Journal of Pediatric Rehabilitation Medicine: An Interdisciplinary Approach 13 (2020) 229–231
DOI 10.3233/PRM-200025
IOS Press

Editorial

Navigating the ethical Scylla and Charybdis of the COVID vaccine

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Keywords: Ethics, COVID-19, vaccine, coronavirus

1. Introduction

Several years ago I had a series of conversations with the founding editor of this journal, Jacob A. Neufeld, about guest editing an issue of JPRM that would focus on ethics in pediatric rehabilitation medicine. Though I am a pediatric craniofacial surgeon and not a physiatrist, I have studied ethics for the past 25 years and share a passion for patients with congenital differences that require a lifetime of attention. We were making progress in putting together some topics we thought the readership of this journal would enjoy when Dr. Neufeld was prematurely taken from us. Months later Elaine Pico and I tried to pick up where we had left off, but after putting out an initial call for papers and having essentially no responses, it seemed that we would not fulfill Dr. Neufeld's vision of having an issue focusing on ethical issues. Then a global pandemic hit that disrupted every aspect of our lives: how we view ourselves, how we take care of our patients, even how we interact with friends, family, and colleagues. Dr. Pico recognized the incredible ethical impact of all this, and we resuscitated the plan for an issue addressing the myriad ethical issues facing us as we try to provide the best possible care to our patients in the midst of the most trying times of our generation. This issue covers many topics you will find relevant to your practice. One issue not addressed by any of the authors in this edition is that of a COVID-19 vaccine. In my role as chair of the Pediatric Ethics Committee of the University of Michigan and Co-Chief of the Clinical Ethics Service of the Center for Bioethics & Social Sciences in Medicine (CBSSM), I am privileged to have discussed the many complicated issues related to a vaccine with my colleagues over the past several months. What follows has benefitted from conversations with my clinical ethics fellow Lulia Kana, my co-chief of clinical ethics, Andrew G. Shuman, and the chief of our research ethics committee, Kayte Spector-Bagdady.

2. Ethical issues

The promise of a COVID-19 vaccine to end the scourge of the coronavirus pandemic and allow a "return to normal" has captivated the imaginations of not only those of us in healthcare, but the entire world. Russia and China have begun to administer vaccines more widely, while at the time of this writing, US pharmaceutical companies are still in phase 3 human trials. The ethical issues surrounding the development, testing, and distribution of a vaccine are legion. On whom should the vaccine be tested? What counts as "safe and effective" in a "warp speed" rush to end a global pandemic? Who should be prioritized when a vaccine becomes available? What if several vaccines become available, but there is no clear "gold standard" due to abbreviated clinical trials? Should a vaccine be distributed within the country where it was developed before sending it to other countries where it might be more urgently needed to prevent uncontrollable spread? Should the vaccine be mandatory for all and/or for those at higher risk

only? What if the population hit the hardest by the pandemic (i.e. Black, Latinx) stands to benefit most from a mandatory vaccination policy, but also has the highest level of distrust of the medical system due to legitimate concerns of systemic racism? There is no consensus on the "right answer" to these tough questions, even among those who share a similar worldview (e.g. liberal academic elites.)

The National Academy of Sciences, Engineering, and Medicine (NASEM) recently closed public discussion of its 114-page preliminary framework for vaccine allocation [1]. Drawing on the experience of the H1N1 influenza outbreak and the Ebola epidemic, as well as guidance from a number of expert position statements from bioethicists, they recommend a four-phased approach to vaccine prioritization. Phase 1 prioritizes high-risk workers in healthcare facilities and first responders, as well as those with multiple co-morbidities that put them at the highest risk of dying if contracting COVID-19. Elderly individuals living in nursing homes are also in this phase. Phase 2 prioritizes teachers and school workers, people in jail, essential workers who cannot telework, homeless people, older adults, and those with moderate comorbidities. Phase 3 includes children and young adults, as well as barbers and salon workers. Phase 4 is everyone else not already vaccinated. Notably, children are not mentioned until phase 3, although children with significant comorbidities *could* qualify in the first phase. The catch is that currently there is no vaccine being developed for use in children [2]. An experimental vaccine for children has not yet entered phase 2 trials, leading most experts to believe that we could be well over a year away from an FDA approved vaccine for children. Hence many of our patients who might meet the criteria to be included in the first "rollout" of a vaccine, will not be eligible because the vaccine has not been proven to be safe or effective in children.

Another troubling issue is vaccine nationalism – the idea that whichever country develops a vaccine should prioritize the members of their own country before exporting the vaccine. Though this concept is condemned by most scholars as amoral and short-sighted given the reality of the global supply chain and interconnectedness of our "global village" [3], countries such as the United States and China have not joined the multinational platform for sharing in development and distribution of a COVID-19 vaccine, COVAX. The COVAX idea is that once a vaccine is developed, it will be distributed among member countries according to criteria developed to optimize global impact. Ezekiel Emanuel and colleagues published a model for fair vaccine distribution that takes a three-phased approach. The first phase is focused on reducing the number of premature deaths, giving priority to those worst off. The second phase prioritizes countries whose economy has been hit the hardest, measured by decline in gross national income, in order to combat the negative effects of widespread poverty in those countries. The third phase prioritizes countries who still have high transmission rates in order to facilitate a "return to normal" as soon as possible for as many as possible. The ethical values undergirding this approach are beneficence, that is, our obligation to act in a way to benefit others and to limit harms; and justice, that is, treat everyone with equal moral regard in terms of their needs, prioritizing those who are disadvantaged [4].

Those of us who primarily take care of children are all too familiar with anti-vaxxers and those who express "vaccine hesitancy." A conversation I frequently have with colleagues asks the questions: Do we accept unvaccinated children into our practice? Do we allow unvaccinated children in our waiting room alongside our chronically ill patients? Do we coax, cajole, or nudge our patients' parents to vaccinate their children? Most of us tend to accommodate parental objection to vaccination, but once a COVID-19 vaccine is developed, proven safe and effective for children, and is available through a phased rollout, should we mandate vaccinations for our patients? Does the scale of the negative effects of the outbreak change how with think about this? Ethicists from Oxford University make a compelling argument for compulsory vaccination, not just for children but for all citizens [5]. They argue that in a global pandemic, declarations of emergency by government authorities have led to extensive quarantines and constraint of our free movement. If this level of bodily constraint is justifiable in combating the spread of a global pandemic, then a compulsory vaccination is as well, as it is much less invasive and harmful than mandatory quarantine and physically distancing from friends, colleagues, and support systems. They suggest a policy where unvaccinated individuals would be mandated to quarantine at home, which still provides a choice – either accept the vaccine or continue to have your physical movement constrained.

There are no easy answers in ethics. In fact, most of the time, we raise more questions than answers. The goal is to promote discourse among members of our profession. We have a responsibility to reflect on these moral ambiguities and to bring our experience, our values, and our wisdom to bear on these issues. Over the

next year, we will witness and contribute to the discussions that try to answer these questions and develop clear and transparent policies to guide our perilous journey between Scylla and Charybdis.

Conflict of interest

The author reports no conflicts of interest.

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