo Jääskeläinen F, Altisent Trota R, Bellver Capella V, Cadena Serrano F, de Los Reyes López M, de la Gándara del Castillo Á, et al. Informe del Comité de Bioética de España sobre los requisitos ético-legales en la investigación con datos de salud y muestras biológicas en el marco de la pandemia de Covid-19. *Madrid.* (2020). Available online at: http://assets.comitedebioetica.es/files/documentacion/Informe CBE investigacion COVID-19.pdf
18. Spanish Agency of Medicines and Medical Devices. Exceptional measures applicable to clinical trials to manage problems arising from the COVID-19 emergency - Agencia Española de Medicamentos y Productos Sanitarios. (2020) Available online at: https://www.aemps.gob.es/informa-en/exceptional-measures-applicable-to-clinical-trials-to-manage-problems-arising-from-the-covid-19-emergency/?lang=en (accessed February 15, 2022).
19. Bugarín González R, Romero-Yuste SM, López Vázquez PM, Casariego Rosón J, Carballeda Feijóo N, Cruz Del Río JM, et al. [Ethics Committee experience during COVID-19 emergency. A brief report.]. *Rev Esp Salud Publica.* (2020) 94: Available online at: https://pubmed.ncbi.nlm.nih.gov/33140740/ (accessed April 22, 2021).
20. Nakazawa M. fmsb: Functions for Medical Statistics Book with some Demographic Data. (2021) Available online at: https://cran.r-project.org/web/packages/fmsb/index.html (accessed February 13, 2022).
21. Gross J. nortest: Tests for Normality. *Compr R Arch Netw.* (2015) Available online at: https://cran.r-project.org/web/packages/nortest/index.html (accessed January 22, 2021).
22. Kassambara A. rstatix: Pipe-Friendly Framework for Basic Statistical Tests. *Compr R Arch Netw.* (2020) Available online at: https://cran.r-project.org/web/packages/rstatix/index.html
23. Hutson G. OddsPlotty: Odds Plot to Visualise a Logistic Regression Model. (2021) Available online at: https://cran.r-project.org/package=OddsPlotty (accessed February 10, 2022).
24. Naureen Z, Beccari T, Marks RS, Brown R, Lorusso L, Pheby D, et al. Ethics committees for clinical experimentation at international level with a focus on Italy. *Acta Biomed.* (2020) 91:e2020016. doi: 10.23750/abm.v91i13-S.10643
25. Bergstraesser E, Nadal D, Özgü H, Kleist P. Deficiencies in paediatric research applications delaying ethics committee approval. *Swiss Med Wkly.* (2020) 150:w20267. doi: 10.4414/smw.2020.20267
26. Borovecki A, Mlinaric A, Horvat M, Supak Smolcic V. Informed consent and ethics committee approval in laboratory medicine. *Biochem medica.* (2018) 28:030201. doi: 10.11613/BM.2018.030201
27. Ransdell LB, Lane TS, Schwartz AL, Wayment HA, Baldwin JA. Mentoring new and early-stage investigators and underrepresented minority faculty for research success in health-related fields: an integrative literature review (2010–2020). *Int J Environ Res Public Health.* (2021) 18:1–35. doi: 10.3390/ijerph18020432
28. Hafsteinsdóttir TB, van der Zwaag AM, Schuurmans MJ. Leadership mentoring in nursing research, career development and scholarly productivity: a systematic review. *Int J Nurs Stud.* (2017) 75:21–34. doi: 10.1016/j.ijnurstu.2017.07.004
29. Hafsteinsdóttir TB, Schoonhoven L, Hamers J, Schuurmans MJ. The leadership mentoring in nursing research program for postdoctoral nurses:

a development paper. *J Nurs Scholarsh an Off Publ Sigma Theta Tau Int Honor Soc Nurs.* (2020) 52:435–45. doi: 10.1111/jnu.12565

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The Network of Services for COVID-19 Vaccination in Persons With Mental Disorders: The Italian Social Health System, Its Organization, and Bioethical Issues

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The adoption of restrictive measures aimed at curtailing the spread of SARS-CoV2 has had a harmful impact on socio-affective relationships, while limiting the scope of interventions and activities to promote social inclusion, with considerable negative repercussions for patients with mental disorders. Vaccination has been and will continue to be a valid tool to overcome the barriers of social isolation and to protect the health of this category of patients. In this paper we present an overview of the Italian network of social and healthcare services for COVID-19 vaccination among patients with mental disorders. Some aspects of medical ethics are discussed in order to share good practices for improving the health of this vulnerable group of people. We then consider the measures implemented by the health system in Italy to deal with the phenomenon of vaccine hesitancy before addressing the issue of autonomy and restricted access to vaccination points. Finally, we illustrate some of the perspectives already adopted by the Italian system, which may be useful to the global scientific community.

Keywords: COVID-19 vaccination, mental disorders, healthcare system, health services, vaccine hesitancy, good practices, ethics

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INTRODUCTION

People with mental disorders, especially severe mental illness, have shown higher rates of COVID-19 morbidity and mortality (1); therefore, vaccination against COVID-19 should be prioritized for this vulnerable group, and this has already been assured in several countries (2, 3).

These patients may have difficulty in adhering to prevention measures (4) due to problems of understanding updated information or challenges in adapting their behavior according to the degree of risk.

The adoption of restrictive measures aimed at reducing the risk of contagion and circulation of SARS-CoV2 necessarily entailed an impoverishment of socio-affective relationships, limiting the scope of interventions and activities to promote social inclusion, negatively affecting the person's wellbeing and causing discomfort and a sense of isolation (5). Vaccination has proved to be an excellent tool for bypassing social isolation barriers. Although vaccination readiness varies widely across countries (6), some studies have shown that people with psychiatric disorders tend to be willing to receive vaccination and that vaccination rates in these populations can be increased by targeted prevention programs (7, 8). However, the threat of resistance or the patient's objective mental inability to accept the vaccination in an autonomous way are issues that should not be neglected. In this context, it is essential to improve the network of assistance services (hospital and territorial) that facilitate access to vaccines. Above all, efforts must be made to increase willingness to get vaccinated.

This paper describes the current organizational model covering Italy's network of vaccination services for patients with mental disorders.

LEGISLATIVE AND ETHICAL PRECONDITIONS FOR MENTAL HEALTH ASSISTANCE

As regards the issue of giving assistance to psychiatric patients in Italy, it is appropriate to highlight Law no. 180 of 1978 (9). The contents of this law were transferred and even more qualified in the law establishing the National Health System, again in 1978 (Law no. 833) (10), giving a unitary breath to all the matter that entered the general health system. This legislation certainly represented a scientific, cultural, and civil achievement, putting an end to the establishment of mental institutions and opening up new paths for the organization of a healthcare system, thereby creating the conditions for restoring full "citizenship" to psychiatric patients. The Italian model, sponsored by the World Health Organization (WHO), has influenced the mental health policies of many other countries aimed at replacing asylums with more effective and efficient forms of territorial assistance.

In this context, important issues of professional medical ethics emerge, which directly call into question the responsibilities of all organizations required to apply the aforementioned law. These aspects concern in particular:

- Proper training of social workers, psychologists, and medical specialists;
- The creation of rehabilitation structures providing different levels of protection;
- Greater attention to psychiatric assistance for minors, especially regarding the mental distress that occurs in adolescence;
- Greater intervention in prevention and early diagnosis;
- The care of seriously ill patients who refuse both medical and psychiatric treatment and are at risk of showing violent behavior;
- Public information and discussion to fight against prejudice toward those with mental illness.

WHO recognizes the essential role of mental health in a person's overall state of wellbeing and ability to interact with others. Evidence indicates that mental disorders, one of the main sources of suffering and disability in the world, are progressively increasing. Due to their complex etiopathogenesis involving other physiological systems, in addition to their chronicity and their effects on the nervous system, mental disorders require a multidisciplinary approach that supports clinical research into biological and psychosocial factors that contribute to vulnerability and the ability of an individual to cope (resilience) with such pathologies. To this end, the Istituto Superiore di Sanità (ISS) in the Italian system constantly promotes research and its application with particular attention to particularly critical phases such as the perinatal period, childhood, adolescence, and senescence.

Since 2018 a working group of the Reference Center for Behavioral Sciences and Mental Health, in line with WHO's Mental Health Action Plan 2013–2030 (11), has been carrying out a coordination action plan to strengthen the national network of psychiatric services, with the aim of disseminating and updating good practices to improve the health of people suffering from mental disorders, as well as their families and the general population (12).

In the psychiatric field, we are often faced with ethical issues: informed consent, the mandatory nature of treatment, professional secrecy, the equitable distribution of resources, and drug experimentation (13). Establishing a therapeutic relationship with the psychiatric patient is often complicated because doctor and patient do not share a similar socio-relational background and because there are barriers to a complete exchange of health information. The psychiatric patient may also encounter major difficulties on important issues: the risk of marginalization in the hospital and healthcare environment; little or no emotional and environmental support; and poor living conditions.

In Italy, for COVID-19 hospitalized patients with psychiatric comorbidities, there is a higher mortality rate than for other comorbidities (14). Furthermore, they are frail patients due to their reduced ability to independently manage their health interests, including (in this context) measures to contain the infection (distance, use of masks, hand washing, etc.). In some cases, these subjects frequent meeting places where the risk of contagion is much higher.

In this pandemic phase, now more than ever, there is a need to implement welfare and therapeutic measures for persons suffering from mental disorders, including minors (15), and to strengthen the network of assistance services for psychiatric patients. COVID-19 vaccination should not be used as a taxable act, but as a suitable tool to prevent forms of social isolation and aggravation of psychiatric illnesses.

THE NATIONAL NETWORK OF MENTAL HEALTH SERVICES

In Italy, the network of mental health services (16) is structured as follows:

Department of Mental Health (Dipartimento di Salute Mentale - DSM)

The Department of Mental Health (DSM) is the set of structures and services tasked with meeting demands linked to the care, assistance, and protection of mental health within the region defined by the local health authority (*Azienda Sanitaria Locale - ASL).*

The DSM is equipped with the following services:

- Day care services: Mental Health Centers (*Centri di Salute Mentale* - CSMs)
- Semi-residential services: Day Centers (*Centri Diurni* - CDs)
- Residential services: residential structures (*Strutture Residenziali* - SRs) divided into therapeutic-rehabilitative and socio-rehabilitative residences
- Hospital services: the Psychiatric Diagnosis and Care Services (*Servizio Psichiatrico di Diagnosi e Cura* - SPDC) and day hospitals.

The scope of available assistance is completed by university clinics and private nursing homes.

Mental Health Center (Centro di Salute Mentale)

The Mental Health Center (CSM) is the primary care provider for citizens with mental illness. It coordinates all interventions for the prevention, treatment, and rehabilitation of citizens with psychiatric pathologies within a given region.

The Center is headed by a multi-professional team consisting of at least one psychiatrist, a psychologist, a social worker, and a professional nurse.

The CSM ensures the following interventions:

- Psychiatric treatments and psychotherapies, social interventions, admission of patients to day centers or day hospital residential structures, and hospitalizations
- Psychiatric diagnosis and psychological interviews to identify appropriate therapeutic-rehabilitative and socio-rehabilitative programs
- Liaison with general practitioners (GPs) to provide psychiatric consultancy and to conduct collaborative therapeutic projects and training activities
- Specialist advice for “border” services (alcoholism, drug addiction, etc.), as well as for residential facilities for the elderly and disabled
- Filtering of hospitalizations and control of hospitalization in accredited private neuropsychiatric nursing homes, in order to ensure therapeutic continuity
- Assessment for the purpose of continuous improvement of the quality of the practices and procedures adopted
- Collaboration with voluntary associations, schools, and social cooperatives.

Day Center (Centro Diurno)

The Day Center (CD) is a semi-residential structure with therapeutic-rehabilitative functions. It has its own team, possibly supplemented by operators from social cooperatives and voluntary organizations. It has suitable and adequately equipped premises. As part of personalized therapeutic-rehabilitation projects, this type of facility enables individuals to follow therapeutic strategies and to experiment and learn self-care skills in areas such as: the activities of daily living, the development of individual and group interpersonal relationships, and the search for employment. The CD can be managed by the DSM or by the private sector and social enterprises. In compliance with national standards for accreditation, relations with the DSM are regulated by specific agreements, which guarantee the continuity of taking charge in the care pathway.

Residential Facilities (Strutture Residenziali)

Residential Facilities (SRs) are extra-hospital facilities where a key part of the therapeutic-rehabilitative and socio-rehabilitative program for persons suffering with psychiatric distress (sent by the CSM) is conducted; this is personalized and periodically verified. These structures aim to offer a network of relationships and emancipatory opportunities, within the framework of specific rehabilitation activities. The residential structures are differentiated according to the intensity of health care and have no more than 20 places. They are located in urbanized and easily accessible locations to prevent any form of isolation of the residents and to encourage social exchange. SRs can be created and managed by the DSM or by the private sector and social enterprises.

Psychiatric Diagnosis and Treatment Service (Servizio Psichiatrico di Diagnosi e Cura)

A Psychiatric Diagnosis and Treatment Service (SPDC) is a hospital service where voluntary and compulsory psychiatric treatments are carried out in hospital conditions. This facility also provides consultancy activities for other hospital services. Located within a hospital (or university polyclinic), each SPDC contains up to 16 beds and is equipped with adequate space for shared activities. The total number of beds tends to be identified as one for every 10,000 inhabitants.

COVID-19 VACCINATION TARGETS FOR PEOPLE WITH SEVERE MENTAL HEALTH DISORDERS

Patients with psychiatric disorders should be considered a vulnerable group for COVID-19 infection and must be provided with early access to COVID-19 vaccination.

Promotion of COVID-19 vaccine uptake among patients with mental illnesses is an important public health priority at the moment, as emerging evidence clearly indicates that patients with psychiatric conditions are prone to higher rates of COVID-19 infection along with its complications (17). As several studies have demonstrated, rates of obesity, hypertension, diabetes, and lung disease (all conditions linked to severe outcomes of COVID-19 disease) in these people are higher than in the general population. Furthermore, there is a risk that the initial psychiatric condition of these patients may become aggravated after the disease if they recover from the COVID-19 infection (18).

Based on these premises, the Italian system has adopted a specific approach to the vaccination against COVID-19 among people with serious mental health problems. As proposed in several studies (19), the objectives are as follows:

a. To reduce the risk of serious illnesses and deaths as a result of SARS-CoV-2 infection;
b. To allow these individuals to protect their psychosocial well-being, maintain social relationships, and reactivate paths of social inclusion;
c. To promote continuity in the care and operation of residential structures;
d. To protect the physical health of family members who are indispensable in the care process and to support health professionals in medical-diagnostic procedures related to COVID-19.

Vaccination procedures are planned in accordance with the local health authorities who can anticipate and thoroughly verify the specific needs of patients and their caregivers. Indeed, ensuring quality approaches and summarize specific elements that lead to in-depth interventions to reach the best solution for the patient, is currently an aspect of continuous scientific study (20).

MEASURES TO FACE THE PHENOMENON OF VACCINE HESITANCY OR RESTRICTED ACCESS TO VACCINATION POINTS

The success of a mass vaccination campaign is based not only on logistical and organizational efficiency and effectiveness, but also on the population's vaccine acceptance in order to achieve an adequate coverage rate. The speed with which anti-COVID-19 vaccines have been developed represents a great achievement for science, but it can generate anxiety, fear, and skepticism, fueling the phenomenon of so-called "vaccine hesitancy," defined by WHO as the delay in acceptance or refusal of safe vaccines despite availability of vaccination services (21). It is a complex and contextualized phenomenon that varies over time and depends on the place and type of vaccine; demographic, socio-economic, and historical-cultural factors also come into play (22). The phenomenon is also related to misinformation, disinformation, and conspiracy theories which are spread in particular through social media. In addition, socio-economic and health inequalities, low levels of education, poor access to accurate information, and the lack of effective public health messages or targeted campaigns to tackle barriers to access are all aspects that can influence vaccine hesitancy among certain populations (23).

What has been done in Italy to address this phenomenon? First of all, a strong vaccination campaign was carried out as part of a plan drawn up by the Ministry of Health in collaboration with the Extraordinary Commissioner for Emergency, the Higher Institute of Health, and AIFA (the Italian Medicines Agency), and this was adopted with a specific decree in March 2021 (24). The aims of conducting a rapid campaign were to promote:

a) effective and timely distribution of vaccines;
b) constant monitoring of needs and supplies;
c) increased daily administration capacity, effective and timely distribution of vaccines, and higher numbers of daily administrations.

In particular, the campaign was structured around three operational lines:

- procurement and distribution
- needs monitoring
- increased levels of vaccine administration.

In addition to the communication campaigns, which targeted everyone, some Italian regions (e.g., Liguria, Veneto) directly included persons with serious mental illness in the category of "fragility" for which vaccination should be a priority.

In this context, many Italian health facilities have experimented with fully equipped mobile vaccination units, which visit residential health facilities and psychiatric centers scattered throughout a given region. This was inspired by initiatives to facilitate vaccine access in other countries, such as the United States (25), and it was recommended in the Decalogue for the Anti-Covid Vaccination Plan 19 by the Italian Society of Hygiene, Preventive Medicine and Public Health as a useful strategy for reaching marginal targets and communities (26).

The implementation of "social distancing" measures aimed at curtailing the spread of SARS-CoV2 has necessarily had a harmful impact on socio-affective relationships, as mentioned previously, causing a sense of isolation, especially among those who already feel socially excluded, and unmasking or amplifying mental disorders in psychiatric subjects (27).

Furthermore, in residential facilities it is challenging for these patients to adhere to preventive measures not only because of their clinical characteristics (perhaps partly non-collaborative or not self-sufficient) but also for reasons linked to the structural limitations of these communities (28).

In the maintenance of social relationships and in the reactivation of social inclusion paths in the context of various activities offered by community services, vaccination against SARS-CoV-2 represents an essential tool of integration by preventing and controlling COVID-19 in communities of people with severe mental health problems (29). For this reason, the figure of the caregiver (family and non-family) is fundamental. In Italy, the decision was taken to vaccinate mentally ill patients at the same time as their caregiver, guardian, or support administrator. Sharing the vaccination has proved to be a key source of support for persons with mental disabilities, giving them a sense of security and reassurance that the act is necessary to protect their health.

The Italian government has allowed all regions of the country to support GPs in promoting vaccination among this category of patients, possibly assisted by nurses. In particular, the vaccination can be administered in various contexts:

- at the GP's surgery;
- at the patient's home
- at out-of-patient facilities.

In-home vaccination is currently reserved for patients for whom transport to the clinic or vaccination centers is contraindicated.

This operating mode is preceded by a telephone triage to verify the presence or absence of suspected COVID-19 symptoms, as well as the existence (or not) of temporary or absolute contraindications to vaccination.

Finally, the Italian Society of Psychiatry (SIP), in addition to underlining the importance of making the vaccination procedure available as quickly as possible to these subjects (to be considered as priority vaccinations), has taken steps to encourage adherence through the intervention of all disease care facilities, where staff have been asked to provide each patient with appropriate counseling, following the indications of recent literature concerning the topic (30).

CONCLUSIONS

People with severe mental health problems have a high risk of contagion and mortality linked to COVID-19, and should therefore have priority access to vaccination.

In light of the above, the following recommendations are proposed for other countries, based on the conclusive indications of practices that have already been adopted by the Italian system:

- Maintain vaccination priority criteria that target patients with mental disorders in the continuing vaccination program;
- Implement measures for the improvement and implementation of social and health services, establishing national funds to allow for the recruitment of nurses, social workers, psychologists, and doctors (31);
- Create and constantly update guidelines or *ad hoc* protocols (with an "ethical" slant that takes into account the attitudes of this type of patient toward the vaccine), including adequate information on the benefits and risks of vaccination, while continuing to evaluate vaccine efficacy and safety and potential interactions with psychiatric drugs;
- Coordinate a coherent and constantly updated information flow, anticipating any critical issues and preparing personalized communications;
- Carry out an adequate assessment of the person's mental state, their decision-making capacity, and convictions regarding refusal or hesitation;
- Guarantee the presence of the caregiver or reference figures in the pre- and post-vaccination phase.

To overcome vaccine hesitancy, vaccination campaigns (32) should provide for the possibility of monitoring the adhesion of peripheral non-hospital micro-areas: only in this way can they be effective and avoid generating discrepancies and social difficulties even among patients with psychiatric disorders, who are already severely affected by the pandemic.

In the future it would be useful to develop a study in collaboration with psychiatric research units, considering specific indicators relating to the patient's personality (e.g., conscientiousness, agreeableness, extroversion, neuroticism, openness) (33) and a stratification of the various psychiatric pathologies. This would lead to the identification of different vaccination priority levels based on the type and severity of mental illness. In fact, the priority in vaccinating certain categories of psychiatric patients may not only be justified for individual wellbeing but also for the community, since during the acute phases of the disease these people may not be able to obey the rules of public health protection (in terms of masking, distance and hygiene) resulting in an exponential risk of catching the virus and spreading it (34).

Finally, independent vaccine safety studies are needed to strengthen vaccine confidence in patients with mental disorders (such studies have already been conducted for other categories of people) (35).

AUTHOR CONTRIBUTIONS

RS drafted the document and acquired the information. PF contributed to the substantial conception of the work. MC analyzed the regulatory information and reviewed it critically. All authors contributed to manuscript revision, read, and approved the submitted version.

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REFERENCES

1. Yalçin M, Sönmez Güngör E, Ergelen M, Beşikçi Keleş D, Yerebakan Tüzer M, Öcek Baş T, et al. Characteristics and outcomes of psychiatric inpatients with severe mental illness and COVID-19: experience from a COVID-19-Specific acute psychiatric ward in Istanbul. *J Nerv Ment Dis.* (2021) 209:884–91. doi: 10.1097/NMD.0000000000001450
2. Peritogiannis V, Drakatos I, Gioti P, Garbi A. Vaccination rates against COVID-19 in patients with severe mental illness attending community mental health services in rural Greece. *Int J Soc Psychiatry.* (2022) 7:207640221081801. doi: 10.1177/00207640221081801
3. Mazereel V, Vanbrabant T, Desplenter F, Detraux J, De Picker L, Thys E, et al. COVID-19 vaccination rates in a cohort study of patients with mental illness in residential and community care. *Front Psychiatry.* (2021) 12:805528. doi: 10.3389/fpsyt.2021.805528
4. Courtenay K. Covid-19: challenges for people with intellectual disability. *BMJ.* (2020) 369:m1609. doi: 10.1136/bmj.m1609
5. Muruganandam P, Neelamegam S, Menon V, Alexander J, Chaturvedi SK. COVID-19 and severe mental illness: impact on patients and its relation with their awareness about COVID-19. *Psychiatry Res.* (2020) 291:113265. doi: 10.1016/j.psychres.2020.113265
6. Lazarus JV, Ratzan SC, Palayew A, Gostin LO, Larson HJ, Rabin K, et al. A global survey of potential acceptance of a COVID-19 vaccine. *Nat Med.* (2021) 27:225–8. doi: 10.1038/s41591-020-1124-9
7. Mazereel V, Vanbrabant T, Desplenter F, De Hert M. COVID-19 vaccine uptake in patients with psychiatric disorders admitted to or residing in a university psychiatric hospital. *Lancet Psychiatry.* (2021) 8:860–1. doi: 10.1016/S2215-0366(21)00301-1
8. Jefsen OH, Kølbæk P, Gil Y, Speed M, Dinesen PT, Sønderskov KM, et al. COVID-19 vaccine willingness amongst patients with mental illness compared with the general population. *Acta Neuropsychiatr.* (2021) 33:273–6. doi: 10.1017/neu.2021.15
9. Law 13 May 1978, n. 180 "*Accertamenti e trattamenti sanitari volontari e obbligatori*". Official Gazzette n.133, 16-05-1978.
10. Law 23 December 1978, n. 833 "*Istituzione del servizio sanitario nazionale*". Official Gazzette n.360, 28-12-1978.
11. Comprehensive Mental Health Action Plan 2013-2030. Available online at: https://www.who.int/publications/i/item/9789240031029.

12. Gigantesco A, Pontarelli C, Veltro F, CBGI Italian Study Group. Psychoeducational group therapy in acute psychiatric units: creating a psychosocial culture. An update of spread and effectiveness of a psychosocial intervention in Italian psychiatric wards. *Ann Ist Super Sanita*. (2018) 54:272–83. doi: 10.4415/ANN_18_04_03
13. Van Staden CW, Krüger C. Incapacity to give informed consent owing to mental disorder. *J Med Ethics*. (2003) 29:41–3. doi: 10.1136/jme.29.1.41
14. Lega I, Nisticò L, Palmieri L, Caroppo E, Lo Noce C, Donfrancesco C, et al. Psychiatric disorders among hospitalized patients deceased with COVID-19 in Italy. *EClinicalMedicine*. (2021) 35:100854. doi: 10.1016/j.eclinm.2021.100854
15. Scendoni R, Cannovo N, Fedeli P, Cingolani M. Legal and ethical issues around Covid-19 vaccination consent in Italian children from 12 years of age. *J Leg Ethical Regul Issues*. (2021) 24:1–4.
16. La rete dei servizi per la salute mentale. Available online at: https://www.salute.gov.it/portale/saluteMentale/homeSaluteMentale.jsp.
17. Liu L, Ni SY, Yan W, Lu QD, Zhao YM, Xu YY, et al. Mental and neurological disorders and risk of COVID-19 susceptibility, illness severity and mortality: a systematic review, meta-analysis and call for action. *EClinicalMedicine*. (2021) 40:101111. doi: 10.1016/j.eclinm.2021.101111
18. Nemani K, Li C, Olfson M, Blessing EM, Razavian N, Chen J, et al. Association of psychiatric disorders with mortality among patients with COVID-19. *JAMA Psychiatry*. (2021) 78:380–6. doi: 10.1001/jamapsychiatry.2020.4442
19. Miles LW, Williams N, Luthy KE, Eden L. Adult vaccination rates in the mentally ill population: an outpatient improvement project. *J Am Psychiatr Nurses Assoc*. (2020) 26:172–80. doi: 10.1177/1078390319831763
20. De Micco F, De Benedictis A, Fineschi V, Frati P, Ciccozzi M, Pecchia L, et al. From syndemic lesson after COVID-19 pandemic to a "Systemic Clinical Risk Management" proposal in the perspective of the ethics of job well done. *Int J Environ Res Public Health*. (2022) 19:15. doi: 10.3390/ijerph19010015
21. MacDonald NE, SAGE Working Group on Vaccine Hesitancy. Vaccine hesitancy: definition, scope and determinants. *Vaccine*. (2015) 33:4161–4. doi: 10.1016/j.vaccine.2015.04.036
22. Larson HJ, Jarrett C, Eckersberger E, Smith DM, Paterson P. Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: a systematic review of published literature, 2007-2012. *Vaccine*. (2014) 32:2150–9. doi: 10.1016/j.vaccine.2014.01.081
23. Razai MS, Osama T, McKechnie DGJ, Majeed A. COVID-19 vaccine hesitancy among ethnic minority groups. *BMJ*. (2021) 372:n513. doi: 10.1136/bmj.n513
24. Ministero della Salute. *Decreto 12 marzo 2021*. Available online at: https://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=79430.
25. Strategies for Helping Older Adults and People with Disabilities Access COVID-19 Vaccines. Available online at: https://acl.gov/sites/default/files/2021-04/ACLStrategiesVaccineAccess_Final.pdf.
26. DECALOGO PER IL PIANO VACCINALE ANTI-COVID 19 a cura della Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica, in collaborazione con l'Osservatorio Italiano della Prevenzione e Fondazione Smith Kline. Available online at: https://www.vaccinarsi.org/assets/uploads/files/SITI_OIP_Decalogo_per_il_piano_vaccinale_anti_COVID_19.pdf.
27. Ali AM, Alkhamees AA, Abd Elhay ES, Taha SM, Hendawy AO. COVID-19-Related psychological trauma and psychological distress among community-dwelling psychiatric patients: people struck by depression and sleep disorders endure the greatest burden. *Front Public Health*. (2022) 9:799812. doi: 10.3389/fpubh.2021.799812
28. Cannovo N, Scendoni R, Fede MM, Siotto F, Fedeli P, Cingolani M. Nursing home and vaccination consent: the italian perspective. *Vaccines*. (2021) 9:429. doi: 10.3390/vaccines9050429
29. Stip E, Javaid S, Amiri L. People with mental illness should be included in COVID-19 vaccination. *Lancet Psychiatry*. (2021) 8:275–6. doi: 10.1016/S2215-0366(21)00068-7
30. Mazereel V, Van Assche K, Detraux J, De Hert M. COVID-19 vaccination for people with severe mental illness: why, what, and how? *Lancet Psychiatry*. (2021) 8:444–50. doi: 10.1016/S2215-0366(20)30564-2
31. Fedeli P, Scendoni R, Cirocchi R, Fede MM, Cannovo N, Cingolani M. The COVID-19 emergency and the professional liability of healthcare providers: the situation in Italy. *J Leg Ethical Regul Issues*. (2022) 25:1–5.
32. Burgess RA, Osborne RH, Yongabi KA, Greenhalgh T, Gurdasani D, Kang G, et al. The COVID-19 vaccines rush: participatory community engagement matters more than ever. *Lancet*. (2021) 397:8–10. doi: 10.1016/S0140-6736(20)32642-8
33. Murphy J, Vallières F, Bentall RP, Shevlin M, McBride O, Hartman TK, et al. Psychological characteristics associated with COVID-19 vaccine hesitancy and resistance in Ireland and the United Kingdom. *Nat Commun*. (2021) 12:29. doi: 10.1038/s41467-020-20226-9
34. Reininghaus EZ, Manchia M, Dalkner N, Bonkat N, Squassina A, Hodl I, et al. Outcomes associated with different vaccines in individuals with bipolar disorder and impact on the current COVID-19 pandemic- a systematic review. *Eur Neuropsychopharmacol*. (2022) 54:90–9. doi: 10.1016/j.euroneuro.2021.09.001
35. Riad A, Pokorná A, Attia S, Klugarová J, Koščík M, Klugar M. Prevalence of COVID-19 vaccine side effects among healthcare workers in the Czech republic. *J Clin Med*. (2021) 10:1428. doi: 10.3390/jcm10071428

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The Evaluation of Physiological Index Changes and Safety Work of Female Medical Staff With Different Medical Protection Standards in the Ward of COVID-19

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Background: Effective personal protective equipment (PPE) contribute to the prevention of COVID-19 infection. However, it is necessary to evaluate the potential risk of different medical protections in the isolation ward of COVID-19.

Objectives: We aimed to explore the dynamics in physiological indexes of medical staff under primary and secondary PPE in the isolation ward of COVID-19 and provide the scientific basis for determining the safe work strategy.

Materials and Methods: In this study, 30 female nurses were selected to simulate medical work under the primary or secondary PPE, respectively. The oral temperature, axillary temperature, heart rate, respiratory rate, blood oxygen saturation, and blood pressure were measured and recorded every 20 min. The subjective adverse symptoms were recorded every 30 min. The blood glucose and weight of the individuals were measured and recorded before and after the trial.

Results: The results indicated that the median trial persistence time in the participants with moderate-intensity work wearing the secondary PPE (70.0 min) was much lower than that with moderate-intensity work wearing the primary PPE (180 min) and with light-intensity work wearing the primary PPE (110 min; $p < 0.05$). Importantly, the heart rate, oral/axillary temperature, and respiratory rate of physiological indexes of the participants under moderate-intensity work wearing the secondary PPE increased significantly faster than the primary PPE ($p < 0.001$), while blood oxygen saturation decreased significantly faster than the primary PPE ($p < 0.001$). In addition, the proportions of subjective adverse symptoms (such as dry mouth, dizziness, palpitations, and anhelation) were much higher than primary PPE ($p < 0.001$). The average sweat volume and blood glucose consumption of participants under moderate-intensity work wearing primary PPE were higher than secondary PPE ($p < 0.001$).

Conclusion: The combination of an exacerbated workload and secondary PPE worn by COVID-19 healthcare workers increases the change in physiological indicators, and in some cases the adverse symptoms, which can affect and even suspend their medical work. For any medical institution, there is room for improvement in terms of bioethics of a "Job Well Done" to reduce the risks of medical activities under secondary PPE.

Keywords: COVID-19, physiological indexes, working hours, security, personal protective equipment

INTRODUCTION

The coronavirus disease 2019 (COVID-19) has become a global pandemic since early 2020 (1), and it is currently in a state of normalized epidemic prevention and control in China. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly contagious virus that is mainly spread through close contact with infected people *via* respiratory droplets from coughing or sneezing. The isolation wards and medical staff of designated hospitals for COVID-19 are facing severe challenges. To ensure the health and safety of medical staff, the National Health Commission has successively issued the multi-edition of "*Technical Guidelines on Prevention and Control of COVID-19 in Medical Institutions*" (2–4). These files stipulated the types of personal protective equipment (PPE) and specifies the selection principles and wearing and taking off procedures of PPE for medical staff in different scenarios. Medical protective gowns, disposable medical caps, N95 medical masks, rubber surgical gloves, medical goggles medical shoe covers, and others are necessary PPE to prevent medical staff from being infected by the virus (5).

Many studies and experts have reported that the use of proper PPE for the medical staff can reduce the risk of infection for medical staff and patients (6, 7). However, when medical staff conduct their work with the necessary PPE, these PPE directly affect the physiology of medical staff, since it generates significant metabolic fatigue (8, 9). More importantly, this metabolic fatigue can not only impact operational capacity (10), but also increase the risk of accidents with PPE, increase cross-contamination, and contribute to physiological stress (9). N95 masks, as an important PPE, have good filtration efficiency for small particles, but also hinder airflow. In addition, the long-term use of N95 masks may cause subjective uncomfortable symptoms (11). Generally, the temperature of the micro-environment of medical staff under PPE is affected by both the indoor environment and the body's heat dissipation, resulting in a series of changes in physiological indicators, and even headaches, fainting, and syncope (12, 13). Previously, it was reported that female COVID-19 healthcare workers wearing PPE more often experienced excessive sweating, fatigue, headache, shortness of breath, and dizziness during medical work (14). Furthermore, nurses work longer consecutive hours than other healthcare workers in COVID-19 isolation wards. Thus, medical staff in infectious disease hospitals are facing working stress, fatigue, and problems related to the use of PPE, especially nursing workers (15, 16).

The COVID-19 pandemic has heightened the use of PPE and hygiene activities among medical workers (17). Although the uses of proper PPE provides strong protection for medical staff in the ward of COVID-19, the potential damages for medical staff of PPE cannot be ignored during the COVID-19 pandemic. Currently, the initial observations from the United Kingdom, Italy, Singapore, and India reported that the PPE-induced heat strain among healthcare workers (18–20). However, the research on physiological indicators and safe working hours in medical staff under different standards of PPE has not been reported. Therefore, it is urgent to explore the medical staff body state in the different types of PPE, and further analyze the influence of medical PPE on the physiological indicators of medical staff, and provide the scientific basis for the establishment of medical safe working criteria and the improvement of medical PPE.

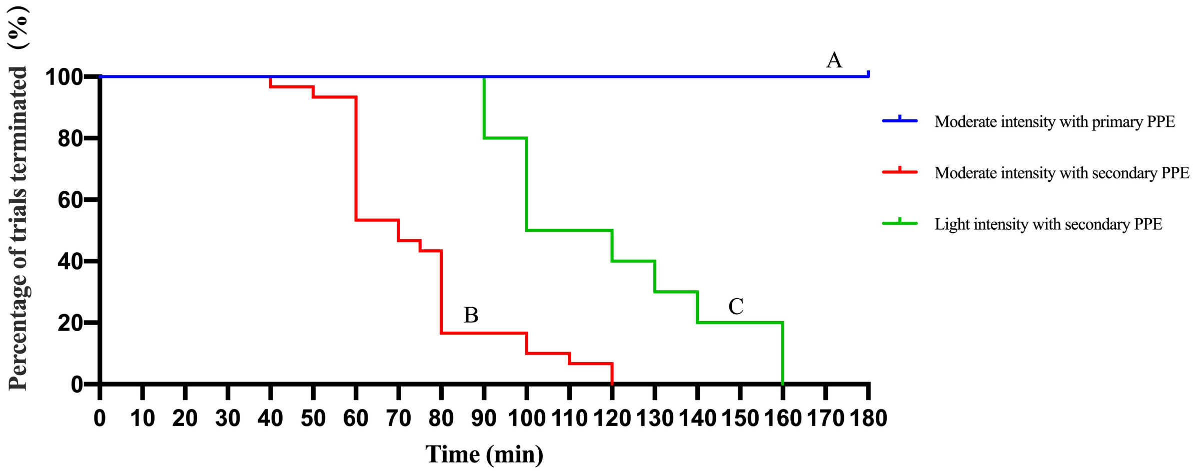
MATERIALS AND METHODS

Study Participants

In this trial, 30 healthy female nurses aged 20–50 years with no underlying health problems were selected for performing light-/moderate-intensity medical work under the primary or secondary PPE. The normal ranges of heart rate, blood pressure, respiratory rate, oral temperature, axillary temperature, and blood oxygen are 60–100 beats/min, 90–139/60–89 mmHg, 12–24 beats/min, < 37.2 °C, < 37.0°C, and 95–100%. These participants were required to maintain a reasonable diet and adequate sleep before the initiation of the trial within 48 h, not take drugs, drink alcohol and coffee, not do vigorous exercise, and not eat food within half an hour before the initiation of the trial (21). Meanwhile, the baseline physiological indicators, such as heart rate, blood oxygen saturation, systolic blood pressure, diastolic blood pressure, respiratory rate, oral temperature, axillary temperature, and weight, were measured and made sure these indicators were within normal ranges (**Supplementary Table 1**). All participants were aware of the objectives, plans, and possible hazards of this trial, and signed the informed consent. The study was conducted in Fuzhou Pulmonary Hospital of Fujian, China, and was approved by the Ethical Committee of Fuzhou Pulmonary Hospital [2021-001(scientific research)-01].

The Environment and Medical Personal Protective Equipment of This Trial

The trial was conducted in a simulated isolation ward in the Fuzhou Pulmonary Hospital, and a thermohygrometer was used to continuously detect the ambient temperature and humidity. During the trial, the indoor ambient temperature of the isolation ward ranged from 32 to 35°C, and the relative humidity was about 60%. The trials were carried out



A	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
B	30	30	30	30	29	28	16	14	5	5	3	2	0	0	0	0	0	0	0
C	10	10	10	10	10	10	10	10	10	8	5	5	4	3	2	2	0	0	0

Groups	Chi square	*P* value
A vs. B	68.61	****
A vs. C	55.92	****
B vs. C	15.33	****

FIGURE 1 | Analysis of trail duration of participants with secondary personal protective equipment (PPE) and moderate-intensity with secondary or primary PPE. ****$p < 0.0001$. The *p* values were calculated using the Log-rank test. PPE, personal protective equipment.

from 2 to 5 pm. This study used brisk walking (1.0 m/s) to simulate moderate-intensity activity and slow walking to simulate light-intensity activity (0.5 m/s) (22). Additionally, the determination of primary and secondary PPE was according to the technical guidelines and expert consensus on the prevention and control of COVID-19 (2–4, 23–26). In this study, the details of primary PPE and the secondary PPE are listed in **Supplementary Table 2**.

Measuring Index and Instruments

We measured and recorded the heart rate, axillary/oral temperature, respiratory rate, and blood oxygen saturation of the research participant using corresponding instruments (**Supplementary Tables 3** and **4**) every 20 min before and during the trial. Additionally, the weight and blood glucose of all participants were measured and recorded before and after the trial. The respiratory rate was calculated by stopwatch and manual counting. All instruments have been regularly tested and qualified by the China National Institute of Metrology. The medical protective gowns and disposable isolation gowns used in the trial meet the national standard GB 19082-2009 (27, 28).

During the trial, the specially-assigned staff asked and recorded the subjective symptoms of the participants every 30 min. When the participants reported discomfort and inability to persist, the safety staff will stop the trial immediately and put them on medical observation. After the trial, the values of each physiological index and the duration of the individual study were measured and recorded immediately.

TABLE 1 | The analysis of physical indicators of participants between primary personal protective equipment (PPE) and secondary PPE after trial.

Variable	Primary PPE (*n* = 30)	Secondary PPE (*n* = 30)	*P* value^a
Heart rate, beats/min	98.67 ± 6.01	139.8 ± 12.75	<0.001
Blood oxygen, %	97.00 (97.00, 98.00)	95.00 (95.00, 96.00)	<0.001
Systolic blood pressure, mmHg	108.87 ± 7.59	105.43 ± 14.83	0.295
Diastolic blood pressure, mmHg	68.5 (65.00, 72.25)	64.50 (61.75, 72.50)	0.147
Respiratory rate, beats/min	23.00 (22.00, 23.00)	34.00 (33.00, 36.00)	<0.001
Oral temperature, °C	37.30 (37.10, 37.40)	38.25 (37.98, 38.50)	<0.001
Axillary temperature, °C	36.90 (36.78, 37.00)	37.70 (37.30, 37.90)	<0.001
Blood glucose, mmol/L	5.36 ± 0.93	4.57 ± 0.98	0.003

^{a}p values were calculated using the paired T-test or the Wilcoxon matched-pairs signed-rank test.
PPE, personal protective equipment.

Statistical Analysis

SPSS 24.0 and STATA/SE 15.0 (STATA Corp, College Station, TX, United States) were used for statistical analysis, and Graphpad Prism 8.0 was used for graph drawing. Continuous variables were presented as mean ± standard deviation (SD) or P_{50} (P_{25}, P_{75}) and tested by the *T*-test or Mann–Whitney test, whereas categorical variables were tested by chi-square tests or Fisher's exact probability test. We modeled and compared the dynamics of heart rate, oral temperature, axillary temperature, respiratory

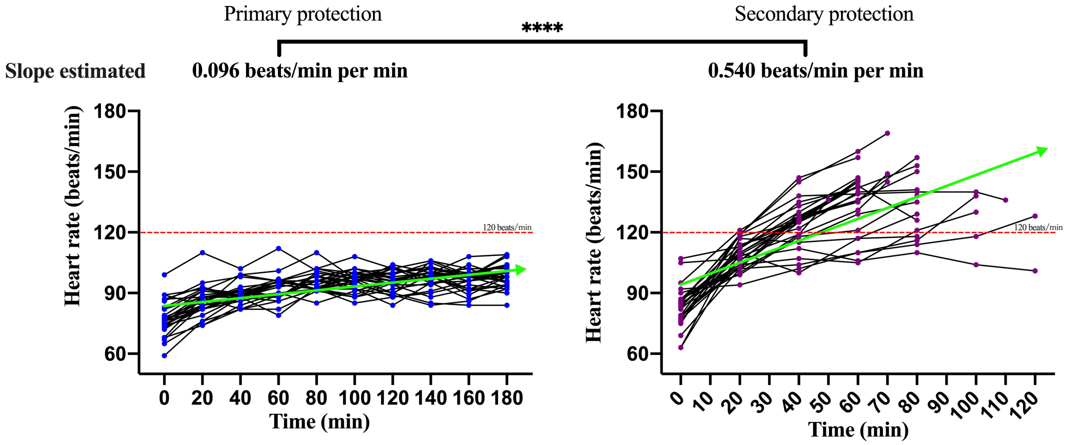


FIGURE 2 | The dynamics of heart rate of participants wearing primary PPE and secondary PPE. ****$p < 0.0001$. The slopes of heart rate during the trial were calculated by generalized estimating equations. PPE, personal protective equipment.

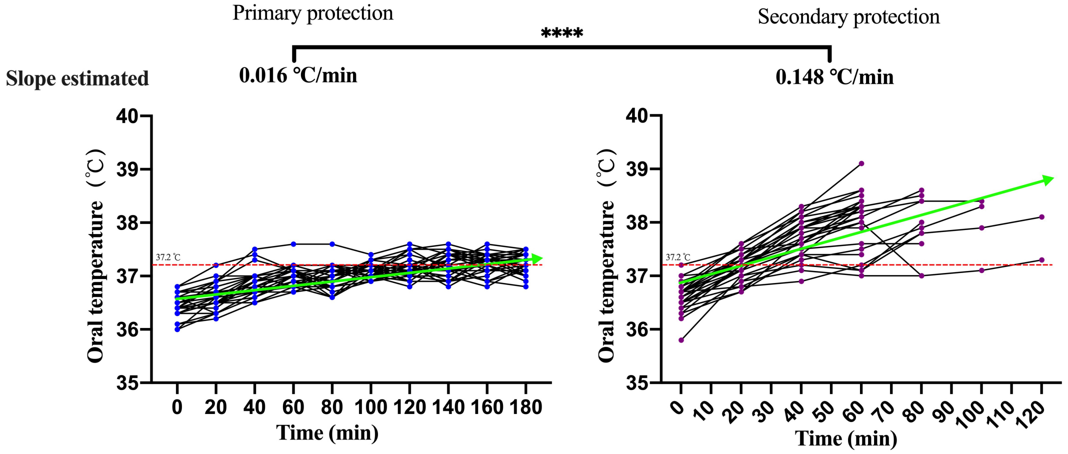


FIGURE 3 | The dynamics of oral temperature of participants with primary and secondary PPE. ****$p < 0.0001$. The slopes of oral temperature during the trial were calculated by generalized estimating equations. PPE, personal protective equipment.

rate, and blood oxygen saturation for the primary PPE and secondary PPE groups during the trial duration using generalized estimating equations (GEE). The value of $p < 0.05$ is considered statistically significant.

RESULTS

Comparison of Percentage of Trial Terminated Between Participants Under Primary Personal Protective Equipment and Secondary Personal Protective Equipment

The results indicated that all 30 participants with moderate-intensity work wearing the primary PPE persisted for 180 min of the trial, but the shortest persistence time was only 40 min and the longest was 120 min for the participants with secondary PPE and none of them completed the 180 min whole trial (**Figure 1**). The proportion of trial terminated of participants under the primary PPE was far more than the secondary PPE (log-rank test, $p < 0.01$). In addition, the median time of participants with secondary PPE performing light-intensity work was 110 min (the range is 90–160 min), which was between moderate-intensity work with secondary PPE and moderate-intensity work with primary PPE (log-rank test, $p < 0.01$; **Figure 1**).

Analysis of the Physiological Index Dynamic of Participants Under Primary Personal Protective Equipment and Secondary Personal Protective Equipment

The changes of the physiological index in participants performing moderate-intensity work under secondary PPE were greater than primary PPE using the paired T-test or the Wilcoxon matched-pairs signed-rank test (**Table 1**). The change speeds of heart

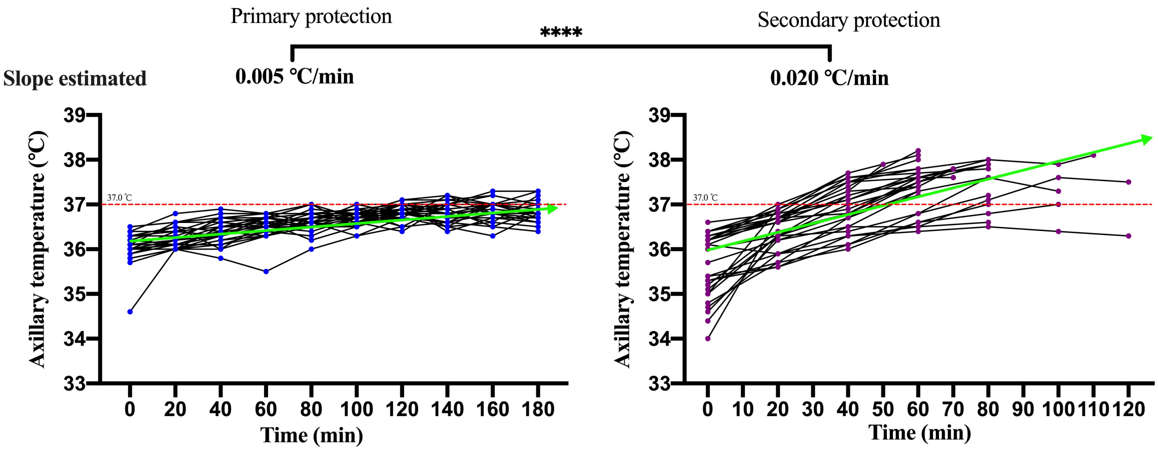


FIGURE 4 | The dynamics of axillary temperature of participants with primary and secondary PPE. ****$p < 0.0001$. The slopes of axillary temperature during the trial were calculated by generalized estimating equations. PPE, personal protective equipment.

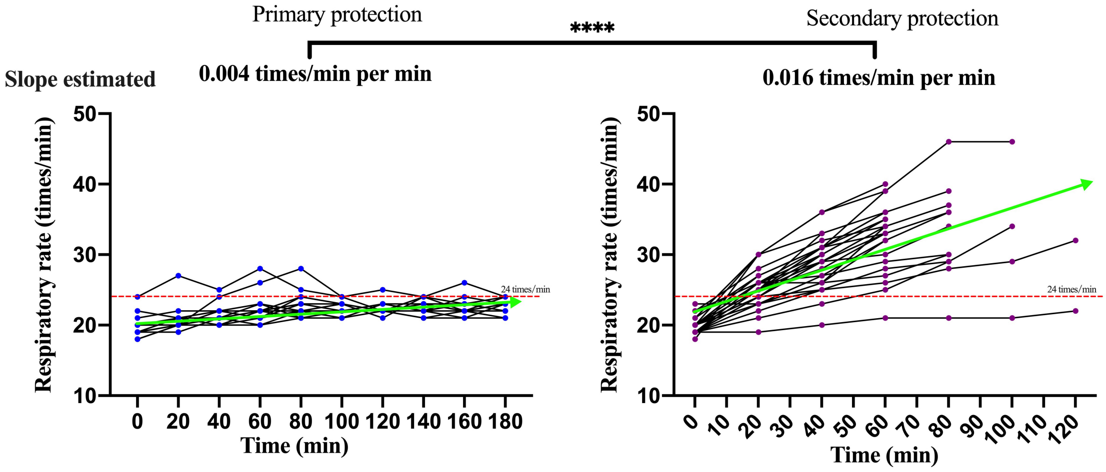


FIGURE 5 | The dynamics of respiratory rate of participants with primary and secondary PPE. ****$p < 0.0001$. The slopes of respiratory rate during the trial were calculated by generalized estimating equations. PPE | personal protective equipment.

rate, oral temperature, axillary temperature, respiratory rate, and blood oxygen saturation were estimated using GEE. As shown in **Figure 2**, the change speeds of heart rate in participants performing moderate-intensity work wearing secondary PPE (0.54 beats/min) were faster than the primary PPE (0.0096 beats/min; $p < 0.0001$). Similarly, the ascending speeds of oral/axillary temperature of participants performing moderate-intensity work wearing secondary PPE (0.148 and 0.020°C/min) were also faster than the primary PPE (0.016 and 0.005°C/min; $p < 0.0001$; **Figures 3**, **4**). Meanwhile, the respiratory speeds of participants with moderate-intensity work wearing primary PPE and secondary PPE were 0.016 and 0.004 beats/min, the difference was statistically significant ($p < 0.0001$; **Figure 5**). In addition, the results showed that the descent speed of blood oxygen saturation of participants with moderate-intensity work under secondary PPE was 0.036%/min, much faster than 0.006%/min of participants under the primary PPE ($p < 0.0001$; **Figure 6**). Additionally, the physiological index changes of participants with secondary PPE performing light-intensity work was between moderate-intensity work with secondary PPE and moderate-intensity work with primary PPE ($p < 0.01$; **Table 2**).

Analysis of the Subjective Adverse Symptoms of the Participants With Primary Personal Protective Equipment and Secondary Personal Protective Equipment During the Trial

The results indicated that the proportion of subjective symptoms, such as dry mouth, dizziness, palpitations, and anhelation of the participants, during the trial rose with the increase of the trial time under the primary PPE and the secondary PPE ($p < 0.001$; **Supplementary Table 5**). Furthermore, the proportions of subjective adverse symptoms, such as dry mouth, dizziness,

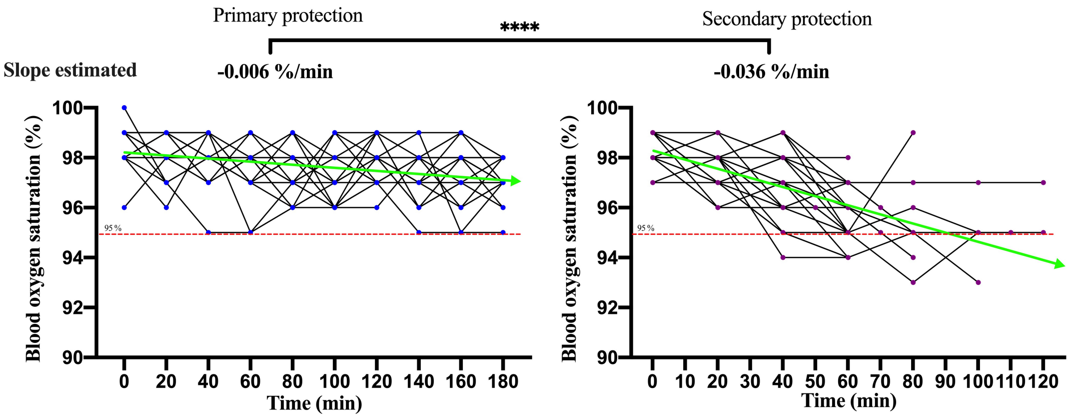


FIGURE 6 | The dynamics of blood oxygen saturation of participants with primary and secondary PPE. ****$p < 0.0001$. The slopes of blood oxygen saturation during the trial were calculated by generalized estimating equations. PPE, personal protective equipment.

TABLE 2 | Comparison of the physiological index changes of participants between light-intensity with secondary PPE and moderate-intensity with secondary or primary PPE.

Variable	Group			*P* value[a]	*P* value[b]
	Light-intensity with secondary PPE	Moderate-intensity with secondary PPE	Moderate-intensity with primary PPE		
Heart rate, beats/min per min	0.228	0.540	0.096	0.033	<0.0001
Systolic blood pressure, mmHg per min	−0.086	−0.070	0.021	0.272	<0.0001
Diastolic blood pressure, mmHg per min	−0.04	−0.045	0.005	0.466	0.004
Respiratory rate, beats/min per min	0.057	0.148	0.016	0.012	<0.0001
Oral temperature, °C per min	0.007	0.016	0.004	0.019	<0.0001
Axillary temperature, °C per min	0.006	0.02	0.005	0.003	0.007
Blood oxygen saturation, % per min	−0.022	−0.036	−0.006	0.039	<0.0001

[a] *The p value was calculated for light-intensity with secondary PPE vs. moderate-intensity with secondary PPE.*
[b] *The p value was calculated for light-intensity with secondary PPE vs. moderate-intensity with primary PPE.*
PPE, personal protective equipment.

palpitations, and anhelation after 30 and 60 min of the trial, in the participants with moderate-intensity work wearing the secondary PPE were higher than that of the participants wearing the primary PPE ($p < 0.001$; **Table 3**). Additionally, the proportions of subjective adverse symptoms, such as anhelation and palpitations after 30 and 60 min of the trial, in the participants with the secondary PPE performing light-intensity work were lower than moderate-intensity work but similar to the participants with the primary PPE performing moderate-intensity work (**Table 3**).

The Sweat Volume and Blood Glucose Consumption of Participants Before and After Trial Under Primary Personal Protective Equipment and Secondary Personal Protective Equipment

The sweat volume was roughly estimated based on weight loss before and after the trial. Although the average trial time of the participants performing moderate-intensity work under the secondary protection was 70.0 min while 180 min under the primary PPE, the average sweat volume of participants under secondary protection was 0.620 kg that was far more than the primary PPE of 0.063 kg (**Supplementary Table 6**). The average sweat volume of participants performing light-intensity work under secondary PPE was 0.510 kg (**Supplementary Table 6**). Meanwhile, the blood glucose of all participants dropped after the trial ($p < 0.0001$; **Figures 7A,B**). Additionally, the blood glucose and weight of the participants before the beginning of the trial under primary protection and secondary protection were similar ($p > 0.05$; **Figure 7C**). After the trial, the blood glucose level of the participants under secondary protection (4.57 ± 0.98 mmol/L) was lower than that of primary protection (5.36 ± 0.93 mmol/L; **Figure 7D**; $p < 0.01$).

Analysis of the Physiological Index Changes of Participants Between Pre-trial and Post-trial

The differences in heart rate, blood oxygen, respiratory rate, oral/axillary temperature, and blood glucose between pre-trial and post-trial in all sub-group participants were statistically significant ($p < 0.05$; **Table 4**). The changes of physiological index in participants performing moderate-intensity work under secondary PPE were the most dramatic.

TABLE 3 | Comparison of subjective symptoms of participants between light intensity with secondary PPE and moderate intensity with secondary or primary PPE after initiation of trial at 30 and 60 min.

Time		Group			*P* value[a]	*P* value[b]	*P* value[c]
	Symptoms	**Light intensity with secondary PPE**	**Moderate intensity with secondary PPE**	**Moderate intensity with primary PPE**			
30 min	Dry mouth	6 (60%)	24 (80.00%)	9 (30.00%)	0.399	0.187	<0.001
	Anhelation	0 (0%)	19 (63.33%)	1 (3.33%)	0.002	>0.999	<0.001
	Dizziness	0 (0%)	7 (23.33%)	0 (0.00%)	0.23	–	<0.001
	Palpitations	1 (10%)	24 (80.00%)	1 (3.33%)	<0.0001	0.442	<0.001
60 min	Dry mouth	7 (70%)	25 (83.33%)	18 (60.00%)	0.648	0.85	0.011
	Anhelation	0 (0%)	20 (66.67%)	1 (3.33%)	<0.0001	>0.999	<0.001
	Dizziness	1 (10%)	25 (83.33%)	0 (0.00%)	<0.0001	0.25	<0.001
	Palpitations	2 (20%)	22 (73.33%)	1 (3.33%)	0.009	0.149	<0.001

[a] *The p value was calculated for light intensity with secondary PPE vs. moderate intensity with secondary PPE.*
[b] *The p value was calculated for light intensity with secondary PPE vs. moderate intensity with primary PPE.*
[c] *The p value was calculated for moderate intensity with secondary PPE vs. moderate intensity with primary PPE.*
PPE, personal protective equipment.

DISCUSSION

Coronavirus disease 2019 is a respiratory infectious disease that is mainly transmitted through droplets and contact and is classified as a Class B infectious disease and managed as a Class A infectious disease in China. According to the relevant technical guidelines and expert consensus (23, 26, 29), it requires that the layout of the COVID-19 isolation ward for receiving and treating patients are divided into three areas and two channels according to work needs. The three areas are the polluted area, the potentially polluted area, and the clean area, respectively. Medical workers need to enter the contaminated area to directly contact patients to carry out various medical activities with high exposure risk, and the corresponding protection level is secondary protection, and tertiary protection is required if necessary. In potentially contaminated areas, there is no need to directly contact patients. The exposure risk is medium, and the corresponding protection level is primary protection. In this study, the research participants wore primary PPE and secondary PPE to simulate clinical activities in the COVID-19 isolation ward. With the progress of the trial, there were obvious differences in the changes of various physiological indicators when the participants with the secondary PPE compared with the primary PPE, and the differences in the incidence of adverse symptoms and the duration of the trial were statistically significant.

The Characteristics and Dynamics of Physiological Indicators in Medical Staff Wore Primary and Secondary Personal Protective Equipment With Moderate-Intensity Activity

The summer temperature of the COVID-19 isolation ward along the south-central coast in China routinely exceeds 30°C. In this study, the indoor ambient temperature of the COVID-19 isolation ward ranged from 32 to 35°C, and the relative humidity was about 60%, and the results showed that in the case of primary PPE, the heart rate of all the participants showed a slow upward trend, but the heart rate of the 180 min trial activity did not exceed 120 beats/min. However, under the secondary PPE, the heart rate of all subjects (0.54 beats/min) was much faster at the ascending speed than that of the primary PPE (0.096 beats/min). At 40 min after the trial began, the heart rates of 66.7% (20/30) participants were higher than 120 beats/min. In addition, we found that the respiratory rate of the participants with the primary PPE was stable throughout the trial, all less than 30 times/min. However, the respiratory rate of the participants with the secondary PPE showed a faster growth rate (0.016 beats/min), which was higher than that of the primary protection (0.004 beats/min). Due to the airtight characteristics and good liquid and gas barrier capabilities of their structure of protective clothing and medical protective masks, medical staff in the isolation ward of COVID-19 are more likely to cause insufficient gas exchange. The micro-environment of the human body under PPE was affected by the environment and the body's heat dissipation, especially for secondary PPE, which accordingly triggers corresponding neural reflexes, resulting in increased breathing frequency and accelerated breathing depth (30, 31). To guarantee the personal safety of the research participants, the trial was stopped when the participants could not persist, thus no extreme changes in physiological indicators were observed.

The Characteristics of Subjective Symptoms in Medical Staff Who Wore Primary and Secondary Personal Protective Equipment With Moderate-Intensity Activity

We collected the subjective perception information of the participants to confirm the changes in physiological indicators. We found that the proportions of palpitations (primary PPE vs. secondary PPE: 3.3 vs. 80.0%) and anhelation (primary PPE vs. secondary PPE: 3.3 vs. 63.3%) of the research participants with the secondary protection were higher than that of the primary

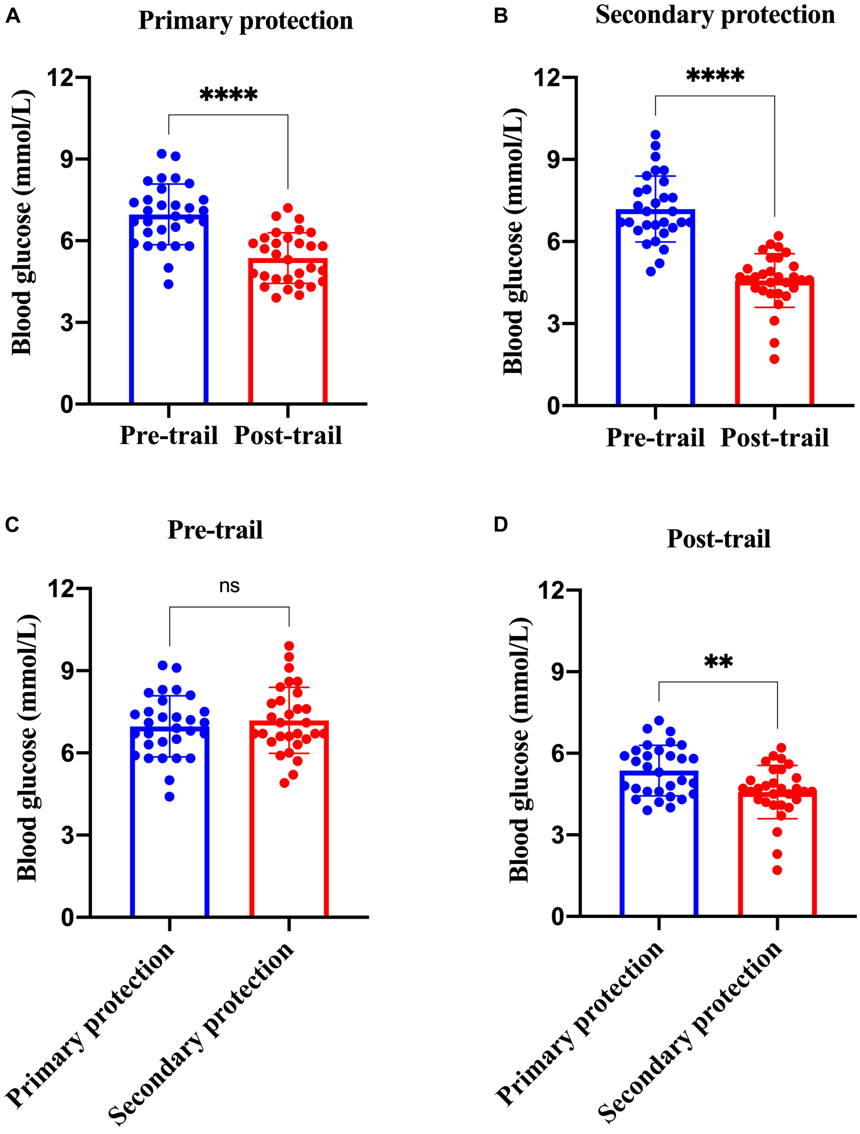


FIGURE 7 | Analysis of blood glucose changes of participants with primary and secondary PPE. **(A)** The blood glucose differences of the research participants before and after the trial under the primary protection; **(B)** the blood glucose differences of the research participants before and after the trial under the secondary protection; **(C)** the blood glucose differences of under the primary protection vs. secondary protection before the trial; **(D)** the blood glucose differences of under the primary protection vs. secondary protection after the trial. $^{**}p < 0.01$; $^{****}p < 0.0001$; and ns, $p > 0.05$. PPE, personal protective equipment.

protection at 30 min since the trial initiation. Mengyu et al. reported that when the subjects wore medical protective clothing, with the increase in exercise intensity and time, it was difficult to maintain a stable microcirculation of thermal-moist, which can lead to a more uncomfortable the subjective perception and the stronger perception of the fatigue (32). This finding was further confirmed in our trial. However, the functions of liquid barrier, microbial barrier, and anti-particle penetration are important performances for medical disposable protective clothing. Medical staff in isolation wards wear medical PPE to block viruses and bacteria. Meanwhile, medical PPE makes the trapped sub-PPE air contain more water vapor relative to the surrounded air (33), causing the body temperature to rise, which may cause a series of subjective discomfort symptom (34–39).

The Analysis of the Safety Work Time in COVID-19 Isolation Ward

Our study revealed that medical staff performing a moderate-intensity activity for 40 min continuously in the COVID-19 isolation ward could influence their physiology. However, medical staff working in polluted areas is hard to replenish water and energy timely due to the special environment. More importantly, when medical staff is extremely tired, quickly taking off PPE in a short period may increase the risk of

TABLE 4 | Analysis of the physiological index changes of participants between pre-trial and post-trial.

Variable	Differences between pre-trial and post-trial					
	Light-intensity with secondary PPE	*P* value	Moderate-intensity with primary PPE	*P* value	Moderate-intensity with secondary PPE	*P* value
Heart rate, beats/min	40.80 ± 12.50	< 0.001[a]	21.50 ± 10.86	< 0.001[a]	56.77 ± 17.32	< 0.001[a]
Blood oxygen, %	–3.40 ± 0.70	0.004[b]	–1.13 ± 14.36	< 0.001[b]	–3.07 ± 1.41	< 0.001[b]
Systolic blood pressure, mmHg	8.70 ± 10.00	0.033[b]	3.00 ± 9.95	0.112[b]	6.37 ± 16.92	0.056[b]
Diastolic blood pressure, mmHg	1.80 ± 8.18	0.44[b]	–0.43 ± 7.24	0.243[b]	3.70 ± 12.97	0.026[b]
Respiratory rate, beats/min	8.30 ± 2.11	0.005[b]	3.70 ± 1.34	< 0.001[b]	14.20 ± 3.62	< 0.001[b]
Oral temperature, °C	1.14 ± 0.33	0.005[b]	0.83 ± 0.31	< 0.001[b]	1.57 ± 0.47	< 0.001[b]
Axillary temperature, °C	1.26 ± 0.33	0.005[b]	0.85 ± 0.40	< 0.001[b]	1.92 ± 0.67	< 0.001[b]
Blood glucose, mmol/L	–2.44 ± 1.13	< 0.001[a]	–2.39 ± 1.21	< 0.001[a]	–2.62 ± 1.35	< 0.001[a]

[a] *p values were calculated using paired T-test.*
[b] *p values were calculated using the Wilcoxon matched-pairs signed-rank test.*

exposure. Therefore, a reasonable arrangement of work intensity and rest time is particularly important for medical staff with different standards of PPE in the COVID-19 isolation ward. In this study, 30 participants were tested under primary and secondary PPE with moderate-intensity activity, respectively, and the results showed that 30 participants with primary PPE persisted for more than 3 h of trial, but the median time of participants with secondary PPE was only 70 min (the range is 40–120 min). Thus, to ensure the personal safety of medical staff in the COVID-19 isolation ward in real medical work, the continuous safe working time of wearing secondary PPE in a high-temperature and high-humidity environment should be kept within 40 min. In addition, the median time of participants with secondary PPE performing light-intensity work was 110 min (the range was 90–160 min), which was between moderate-intensity work with secondary PPE and moderate-intensity work with primary PPE. Therefore, the rational arrangement of medical activities of different intensities contributes to reducing work fatigue and prolonging safe working hours.

The Analysis of the Sweat Volume and Energy Expenditure

To further evaluate the physical exertion of the research participants in medical activities under primary protection and secondary protection, this study monitored the subjects' body weight and blood glucose before and after the trial, and then assessed their sweating and energy consumption during the trial. The results showed that the average weight loss of the research participants with primary protection was 0.063 ± 0.076 kg, and the wet range of cotton hand-washing clothes was about 10%. The average weight loss of the research subjects wearing secondary protection was 0.62 ± 0.202 kg, and the wet range of the cotton handwashing clothes worn by the research participants was more than 80%. It was worth noting that the test duration of all research participants under the primary protection reached 180 min, while the average trial duration of the research participants under the secondary protection was only 70.0 min. Thus, the average weight loss rates of the research participants under the primary protection and secondary protection were 21 and 504 g/h, respectively. It showed that the physical exertion and sweating of medical staff under secondary protection during moderate-intensity medical activities are much higher those under primary protection. The previous literature (28) demonstrated that when the human body sweats too much in a short period, it will cause symptoms, such as increased body temperature, dryness in the mouth, nausea, and vomiting. A large amount of sweat in the protective clothing cannot evaporate, causing the protective clothing to be damp, increasing the perception of discomfort and fatigue in the human body, and then the possibility of causing accidents to medical staff is greatly increased. Additionally, all participants of this study were tested blood for glucose tests at the beginning and end of the trial respectively. The results of the study showed that there was no statistically significant difference in blood glucose levels between the research subjects of the two groups at the beginning of the test. However, the declining of the blood glucose level of the participants under the secondary protection was greater than that of the primary protection ($p < 0.01$). Given the above results and the special environment of the isolation ward, the medical staff was unable to eat, drink, and intake sugar timely. Therefore, before entering the contaminated area work, medical staff should eat properly to prevent entering the contaminated area on an empty stomach to work, especially the staff of the night shift.

Suggestions to Reduce the Adverse Impacts of Wearing Enhanced Personal Protective Equipment

Undoubtedly, reducing exposure time and taking longer breaks benefit medical staff's work shifts to deal with the medical work and PPE-induced discomfort. Previously, studies demonstrated that conducting a 3:1 work-rest ratio can sharply decrease thermal strain during moderate-intensity work, especially for older employees (40, 41), and the adverse effects of PPE (i.e., thirst, exhaustion, and headache) were associated with longer work shift durations (42). Therefore, we suggest that the work shifts of healthcare workers with moderate-intensity wearing PPE should be interrupted by longer breaks and older healthcare workers try to avoid the long-time medical activity of moderate intensity, which can improve the physical and cognitive performance of medical staff and thereby reduce the risk of accidental injuries and contamination. In addition, to alleviate heat strain and discomfort of healthcare workers with PPE, we can perform heat mitigation strategies, such as pre-cooling, to reduce the indoor temperature in the COVID-19 isolation ward (43–45). These strategies were validated in other studies that could relieve physiological and perceptual responses in athletes, firefighters, and military personnel (46–48). In addition, it was reported that some wearable devices [i.e., a phase change material cooling vest and PAPR (3M® Versaflo® TR-300 series)] could significantly improve thermal comfort among medical staff working at COVID-19 wards wearing PPE (49, 50). Lastly, the psychological state can directly affect physiological responses (51, 52), and we suggest that clinical managers should pay attention to the mental status of medical staff, promptly identify problems, and provide guidance to affected workers, and reduce their working hours and duration of wearing PPE (53).

The Limitations in This Study

Certain limitations of our study should be acknowledged. First, the study has a small sample size, especially for the light-intensity with a secondary PPE group, and only included medical staff at a single medical center. Second, our research is limited to the study of the physiological and anthropometric parameters cited in the methodology, but the psychological indicators, such as anxiety and tension, are not measured and discussed. Third, although we stratified the working intensity to light intensity and moderate work according to the routine medical activities, the working intensity simulated in this trial did not fully reflect the working intensity of real clinical practice. Thus, the results of this study should be carefully interpreted and validated in clinical practice. Further laboratory and environmental studies examining the physiological impact of PPE among COVID-19 would be extremely beneficial.

CONCLUSION

In summary, the combination of an exacerbated workload and secondary PPE worn by COVID-19 healthcare workers increases the change in physiological indicators, and in some cases the adverse symptoms, which can affect and even suspend their medical work. Thus, taking mandatory regular breaks, arranging reasonable work intensity, and maintaining optimum temperature in the working environment accord with the principle of Bioethics of a "Job Well Done" during the COVID-19 pandemic and are beneficial to safety work in medical staff.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Ethical Committee of Fuzhou Pulmonary Hospital. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MZ: conception, design, and finalization of the manuscript. JZ: acquisition, analysis, and interpretation of data, and revision and finalization of the manuscript. JY: acquisition of data and draft of the manuscript. XG: perform the data analysis and figures plott. All authors read and approved the final manuscript.

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REFERENCES

1. Lu R, Zhao X, Li J, Niu P, Yang B, Wu H, et al. Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. *Lancet.* (2020) 395:565–74. doi: 10.1016/s0140-6736(20)30251-8
2. The National Health Commission of China. First Edition of The Notice on Printing and Distributing Technical Guidelines on Prevention and Control of COVID-19 in Medical Institutions: National Health Office Medical Letter. (2020). Available online at: http://www.gov.cn/zhengce/zhengceku/202001/23/content_5471857.htm (accessed March 25, 2022).
3. The National Health Commission of China. *The Second Edition of The notice on Printing and Distributing Technical Guidelines on Prevention and Control of COVID-19 in Medical Institutions: Comprehensive Publishing of Joint Prevention and Control Mechanism*. (2021). Available online at: http://www.gov.cn/xinwen/2021-09/14/content_5637147.htm (accessed March 25, 2022).
4. The National Health Commission of China. *The Third Edition of the Notice On Printing and Distributing Technical Guidelines on Prevention and Control of COVID-19 in Medical Institutions: Comprehensive Publishing of Joint Prevention and Control Mechanism*. (2021). Available online at: http://www.gov.cn/xinwen/2021-09/14/content_5637147.htm (accessed March 25, 2022).
5. Verbeek JH, Rajamaki B, Ijaz S, Tikka C, Ruotsalainen JH, Edmond MB, et al. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. *Cochrane Database Syst Rev.* (2019) 7:Cd011621. doi: 10.1002/14651858.CD011621.pub3
6. Adams JG, Walls RM. Supporting the Health Care Workforce During the COVID-19 Global Epidemic. *JAMA.* (2020) 323:1439–40. doi: 10.1001/jama.2020.3972

7. Chang D, Xu H, Rebaza A, Sharma L, Dela Cruz CS. Protecting health-care workers from subclinical coronavirus infection. *Lancet Respir Med.* (2020) 8:e13. doi: 10.1016/s2213-2600(20)30066-7
8. Maynard SL, Kao R, Craig DG. Impact of personal protective equipment on clinical output and perceived exertion. *J R Army Med Corps.* (2016) 162:180–3. doi: 10.1136/jramc-2015-000541
9. Martín-Rodríguez F. Metabolic fatigue in resuscitators using personal protection equipment against biological hazard. *Invest Educ Enferm.* (2019) 37:e04. doi: 10.17533/udea.iee.v37n2e04
10. Calfee MW, Tufts J, Meyer K, McConkey K, Mickelsen L, Rose L, et al. Evaluation of standardized sample collection, packaging, and decontamination procedures to assess cross-contamination potential during Bacillus anthracis incident response operations. *J Occup Environ Hyg.* (2016) 13:980–92. doi: 10.1080/15459624.2016.1200725
11. Rebmann T, Carrico R, Wang J. Physiologic and other effects and compliance with long-term respirator use among medical intensive care unit nurses. *Am J Infect Control.* (2013) 41:1218–23. doi: 10.1016/j.ajic.2013.02.017
12. Ong JJY, Bharatendu C, Goh Y, Tang JZY, Sooi KWX, Tan YL, et al. Headaches Associated With Personal Protective Equipment – A Cross-Sectional Study Among Frontline Healthcare Workers During COVID-19. *Headache.* (2020) 60:864–77. doi: 10.1111/head.13811
13. Swaminathan R, Mukundadura BP, Prasad S. Impact of enhanced personal protective equipment on the physical and mental well-being of healthcare workers during COVID-19. *Postgrad Med J.* (2022) 98:231–3. doi: 10.1136/postgradmedj-2020-139150
14. Bongers C, de Korte JQ, Zwartkruis M, Levels K, Kingma BRM, Eijsvogels TMH. Heat Strain and Use of Heat Mitigation Strategies among COVID-19 Healthcare Workers Wearing Personal Protective Equipment-A Retrospective Study. *Int J Environ Res Public Health.* (2022) 19:1905. doi: 10.3390/ijerph19031905
15. Galehdar N, Toulabi T, Kamran A, Heydari H. Exploring nurses' perception of taking care of patients with coronavirus disease (COVID-19): a qualitative study. *Nurs Open.* (2021) 8:171–9. doi: 10.1002/nop2.616
16. Rathnayake S, Dasanayake D, Maithreepala SD, Ekanayake R, Basnayake PL. Nurses' perspectives of taking care of patients with Coronavirus disease 2019: a phenomenological study. *PLoS One.* (2021) 16:e0257064. doi: 10.1371/journal.pone.0257064
17. Marraha F, Al Faker I, Charif F, Chahoub H, Benyamna Y, Rahmani N, et al. Skin reactions to personal protective equipment among first-line COVID-19 healthcare workers: a survey in Northern Morocco. *Ann Work Expo Health.* (2021) 65:998–1003. doi: 10.1093/annweh/wxab018
18. Lee J, Venugopal V, Latha PK, Alhadad SB, Leow CHW, Goh NY, et al. Heat Stress and Thermal Perception amongst Healthcare Workers during the COVID-19 Pandemic in India and Singapore. *Int J Environ Res Public Health.* (2020) 17:8100. doi: 10.3390/ijerph17218100
19. Davey SL, Lee BJ, Robbins T, Randeva H, Thake CD. Heat stress and PPE during COVID-19: impact on healthcare workers' performance, safety and well-being in NHS settings. *J Hosp Infect.* (2021) 108:185–8. doi: 10.1016/j.jhin.2020.11.027
20. Messeri A, Bonafede M, Pietrafesa E, Pinto I, de'Donato F, Crisci A, et al. A web survey to evaluate the thermal stress associated with personal protective equipment among healthcare workers during the COVID-19 pandemic in Italy. *Int J Environ Res Public Health.* (2021) 18:3861. doi: 10.3390/ijerph18083861
21. Zhaohua Z, Luyao L, Ruiping A. Thermal-wet comfort evaluation of head and torso ventilation of pipe garment. *J Text Res.* (2020) 41:88–94.
22. Xiao-qiang J, Min Z, Bei-chuan G, Bin C, Huan-jie L, Ye-wei C. Changes of artificial environment and physiological indexes of medical staff in COVID-19 ward. *J Saf Environ.* 22:1–10. doi: 10.13637/j.issn.1009-6094.2021.1588
23. Liuyi L, Yu-Xiu G, Liu-Bo Z. Regulation for prevention and control of healthcare associated infection of airborne transmission disease in healthcare facilities. *Chin J Infect Control.* (2017) 16:490–2. doi: 10.7196/SAMJ.2021.v111i3.15381
24. The National Health Commission of China. *The Notice on Further Strengthening the Management of Strictly Grading and Zoning Use of Medical Protective Clothing During the Epidemic Period.* (2020). Available online at: http://www.nhc.gov.cn/wjw/gfxwjj/list.shtml (accessed March 25, 2022).
25. The National Health Commission of China. *The Notice on Printing and Distributing Technical Guidelines for the Protection of Medical Personnel During the COVID-19 Epidemic (Trial Implementation) (National Health Office Medical Letter [2020] NO. 146).* (2020). Available online at:http://www.nhc.gov.cn/ (accessed March 25, 2022).
26. Chun-hui L, Xun H, Meng C, Ping C, Wen-sen C, Xiu-wen C, et al. Expert consensus on personal protection in different regional posts of medical institutions during COVID-19 epidemic period. *Chin J Infect Control.* (2020) 19:199–213.
27. Standardization Administration of China. *Technical Requirements for Medical Disposable Protective Clothing.* Beijing: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (2003).
28. Wenjing D, Wen-feng X, Yanhui W, Zhang N, FaWang S. Sampling test of national medical equipment for medical disposable protective clothing. *Med Equip.* (2018) 31:38–9.
29. Chinese Ministry of Health Expert Group. Technical guidelines for nosocomial infection control of Influenza A (H1N1). *Chin J Infect Control.* (2009) 8:220–4.
30. Xiaowei X, Yan W, Mei G, Xuelian F, Xinzhen M, Xue G. Qualitative study on the psychological experience of civil nurses in COVID-19 response. *J Prev Med Chin People's Liberation Army.* (2020) 38:104–7.
31. Jinhong R, Yumian G, Jing N. Cause analysis and countermeasure of discomfort in medical staff working in isolation ward during outbreak of COVID-19. *Tianjin J Nurs.* (2021) 29:97–9.
32. Mengyu N, Shuwen P, Hongqin D, Kaimin L. Relationship between thermal-moist comfort of medical protective clothing and human fatigue. *J Text Res.* (2021) 42:144–50. doi: 10.13475/j.fzxb.20201003607
33. Taylor NA. Challenges to temperature regulation when working in hot environments. *Ind Health.* (2006) 44:331–44. doi: 10.2486/indhealth.44.331
34. Lucas RAI, Wilson LC, Ainslie PN, Fan JL, Thomas KN, Cotter JD. Independent and interactive effects of incremental heat strain, orthostatic stress, and mild hypohydration on cerebral perfusion. *Am J Physiol Regul Integr Comp Physiol.* (2018) 314:R415–26. doi: 10.1152/ajpregu.00109.2017
35. Nunfam VF, Adusei-Asante K, Van Etten EJ, Oosthuizen J, Frimpong K. Social impacts of occupational heat stress and adaptation strategies of workers: a narrative synthesis of the literature. *Sci Total Environ.* (2018) 643:1542–52. doi: 10.1016/j.scitotenv.2018.06.255
36. Gun R. Deaths in Australia from work-related heat stress, 2000-2015. *Int J Environ Res Public Health.* (2019) 16:3601. doi: 10.3390/ijerph16193601
37. Rivas E, Allie KN, Salvador PM. Progressive dry to humid hyperthermia alters exercise cerebral blood flow. *J Therm Biol.* (2019) 84:398–406. doi: 10.1016/j.jtherbio.2019.07.036
38. Caldwell HG, Coombs GB, Howe CA, Hoiland RL, Patrician A, Lucas SJE, et al. Evidence for temperature-mediated regional increases in cerebral blood flow during exercise. *J Physiol.* (2020) 598:1459–73. doi: 10.1113/jp278827
39. Shibasaki M, Sato K, Hirasawa A, Sadamoto T, Crandall CG, Ogoh S. An assessment of hypercapnia-induced elevations in regional cerebral perfusion during combined orthostatic and heat stresses. *J Physiol Sci.* (2020) 70:25. doi: 10.1186/s12576-020-00751-4
40. Meade RD, Poirier MP, Flouris AD, Hardcastle SG, Kenny GP. Do the threshold limit values for work in hot conditions adequately protect workers?. *Med Sci Sports Exerc.* (2016) 48:1187–96. doi: 10.1249/mss.0000000000000886
41. Lamarche DT, Meade RD, D'Souza AW, Flouris AD, Hardcastle SG, Sigal RJ, et al. The recommended Threshold Limit Values for heat exposure fail to maintain body core temperature within safe limits in older working adults. *J Occup Environ Hyg.* (2017) 14:703–11. doi: 10.1080/15459624.2017.1321844
42. Tabah A, Ramanan M, Laupland KB, Buetti N, Cortegiani A, Mellinghoff J, et al. Personal protective equipment and intensive care unit healthcare worker safety in the COVID-19 era (PPE-SAFE): an international survey. *J Crit Care.* (2020) 59:70–5. doi: 10.1016/j.jcrc.2020.06.005
43. Gao C, Kuklane K, Wang F, Holmér I. Personal cooling with phase change materials to improve thermal comfort from a heat wave perspective. *Indoor Air.* (2012) 22:523–30. doi: 10.1111/j.1600-0668.2012.00778.x
44. Bongers CC, Hopman MT, Eijsvogels TM. Cooling interventions for athletes: an overview of effectiveness, physiological mechanisms, and practical considerations. *Temperature.* (2017) 4:60–78. doi: 10.1080/23328940.2016.1277003

45. Bongers CC, de Korte JQ, Catoire M, Greefhorst J, Hopman MTE, Kingma B, et al. Infographic. Cooling strategies to attenuate PPE-induced heat strain during the COVID-19 pandemic. *Br J Sports Med.* (2021) 55:69–70. doi: 10.1136/bjsports-2020-102528
46. Bongers CC, Thijssen DH, Veltmeijer MT, Hopman MT, Eijsvogels TM. Precooling and percooling (cooling during exercise) both improve performance in the heat: a meta-analytical review. *Br J Sports Med.* (2015) 49:377–84. doi: 10.1136/bjsports-2013-092928
47. Ciuha U, Grönkvist M, Mekjavic IB, Eiken O. Strategies for increasing evaporative cooling during simulated desert patrol mission. *Ergonomics.* (2016) 59:298–309. doi: 10.1080/00140139.2015.1061142
48. Hemmatjo R, Motamedzade M, Aliabadi M, Kalatpour O, Farhadian M. The effect of practical cooling strategies on physiological response and cognitive function during simulated firefighting tasks. *Health Promot Perspect.* (2017) 7:66–73. doi: 10.15171/hpp.2017.13
49. de Korte JQ, Bongers CCWG, Catoire M, Kingma BRM, Eijsvogels TMH. Cooling vests alleviate perceptual heat strain perceived by COVID-19 nurses. *Temperature.* (2020) 9:103–13. doi: 10.1080/23328940.2020.1868386
50. Rhee MSM, Lindquist CD, Silvestrini MT, Chan AC, Ong JJY, Sharma VK. Carbon dioxide increases with face masks but remains below short-term NIOSH limits. *BMC Infect Dis.* (2021) 21:354. doi: 10.1186/s12879-021-06056-0
51. VanderZee KI, Buunk BP, Sanderman R. Social comparison as a mediator between health problems and subjective health evaluations. *Br J Soc Psychol.* (1995) 34:53–65. doi: 10.1111/j.2044-8309.1995.tb01048.x
52. Salovey P, Rothman AJ, Detweiler JB, Steward WT. Emotional states and physical health. *Am Psychol.* (2000) 55:110–21. doi: 10.1037//0003-066x.55.1.110
53. Li F, Jiang T, Shi T, Liu Y, Liu X, Xu G, et al. Factors that affect the duration of wearing disposable personal protective equipment by healthcare professionals in Wuhan during treatment of COVID-19 patients: an epidemiological study. *Nurs Health Sci.* (2021) 23:245–54. doi: 10.1111/nhs.12814

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Participatory Approach to Develop Evidence-Based Clinical Ethics Guidelines for the Care of COVID-19 Patients: A Mixed Method Study From Nepal

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During health emergencies such as the COVID-19 pandemic, healthcare workers face numerous ethical challenges while catering to the needs of patients in healthcare settings. Although the data recapitulating high-income countries ethics frameworks are available, the challenges faced by clinicians in resource-limited settings of low- and middle-income countries are not discussed widely due to a lack of baseline data or evidence. The Nepali healthcare system, which is chronically understaffed and underequipped, was severely affected by the COVID-19 pandemic in its capacity to manage health services and resources for needy patients, leading to ethical dilemmas and challenges during clinical practice. This study aimed to develop a standard guideline that would address syndemic ethical dilemmas during clinical care of COVID-19 patients who are unable to afford standard-of-care. A mixed method study was conducted between February and June of 2021 in 12 government designated COVID-19 treatment hospitals in central Nepal. The draft guideline was discussed among the key stakeholders in the pandemic response in Nepal. The major ethical dilemmas confronted by the study participants (50 healthcare professionals providing patient care at COVID-19 treatment hospitals) could be grouped into five major pillars of ethical clinical practice: rational allocation of medical resources, updated treatment protocols that guide clinical decisions, standard-of-care regardless of patient's economic status, effective communication among stakeholders for prompt patient care, and external factors such as political and bureaucratic interference affecting ethical practice. This living clinical ethics guideline, which has been developed based on the local evidence and case stories of frontline responders, is expected to inform the policymakers as well as the decision-makers positioned at the concerned government units. These ethics guidelines could be endorsed with revisions by the concerned regulatory authorities for the use during consequent waves of COVID-19 and other epidemics that may occur in the future. Other countries affected by the pandemic could conduct similar studies to explore ethical practices in the local clinical and public health context.

Keywords: COVID-19 ethics, health emergency, clinical ethics, pandemic, preparedness, health for all

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INTRODUCTION

The successive waves of coronavirus disease (COVID-19) pandemic hit the national health systems of countries worldwide, directly disrupting their capacity and resources (1). The exponential COVID-19 cases, during the 2020 and 2021 waves, overwhelmed the health facilities in Nepal too (2, 3). With a meager number of 512 ventilators and 1,180 intensive care unit (ICU) beds across the country, the availability of bedside care for critical patients was severely compromised (4). As of 30 December 2021, there were nearly seven thousand active cases of COVID-19 in the country and over 11 thousand people had died, and during the second wave, due to the increased influx of patients with Omicron variant, both public and private hospitals had to operate at their full capacity (5–8).

During the first and second waves of pandemic, the surge of patients in healthcare facilities of Nepal resulted in the breakpoints after which, the patients had to be asked to return home without treatment (9, 10). The Nepali government was not able to scale up free SARS-CoV-2 testing services across the country, which resulted in the shift in testing through private laboratories where tests were rather expensive for a low-income families (11). The pandemic also created logistic and management challenges for health workers (12).

A high influx of the poor patients caused severe delays in testing as well as hospitalization of confirmed cases, resulting in high mortality rates (13). Some of the patients who arrived at the hospital were financially crippled, but at the same time, hospital admission charges went up to 50–200 USD per day and 100–300 USD per day in public and private hospitals, respectively (14). As a consequence, some healthcare workers had to compromise the quality of healthcare to their patients. The existing national health insurance program, which does not cover the majority of the needy population nor provides satisfactory healthcare to the enrolled, did not support COVID-19 care either (15).

COVID-19 created resource scarcity not only in Nepal but globally, which disrupted the existing patient management protocols and brought public healthcare ethics challenges (5, 16, 17). When resources are not sufficient during pandemics, the protection of a larger population gets more priority compared to individual treatment and care (18). In Nepal, an unequal geographical distribution of healthcare facilities and a longstanding shortage of trained manpower affected health service delivery (19).

Ethical challenges complicated the pandemic response in many countries (16). In the Nepali model of COVID-19 response, the ethical challenge faced by front-line workers is unknown and has not been studied yet (20). There is no baseline information about the nature and dynamics of ethical issues that are directly stemming from a patient's financial roots, and more importantly, we do not know how healthcare workers are addressing these ethical challenges at the ground level in the background of weaker health systems. We hypothesized that the ethical decisions for clinical management of COVID-19 patients in the designated hospitals are based on the existing government issued guidelines such as interim clinical guidelines for the care of COVID-19 patients; infection prevention and control guidelines, and professional ethical guidelines during the COVID-19 pandemic, which are inadequate for addressing all ethical challenges (15, 21). Moreover, these guidelines were prepared by a group of experts, without taking input or feedback from the clinical end-users, nor addressing ethical dilemmas they would face while providing care to the poor and vulnerable. In contrast, the present study used the bottom-up approach—information collected from the end-users followed by inputs from the experts, with further opportunities provided to the end-users to contribute and feedback on the guideline drafts.

At various national forums and through the media, many frontline clinicians highlighted an urgent need for clinical ethics guidelines focused on health emergencies. Therefore, an idea of "participatory research" was developed by the study team, who, then, contested for the global award announced by the World Health Organization, Health Ethics & Governance Unit through the Public Health Emergency Preparedness and Response Ethics Network (PHEPREN) in 2020. It was expected that the research findings and the end product, i.e., ethics guidelines, would be endorsed with revisions by the concerned medical regulatory authorities in Nepal.

This study, in particular, aimed to develop a guideline to address syndemic ethical dilemmas during the clinical care of SARS-CoV-2 infected population who are unable to afford standard care and to explore the opinions and views of frontline health workers, health experts, and relevant stakeholders regarding ethical dilemmas during clinical care of financially troubled COVID-19 patients in the country.

METHODOLOGY

Study Design

This is a mixed method study conducted in the government designated COVID-19 treatment hospitals in the Kathmandu valley and among the key stakeholders in pandemic response in Nepal. The study was conducted between February and June 2021, in collaboration with the Nepal National Unit of the UNESCO Chair in Bioethics, which is located in B.P. Koirala Institute of Health Sciences (BPKIHS), Dharan, Nepal.

Study Participants

Fifty healthcare professionals consisting of specialist doctors, medical officers, nurses, and health assistants from 12 hospitals designated for COVID-19 treatment (six public, six private) were enrolled for quantitative and qualitative data collection. This sample size reflects the minimum of four healthcare professionals from each hospital enrolled in a time constrained situation in a pandemic, which is six-fold of what is considered the minimum in a Delphi method. Additionally, 15 expert individuals were interviewed to collect additional qualitative data. The stakeholders engaged in this study were divided into five major groups: frontline COVID-19 responders (*group A*) and representatives of the government of Nepal (*group B*), humanitarian bodies (*group C*), regulatory bodies and professional associations (*group D*), and health specialists (*group E*). Details of each stakeholder group are given in the table below (**Table 1**).

TABLE 1 | List of stakeholders who participated in the study.

Group	Stakeholders group	Participated stakeholders
A	Medical workforce	Frontline COVID-19 responders from 12 selected hospitals
B	Government of Nepal	Ministry of Health and Population - Health Emergency Operation Center (HEOC)/ Health Emergency Disaster Management Unit (HEDMU), COVID-19 Crisis Management Center (CCMC)
C	Humanitarian bodies	Nepal National Unit of UNESCO Chair in Bioethics (BPKIHS)
D	Regulatory bodies and professional associations	Nepal Medical Council (NMC), Nepal Nursing Council, Nepal Medical Association, Nepal Nursing Association, Nepal Critical Care Society, Nepal Geriatric Society
E	Other health specialists	Emergency and Family medicine, Anesthesia, Child health, Women's health, Mental health, Public health, Infectious diseases, Medical education, Medical ethics

Study Tool

A study questionnaire was developed by the study team (**Supplementary File 1**) to collect participants' socio-demographic data and measure the ethical challenges faced by them (using a Likert scale) during the first wave of COVID-19 (March 2020 to January 2021). Ethical dilemmas/challenges were categorized into four levels: (a) contextual challenges (resource scarcity and patients' socioeconomic status), (b) challenges in the decision making process, (c) provider-related challenges, and (d) patient-related challenges (22). The quantitative study was followed by the qualitative components: interviews with the key informants, followed by discussion among stakeholder groups (Delphi process) to prepare a list of ethical dilemma situations and potential solutions (23).

Research Activities

Activity I: Identification of Stakeholders and Initial Interaction to Introduce the Problem and Research Questions

We identified 50 healthcare workers who were working in COVID-19 hospitals and were also members of professional organizations mentioned in Group A (**Table 1**). We approached 12 tertiary hospitals located in Bagmati province (**Figure 1**), that were treating COVID-19 patients, given the sustained surge of cases in these facilities. Study participants were physicians (emergency, critical care, and medical officers), nurses, paramedics, and public health officers, where gender distribution was accounted for. They were selected through the recommendation of COVID-19 focal persons in each hospital. A formal invitation to the session was sent to them along with a participant information sheet and consent form. For those agreeing to participate, a set of semi-structured questionnaires for discussion was sent by email a day before the scheduled session.

Twelve facility-based groups were formed out of 50 nominated individuals. A 30-min virtual interactive session (recorded version) was conducted for each group, and the session was facilitated by one of the co-investigators. The interactive session with one group was blinded to the other groups. Five-open ended questions (which represented the major ethics-related themes: equity, justice, transparency, patient's autonomy, and professional hierarchy) were discussed in detail. All recorded responses were anonymized before data analysis, which is described in the data management section.

Activity II: Key Informant Interviews With Stakeholder Groups

Interviews with the experts were scheduled to discuss the ethical challenges documented from an activity I (see above) and the potential solutions to context-specific challenges. Fifteen experts were identified (five from group A, two from group B and group C each, and six from groups D and E). A formal letter was sent to the president or the director of each institute listed in groups B–E, with a request to nominate these experts. Of 15 interviews, 11 were conducted in-person whereas 4 were conducted virtually. Two or more investigators facilitated each interview. The information generated in the form of an audio draft of around 30-min interview was transcribed by the project team, then sub-categorized into five dilemma situations (described in the results section as pillars) along with their solutions, altogether developing a draft of clinical ethics guideline.

Activity III: Expert Review of COVID-19 Clinical Ethics Guidelines

This session recalled 10 experts from previous sessions (Activity I–II) and recruited five new participants from groups A–D (**Table 1**) following similar selection methods as described above. The additional informed consent form was added to cover this session. The draft guideline was emailed to all participants 48 h prior to the review meeting. The session was conducted in-person, and moderated by an investigator. All feedback were audio-recorded and all suggestions were incorporated into the draft guidelines.

Activity IV: Dissemination of COVID-19 Clinical Ethics Guidelines to End Users for Feedback and Orientation

The near final version of clinical ethics guidelines along with a standard feedback form was sent out by email to 50 end-users from an activity I. All of them responded. The same feedback form was also used to measure the impact of ethics guidelines (based on scores on the Likert scale) reflecting upon the practicality and usefulness of the guidelines, as well as the barriers to its uptake and application in pragmatic settings. Additionally, a half-day virtual orientation session was organized to orient other 20 end-users of the guidelines, who were identified through the recommendation of COVID-19 focal persons of the designated hospitals. The session was facilitated by two investigators. During the session, we used the feedback questionnaire form (**Supplementary File 1**) to collect participants' feedback on COVID-19 clinical ethics guidelines as well as the feedback on the effectiveness of the orientation program.

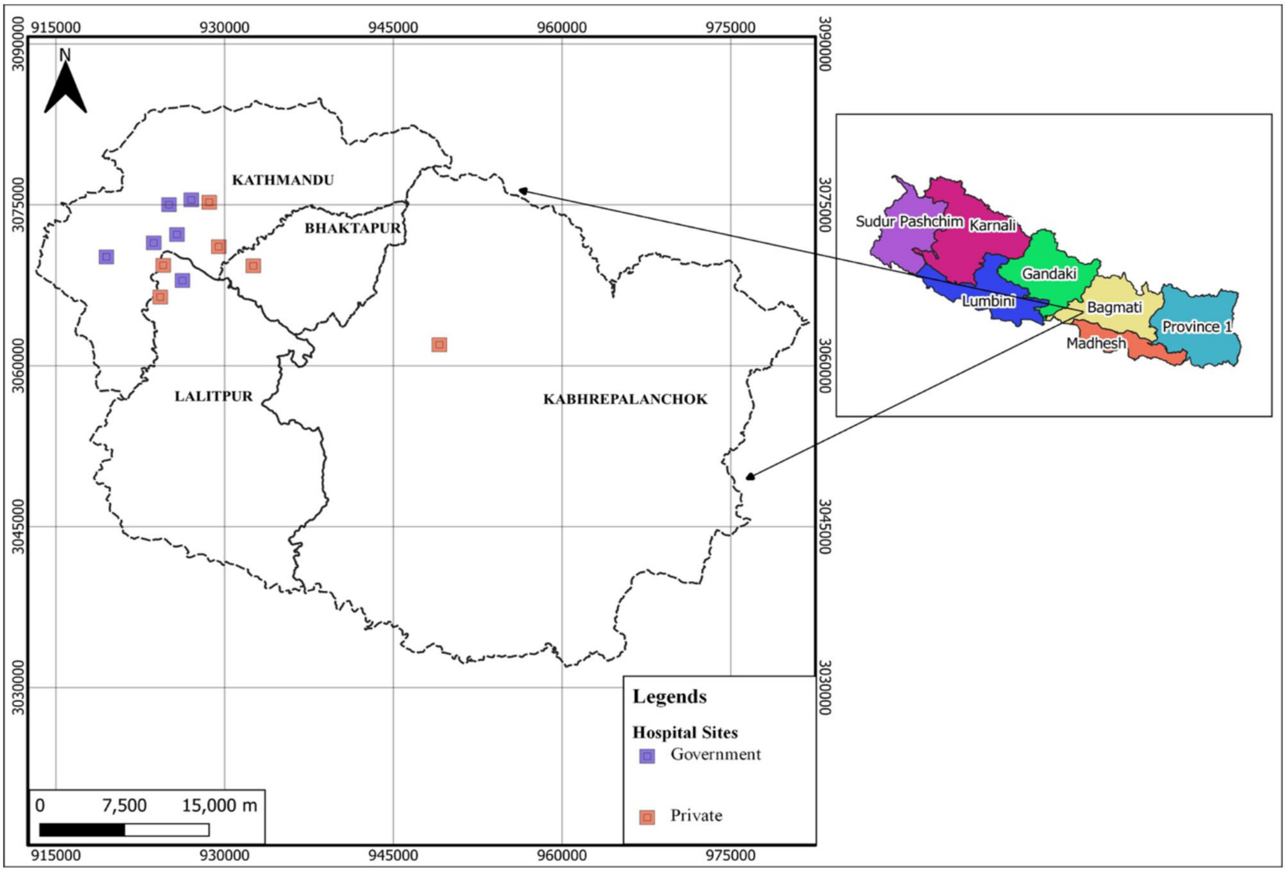

FIGURE 1 | Geographical information system (GIS) map showing the location of 50 health professionals recruited from 12 COVID-19 hospitals, created using ArcGIS (Esri GIS, California, USA).

Data Management and Translation

All the virtual recordings were done via *Microsoft teams (version 4.8.19.0)* and face-to-face meetings were recorded utilizing *Philips DVT-4110*. Each recording was transferred to the project computer as an audio file. After deidentification of the audio files, they were transcribed, and the original file containing audio recordings was stored in the project computer as an encrypted password protected item. As all of the interactive sessions and interviews were conducted in the Nepali language, all of the data were translated into English version during analysis.

Ethical Approval

Before data collection, ethical approval was obtained from the Institutional Review Committee of the B.P. Koirala Institute of Health Sciences (*Ref. No. 497/077/078-IRC, Code No. IRC/2099/021*) and the WHO COVID-19 Research Ethics Review Committee (*Ref. No. CERC.0088, 3/3/2021*). A written informed consent was provided by the study participants for their participation in the respective activity.

RESULTS

Fifty frontline healthcare professionals were recruited in this participatory study from 12 different COVID-19 treating hospitals (**Figure 1**). The median age of the participants was 32.5 years [SD ± 6.14, (IQR: 28 to 34.75 years)] and 50% were female. Of all participants, 40% were specialist doctors (internal medicine, infectious disease, anesthesia, and critical care), 20% were nurses, 13.3% were junior doctors, and 10% were health assistants. Half of the participants (53.3%) were from private COVID-19 hospitals and 36.7% had >10 years of work experience in their related fields. The participants' score (Likert scale) for ethical challenges confronted during the COVID-19 pandemic (March 2020 to January 2021) was not significantly (Mann–Whitney *t*-test) associated with participants' gender and primary work institution (private vs. public).

Out of 15 experts interviewed on a one-to-one basis, three were female. All of them held the leadership position at their respective institution, as mentioned in **Table 1**.

The major findings of this participatory study are summarized below under five sub-sections considered as the five pillars of clinical ethical practice during public health emergencies (**Figure 2**).

Pillar I: Optimal Allocation of Resources for Equitable Patient Care

It was observed that lack of medical resources including qualified human resources is a key problem during health emergencies

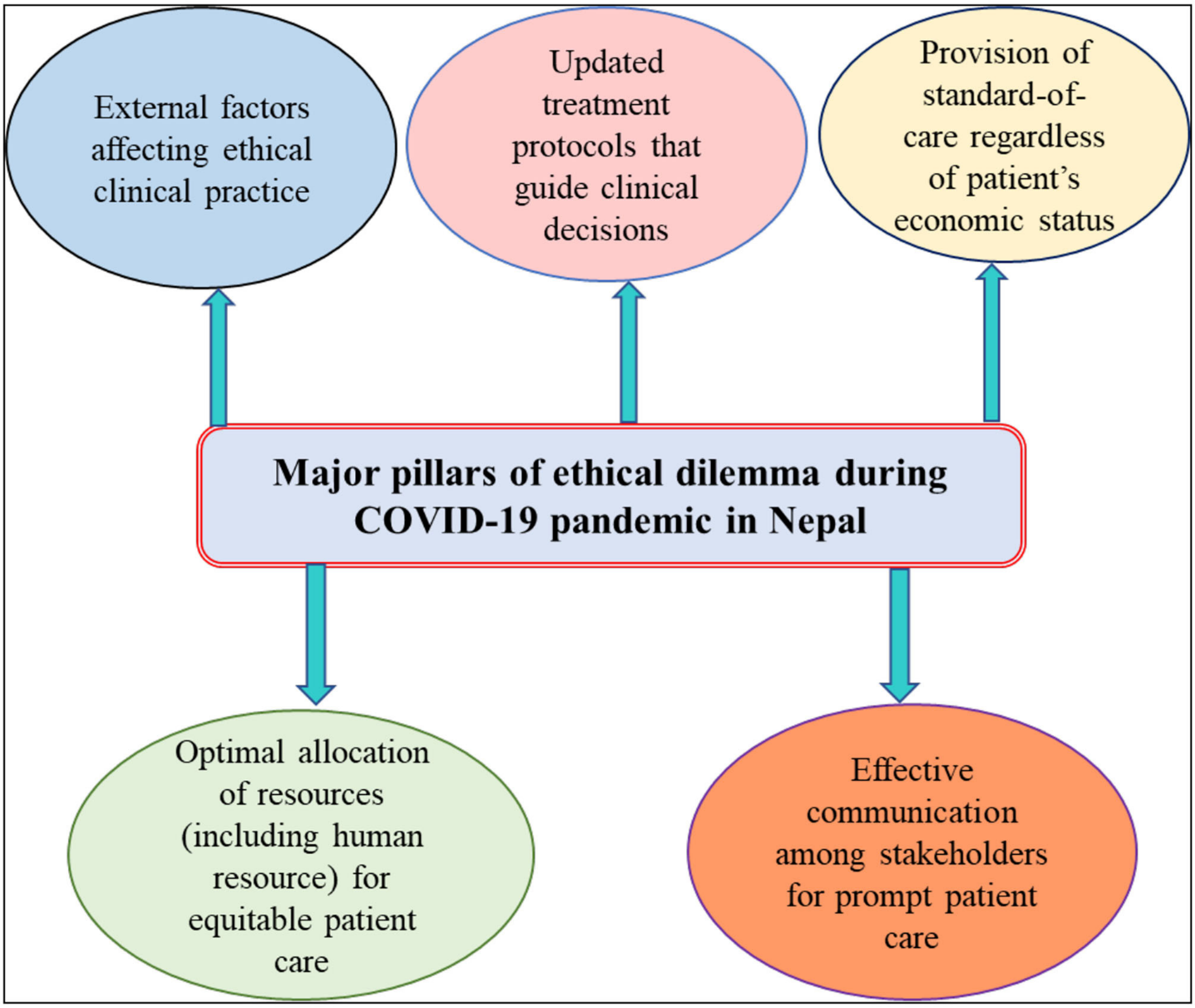

FIGURE 2 | Major ethical dilemmas experienced or observed by healthcare professionals of Nepal during the COVID-19 pandemic.

such as COVID-19. Existing gaps in the medical curriculum about public health emergencies and their management is another issue in Nepal. Other recurrent issues faced by the healthcare facilities during the COVID-19 pandemic included: proper allocation of trained clinical staff for COVID-19 care, procurement of consumables including personal protective equipment, sanitizers, etc., and choosing suitable diagnostic methods for case detection. Other commonly reported issues included: dilemmas in decision making regarding resource allocation for patients' vs. healthcare workers, the challenge in deploying a non-COVID-19 workforce for COVID-19 care, and looming shortage of health and care workers due to quarantine and isolation requirements post-exposure. The introduction of evidence-based courses on public health emergencies, emerging infectious diseases, and epidemics targeted at frontline workers was one of the recommended solutions to these issues.

Study participants advised that identification of the breakage point of resources is crucial during a pandemic as it could help hospital managers to anticipate the scarcity and means to tackle such problems during a health emergency. In addition, a defined breakage points could help to start procurement and hiring of medical resources and staff ahead of a pandemic emergencies. Especially, the local private–public partnership could be practiced for the procurement of raw materials to manage limited resources. In summary, study participants advised the establishment of new structural units to manage relevant expertise and resources promptly during health emergencies.

TABLE 2 | Major ethical dilemmas/challenges experienced by healthcare professionals in decision-making process during COVID-19 pandemic.

Pillars of ethical clinical practice	Identified challenges	Possible solutions and recommendations
I) Optimal allocation of resources (including human resource) for equitable patient care	1. Qualification of medical workforce and gaps in curriculum	• Introduction of evidence-based courses on public health emergencies, increase course hours/credits for emerging infectious diseases and epidemics • Mandatory aptitude test (with ethics related assessments) as a screening tool for pre-medical students • Training on IPC guidelines should be made mandatory for all healthcare workers with annual re-certification.
	2. Resources, including PPE, ventilators, ICU beds, etc. have a finite amount given they are continuously manufactured, and they must be restocked upon consumption. However, restocking during health emergency is a challenge. How can we prepare ourselves?	Breakage point of resources is different for different resources, thus, should be defined on a case-by-case basis. This definition will help to anticipate the scarcity and means to tackle it.
	3. Issues about deployment of trained clinical staffs for COVID-19 care, procurement of consumables such as PPE, sanitizers, etc. and choosing suitable diagnostic methods for case detection. How can we minimize the resource strain during health emergencies? How can we ease procurement of construction materials for establishing new COVID-19 wards or repurposing the existing wards for COVID-19 care?	• Government stakeholders as well as hospital managers should have a breakage point defined for each resource, then, they should start the procurement and hiring ahead of such point. • It would be ideal if each hospital would anticipate new structural development in pandemic so that relevant expertise and resources could be managed promptly. In Nepali setting, some of the innovative approaches were utilized for minimizing the impact of limited resources (e.g., in house manufacturing of PPE, hospital beds, oxygen plant; local public private partnership for raw material production or procurement).
	4. Given the nature of pandemic due to emerging disease, the information and guidelines may not always appear promptly especially during initial days of pandemic. Who should decide for the resource allocation in healthcare facilities?	• The best party for deciding resource allocation during health emergency is the hospital itself. • A core team including physicians, nurses, administrative personnel, and technicians with variety of experience might provide a holistic idea on resource allocation. • It is also important not to heavily engage clinicians in the decision-making process for resource allocation. However, the core team should listen to the insights and experience of frontline responders regarding resource allocation for healthcare workers and patients. • The core team should protect healthcare workers from accusation of bias in resource allocation, for e.g., favoritism for certain patients and negligence for others.
	5. How should resource allocation among patients vs.. healthcare workers be decided?	• The resource allocation decisions should not be influenced by the patient's gender, religious or political views, ethnicity, financial status etc. However, we should be aware of fact that complete elimination of all this bias is impossible, so we should work more on minimizing the disparities and discrimination. • Decision on need-based resource allocation could be implemented. For example, PPE allocation will have different rationale compared to ICU beds and ventilators. Hence, creating a subtopic on "resources" and defining the breakage point for all resources is necessary. • Resource allocation process should also cater to the needs of healthcare professionals regardless of their hierarchy in the institution.
	6. Challenge in deploying non-COVID-19 work force for COVID-19 care	A role model based leadership is optimal and can impact positively for motivating the existing workforce for their smooth transition to COVID-19 care.
	7. Shortage of health-care professionals for COVID-19 care due to quarantine and isolation requirements after exposure to infected patients	• Deployment of highly trained but inactive health care workforce into the frontline would be an alternative of managing human resource at the time of health emergencies. • Inclusion of newly trained medical students and interns in the front responders' list could help fill the human resource gap. • Medical or nursing licensing procedure can be eased to pool trained manpower for quick deployment during health emergencies.

(Continued)

TABLE 2 | Continued

II) Updated treatment protocols that guide clinical decisions	1. Screening, diagnostic and testing tools/strategies vary between hospitals	Steps for standardization of tools/strategies: collection and review of global practices, guidelines, and strategies – select those most suitable for the local context – make uniform tools that could be applied in all types of hospitals – adopt the tools/strategies as pilot followed by nationwide roll out.
	2. What is the optimal timeline and duration of in-hospital treatment of COVID-19 patients?	Need of locally contextualized guidelines and protocols regarding when to end quarantine/ isolation/ ICU/ hospital care for infected patients.
	3. Pandemic response related institutional policies and regulations vary between hospitals	Need of uniform policies and regulations in all private hospitals across the nation regarding pandemic response.
	4. Patient's clinical care needs vs. hospital's profit motives (especially in private hospitals)	Need of hospital ethics guidelines (from admin/ management perspectives).
	5. Home nursing care provision for COVID-19 patients	• Home care should be permitted for registered institutions only, that too for preventive and promotive care only. • Discourage this service unless there is a code of ethics; there should be regulations for nurses who want to provide home nursing services with their individual discretion or through authorized channels.
	6. Use of Robot nurses for COVID-19 patients	Need of protocol and regulations for/against the use of Robot nurse, although it has been conditionally approved by the MOHP as a trial service.
	7. Use of under trial drugs and procedures (such as remdesivir, dexamethasone, ivermectin, CPT)	Need of clear and timely guidelines to regulate use of unapproved treatments (such as CPT with measure of neutralizing antibodies).
III) Provision of standard-of-care regardless of patient's economic status *Applicable to both public and private service providers*	1. Unclear guidelines and notices, with frequent changes, about treatment subsidies for COVID-19 infected individuals and designated centers for the same	Autonomy should be given to the hospital management in deciding treatment for the poor. Government authorities, in turn, could revitalize existing universal medical ethics and professional codes during crisis and support formation of a social welfare committee in each hospital to address poor patient related issues.
	2. Drugs under trial (such as remdesivir) were not available in all hospitals and to all patients	• All hospitals meeting the standards for clinical research should be enrolled into clinical trials and their names should be circulated to all treatment facilities. • Physicians working elsewhere could coordinate transfer of patients to the designated research hospitals so that they can be enrolled into trial.
	3. Some drugs and procedures (remdesivir, steroid, plasma therapy) were not accessible to poor patients due to unregulated price hike and artificial shortage	• Treating physicians, hospital management or staff welfare committee (SWC) could coordinate/lobby with national research and regulatory bodies and pharmaceuticals to ensure poor patient's access to emergency medicines at affordable price. • Hospitals could write a formal letter to the philanthropists and donor organizations requesting in kind contribution to the poor patient fund.
Public service providers	4. Cumbersome paperwork for patients to qualify or self-declare poor status to take subsidies and benefits	Treating physicians should continue providing care to the likely poor patients until their paperwork is complete. Physicians can later confirm the poor status of patients through hospital management or SWC, whenever the required documentation is complete.
Private service providers	5. High cost of in-patient care, especially intensive care (ICU)	• Hospitals should admit only those patients who require hospitalized care but ensure continuation of telehealth services to mild cases, transfer asymptomatic or mild cases to the government-designated isolation centers. • Government could begin market survey to make treatment packages (including individual drug prices) uniform and reasonable across all health facilities (public or private).
	6. Some poor patients were turned away from the hospital gate just because of inability to pay deposit amount in advance	• Treating physicians should strictly follow medical ethics and professional codes of conduct. • Clauses of hospital ethics should be regulated by SWC. • Hospital management should not encourage unethical practices and disparities based on the financial status of patients.

(Continued)

TABLE 2 | Continued

	7. Clinicians as the owner of hospitals or taking the leadership role in the management could have influenced pandemic response and clinical decision-making process	Remove selection bias while nominating SWC members.
	8. Dilemma among health care professionals around patient needs vs. patient or relative's request vs. professional ethics. How can it be minimized?	Healthcare professionals should review the rationale and evidence behind use of sophisticated and non-recommended tests such as HRCT Lung (patient need vs. patient/family request vs. professional ethics), use of blanket therapy for treatment of mild to severe patients (which compels patients to pay out of their pocket) such as steroids, broad spectrum antibiotics, antifungal, and other repurposed drugs and therapy).
IV) Effective communication among stakeholders for prompt patient care	1. Each hospital (public or private) with RT-PCR lab facility was required to report to the government before relaying test results to the patients. Many patients complained about the delay and their ignorance about the next steps	The government should respect the autonomy of service provider and patient with regards to test reports. Along with the test result, it would be better to disseminate IPC information and the next steps for the individuals who deposited their specimens for COVID-19 testing (regardless of test result).
	2. Unclear treatment guidelines and protocol	• Treating physicians may continue patient care based on the evidence and experience while remaining vigilant to the new directions from the government. • The government should allow clinical autonomy to physicians until a centralized evidence synthesis institution is established.
	3. Several questions asked by patients/families could not be answered by the clinicians due to lack of evidence.	It is the responsibility of a qualified clinician to remain up to date regarding evolving evidence and share any new information to the patients in a lay language. Treating physicians should provide updates to the patients/ families on a regular basis. Ensure adequate care contact time between service providers and patients/families.
	4. Professional hierarchy affected clinical decision-making process	• Experienced and qualified junior professionals should be given equal autonomy even under no or minimal supervision of senior professionals to save time while providing clinical care to the needy patients during health emergencies. • Medical or nursing councils should remain standby to resolve any pertinent issues regarding hierarchy that might affect optimum clinical care.
	5. Misinformation and infodemic circulating in free social media platforms; Social stigma about COVID-19; Poor access to the right and adequate information, especially for people with digital illiteracy and those from minority ethnic groups	• Public media platforms should be given to the genuine experts and non-experts should be restricted from sharing unsolicited opinions. • Rapid communication groups or social media pages may be formed to run instant debates and discussion on emerging topics. • All stakeholders should disseminate positive message through social channels such as radio, daily newspapers, TV, etc. to reduce misinformation and stigma. • Infodemic about unapproved tests, treatment, and prevention strategies (for example, Ct value information was not need in RT-PCR report) should be discouraged by the government and professional societies. • Government's communication strategy should prioritize translating and disseminating all relevant public information in all local languages to reach ground level communities.
Communication amongst service providers	6. Because COVID-19 was an emerging disease, there was a dearth of information and updates even from authentic sources.	• It is the responsibility of a qualified clinician to remain up to date regarding evolving evidence. • Hospital should identify a dedicated staff who can track all relevant sources of information, collate up-to-the minute updates regarding emerging disease that are available on the internet, and disseminate the findings to the clinical and management team on a daily basis.
	7. Inadequate information regarding service availability in COVID-19 treating hospitals (especially oxygen beds, ICU service, ventilators) which hampered timely and safe referral/transfer of moderate to severe patients	• Mapping of available services through government or non-governmental authorities (such as HEOC, NMA) with hourly updates, public dissemination of updated contact list of service providers in each hospital, and instant communication through social media platforms such as Viber group/WhatsApp group/Facebook group.

(Continued)

TABLE 2 | Continued

• Dedicated and qualified healthcare as well as managerial personnel could be recruited for Hotline services offered by the government.	8. Lack of proper information regarding effective use of PPE (especially doffing) while providing care to infected patients and the follow-on steps (whether or not required to stay on isolation after seeing infected patient, timeline for return to care, degree of precautions to be taken at home). Limited training slots for healthcare providers, so not all staff could receive the training.	• There should be a provision for continuous and on-demand training opportunities for all levels of healthcare providers. • Training should be provided in a simple and understandable language with hands-on learning. • Hospital management and senior professionals should provide clear guidance and directives to the junior staffs.
V) External factors affecting ethical clinical practice	a. Administrative hassle for research ethics approval and unclear rational behind selection/designation of research centers	Expedited and free of cost processing of research proposals submitted to the ethical review committees. Designate research centers based on qualified human resource, quality of patient care with ICU back up, and availability of advanced technology.
	b. Gender related incidents and violence in isolation centers	The government should manage supervision of isolation centers from violence, gender, and GBV perspectives.
	c. Undue pressure and influence from higher officials and political figures for priority care of their families, relatives, and friends	• Senior members of the hospital, government's high-ranking officials and politicians along with their cadres should follow IPC measures when they visit hospital for whatsoever reason. • They should not influence the priority setting of COVID-19 care to the infected patients. • Concept of "health equity" and "health for all" should be understood by everyone.
	d. Healthcare providers were prone to contracting infection due to exposure at workplace	Recognition of COVID-19 as occupational disease, especially for HCWs.

GBV, gender-based violence; PPE, personal protective equipment; ICU,intensive care unit; SWC, Staff Welfare Committee; CPT, convalescent plasma therapy; IPC, infection prevention and control; Ct, threshold cycle; HCWs, healthcare worker.

Pillar II: Updated Treatment Protocols That Guide Clinical Decisions

Study participants reported different issues related to the COVID-19 treatment approach and decision making which include varying screening and testing strategies between hospitals, patient's clinical care needs vs. hospital's profit motive. On top of all, variations in institutional policies and regulations were also observed in the hospitals. These facilities were devoid of contextualized guidelines to provide efficient health services to the COVID-19 patients. As a solution, participants suggested health facilities formulate their own ethics guidelines from administrative and management perspectives for prompt and efficient response to public health emergencies. Participants realized the importance of clear and timely updated guidelines to control and regulate unapproved treatment methods such as under trial therapy and herbal medicines.

Pillar III: Provision of Standard-of-Care Regardless of Patient's Economic Status

High fees for hospitalization, especially intensive care, in both public and private facilities were found to be the most common issue observed by all study participants. The COVID-19 patients had to suffer due to unclear guidelines and notices from the government, with frequent changes, especially about subsidized care and designated facilities for the same. Unfortunately, some patients were forced to turn away from the hospital entrance just because of their inability to pay the deposit amounts in advance, particularly in private hospitals. Most notably, healthcare professionals were deficient in the rationale behind the use of blanket therapy for the treatment of mild to severe COVID-19 patients. Study participants highlighted the importance of strictly following medical ethics and professional codes of conduct to reduce treatment disparities based on the patient's financial status.

Pillar IV: Effective Communication Among Stakeholders for Prompt Patient Care

During the first wave of the COVID-19 pandemic, all hospitals in Nepal were required to report PCR tests conducted in their lab to the government before relaying the results to the patients. Because of this rule, many patients complained about the delay in getting PCR results and deferred treatment. The lack of clear diagnostic and treatment protocols and guidelines embellished the situation, coupled with the longstanding practice of professional hierarchy for clinical decision making.

Misinformation and infodemic about SARS-CoV-2 infection and new emerging SARS-CoV-2 variants also intensified public panic, especially among the minority indigenous groups and people with poor health literacy. Study participants agreed that up-to-date information to the public with evolving evidence disseminated through authorized channels is very important to avoid unnecessary havoc during health emergencies. On the other hand, each health professional should be made aware and well trained in scientific communication, effective use of PPE, and appropriate patient referral and follow-up mechanisms. It is also a fundamental responsibility of the hospital management to arrange relevant e-learning courses and hands-on training for all staff on a regular basis – before, during, and after health emergencies.

Pillar V: External Factors Affecting Ethical Clinical Practice

Study participants reported undue pressure and influence from senior members of the hospital, high government officials and bureaucrats, and political figures to prioritize their family, relatives, or friends for COVID-19 care, sometimes trespassing the in-patient units and ignoring the institution's infection prevention and control (IPC) measures. Similarly, some study participants experienced hurdles to get the ethical approval from regulatory bodies to conduct research related to COVID-19. The government and institution's reluctance for the recognition of COVID-19 as an occupational disease, especially for healthcare workers (HCWs), was a unique challenge noted by the study team.

A detailed explanation of ethical challenges and dilemmas experienced or observed by the healthcare professionals of Nepal during COVID-19 patient care has been given in **Table 2**, where a summary of possible solutions and recommendations is also mentioned.

DISCUSSION

Health emergencies such as the COVID-19 pandemic emphasize the importance of clinical ethics which values the greater good of the whole society rather than individual demands and rights (24–27). The COVID-19 pandemic has raised various ethical concerns, especially in the low to middle-income countries (LMICs). Most of the ethical concerns are around sharing and allocation of medical resources, triaging and care of the sick patients, preparedness and readiness of the health facilities and overall health systems, information sharing mechanisms, intellectual property rights, community engagement for health emergency decisions, and inequity in healthcare (16, 28). This end-user participatory study developed evidence-based ethical guidelines for the care of COVID-19 patients in Nepal, based on the major ethical dilemmas confronted by study participants which can be broadly categorized into five sections: (i) rational allocation of medical resources; (ii) appropriate treatment protocols to guide clinical decisions; (iii) patient's economic status affecting optimal treatment and care; (iv) effective communication among stakeholders for better healthcare service; and (v) undue pressure and IPC breach by political and bureaucratic figures.

As in other countries, the resource allocation process in Nepal was exacerbated by the shortage of essential medical products including PPE, ventilators, beds, oxygen, and medicines, which created a high level of insecurity and uncertainty among COVID-19 patients and caregivers (16, 29–31). During the pandemic, appropriate criteria and norms could have been established for the distribution of already scarce critical care supplies on a case-by-case basis. Each hospital could have established a rapid response team comprised of clinicians and hospital managers which could provide the right direction for resource management. A transparent and open communication amongst hospital staff is also crucial during a health crisis to make quick decisions for a scientific allocation of resources including the health workforce (32).

Most importantly, resource allocation decisions should not be influenced by ethnicity, gender, religious or political view, and the financial status of the patients (33). For ease of allocation, resources can be divided into as many parts as possible, so that need-based decisions could be implemented. For example, the rationale for PPE allocation could be different compared to intensive care ventilators. Thus, creating a subcategory of the resource and then defining the point of breakage for each subcategory would be necessary for prompt and scientific allocation (34).

Like other countries, Nepal also experienced the challenge of repurposing the non-COVID-19 healthcare workforce for COVID-19 care (12, 18, 35). A looming shortage of healthcare workers was worsened due to strict quarantine and isolation obligations after minimal exposure to the infected patients. To mitigate the shortage, this study suggests the identification and deployment of a highly trained but clinically less active healthcare workforce at the time of health emergencies. Moreover, it would important to advocate for medical education reform as ethics education or training is missing in the medical curriculum of Nepal (36, 37).

Lack of standard protocols for screening and testing of COVID-19 suspects, lack of clear treatment guidelines, and dilemma about prognosis scoring of critical patients were found to be the major ethical challenges faced by the majority of physicians. A similar scenario was prevalent in India, South Africa, the UK, and globally (16, 35, 38). Particularly, it was unclear when to end the quarantine, isolation, or hospitalization requirements, not only for the patients but also for the exposed healthcare workers. There was also a lack of clear and updated guidelines regarding the use of unapproved COVID-19 treatments such as remdesivir and convalescent plasma therapy (39). On another hand, participation of health institutions in large research was affected due to a lack of clear and contextual health emergency-focused "research ethics" guidelines (40, 41).

The financial motives of some of the large private providers also overshadowed the optimal clinical care needs during the COVID-19 crisis, as some patients were forced to struggle with high treatment costs (42). The availability of ICU beds surpassed the epidemic intensity and its simple solutions, such as the transfer of ICU patients from central to regional hospitals, were not implemented. Surprisingly, private hospitals and nursing home facilities did not receive positive feedback and support from the policy-makers despite their interest and capacity to initiate care and treatment of COVID-19 patients. The study participants suggested the utilization of nursing or care home facilities to provide appropriate and safe care for COVID-19 recovered patients who need short-term or long-term residential care (43).

Frequent changes in the government's work plan and directives regarding subsidies to the poor and vulnerable COVID-19 patients were another reason for the ethical dilemma that the clinicians faced. This study observed that the formation of a "social welfare committee" in each hospital, particularly during a health crisis, could be a fast-track to addressing the issues of the poor and vulnerable patients. Tireless paperwork required for the patients to qualify or self-declared "poor status", even to get minimum benefits became a burden for the majority of patients. There was a need for a proper channel that could have coordinated among hospital management, treating physicians, regulatory authorities, and pharmaceutical bodies to ensure the poor's access to basic and emergency services as well as medicines at affordable prices. The study participants also advised the government to conduct a market research to estimate price variations across health facilities, then develop a uniform and consistent treatment and benefits packages (44).

The study also highlighted the need to reinforce the clinical workforce to strictly follow medical ethics and professional codes during patient triage and treatment. It was advised that the clinicians should admit only those patients who genuinely require in-patient care, but at the same time ensure the continuation of telehealth services for ambulatory patients wherever possible. Asymptomatic or mild patients could be transferred to the government-designated isolation centers to minimize overcrowding in tertiary level COVID-19 designated hospitals. It should be mandatory for everyone to follow the hospital's IPC measures, even the senior members of the hospital, government's high-ranking officials, or political leaders, whenever they enter the facility regardless of the purpose. In prescribing behavior, the physicians could be advised not to use blanket therapy approach for treating mild to severe COVID-19 patients, as a method not only to reduce the patient's out-of-pocket expenses but also to minimize the risk of drug resistance (45).

Shared decision-making and open communication among stakeholders can help improve patient care at the time of a health crisis (46), but both methods were lacking in the healthcare facilities of Nepal during the COVID-19 pandemic. The civil society organizations, national/international non-government organizations, and local/provincial governments could have played a role in solving ethics-related issues by utilizing their pre-established coordination and communication channels. Few examples of effective communication which could benefit the patients and their relatives at the time of emergency are hourly updates on the availability of essential health services (e.g., oxygen, isolation beds, ICU beds, ventilator) at public and private health facilities, updated contact list of on-duty service providers, and mechanism for instant communication through social media channels. On the other hand, it is important to verify the information and updates based on the evidence available and disseminate them through authorized communication channels to avoid unnecessary public havoc during health emergencies (13).

It was also observed that professional hierarchy in an institution affected the clinical decision-making process and delayed care of COVID-19 patients. As a solution, qualified junior health professionals could be allowed equal autonomy to provide clinical services to the patients, under minimal supervision of seniors, at the time of crisis (47).

This participatory study enhanced the capacity of end-users, i.e., frontline clinicians and healthcare workers, to some extent, which will help them address ethical issues that may arise during routine and emergency clinical management of the patients. And, to sustain the mechanism, continuous training should be provided to all healthcare workers, regardless of their position or level, to update them about rapidly changing clinical scenarios during a health emergency.

CONCLUSION

The COVID-19 pandemic posed a wide range of challenges to the health systems of Nepal, but also an important prospect to reflect and develop new methods and models of delivering clinical services in an ethical way, which is essential at the time of public health emergencies. Our findings suggest that the majority of clinical ethics dilemmas while providing health services to the needy patients were stemming from resource allocation, treatment protocols for clinicians, patients' socio-economic status, communication strategy, and political/bureaucratic support. We suggest that a co-design bottom-up approach and synergistic model of care might be helpful for rationing limited resources and priority setting to ensure quality clinical care for all patients. There might be a need for an overhaul of the health infrastructure on par with the preparation drill for pandemic-like situations in each health institution to minimize the potential ethical dilemma. In addition, this living clinical ethics guideline, which has been developed based on the local evidence and case stories of frontline responders, is expected to inform the policy-makers as well as the decision-makers positioned at the concerned government units. The guidelines could be endorsed with revisions by the concerned regulatory authorities for the use during consequent waves of COVID-19 and other epidemics that may occur in the future. The Nepal National Unit of UNESCO Chair in Bioethics, a study collaborator, could facilitate the implementation and routine update of the guidelines by key health system actors, such as the social security division at the Department of Health Services and the Health emergencies unit at the WHO country office. Learning from the findings of this study, other countries affected by the pandemic could conduct similar studies to explore ethical practices in the local clinical and public health context.

LIMITATIONS

Standard clinical ethics guidelines are important, but these are not the only solutions to ensure quality health services for the poor and vulnerable populations. Overall health systems of the country need to be strengthened to provide health coverage to all people regardless of their financial status. An ethical practice of health service delivery should be a joint venture of health service providers in both public and private sectors, national health insurance and social protection programmes, and relevant regulatory bodies of the government.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/**Supplementary Material**, further inquiries can be directed to the corresponding author/s.

ETHICS STATEMENT

Ethical approval for the study was obtained from the Institutional Review Committee of BPKIHS (Ref. No. 497/077/078-IRC, Code No. IRC/2099/021) and the WHO COVID-19 Research Ethics Review Committee (Ref. No. CERC.0088, 3/3/2021). The participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

SB and AA conceptualized the study. SB, AA, JD, and SK implemented it. DRS supervised the whole project and contributed as PI. BR analyzed the data, designed maps and figures, drafted the initial version of manuscript, significantly contributed in editing, and revision of the manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.873881/full#supplementary-material

REFERENCES

1. WHO. *Coronavirus Disease (COVID-19) – Epidemiological Update*. (2022). Available online at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports (accessed December 2, 2021).
2. Dahal S, Luo R, Subedi RK, Dhimal M, Chowell G. Transmission dynamics and short-term forecasts of COVID-19: Nepal 2020/2021. *Epidemiologia.* (2021) 2:639–59. doi: 10.3390/epidemiologia2040043
3. Basnet BB, Bishwakarma K, Pant RR, Dhakal S, Pandey N, Gautam D, et al. Combating the COVID-19 Pandemic: Experiences of the First Wave From Nepal. *Front Public Health.* (2021) 9:613402. doi: 10.3389/fpubh.2021.613402
4. Neupane P, Bhandari D, Tsubokura M, Shimazu Y, Zhao T, Kono K. The Nepalese health care system and challenges during COVID-19. *J Global Health.* (2021) 11:1–3. doi: 10.7189/jogh.11.03030
5. Rayamajhee B, Pokhrel A, Syangtan G, Khadka S, Lama B, Rawal LB, et al. How Well the Government of Nepal Is Responding to COVID-19? An experience from a resource-limited Country to confront unprecedented pandemic. *Front Public Health.* (2021) 9:85. doi: 10.3389/fpubh.2021.597808
6. Ministry of Health and Population N. *COVID-19 Dash Board*. (2021). Available online at: https://covid19.mohp.gov.np/ (accessed January 10, 2022).
7. Post TK. *Nepal COVID-19 Updates*. (2021). Available online at: https://kathmandupost.com/covid19 (accessed January 29, 2022).
8. Sharma G. Nepal detects first two cases of Omicron variant - health ministry. *Reuters.* (2021). Available online at: https://www.reuters.com/world/asia-pacific/nepal-detects-first-two-cases-omicron-variant-health-ministry-2021-12-06 (accessed December 10, 2021).
9. Weissenbach B. COVID-19 spirals out of control in Nepal: "Every emergency room is full now". *Natl Geogr Mag.* (2021). Available online at: https://www.nationalgeographic.com/culture/article/a-pandemic-surge-threatens-livelihoods-in-nepal (accessed May 14, 2021).
10. Shakya DR, Thapa SB, Kar SK, Sharma V, Uchida N, Ortiz MR, et al. COVID-19 across countries: situation and lessons for pandemic control. *J BP Koirala Institute of Health Sciences.* (2020) 3:9–27. doi: 10.3126/jbpkihs.v3i1.30311
11. *GDP per capita (current US$) - Nepal*. (2021). Available online at: https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=NP (accessed January 14, 2022).
12. Bhattarai S, Dhungana J, Ensor T, Shrestha UB. Assessment of service availability and Infection prevention measures in hospitals of Nepal during the transition phase of COVID-19 case surge. *medRxiv.* (2020). doi: 10.1101/2020.05.13.20097675
13. Shakya DR, Shrestha RR, Koirala S, Kafle SU, Subedi P, Anand A, et al. Social responsibility for health during COVID-19 pandemic. *J BP Koirala Institute of Health Sciences.* (2021) 4:48–55. doi: 10.3126/jbpkihs.v4i1.36091
14. Lama P. Kathmandu's private hospitals fleece Covid-19 patients, multiplying crisis. *Onlinekhabar*. (2021). Available online at: https://english.onlinekhabar.com/kathmandus-private-hospitals-fleece-covid-19-patients-multiplying-crisis.html (accessed May 11, 2021).
15. (NMC) NMC. *Interim Clinical Guidance for care of patients with COVID-19 in healthcare settings*. (2021). Available online at: https://nmc.org.np/interim-clinical-guidance-for-care-of-patients-with-covid-19-in-health care-settings-3 (accessed January 4, 2022).
16. McGuire AL, Aulisio MP, Davis FD, Erwin C, Harter TD, Jagsi R, et al. Ethical challenges arising in the COVID-19 pandemic: an overview from the Association of Bioethics Program Directors (ABPD) task force. *Am J Bioethics.* (2020) 20:15–27. doi: 10.1080/15265161.2020.1764138
17. Kooli C. COVID-19: Public health issues and ethical dilemmas. *Ethics Med Public Health.* (2021) 17:100635. doi: 10.1016/j.jemep.2021.100635
18. Behrens KG. Clinical Ethical Challenges in the COVID-19 Crisis in South Africa. *Wits J Clin Med.* (2020)2(SI):29–32. doi: 10.18772/26180197.2020.v2nSIa5
19. Peter Gill JRS. COVID-19: Nepal in Crisis. *The Doiplomat.* (2020). Available online at: https://thediplomat.com/2020/06/covid-19-nepal-in-crisis (accessed December 15, 2021).
20. Subedi N. Ethical challenges in medical practice in the context of Coronavirus disease 2019 in Nepal. *J of Gandaki Medical College - Nepal.* (2020) 13:1–3. doi: 10.3126/jgmcn.v13i1.29257
21. Government of Nepal MoHaP. *Nepal Health Sector Emergency Response Plan COVID-19 Pandemic*. (2021). Available online at: https://mohp.gov.np/

eng/about-us/divisions/health-emergency-disaster-management (accessed January 22, 2022).

22. Kapiriri L. Medical ethics and bedside rationing in low-income countries: challenges and opportunities. Bioethics-medical, ethical and legal perspectives InTech: Croatia. (2016):199–213. doi: 10.5772/65089
23. Fletcher AJ, Marchildon GP. Using the Delphi method for qualitative, participatory action research in health leadership. *Int J Qualit Methods.* (2014) 13:1–18. doi: 10.1177/160940691401300101
24. Farrell TW, Francis L, Brown T, Ferrante LE, Widera E, Rhodes R, et al. Rationing limited healthcare resources in the COVID-19 era and beyond: ethical considerations regarding older adults. *J Am Geriatr Soc.* (2020) 68:1143–9. doi: 10.1111/jgs.16539
25. Dove ES, Kelly SE, Lucivero F, Machirori M, Dheensa S, Prainsack B. Beyond individualism: Is there a place for relational autonomy in clinical practice and research? *Clin Ethics.* (2017) 12:150–65. doi: 10.1177/1477750917704156
26. Mackenzie C, Stoljar N. *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self.* New York, NY:Oxford University Press (2000).
27. Tanveer F, Khalil AT, Ali M, Shinwari ZK. Ethics, pandemic and environment; looking at the future of low middle income countries. *Int J Equity Health.* (2020) 19:1–12. doi: 10.1186/s12939-020-01296-z
28. Bansal P, Bingemann TA, Greenhawt M, Mosnaim G, Nanda A, Oppenheimer J, et al. Clinician wellness during the COVID-19 pandemic: extraordinary times and unusual challenges for the allergist/immunologist. *J Allergy Clin Immunol.* (2020) 8:1781–90. e3. doi: 10.1016/j.jaip.2020.04.001
29. Chen Q, Liang M, Li Y, Guo J, Fei D, Wang L, et al. Mental health care for medical staff in China during the COVID-19 outbreak. *Lancet Psychiatry.* (2020) 7:e15–e6. doi: 10.1016/S2215-0366(20)30078-X
30. Wicclair M. Allocating Ventilators During the COVID-19 Pandemic and Conscientious Objection. *Amn j Bioethics.* (2020) 20:204–7. doi: 10.1080/15265161.2020.1777347
31. Robert R, Kentish-Barnes N, Boyer A, Laurent A, Azoulay E, Reignier J. Ethical dilemmas due to the COVID-19 pandemic. *Ann Intensive Care.* (2020) 10:1–9. doi: 10.1186/s13613-020-00702-7
32. Asante AD, Zwi AB. Factors influencing resource allocation decisions and equity in the health system of Ghana. *Public Health.* (2009) 123:371–7. doi: 10.1016/j.puhe.2009.02.006
33. WHO. *Coronavirus disease (COVID-19): Ethics, resource allocation and priority setting.* (2020). Available online at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/coronavirus-disease-covid-19-ethics-resource-allocation-and-priority-setting.
34. Vindrola-Padros C, Andrews L, Dowrick A, Djellouli N, Fillmore H, Bautista Gonzalez E, et al. Perceptions and experiences of healthcare workers during the COVID-19 pandemic in the UK. *BMJ Open.* (2020) 10:e040503. doi: 10.1136/bmjopen-2020-040503
35. Adhikari R. Ethics in undergraduate medical courses in Nepal. *Kathmandu Univ Med J.* (2013) 11:1–3. doi: 10.3126/kumj.v11i1.11014
36. Miyasaka M, Akabayashi A, Kai I, Ohi G. An international survey of medical ethics curricula in Asia. *J Med Ethics.* (1999) 25:514–21. doi: 10.1136/jme.25.6.514
37. Coumare VN, Pawar SJ, Manoharan PS, Pajanivel R, Shanmugam L, Kumar H, et al. COVID-19 Pandemic-Frontline Experiences and Lessons Learned From a Tertiary Care Teaching Hospital at a Suburban Location of Southeastern India. *Front Public Health.* (2021) 9:673536. doi: 10.3389/fpubh.2021.673536
38. Das SK, Ranabhat K, Bhattarai S, Karki KB, Gyanwali P, Paneru HR, et al. Combination of convalescent plasma therapy and repurposed drugs to treat severe COVID-19 patient with multimorbidity. *Clin Case Reps.* (2021) 9:2132–7. doi: 10.1002/ccr3.3964
39. Wright KS. Ethical research in global health emergencies: making the case for a broader understanding of 'research ethics'. *Int Health.* (2020) 12:515–7. doi: 10.1093/inthealth/ihaa053
40. Bioethics NCo. Research in Global Health Emergencies: Ethical Issues. Nuffield Council on Bioethics (2020). Available online at: https://www.nuffieldbioethics.org/assets/pdfs/RGHE_Short_report_web_version1.pdf (accessed January 25, 2022).
41. Singh DR, Sunuwar DR, Shah SK, Karki K, Sah LK, Adhikari B, et al. Impact of COVID-19 on health services utilization in Province-2 of Nepal: a qualitative study among community members and stakeholders. *BMC Health Serv Res.* (2021) 21:1–14. doi: 10.1186/s12913-021-06176-y
42. Grabowski DC, Mor V. Nursing home care in crisis in the wake of COVID-19. *J Am Med Assoc.* (2020) 324:23–4. doi: 10.1001/jama.2020.8524
43. Solbakk JH, Bentzen HB, Holm S, Heggestad AKT, Hofmann B, Robertsen A, et al. Back to WHAT? The role of research ethics in pandemic times. *Med Health Care Philoss.* (2021) 24:3–20. doi: 10.1007/s11019-020-09984-x
44. *COVID treatment in private hospitals not accessible to all Nepal.* (2021). Available online at: https://thehimalayantimes.com/nepal/covid-treatment-in-private-hospitals-not-accessible-to-all.
45. Rubinelli S, Myers K, Rosenbaum M, Davis D. Implications of the current COVID-19 pandemic for communication in healthcare. *Patient Educ Couns.* (2020) 103:1067. doi: 10.1016/j.pec.2020.04.021
46. Lippi D, Bianucci R, Donell S. Role of doctors in epidemics: historical perspectives and implications for COVID-19. *Int Emerg Med.* (2020) 15:883–4. doi: 10.1007/s11739-020-02351-x
47. Baines P, Draper H, Chiumento A, Fovargue S, Frith L. COVID-19 and beyond: the ethical challenges of resetting health services during and after public health emergencies. *J Med Ethics.* (2020) 46:715–6. doi: 10.1136/medethics-2020-106965

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The Wounded Healer: A Phenomenological Study on Hospital Nurses Who Contracted COVID-19

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Since the pandemic began nurses were at the forefront of the crisis, assisting countless COVID-19 patients, facing unpreparedness, social and family isolation, and lack of protective equipment. Of all health professionals, nurses were those most frequently infected. Research on healthcare professionals' experience of the pandemic and how it may have influenced their life and work is sparse. No study has focused on the experiences of nurses who contracted COVID-19 and afterwards returned to caring for patients with COVID-19. The purpose of this study was therefore to explore the lived personal and professional experiences of such nurses, and to describe the impact it had on their ways of approaching patients, caring for them, and practicing their profession. A phenomenological study was conducted with 54 nurses, through 20 individual interviews and 4 focus groups. The main finding is that the nurses who contracted COVID-19 became "wounded healers": they survived and recovered, but remained "wounded" by the experience, and returned to caring for patients as "healers," with increased compassion and attention to basic needs. Through this life-changing experience they strengthened their ability to build therapeutic relationships with patients and re-discovered fundamental values of nursing. These are some of the ways in which nurses can express most profoundly the ethics of work done well.

Keywords: attitude of health personnel, COVID-19, life change events, nurse, wounded healer

INTRODUCTION

The spread of COVID-19, declared a pandemic by the World Health Organization in March 2020, put a strain on all healthcare systems (1). In just a few weeks, the number of hospitalized patients multiplied, dramatically increasing the workload of healthcare professionals (2). Since the beginning nurses were at the forefront of the pandemic scene, assisting countless COVID-19 patients, facing uncertainty, unpreparedness, misinformation and lack of adequate personal protective equipment (PPE) (3) that heavily exposed them to safety risk factors (4). They immediately and repeatedly had to modify teams, activities, procedures and reorganize workplaces. They assisted patients in a new and unpredictable situation (5, 6), engaging in highly invasive procedures (e.g., oro-tracheal intubation to maintain adequate respiration) and end-of-life conversations, and witnessing their patients' isolation from family and friends (6). In this scenario, nurses also had to change their way of approaching patients, providing task-oriented care, and inevitably reducing the time of direct patient care, with a decrease of fundamental nursing care activities such as touch, physical contact, and non-verbal communication (7).

Although the World Health Organization and many scientific associations have published guidelines and recommendations to reduce the risk of COVID-19 transmission among health professionals (8, 9), over the course of the pandemic cases of positivity increased, and healthcare systems and organizations also faced a personnel shortage. Although data on infection and mortality are not internationally homogeneous, the COVID-19 infection rate in healthcare professionals has been estimated to be between 3 and 29% (10) and mortality at one out of every 100 positive (11). Nurses were the healthcare workers most frequently infected (48%), followed by physicians (25%) -who recorded a higher death rate (11, 12) and by other healthcare workers (23%) (4, 13).

In 2 years of the pandemic, research on the effects of COVID-19 on health professionals has focused on the need for supporting them (14) and on identifying interventions introduced to limit the impact of the pandemic on organizational wellbeing, such as redistribution of workloads, reorganization of care models, control of burnout, training on the use of personal protective equipment, health surveillance and the establishment of psychological support desks (15–18). There has also been a focus on nurses' physical and psychological health, in terms of stress, anxiety, post-traumatic stress disorder and insomnia (15, 19–23).

However, few studies have evaluated healthcare professionals' experience of this pandemic and how it may have influenced their life and work. The qualitative and mixed-method studies conducted on nurses' experiences at the time of the pandemic found a number of issues and emotions felt in facing the unknown and in the care of complex patients with new needs (18, 24, 25). Nurses reported that they were afraid of contracting the virus and exposing their family members to it, that they were stigmatized by society as a source of infection, that they believed they had not received enough support from organizations, and that they needed psychological and spiritual support for themselves and for patients (24, 26–28). Specifically, only two studies explored the experience of nurses who contracted the virus, but they were limited to the hospital isolation (29) or quarantine and treatment period (30).

No study has been found that focused on the experiences of hospital staff nurses who, after contracting COVID-19, returned to caring for patients with COVID-19. These experiences can have a different impact on the personal and professional lives of nurses comparing with those during the illness or those of nurses who did not become ill.

Therefore, the purpose of the present study was to explore the lived personal and professional experiences of hospital nurses in Italy who, after contracting COVID-19, returned to caring for patients with COVID-19, to elucidate the impact it had on their way of approaching patients, caring for them, and practicing their profession.

MATERIALS AND METHODS

Study Design

A qualitative study was conducted with a descriptive phenomenological approach based on Husserl's (31) life world perspective, in order to understand in depth the lived experiences of nurses who contracted COVID-19, from an individual, social and occupational point of view (32, 33). Phenomenology deals with the phenomenon of consciousness, as regards to the totality of lived experiences belonging to a single person (31). It focuses on the existential meaning that is common to all people who have the experience (34). The descriptive method of Giorgi (35) was used, which is based on 5 steps: data collection, data reading, data division into sub-parts, organization and reprocessing of data in ordinary, comprehensible language for dissemination, and describing the structure of the phenomenon. The COREQ checklist was followed for drafting and conducting the study (36).

Participants

The study was conducted in a 600-beds University Hospital located in a big city in central Italy that in the first wave of the pandemic was entirely dedicated to the care of COVID-19 patients. During the first and the second wave of the pandemic overall 120 nurses (about 7 and 5,6% of total nurses, respectively) contracted COVID-19, either at work or outside the hospital. A purposive sampling method was used to select a heterogeneous sample of nurses with regard to age, sex, years of work, severity of disease, clinical area (e.g., medical, surgical, ICU) and family status (37–39). All nurses who cared for COVID-19 positive patients for at least 2 weeks and had become positive for COVID-19 were considered. Their names were gathered through the internal organization notification system of the nurses who became positive for COVID-19 as taken into care by the Hospital' s Occupational Medicine. A letter was sent to each of these nurses giving information about the study and asking their consent to participate.

Data Collection and Instruments

Data collection lasted from March to June 2021. First, 20 individual interviews were conducted from March to April 2021; then, 4 focus groups were held between May and June 2021 with 34 nurses who had not been interviewed previously.

A topic interview guide was developed, piloted with the first five participants (three women and two men), and then used to also conduct the remaining interviews. It included open-ended questions focused on the subjective experiences of nurses who had become COVID-19 positive patients, to explore in-depth the perceived emotional, cognitive and relational meaning of being ill, and impact the disease had on daily life (family relationships, home organization) and on the relationships with work organization, colleagues and patients, when returning to work. Examples of questions were the following: How did you live through the experience of being positive for COVID-19 (perceptions, feelings, thoughts)? What did it mean for you to be COVID-19 positive? What kind of impact has your illness had from an emotional, cognitive, relational point of view? What do you think has changed in your life and your relationship with others (family, friends, patients) after this experience? How did you feel about returning to a relationship with patients (positive or not) after your illness? Four focus groups were then held using a similar topic guide, to further explore the personal themes that crossed the different interviews, to identify common experiences and interactions with colleagues, patients, family and the impact of COVID-19 on their life.

Individual in-depth interviews and focus group discussions were conducted in Italian by four researchers who were experts in qualitative interviewing and focus groups moderation. Each interview and focus group was conducted by two researchers, one acting as interviewer/moderator and the other as observer and assistant, welcoming participants, collecting signed consent forms and socio-demographic data, audio-recording, and taking field notes including relational dynamics, interpersonal climate, and non-verbal communication. The researchers created a warm, non-threatening atmosphere, giving participants the confidence to answer as spontaneously and truthfully as possible. The focus groups and interviews were held in reserved spaces without potential noise distractions, digitally recorded, transcribed, and integrated with the field notes. The focus groups followed an adapted version of the interview topic guide, to address the issues that had emerged in the interviews while capitalizing on the group discussion to identify common experiences.

Data Analysis

Data were analyzed following the steps of Giorgi's phenomenological descriptive approach (35): (1) interviews transcription and reading (they were read several times, to understand the experiences of COVID-19 positive nurses in depth); (2) data subdivision into sub-parts; (3) organization and linguistic re-phrasing of data; (4) describing the structure of the phenomenon. After the first reading of the data, the research team focused on the text as a whole, not analyzing the thematic aspects of the phenomenon, but highlighting the general sense of the entire situation experienced by COVID-19 positive nurses. In the second step, the subdivision of the data into sub-parts, analysis of the text for each participant was carried out, marking the different units of meaning—small parts of the text with meaning relevant to the study expressed in the language of the participant—and further clarifying them linguistically. In the third step, organization and linguistic re-phrasing of the data, the units of meaning were re-described to express their explicit values, standardizing them in ordinary, comprehensible language. In the last step, describing the structure of the phenomenon, a similar procedure was followed, and the units of meaning were transformed with the help of free imaginative variation. Free imaginative variation is the intellectual process by which researchers consider different examples of a phenomenon to discover its constant and essential elements. The purpose of this process was to determine which unit was essential for the phenomenon analyzed, and to describe the essential structure of the lived experience from the perspective of healthcare professionals, first as professionals and then as patients. Given that the outcome of phenomenological analysis is not the essential structure but how the structures relate to the various manifestations of an essential identity (35), the structures understood as essences and their relationships were made explicit, leading researchers to uncover the themes, subthemes and general structure described below.

Ethical Considerations

The study was conducted in accordance with the Helsinki principles (40) and was approved by the Ethics Committee of the hospital where the study was conducted (Protocol No. 80/20). Eligible nurses were informed about the study aims and procedures; it was explained that participation was voluntary, and that they could withdraw at any time. They were also informed that their data would be treated confidentially, and their identities would not appear in written records. Willing participants signed an informed consent to study participation and to data treatment in accordance with current law regarding privacy. The individual interviews and the focus groups were conducted in a quiet, dedicated room, which guaranteed full privacy. The data were collected, processed, and analyzed in compliance with privacy and anonymity: in the transcription phase, participants' names were replaced by alphanumeric codes.

Rigor

Following the principles of qualitative research (41, 42), the research team worked to ensure the rigor of the study on five criteria: credibility (strategies implemented to ensure the credibility of results), dependability (use of approaches designed to ensure the replicability of the results), confirmability (ensuring that the results faithfully represent the participants' narratives), transferability (degree of agreement of the results of a study with other settings similar to the study area) and authenticity (providing details of the descriptions of the participants' experiences and feelings experienced by the participants in relation to the phenomenon studied). These criteria were ensured in the study by writing out the method in detail, the use of a topic guide for focus groups and interviews, transcription of notes, recording of meetings, phase analysis, and the enrolment of nurses from varied socio-demographic and clinical backgrounds. Moreover, only the meaning units that appeared with a reasonable frequency in different interviews and groups were included. Most words were repeated 5–10 times each or more.

RESULTS

Fifty-four nurses, 39 female and 15 male, with a mean age of 43.6 ± 7.5 (range 30–57) years and mean work experience of 11.5 ± 6.6 (range 1–19) years, participated in this study: 20 in the individual interviews and 34 in the 4 focus groups. They were COVID-positive for a mean of 30.9 ± 13.6 (range 7–58) days. Most nurses quarantined at home ($n = 44$), and only ten were hospitalized for a mean of 17.8 ± 15.9 (range 2–46) days. Participants in each focus group ranged between 7 and 10 nurses (total 34, 23 female and 9 male).

The findings include the general structure and two themes with six and three subthemes, respectively, which will be presented below with excerpts from the transcripts to support them. The sources will be identified with alphanumeric codes for the individual interviews (IN1–20) and for the group discussions (FG1–4).

General Structure: The Wounded Healer

The overarching theme that emerged from the findings is that of the "wounded healer," who is a nurse who contracted COVID-19, survived and recovered, but remained "wounded" by the experience and returned to caring for patients as a "healer," with increased compassion and attention to basic needs.

Theme 1: Wounded: Contracting COVID-19 Generates Profound Personal and Social Changes

Traumatic Experience

Nurse participants described their experience as a traumatic and strongly negative one. For instance, they said: *"It was devastating, a deep chasm with no way out" (IN8), "It was a calvary" (FG1), "We lived it as a tragedy, because we were the first and we did not know how it would end, and how to manage it" (IN8)*, and *"It was an emotional and physical trauma"*. They reported unpleasant emotions such as anger, meaninglessness, fear, sadness, tiredness, worry, anxiety, and guilt. For instance, one participant noted: *"I sank into this meaningless situation"*. Another shared: *"The fear: shall we come back to normal life? (FG3)"*. Interestingly, one nurse voiced her experience as follows: "*I felt discomfort due to the broken relationship between me and my body" (IN6)*, and another said: *"Our energies ran out (. . .) mine ran out to the point of being extinguished" (IN20)*. Fear, anxiety and worry were experienced not only for their own lives, but also, especially, for other people's lives. They were afraid of infecting their family, colleagues, or weak patients. For instance, they said: "*As long as you are single, you worry less" (IN18);* and also: *"As a daughter (you feel) the fear of harming your mother, and as a mother (you feel) the fear of harming your daughter" (IN19)*. Similarly, they felt guilty when they infected their family members or patients and expressed their sadness at "*being cause of the suffering of others" (IN18)*, and also: *"You feel guilty if the patient is positive" (FG3)*, and as another put it: *"this (feeling guilty about my daughters) floored me, it did not knock me out completely but it did floor me" (IN9)*.

Revelation of One's Own Vulnerability

Nurses expressed becoming aware of not being immune, feeling defenseless, powerless, and inadequate to face the situation. For instance, one participant noted: "*It made all of us vulnerable, including those who had felt powerful before" (IN6)*. Feelings of powerlessness and lack of control were described by saying: "*I am trying to mend something that got out of my control" (IN11),* and using the images of being like "*a boat overwhelmed by a storm or a crazy ball in a pinball machine" (FG4)*. They felt "*powerless by depending on the help of others (FG1)* and "*humiliated because depending on other (to bring them the meals)" (FG2)*. Loss of freedom was also reported as: *"I felt like a butterfly without wings" (IN9)*. They seem to have discovered that in this *"unpredictable situation" (FG4)* they *"are not as essential as in the beginning" (IN20)* to solve it, and that *"on getting to a certain point we must surrender" (IN14)*.

Impact on Family Life

Participants reported the impact of their disease on family life, particularly on young children, as a hard experience. For instance, they said: *"The worst sensation: leaving my little baby and not knowing what was waiting for me" (IN18); "All the children were crying, full of fear" (IN8)* and *"They said: Mum, please, get better and change your job, I don't like your job" (FG3)*. The need for physical contact with loved ones was clear both for children and adults: *"It was devastating for the children to stay physically far from their mother" (FG1), "Children cannot live in social isolation" (IN6); "My husband sent me a heart-shaped pillow. I hugged it in that hospital bed, as if all my family were there with me" (IN8)*. They wanted to protect their family and were worried about the possibility of infecting them. Thus, when they infected some or all of their families, they felt guilty: *"I did not think of myself at all, I was not focused on myself, but on my family," "I worried about my family: I infected my 2-year-old daughter, and my pregnant wife" (FG3)*.

When isolation was lived at home together with the family, sometimes it became an opportunity for sharing life in a deeper way than ever: *"Staying at home for one month will never happen again, and I lived it to the full. We managed time together, the four of us in 50 square meters of space. I made the most of it, actively and enjoyably. I had many things to do that could be done at home, and they (children) were in DAD (remote school classes). Actually, for a month I "detoxed." I looked at the positive side of the event, living it as a new experience for me and my family. It united us." (FG1)* And another nurse noted: *"We all became (Covid) positive (in my family): the paradoxical happiness of being able to hug each other and stay together" (FG3)*.

Isolation

Participants reported having experienced physical and social isolation (in the family, in the hospital, among colleagues, and in their neighborhood). In many instances they spoke about loneliness, isolation (which was also referred to as a protection) and being confined in the home. A nurse noted: "*I felt I was all alone, just me and the virus" (IN8)*. And another said "*This Covid has opened up this issue, of leaving people alone and thinking that they could manage" (IN20)*. Isolation was experienced as being enclosed in a room or house: *"I felt shut in, under house arrest" (FG4), "now that I too have been shut in a room, far away from loved ones. . . " (FG3)*. A particularly terrible experience was reported by a nurse who was put in sealed bio-containment, as being *"like in a coffin, a niche" (IN8)*. Nurses noted strongly how they missed physical contact. For instance, they reported: *"How important a hug is, what a consolation" (IN8)*. They recognized the importance of physical contact for patients too by saying: *"Lack of contact in hospitals, in my view, is something that just isn't fair" (IN6)*; and also: *"It is traumatic that now I cannot touch them" (IN15)*.

Conflicting Social Image of the Nurse

This theme describes how nurses perceived the impact that COVID-19 has had on the social image of nurses. Nurses reported that, on the one hand, society has praised them and described them as heroes and angels, making them feel trustworthy custodians of health; on the other hand, it has considered them as sources of infection, leading to perceived abandonment and ingratitude by society. For instance, they shared: *"Someone who praised you and described you as a hero and angel, later accuses you of being an infector and lacks gratitude toward you" (FG3); "We experienced the hero moment, but then if you are a nurse, they give you a dirty look (FG4)"; "First, heroes who save Italy, the nurse with Italy in her arms: "We trust you"... but then we are abandoned" (IN20).*

Sense of Injustice, Abandonment and Solidarity

Feelings of injustice were voiced, in particular because of lack of organization and resources, such as PPE: "*They were not able to manage some situations" (IN20), "I am disappointed by the injustice" (IN14), "They asked too much of us" (IN20), "Access to care became impossible" (IN6)*. In many cases the loneliness caused by isolation generated experiences of abandonment, by society, healthcare services in the community and the organization they belong to. They reported: *"As soon as you become COVID-19 positive you are abandoned to yourself" (FG3), "I felt I was not being supported" (IN9), "A patient cannot be abandoned in these conditions" (IN4)*. For others, by contrast, it gave rise to experiences of solidarity and closeness (from neighbors, colleagues, superiors, the organization, etc.).

Theme 2: The Healer: Rediscovering the Origins of Nursing Profession and Its Founding Values

This theme describes how the experience of contracting COVID-19 has helped nurses rediscover important aspects of nursing and the founding values of their profession.

New Knowledge for the Management of Basic Care Needs

Nurse participants reported having gained more knowledge and preparation on how to manage the care needs of patients with COVID-19 in terms of priorities, methods, and times of the procedures related to basic care needs: *"In the minutes it takes to brush the patient's teeth, the patient desaturates, therefore you really have to hurry… you can see him struggling. (…) Many patients have blood thinning and the oral cavity must be well cared for otherwise it will bleed" (IN18); "You change the diaper, make them drink, feed them, dry the secretions, find a suitable pillow, move the helmet, fix the tube. If you ensure their comfort, they may be able to overcome the disease" (IN19); "It may seem trivial, but you have to be careful: you have to think before you do anything" (IN3).*

A Deeper Understanding of the Patient's Needs

Nurses noted that they have acquired a deeper understanding of patients' and their family members' needs thanks to a process of identification that led to a change in the care relationship: "*I remember when I was on the other side. You see in that person what you have already experienced, and you identify yourself more with their sufferings" (FG2); "Now I also take care of the little things that give joy because they are the ones that I missed the most" (IN8).*

Participants reported feeling more involved in the relationship with the patient and showing more empathy toward the communicative and emotional needs of the patient. *"Now it is difficult to remain detached, I understand patients better and I get more in tune" (FG1); "Personal experience has allowed me to increase that degree of empathy that has always been a part of me" (FG2); "They are isolated, they have no contact with the outside world and you try to put them in communication by making video calls to relatives" (FG1); "Patients stay months in bed, nobody sees them... there is a need for humanity (IN19)"; "I am now much warmer toward those who are sick, I feel like cuddling them" (IN8).*

Rediscovering the Bond With Colleagues and the Founding Values of the Nursing Profession

The nurses shared that the perception of the closeness, support, and solidarity of colleagues strengthened the bond between them: "*I have greatly strengthened the bond with colleagues as sisters" (FG4); "My colleagues have always been close to me: I expressed my thoughts only to them"; "Fantastic colleagues, we supported and backed up each other, respecting those who needed to be left alone..." (IN6); "I received a solidarity that I did not expect" (IN10); "Their unexpected affection has enriched me" (IN4).* Finally, nurses claim that they have rediscovered the value of their profession and what motivates them to exercise it: *"I have rediscovered the true value of this profession (…) I have recovered the enthusiasm of the beginnings for my profession" (FG4); "I feel like a new nurse" (IN8); "As soon as I had the chance I ran back to work, because it is my strength" (IN9).*

DISCUSSION

This study aimed at uncovering the lived personal and professional experiences of nurses who, after being affected by COVID-19, returned to patient care. The main finding of the study is that the nurses who contracted COVID-19 became "wounded healers": they recovered but remained "wounded" by the illness experience and returned to caring as "healers" with increased compassion, empathy, and attention to patients' fundamental needs. The nurses' experience of being ill with COVID-19 changed them profoundly, both personally and professionally. It influenced their way of perceiving life and social relationships. It showed them their human vulnerability and powerlessness. Having suffered from the same illness provided them with a much deeper understanding of their patients' and families' experiences and needs. Through this life-changing experience, they gained new knowledge, strengthened their ability to empathize and re-discovered fundamental values of nursing.

The archetype of the wounded healer is rooted in the Greek myth of Chiron. The immortal centaur Chiron was wounded by Heracles' arrow and suffered unbearable pain for the rest of his life. He was able to transcend and transform his suffering in order to heal others, becoming a legendary healer. Because of his wound he gained transformative characteristics that are crucial to help the healing of others (43). The term "wounded healer" as such was first used by Jung who believed that only a "wounded" physician could heal effectively (44, 45). The notion of wounded healer, generated in the field of psychiatry and psychotherapy, expanded to include any helping profession including nurses, who involve their unique personal characteristics when addressing the needs of vulnerable people (46).

Marion Conti-O' Hare (47) developed the theory of the "Nurse as Wounded Healer" with the tenet that individuals exposed to personal trauma can develop either effective or ineffective coping strategies. Individuals with ineffective coping, whose trauma is not recognized and whose pain is unresolved, may act as "walking wounded," projecting their conflicts on patients and colleagues and being less able to show empathy with others. By contrast, individuals who deal effectively with the trauma are able to recognize, transcend and transform their pain into healing. Although the "scar" remains, personal injuries that have been the object of deep reflection not only will not undermine care provision, but can lead nurses to become "wounded healers," by improving their ability to build therapeutic relationships with patients (47). It is not only their suffering that transforms them into healers but also the awareness of their woundedness and their willingness to accept and transcend it, by integrating it into their relationship with their patients.

Nurses who were affected by COVID-19 could take advantage of their own experience of suffering, powerlessness, vulnerability and needing more care than they received, to improve their care for patients. On crossing into the world of patients and finding themselves at the mercy of the illness, not immune but care dependent, nurses seemed unprepared for the feelings of powerlessness associated with contracting COVID-19, and experienced something like a "shock of becoming a patient" (18, 48). Indeed, nurses' vulnerability may be different and greater than for other patients, as nurses are more used to giving care and less used to receiving it. Moreover, they have greater knowledge, and therefore perhaps also greater expectations, and feel the need to stay in control of the care process (48–50). However, these nurses were able to learn from their experience through analysis and reflection, which enabled them to fill their relationships with patients with therapeutic content. Nurses reacted with greater empathy and a greater ability to identify themselves with patients, and that enabled them to better personalize their care to the needs of each patient, a care that they had sometimes missed when they were sick, and that they would have wished for themselves. They were no longer in an asymmetric or paternalistic relationship with patients (51). These nurses came back to patient care more aware of being part of the same vulnerable and mortal humanity as the patients they were caring for. This mindfulness of their own fragility, brokenness and connectedness to others enabled them to be companions and healers of others who were suffering (52). As Conti-O' Hare (47) put it: "When people who have developed wounding gain sound insights into their own situations they are in a better position to communicate human warmth, which in turns helps patients heal" (p. 2). This ability to build therapeutic relationships with patients is one of the most profound ways in which nurses can express the ethics of work done well (53–55).

Contracting COVID-19 generated profound personal and social changes in nurse participants. They described it as a highly traumatic experience, reported feeling vulnerable because of their direct contact with COVID-19 patients, expressed concerns about their health and that of their family, and awareness of being a possible source of infection for their family members, in line with previous studies conducted with healthcare professionals involved in the frontline during the pandemic (5, 56–58).

The experience of isolation was also reported as strongly impacting nurses' feelings. Social and physical isolation was perceived as something unfair and terrible for human beings, especially for vulnerable people such as patients and children. This is also in line with previous research (59, 60), describing how exposure to biological risks, such as the pandemic, could be a major source of stress for nurses, leading them to isolate themselves physically from their family members, to protect them from possible contamination (14).

Being COVID-19 positive also had a profound impact on nurses because of the social image of the nurse who at the beginning was perceived as a hero, and afterwards as a source of infection associated with stigma. This conflicting image has also been described by Alsaqri et al. (61) in a qualitative work reporting how nurses diagnosed with COVID-19 found themselves being stigmatized both in their workstation and the community, during quarantine and even after complete recovery.

Participants complained of feeling abandoned by healthcare organizations, community and society, and reported feeling a profound sense of injustice about this because they were infected while serving at the frontline of a dangerous pandemic. This accords with similar reports of unsupportive environments (61). However, nurses in this study also reported numerous offers of presence and solidarity from colleagues, superiors and other members of their healthcare teams that made them feel accompanied and thought about during their isolation period. This represented a great solace during those difficult times, and in most cases facilitated their return to caring for patients with COVID-19 within the same team.

Because of the process of reflection, transformation and transcendence of their own illness experience, nurses became able to rediscover the founding values of nursing. This was shown, in particular, by their gaining a new understanding and knowledge of the importance of little things when attending to basic patient needs (7), personalizing care and strengthening the bond with colleagues.

Although generalization is not a goal for qualitative studies, we used strategies able to warrant transferability of results to other settings. However, the study was conducted in a single center with self-selected participants who therefore may not be representative of all nurses who recovered from COVID-19 and came back to care for patients with COVID-19.

CONCLUSION

Findings from this study are highly relevant to nursing and should inform nursing hospital management and education. Each human life is exposed to traumas, over and beyond COVID-19. Nurse managers and educators should be aware that for "wounded" nurses not to remain "walking wounded," but to take the path of becoming "wounded healers," traumatic experiences need to be interiorized and transformed. To help this process, managers should foster significant relationships with nurses enabling them to engage in trusting discussions, to reflect on their own experiences and transform them into "living material" with the potential of becoming a personal life project, able to orient care activities. Similarly, educators should develop educational paths in which students are stimulated to learn from traumatic experiences and become wounded healers. To this end educational settings must be student-centered, and prioritize trusting relationships with students, enabling them to share their experiences and look for help to reflect on and rework them. These are not simple or common tasks. They require nurse managers and educators being prepared to help nurses and students in this transformational reflective path. The COVID-19 pandemic has offered a chance to rediscover and rethink the nursing profession, especially through the priority attached to basic patient care. As each crisis can represent an opportunity, becoming wounded healers has shown great potential for promoting the personal and professional growth of nurses that can also result in "well done care work" (53). We must capitalize on these lessons learned and use them to produce rich fruits in present and future generations of nurses.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Protocol No. 80/20. The patients/participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

AUTHOR CONTRIBUTIONS

MP: conceptualization, methodology, investigation, formal analysis, data curation, visualization, and writing—original draft. JF: conceptualization, methodology, visualization, writing—original draft, and writing—review and editing. CM: investigation and formal analysis. BA and AM: conceptualization, investigation, formal analysis, and writing—original draft. LL and GC: conceptualization, investigation, and formal analysis. FZ: conceptualization and writing—original draft. MD: conceptualization, writing—review and editing, and supervision. AS: conceptualization, methodology, writing—original draft, writing—review and editing, and supervision. All authors contributed to the article and approved the submitted version.

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REFERENCES

1. Zerbini G, Ebigbo A, Reicherts P, Kunz M, Messman H. Psychosocial burden of healthcare professionals in times of covid-19—a survey conducted at the university hospital Augsburg. *Germany Med Sci.* (2020) 18:Doc05. doi: 10.3205/000281
2. Ulrich CM, Rushton CH, Grady C. Nurses confronting the coronavirus: challenges met and lessons learned to date. *Nurs Outlook.* (2020) 68:838–44. doi: 10.1016/J.OUTLOOK.2020.08.018
3. Jackson D, Bradbury-Jones C, Baptiste D, Gelling L, Morin K, Neville S, et al. Life in the pandemic: some reflections on nursing in the context of covid-19. *J Clin Nurs.* (2020) 29:2041–3. doi: 10.1111/JOCN.15257
4. Gómez-Ochoa SA, Franco OH, Rojas LZ, Raguindin PF, Roa-Díaz ZM, Wyssmann BM, et al. COVID-19 in health-care workers: a living systematic review and meta-analysis of prevalence, risk factors, clinical characteristics and outcomes. *Am J Epidemiol.* (2021) 190:161–75. doi: 10.1093/AJE/KWAA191
5. Fernandez R, Lord H, Halcomb E, Moxham L, Middleton R, Alananzeh I, et al. Implications for covid-19: a systematic review of nurses' experiences of working in acute care hospital settings during a respiratory pandemic. *Int J Nurs Stud.* (2020) 111:103637. doi: 10.1016/J.IJNURSTU.2020.103637
6. Morley G, Grady C, Mccarthy J, Ulrich CM. Covid-19: ethical challenges for nurses. *Hastings Cent Rep.* (2020) 50:35–9. doi: 10.1002/HAST.1110
7. Jørgensen L, Pedersen B, Lerbæk B, Haslund-Thomsen H, Thorup CB, Albrechtsen MT, et al. Nursing care during covid-19 at non-covid-19 hospital units: a qualitative study. *Nord J Nurs Res.* (2021) 19:205715852110474. doi: 10.1177/20571585211047429
8. Nicola M. O' Neill N, Sohrabi C, Khan M, Agha M, Agha R. Evidence based management guideline for the covid-19 pandemic - review article. *Int J Surg.* (2020) 77:206–16. doi: 10.1016/j.ijsu.2020.04.001
9. World Health Organization(WHO). *Maintaining Essential Health Services: Operational Guidance for the Covid-19 Context interim guidance, 1 June 2020.* Geneva: WHO (2020). p. 1–55.
10. Wang D, Hu B, Hu C, Zhu F, Liu X, Zhang J, et al. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus–infected pneumonia in Wuhan, China. *JAMA.* (2020) 323:1061. doi: 10.1001/jama.2020.1585
11. Bandyopadhyay S, Baticulon RE, Kadhum M, Alser M, Ojuka DK, Badereddin Y, et al. Infection and mortality of healthcare workers worldwide from Covid-19_ a systematic review. *BMJ Glob Heal.* (2020) 5:e003097. doi: 10.1136/bmjgh-2020-003097
12. Suárez-García I, Martínez DE. Aramayona López MJ, Sáez Vicente A, Lobo Abascal P. SARS-CoV-2 infection among healthcare workers in a hospital in Madrid, Spain. *J Hosp Infect.* (2020) 106:357–63. doi: 10.1016/j.jhin.2020.07.020
13. Elfström KM, Blomqvist J, Nilsson P, Hober S, Pin E, Månberg A, et al. Differences in risk for SARS-CoV-2 infection among healthcare workers. *Prev Med Rep.* (2021) 24:101518. doi: 10.1016/j.pmedr.2021.101518
14. Firew T, Sano ED, Lee JW, Flores S, Lang K, Salman K, et al. Protecting the front line: a cross-sectional survey analysis of the occupational factors contributing to healthcare workers' infection and psychological distress during the covid-19 pandemic in the USA. *BMJ Open.* (2020) 10:1–12. doi: 10.1136/bmjopen-2020-042752
15. Lai J, Ma S, Wang Y, Cai Z, Hu J, Wei N, et al. Factors associated with mental health outcomes among health care workers exposed to coronavirus disease 2019. *JAMA Netw Open.* (2020) 3:e203976. doi: 10.1001/jamanetworkopen.2020.3976
16. Paguio JT, Nursing MA, Su JJ. Systematic review of interventions to improve nurses' work environments. *J Adv Nurs.* (2020) 76:2471–93. doi: 10.11111/jan.14462

17. Rivett L, Sridhar S, Sparkes D, Routledge M, Jones NK, Forrest S, et al. Screening of healthcare workers for SARS-CoV-2 highlights the role of asymptomatic carriage in covid-19 transmission. *Elife.* (2020) 9:1–20. doi: 10.7554/eLife.58728.sa2
18. Zaghini F, Fiorini J, Livigni L, Carrabs G, Sili A, A mixed methods study of an organization' s approach to the covid-19 health care crisis. *Nurs Outlook.* (2021) 69:793–804. doi: 10.1016/j.outlook.2021.05.008
19. Ahn MH, Shin YW, Suh S, Kim JH, Kim HJ, Lee K-U, et al. High work-related stress and anxiety as a response to COVID-19 among health care workers in South Korea: Cross-sectional online survey study. *JMIR Public Health Surveill.* (2021) 7:e25489. doi: 10.2196/25489
20. Chew NW, Lee GK, Tan BY, Jing M, Goh Y, Ngiam NJ, et al. A multinational, multicentre study on the psychological outcomes and associated physical symptoms amongst healthcare workers during COVID-19 outbreak. *Brain Behav Immun.* (2020) 88:559–65. doi: 10.1016/j.bbi.2020.04.049
21. Huang Y, Zhao N. Generalized anxiety disorder, depressive symptoms and sleep quality during covid-19 outbreak in China: a web-based cross-sectional survey. *Psychiatry Res.* (2020) 288:112954. doi: 10.1016/j.psychres.2020.112954
22. Vagni M, Maiorano T, Giostra V, Pajardi D. Coping with covid-19: emergency stress, secondary trauma and self-efficacy in healthcare and emergency workers in Italy. *Front Psychol.* (2020) 11: 566912. doi: 10.3389/fpsyg.2020.566912
23. Yin X, Zeng L, A study on the psychological needs of nurses caring for patients with coronavirus disease 2019 from the perspective of the existence, relatedness, and growth theory. *Int J Nurs Sci.* (2020) 7:157–60. doi: 10.1016/j.ijnss.2020.04.002
24. Galehdar N, Toulabi T, Kamran A, Heydari H. Exploring nurses' perception of taking care of patients with coronavirus disease (covid-19): a qualitative study. *Nurs Open.* (2021) 8:171–9. doi: 10.1002/nop2.616
25. Yoshioka-Maeda K, Iwasaki-Motegi R, Honda C. Preventing the dysfunction of public health centres responding to covid-19 by focusing on public health nurses in Japan. *J Adv Nurs.* (2020) 76:2215–6. doi: 10.1111 /jan.14409
26. Akkuş Y, Karacan Y, Güney R, Kurt B. Experiences of nurses working with COVID-19 patients: A qualitative study. *J Clin Nurs.* (2022) 31:1243–57. doi: 10.1111/jocn.15979
27. Chrysoula D, Despoina P, Ioannis K, Polyxeni M, Eftychia F, Nikoletta M. Stress, anxiety and depression in nurses during covid-19 pandemic: evaluation of coping strategies. *Int J Nurs.* (2021) 8:1. doi: 10.15640/ijn.v8n1a1
28. Monjazebi F, Dolabi SE, Tabarestani ND, Moradian G, Jamaati H, Peimani M. Journey of nursing in covid-19 crisis: a qualitative study. *J Patient Exp.* (2021) 8:237437352198991. doi: 10.1177/2374373521989917
29. He J, Liu L, Chen X, Qi B, Liu Y, Zhang Y, Bai J. The experiences of nurses infected with covid-19 in Wuhan, China: a qualitative study. *J Nurs Manag.* (2021) 29:1180–8. doi: 10.1111/jonm.13256
30. Özlük B, Bikmaz Z. The experiences of nurses diagnosed with covid-19 in Turkey: a qualitative study. *Nurs Health Sci.* (2021) 23:916–24. doi: 10.1111/nhs.12881
31. Husserl E. *Ideas: General Introduction to Pure Phenomenology.* Torino: Einaudi (1913).
32. Creswell JW, Poth CN. *Qualitative Inquiry and Research Design: Choosing Among Five Approaches*. 4th ed. Thousand Oaks, CA: Sage Publications, Inc. (2016).
33. Rodriguez A, Smith J. Phenomenology as a healthcare research metod. *Evid Based Nurs.* (2018) 21:96–8. doi: 10.1136/eb-2018-102990
34. Lopez KA, Willis DG. Descriptive versus interpretive phenomenology: their contributions to nursing knowledge. *Qual Health Res.* (2004) 14:726–35. doi: 10.1177/1049732304263638
35. Giorgi A. The theory, practice, and evaluation of the phenomenological method as a qualitative research procedure. *J Phenomenol Psychol.* (1997) 28:235–60. doi: 10.1163/156916297X00103
36. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (coreq): a 32-item checklist for interviews and focus groups. *Int J Qual Heal Care.* (2007) 19:349–57. doi: 10.1093/intqhc/mzm042
37. Polit DF, Beck CT. The content validity index: are you sure you know what' s being reported? Critique and recommendations. *Res Nurs Health.* (2006) 29:489–97. doi: 10.1002/nur.20147
38. Sandelowski M. Focus on research methods: whatever happened to qualitative description? *Res Nurs Heal.* (2000) 23:334–40. doi: 10.1002/1098-240X(200008)23
39. Bradshaw C, Atkinson S, Doody O. Employing a qualitative description approach in health care research. *Glob Qual Nurs Res.* (2017) 4: 2333393617742282. doi: 10.1177/2333393617742282
40. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA J Am Med Assoc.* (2013) 310:2191–4. doi: 10.1001/jama.2013.281053
41. Guba E, Lincoln YS. Paradigmatic controversies, contradictions, and emerging confluences, revisited. *Sage Handb Qual Res.* (2011) 4:97–128.
42. Lincoln YS, Guba EG. Paradigmatic controversies, contradictions and emerging confluences. *Sage Handb Qual Res.* (1994) 163–194.
43. Groesbeck CJ. The archetypal image of the wounded healer. *J Anal Psychol.* (1975) 20:122–46. doi: 10.1111/j.1465-5922.1975.00122.x
44. Jung C. *Fundamental Questions of Psychotherapy*. Princeton: Princeton University Press (1951).
45. Jung C. *Ma Vie: Souvenirs, Rêves Et Pensées Recueillis Et Publiés*. In: Par Aniéla Jaffé, ed. Paris: Gallimard (1967).
46. Christie W, Jones S. Lateral violence in nursing and the theory of the nurse as wounded healer. *Online J Issues Nurs.* (2014) 19:27–36. doi: 10.3912/OJIN.Vol19No01PPT01
47. Conti-O' Hare M. *The Nurse as Wounded Healer: From Trauma to Transcendence.* Burlington MA: Jones and Bartlett Learning (2002).
48. De Marco RF, Picard C, Agretelis J. Nurse experiences as cancer survivors: part i—personal. *Oncol Nurs Forum.* (2004) 31:523–30. doi: 10.1188/04.ONF.523-530
49. Duke J, Connor M. Senior nurses as patients: narratives of special and meagre care. *Contemp Nurse.* (2008) 31:32–43. doi: 10.5172/conu.673.31.1.32
50. Prenkert M, Carlsson E, Svantesson M, Anderzén-Carlsson A. Healthcare-professional patients' conceptions of being ill and hospitalised - a phenomenographic study. *J Clin Nurs.* (2017) 26:1725–36. doi: 10.1111/jocn.13604
51. Delmar C. The excesses of care: a matter of understanding the asymmetry of power. *Nurs Philos.* (2012) 13:236–43. doi: 10.1111/j.1466-769X.2012.00537.x
52. Corso VM. Oncology nurse as wounded healer: developing a compassion identity. *Clin J Oncol Nurs.* (2012) 16:448–50. doi: 10.1188/12.CJON.448-450
53. Candela Ml, Piredda M, Marchetti A, Facchinetti G, Iacorossi L, Capuzzo MT, et al. Finding meaning in life: an exploration on the experiences with dependence on care of patients with advanced cancer and nurses caring for them. *Support Care Cancer.* (2020) 28:4493–9. doi: 10.1007/s00520-020-05300-8
54. Liaschenko J, Peter E. Nursing ethics and conceptualizations of nursing: profession, practice and work. *J Adv Nurs.* (2004) 46:488–95. doi: 10.1111/j.1365-2648.2004.03011.x
55. Piredda M, Candela ML, Mastroianni C, Marchetti A. D' Angelo D, Lusignani M, et al. "Beyond the boundaries of care dependence". *Cancer Nurs.* (2020) 43:331–7. doi: 10.1097/NCC.0000000000000701
56. Liu Q, Luo D, Haase JE, Guo Q, Wang XQ, Liu S, et al. The experiences of health-care providers during the covid-19 crisis in China: a qualitative study. *Lancet Glob Heal.* (2020) 8:e790–8. doi: 10.1016/S2214-109X(20)30204-7
57. Zhang Y, Wei L, Li H, Pan Y, Wang J, Li Q, et al. The psychological change process of frontline nurses caring for patients with covid-19 during its outbreak. *Issues Ment Health Nurs.* (2020) 41:525–30. doi: 10.1080/01612840.2020.1752865
58. Gunawan J, Aungsuroch Y, Marzilli C, Fisher ML, Nazliansyah, Sukarna A. A phenomenological study of the lived experience of nurses in the battle of Covid-19. *Nurs Outlook.* (2021) 69:652–9. doi: 10.1016/j.outlook.2021.01.020
59. Sarafis P, Rousaki E, Tsounis A, Malliarou M, Lahana L, Bamidis P, et al. The impact of occupational stress on nurses' caring behaviors and their health related quality of life. *BMC Nurs.* (2016) 15:1–9. doi: 10.1186/s12912-016-0178-y
60. Sili A, Fida R, Zaghini F, Tramontano C, Paciello M. Counterproductive behaviors and moral disengagement of nurses as potential consequences of stress-related work: validity and reliability of measurement scales. *Med Lav.* (2014) 105:382–94. doi: 10.1109/WPT.2016.7498794
61. Alsaqri S, Pangket P, Alkuwaisi M, Llego J, Alshammari MS. Covid-19 associated social stigma as experienced by frontline nurses of hail: a

qualitative study. *Int J Adv Appl Sci.* (2021) 8:52–7. doi: 10.21833/IJAAS.2021.08.007

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"*What Other Information Is There?*": Identifying Information Gaps, Perceptions and Misconceptions on COVID-19 Among Minority Ethnic Groups in the Netherlands

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Background: Multiple media platforms and various resources are available for information on the novel coronavirus disease (COVID-19). Identifying people's preferences is key to building public confidence and planning for successful national or regional health intervention strategies.

Methods: Using exploratory mixed-methods including a short survey, interviews and participant observation, this cross-sectional study of 160 respondents from the Ghanaian-Dutch, Afro and Hindustani Surinamese-Dutch communities in Amsterdam, the Netherlands was conducted. Data collected between February to April 2021, included demographics characteristics, knowledge, opinions, preferred source of information, behavioral factors, and information gaps on COVID-19 prevention measures, responses and decision-making of respondents. Descriptive statistics and follow-up in-depth interviews were conducted to determine the relationship between respondents' demographics, information sources, and attitudes/behaviors toward COVID-19.

Results: The findings of this study indicated that although many of the respondents from these communities had good knowledge on COVID-19, its modes of transmission and prevention measures, their willingness to take up initiatives and prioritize self responsibility toward their health are tied to their communal life. The respondents in this study demonstrated high value for social lives and relied on their connections with friends and families in shaping, obtaining, processing and utilizing COVID-19 information to build a sense of responsibility toward the uptake of COVID-19 prevention measures despite recent decline in number of cases.

Conclusion: This sense of responsibility means their active participation and ownership of interventions to address the specific personal concerns and that of their community. However, different factors play influential roles toward the behavior choices of our respondents regarding the COVID-19 prevention.

Keywords: COVID-19, Ghanaian-Dutch, Surinamese-Dutch, perceptions, information gap, misconceptions

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INTRODUCTION

Since its discovery in December 2019 in Wuhan city, the Hubei province of China, the Coronavirus disease (COVID-19) rapidly evolved into a global pandemic affecting the normal functioning of all nations, societies, and health systems (1). The COVID-19 pandemic is considered as one of the biggest global health crisis of this century and continues to impose enormous strain on individuals, communities and healthcare systems (2). As of 6th April 2021 when data collection for this study was at concluding stage, the World Health Organization (WHO) estimates showed that more than 130 million people had contracted COVID-19 with over 2.8 million reported deaths globally (3).

At the onset of the pandemic, the WHO strongly recommended countries to implement interventions to curb the rapid spread of COVID-19 by minimizing contact between infected and uninfected persons (4). So far, these measures have included mass testing, lockdowns, staying/working from home, physical distancing, self-isolation/quarantine, use of personal protection equipment (including use of face/nose masks), rigorous methods of personal hand hygiene and the rollout of various national mass vaccination (4–6). In the Netherlands, these measures included the imposition of ban on large gatherings, closure of schools and public places (5). These mitigation measures were targeted at reducing the burden of healthcare systems, rapid transmission and curb the mortality rates related to COVID-19 (4, 5, 7, 8).

These measures were necessary at the onset of the pandemic to help health systems and policymakers to adopt strategies to adequately tackle the virus. However, certain community risk perceptions and poor adherence to these preventive measures have led to an increased rate of infection as seen in Ethiopia and the Netherlands (9, 10). For instance, a significant proportion of young people particularly university students assumed that the disease only affects the elderly and people with underlying medical conditions (11, 12). Others have considered COVID-19 as hoarse and assume perhaps it is a political conspiracy to control people (13, 14). These happenings epitomized the level of misconception, laxity of government and public health policies, inadequate education, inadequate information, and misperceptions toward COVID-19 (15). The continuous growth of these negative ideas and behaviors toward the global fight against COVID-19 remains a great concern that needs to be addressed.

COVID-19 continuous to be regarded as a major public health threat globally. In the Netherlands, official figures from the National Institute for Public Health and Environment [Rijksinstituut voor Volksgezondheid en Milieu (RIVM)] showed that more than 1.3 million people have been confirmed to have contracted COVID-19, with 16,629 reported deaths as of 6th April 2021 (5). The Netherlands ranks 21st worldwide, and 10th in Europe regarding the distribution burden of COVID-19 reported cases (16). To this effect, the Dutch government initiated rigorous COVID-19 testing/screening program (Test locations) in all its administrative municipalities (GGDs), with strong enforcement of curfews at some periods in attempt to halt the spread of the virus (5). Efforts to increase community awareness have also been initiated (17).

In Amsterdam, where this study was conducted, the risk of COVID-19 remains high. A recent study conducted among six (6) ethnic groups in Amsterdam revealed that the minority ethnic communities in the Zuidoost sub-district of Amsterdam had the highest COVID-19 antibody prevalence (10). Their findings also revealed that the these ethnic minority communities had the lowest numbers in terms of testing per 100 thousand residents and appeared to be the hardest hit in Amsterdam (10, 18). The minority ethnic groups that have been severely affected by the COVID-19 pandemic include the Ghanaian-Dutch, Afro Surinamese-Dutch and the Hindustani Surinamese-Dutch communities in Amsterdam (10).

People's knowledge, opinions, perception and beliefs are determinants of health behaviors (19). To this effect, there is the need for information on these communities perceptions and knowledge of the COVID-19 recommended prevention measures. However, to date, no study has been carried out to assess these communities information needs and behavioral responses toward COVID-19 mitigation measures in the study area. Therefore, this study aimed to assess the information gaps, behavioral factors, knowledge and perceptions on COVID-19 among the Ghanaian-Dutch and Surinamese-Dutch (Afro- and Hindustani) residents in Amsterdam. It is important to note that data collection for this study was collected from February to April 2021. Despite the rapid development in terms of mass vaccination, reduction in cases, severity of the disease and reduction in hospitalization, there are people who rationalize these developments as prove that COVID-19 was a hoarse, created by goverments to regulate the population. We show that the evolving situations of the pandemic reproduces and further contextualizes our understanding of the pandemic and how people respond and adapt to their changing information needs.The findings of this study will also help decision-makers and COVID-19 task forces design and inform public health communication efforts toward eradicating this pandemic or future pandemics among minority ethnic communities.

METHODOLOGY

Study Area

The study was conducted in the Zuidoost sub-district of the city of Amsterdam, the capital and most populous city of the Netherlands. Historically, this area has gained a reputation of high social life, an entertainment and shopping hub mostly due to its open, modern architecture and multiethnic population. Earlier report of the number of people tested for COVID-19 per 100 thousand residents revealed that the Zuidoost was one of the sub-districts with the lowest testing rate and also one of the hardest hit areas in Amsterdam (10, 18). The Zuid Oost area of the municipality is ethnically highly diverse, and often referred to as Amsterdam city's "black neighborhood" due to the settlement of African migrants (20). Official records show that the three largest ethnic groups that reside in this sub-district are people of Ghanaian descent, Afro and Hindustani Surinamese descent (21, 22).

Study Population

Respondents in this study were selected from the Ghanian-Dutch, the Afro and Hindustani Surinamese-Dutch Communities in Amsterdam. There is a wide diversity among the Surinamese-Dutch populationin in the Netherlands. Surinamese with an African background (referred to as Afro Surinamese or "Creole" in the Dutch context) are those who trace their roots to West African, and those with a South-Asian background (referred to as "Hindustani" in the Dutch context) have their roots in North India (23). According to figures published by the Statistics Netherlands, there are 356,402 people of Surinamese origin, making up nearly 2.1% of the Dutch population (22). Available records showed that about half of the 12,184 officially registered people of Ghanaian descent in Amsterdam reside in the Bijlmermeer (popularly known as Bijlmer), a suburb of Zuid Oost (Southeast) municipality (21, 24) and they form a closely-knit community and are predominantly religious (24, 25).

Study Design

This was a community-based cross-sectional study that applied a mixture of quantitative and qualitative methods including administration of survey, participant observation and in-depth interviews, which allowed for triangulation of the data to increase its accurateness. Data collection was conducted from 3rd February, 2021 to 30th April, 2021.

Ethical Considerations

The Ethics Advisory Board of the Amsterdam Institute of Social Science (AISSR) at the University of Amsterdam (UvA) approved this study as part of a bigger research project. The purpose, nature, and procedures of the study were clearly explained to all potential respondents. All respondents who took part in this study understood that participation in the study was voluntary and that they could withdraw from the study at any time. To ensure the anonymity of the respondents, we have used pseudonyms and changed their occupations, and places of residence when these characteristics were not directly relevant to the analysis in this article.

Data Collection

Recruitment of Study Respondents

This study included respondents aged 18 years, who were recruited through personal invitations on the streets, from churches, online social media platforms, community parks, and snowballing.

Structure of the Survey

Based on review of relevant literature, a standard structured survey was design and used to collect data on socio-demographics (age, gender, level of education, occupation, ethnicity and household composition), knowledge about the likely sources of contracting COVID-19, prevention measures and information gaps/needs on COVID-19 for respondents and their community.

In-depth Interviews

In-depth interviews (IDI) were conducted as a follow-up to the collection of the survey data when respondents indicated that they would like to be invited for further interviews. During the IDIs, the questions that generated further elaborations from the respondents were probed to investigate reasons for any discrepancies between what people said or do with data from the survey. In addition, this study explored further to understand the choices people made regarding obeying the COVID-19 mitigation measures or otherwise and the motivations behind those choices. This research technique was adopted to ensure the validity of the data on social behaviors and provide an understanding of the factors behind the choices people made. The IDIs were also used to discuss *immediate past* practices of respondents that informed their current behavior, knowledge and opinions. This allowed for the researchers to link the choices of the respondents to context and changing time.

Participant Observation

Participant observation was a continuous element during data collection of all the 36 in-depth interviews. Substantial amount of time was spent to follow-up or accompany our respondents to places that our study respondents frequently visited as well as popular public places that Amsterdam residents of Ghanaian or Surinamese background visited mostly for shopping or to socialize. The research team also visited some churches to observe the interaction among congregants present. Besides generating important contextual information, participant observation enabled the building of rapport with respondents and also generated conversations on respondents knowledge on COVID-19. These observations were very useful in analyzing question we asked respondents that required them to indicate frequency of an action and allowing them to bring out their lived experience and show the internal structure in their surroundings, environment or society.

Determination of Study Variables

Knowledge on COVID Modes of Transmission

The composite variable for measuring knowledge about the likely sources (places) of contracting COVID-19 were listed as presence at Church/Mosque, workplace, home, funerals, weddings, public and social events, restaurants/bars, public transport, marketplaces/shops, general practitioner/dentist/pharmacy post, travel and others as identified by the respondents. Respondents who selected the median, six or more of these places were labeled as having good knowledge, from 3 to 5 as having average knowledge and 2 or below as poor knowledge (26).

Knowledge on COVID-19 Prevention Measures

The composite variables for measuring knowledge on COVID-19 prevention measures were listed as proper hand washing and hygiene, using a face mask, keeping 1.5m physical distance, staying home, avoiding social and public gatherings, avoid or reduce visiting friends and family and getting tested and vaccinated for COVID-19. Respondents who selected the median or above the score (six or more) of these measures were labeled as having good knowledge, from 3 to 5 as having average knowledge and 2 or below as poor knowledge (26). For each measure, a proportion of respondents who know about it were calculated as a percentage.

Behavioral Risk of Contracting COVID-19

This was measured using the frequency of visits to crowded places or mass gatherings that make it likely to contract COVID-19. Respondents who visited these places *Always*, were classified as at high risk, *Sometimes* and *Often* as at moderate risk and rarely or never as at low risk.

Information Gaps

Respondents to this survey were asked to indicate their willingness (Yes, No or maybe) to receive additional information on COVID-19 and also list the specific kind of information on COVID-19 that they and/or members from their community would like to receive. In addition, respondents were requested to state their main sources of acquiring information on COVID-19.

Data Analysis

The data collected through printed questionnaires and Google forms were entered into excel and exported for analysis using SPSS software (SPSS Inc). The descriptive proportions of respondents who used each common source to obtain information about COVID-19 were presented in terms of number and percentage. When applicable, relevant quotations of study participants from the in-depth interviews were cited to demonstrate the point and analysis.

RESULTS

Socio-Demographic Characteristics of Study Respondents

At the end of the survey, a total of 160 responses for the survey and 36 IDI were collected through face-to-face, telephone and online interviews. The tabular presentation of the sociodemographic characteristics of the study respondents have previously been published (27). In brief, there were a total of 86 (53.8%) male respondents compared to females 74 (46.2%). Unlike the Afro ($n = 54$) and Hindustani ($n = 49$) Surinamese-Dutch, there were more female respondents than the males among the 57 respondents from the Ghanaian-Dutch community. Respondents belonging to the 18–25 years age group constituted the lowest proportion while those in the 36–45 years had the highest proportion, with a median age range of all the respondents between 36–45 years. All but one of the respondents had some level of formal education ranging from primary school to doctoral degrees. The single most popular employment sector for majority of the respondents was in the hospitality/catering field 23 (14.4%), followed by the unemployed or retired category 21 (13.1%) and healthcare 21 (13.1%). A total of 29 (18.1%) respondents preferred not to answer the question regarding their employment area. The majority of respondents' households were composed of 5 or more people 43 (26.9%), followed by those that had 2 persons, 42 (26.3%) and 3 persons 27 (16.9%). There were 61 individual respondents' homes with 2 adults living together, which constituted the highest proportion (38.1%).

Knowledge Level and Behaviors Toward COVID-19

Table 2 shows that nearly half, 78 (49.1%) of the 160 respondents demonstrated good knowledge on the likely sources or places people could contract COVID-19. A further 45 (28.1%) also demonstrated average knowledge level while a lower proportion of respondents 37 (22.8%) showed poor knowledge level on how people could contract COVID-19. With regards to knowledge of respondents on COVID-19 prevention measures, our results revealed that a total of 86 (53.8%) respondents had good knowledge of the recommended prevention measures in the Netherlands. Additional 20 respondents (20%) demonstrated average knowledge while 42 (26.2%) respondents demonstrated a poor knowledge level on the recommended COVID-19 prevention measures (**Table 1**).

The results also showed that over a third of the respondents 58 (36.4%) demonstrated low behavioral risk of contracting COVID-19 as they indicated that they avoid or rarely used the public transport, or attended public and social events i.e., the church, mosque, supermarket, public transport, visit friends and family, among others. More than half 87 (54.5%) had a moderate behavioral risk of contracting COVID-19 as they often or sometimes visited some of the locations noted earlier. Only 15 (9.1%) of the respondents showed high-risk behavior, as they were always present at public and social events (**Table 1**). It was also observed from our fieldwork that in as much as there was lockdown, it hardly deterred people from still gathering together in large numbers. More so, the study area as indicated above had many shops and so while only essential stores were open there were still many market activities at the period. From our in-depth interviews, we noted that the top three measures respondent had difficulty adhering to included wearing a face and

TABLE 1 | Knowledge level and behavioral characteristics toward COVID-19 among respondents from the Ghanaian-Dutch (GD), Afro-Surinamese (ASD), and Hindustani Surinamese-Dutch (HSD) communities in Amsterdam.

Variable	GD	ASD	HSD	Total
Knowledge on likely places to contract COVID-19				
Good	28	26	24	78 (49.1%)
Average	16	17	12	45 (28.1%)
Poor	13	11	13	37 (22.8%)
Knowledge of COVID-19 prevention measures				
Good	30	30	26	86 (53.8%)
Average	12	10	10	32 (20.0%)
Poor	15	14	13	42 (26.2%)
Behavioral risk of contracting COVID-19				
High	5	6	4	15 (9.1%)
Moderate	32	30	25	87 (54.5%)
Low	20	18	20	58 (36.4%)

nose mask, avoiding visits to friends and family, and maintaining an interpersonal physical distance of 1.5 m. Analysis of our in-depth interviews from this study revealed that some respondents felt that their close relatives would not contract COVID-19 and therefore did not need to keep the 1.5 m physical distances, wear a facemask, or avoid hugging and handshakes. Regarding face and nose mask, some people struggled with having something covering their faces or their well-done make-up. "I can't breathe with a mask on", "wearing face mask is uncomfortable", "I can not speak well with face mask" and "I am not sure my voice and words come out clear enough", "the face mask covers my beautiful make-up and cleans it" were common complaints.

Information Gaps

Respondents Information Needs

The survey revealed that out of the 57 Ghanaian-Dutch respondents, 19 (33.3%) indicated that "Yes" they needed to receive more information about COVID-19 (**Figure 1**). In addition, 12 (21%) indicated that they "maybe" be open to receive more information on COVID-19. However, the majority (45.7%) answered "No", indicating they did not need any more information. Equally, among the 54 Afro Surinamese-Dutch respondents who were asked, "would you like to receive more information about COVID-19?" 15 (28%) answered "yes", indicating their need for more information on COVID-19. A further 11 (20%) of respondents answered "maybe", showing that they were open to receive at least some additional information on COVID-19. However, more than half, 28 (52%) answered "No", indicating that they have already had enough information and did not need any extra information. Out of the 49 respondents from the Hindustani Surinamese-Dutch community in Amsterdam, 26 (53%) responded "yes", indicating that they would need to receive more information on COVID-19. In contrast, 20 (41%) responded "No", showing that they did not need more information on COVID-19. Three respondents (6%) indicated that "maybe" they would like to receive additional information on COVID-19. Our in-depth interviews revealed that some respondents who did not like to receive additional information on COVID-19 because they were "tired of this Corona" and therefore preferred not to know more. According to one of the Afro Surinamese-Dutch woman we spoke:

> *What other information is there. Is the old story we keep hearing? They do not try to even update it any better. They will tell us to wash hands, 1.5 meter, wear mask … Are we not just tired of this Corona? When I hear Corona I put my TV off. It's too much.…*

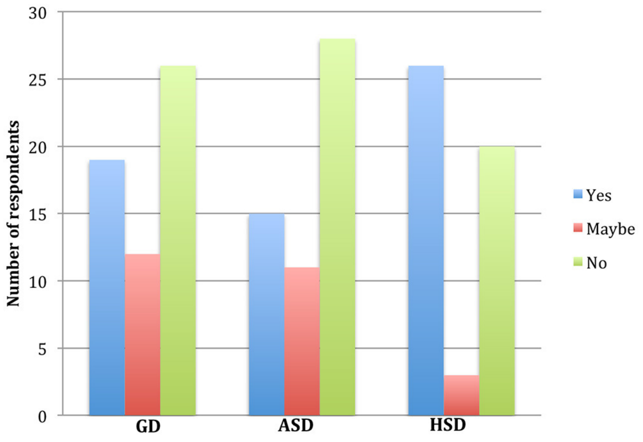

FIGURE 1 | The proportion of respondents answer to the question "would you like to receive more information about COVID-19?" *The blue bars indicate a "yes", red bars indicate a "maybe" and the green indicate a "No" responses to the question among respondents from the Ghanaian-Dutch (GD), Afro-Surinamese Dutch (ASD) and the Hindustani Suriname-Dutch (HSD) communities in Amsterdam.*

TABLE 2 | Top five (5) kinds of information on COVID-19 needed by respondents from the 3 selected communities.

Ghanaian-Dutch respondents n = 57	
1	Impact of the vaccine on their overall health
2	When they will receive a letter or a call for appointment to get vaccinated
3	Types of COVID-19 vaccines and their efficacy
4	COVID-19 vaccination and the possible side effects
5	Explanation on how the vaccine works and scientific data that supports it
Afro Surinamese-Dutch n = 53	
1	COVID-19 Vaccine, it's efficacy and side effects
2	How to protect oneself against COVID-19
3	Everything about COVID-19
4	The different kinds of COVID-19 vaccines and how to choose
5	COVID-19 variants and its significance
Hindustani Surinamese-Dutch n = 47	
1	Prevention/protection practices without vaccination
2	COVID-19 vaccination and possible side effects
3	Types of COVID-19 vaccines and their efficacy
4	COVID-19 variants and its implication of health
5	Post COVID-19 recovery and health effects

Kind of Information Respondents Needed

As listed in **Table 2**, quite a high proportion of respondents among the Ghanaian-Dutch respondents wanted to know more about the COVID-19 vaccination and the possible side effects. Most of them expressed their fear about the possible negative impact of the vaccine on their overall health especially when they described themselves as obese/overweight or had chronic diseases such as hypertension and diabetes. To some, they wanted to be vaccinated and needed to know when they might receive a letter or a call for appointment to get vaccinated. It was also common for people to inquire further about the different vaccines available and which had minor or no side effects.

Based on individual responses from the Afro Surinamese-Dutch community, information on the COVID-19 vaccine, its efficacy and side effects, how to protect oneself against COVID-19, and the different kinds of COVID-19 vaccines and how to choose were mostly stated. The issue about the variants of COVID 19 was a concern to many participants, the different

TABLE 3 | The list of top 5 kinds of information perceived by respondents to be needed by their respective communities.

Ghanaian-Dutch respondents n = 57	
1	COVID-19 Vaccine, its efficacy and side effects
2	Explanation on how the vaccine works and scientific data that supports it
3	Types of COVID-19 vaccines and their efficacy
4	COVID-19 vaccination and the possible side effects
5	Everything about COVID-19
Afro Surinamese-Dutch n = 53	
1	Uncertainties/Theories about the existence of COVID-19
2	The need to adhere to the COVID-19 safety and prevention protocols
3	Everything about COVID-19
4	The influence of the views of family and friends on COVID-19
5	COVID-19 variants and its significance
Hindustani Surinamese-Dutch n = 47	
1	COVID-19 vaccine and its effects
2	Types of COVID-19 vaccines and the scientific reports on their efficacy
3	COVID-19 variants and its implication on health
4	Updates of every information on COVID-19
5	Prevention/protection without vaccination

vaccines available and which had minor or no side effects, explanation on how the vaccine works and scientific data that supports it, how the coronavirus spreads and how to acquire immunity, measures related to education particularly for students, and when the COVID-19 pandemic will end. Only a few respondents needed to know everything about COVID-19.

In the Hindustani Surinames-Dutch community, a major proportion of the respondents wanted to know more about the COVID-19 vaccination and the possible side effects. Most of them expressed their fear about the possible negative impact of the vaccine on their overall health. There appear to be so much news on the new COVID-19 variants and how fast they spread. However, some respondents wanted to know the implication of contracting any of the new variants of the virus and whether it could have more debilitating effects on their health. A section of the respondents also wanted to receive information on alternative ways to deal or protect themselves from COVID-19 without taking the vaccination.

Respondents' Perceived Community Information Needs

Many of the respondents 29 (50.9%) out of 57 from the Ghanaian-Dutch community, indicated "Yes" that people in their community needed more information on COVID-19. Out of 53 respondents from the Afro Surinamese-Dutch community in Amsterdam, majority proportion, 37 (70%) were of the view that perhaps people within their community would need to receive more information on COVID-19 while among the 47 Hindustani Surinamese-Dutch respondents, 16 (34%) answered "Yes", that people in their community needed more information on COVID-19. The top five kinds of information respondents from each community mentioned are listed in **Table 3**.

TABLE 4 | The primary sources used by respondents from the three communities to obtain information on COVID-19.

Sources of information used by Respondents	GD	ASD	HD	Total (%)
N	56	51	47	154 (100)
TV/Radio programme	20	14	10	44 (28.6)
Social media (whatsapp, facebook, etc)	7	7	7	21 (13.6)
Family and friends	8	7	12	27 (17.5)
Search engines/internet	3	14	4	21 (13.6)
website of GGD Amsterdam/RIVM	11	4	9	24 (15.6)
Emails/text/calls	1	0	0	1 (0.6)
Huisarts/ health workers	1	0	1	2 (1.3)
Newspapers/Flyers/Brochures	0	1	0	1 (0.6)
Others	5	4	4	13 (8.4)

Some respondents noted that more information about the COVID-19 vaccination, the types of vaccines being used at the "Prik locaties in Amsterdam", scientifically proven information and efficacy of the vaccines, and how people could achieve immunity or protection from COVID-19 without the vaccines. Some respondents indicated that some people in their community appeared not updated about the current happenings on COVID-19, and so they may need updates on all the general information on COVID-19.

Sources of Information on COVID-19

Among the respondents from the Ghanaian-Dutch community, TV/Radio programmes (both international and Netherlands-based news) were the most referred to source of information 20 (35.9%). followed by the dependence on Social media (Whatsapp, Facebook, etc) 7 (12.3%) as shown in **Table 4**. Among the Afro Surinamese-Dutch community, the Dutch TV/radio programmes 14 (27%) and the use of internet/search engine portals 14 (27%) were mostly used as sources of information. The dependence on family and friends 7 (14%) and Social media platforms 7 (14%) were the joint second most used sources of information on COVID-19. Only a single respondent (2%) relied on Newspapers/Flyers/Brochures. The Hindustani Surinamese-Dutch community in Amsterdam appeared to be highly dependent on family and friends 13 (26%) as the primary source of information on COVID-19 followed by the TV/Radio programmes 10 (21%), the internet/website search engine portals 9 (19%) and Social media 7 (15%).

During an in-depth interview with some of the respondents on why they preferred certain source of information, one of the Ghanaian-Dutch man, explained that "information is now everywhere" but he was careful what information to rely on and he preferred to listen to Dutch News portals because

> *I live here now and I have to really understand what is happening here. Aside news, when I need very specific information I just go to the RIVM website and I get the most reliable and updated information.*

Unlike the Afro and Hindustani Surinamese-Dutch respondents who understand and speak the Dutch language, many respondents from the Ghanaian-Dutch community had inadequate understanding of the Dutch language. Despite the situation, some of the respondents from the Ghanaian-Dutch community noted that they always preferred to listen to Dutch news with their children or asked their adult or teenage children to explain to them what was said in the news when they did not fully understand. Some respondents also noted that some individuals within the community took up the responsibility to translate all the broadcast from the news and press conferences by the Dutch prime minister or minister of health into common ethnic-matched languages and shared on the social media platforms. These audio or video recordings were targeted to people within the communities that did not fully understand the Dutch language. Some respondents from the three ethnic communities expressed their appreciation for these interventions and patronized such sources of information as "the language was deemed simple, relatable, and comes home". In this context, we observed from our fieldwork that simple language and being able to easily understand the information is important to many people within these communities.

However, in some cases the translations of such important information from Dutch to other languages have been received with less attention. According to a male respondent from the Hindustani Surinamese-Dutch "some social media explanations provided only a little information and in such situation certain vital elaborations are missed". The vice-versa situation is when original messages are overly explained to loose the actual content. It is therefore important for translations to be accurate, clear and timely. In view of this, people from the Ghanaian-Dutch, Afro and Hindustani Surinamese-Dutch communities make efforts to search for specific information that they can relate with and apply to their situation. It is one thing to get the message about COVID-19 out, but more important is to get that message right through reachable sources and within time.

Age-Dependent Variation to Sources of Information Use

Age-dependent analysis of the data indicated that international news portals were the most preferred source of information on COVID-19 among respondents aged 35 years and above. In addition to this, Dutch news portals were the most popular among respondents aged 18 to 35 years, but remained the most preferred among respondents aged 56 years and above. Religious meetings, family and friends and social media were the most popular sources of information on COVID-19 among respondents aged 46 to 55 years. More so, the use of social media for information on COVID-19 was widely common among respondents aged 35 to 55 years old. Generally, the results also indicated that a majority of the total respondents relied highly on their preferred sources of information because of the tendency to provide them with authentic reports (58.9%) followed by readily available information (23.9%) and the simplicity of the language used (21.13%) and easy of understanding (14.08%).

DISCUSSIONS

Some research works show that the coronavirus pandemic generated a lot of media attention and education on COVID-19 control and prevention measures globally (28, 29). These education and media attention were often geared to reveal public perceptions and experience about the pandemic, and also identify factors that hamper or support efforts to curb global spread of the disease (28). Some study findings identified the need for widespread, and continuous public health education about the virus and COVID-19, especially among certain populations (30, 31). This was mainly because the knowledge level was perceived to be low among people from certain minority ethnic groups, those who had low education and low-income levels, black women and the unemployed (30, 31). In the Netherlands, the assumption from public discourse shows that people from minority ethnic groups have poor knowledge, or lack sufficient understanding of their attitudinal and behavioral risks to the coronavirus (32). However, this remains an assumption as this study revealed that majority of the respondents from the Ghanaian- and Surinamese-Dutch demonstrated good knowledge on the modes of transmission and prevention or mitigating measures about COVID-19.

As discussed in an earlier study (33), knowledge level on COVID-19 is linked directly to preventive behaviors that are important to reduce COVID-19 spread within Ghanaian-Dutch communities in the Netherlands. In this present study, our findings showed that a little over a third of the respondents (36.4%) demonstrated low behavioral risk of contracting COVID-19 as they indicated that they avoid or rarely used the public transport, or attended public and social events i.e., the church, mosque, supermarket, public transport, visit friends and family, among others. More than half (54.5%) had a moderate behavioral risk of contracting COVID-19 as they often or sometimes visited some of the locations noted earlier. These findings suggest that majority of people from the Ghanaian-Dutch, Afro Surinamese-Dutch and Hindustani Surinamese-Dutch appear to translate their good knowledge on COVID-19 into good preventive behaviors (i.e., low to moderate behavioral risk of contracting COVID-19). However, about 9.1% of the respondents showed high-risk behavior, as they were always present at public and social events. and reported that they had difficulty following some specific measures such as wearing a face/nose mask, avoiding visits to friends and family, and maintaining an interpersonal physical distance of 1.5 m. Regarding visiting friends and family, interestingly, many respondents in this present study particularly from the Ghanaian-Dutch community, found it difficult to turn down an invitation from family and close friends. This is not only because they were worried about maintaining these closer relationships, but also because, respondents perceived that their family and friends were less likely to contract COVID-19. These findings underscore the importance of social impressions, as people are concerned about what others think of them, and prioritize their views than what they must do.

Earlier studies have shown that unfavorable behaviors toward COVID-19 prevention are exacerbated by people's work or job category (34). In this present study, majority of the respondents were classified as essential workers, particularly healthcare and that the nature of their jobs made it difficult to maintain 1.5 m distances from their clients, patients and work colleagues. The findings in this study appear to reinforce the plight of essential workers (34, 35). It is therefore important for adequate measures to be taken to protect essential workers from risks linked to their job or work. From this perspective, it becomes imperative to distinguish between persons whose behavior increases exposure to contracting COVID-19 based on their occupation or in relation to close relations.

Is This a Sign of Information Fatigue or a Lack of Information?

Global attempts to promote knowledge about the COVID-19 pandemic led to the ubiquity of health-related information across all media platforms. However, recent research suggests that "abundant" accessibility of information on COVID-19 could lead to adverse psychological effects, including anxiety, panic-based hoarding, and other unhealthy behaviors (28). Some of these consequences have been explained with the notion of information fatigue or overload (28, 29). Our findings highlight that many of the respondents who said they did not need to get more information on COVID-19 were concerned about getting "old" information. They felt that it was the same recycled information that they kept receiving and therefore did not see the need to get more. Other respondents also felt "tired of this Corona" and preferred not to know more.

This observed lack of interest has been shown to either influence or obscure the successful uptake and utilization of the information to either change or improve their behavioral choices regardless of the amount of information disseminated (36). As suggested in a recent study in Germany by Skulmowski and Standl (37), individual organizations interested in keeping people informed concerning COVID-19 should consider the use of personalized information strategies that avoid inducing negative emotional states. This present study by extension suggests that for minority ethnic groups, it is essential for surveys to be conducted on periodic intervals or employ digital innovations to ascertain specific information the people would need and engage with.

Alternatively, since this study was conducted during the second wave amid strict lockdown measures, many of the respondents had assimilated a lot of information on COVID-19. During the initial outbreak, many respondents were occupied with arming themselves with every bit of information they could find or help them stay safe. As a result most of the information that were shared on the television and other media platforms were things they already know about and so did not see the need to know more. A lot of the restrictions and regulations had become a second nature or habit of high proportion of our respondents and thus they felt the information was old. Thus, a reason for rejection for more information on COVID-19 became a natural consequence. Another explanation suggested by other researchers show that COVID-19 information fatigue had developed and made the public less interested in news surrounding the issue due to the ubiquity of the same information concerning COVID-19 (37, 38). The public may have become disinterested of this topic, at least in the sense that no active search for information is perceived to be necessary.

More so, some respondents did not want to receive more information on COVID-19 because of the persistence focus by the media on "bad news" that is, total number of persons who have contracted or died from the disease. The COVID-19 pandemic has been associated with pain, anxiety, depression, and loneliness among other mental health issues in the Netherlands (39, 40). According to some research findings, the repetition, relative abundance of recycled news and ubiquity of COVID-19 information particularly those that invoke worrying bad memories or health-related issues could lead people into a state of anger and also desensitized others (37, 41). This present study revealed that some respondents who did not need more information appeared to be more open to know more about how to "encourage and lift people up".

While certain category of respondents did not seek additional information about COVID-19 public health-related topics and the negative effects of the pandemic, a large proportion wanted to know more about specific concerns. In this study, a many respondents across the three study communities wanted to know more about the COVID-19 vaccination and the possible side effects. Most of them particularly from Hindustani Surinamese-Dutch and Ghanaian-Dutch communities described themselves as obese/overweight or had chronic diseases such as hypertension and diabetes and feared the possible negative implication for their overall health and wellbeing. As uncertainties and misinformation appear to proliferate during this pandemic (42), directing communication efforts to specific populations, including those considered not at high risk such as younger adults could be beneficial to providing these groups with accurate and needed information.

At present, majority of the news have focused on the COVID-19 variants and how fast they spread. To some respondents, beyond the fast spread of the new COVID-19 variants they did not understand the implication of contracting any of the new variants of the virus. As the world health organization is working with researchers, health officials and scientists to understand what impact the new variants of the COVID-19 virus have on vaccines, a lot of respondents were waiting to decide their next actions toward COVID-19. Preliminary analyses have showed that the South Africa variant (501Y.V2) was associated with in-hospital mortality that was 20% higher in the second wave in South Africa than in the first wave (43). This finding was due mainly to the greater transmissibility of this variant, which rapidly overburdened health services and thus compromised timely access to hospital care and the quality of that care. The UK variant (B.1.1.7) has also been shown to be associated with a higher risk of death (44). A lot still remain unknown about the Delta and omicron variants among others beyond the greater transmissibility of this variant.

A section of the respondents also wanted to receive information on alternative ways to deal or protect themselves from COVID-19 without taking the vaccine. There is widespread acceptance of COVID-19 vaccines as the major breakthrough toward the fight and rapid eradication of the coronavirus disease (45). As we showed in an earlier publication (27), out of the total of 55 Ghanaian-Dutch respondents only 2 (3.6%) had taken vaccine and nearly half (47%) of the respondents indicated their readiness to take the COVID-19. Only 7 (13%) out of the 54 respondents from the Afro Surinamese-Dutch had already received the COVID-19 while nearly half 26 (49%) of the respondents indicated their willingness get the vaccine. Also among the Hindustani Surinamese-Dutch respondents, only 7 (14%) of the respondents had received the vaccine with nearly a half (47%) also willing to take the vaccine (27). A large proportion of respondents were not interested in taking the vaccine among the minority ethnic groups and this finding is consistent with earlier publication indicating about 40% of the Dutch population opposed the COVID-19 vaccine (46). As the findings of this present study shows that achieving a high uptake of the COVID-19 vaccine will be a challenge (45) and some respondents only wanted to receive information on alternative ways to deal or protect themselves from COVID-19 without taking the vaccine.

Diverse Platforms Required for COVID-19 Education

The findings from this study showed that people from different communities use diverse ways to access information on COVID-19, and these various sources of information had various impacts on how people adhere to the COVID-19. The news around COVID-19 keeps changing rapidly especially with new data on research and there seem to be a lot of (mis)information also shared. This shows that if misinformation spreads across friends and family people could take that information as the truth.

Our results show that substantial misinformation and uncertainty about the virus and COVID-19 existed at the time of the conduct of this study particularly about vulnerable or most affected groups, transmission and risk-reduction strategies. From the point of view of our respondents, there appeared to be some uncertainties or theories about the existence of COVID-19. Some respondents feared their age, and the presence of other health conditions made them more vulnerable and that they could easily succumb to COVID-19. Earlier research works showed that elderly people who contracted COVID-19 were more likely to develop severe manifestations of the disease (47). However, accumulating evidence shows that there is the need to distinct between healthy aging and aging with frequent occurrence of multiple comorbidities (48). The suggestion is that although age is one of the major risk factors for COVID-19, most of the complications from COVID-19 arise out of the pre-existing health conditions. It is therefore very important for education to be intensified to draw a clear distinction so that the impression is not created that old age is synonymous to death when one contracts COVID-19.

The findings of this study demonstrate the information needs, knowledge level, perception and misconception about the COVID-19 pandemic among some minority ethnic groups in the Netherlands. This calls for additional education and training in public health preparedness in the Ghanaian-Dutch, Afro Surinamese-Dutch and Hindustani Surinamese-Dutch communities in Amsterdam. Besides improving the knowledge, attitude and preventive behaviors toward COVID-19 among minority ethnic groups, the respondents' feedback about the current pandemic can help policy makers and management taskforces to further align public education for effective outcomes in the these three communities in the Netherlands.

The major limitation of this study was that data collection was conducted at the period when the COVID-19 infection rate in the Netherlands had reached its second peak (second wave) admist strict lockdown that made it difficult to recruit a high number of study participants. In addition, the views expressed by individuals do not represent the collective or generalized view of the entire study population as only 33 out of the 160 respondents participated in the in-depth interviews. Although we provide timely and relevant data, there are certain limitations to this study. Our survey was time specific and as we can see from on-going developments, there is the need for further research to understand the changing dynamics regarding information needs of diverse group of people. Further research may explore the changing roles in mobilizing stakeholders to employ data-driven interventions in the management of pandemics.

CONCLUSION

The COVID-19 pandemic continues to have a devasting effect, but there have been relaxations of COVID-19 regulations in many countries, which comes with several questions from people to know what this means for their wellbeing and that of others. In this study, respondents showed an overall good knowledge and perception of COVID-19; however, there appears to be a low level of compliance or adherence to the COVID-19 prevention and safety measures. In as much as there was lockdown during collection of data for this study, it hardly deterred people from still gathering together in large numbers. More so, the study area as indicated above had many shops and so while only essential stores were open there were still many market activities at the period. Therefore, there is a need to encourage and remind people to follow the preventive protocols and disseminate appropriate information timely to safeguard the safety of vulnerable people's lives. A high proportion of the respondents underscored how the COVID-19 pandemic had affected their new sense of awareness and responsibility to keep themselves and their close relations safe. These respondents raised concerns about the persistent circulation of "bad news" on COVID-19 to the neglect of the flourishing or "good news". Many thus advocated for messages that provide encouragement and hope that collective action and responsibility could go a long way to alleviate some of the negative consequences of the COVID-19 pandemic. The reasons behind why some respondents felt there was bad news in the media, however, there are on-going fieldwork and data collection to analyse how respondents felt and the full reasons behind that.

As our data showed the impact of the COVID-19 pandemic on public health requires a global bioethical reflections and responses as discussed in the recently published special issue on "Ethics and COVID-19: The Bioethics of a 'Job Well Done' in Public Health" by the Frontiers Health services journal. People's information choices go beyond the individual and incorporate ideas of health with social factors, based on a more relational approach (49). Our findings highlight how the COVID-19 pandemic has revealed the reality of policy gaps and information gaps that people from minority ethnic groups are confronted with and its effect on their well-being. Many people's concerns arise from inadequate information or disinformation or not knowing where to get the right and accurate information. Given this, policymakers may need to tailor efforts into regular updates and resources that provide complete answers to the concerns that arise from time to time. Specifically to COVID-19 vaccination, information dissemination and the safety or efficacy and benefits of the COVID19 vaccination are necessary. Specific focus should be the importance and efficacy of vaccines, and messages should counteract and dispel erroneous previously held views on vaccines.Therefore, it is crucial to scale up the community's awareness of COVID-19 prevention, testing, vaccination, and mitigation strategies through appropriate media outlets.

As our research shows, information and education programs on dispelling myths and fact-checking conflicting information on COVID-19 continue to evolve. Subsequent research may need to focus on how after a proportionally high number of vaccinations, people perceive risk and seek information. We suggest that there is the need to look at how health officials, government authorities, and religious leaders among others make a concerted and cohesive effort in information dissemination taking into consideration changing times.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by AISSR Ethics Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

AZB and DA-B conceived and planned the study, methodology and execution, supervised, carried out the data collection, verified the analytical methods, discussed the results, and contributed to the final manuscript. Both authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/frhs.2022.824591/full#supplementary-material

REFERENCES

1. Imai N, Dorigatti I, Cori A, Donnelly C, Riley S, Ferguson N. *Report 2: Estimating the Potential Total Number of Novel Coronavirus Cases in Wuhan City, China*. London: Imperial College London (2020).
2. Gates B. Responding to Covid-19 — A once-in-a-century pandemic? *N Engl J Med.* (2020) 382:1677–9. doi: 10.1056/NEJMp2003762
3. World Health Organisation. *Coronavirus disease (COVID-19) Weekly Epidemiological Update and Weekly Operational Update March/April 2021.* (2021). Available online at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports. (accessed July 6, 2021).
4. World Health Organisation. *COVID-19 Strategy Update 14th April 2020.* (2020). Available online at: https://www.who.int/docs/default-source/coronaviruse/covid-strategy-update-14april2020.pdf (accessed July 6, 2021).
5. RIVM, Rijksinstituut voor Volksgezondheid en Milieu. (2021). *Committed to Health and Sustainability, Current Information About COVID-19.* Available online at: https://www.rivm.nl/en/coronavirus-covid-19/current-information (accessed July 14, 2021).
6. Oxford COVID-19 Government Response Tracker. *Government Response Tracker Now Includes Data on Vaccination Policies Around the World.* (2021). Available online at: https://www.bsg.ox.ac.uk/news/government-response-tracker-now-includes-data-vaccination-policies-around-world (accessed December 21, 2021).
7. Cao X. COVID-19: immunopathology and its implications for therapy. *Nat Rev Immunol.* (2020) 20:269–70. doi: 10.1038/s41577-020-0308-3
8. Khadka S, Hashmi FK, Usman M. Preventing COVID-19 in low-and middle-income countries. *Drugs Ther Perspect.* (2020) 36:250–2. doi: 10.1007/s40267-020-00728-8
9. Asnakew Z, Asrese K, Andualem M. Community risk perception and compliance with preventive measures for COVID-19 pandemic in Ethiopia. *Risk Manag Healthc Policy.* (2020) 13:2887–97. doi: 10.2147/RMHP.S279907
10. Coyer L, Boyd A, Schinkel J, Agyemang C, Galenkamp H, Koopman AD, et al. SARS-CoV-2 antibody prevalence and determinants of six ethnic groups living in Amsterdam, the Netherlands: a population-based cross-sectional study, June-October 2020. *medRxiv.* (2021) 03.08.21252788. doi: 10.1101/2021.03.08.21252788
11. Amgain K, Neupane S, Panthi L, Thapaliya P. Myths versus truths regarding the novel coronavirus disease (COVID-2019) outbreak. *J Karnali Acad Health Sci.* (2020) 3:1–6. doi: 10.3126/jkahs.v3i1.28367
12. Oliver RM. What makes young people think positively about social distancing during the corona crisis in Germany? *Front Sociol.* (2020) 5:61. doi: 10.3389/fsoc.2020.00061
13. Bodner J, Welch W, Brodie I. *COVID-19 Conspiracy Theories: QAnon, 5G, the New World Order and Other Viral Ideas*. Jefferson: McFarland (2020).
14. Grimes DR. Medical disinformation and the unviable nature of COVID-19 conspiracy theories. *PLoS ONE.* (2021) 16:e0245900. doi: 10.1371/journal.pone.0245900
15. Morgan M. Why meaning-making matters: the case of the UK Government's COVID-19 response. *Am J Cult Sociol.* (2020) 8:270–323. doi: 10.1057/s41290-020-00121-y
16. Worldometer. *COVID-19 CORONAVIRUS PANDEMIC: Cases, Deaths and Recovered.* (2021). Available online at: https://www.worldometers.info/coronavirus/ (accessed on July 14, 2021).
17. de Boer H. COVID-19 in Dutch higher education. *Stud High Educ.* (2021) 46:1; 96–106, doi: 10.1080/03075079.2020.1859684
18. NL Time. *Poorer Neighborhoods Hit Harder by Covid-19 Infections: Report. Monday, October 12, 2020.* (2020). Available online at: https://nltimes.nl/2020/10/12/poorer-neighborhoods-hit-harder-covid-19-infections-report (accessed November 1, 2021).
19. Reiter PL, Mira LK. Racial/ethnic differences in knowledge, attitudes, and beliefs about COVID-19 among adults in the United States. *Front Public Health.* (2021) 9:653498. doi: 10.3389/fpubh.2021.653498

20. SEO Economisch Onderzoek. Amsterdam, Netherlands: Self-Evaluation Report. *OECD Reviews of Higher Education in Regional and City Development.* Amsterdam: IMHE (2009).
21. CBS, Centraal Bureau voor de Statistiek. *Statistics Netherlands. StatLine – Bevolking; leeftijd, herkomstgroepering, geslacht en regio*. Kralendijk: CBS (2018).
22. CBS, Centraal Bureau voor de Statistiek. Statistics Netherlands. *StatLine – Bevolking; leeftijd, herkomstgroepering, geslacht en regio*. Kralendijk: CBS (2021).
23. Van der Veer P, Vertovec S. Brahmanism abroad: on caribbean hinduism as an ethnic religion. *Ethnology.* (1991) 30:149–66. doi: 10.2307/3773407
24. Bakuri A, Spronk R, van Dijk R. Labour of love: Secrecy and kinship among Ghanaian-Dutch and Somali-Dutch in The Netherlands. *Ethnography*. (2020) 21:394–412. doi: 10.1177/1466138120938808
25. Bakuri AZ. *In Pursuit of Well-Being: Sexuality and Religion Among Ghanaian-Dutch and Somali-Dutch in the Netherlands*. PhD Dissertation. Amsterdam: University of Amsterdam, The Netherlands (2021).
26. Azene ZN. Merid MW, Muluneh AG, Geberu DM, Kassa GM, Yenit MK, et al. Adherence towards COVID-19 mitigation measures and its associated factors among Gondar City residents: a community-based cross-sectional study in Northwest Ethiopia. *PLoS ONE.* (2020) 15:e0244265. doi: 10.1371/journal.pone.0244265
27. Antwi-Berko D, Bakuri AZ, Otabil K*B*. Kwarteng A. Determinants and variations of COVID-19 vaccine uptake and responses among minority ethnic groups in Amsterdam, the Netherlands. *Front Public Health.* (2022) 10:761987. doi: 10.3389/fpubh.2022.761987
28. Oyebode O, Ndulue C, Adib A, Mulchandani D, Suruliraj B, Orji FA, et al. Health, psychosocial, and social issues emanating from the COVID-19 pandemic based on social media comments: text mining and thematic analysis approach. *JMIR Med Inform.* (2021) 9:e22734. doi: 10.2196/22734
29. Williamson B, Eynon R, Potter J. Pandemic politics, pedagogies and practices: digital technologies and distance education during the coronavirus emergency. *Learn Media Technol.* (2020) 45:2, 107–14, doi: 10.1080/17439884.2020.1761641
30. Ali S, Foreman J, Tozan Y, Capasso A, Jones A, DiClemente R. Trends and predictors of COVID-19 information sources and their relationship with knowledge and beliefs related to the pandemic: nationwide cross-sectional study. *JMIR Public Health Surveill.* (2020) 6:e21071 doi: 10.2196/21071
31. McCormack LA, Squiers L, Frasier AM, Bevc C, Lynch M, Bann CM, et al. Gaps in Knowledge About COVID-19 Among US Residents Early in the Outbreak. *Public Health Rep.* (2021) 136:107–16. doi: 10.1177/0033354920970182
32. Van der Leun JP, van der Woude MAH. Ethnic profiling in the Netherlands? A reflection on expanding preventive powers, ethnic profiling and a changing social and political context. *Pol Soc.* (2011) 21:4, 444–55. doi: 10.1080/10439463.2011.610194
33. Antwi-Berko D, Bakuri AZ. *Adherence to COVID-19 Preventive Measures Among the Ghanaian-Dutch Community in the Netherlands; a Mixed Method Study in Amsterdam.* (2021). Available online at: http://dx.doi.org/10.2139/ssrn.3907843 (accessed August 1, 2021).
34. The Lancet. The plight of essential workers during the COVID-19 pandemic. *Lancet.* (2020) 395:1587. doi: 10.1016/S0140-6736(20)31200-9
35. Guerrero LR, Avgar AC, Phillips E, Sterling MR. They are essential workers now, and should continue to be: social workers and home health care workers during COVID-19 and Beyond. *J Gerontolog Soc Work.* (2020) 63:6–7, 574–6. doi: 10.1080/01634372.2020.1779162
36. Griffin RJ, Dunwoody S, Yang ZJ. Linking risk messages to information seeking and processing. *Ann Int Comm Assoc*. (2016) 36:323–62. doi: 10.1080/23808985.2013.11679138
37. Skulmowski A, Standl B. COVID-19 information fatigue? A case study of a German university website during two waves of the pandemic. *Hum Behav Emerg Tech*. (2021) 3:350– 356. doi: 10.1002/hbe2.260
38. Koh PKK, Chan LL, Tan EK. Messaging fatigue and desensitisation to information during pandemic. *Arch Med Res.* (2020) 51:716–7. doi: 10.1016/j.arcmed.2020.06.014
39. Luijten MAJ, van Mulekom MM, Teela L, Polderman TJC, Terwee CB, Zijlmans J, et al. The impact of lockdown during the COVID-19 pandemic on mental and social health of children and adolescents. *Qual Life Res*. (2021) 15:1–10. doi: 10.1101/2020.11.02.20224667
40. van Tilburg TG, Steinmetz S, Stolte E, van der Roest H, de Vries DH. Loneliness and mental health during the COVID-19 pandemic: A study among Dutch older adults. *J Gerontol B Psychol Sci Soc Sci*. (2020) 76:e249–55. doi: 10.1093/geronb/gbaa111
41. Baseman JG, Revere D, Painter I, Toyoji M, Thiede H, Duchin J. Public health communications and alert fatigue. *BMC Health Ser Res.* (2013) 13:295. doi: 10.1186/1472-6963-13-295
42. Kim HK, Ahn J, Atkinson L, Kahlor LA. Effects of COVID-19 misinformation on information seeking, avoidance, and processing: a multicountry comparative study. *Sci Commun.* (2020) 42:586–615. doi: 10.1177/1075547020959670
43. Pearson CAB, Russell TW, Davies N, Kucharski AJ, CMMID COVID-19 working group, Edmunds WJ, et al. *Estimates of Severity and Transmissibility of Novel SARS-CoV-2 Variant 501Y.V2 in South Africa*. London: CMMID Repository (2021).
44. Horby P, Huntley C, Davies N, Edmunds J, Ferguson N, Medley G,Semple C. *NERVTAG Paper on COVID-19 Variant of Concern B.1.1.7.* London: Department of Health and Social Care, Scientific Advisory Group for Emergencies (2021).
45. Loomba S, de Figueiredo A, *Piatek SJ, de Graaf K, Larson HJ*. Measuring the impact of COVID-19 vaccine misinformation on vaccination intent in the UK and USA. *Nat Hum Behav.* (2021) 5:337–48. doi: 10.1038/s41562-021-01056-1
46. DutchNews.nl. *Why Are so Many People in the Netherlands Opposed to a Covid Vaccine?* (2020). Available online at: https://www.dutchnews.nl/news/2020/12/why-are-so-many-people-in-the-netherlandsopposed-to-a-covid-vaccine/ (accessed July, 15 2021).
47. Liu Y, Huang F, Xu J, Yang P, Qin Y, Cao M, et al. Anti-hypertensive Angiotensin II receptor blockers associated to mitigation of disease severity in elderly COVID-19 patients. *MedRxiv.* (2020) 20039586. doi: 10.1101/2020.03.20.20039586
48. D'ascanio M, Innammorato M, Pasquariello L, Pizzirusso D, Guerrieri G, Castelli S, et al. Age is not the only risk factor in COVID-19: the role of comorbidities and of long staying in residential care homes. *BMC Geriatr.* (2021) 21:63. doi: 10.1186/s12877-021-02013-3
49. Valera L, López Barreda R. Bioethics and COVID-19: considering the social determinants of health. *Front Med.* (2022) 9:824791. doi: 10.3389/fmed.2022.824791

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