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Canada

Best Brains EXCHANGE

CIHR Best Brains Exchange

A Path Forward for the Assisted Human Reproduction Act

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Executive Summary

On March 13, 2018, Health Canada, in collaboration with the Knowledge Translation Strategy Unit of the Canadian Institutes of Health Research (CIHR), brought together a number of key stakeholders to begin a conversation on the path forward for the Assisted Human Reproduction (AHR) Act, in a one day Best Brain Exchange (BBE) meeting.

The main objective of the meeting was to bring together subject matter experts in various areas of AHR to:

- share individual perspectives on the current legislative oversight of the AHR Act and explore alternative approaches for overseeing certain aspects of AHR;
- identify any potential gaps in AHR related information and discuss the need for collecting and overseeing such information; and
- explore ways of meaningfully engaging Canadians on the topic of AHR moving forward.

Although certain key themes related to governance, data and engagement emerged from the day's discussions; stakeholders' perspectives on each topic were often divided. On the topic of governance, many participants voiced their concerns with using criminal law and its associated penalties to oversee activities under the AHR Act. Instead, many advocated for applying a more flexible, less punitive approach to oversee certain aspects of AHR. However, it was clear from the day's discussions that participants' views were divided on the prohibitions currently in place under the AHR Act, and the best approach for their legislative oversight moving forward.

On the topic of data collection and oversight, there was unanimous acknowledgement that data related to third-party AHR is lacking in Canada. A national level data gathering process was seen as essential to help fully inform the landscape of AHR in Canada. However, views differed on who would be best positioned to collect and oversee such information.

Stakeholders were in agreement on the importance of having meaningful engagement with Canadians on the topic of AHR and its legislative oversight moving forward. Most agreed that public education is a necessary precursor for effective engagement given the rapid advancements in science and the ethical complexity of the issues. In spite of this, views were not aligned on who to engage, when to engage, and the best approach for achieving meaningful engagement.

Overall the BBE was deemed successful as it provided an opportunity for Health Canada to begin a conversation with key stakeholders on the path forward for the AHR Act. The diverse perspectives shared with Health Canada during the meeting underscored the complexity of the issues at hand, the lack of available data, and the need to engage more broadly to determine if the current legislative oversight continues to reflect Canadian values, prior to making any legislative amendments.

Introduction

A BBE is a one-day, in-camera meeting that brings together policy makers, researchers, ethicists, industry experts, advocates, and engagement experts to discuss a health topic of shared interest and high priority to all – in this case, assisted human reproduction. These informal gatherings promote interaction, exchange and mutual learning between subject matter experts and policy makers. The invitation-only events enable open dialogue around the relevance of the evidence to the current policy context and they help foster relationships among interested parties.

On March 13, 2018, Health Canada brought together a number of key stakeholders in a BBE titled “The Path Forward for the AHR Act”. This report is intended to provide an overview of the proceedings and a record of the meeting discussions, to help guide Health Canada as it explores a path forward for the Act.

BBE objectives and structure

The goal of this BBE was to bring together subject matter experts in various areas of AHR to begin dialog with Health Canada on the path forward for the AHR Act. The main meeting objectives were to:

1. Discuss the impacts of the current legislative oversight of the AHR Act, from the perspective of key stakeholders groups and explore alternative approaches for overseeing certain aspects of AHR (governance);
2. Identify gaps in knowledge on AHR in Canada and how to address these gaps (data);
3. Explore ways of meaningfully engaging Canadians on the topic of AHR to determine if the views of Canadians may be changing with respect to the current prohibitions under the AHR Act (engagement).

The meeting objectives were informed by a number of factors, including:

- An increasing number of Canadians are turning to AHR technologies, for a variety of reasons;
- Recent consultations have revealed that some stakeholders believe parts of the Act are not keeping up with scientific progress or with Canadian values;
- Meaningful engagement is needed to determine if the values of Canadians with respect to AHR and its legislative oversight are shifting.

The BBE discussions were structured to follow these objectives, with one session for each, comprised of panel presentations followed by a question and answer period. The day finished with two open discussions, one on impacts and perspectives for overseeing aspects of AHR and one on key messages for Health Canada.

These presentations and discussions, together with further input submitted by participants in writing, form the basis for this report. Chatham House rules were followed during the meeting, meaning that participants (apart from presenters) are not identified in this report, nor are their comments attributed.

It is important to note that the points raised by participants during the discussions reflect their own views, and in some cases, relate to AHR issues that are beyond the scope of federal oversight. It is also important to note that during the day, there was significant repetition in the discussions.

Background: The Assisted Human Reproduction Act

The genesis of the AHR Act lies in the 1993 report of the Royal Commission on New Reproductive Technologies (RCNRT). In 2004, the AHR Act received Royal Assent; many sections, however, did not come into effect pending the development of regulations. In 2007, Section 8, dealing with consent, was brought into force with supporting regulations.

In 2010, the process of developing regulations was brought to a halt when the Supreme Court of Canada ruled that many of the Act's provisions were unconstitutional due to infringement on provincial/territorial jurisdiction. Among those, were provisions related to the Assisted Human Reproduction Agency of Canada and its authority to collect, analyze and manage health reporting information. In 2012, the unconstitutional provisions were repealed and federal oversight reduced to a limited number of areas. As a result, several sections of the Act are not yet in force (see Annex A).

In 2016, the Minister of Health published a notice announcing Health Canada's intent to bring into force the dormant sections of the AHR Act, and develop supporting regulations as needed. While feedback from stakeholders revealed general support for the regulatory project, a number of comments focused on broader issues that were beyond the scope of the regulatory work. A second consultation, held in July 2017, provided stakeholders with an opportunity to comment on the details of the key policy proposals, and the feedback obtained was used to inform the development of the draft regulations. In January 2018, Health Canada published a summary of these comments in a *What We Heard Report*.

The intent of the BBE was to begin dialog on legislative issues raised by stakeholders during the recent consultations that have been identified by Heath Canada as out of scope of the regulatory work currently underway.

Setting the scene

The day began with two presentations from Health Canada representatives, to introduce the subject area and set the parameters for discussion.

Cathy Parker, Director General of the Biologics and Genetic Therapies Directorate, underscored that while Health Canada is moving forward at present with regulatory changes, the department is open to considering the need for legislative amendments to the AHR Act and that this BBE is the first step in opening dialogue on this topic with Canadians.

Liz Anne Gillham-Eisen, A/Director of the Office of Policy and International Collaboration, followed up on Ms. Parker's presentation by providing a more detailed timeline of the AHR journey from the Royal Commission on New Reproductive Technologies to present day. She provided details on the status of the AHR Act, including which sections are in force, and those for which regulations are currently being developed. She identified issues of compensation, decriminalization and scientific research as needing broader consultations, noting that this BBE was the beginning of that process.

Session One: Impacts and perspectives for overseeing aspects of AHR

The first two presentations were delivered by Professor Bartha Maria Knoppers, Canada Research Chair in Law and Medicine and Director of the Centre of Genomics and Policy at McGill University; and Dr. Françoise Baylis, Canada Research Chair in Bioethics and Philosophy at Dalhousie University.

The AHR Act: Governance Perspectives (Bartha Maria Knoppers)

Prof. Knoppers focused on international governance of AHR. She provided a survey of international conventions and agreements beginning with the *Universal Declaration on the Human Genome and Human Rights* (1997). Three major approaches to governing AHR have emerged:

- criminal law;
- regulatory approaches;
- policy guidelines.

Prof. Knoppers pointed out that the criminal approach to governing AHR under the AHR Act has stifled debate by virtue of its prohibitions and associated criminal penalties. On the other hand, the regulatory approach using statutory law is often interpreted by Research Ethics Boards; thus, it can be "practical" and incorporate changing norms. Finally, the policy approach involving guidelines can be updated by professional and patient organizations. A brief overview of the approaches taken in 17 countries throughout the world demonstrated that most

jurisdictions, including Canada, incorporate elements of all three approaches in governing AHR.

Prof. Knoppers also provided results of a discussion surrounding the possible review of the AHR Act undertaken in collaboration with the Stem Cell Network. It achieved consensus on underlying principles that could influence any review of the AHR Act so as to ensure that Canadians can benefit from scientific advances in AHR. There is a preference for regulations over criminal law and a need to distinguish between research and clinical activities. The Consensus Statement[1] recommended that:

- Basic and pre-clinical research on human germ cells and embryos in the earliest stages of development should be allowed;
- The current definition of human embryo in the AHR Act should be maintained, but not include synthetic embryo-like structures not intended to create a human being;
- The 14-day limit on human embryo research and the ban on the reproductive uses of clones and chimeras should be maintained;
- The creation of human embryos for research purposes should be permitted;
- Mitochondrial replacement therapy (to prevent serious mitochondrial diseases) should be permitted once demonstrated to be safe and effective;
- Pre-implantation genetic testing should be subject to professional guidance rather than federal legislation; and
- The regulation of research and practice should respect individual autonomy in reproductive and health decision-making, while an evidence-based and current understanding of Canadian societal values and concerns should guide regulatory reform of both research and practice.

Prof. Knoppers also called for public consultations, the strengthening of scientific literacy, and an independent review body charged with guiding ongoing reforms to the AHR Act in light of scientific advances.

Where to from Here? A Canadian Strategy for AHR (Françoise Baylis)

Dr. Baylis' presentation focused on three areas: key challenges with the current legislation; alternative oversight mechanisms; and activities for which federal oversight may be appropriate and needed. Her primary focus, particularly in terms of challenges, was third-party involvement through gamete donation and surrogacy.

Among the challenges she identified were:

- the current market for donor sperm and eggs, as well as surrogacy;

[1] Dr. Knoppers is one of the signees of the Consensus Statement.

- disdain for the law among those providing and brokering donor gametes and surrogacy services;
- harms to egg donors and the absence of robust scientific research (adequate evidence) to support informed decision-making; and
- medical tourism (which includes Canadians going abroad to access gametes and surrogacy, as well as foreigners seeking Canadian egg donors and surrogates).

Dr. Baylis stated that she supports the legislation and its prohibitions, particularly when it comes to cloning, creating embryos for research and genome editing/mitochondrial replacement. She noted that the AHR Act has never been tested, as it has never actually been fully in force. She noted her support for using the criminal law when:

- the objective is to protect the health and safety of the public and to prevent unethical activity;
- a ban is rationally connected to, and necessary to achieve, the objective, noting that a ban is the most effective means to prevent an activity from happening; and
- the deleterious effects of the ban are balanced by its salutary effects.

Dr. Baylis noted that criminal law should be used to regulate research just as it regulates the practice of medicine (e.g., medical assistance in dying, or MAiD), and that a criminal ban is appropriate when the federal government has deemed conduct against “public health, safety and morality.” She added that distributed governance models (research ethics and professional self-regulation) are significantly flawed because their very structures set up an inherent conflict of interest. Instead, Dr. Baylis called on Health Canada to “believe in the legislation”: to complete the current development of regulations to bring the Act fully into force, to educate the public about the legislation, and then to enforce the legislation. She also called on Health Canada to create a formal grievance process, managed through an ombudsperson or an oversight office, to resolve problems as they arise.

Dr. Baylis concluded with a call for increased federal/provincial/territorial cooperation and harmonization, which should include harmonized consent forms, standardized birth certificates, equal protections under family law, as well as strategies for removing barriers to accessing AHR and adoption. She also called for similar approaches to data collection (personal health information registry; data about the health of egg donors, surrogates, children born of AHR technologies; pregnancy success rates, etc.) and responses to medical tourism and transnational trade in reproductive tissues.

Discussion

Criminal law vs. regulatory/policy approach

Many participants noted that the criminal law is a blunt and rigid instrument for overseeing AHR, and most agreed that a regulatory/policy approach was better suited for managing the issues highlighted by the two presenters, particularly in the area of research, given the rapid pace of scientific advancements.

The reasons for objecting to criminal prohibitions were varied:

- Some were concerned that adequate judicial resources to deal with criminal-law prohibitions would not be available, particularly in the wake of the Jordan decision by the Supreme Court.
- Others were concerned that criminal prohibitions on gamete donors were unenforceable because, as one participant noted with some hyperbole, "you can't jail parents."
- Still others noted that the criminal "taint" inherent in criminal prohibitions inhibits discussion of important issues.

There was general agreement that, even if criminal prohibitions are reasonable in the clinic, they are not suited for the research arena, where new advances take place and where the evidence is generated on which to make decisions about these advances. Some expressed concern that prohibitions affecting research, in particular, could mean that scientific advances would not take place in Canada, thus denying Canadians their benefits. Particular emphasis was placed on the problems created by prohibiting the creation of embryos for research purposes, which was seen as deleterious and described as a signal failure of the AHR Act.

The need for oversight

There was general agreement on the need for an independent review board/agency that would have two roles: as a destination for AHR-related complaints and concerns, particularly regarding the use of third parties, whether for gamete donation or surrogacy; and, a central point for ongoing review of the AHR Act. Such an oversight body was also seen as a means of maintaining a national (as opposed to federal) role in an area where many regulations occur at the provincial/territorial level.

Ethical aspects of commercialization

Criminal prohibitions on commercialization are based on the belief that such activities as related to sperm, eggs and *in vitro* embryos are ethically wrong and can lead to commodification and exploitation. At least one participant felt that this ethical concern remains valid and still merits a criminal response.

Others felt that, despite the validity of concerns related to commercialization, criminal prohibition is not an appropriate response. One participant noted that despite efforts to attract altruistic donors over the past 13 years, there hasn't been much success in part because donors' desire for compensation has been

ignored. However, it was noted by another participant that many who expressed this view were also those who stand to financially benefit from commercialization.

Session Two: Gaps in knowledge on AHR in Canada and how to address them

The second session, addressing gaps in knowledge, featured presentations by Mark G. Evans, Executive Director of the Canadian Fertility and Andrology Society and Vanessa Gruben, an associate professor at the University of Ottawa's Faculty of Law.

Information Needs for Assisted Human Reproduction (Mark Evans)

Mr. Evans focused his presentation on the Canadian Assisted Reproductive Technologies Registry (CARTR), a voluntary collaboration among 35 *in vitro* fertilization (IVF) clinics and medical directors across Canada housed at the Canadian Fertility and Andrology Society (CFAS). CARTR has been collecting and reporting on assisted reproductive technology data since 2004, focusing on IVF outcomes and trends. An IVF Improvement Committee has helped to bring clinics in Canada up to a consistent standard while assisting clinics with instituting reforms based on the data collected (e.g., reduction in multiple pregnancy rates). Data from CARTR is presented at CFAS annual meetings; CFAS is considering how best to present the data so it is of use to the general public since data is notoriously complicated to disseminate, particularly while ensuring the needed context is also provided.

In 2012, CARTR merged with the Better Outcomes Registry & Network (BORN) in Ontario, allowing data on IVF to be linked with birth outcomes for children born through IVF. IVF clinics have a near 100% reporting rate even if it is done on a voluntary basis.

In overall comments about the availability of AHR data, Mr. Evans noted that general information is readily available to the public, but that it is decentralized and often difficult to compare. Data surrounding IVF are available, mostly due to the work of CARTR, but non-IVF data are more limited, particularly for utilization, safety and outcomes of these treatments. Some data, such as third party and international use, as well as the long-term health of children and mothers or surrounding the use of donated gametes or surrogacy, is non-existent.

He concluded by saying there is a pressing need for national-level data on AHR, and that European and Scandinavian countries could be potential models for such data collection.

AHR: Identifying Information Gaps (Vanessa Gruben)

Ms. Gruben's presentation dealt with data gaps regarding the use of third parties, whether through donated gametes or surrogacy. Throughout her presentation, she emphasized the need for high-quality, consistent and accessible data (including through donor registries) to promote the health of both gamete donors and the children born from AHR; for research purposes; to promote health and well-being; and to instill public confidence.

She identified several areas where information is missing:

- There is very little demographic information available about egg donors and no outcome information about the use of their frozen eggs. She noted the importance of these data, given the increase in donations and their use in conception. There is also no long-term data on donor health and well-being and no tracking, either short-or long-term, of egg donors, despite concerns and anecdotal evidence about the long-term health risks of egg donation.
- There is a lack of information about donor-conceived children, including health outcomes as well as information about genetic relationships such as identifying and non-identifying information about donors and about half siblings.
- There is little information on the demographics of women who choose to be surrogates or on the residency of the intended parents, important information for understanding the impact of surrogacy (national and international) on the healthcare system.
- There is a lack of qualitative data on the lived experiences of donors, surrogates, children born of AHR technologies and intended parents. There has been no reporting on the outcomes of traditional surrogacies (i.e. where the surrogate's own egg was used to create the embryo) and limited information on gestational surrogacies (i.e. where the embryo is genetically unrelated to the surrogate). Information concerning international surrogacy and the impact it has on our healthcare system is particularly lacking.

Finally, Ms. Gruben identified the key components of an information framework to address the lack of these data. According to her, such a framework must include:

- Mandatory, rather than voluntary data collection
- National coordination
- Accessibility for the general public
- Qualitative research to determine participants' experiences.

Discussion

The crucial importance of data

Participants were unanimous in emphasizing the importance of using data as evidence for monitoring and assessing AHR effectiveness and outcomes, for

safely integrating new scientific advances into the clinic and, for protecting the health of donors and children born through AHR. While data on IVF is available through CARTR-BORN, there is a shortage of equivalent data on third-party reproduction.

Many emphasized the critical nature of such data, noting that self-reporting is not working, and stressing the need for a national approach for overseeing data collection and reporting. Among the functions of an organization overseeing third party data on AHR would be:

- Maintaining the identifying and non-identifying information on third-party donors and surrogates;
- Enabling the linkage of donor health and socio-economic data to longer-term health outcomes for both donors/surrogates and children.

Participants felt that data collection should be mandatory and collected with careful attention to privacy, transparency and accessibility. Many saw the criminal prohibitions contained in the Act as the primary barrier to collecting information from donors and surrogates in particular.

Some participants suggested that the adverse drug event data collection could be a model for AHR data collection, while others suggested the national organ donation registry as a model that overcomes provincial/territorial jurisdiction through a national approach. Others suggested that the CFAS, given its experience with CARTR, could be well placed to manage the data collection and dissemination process.

Importance of data on egg and sperm donation and use

Concerns in this area were primarily linked to egg donation, including the variable quality of egg-donor clinics and lack of data to empirically identify the potentially problematic ones. Currently, potential donors rely on grassroots advocacy to learn which clinics to avoid. Some participants felt that clinics sometimes dismiss donors' concerns, such as ovarian hyper-stimulation syndrome, and do not track long-term health outcomes of donation. A national approach to data collection could help offset these problems. The data collected could also be used for research purposes.

Participants also noted that most sperm is imported from the US, which means there is limited Canadian-specific data on third party AHR.

Importance of data for children born through AHR

One of the key principles of the AHR Act is to protect the health and well-being of children born through AHR. In order to achieve this goal, it is first necessary to determine what kind of information is important to children and then ensure that it is available. Participants felt it is also important for Canada to align with an international trend toward more openness in identifying donors and surrogates, ensuring such information is kept in a registry, and implementing bans on anonymity. Many participants called for Health Canada to consider promoting

access to donor identification in order to protect the health and well-being of children born through AHR in Canada.

Importance of clinic-specific data

There was some discussion on the utility of clinic-specific data, particularly with regard to IVF. Some participants identified the importance of such data while others highlighted the problems with their interpretation, particularly by the public. For instance, clinics that only accept patients with a good prognosis will have a higher success rate than those that accept all patients regardless of prognosis. There is also a danger of clinics refusing patients with poor prognoses because of the impact on their success rates. Data made available, therefore, require interpretation and explanation in order to be of value to potential patients.

Despite these hurdles, there was a general feeling that clinic-specific data should be available and that in addition to success rates, adverse events such as thawing/destroying of embryos or adverse patient events should be tracked.

Session Three: Exploring ways of engaging Canadians and determining their views on the topic of AHR

The presentation for this session was given by Kieran O'Doherty, an Associate Professor in the psychology department at the University of Guelph whose research focuses on community engagement and public deliberation, particularly in areas of social and ethical aspects of health.

Exploring ways of engaging Canadians and determining their views on the topic of AHR (Kieran O'Doherty)

Dr. O'Doherty's presentation explored ways of meaningfully engaging Canadians on the topic of AHR, to learn whether their views are changing with regard to the prohibitions contained in the AHR Act. He considered the mechanisms available to gauge the views of Canadians and how to link public engagement mechanisms with policy challenges.

Throughout his presentation, Dr. O'Doherty emphasized the fluid and changing nature, not just of the views of Canadians, but also of AHR technology and its regulatory landscape, necessitating further public engagement. He emphasized the pitfall of assuming there is a single body constituting the "Canadian public". He also highlighted the need to understand the different views of stakeholders, communities and individuals, and accommodate the tensions among different positions and conflicting values. He recognized the need to ask if anyone is missing from the conversation, such as those who may not yet be affected by AHR, in order to be able to gauge the "range of values" of Canadians.

He then discussed the range of methodologies and mechanisms for engaging Canadians:

- "One-way" mechanisms such as online consultations, focus groups, requests for positions and comments;
- Town-hall meetings and public debates, which are more of a two-way mechanism, but usually feature people arguing their own positions rather than seeking solutions; and
- Deliberation, which supports informed input from a diverse public and involves negotiating trade-offs and value conflicts.

The last mechanism, Dr. O'Doherty said, is the preferred method for issues involving beliefs and values but requires investment in public education, to ensure there is a common foundation for such conversations.

Finally, Dr. O'Doherty noted that the issue is not whether public perspectives have changed, but that the technologies have changed, such that the possibilities for AHR are significantly different, meaning that the results of public engagement activities carried out more than 20 years ago may not pertain to the AHR landscape of today. Moreover, given that public understanding of new technologies such as gene editing is uncertain, engagement mechanisms should include:

- educational components to provide trustworthy information from multiple perspectives;
- opportunities for individuals and groups to express their hopes and concerns, particularly those not part of organized groups;
- explicit consideration of the range of positions expressed; and
- public discourse and deliberation with transparent weighing of benefits and risks and balancing of conflicting values.

Dr. O'Doherty noted that at the heart of engagement on AHR are key essential questions that require considerable public debate: How do we want to live? What kind of world do we want to live in?

Discussion

The why and how of engagement

While there was general support for engagement[2], participants felt that any future engagement on AHR should be carefully considered in terms of its goals, who should be involved in leading and participating in the process, and how the results of the engagement should be used to inform the future direction of the Act. However, some suggested holding off further engagement until the AHR Act and its regulations are fully in force, and focusing on public education in the meantime.

[2] Participants largely used the terms "consultation" and "engagement" interchangeably. This report uses the term "engagement."

In terms of goals, public education was the most commonly identified goal, as well as breaking down stigma around infertility and engaging Canadians in an open dialogue.

Participants felt that to justify another engagement opportunity, it would need to involve groups not previously engaged in consultations on AHR – a move away from "the usual suspects". In particular, they identified those living in remote or northern communities, LGBTQ2 community members, donors, and donor conceived families, as important contributors to the conversation.

Finally, while it was deemed important to define how results will be used before undertaking engagement activities, there was little or no discussion on this topic.

The impact of the criminal law on public engagement

There was a consensus that criminal prohibitions under the AHR Act would serve as a barrier to public engagement. Donors and surrogates, in particular, may be reluctant to speak out due to perceived concerns about the legality of their actions. Guarantees of confidentiality and anonymity were seen as possible resolutions to this barrier.

The focus of engagement activities

Given the expense and time commitment of public engagement, participants agreed on the need for a clear focus for such activities. There were, however, varying views on what public engagement on AHR should be focused on.

Some felt that the focus should be on criminally prohibited activities related to payment, as their effects are widespread, affecting things such as costs, accessibility, and stigma.

Some participants viewed research as a good starting point, as we know much more about the science of AHR than at the time of the Royal Commission. Engagement was also seen as benefiting research, particularly in the field of social sciences, as public beliefs and attitudes are an important starting point for defining research questions.

Others saw broad engagement on "Canadian values" as unnecessary; some of these participants said that focused discussions on policy positions or suggested amendments to the AHR Act are needed instead.

Session Four: A discussion on the impacts and perspectives for overseeing aspects of AHR

This session was intended to build on the discussion that was held during the first session of the day. The discussion focused on:

- key challenges facing Health Canada as it explores a path forward for the AHR Act;
- AHR activities for which an alternative mechanism of oversight would be more appropriate; and
- AHR-specific activities for which federal legislative oversight is appropriate/needed.

Key Challenges

Governance

Most participants agreed that the lack of a clear enforcement mechanism was a critical weakness of the AHR Act. This has led to an inability to determine when criminal charges are laid, and what the role of the government is in laying these charges. Participants cited, in particular, a need for oversight to protect donor health and safety, to oversee the activities of fertility consulting agencies, and to decide on whether and how new scientific advances are integrated into the provision of care.

"We have sacrificed all other important issues on the altar of non-compensation."

There was also general agreement on the need for greater oversight on the use of donor eggs and sperm, from the very specific (e.g. donor sperm is exempt from taxation but eggs are not) to the more general (e.g. the need to protect not only donated sperm and eggs but the donors as well).

Many felt that oversight of donor eggs and sperm needs to address the issue of compensation, which was seen as inhibiting the availability of Canadian gametes and requiring their importation. There was also some discussion regarding the unintended consequences of the prohibition on payment, including the inability to track donors and their donations, and its overall ineffectiveness at preventing payment. Several participants referred to the existence of a "grey market", which harms donors, surrogates, and children born through third party donation.

"A one-size-fits-all approach [to regulation] is unlikely to succeed."

Among targets for regulation, several participants identified the need to heavily regulate and license surrogacy agencies, following the model of adoption agencies.

At least one participant noted that regulations currently under development for section 12 of the AHR Act will limit eligible expenditures for donors and surrogates, and suggested that other compensation models are available and may be more appropriate, such as the flat fee model in the UK.

In discussions on governance, the question of criminal law as applied to research was raised a number of times. Many participants emphasized that it is unacceptable to not allow the creation of *in vitro* embryos for research purposes since there are too many areas where research is needed. Participants felt that the supply of donated embryos from IVF clinics is not sufficient and without other embryo sources, basic science cannot move forward. It was generally felt that the criminal law is a blunt instrument leaving no room for interpretation. As an

"We have conflated research and clinical practice to the detriment of research."

example, the 14-day limit for embryo research was seen as too restrictive and should be more flexible, depending on the project. Many felt that a review/oversight body would be a better option than criminal law for overseeing research.

Participants had different suggestions for a regulatory approach; noting that no single approach was likely to cover all situations. Others noted that, given rapid scientific advances in the field of AHR, a flexible mechanism for their oversight may be appropriate, citing the Canadian Institutes of Health Research's Stem Cell Oversight Committee as a possible model.

Finally, participants identified the need for better information and communication around the AHR Act, suggesting that Health Canada could issue interpretive bulletins so Canadians can know if they are breaking the law. For instance, areas such as the use of embryo-like structures for research purposes are ambiguous under the current AHR Act and further clarification is needed.

Data

Data was seen as an equally important challenge in AHR. Many participants felt that data collection on the health outcomes of donors, surrogates, and children born of AHR is lacking in third-party reproduction. Information on AHR should be made accessible to patients and to the wider public.

While data collection is important, participants indicated that having a national approach is also crucial, one that brings together the federal and provincial/territorial governments to collect, maintain, and use data. Such a process would likely require harmonization of family law in particular, including laws governing family formation, definitions of parenthood, and rules regarding anonymity.

Engagement

Noting the importance of engagement, participants were in agreement on the need for public education in and of itself and as a support for meaningful engagement with Canadians. Such education would need to encompass better understanding of the general area of fertility, to support a better-informed public; scientific advances (such as germline editing) and the questions arising from such research; and issues such as donor anonymity, surrogacy and egg and sperm donation. The goal of engagement, as opposed to education, would be to help gauge the values and ethics of Canadians on issues related to AHR rather than reach a consensus.

AHR-specific activities for which an alternative oversight mechanism may be appropriate

This session dealt entirely with questions on governance/oversight. The majority of participants felt there was a need to substitute criminal prohibitions with

regulatory and other oversight mechanisms. Specific points were raised with regard to research and third-party reproduction.

Research

As stated throughout the day and in many different contexts, the criminal law was considered by most, an inappropriate instrument to govern research, particularly given the need to encourage innovation and adapt to new discoveries and technologies. Most participants agreed that there is no reason to criminalize research on human eggs, sperm or *in vitro* embryos if their use is not going to result in a live birth. Instead, a robust peer review and oversight with regulatory consequences was seen as a more appropriate mechanism in the case where norms are not followed.

"Bans and moratoria throw out the research baby with the cloning/eugenics/ethics bathwater."

Indeed, as stated before, there was a strong consensus on the need to separate research from clinical practice when regulating AHR.

Egg Donation and Surrogacy

Many felt that egg donation and surrogacy are key areas of AHR that require proper oversight, with regulations and licensing. Given that it is illegal to purchase eggs from a donor, or pay a person to be a surrogate or make surrogacy arrangements, there is variable quality among the existing consulting agencies and the services they provide, ranging from awful to excellent and Canadian donors and surrogates are left without sufficient protection.

In general, participants underscored the need for a pan-Canadian approach to regulating egg donation and surrogacy, with a focus on safety and quality of care. It was suggested that Health Canada could provide the needed oversight.

However, the question of compensation for donation and surrogacy was also raised, with some calling for reasonable compensation being permitted. However, some participants noted that there are other models for such payment, not just those in place in the United States and at least one participant again, suggested a flat-fee model.

Areas of AHR that require federal oversight

Many participants expressed the view that prohibitions, with criminal sanctions, should only be used on activities that are believed to remain unquestionable in the foreseeable future; reproductive cloning and animal-human hybrids were considered by some, to be the only two activities under the AHR Act that should stay prohibited.

Data collection was another area where participants believed that oversight is needed, for the long-term health and well-being of donors and children, to keep needed registry-type information about donors and children, and to support research into various aspects of third-part reproduction. Again, while a strictly federal approach is not possible, participants felt strongly that a pan-Canadian approach is necessary.

At least one participant felt that the AHR Act and its prohibitions should remain unchanged, and that the current federal legislative oversight of AHR was appropriate. However, most agreed that given the changing values and scientific evidence, a process and timeline for regular review of the AHR Act is needed.

Session Five: Key messages for Health Canada

Participants' key messages for Health Canada built on comments made throughout the day and included general comments, as well as comments related to governance, data and engagement.

General

A few participants stated the need to allow new regulations to take effect and evaluate their impact prior to making any legislative amendments. Others suggested that moving ahead with new regulations based on a 30-year-old understanding of Canadians' views is concerning.

Some participants suggested delaying the making of Section 12 regulations until there is a better understanding of what Canadians, including patients, the LGBTQ community, families, surrogates, and egg donors want.

"We need a model of compensation for third-party Assisted Reproductive Technology that encourages donation/ surrogacy but is not exploitive and that brings the process out of the grey market."

Many felt that the issue of compensation in third-party reproduction required action. Others, however, expressed frustration at the way compensation has taken over discussions on third-party reproduction.

Some participants stated that egg donors in particular need guarantees of care and safety through better oversight of clinics. These participants emphasized the need to address the long-term health and safety of women donating eggs as well as those acting as surrogates.

Governance

Most participants emphasized the need to remove criminal prohibitions from the AHR Act and instead, adopt a more flexible, less punitive approach for overseeing certain aspects of AHR. These participants highlighted that criminalization of payment for gamete donation or surrogacy was driving these practices underground, making it hard to find Canadian donors or surrogates, and preventing the provision of safe and high-quality care to donors and surrogates.

However, some participants stressed the need for a clear reimbursement model rather than a compensation model, while at least one advocated for Health Canada to retain the current prohibitions related to payment.

Many participants stated that Health Canada should enable important scientific research, currently prohibited under the AHR Act, for the benefit of Canadians. Even if some criminal prohibitions remain, it was felt that the Act should differentiate between clinical care and research. A robust research program was seen as crucial to understanding embryonic development. However, participants stated that even if research isn't prohibited, oversight of scientific advances is still needed. Some felt this oversight could be provided by CIHR.

Some participants called for a regular review of AHR oversight in Canada, with provinces and territories as well as professional and voluntary organizations playing a role. Such oversight body should prioritize the interests, needs, and views of children conceived through AHR. A few messages called for Health Canada to undertake an immediate review the Act while others stated that a review should be delayed until regulations currently under development have been implemented and evaluated.

Data

Participants emphasized the need for data as one of the most pressing AHR-related issues. They advised Health Canada that several kinds of data are needed, the most important being longitudinal data in order to understand long-term health impacts on children/donors/surrogates/parents. There is also a need for registry data to enable linking of donors and children born of their donation. Participants also stated that Health Canada needs to lead a national approach on data collection to inform good policy development.

"I am hoping that building data bridges, not silos, will be an outcome for Canada's assisted human reproduction community."

Engagement

Participants were emphatic on the need for public engagement, especially given the complexity of issues and speed of scientific advances such as innovative gene editing technologies. They were consistent in calling for a focus on the views of the broader Canadian society, not only stakeholders, as the issues impact future generations and the public health system.

Participants saw public education as an essential precursor to effective engagement, with a focus on ethical as well as scientific literacy. They saw deliberative discussion as the best way to combine both education and engagement.

Participants emphasized the importance of Health Canada's leadership role in expanding the conversation, working with the provinces and territories, and ensuring safety, accountability, and consistency in policy development moving forward.

Conclusion

The BBE provided an opportunity for Health Canada to bring together policy makers, researchers, ethicists, industry experts, advocates, and engagement experts to begin a conversation on the path forward for the AHR Act. The diverse perspectives shared with Health Canada during the meeting underscored the complexity of the issues at hand, the lack of available data, and the need to engage more broadly to determine if the current legislative oversight continues to reflect Canadian values, prior to making any legislative amendments.

Next steps

Although the issues raised during the BBE are out of scope of the regulatory work currently under way by Health Canada, or are beyond federal jurisdiction, they highlight important areas for consideration, analysis, and consultation. Moving forward, Health Canada will assess the meeting outcomes in detail and continue to engage Canadians in meaningful conversations on the best path forward for the AHR Act.

Annex A: The AHR Act Today

Prohibited Activities in Force	Prohibited Activities Not in Force

Scientific Research and Clinical Procedures Section 5 of the Act prohibits certain unacceptable scientific research and clinical procedures, such as human cloning, creation of an embryo for non-reproductive purposes, sex selection for non-medical reasons, altering the genome such that it can be transmitted to descendants, etc. **Commercialization** Section 6 of the Act prohibits payment for surrogacy. Section 7 of the Act prohibits the purchase of human reproductive material and the purchase and sale of *in vitro* embryos. **Consent** Section 8 of the Act prohibits the use of reproductive material unless consent is obtained from the donor, in accordance with the *Consent to Use Regulations*. **Minimum age for gamete donors** Section 9 of the Act prohibits any person to obtain sperm or ova from a donor under 18 years of age, or use any sperm or ova so obtained, except for the purpose of preserving it for the minor's own future reproductive use	**Sperm and ova safety** In 2012, a new section 10 of the Act was introduced which prohibits the distribution, use and importation of sperm and ova for third-party reproductive use, unless processed in accordance with regulations. **Reimbursement** Section 12 of the Act prohibits the reimbursement of certain expenditures to donors and surrogates, unless done in accordance with the regulations and supported by a receipt. Section 12 also prohibits the reimbursement of lost income to a surrogate, unless certified by a medical professional and done in accordance with the regulations. **Administration and Enforcement** Sections 45-58 of the Act allow the Minister to designate inspectors for the purposes of administering and enforcing the Act and provide inspectors the authority to do so.