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Reflections on Two Decades of Bioethics: Where We Have Been and Where We Are Going

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The *American Journal of Bioethics* (AJOB) emerged at a time when bioethics, though still a young discipline, was described by some as at a critical crossroads.¹ Commentators noted that bioethics began as a scholarly, reflective, academic enterprise but was increasingly focused on providing practical services to institutions and clients, and worried whether the field could productively and coherently accommodate both bioethics scholars and practitioners.² Ten years later, bioethics remains a field comprised of some who are primarily scholars, some who are primarily practitioners, and some who are scholar-practitioner hybrids. Bioethics scholarship rests on a foundation of moral philosophy, but also incorporates law, policy studies, empirical studies, analysis of government or international guidelines, standards of practice, case studies, and more.

As for most, my perspective of where the field has been and where it is going is colored by my own experiences. My background education is both practice based (nursing) and conceptual (philosophy) – and I consider it a privilege to be a ‘hybrid’ bioethicist- involved in both bioethics practice and bioethics scholarship. For this essay, I chose to discuss 4 short cases to reflect on bioethics over the last decade and speculate about the next decade. Although based on my own experiences, each case has been embellished for clarity and effect. My future scenarios are deliberately optimistic, yet of course, they are simply guesses, an exercise inspired by “Choose your own adventure,” a popular children’s book series that allows the reader to create the story ending.³ It is conceivable, however, that my future predictions are too optimistic and due to constricting resources or shifting societal priorities or values, the growth and influence of bioethics will lose speed. It is also possible that with increasing numbers of certificate, masters, and doctoral programs in bioethics, the future bioethicist will be much more specialized than today; there will be distinct career paths for scholars and practitioners and policy wonks, and ultimately fewer hybrids. Losing some of the rich diversity of perspectives that comes with bioethicists trained in different disciplines would be unfortunate. At the same time, specialization and focused expertise has the advantages of allowing bioethicists to engage and integrate in complex areas of science, health care, and policy. Now for the cases:

Case 1. Whole Genome Sequencing

The year is 2002, the setting is an IRB (institutional review board) meeting at an Academic Medical Center. An investigator submits a research proposal to the IRB that includes plans for storing DNA for future studies. The consent form asks participants to indicate on a menu of choices whether or not they will allow their blood or tissue to be stored and used for future research. The menu options include: 1) participants give investigators permission to

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use the blood or DNA for any future research deemed important, 2) the participant wants to be re-contacted before her DNA is used for future research, or 3) the participant does not allow any future use of their samples or DNA. The consent form describes that the specimens will be coded and notes among the possible risks that genetic information could have a negative impact on insurability or employment. The bioethicist and geneticist are consulted to discuss whether the consent language is adequate for informing participants, the choices are reasonable, and the investigator's plans for future use are appropriate. Fast forward to 2012, the IRB is scheduled to review a protocol proposing to run whole genome sequences (WGS) on enrolled participants and also to store these data in the NIH database of genotypes and phenotypes (dbGAP) to be shared with other investigators for Genome Wide Association Studies. The consent form notes that access to health insurance and employment should not be affected because of the Genetic Non-discrimination Act (GINA), and explains the possible risks of data sharing and re-identification. The IRB, referencing the 2012 report of the Presidential Commission on the Study of Bioethical issues, asks a practicing bioethicist knowledgeable about genetics to help them evaluate the adequacy of the investigator's proposal for protecting privacy, the consent language, and the investigator's proposed plan to not return incidental findings to the participants. In 2021, most people in the U.S. have had their whole genome sequenced by their health care provider as a routine part of care and have access to their own sequence data stored in the cloud. Each person can decide whether or not and how she wants to share her sequence data with researchers through a menu of research studies publicly listed on a smart phone application. The IRB reviews proposals to include a particular research study on the application menu, but the regulations do not require IRBs to get involved in individual decisions about sharing genomic sequence data. Practicing bioethicists are available to serve as consultants to individuals who are unsure of the implications of sharing their WGS, or who want help understanding the value of proposed research. Bioethics scholars are focusing on those marginalized members of society who do not have access to their WGS, either because it was not done by their health care providers, or because they had their genome sequenced without their knowledge, for example in the military, in prison, or in the workplace. The US Parliament is debating the possibility of requiring employers with 50 or more employees to make sequencing available to all employees through the workplace health clinic and to ensure that all employees have access to their own sequencing data.

Case 2. Goals of Care

A nurse on a busy oncology unit in 2002 is concerned about the aggressiveness of care being given to a particular patient with terminal cancer. The nurse knows the patient well and knows she is reluctant to say anything that might disappoint her doctor or her spouse, but she has quietly indicated to the nurse that she has had enough. The nurse, despite knowing through experience that the attending physician can be difficult to deal with, seeks advice and assistance from the bioethics consultant. The bioethicist helps to facilitate discussions with the team, the patient and her family and discuss the goals of care. Although the attending physician makes changes to the treatment plan based on the patient's wishes, the option of hospice is not discussed. The physician reprimands the nurse for interfering with his case and wanting to "give up" on his patient. Fast forward to 2012, a busy oncology nurse wants to help her patient with advanced cancer to articulate her concerns and reluctance to continue aggressive treatment. The nurse tells the attending physician that she plans to call for a bioethics consultation. The oncologist agrees and together they organize a meeting including members of the team and the patient and her family to discuss the goals of care, the patient's wishes and preferences, and to decide together on a course of action. Treatment options are reviewed, including the possibility of hospice. The nurse is commended for advocating for her patient and for calling in bioethics. Now it is 2021, oncology patients are most often treated in Patient Centered Medical Homes, where the

continuity of care is managed by a multidisciplinary team of providers that includes an embedded and credentialed clinical bioethicist. Soon after the patient's cancer is diagnosed, a multidisciplinary meeting is held with the patient's health care team, the patient, and her family to discuss treatment options and establish goals of care. They plan to meet as a group every 4–6 weeks to revisit or refine the goals. At the first meeting, the extent and stage of the patient's disease are explained, treatment options are discussed, the importance of the patient's choices and preferences are emphasized, and resources available to help the patient understand and negotiate the options are described and made accessible. Over time, the patient, with the support of the team including the bioethicist, alters the goals of care to fit her changing situation. When treatment options seem more aggressive than she wants, and her cancer continues to advance, the patient seamlessly moves into hospice care, fully supported by her team.

Case #3. Paying research participants

Many were concerned in 2001 that payment to research participants was ethically problematic. Paying people was considered potentially coercive or unduly influential, likely to cause individuals to participate in research that they otherwise would not participate in, or research that was objectionable and risky, and possibly skewing the research pool and therefore the science. IRBs and institutional policies put limits on the amount of money that could be offered to participants in research. Bioethicists argued about the meaning of coercion and undue inducement, and collected empirical data on the practice of paying research participants. By 2012, the bioethics literature on payment to research participants had expanded and payment had been discussed and debated at many bioethics conferences. Information about payment for studies was often available on line, and payment was clearly described in consent forms for those studies that offered payment. Otherwise nothing had changed, many still found paying research participants problematic and worried about the possibility of payment being coercive or an undue inducement. By 2021, the bioethics literature had further expanded on this topic, while research budgets continued to decline. Investigators rarely proposed to pay research participants except in studies for those studies that they thought recruitment would cease without payment. IRBs still worried about coercion and undue inducement from payment, but were more worried about the probability of a study not being able to recruit an adequate number of participants. **OR** By 2012, the bioethics community through empirical evidence had convinced the leaders of NIH, OHRP, and FDA that payment did not compromise informed consent and was not coercive or unduly influential. NIH guidance explained how to pay participants fairly and recommended payment for many types of clinical trials in order to make research participation revenue neutral for most studies and to enhance recruitment. In addition, a system of compensation for research injury had been established. With the new guidance and a new regulatory mandate, IRBs no longer worried about payment being coercive or an undue inducement. Bioethicists continued to focus their attention on the ethical issues evolving from the adoption of extensive learning health systems which had successfully obscured the previously held distinction between research and clinical care, and had rendered the question about payment moot.

Case #4. Global research and global health

A group of placebo controlled clinical trials testing interventions to reduce transmission of perinatal HIV had stirred up a debate about international research ethics that was still roaring and controversial in 2002. Some criticized these trials as emblematic of an ethical “double standard” by which researchers were exploiting the economically disadvantaged in the developing world through conducting studies that could not pass ethical muster in the US, and appealed to the Declaration of Helsinki that strictly denounced the use of placebo

when there was an existing treatment. Those who defended the HIV trials argued that the placebo-controlled design was necessary and justified in order to answer questions of relevance and value to the host countries where the research was conducted. The bioethical debate continued and expanded. The World Medical Association clarified and approved revisions to the Declaration of Helsinki that allowed the possibility of placebo use even when existing treatment existed if there were compelling scientific reasons and no serious or irreversible risk of giving no treatment to participants. By 2012, the volume of clinical research sponsored by the US but conducted overseas had skyrocketed and some emerging economies were competing for more research in their countries. Bioethics scholars, although still debating placebo use and compelling scientific exceptions, had turned their attention to whether avoiding exploitation should be the major concern in international research and to proposing collaborative research partnerships, theories to justify benefit sharing and models for doing so. The ranks of those educated in research ethics had grown. Bioethicists around the world had taken positions of visibility and influence, and were beginning to work collaboratively across borders. By 2021, international collaborators from around the globe, who had been committed to working together as partners to design and conduct research of high ethical and scientific quality research, were now collaborating on other issues of importance to global health and global justice. Bioethicists serve as clinical and research consultants, members of oversight committees and policy bodies, and it is also common for bioethicists to be embedded as members of research and health care teams.

Conclusion

Bioethics matured from 2001 to 2012, there was much growth in some areas yet little progress in others. The earliest issues of AJOB illustrated that the field of bioethics was grappling with the bioethical implications of leading edge and sometimes contentious scientific advances - such as preconception gender selection, selling oocytes, and implications for families of genetic testing, as well as highlighting long standing topics that warrant continued debate and scholarship and are important to practice, including justice in health care, payment to research subjects, and methods in ethics consultation⁴. A decade later, many of the same issues remain at the forefront of debate and scholarship. As the next decade unfolds, my hope and expectation is that bioethics will continue to flourish and be productive and influential in areas related to leading edge science, systems of health care, professional-patient/subject interactions, and global health and justice as well as many others. For this productive journey, we are likely to continue to need bioethics scholars, bioethics practitioners, and hybrids to work together and to each bring their specialized skills and expertise to the table.

Every day you may make progress. Every step may be fruitful. Yet there will stretch out before you an ever-lengthening, ever-ascending, ever-improving path. You know you will never get to the end of the journey. But this, so far from discouraging, only adds to the joy and glory of the climb. Sir Winston Churchill (1874- 1965)⁵.

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