Research Ethics and Integrity Challenges During Pandemics: The Research Foundation of the PREPARED Code

Pamela Andanda[1(✉)], Langelihle Mlotshwa[1], Orla Drummond[2], Vilma Lukaševičienė[3], Giulia Inguaggiato[4], and Klaus Leisinger[5]

[1] School of Law, University of the Witwatersrand, Johannesburg, South Africa
pamela.andanda@wits.ac.za
[2] Trilateral Research, Belview Port, Ireland
[3] The Division of Medical History and Ethics in the Medical Faculty of Vilnius University, Vilnius, Lithuania
[4] Department of Ethics, Law and Humanities, Amsterdam Public Health Institute, Amsterdam UMC, Vrije Universiteit Amsterdam, Amsterdam, The Netherlands
[5] Foundation Global Values Alliance, Basel, Switzerland

Abstract. Crises and public health emergencies can have devastating and wide-ranging impacts across healthcare, social, cultural, economic and political contexts. Against this backdrop, many research ethics and research integrity challenges can be exacerbated, and new ones can emerge as researchers and other stakeholders find themselves in testing and unstable environments. Learning from these challenges, to prepare for similar future crises, requires a broad perspective and encompassing vision. It also requires careful identification and analysis of challenges to ensure that guidance for future crises has real-world applicability. A risk-based approach to ethics code development begins with the identification of ethics risks or challenges, which itself requires extensive research. This chapter describes the research foundation upon which the PREPARED Code was built. It presents an overview of the results of an in-depth review of published literature in nine languages, additional scoping reviews on Ebola and avian flu, investigations into the challenges experienced by groups who were disadvantaged during the COVID-19 pandemic, an analysis of the human rights challenges in the context of sudden global crises, an investigation into how one pharmaceutical company overcame governance challenges to produce a vaccine in record time, and an analysis of pandemic research ethics guidance documents. Together the findings from these activities constituted a strong foundation for the development of the PREPARED Code.

Keywords: Research ethics · research integrity · pandemic ethics

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1 Introduction

There are various ways to build the foundation for new ethics codes. As outlined in Chap. 3, the PREPARED team chose the risk-based approach combined with extensive consultations. This required identifying and analysing emergent and exacerbated research ethics and integrity challenges during pandemics.

In this chapter, we describe the main research results that provided the foundation for the PREPARED Code. In particular, we present selected findings from:

- a review of the published literature from the COVID-19 pandemic in nine languages (English, Chinese, French, German, Hindi, Japanese, Korean, Russian and Spanish) and additional scoping reviews in English on Ebola and avian flu epidemics (Sect. 2)
- investigations into the challenges experienced by groups who were probably disadvantaged because of the pandemic, including health and social care workers, people with disabilities, women researchers and highly marginalised groups such as the Nairobi sex workers (Sect. 3)
- an analysis of human rights challenges in the context of sudden global crises (Sect. 4)
- an investigation of how one pharmaceutical company overcame governance challenges to produce a vaccine in record time (Sect. 5)
- an analysis of pandemic research ethics guidance documents (Sect. 6).

The research ethics and integrity challenges identified through the above methods were validated in workshops with researchers, policymakers and advisers, research ethics and research integrity experts, and patient groups and their representatives, as described in Chap. 5.

2 Literature Reviews in Nine Languages

To capture as many challenges as possible for research ethics and research integrity during times of crisis, and to avoid linguistic bias, literature reviews were conducted in English, Chinese, French, German, Hindi, Japanese, Korean, Russian and Spanish. These reviews focused primarily upon the COVID-19 pandemic, but additional scoping reviews were undertaken in English on the Ebola epidemic, which the World Health Organization (WHO) declared a "public health emergency of international concern" in 2014 (Gostin et al. 2014), and on the avian flu epidemic (Mittal and Medhi 2007).

The types of literature searched included peer-reviewed and non-peer-reviewed academic literature, grey literature, articles in the media, and official guidance and advice, depending on where the best sources of information could be found in each language. This helped maximise the number of risks identified. Three of the reviews, Korean, German and Chinese, have been published in full elsewhere (Park and Kim 2024; Seedall and Tambornino 2024; Zhu et al. 2024).

Together, the reviews generated a vast amount of rich data that was subsequently pooled for analysis and led to the identification of 160 challenges for research ethics and research integrity (see Chap. 5). Since it would not be possible to describe all 160 identified challenges here, this section includes a synopsis of the primary challenges that were uncovered for various stakeholders in the research process. Examples from the different language reviews are provided for illustrative purposes.

2.1 Challenges for Research Ethics Committees

Research ethics committees have a vital role during pandemics. They must help to ensure that research is conducted ethically and safeguard the rights and wellbeing of participants, while facilitating rapid scientific advancements (Tamariz et al. 2021). Numerous challenges for research ethics committees during the COVID-19 pandemic were reported across many of the language reviews. For instance, the English review revealed how research ethics committees experienced increased workloads and demands for rapid review of research protocols due to the urgency brought about by the pandemic (Marzouk et al. 2021; Shekhani et al. 2021; Tamariz et al. 2021; Kadam et al. 2022).

Similarly, the Spanish literature describes the widespread sense of urgency during the pandemic that led to the acceleration of research pathways. This inevitably put pressure on the ethics review processes in Spanish-speaking regions (Barajas and Valderas 2020; Espinoza-Navarro and Rivera-Gutiérrez 2021; Mendoza and Abreu 2021). For instance, in Spain, where research ethics committee members are normally also healthcare professionals, the frequency of the review meetings increased from once a month to once a week, adding to their existing burdens (Bugarín-González et al. 2020).

In Korea, where research ethics approval normally takes one or two months, the government requested that the review process be shortened to less than a week (Park and Kim 2024). With additional workloads, time pressures and the switch to online working, research ethics committees were forced to seek alternative ways to function during the pandemic, balancing the acceleration of review processes with the maintenance of methodological rigour (Barajas and Valderas 2020; Mendoza and Abreu 2021).

The English review also highlighted challenges associated with a lack of precise guidelines, especially in the early stages of the pandemic (Marzouk et al. 2021). New trial designs presented challenges, with regular adjustments of studies to reflect evolving guidelines on COVID-19 (Marzouk et al. 2021). The protocols for these new designs required general expertise in ethics and public health preparedness, which was not always available due to the demands on members to review more proposals within a limited time (Tamariz et al. 2021). Some protocols were of poor quality as they were hastily prepared by eager researchers who wanted to join the race for research results (Marzouk et al. 2021; Shekhani et al. 2021), thus compelling committee members to spend more time on the scientific quality of the protocols than on the ethics (Shekhani et al. 2021). Additionally, and in spite of their extra efforts, the opinions of research ethics committees were not always respected. For instance, out of 42 sites in a multicentric trial in India, the decision of the Central Ethics Committee was followed by only three sites (Bassi et al. 2022).

2.2 Challenges for Participants

During the COVID-19 pandemic, the urgent need to develop treatments and vaccines often led to expedited research processes, compromising the thoroughness of informed consent (Goldman and Gelinas 2021). For instance, the Chinese review reported that after the outbreak of the pandemic, there were three main concerns about informed consent (Cheng et al. 2020; Ding et al. 2020; Zhang 2020; Hu and Dong 2021): first, that signing informed consent forms in the isolation wards might cause contamination; second, that signing these forms would be difficult for potential human participants

who were critically ill and confined to isolation wards with no family members or legal representatives; and third, that the desire to obtain informed consent speedily for urgent projects might create a type of "therapeutic misunderstanding" on the part of patients, through insufficient explanation by researchers and the patients' own eagerness to get treatment. This could result in neglect of the risks associated with participation in the research.

In Korea, because it was difficult to obtain consent through face-to-face discussions with patients who were quarantined and undergoing treatment for COVID-19, several alternatives were proposed, including telephone or video explanations, consent from legal representatives, and the storing of photographs of consent forms as a substitute for written consent (Shin 2020). And ethical breaches of the requirements for informed consent in clinical research did occur. For instance, the French press reported breaches of informed consent requirements in at least three research projects in one institution alone (Larousserie 2022).

Balancing the potential benefits of research against the risks to participants became more complicated during the pandemic. The high transmission rate of COVID-19 and limited knowledge about the virus meant that researchers were working in a climate of uncertainty, which made it difficult to be confident about participant safety (Bierer et al. 2020). The most extreme example of this challenge could be seen in the vigorous debate regarding the permissibility of human challenge studies during the early phases of the pandemic, before effective COVID-19 vaccines were developed.

Human challenge studies – that is, the intentional infection of healthy volunteers with the virus in a controlled environment – were widely proposed as a quick way of gaining insights into COVID-19, as well as of speedily testing potential treatment and vaccine candidates (Chappell and Singer 2020). However, concerns were raised about lowering ethical standards to enable these studies to proceed, with unknown risks to participants (Weijer 2024). In Korea, academic papers examined the risks, benefits and ethical considerations of participant consent, analysing historical cases of human challenge trials for diseases like dengue fever, cholera and Zika virus (Choi 2020; Fang et al. 2020; Jung and Kim 2020; Lee 2020). In the German literature, the intentional infection of participants stirred painful memories of the Nazi atrocities in Europe (Jamrozik and Selgelid 2020), but many researchers recommended human challenge studies for their scientific potential, and because there was a lack of comparable alternative methods to achieve rapid and accurate results (Faust et al. 2020). However, strict approval procedures requiring painstaking risk calculations discouraged German scientists from opting for such studies (Tambornino and Lanzerath 2020).

2.3 Challenges for Researchers

Researchers were also affected during the COVID-19 pandemic by demands related to the change in work patterns and the pressure to generate helpful, evidence-based information. The situation in Germany was not untypical: following the rise of #ichbinhanna (I am Hanna), a viral campaign evolved, amplifying the voices of researchers at German universities struggling with job insecurity and excessive workloads. The pandemic was widely regarded as the tipping point in academic workplace dynamics (Mittermeier 2021). It worsened the already precarious working conditions at many universities and

research institutions. The COVID-19 crisis deepened existing inequalities in academia, particularly affecting women researchers. As remote work became the norm, or was even mandated, across much of German-speaking Europe, women were increasingly expected to manage childcare and household responsibilities, leaving less time for scientific work (Taschwer 2022). Consequently, women-authored publications declined, and their citation rates dropped in comparison to male authors, a trend shown to undermine research integrity (Miller, Valeva, Prieß-Buchheit 2022).

2.4 Challenges for Healthcare Staff

A vast body of literature has explored the challenges faced by healthcare workers during the COVID-19 pandemic (Ehrlich et al. 2020), with many also taking on research responsibilities. For example, in Wuhan, China, the city where COVID-19 was first identified, when the number of patients surged exponentially in the early stages of the outbreak, shortages of personnel forced healthcare providers to juggle both patient care and scientific research, and they struggled to balance these demanding roles (Wu et al. 2021). Additionally, the heavy workload often left them with insufficient time and energy for follow-up visits, limiting their ability to collect essential patient data needed for research completion (Liu et al. 2020).

2.5 Challenges for Societies

The primary challenges for societies that emerged during the COVID-19 pandemic were associated with the trustworthiness of science and the messages relayed via the media. For instance, the Spanish review revealed that the pandemic contributed to a lack of rigour in articles published as pre-prints, or fast-tracked for publication, that were later retracted (Dadalto et al. 2020; Bermúdez and Maldonado 2021). The haste with which articles were being published also increased the risk of irresponsible research practices such as plagiarism, duplicate publication, falsification, fabrication, gift authorship, conflicts of interest and inadequate peer review (Bermúdez and Maldonado 2021). And in India, Todhunter (2021) reported a lack of rigour in the interpretation of research findings leading to the dissemination of misleading information.

People were desperate for news of a cure. Early in the pandemic, the potential use of hydroxychloroquine as a treatment for COVID-19 became a talking point in France when a professor announced the "endgame" against the new coronavirus. He claimed that hydroxychloroquine, a synthetic derivative of quinine and normally prescribed for malaria, could inhibit the virus within a few days (jmichel2you 2020). The controversial use of this drug spread quickly around the world, as could be seen, for instance, in India (Bangalore et al. 2020; Chaturvedi et al. 2020) and Germany (Christian 2022), where the debate provided an impetus for the rigorous scrutiny of studies.

The Russian review reported how the speed with which the COVID-19 Sputnik vaccine was developed and approved raised concerns about its safety and efficacy (Bucci et al. 2020). Russia became the first country in the world to approve a COVID-19 vaccine for widespread public use in August 2020, but the vaccine's efficacy and safety were allegedly announced before the clinical trials had been completed or data published

(Cohen 2020). It was also alleged that vaccine trial data may have been manipulated and duplicated (Heidt 2022).

The lack of effective coordination of clinical studies had impacts on the quality of scientific data (Bompart 2020). As reported in the German literature, a lack of upstream coordination resulted in high overlap, high competition and, subsequently, a recruitment crisis that bred methodological weaknesses (Faust et al. 2020; Hirt et al. 2021; Pearson 2021), all of which had an impact on the reliability of study findings.

A further challenge for society concerned the routine exclusion of vulnerable individuals and groups (like pregnant women and elderly persons) from research. The practice may have prevented certain groups from accessing the benefits of research, ultimately rendering them more vulnerable. This challenge also generated debate around the world. For instance, in Korea it was argued that the exclusion of individuals or groups solely because of their vulnerability, without scientific or ethical justification, was not acceptable (Yoo and Kim 2021).

2.6 Global Challenges

The COVID-19 pandemic exacerbated existing socioeconomic vulnerabilities and inequalities globally. Much of the identified Spanish literature referred to global inequality in research risks, burdens, benefits and resource distribution. Some of it stressed the need to pay extra attention to potential cases of ethics dumping in times of crisis, highlighting that the rights and safety of vulnerable populations should not be overlooked for "the greater good" (Lopez 2021; Schveitzer and Thome 2021), or the risks and benefits of COVID-19 research unfairly allocated (Flores 2020; Manchola-Castillo 2022).

The issue of open data-sharing also brought inequalities and prejudice to light. The WHO advises that all parties who are involved in public health surveillance should share data in a timely fashion (WHO 2017, Guideline 15). Nevertheless, although there were calls for data-sharing in the spirit of promoting open science during the pandemic (Kadakia et al. 2021), Southern African countries were unjustly ostracised and subjected to travel bans by high-income countries when their scientists shared the genomic sequencing data of the omicron variant of COVID-19 (B.1.1.529) with the global community (Mallapaty 2021; Moodley et al. 2022).

2.7 Comparison with Ebola and Avian Flu

We do not know whether there will be another pandemic. If there is, we cannot be certain that the research ethics and research integrity challenges will be the same as those that arose during the COVID-19 pandemic. Consequently, the PREPARED team also searched for research ethics and research integrity challenges that were reported during the Ebola and avian flu epidemics.

The key differences between the COVID-19, Ebola and avian flu outbreaks lay in the nature of the infectious agents, the scale of the outbreaks and their geographical distribution. While COVID-19 had a global impact, affecting nearly every country, Ebola and avian flu remained more geographically contained. As a result, there were significantly fewer articles identified as relevant to the scoping reviews on Ebola and avian flu (ten and nine respectively). Nevertheless, common themes emerged for the three diseases,

including the difficulties of balancing rapid research deployment and rigorous ethical standards, the challenges of conducting equitable research in resource-limited settings and multiple issues related to misinformation and rushed publication.

One area of difference, due to the nature of the virus, was that biosafety concerns were particularly prominent for avian flu. Ethical debates arose around gain-of-function research, which involves enhancing or introducing new functions through genetic manipulation (Swazo 2013). In the context of infectious disease research, gain-of-function may alter the pathogenicity, infectivity, transmissibility or host range of the pathogen. This raises concerns about dual use, as research aimed at understanding and mitigating threats could also be misused to develop bioweapons (Shinomiya et al. 2022).

Additionally, Ebola outbreaks underscored the importance of community trust, engagement and culturally sensitive research practices. Mistrust of foreign medical interventions led to resistance in some affected regions, reinforcing the need for ethical frameworks that respect local customs and actively involve community stakeholders in decision-making processes (Wilhelmy et al. 2022).

3 Challenges Experienced by Groups Who Faced Extraordinary Burdens During the COVID-19 Pandemic

Given the widespread and complex impacts of the COVID-19 pandemic, the PREPARED team recognised the importance of embedding research ethics procedures within a broader social framework. Drawing on Horton's (2020) concept of the COVID-19 pandemic as a *syndemic*, the team acknowledged that addressing underlying social and economic inequalities was essential for ensuring that nations were ethically prepared for future pandemics. Relying solely on biomedical questions, such as the search for treatments and vaccines, would not resolve broader health crises fully. Viewing the COVID-19 pandemic as a syndemic highlights its deep social roots and the interconnectedness of the virus with other socioeconomic factors that disproportionately affect disadvantaged individuals and groups (Horton 2020).

At the heart of this approach is a dedication to social justice, achieved by elevating the voices and experiences of key populations who faced disproportionate hardships during the COVID-19 pandemic.

Accordingly, the PREPARED team learnt from the experiences of

1. people on the poverty line who faced severe additional threats to their livelihoods
2. people with disabilities
3. groups that suffered disproportionate burdens due to their gender
4. frontline personnel in the health and social care sector.

By integrating these diverse perspectives, the PREPARED team aimed to ensure that future research endeavours would be both ethically sound and socially responsive, addressing the complex realities of those most affected by global crises. In the following paragraphs, we provide a short summary of the key challenges experienced by the groups we investigated.

3.1 People on the Poverty Line Who Faced Severe Additional Threats to Their Livelihoods

Thanks to their long-standing community engagement programmes, Partners for Health and Development in Africa (PHDA) were well positioned to organise a bottom-up consultation with sex workers and healthcare providers in Nairobi to inform the PREPARED Code. The challenges encountered between March and December 2020, during the COVID-19 pandemic, by those enrolled for HIV prevention and treatment services at ten clinics run by PHDA in the Nairobi area (Kimani and Adhiambo Odhiambo 2023) were discussed.

This consultation enabled the PREPARED team to learn from a highly marginalised group that was severely affected by COVID-19. The COVID-19 pandemic had a devastating impact on sex workers, exacerbating stigmatisation and discrimination and exposing them to increased violence from clients, police and society. Abrupt restrictions like curfews and lockdowns threatened their livelihoods, forcing many into risky behaviours such as unprotected sex, due to financial constraints and the closure of clinics providing essential supplies. These hardships were combined with stigmatising COVID-19 testing and treatment practices, as well as restrictions on funerals and weddings, which deprived communities of traditional grieving processes and sometimes led to post-traumatic stress disorder.

Having to work at home exposed sex workers to discrimination from neighbours and heightened stigma, while the shift to social media to find new clients increased the risks of violence: sex workers reported that the risk of rape or that of unprotected forced sex was higher with clients met through social media than those encountered face to face or via existing contacts. These tribulations, coupled with isolation from social support networks, posed a severe threat to mental health. Additionally, a lack of understanding about COVID-19 safety measures deepened mistrust and fear. Combined, these factors increased stigma and poverty and led to higher risks of HIV infection (Schroeder et al. 2024). The overlapping challenges aggravated the systemic vulnerabilities and social marginalisation sex workers faced during the pandemic (Kimani and Adhiambo Odhiambo 2023).

3.2 People Living with Disabilities

During global crises like the recent COVID-19 pandemic, people with disabilities are in an especially vulnerable situation (Shakespeare et al. 2021). The pandemic served to exacerbate their potential marginalisation through service disruptions, public health measures and their greater risks of adverse outcomes from the virus (Partington and Chatfield 2023b).

Consultations with disabled people and their carers were conducted in collaboration with Comensus, a service-user and carer community group that enables people with disabilities and their carers to participate in research and training. Thirteen participants contributed through informal conversations, either individually or in groups, or by submitting reflective thoughts in writing or via audio recordings. Participants reported that the measures taken to mitigate the pandemic led to increased marginalisation, social injustices and failure to uphold the rights of people with disabilities and their carers. The

main challenges reported by these groups related to disrupted and deteriorating services, the fact that life got and stayed smaller because of lockdowns and restrictive measures, and the difficulties of grappling with new rules and new information (Partington and Chatfield 2023b).

3.3 Disproportionate Burdens Due to Gender

The experiences of women researchers were explored through a scoping review of qualitative literature on their experiences during the pandemic (Inguaggiato et al. 2024), as well as qualitative data collection and analysis conducted in Cyprus through conversations with women researchers from various fields (Antoniou et al. 2024). These studies revealed common experiences among women researchers worldwide. Researchers reported an increase in care responsibilities both at home and at work, a decrease in academic productivity impacting career growth, a lack of support from institutions and family members, and difficulty in reconciling and managing conflicts between private and professional identities and roles. Additionally, women researchers faced forced flexibility, challenges adapting to new research methodologies, and difficulties with online teaching mandated by lockdowns. Overall, the pandemic exacerbated existing gender inequalities in the research professions and reinforced gendered power dynamics in academia.

3.4 Frontline Personnel in the Health and Social Care Sector in the UK and South Africa

Understanding the challenges healthcare workers face is crucial in contextualising research conducted during pandemics. Since healthcare workers are directly or indirectly affected by pandemic-related clinical studies, their perspectives must be included in the creation of ethics guidelines for conducting research during pandemics (Partington and Chatfield 2023a).

The PREPARED team studied the experiences of frontline personnel in the UK (Partington and Chatfield 2023a), and social and healthcare workers in South Africa (Mlotshwa et al. 2023). These two countries recorded some of the highest numbers of COVID-19 cases and deaths in Europe and Africa, respectively (Mbunge 2020; Konstantinoudis et al. 2022).

To gather the experiences of social and healthcare workers in South Africa, the team undertook a scoping review of relevant literature. For the frontline personnel in the UK, a meta-ethnographic analysis of published qualitative studies was conducted. Common findings from the two approaches revealed that professionals working in the health and social care sectors experienced difficulties in adapting to sudden changes, expressed a need for support and leadership, and reported physical and emotional burdens as well as safety concerns (Mlotshwa et al. 2023; Partington and Chatfield 2023a).

4 Analysis of Human Rights Challenges in the Context of Sudden Global Crises

To explore the underpinning legal issues relating to crises and emergencies, the PREPARED team carried out a legal and human rights analysis. This included a thorough scoping of the main legal sources, human rights instruments and reports from committees and special rapporteurs. This information was coded via a thematic framework informed by key legal and human rights issues in times of crisis. Following the creation of this framework, an extensive literature review was conducted for the emergent themes, with each theme subjected to a dedicated literature search.

This analysis also aimed to highlight the wider challenges of the global COVID-19 pandemic, assuming that understanding of the vulnerabilities endured by marginalised communities during crises and emergencies leads to enhanced ethical research practice (Drummond 2023). Findings were themed into three main sections:

1. legal, structural and overarching issues
2. human rights obligations
3. marginalised communities.

4.1 Legal, Structural and Overarching Issues

The analysis centred on the rule of law during crises and emergencies, the development of administrative laws during these times, and the use of emergency laws and powers. A key finding was that government responses to COVID-19 provoked a range of national legal responses aimed at galvanising the mitigation of negative impacts. However, these legal mechanisms had far-reaching effects on fundamental rights and freedoms as the legal landscape shifted precipitately to block the transmission of the virus. The rapid implementation of legislative and regulatory solutions raised several concerns, particularly in relation to the erosion of elementary foundations of the rule of law. These included, but were not limited to, ad hoc lawmaking decisions, the imperfect drafting quality of legislation, the lack of consultation processes or scrutiny, and the accelerated promulgation of laws.

Admittedly, crises and emergencies pose significant challenges to governing structures, but this does not lessen the responsibility of those structures to ensure that the main tenets of the rule of law are adhered to (Cormacain 2020). The COVID-19 pandemic generated a significant volume of primary and secondary legislation over a very short period, but, crucially, the rule of law still requires proper accountability and lawmaking procedures to be followed, even in times of emergency and crisis (Cormacain 2020).

To prepare for any future crisis or emergency, it is essential that governments learn lessons from the legal and regulatory responses to COVID-19, acknowledge the weaknesses of those responses, and develop frameworks for future solutions. Any plans for legal preparedness must ensure that the rule of law forms the elemental basis of all future action and aids the protection of fundamental rights and freedoms.

4.2 Human Rights Obligations

The exploration of human rights obligations identified key strands in relation to the COVID-19 pandemic. These included issues such as the right to health and healthcare, and the protection of healthcare professionals and frontline workers. In addition, the analysis explored vaccine development from a human rights perspective, including equitable global access and the overarching right to science. Taking into account the rise of disinformation and misinformation, the analysis included the right to accurate information and the right to the protection of privacy. Also addressed were human rights in the context of global food security and access to housing, water, sanitation and hygiene, and the protection of the environment during times of crisis and emergencies.

Being prepared for future crises and emergencies means that effective international cooperation and solidarity must be ensured to safeguard the protection of human rights. To enable this, structural inequalities in relation to preparedness have to be corrected. The analysis acknowledged that infrastructural underinvestment in valuable support services was one of the key areas for examination and mitigation. In essence, to prepare for any future healthcare crisis, global inequities need to be addressed head-on. Investment in healthcare systems is urgently required. Additionally, further strengthening of labour laws is needed to protect frontline workers. Vaccine inequity must be eradicated. There is a necessity and an obligation upon states to ensure access to accurate information and to protect personal data during crisis and emergency.

In addition, the analysis noted that while it was vital to adopt a human rights approach to emergency and crisis responses, it was even more imperative to eradicate marginalisation in normal times. Human rights violations such as homelessness, disability, inequality, lack of access to essential healthcare, lack of access to water and sanitation, and gender-based violence must be eradicated. The analysis concluded that these were the challenges faced today that needed to be tackled to be better prepared for tomorrow.

4.3 Marginalised Communities

The human rights analysis noted that crises and emergencies could compound existing inequalities and worsen human rights violations, or create new ones, for many communities. During the development of the thematic framework, several distinct communities that were detrimentally impacted by the COVID-19 pandemic were identified. These included:

- poorer communities
- children and young people
- women and girls
- LGBTQ+
- minorities
- indigenous people
- migrants, displaced people and refugees
- older people
- people in detention or in institutions
- persons with disabilities

While the needs of specific groups were considered, it was also acknowledged that individuals might well belong to more than one of these groupings, thus layering inequalities into entrenched and intractable patterns. Although they were separated into distinct themes for the purposes of the analysis, members of each identified community are not homogeneous. These communities do not exist in silos of inequality. Overlapping and intersectional inequalities therefore must be taken into account when considering individual needs, human rights and legal obligations.

Ultimately, "[i]n order to prepare for the next crisis or emergency, it is essential that no one is left behind. There is a need for a global commitment to responding or preparing for crises and emergencies in a way that is sensitive to the most marginalised communities" (Drummond 2023). Strategically, it is essential that the communities identified above be included at the planning stages of crisis preparedness and that their experiences of crisis and crisis management be taken into account. As the meaningful participation of all citizens is an assured human right, this approach is essential to provide an empowering environment where marginalised communities can retell their experiences and help shape future planning.

5 Overcoming Governance Challenges in the Pharmaceutical Industry

In addition to looking at the experience of marginalised populations and the human rights situation during the COVID-19 pandemic, the PREPARED team also examined the successful story of BioNTech, which "won … the race for a COVID-19 vaccine … without purposefully infecting healthy participants with an infectious agent that can cause severe illness or death and for which no rescue therapy had existed" (Leisinger and Schroeder 2024: 847). The biotechnology company developed a life-saving vaccine with over 90% efficiency in less than one year and in accordance with existing principles of good clinical practice.

There are three key lessons to be drawn from the case.

First, the fact that the Paul Ehrlich Institute and BioNTech had been engaged in a professional dialogue for many years created an atmosphere of mutual trust. On this basis, and given the urgency of the situation, a presentation slot for a planned vaccine study was provided within a week rather than within three months (Leisinger and Schroeder 2024: 849).

Second, while all existing good clinical practice regulations were adhered to, increased efficiency was achieved by combining and overlapping different development phases and by regulators implementing a rolling review of clinical trial data.

Third, the development process was also accelerated by risking the security of company assets (BioNTech vaccine candidates) and partnering with the much larger pharmaceutical giant Pfizer, with only a letter of intent in place. This was most unusual, because a letter of intent does not protect assets that have been shared. The drafting process for a full collaboration agreement normally takes at least six months (Miller, Türeci, Şahin 2022).

> During this time, no proprietary technology (like BioNTech's vaccine candidates) would normally be shared. One day after the letter of intent was signed, Uğur

> Şahin, the co-founder of BioNTech, instructed his disbelieving team to "share everything". (Leisinger and Schroeder 2024: 853).

This case study showed that the speed of vaccine development can be accelerated significantly while research ethics and research integrity values are preserved.

6 Analysis of Pandemic Guidance Documents

Chapter 3 notes that the PREPARED team combined a risk-based approach to ethics code development with extensive consultations. At the same time, the team undertook a detailed gap analysis of existing ethics codes to check that no relevant ethics issues had been overlooked. In line with the reasonable assumption that code- and drafter-based guidance might not always link to real world challenges but may sometimes be based on conjecture (see Chap. 3), challenges that came from the gap analysis were then to be verified through a new search of the literature and consultation with experts. So, what did we find?

To identify relevant ethics codes for the analysis, the primary search for the PREPARED team was undertaken by the senior librarian, Kelly Laas, at the Illinois Institute of Technology in Chicago. This library hosts the largest collection of ethics codes in the world. The search, undertaken in 2023, was limited to documents in the English language and focused on ethics and integrity guidance relevant to global crises and pandemics. It generated 103 ethics documents on global crises and pandemics, with 36 documents having been issued prior to 2020 and almost twice as many (67) since 2020.

The ethics documents identified by the Chicago search were reviewed manually by the PREPARED team to identify further relevant documents based on their references. Additional searches were also undertaken in the following databases: Council of Europe Bioethics COVID-19, WHO publications, the OECD iLibrary, national competent authorities and Council of Europe national ethics committees. This process identified another 133 ethics documents.

Documents from the Chicago search and the additional search (236 codes, recommendations and guidelines) were reviewed manually and selected for further analysis if they met the following inclusion criteria: the document was adopted during the COVID-19 pandemic, at least part of the document was relevant to the conduct of research during the COVID-19 pandemic, it was written in English, and it was issued by an international or national institution, organisation or association. The search was not limited to a specific country or region. Ninety-seven documents met these inclusion criteria. Most had been adopted by national government agencies (42), followed by international organisations (28), ethics bodies (11), professional associations (7), nongovernmental organisations (3), scientific councils (3) and universities (3).

Content analysis was used to examine the content and contextual meaning of selected documents (Hsieh and Shannon 2005). Documents were analysed using MAXQDA Analytics Pro software (2022 version) for coding into the main predefined categories: ethics and integrity issues (challenges), virtues, principles and articles.

The challenges were extracted from the database and compared with the challenges derived from the primary research undertaken by the PREPARED team, that is, the

reviews in nine languages. How the challenges were formulated in existing ethics guidance helped refine the PREPARED Code (e.g. see Chap. 5 on the addition of "quality-controlled" to the data-sharing article). However, none of the challenges extracted had not already been identified by the risk-based analysis.

7 Conclusion

This chapter provides an illustrative overview of the findings that constitute the research foundation for the PREPARED Code. Reviews of the published literature from the COVID-19 pandemic, additional scoping reviews on the Ebola and avian flu epidemics, empirical and literature-based studies revealing general challenges for groups in vulnerable situations, and findings from the human rights analysis, taken together, all ensure that the PREPARED Code is built on real-world risks. The analysis of pandemic and crisis guidance documents helped us confirm that the risk-based approach had not overlooked any major challenges.

The argument of Sutrop and colleagues that "the process of drafting codes of ethics should be as inclusive as possible" (2020: 81) can be applied to the development of the PREPARED Code. Not only was the research basis broad, including the perspectives of those in vulnerable situations, but findings were also subsequently validated through workshops and consultation with diverse stakeholders such as policymakers and advisers, experts from the pharmaceutical industry, research ethics and research integrity colleagues, and patient groups and their representatives (see Chap. 5).

By letting the views and experiences of marginalised groups take centre stage, we have endeavoured to ensure that the PREPARED Code will support those who need it the most. In times of crisis, no one should be left behind. Therefore, preparedness should be planned in a way that is sensitive to the most marginalised communities. This includes the empowerment of these communities to relay their experiences, their thoughts and concerns, and their opinions on the best courses of action for their needs.

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