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# Ethical challenges in the COVID-19 research context: a toolkit for supporting analysis and resolution

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**ABSTRACT**

COVID-19 is compromising all aspects of society, with devastating impacts on health, political, social, economic and educational spheres. A premium is being placed on scientific research as the source of possible solutions, with a situational imperative to carry out investigations at an accelerated rate. There is a major challenge not to neglect ethical standards, in a context where doing so may mean the difference between life and death. In this paper we offer a rubric for considering the ethical challenges in COVID-19 related research, in the form of an ethics toolkit for global research developed at the University of Edinburgh in collaboration with more than 200 global researchers from around the world. This toolkit provides a framework to support confrontation of ethical conflicts through the integrated and iterative analysis of Place, People, Principles and Precedents, throughout the research journey. Two case analyses are offered to exemplify the utility of the toolkit as a flexible and dynamic tool to promote ethical research in the context of COVID-19.

**KEYWORDS**

COVID-19; research; ethics; integrity

## Introduction

COVID-19 was identified late December 2019 following an aggressive outbreak in China (Li et al., 2020). On March 11th World Health Organization [WHO] declared the outbreak a pandemic and by the end of June 2020 the virus had reached six continents, approaching 10,000,000 infections and 500,000 deaths (WHO, 2020a). At a global level, international organizations and governments have promoted measures to decrease the speed of spread, prevent contagion and decrease mortality (United Nations, 2020) through promotion of hygiene habits, the use of masks, to more extreme measures such as the closure of shops and borders, and isolation or quarantine of entire populations (Brooks et al., 2020; WHO, 2020b). Still, in some countries the rate of infection and the number of deaths has continued apace, leading to increased global efforts to investigate the virus, and generate prevention and treatment strategies (Kupferschmidt & Cohen, 2020).

These measures have brought a series of ethical conflicts at different levels. Measures implemented by governments have involved choosing between health outcomes, social outcomes and economic outcomes (McKee & Stuckler, 2020). Frontline health practitioners have faced demands that exceed the amount of resource available in most countries and which have required decisions such as which patients to allow into hospitals and which to prioritize for the use of mechanical ventilators (British Medical Association, 2020a). At each level, organizations have operated from preexisting professional ethical guidelines or emergency guidelines developed during previous natural disasters or emergencies

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(British Medical Association, 2020b; Chiumento et al., 2017; DePergola, 2020; UK Government, 2013/2017).

In this document, we will focus on ethical challenges for research. Due to the global crisis that COVID-19 has generated, national and international research agencies have launched urgent calls to action (Frontiers, 2020; WHO, 2020c). Although there is an undeniable need for research that can quickly provide useful information to deal with the current phenomenon, this global humanitarian imperative brings with it an increased responsibility (Mormina et al., 2020). A diverse range of ethical conflicts are arising in the context of COVID-19 and require close and iterative attention as they emerge, indeed as they evolve, through the lifecycle of this pandemic and throughout the research journey (WHO, 2020d). Though speed is essential, ethical rigor should not be relaxed since, in a context such as COVID-19, unethical or negligent action could have serious consequences for research participants and for society more broadly, now and in the future (Mormina et al., 2020; WHO, 2020d).

While the ethical conflicts faced by researchers are not necessarily unique to COVID-19 this global and rapidly evolving context is bringing complex challenges into sharper focus and to a broader audience. Challenges that have largely been the remit of researchers in LMIC's facing health epidemics, are now in the daily scope of researchers around the world. Specifically, the context is one of humanitarian crisis driving an urgent need for scientific evidence to underpin life-saving intervention for individuals and communities. In such a consequential context, haste can mean that ethical challenges may be overlooked or neglected, potentially producing a second wave of effects on physical health, emotional health and community health. Poorly conducted research can decrease confidence in the recommendations of scientists and authorities, act as a disincentive to collaborate or participate in research, contribute to general disinformation and potentially contribute to stigmatization of vulnerable groups (DePergola, 2020). This article provides an architecture to support researchers to prioritize integrity and ethics during COVID-19, despite the time pressure and urgent need for solutions. This paper highlights that we have tools and relevant experience from the global research community to bring to bear on this unprecedented worldwide research challenge.

In this pandemic context, ethical challenges are particularly pertinent for the medical sciences as is evident in the challenge of generating vaccines and recruiting participants to clinical trials (Angus, 2020). In addition to the pressure of the health emergency itself, researchers face the pressure of responding to the political demands of funding agencies and governments (Dean et al., 2020; Gellert, 2020). However, ethical challenges are not limited to the medical sciences. Engineering sciences also face important ethical dilemmas, for example, in the development of new technology such as mechanical ventilators and the question of whether to support development for humanitarian use or potential commercial use. Similarly, the development of mobile apps and new technologies to aid the tracking of people during the pandemic raises significant privacy concerns that would be prohibitive under normal circumstances. Social sciences also have a critical role in the current situation in developing an understanding of social corollaries of the pandemic and factors that may influence uptake and adherence with preventative measures such as physical distancing. Social science research can shape, for better or worse, the population's understanding of the problem, adherence to preventive measures and the adequate treatment of the emotional consequences of the pandemic and the social measures taken to confront it (e.g., confinement) (Dalton et al., 2020; Meagher et al., 2020). Shaping and influencing behaviour on a mass scale raises questions about cultural validity, individual human rights and secondary effects of social manipulation.

In this paper, we propose that a global research toolkit (Reid et al., 2019) – developed in the context of a project at the University of Edinburgh, in collaboration with more than 200 global researchers from more than 30 countries and 60 different disciplines – can be useful to assist researchers in analyzing and responding to the dynamic ethical challenges they face throughout this pandemic (see https://www.ethical-global-research.ed.ac.uk). This toolkit, rather than offering ethical regulation, offers a flexible frame of reference which promotes contextual ethical reflection and accountability within research teams as part of "business as usual".

The global research toolkit proposes two fundamental axes of reflective analysis: iterative ethical analysis throughout the research journey, and ethical analysis based on the 4Ps model (See Figure 1).

## Ethics Throughout The Research Journey

The commitment to ethical consideration throughout the research journey arises in opposition to the idea that research ethics is only associated with the process of applying for project approval from an ethics committee. Ethical accountability starts before the project begins by considering the research culture of our institutions and their ability to support ethical practice in complex inter-cultural projects including evaluating the ethics of the germinal ideas of the study; it continues through project development and data collection with priority being given to accountability to our participants and partners; to analysis, interpretation and dissemination in a way that ensures both cultural and contextual sensitivity, as well as accuracy; and extends beyond the life of the project to the legacy that our research leaves – both intended and unintended.

In the context of COVID-19, the rapid execution of research has been prioritized encouraging the normal steps of an investigation to be carried out at a faster rate than usual, running the risk of overlooking this critical reflective process and also of not recognizing some of the unfamiliar challenges confronting us (Kupferschmidt & Cohen, 2020). Our desire in this paper is not to offer an exhaustive list of all the possible ethical challenges since these will depend on the context of each investigation. Instead, we offer a framework to support a prospective and retrospective analysis. In addition, we offer some indicative examples of ethical conflicts in the different stages of the COVID-19 research journey. As seen in Figure 1, our toolkit scaffolds careful consideration of at least 13 different stages of the research journey, connected through an iterative process of ethical reflection. For brevity, in this paper, we have grouped the 13 stages of the research journey into the foundational, analytic and translation phases.

### *Foundational phase: from research culture to ethics application*

The ultimate success of a research project depends upon laying down solid foundations on which to build the work. In the COVID-19 context the development of a research idea, the formation of a work team, development of collaborative partnerships, the elaboration of the proposal and even the process of ethical application, is, by necessity, hastier and may compromise the strength of this foundation.

Past months have seen scientific communities coming together to establish local and international research teams. This will bring with it tensions, particularly as the research space has previously been one of competition in a system whose traditions rewards competition and encourages institutions and individuals to take advantage of opportunities for financial gain and career progression. Angus (2020) argues that funding agencies, authorities and universities must actively create an integrated environment with incentives for collaborative work, which allows the pandemic to be faced more efficiently, for example, "pharmaceutical companies need support and incentives from regulatory authorities to participate in collaborative trials; and academic investigators need a structure that provides academic credit and incentive to collaborate in efforts where they might otherwise perceive anonymity and loss of control" (p. 1986). While these structural factors are important, it is equally important that each research team begins their partnership by thinking together about, and taking ownership of the ethical challenges of bringing a diverse team together, and also the ethical challenges inherent in researching in, and about, a humanitarian crisis. To successfully face such ethical challenges a team may need clinical, methodological, analytical, cultural and relational expertise.

Preparing applications for grants and ethics committees also becomes a major ethical challenge, both for applicants – who must plan investigations in a short time and without much underpinning evidence-base relevant to health emergencies of this magnitude – as well as for review committees and ethical committees – who have a responsibility to accept or reject projects potentially beneficial to humanity. To preempt common ethical challenges, committees are looking for evidence of co-creation of design and of

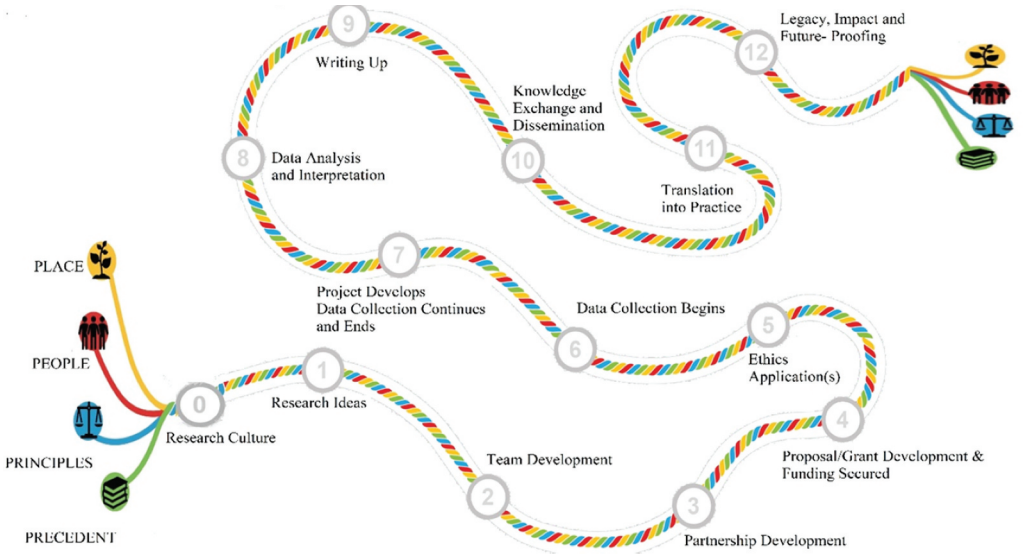


**Figure 1.** Fundamental axes of the toolkit.

clear requests for engagement by all partners but speed may mean that these essentials are recorded as complete when in fact they are still in progress. Meagher et al. (2020) highlight the ethical conflict of planning clinical trials without having enough evidence to hypothesize that the different intervention conditions can be beneficial (or even harmful) for the participants. Conversely, *not* progressing such trials in a timely way will, inevitably, mean that there are more deaths. Although this conflict exists beyond the COVID-19 pandemic, in this context it can lead researchers and ethics committees to make more hasty decisions given the urgent need to have measures to cope with the rapid spread of the virus.

### *Analytic phase: fieldwork and analysis of results*

This stage includes the data collection process, the project delivery, but also the process of analysis and writing of reports. There are multiple ethical challenges inherent in the recruitment process with the population and also the researchers at risk of becoming ill, experiencing serious side effects or directly at risk of dying (Van Griensven et al., 2016). As such, it is essential that researchers ask, for example, how do we create a safe working environment for our research team and also for our participants? Further, how do we promote an informed consent process in a population highly expectant of the potential benefits of research (and fearful of no intervention) and how do we manage the expectations of the participants and the community. There is evidence that people with serious illnesses have unrealistic expectations about the potential positive effects of participating in a clinical trial, which forces researchers to be careful, not take advantage of that excess motivation and need, and generate processes of informed consent allowing participants to make a free and truly informed decision (Weinfurt et al., 2008). This can become particularly difficult in more vulnerable communities where there is a large difference in power between community members and their leaders, between community members and researchers, or when there are language barriers or low literacy that hinders the process (Landram, 2018; Molyneux et al., 2005; Nyambedha, 2008). We can see an example of this in refugee communities, whose conditions place residents at heightened risk of infection, and also creates increased vulnerability when it comes to informed consent to participate in trials. Desperation, panic, preexisting trauma, mental health vulnerabilities and poor communication in a refugee camp setting may make it difficult for residents to feel that they have a choice in participating in the research,

or indeed, to ascertain the difference between health services offering healthcare and researchers trialing new treatment options (Hugman et al., 2011).

In the middle stage of the research, the issue that has received the most attention during COVID-19 is the need to carry out clinical trials with sufficient rigor in the randomization of the groups and in data collection. In addition to the usual ethical conflicts over the use of placebos and work with control groups, physical distancing measures may affect the recruitment of the sample in turn impacting data validity and reliability of the collection process; and time constraints may prevent follow-up measurement to validate the results (Angus, 2020; McDermott & Newman, 2020). This is especially salient when questionnaires or interviews are conducted by telephone or internet, which requires researchers to consider whether those without internet connection are being excluded from research and how this sampling bias may affect the internal and external validity of the results (Ross et al., 2005), especially in the countries with unequal access to internet (Langer et al., 2017).

These issues should be carefully, preemptively, considered and also reported in the analysis of result and in the writing process, with particular reference to the internal and external validity of results, the bias and the limitations of new evidence obtained under non-ideal methodological conditions. As the GRADE research quality framework reminds us, the best available evidence should not be elevated to the status of best practice unless the quality of the research supports such a claim – this is a particularly important ethical edict when there are implications for clinical practice (Atkins et al., 2004). When the evidence is preliminary or poor, then other factors should also be considered in guiding treatment recommendations. Such preexisting guidelines provide an important form of precedent in determining ethical action in uncharted waters.

### *Translation phase: from the dissemination of results to the analysis of the legacy*

Ethical conflicts can be present even after research reports have been completed and findings published. This is an issue often neglected by research teams and highlights the importance of encouraging a reflective process that continues throughout the stages of dissemination, exchange of information and application to practice.

In addition to potentially finding a cure for COVID-19, involvement in COVID-19 research runs the risk of stigmatization of countries, social groups or infected individuals. The way in which researchers conceptualize and disseminate their results will likely influence whether they contribute to information and education or favour discrimination against certain groups – it is noteworthy that issues of racism and nationalism have become increasingly prominent in different parts of the world affected by the pandemic (Devakumar et al., 2020). Scientists in all areas have an ethical duty to transmit information in a clear, accessible, quick and reliable way, sharing negative results as well as positive outcomes. This challenge has been evident across different media during the pandemic, with calls on the scientific community to speak up but also to speak responsibly with the understanding that such reports can support positive responses but can also generate panic reactions and reinforce myths and stereotypes. Many scientists are not practiced at translating their research into lay-language that can be understood clearly by the broader community. However, it is our ethical responsibility to do so.

In the academic fraternity, rapid data sharing is being encouraged as the basis for effective public health action (Dye et al., 2016; Meagher et al., 2020; Moorthy et al., 2020). Journals and editorial committees are streamlining publication processes in order to help disseminate results relevant to humanity (Whitty et al., 2015). Open access publication has also become key in sharing findings quickly with the research community while submitting them to the scrutiny of peer review (Moorthy et al., 2020). This unprecedented circumstance is resulting in pressure to rapidly change our traditional ways of working, bringing with it, a myriad of new ethical challenges to do with privacy, quality and impact.

The impact and legacy of COVID-19 research is also bound up with ethical dilemmas related to application. For example, if a vaccine is found soon, will it be used with a priority on humanitarian or commercial impacts? Who will make these decisions – will it be researchers, governments or

pharmaceutical companies who have funded the research? It is a fact that affluent nations have more resources to carry out relevant research. Failure to share findings and treatments would mean potentially increasing the already evident disparities in global health that would leave some sectors at a much greater disadvantage in the current, and future, health crises (Meagher et al., 2020). Conversely, quicker dissemination means results will be still preliminary and should therefore be shared responsibly – a delicate balance to strike (Gellert, 2020).

In sum, there are a myriad of ethical issues facing COVID-19 researchers. It is our view that a framework to support reflective analysis of ethical issues at each stage of the research journey facilitates higher levels of awareness, prospective planning and accountability within research teams. Discussion of these issues amongst team members and with research partners also consolidates the strength of the working relationship during complex, dynamic and rapidly unfolding circumstances.

## The 4Ps Model

The Global Research toolkit proposes that analysis of ethical issues throughout the research journey can be greatly facilitated by considering complementary aspects of the research endeavor, specifically, Place, People, Principles and Precedents. This 4Ps model proposes that ethical challenges often involve each of these 4 interrelated elements, and that consideration of these elements can also point us to contextually-relevant solutions.

### *Place*

"Place" refers to the context in which the research is being carried out and/or in which the findings will be applied. This includes considering cultural, political, economic, and social forces. Addressing "Place" is key in demonstrating our respect for universal human rights by making sure that we honour the specific context in which the research is carried out. Designing methodologies that are responsive to context, makes it significantly more likely that the project will be successful and that the results will be valid and meaningful.

There are risks of ignoring key ethical issues of "place" in an emergency or humanitarian context when in fact we should be more, not less, accountable for our actions – this is a challenge perhaps familiar to global health researchers but less so to the many researchers entering this global stage for the first time. During a global pandemic, there are increased ethical challenges associated with working with highly vulnerable populations, either because they are fighting the virus or because of fear and panic associated with trying to avoid the virus may make communities and individuals less able to make clear and reasoned decisions.

COVID-19 research will require a contextualized approach as conducting research in countries where the pandemic is uncontrolled will have different requirements and pose different challenges to conducting research in countries where the most acute phase has already passed (or has not yet started). Similarly, possibilities for COVID-19 research may be different in countries under dictatorial vs. democratic governments.

Globally we need solutions, however solutions may be effective in one context, but not in another. For example, the effect of quarantines or social isolation in regions, or areas of high income is markedly different from regions and areas that have limited income, where many families live in overcrowded houses, and who obtain and spend their money daily on the basis of a survival economy. In these contexts, interdisciplinary research faces the challenge of addressing the medical, social and economic aspects of the pandemic, and also political or governmental actions (Mesa Vieira et al., 2020).

It is also important that the ethical implications of recruitment in these contexts is considered without taking advantage of the vulnerability of participants and whilst respecting their identity, and their own cultural or social regulations. For example, in some more collectivist cultures and communities, the informed consent process also involves consulting the leaders or authorities of the

community as a prior step to requesting individual informed consent (Fitzpatrick et al., 2016; Flicker et al., 2007). Or, in communities where there is low level of literacy, it is necessary to design innovative methods to obtain an informed consent (Alaei et al., 2013). Place-based consideration of these challenges will guide researchers to more effective solutions.

## People

"People" includes all those involved in the research: research team, funding sources, institutions, international partners, participants, potential beneficiaries, etc. The COVID-19 crisis requires international, interdisciplinary and inter-sector collaboration, but that collaboration brings with it differences in research power and expertise that can translate into ethical tensions within the team, reflected in the establishment of dysfunctional leadership patterns, unequal division of labour and authorship conflicts (Obono et al., 2006). These need identification and discussion to prevent and remediate poor teamwork and poor-quality research. The toolkit scaffolds this process.

Ensuring the wellbeing of researchers and research participants in the context of a pandemic is also an evident challenge. In this context of a pandemic that is affecting people's physical, emotional and social well-being, the person-centreed research approach - which places the well-being of participants and researchers above other things - seems to be of critical importance (Tinelli et al., 2018). There is a general acceptance that the vulnerability status of both researchers and participants will be higher during COVID-19 and vigilance is required from research teams to ensure that a preventative and responsive approach is adopted.

Prioritizing the "human face" of research also extends to determining the country where the first vaccine trials will be carried out to ensure that we do not fall into neo-colonialist practices. Traditionally, neocolonialism in research has been defined as the process in which researchers, agencies or institutions from countries with high economic incomes "exploit" people from low-income countries or vulnerable areas in their research (Rakowski, 1993). There is already controversy around whether to start testing COVID-19 vaccines in Africa – the challenge, to balance considerations of greatest need with greatest risk (BBC, 2020). The toolkit supports researchers and ethics committees to be alert and actively responsive to these dilemmas and to encourage discussion between research partners.

"People" also form an important part of the solution in facing ethical challenges. It is important to consider the organizations, people, regulatory entities or colleagues that could help us or advise us on how to best face ethical issues. Ethics committees are called upon to be vigilant to the calls for help from researchers in the field, but this is challenging to achieve in real-time and during a period of such institutional disruption. We must look beyond this. Professional support networks are key – the "Global Academic Village" is an often-untapped resource for researchers to access collegial support in solving ethical dilemmas in the field. Never has this been more important than during this unprecedented global crisis. The toolkit supports research teams to develop a plan for field work that identifies key people with relevant expertise from the community, from the university, from the international network, etc. that can help resolve ethical issues as they arise.

## Principles

"Principles" refers to the values that should guide ethical research. During the process of creation the toolkit the participants highlighted seven principles can be a compass to help researchers to respond to ethical challenges during the research journey: Do no harm (Recognize the gravity and ethical implications of doing harm); Enable flourishing (Enable necessary and urgently needed change); Connect: People and planet first (Invest in relationships – recognize they are the heart of research – listen carefully, be trustworthy, transparent and accountable, and behave honourably); Be aware. Be brave. Be safe (Identify and respond vigilantly to ethical challenges, being alert to safety considerations); Invest in our own learning (Be self-aware and actively strengthen interpersonal skills and

reflective practice); Prioritize context and compassion (Work in a contextually appropriate compassionate way); Maintain Commitment (Be reflective, accountable and persistent, particularly when faced with challenges) (Reid et al., 2019).

Applied to COVID-19 context, Arora and Arora (2020) talk about the balance of risk and benefit in medical decision making, which is also relevant in the research area, for example, thinking in potential candidates to test a vaccine or medicine.

Our values can also help us navigate the conflict between economic interests and humanitarian interests associated with the dissemination of relevant new knowledge. We know that many COVID-19 research projects are financed by pharmaceutical companies – with commercial interests in the research findings – or by governments that may want to privilege their political allies over their rivals when it comes to sharing new medicines. For DePergola (2020), the decision should be done based an important ethical principle – applicable to both the practice of medicine in the context of COVID-19 and research – "limited resources should be allocated so as to maximize the number of lives saved" (p. 4). Although this type of debate goes beyond the research teams, researchers should nevertheless reflect on their positionality and potential conflicts of interest.

We can add the difficulties of establishing procedures with scientific rigour in these contexts of urgency and limited resources. For example, there is often an ethical conflict between the validity of the data and the safety of the participant. To Meagher et al. (2020) the safety and well-being of the participants must always be prioritized, but they emphasize that the application of this principle in the practice of research in the context COVID-19 can be very difficult for some researchers. For example, it may not be possible to carry out the follow-up measurements for a clinical trial due to the health conditions of the participant, because of regulations to avoid social contact, or prohibition of making trips between or to certain cities. In this context, it is valid that the researcher questions what to privilege (having reliable data that can benefit society) or the health of that particular participant. The idea of the toolkit is that researchers reflect on these principles and seek the answers that best suit their work context, always respecting the ethical and regulatory principles of their discipline, as well as local regulations and customs and in rapidly changing humanitarian, epidemic or pandemic contexts, the emerging national advice.

### *Precedent*

"Precedent" refers to the need to analyze past experiences of similar ethical conflicts that can help us understand and resolve current ethical conflicts. It is especially relevant to review the current ethical regulations that will reflect the accumulation of experiences from previous incidents (eg. US Food and Drugs Administration, 2020; UNESCO, 2005). Additionally, although the current global health crisis is different in form and magnitude from previous health crises, researchers can find precedents for conflicts and ethical solutions in previous publications referring to similar situations, such as the case of Ebola research (Gailits & Nouvet, 2018) or the HIV studies (Heimer, 2013), wars (Helbardt et al., 2010) or natural disasters (Hunt et al., 2016). For example, we know – since the Ebola epidemic crisis – that it is necessary to have a fluid strategy of sharing research results to policy makers to be able to use this information in a timely manner for the benefit of the population (Modjarrad et al., 2016). This precedent may support an investigator to take the necessary ethical measures to make their data accessible in the service of the international scientific community in order to expedite the finding of treatments for COVID-19.

Researchers also have the challenge of "generating a precedent" for ethical conduct in research that helps future researchers face similar ethical conflicts (Angus, 2020). In this spirit Dean et al. (2020) have recently published a paper – which already serves as a precedent – to guide clinical trials in the context of COVID-19. Based on what they learned in previous health crises, they provide technical recommendations to achieve the research objectives in times of pandemic. At the same time that they give some relevant advice for ethical conduct, such as the need to establish collaborative and transparent work between the various stakeholders.

The global ethics toolkit supports researchers to consider each of these 4Ps and how they are relevant and inter-related during the different stages of the research journey. The intention is to heighten awareness of ethical issues and to support evaluation of ethical conflicts in real-time, through their iterative consideration and integrated analysis. In the following section, we offer two examples on how to apply this framework in the resolution of a possible ethical conflict. This is purely illustrative as the proposed solution to the ethical conflict will depend on the specific context in which the challenge arises and the rapidly changing circumstances as the project progresses.

## Case Analysis 1

The case to be presented mainly covers the difficulty of establishing collaborative relationships between research teams. It is clear that the complexity of the current health crisis requires collaborative, interdisciplinary, inter-university, inter-sectoral and inter-cultural work. However, sometimes the personal interests of research teams or universities may conflict with the scientific and humanitarian interest of having new relevant knowledge to face the pandemic. See Table 1.

As we have already outlined, this solution only seeks to exemplify the reasoning behind the toolkit, we do not expect this solution to be generalizable to other contexts, beyond the illustrative exercise. For example, the power to authorize international university collaboration could vary between countries and universities (Place). Dr. AV or Dr. CB, for example, may not have the powers to solely approve the collaboration. Where one or both universities prevent the inter-university collaboration, an alternative option for developing the COVID-19 vaccine have to be explored, not doing this raises its own ethical questions. Alternatively, Dr. AV, who understands that the interest of humanity is more important than personal interests (Principle), could seek collaborators outside Dr. CB's university or share his preliminary ideas with the same collegiate international organization that once mediated between the two universities. Dr. AV's principle that prioritizes humanity is a powerful motivation that could allow him to explore the two options. In the latter case, the international organization will be the unifier and mediator that either establishes a new outfit or bring-in a third university that is located outside the two countries to serve as an host for the participating researchers in the vaccine development (People). In both situations, a collaboration contract that defines the relationship between all the parties must be signed to avoid future conflict; this could become an option for bringing experts in rival universities together in future (Precedent). The role of international organizations in consultation for and in the actual vaccine development and its trial is not new (e.g., Chataway et al., 2007; Guenter et al., 2000; Hanlin, 2008). The toolkit simply leads researchers through consideration of these issues and assists them to define what is most likely to work in their circumstances.

## Case Analysis 2

The second case analysis addresses the ethical conflict in clinical trials where new medical procedures are tested, in this case a vaccine for COVID-19. The case is located in a refugee camp where there are low resources and a vulnerable population, with high risk of contagion and with high expectation of receiving help. In this context, power differences between researchers and potential participants can easily lead to exploitation of the community. In the case, we analyze issues such as the balance between risk vs. benefit, informed consent, language barriers and the following of ethical protocols and local regulations. Please see Table 2.

Again, we are mindful that the proposed solution in this example, may not work in all contexts. For instance, it is possible that inhabitants of the refugee camp may not frequently interact with their host community, thus reducing the risk of contacting COVID-19 – a possibility that the toolkit anticipates by prioritizing deep understanding of the research location and context (Place). Disregarding this aspect, as will be discussed below (Precedent), could raise ethical issues. Inhabitants of the camp may thus require – or even prefer – to be tested for COVID-19 before they confirm whether or not to

**Table 1.** Case analysis 1.

| Ethical issue | Part(s) of the research Journey? | Understanding the dilemma | Ethical Reflection | Ethical Response |
|---|---|---|---|---|
| The research of Dr. AV and his team seeks to contribute to the development of a vaccine against Covid-19.<br>Dr. AV knows that the research would benefit greatly if he established collaborative work with Dr. CB's team.<br>Doctors AV and CB come from two major universities competing for leadership in the area. In recent years, their relationship has been deteriorated by conflict of interest (research funds, authorship and commercial rights).<br>Dr. AV is unsure whether to start collaborative work with Dr. CB despite the benefits this would bring for research and, eventually, for humanity | 0. Pre-Stage<br>1. Research Idea<br>2. Team Development<br>3. Partnership Development<br>4. Proposal/Grant Development and Funding<br>5. Ethics Applications(s)<br>6. Data Collection Begins<br>7. Project Develops and Ends<br>8. Data Analysis<br>9. Writing Up<br>10. Knowledge Exchange and Dissemination<br>11. Translation into Practice<br>12. Legacy and Impact | **Place:** Both research teams work at rival universities located in neighboring countries. The culture in both universities enhances competition more than collaboration.<br>**People:** Dr. AV and CB work in the same area, the last 20 years have competed for the same research funds. In the last congress of their specialty they were involved in a heated public altercation<br>**Principles:** Dr. AV's dilemma is whether to privilege his personal interests (and that of his university) or ensure the progress of research in a global health emergency.<br>**Precedents**: What are the national and international regulations in this regard? Has this happened before? How has it been resolved? | **Place:** Both rival universities have worked together in the past. There is a cooperation agreement that offers suggestions for regulating collaboration between them.<br>**People:** It is important to ask: who on Dr AV and Dr CB's teams or universities could help overcome this impasse? Is there someone from other universities or research teams who can help?<br>**Principles:** Dr. AV understands the interest of humanity over personal interests are more important, but at the same time he is aware that conflicts of interest could cause the project to fail, even working together with Dr CB.<br>**Precedents:** There are antecedents of similar situations among other investigation teams that have been mediated by a collegiate international organization. | Dr. AV discussed the issue with his research team. All agreed on the undeniable benefit of working with Dr. CB's team.<br>One of the team members suggested also inviting Dr AS to join the project. Dr AS has worked in collaborations with both teams for the last 5 years, so could offer a technical contribution, but also act as a "bridge" and potential mediator.<br>Later, Dr. AV reviewed the collaboration agreement between the two universities which highlighted that the process for determining authorship and commercial rights of the findings was well regulated.<br>In addition, Dr AV asked for advice to the international scientific society he and Dr CB are members.<br>As such, Dr AV invited Dr CB and Dr AS to join the project. Before commencing, they defined the limits of the relationship, signing a collaboration contract (which specified roles, functions, authorship and possible commercial rights). |

**Table 2.** Case analysis 2.

| Ethical issue | Part(s) of the research Journey? | Understanding the dilemma | Ethical Reflection | Ethical Response |
|---|---|---|---|---|
| You are working in a refugee camp with 2,000 people living a context of poverty, overcrowding, weak health system, and difficulties accessing basic services. Under these conditions, the risk of transmission of Covid-19 is high. A colleague – working on a vaccine – asks you to arrange clinical trials in the refugee camp. You are unsure of the appropriateness of the request, given the level of vulnerability of the population. Your main concern is that the community may not understand the scope of the vaccine test, or the difference between a trial and a proven treatment, and may not be in a position to provide informed consent, and may have expectations that exceed reality. You do not want to exploit the community | 0. Pre-Stage<br>1. Research Idea<br>2. Team Development<br>3. Partnership Development<br>4. Proposal/Grant Development and Funding<br>5. Ethics Applications(s)<br>6. Data Collection Begins<br>7. Project Develops and Ends<br>8. Data Analysis<br>9. Writing Up<br>10. Knowledge Exchange and Dissemination<br>11. Translation into Practice<br>12. Legacy and Impact | **Place**: In the camp, preventive measures (hygiene and social/physical distancing) are not possible due to overcrowding and lack of basic services – likely rates of infection will be high and services low. A successful vaccine could make a very significant humanitarian difference. Previous experience of research is low whereas access to humanitarian aid services is high – these could be confused.<br>**People**: Refugees are anxious for help. Expectations are high, and understanding of the implications of clinical trials is low<br>**Principles**: The importance of Covid-19 clinical trials are known, but given the associated risks, informed consent is of utmost importance.<br>**Precedents**: Previous studies clearly show that vulnerable populations have exaggerated expectations of the benefits of clinical trials (e.g., Weinfurt et al., 2005) | **Place:** In the camp, there is a hierarchical structure with leaders validated/ respected by the community<br>**People**: Within the leaders, there are individuals with basic knowledge of medicine who are willing to explain the scope of trial to the population.<br>**Principles**: You are aware that the community has to understand the risks vs. benefits of trial. Your intention is to explain in a clear and transparent way that is understood by the community.<br>**Precedents**: There are protocols for conducting vaccine trials in vulnerable settings and for gaining culturally sensitive informed consent (e.g., Bonhoeffer et al., 2013). In addition, countries have their own regulations that must be reviewed before proceeding. | The research team meets with community leaders to explain the research, the risks, and potential benefits. The discussion is led by a member of the research team who speaks the local language. Community leaders offer to collaborate in the process of explaining the scope of the research to the community.<br>Workshops are held in the community where the research risks and benefits are explained. This is conducted in the local language, supported by an explanatory video.<br>After receiving clear information some participants decide to freely consent (knowing that they also have a right not to participate) and others choose not to.<br>Those interested in taking part will participate in individual interviews to ensure they understand the risks and can provide informed consent freely. After receiving clear information some participants decide to freely consent (knowing that they also have a right not to participate)<br>In addition, the recruitment process respects local protocols and is in accordance with what is required by the local authorities. |

participate in the clinical trial (People). Access to such information empowers the camp residents to make an informed decision on their participation and give informed consent for the proposed clinical trials (Principle). In such a research setting, a more ethical entry point into the community could be to propose COVID-19 test.

If the results of the COVID-19 test show that no member of the community is infected, then it seems important to encourage the authorities or funders to improve the living conditions in the camp on one hand and on the other support and mobilize the refugees to adopt precautionary practices such as wearing face masks, social distancing, and using alcohol-based sanitizers. In doing this, the research team would have avoided repeating, for instance, a flaw of the Tuskegee experience that did not, among other issues, consider it ethical to transparently inform two-thirds of the research participants (and other stakeholders) that were in advanced stages of syphilis (Obono et al., 2006). Conducting preliminary tests to confirm the need for clinical trial of the COVID-19 vaccine thus meets all the 4Ps in the toolkit: i.e. it takes account of the need to understand the humanitarian context (Place), it provides the refugees with a basis to make informed decision and give informed consent (People), guided by the values of transparency (Principle), and avoiding the mistake of a landmark unethical experiment (Precedent).

In a situation where the clinical trial was propelled by confirmed reports of the spread of COVID-19 in the camp, an alternative approach could be for the research team to not only work with the community leaders but also with local experts – e.g., scientists, doctors and public health institutions. This could be a useful approach where all or a significant part of the funding, team and expertise comes from outside the country hosting the refugees. In addition to building trust with the refugees (People), working with local stakeholders and experts will bring some measure of transparency to the process (Principle). Involving local experts, alongside the community leaders with knowledge of medicine, could provide clearer explanation of the clinical trials, its risks and benefits to the refugees. This is also important for achieving informed consent. Meanwhile, the differing circumstances of each refugee, their gender, age, and even their length of stay in the camp could throw up difficult but important questions that must be ethically addressed. Refugees are generally a vulnerable group that must be specially treated; children, people living with disabilities, and people with existing health conditions all require an even more special treatment and ethical approach. In this case, an alternative approach is to work with local stakeholders to, first, identify the most vulnerable groups in the refugee camp and then explore how they can be ethically recruited into or excluded from the clinical trial.

Given the high risk of COVID-19 in the camp, the research team could also build into their discussions with the community some elements of beneficiality. Beneficiality, however, could also lead to unethical decisions or reinforce power imbalance between the research team and the refugees, especially as not all refugees may choose to participate in the trial voluntarily. Yet, questions of beneficiality could include: do refugees in the camp receive preferential treatment if the clinical trial is found to be effective or receive some other forms of support in the posttest period? In answering these questions and others, incentives should be unconditional regardless of whether refugees decide to participate, change their minds in the middle of participation or complete the trial process. This could range from offering to support the refugee camps with facilities to providing information to local authorities, possible funders, and community leaders on how best to reduce the spread of the virus. But in making these choices it is also crucial to accommodate the voices of the refugees. Refugees (and other research participants in general) must not be silenced in research but should be rather encouraged to co-create the meaning(s) of beneficiality and ethical research. The need for this bottom-up approach resonates with the South African Sans people when they initiated the San Code of Ethics in 2017 for researchers (Precedent). The ethics toolkit discussed *precedent* from a holistic background that generally encompasses learning best ethical practices from relevant literature (and experiences) of other researchers and research participants, including traditional knowledge.

We hope that the two cases serve as useful examples for the utility of the toolkit framework for researchers facing COVID-19.

## Discussion

The current global situation requires the collective efforts of many different agents to face the pandemic. Doctors, nurses, and other front-line practitioners and key workers are exerting immense effort in tackling the effects of the virus (Legido-Quigley et al., 2020). This effort is being complemented by scientists from all disciplines, collaborating to produce new evidence of preventive measures and treatments to deal with COVID-19 and its associated ills, including the impact on mental health of individuals and the longer-term impacts on the social, economic and political structure of societies Inchausti et al., 2020; Kupferschmidt & Cohen, 2020).

Researchers are under pressure to find effective, efficient solutions in the shortest possible time. While we support the community of researchers who have responded to this call with haste and responsibility, we recognize that this must be without neglecting compliance with ethical standards consistent with contemporary science practice and compatible with international ethical regulations (e.g. US Food and Drugs Administration, 2020; UNESCO, 2005). However, we are aware that the characteristics of a pandemic like that of COVID-19 emphasizes.

This pandemic has elucidated the gaps what Heimer (2013) calls the "ethics on the books vs. ethics in action". In this document, we offer a toolkit – developed collaboratively with researchers around the world – that can help researchers actively carrying out research to analyze and search for solutions to everyday ethical conflicts (Reid et al., 2019).

This toolkit does not compete with other relevant regulatory frameworks to do research in COVID-19 context, but it offers a framework that will help researchers from different disciplines reflect on the ethical challenges they face and allow them to integrate these current regulatory frameworks (principles and precedents) with elements of the cultural, economic and health context, of the pandemic by COVID-19 (Place) and thinking in the people involved in the research process or potential beneficiaries of its results (now or in the future) (People).

We believe that this toolkit can establish bridges between the "ethics of books" and the "ethics in action" since both dimensions must be connected to face a challenge like COVID-19. Our outline offers illustrations in the form of case studies to provide the reader with general idea of the application of the model, and as noted some of the cases analyzed could have taken alternative directions in different circumstances. The original source provides more detailed information on the toolkit and its uses (Reid et al., 2019). Some of the ethical challenges described in this paper are not unique to COVID-19, but the current context has new constraints and will require new solutions.

the toolkit encourages a bespoke analysis of ethical conflicts, incorporating the contextualized analysis of the 4 Ps iteratively throughout the research journey. We hope that this tool and the underpinning wisdom of our more than 200 global research colleagues, will prove useful to researchers confronting the challenges of COVID-19.

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