Catholic Health Alliance of Canada
Alliance catholique canadienne de la santé

The Ethics Network of the Catholic Health Alliance of Canada has developed this framework document, one in a series of ethics resources to support each sponsor organization's response to COVID-19. While it reflects a consensus of opinion of relevant principles and moral approaches to address issues arising during the pandemic, the framework is meant to be adapted to each sponsored organization's unique context and circumstances. For more information, please contact Dr. Hazel Markwell, Theology, Policy and Ethics Advisor at hazel.markwell1@gmail.com

Ethical Issues Concerning Vaccines Derived from the Tissues of Aborted Fetuses - July 2020

***Executive Summary*:** This document addresses ethical issues related to vaccine research that makes use of human cell lines derived from the tissues of aborted fetuses. These issues have been highlighted by efforts around the globe to develop a vaccine for the COVID-19 virus. The CHAC Ethics Network welcomes these efforts, and regards this as an opportunity to clarify the Catholic moral outlook on these issues. The document contains four substantive sections:

- *Section I* lays out some relevant scientific background. Some vaccine research makes use of human cell lines derived from tissues of fetuses that were aborted several decades ago. The fetuses were not aborted for research purposes, and the use of these cell lines is not contingent on access to any additional fetal tissue. The cells currently used for research were never part of the fetus's bodies. Further, neither the research nor vaccine use involve the injection of fetal tissue into a patient.

- *Section II* summarizes some of the main Church teachings on the use of vaccines which have been developed using the relevant cell lines. Church teachings on the ultimate value of human life and the moral impermissibility of abortion are affirmed. And while alternative research methods using ethically derived materials and methods should be promoted, there is no categorical ethical prohibition on the use of vaccines developed using the problematic cell lines.

- *Section III* explores broader ethical issues related to vaccine research. While Catholics must be attentive to ethical issues associated with the use of cell lines derived from the tissues of aborted fetuses, these issues should not consume all of our attention. We must also attend to ethical issues related to the design of vaccine

trials, the participation of human subjects in such trials, and the availability of the vaccines which, it is hoped, will be the products of successful research.

- *Section IV* offers some more general remarks on the commitments of the Catholic moral tradition with respect to research ethics. It affirms in particular the tradition's recognition of the great value of science, and it highlights the Catholic commitment to high quality biomedical research aimed at bringing protection and healing to those in need.

Introduction

The COVID-19 pandemic has caused widespread hardship, illness, and death. Quite appropriately, governments and organizations around the world have responded to this disaster by supporting research aimed at the development of a COVID-19 vaccine. The CHAC Ethics Network welcomes these efforts; the successful development of a safe and effective vaccine would prevent countless deaths and help put an end to the COVID-19 pandemic.

However, some vaccine research makes use of human cell lines derived from the tissues of aborted fetuses. In this document, we explore the ethical issues associated with the use of these cell lines in vaccine research and development. Section I lays out some relevant scientific background. Section 2 summarizes some of the main church teachings on these issues. Section 3 explores broader ethical issues related to vaccine research. Section 4 concludes with some brief remarks on the idea of a distinctively Catholic research ethics.

Section I – Scientific Background

Coronaviruses (CoVs) are single-stranded RNA viruses that can produce diseases in humans and many other hosts (Dhama et al.). CoVs are responsible for past epidemics including severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and the current COVID-19 pandemic caused by the SARS-CoV-2 virus. There are no approved therapies/vaccines for COVID-19; however, many of the current therapeutic strategies have their origins in the response to SARS and MERS. A major reason for the lack of commercially available vaccines or therapeutic agents against CoVs might be the lack of interest among pharmaceutical companies given the relatively short duration of previous pandemics, and the relatively small populations affected by them. Given the burden of COVID-19, however, there is now intense interest and funding being allocated to research for the prevention and treatment of COVID-19 infections (Dhama et al.).

Development of a vaccine against SARS-CoV-2 is one of the strategies to end the COVID-19 pandemic. Vaccines stimulate the immune system to produce immune responses that protect individuals from infection. In the early days of vaccine development, live attenuated or inactivated pathogens were injected into individuals to protect them from future infections.[1]

[1] https://www.historyofvaccines.org/content/articles/human-cell-strains-vaccine-development

Today, a wide variety of approaches are used to develop vaccines. However, a key step remains finding a component of the pathogen that is safe yet effective in sensitizing the immune system such that if the vaccinated individual encounters the pathogen, their immune system will have the ability to effectively fight the infection. These antigens may contain live pathogens that have been inactivated, pathogens that have been killed, or some component of the pathogen like the protein that coats a virus.

To develop vaccines on an industrial scale, the antigen needs to be mass produced. Animals or animal cells have often been used to produce the antigens for vaccine development, but this process is costly, and it can be dangerous because animals may be carrying their own bacteria and viruses that could infect human beings. For these reasons, the use of human cell strains was seen as a significant advancement. Cell strains are immortalized cell lines that can grow indefinitely. Normally, cells can reproduce a certain number of times and then they cease to grow. Cell lines have undergone either a mutation or some other manipulation to allow them to grow indefinitely. The HeLa cell line is one example. It was started from cervical cancer cells taken from a woman named Henrietta Lacks in the 1950s. Her cells were taken for research purposes without her consent, and they still represent a commonly used cell line, despite this controversy.

Some cell lines are derived from tissues of aborted fetuses. The WI-38 cell line is one such strain, created in the 1960s during the rubella epidemic. Pregnant women infected with rubella can have children with serious birth defects. This risk led many women to terminate their pregnancies due to the serious risks from congenital rubella syndrome. Fetal lung tissue from one such abortion in the 1960s was used to create the WI-38 cell line. The WI-38 cell line has been used to attenuate the rubella virus for vaccine production and is still used throughout much of the world today as part of the combined MMR (measles, mumps, and rubella) vaccine.[2]

Cell lines derived from fetal tissue and non-fetal tissue continue to be used in vaccination research and development. They can be frozen, stored, and they can grow indefinitely under the right conditions. It is important to note that cell lines derived from fetal tissue are not contingent on access to any additional fetal tissue. In addition, the antigens are always isolated from the fetal cells. This means that no fetal tissue is ever injected into a patient. However, given the origin of the WI-38 cells and several other similar cell lines developed at around the same time, ethical questions about their use remain.

Section II – Church Teaching

In the Catholic tradition, the moral and ethical issue arising from the development, production, and marketing of vaccines that are linked to aborted fetal tissue is not new. It was authoritatively addressed by the Pontifical Academy for Life, on behalf of, and approved by the Congregation for the Doctrine of the Faith in June 2005.[3] Along with the

[2] https://www.historyofvaccines.org/content/articles/human-cell-strains-vaccine-development
[3] https://www.immunize.org/talking-about-vaccines/vaticandocument.htm

Pontifical Academy for Life's statement, a published report subsequently appeared later that month in *Medicina e Morale* (vol. 54, no. 3, 2005) by Angel Rodríguez Luño.[4] A subsequent "note" was also provided by the Pontifical Academy for Life on July 31, 2017.[5]

In the original 2005 statement, the Pontifical Academy for Life examined the moral lawfulness of using vaccines prepared using human cell lines derived from the tissues of aborted human fetuses, such as WI-38. Specifically, in the Pontifical Academy for Life's translated *Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Foetuses*, the question posed was:

> "If someone rejects every form of voluntary abortion of human foetuses, would such a person not contradict himself/herself by allowing the use of these vaccines of live attenuated viruses on their children? Would it not be a matter of true (and illicit) cooperation in evil, even though this evil was carried out forty years ago?"[6]

The Pontifical Academy for Life recognized the dilemma posed by severe outbreaks of infectious disease such as rubella (German measles), as well as the associated risks to pregnant women from congenital rubella syndrome. For example, during the 1964 epidemic mentioned above, significant loss of life occurred as a result of spontaneous abortions and neonatal deaths. Severe comorbidities were also common among surviving infants, many of whom were left deaf, blind, or mentally impaired. As previously described, several fetal cell lines were developed around this time and have been used to develop a vaccine for rubella. These cell lines have also been used in the development of vaccines for immunization against chickenpox, mumps, measles, Hepatitis A, and polio, among others.

While no abortions were ever procured for the purpose of vaccine development, and no further abortions were performed to perpetuate the cell lines, an ethical problem remains. Are the researchers engaged in vaccine development and the parents who are compelled to protect their children complicit in benefiting from the original wrongdoing, albeit remotely?

The Pontifical Academy for Life reflected on this dilemma in light of the principle of licit cooperation in evil, asking to what degrees various parties would share in the formal act of wrongdoing, either by intent, or by providing some form of assistance in the procured abortions. They noted three categories of people who were involved in the cooperation in evil: those who prepare the vaccine; those who market the vaccine; and those who use the vaccine. The Pontifical Academy for Life concluded that doctors or those parents who:

> "resort to the use of these vaccines for their children, in spite of knowing their origin (voluntary abortion), carry out a form of *very remote mediate material cooperation*, and thus very mild, in the performance of the original act of abortion, and a *mediate material cooperation,* with regard to the marketing of cells coming from abortions,

[4] see abstract at: https://www.medicinaemorale.it/index.php/mem/article/view/388
[5] http://www.academyforlife.va/content/pav/en/the-academy/activity-academy/note-vaccini.html
[6] Pontifical Academy for Life, June 9, 2005, 2.

> and *immediate,* with regard to the marketing of vaccines produced with such cells. The cooperation is therefore more intense on the part of the authorities and national health systems that accept the use of the vaccines."[7]

However, according to the Pontifical Academy for Life, in 2005, it was the aspect of *passive cooperation* which stood out the most, hence their position that "it is up to the faithful and citizens of upright conscience (fathers of families, doctors, etc.) to oppose, even by making an objection of conscience, the ever more widespread attacks against life and the "culture of death" which underlies them."[8] They concluded that the use of the vaccines derived from the two aborted fetuses in the 1960s should be "understood as being a passive material cooperation and, in its mildest and remotest sense, also active, morally justified as an *extrema ratio* due to the necessity to provide for the good of one's children and of the people who come in contact with the children (pregnant women)." They also noted that this cooperation occurs "in a context of moral coercion of the conscience of parents" who are unjustly placed in the position of having to act against their conscience or put the health of their children at risk.

In a subsequent "Note on Italian Vaccine Issue" from the Pontifical Academy for Life in July 2017, this position was further articulated. In this document they note that "the cell lines currently used are very distant from the original abortions and no longer imply that bond of moral cooperation indispensable for an ethically negative evaluation of their use"[9] This leads them "to exclude that there is a morally relevant cooperation between those who use these vaccines today and the practice of voluntary abortion."[10] As such they advise that these vaccines can be used "with a clear conscience and that their use "does not signify some sort of cooperation with voluntary abortion."[11]

While addressing this conflict of conscience in the use of such vaccines, the 2005 statement by the Pontifical Academy for Life nevertheless emphasized that there is a moral duty to develop vaccines that are not derived from aborted fetal tissue, irrespective of how many generations have passed. They also affirmed the need to publicly advocate for ethical vaccine research as an act of conscientious objection, and to avoid any perception of acceptance of abortion in keeping with a "culture of death."

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[7] Pontifical Academy for Life, 2005, 5.

[8] Ibid.

[9] Pontifical Academy for Life, 2017.

[10] Ibid.

[11] It is important to recognize however, that some have expressed concerns regarding this 2017 statement. In an article in *LifesiteNews* on March 26, 2019, the author writes that the 2017 statement from the Pontifical Academy for Life represents a "subtle shift in support of aborted fetal vaccines." The article also notes that the fact that the abortions from which the cell lines have been derived occurred over fifty years ago "does not ameliorate their violence and horror." The article also cites Judie Brown, American Life League president, who says, "As we have seen on many other questions, the reconstituted PAV [Pontifical Academy for Life] backslides into positions that no longer reinforce the conscience protections of Catholic parents, and Catholics in general seek in order to live their lives in faith and trust in Christ."

The current COVID-19 pandemic has led to widespread loss of life and hardship around the world, and urgent international effort and cooperation are needed to develop a vaccine. A number of faith groups and organizations including the Catholic Health Alliance of Canada and the Canadian Catholic Bioethics Institute have appealed to government, affirming such urgent need, while also rightfully advocating for the production, use, and marketing of ethical vaccines that are not derived from illicit cell lines such as WI-38. The Ethics Network, on behalf of the Catholic Health Alliance of Canada also affirms this position, underscoring the timeless relevance of the 2005 Pontifical Academy for Life statement and its further comments in 2017.

While vaccine development is necessary to save lives, the Catholic moral tradition remains firmly rooted in a consistent ethic of life, according to which the bringing about of good can never justify the doing of evil. Every effort must be made to avoid cooperating with wrongdoing, in actuality or in perception.

The original cell lines have since grown independently, and the descendant cells used today for vaccine research and development are not the cells from the two original aborted fetuses. Nevertheless, in conscience and in solidarity with the unborn, the community of faith is compelled to advocate on behalf of ethical research and vaccine development in the face of COVID-19 or any other future viral threat.

Section III – Broader Ethical Issues in Research

While ethical reflection is important regarding the cell lines used in vaccine research and development, it is also important to highlight other ethical issues related to vaccine creation. These considerations tend to fall into the following three categories: (1) vaccine trial designs; (2) participation of human subjects in vaccine research; and (3) availability and appropriate dissemination of vaccines.

Vaccine Trial Designs

Fundamentally, the purpose of any vaccine development is two-fold: to ensure that the vaccine is efficacious and safe. There are many considerations that need to be addressed when designing any research trial, including the use of placebos, whether a trial is blinded, and the often-nuanced difference between research and treatment. However, vaccine trials pose unique challenges, particularly in a pandemic setting. One of the most significant challenges is time. Unfortunately, the longer it takes to develop a vaccine, the greater the public health harm.

From an ethical perspective, any vaccine in development must be safe and have no or minimal adverse reactions in human subjects. After determining that a COVID-19 vaccine is safe and has some evidence of efficacy (i.e. research participants have developed some antibodies), there needs to be a study large enough to establish that vaccine recipients either do not become ill, or have lesser symptoms when exposed to COVID-19. One of the greatest issues with the design of this kind of study is whether a human subject will ever become exposed to COVID-19.

One proposed solution is the use of challenge-studies, in which a vaccine recipient would be directly infected with COVID-19 in order to determine the efficacy of the vaccine. Directly infecting an individual with a potentially deadly illness raises many ethical questions, including whether the human subject ought to be permitted to make this autonomous choice. Is it ethically permissible for an individual to consent, are there limitations on who ought to be able to expose themselves? The literature has discussed challenge-study participants being elderly persons who were likely to die in the foreseeable future, or health care workers who were likely to be exposed.

Participation of Human Subjects

Regardless of the design of the trial, it is of utmost importance that those who are participating in vaccine development as human subjects are protected. Participants should be aware of all risks before consenting and their consent ought to be free from undue influence. Importantly, in situations where individuals are likely to be exposed to COVID-19, it is important that human participants are not seeking trial involvement as a means of protection or "treatment." Lastly, any adverse events should be appropriately investigated and health care interventions should be offered to participants.

Availability and Dissemination of Vaccine

After the creation of a vaccine there will be ethical questions about who ought to have access to the vaccine first. It is important that vaccines are disseminated in an equitable manner. In this context, equity requires that those at higher risk ought to receive the vaccine first, and that the cost of the vaccine should be appropriately based upon what countries and governments can afford. Additionally, vaccines should not be allocated based upon individual socio-economic status.

Section IV – Catholic Research Ethics

As the above reflections bring out, the Catholic objection to relying on cell lines derived from the tissue of electively aborted fetuses does not rest on any hostility towards vaccination research in particular, or towards biomedical science in general. Rather, it is part of a reasoned system of constraints rooted in the Catholic moral tradition. These constraints aim to ensure that scientific advancement respects the ultimate value of human life, and that it remains directed to the benefit of humanity. This means that research must avoid cooperation in the destruction of human life. But it also means that research participants must be protected from exploitation, that research methodologies must be rigorous and professional,[12] and that the health benefits of research must be equitably distributed.[13] In this sense, the prohibition on the use of fetal tissue is part of a broader Catholic research ethics which requires that science be "directed to defined ends and put in dialogue with the world of values."[14]

[12]Pontifical Academy for Life, 2003, 7.

[13] Congregation for the Doctrine of the Faith, 2008, 3.

[14] Pontifical Academy for Life, 2003, 2.

It is important to emphasize, however, that this Catholic ethic of research involves more than just moral constraints. It also recognizes the great value of science, and it includes a positive commitment to support high quality biomedical research aimed at bringing protection and healing to those in need.[15] On one hand, this domain of scientific activity is a good in that it enables the development and exercise of valuable human capacities; ethically pursued, research promotes intellectual excellence, advances the search for knowledge, and gives meaning to human ingenuity. In the Catholic view, therefore, practical biomedical research allows human beings to participate in the creative power of God, and to act as stewards of the "value and intrinsic beauty of creation."[16]

Most importantly, however, the Catholic moral tradition recognizes the contributions made by biomedical research to the well-being of the human community.[17] Research agendas and practices must be constrained by respect for human life, of course. But this same respect should also motivate a commitment to care and compassion, particularly for those who are vulnerable and in need. To meet this commitment, Catholic organizations must support biomedical research into novel therapeutic and preventative medical interventions. Through these interventions, we become better able to honour the calls to alleviate suffering and to care for the ill and dying.

In sum, the Catholic tradition seeks an approach to research that is both constrained and motivated by respect for human life. This approach genuinely commends all efforts to develop a COVID-19 vaccine using ethically defensible research methods and materials. When scientific advancement meets these conditions, it lives up to its promise as "an invaluable service to the integral good of the life and dignity of every human being."[18]

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