The Belmont Report at 40: Reckoning With Time

It was the summer of 1972 when a stunned nation first learned of the infamous Tuskegee Syphilis Study, during which hundreds of poor, disease-stricken black men from Macon County Alabama, had been deliberately left untreated for 40 years.

Coming on the heels of multiple, earlier examples of unethical human experimentation, the Tuskegee Syphilis Study made it plain that the moral foundation of human subject research was in desperate need of repair. Blind reliance on the Nuremberg Code and the Declaration of Helsinki was no longer going to suffice.

It was against this backdrop that Congress resolved to act. Numerous hearings and multiple spirited discussions later, an agreement was struck to constitute the "Commission." The outgrowth of a retreat held at the Smithsonian Institution's Belmont Conference Center, the *Belmont Report* lays out a principled analytical framework to "guide the resolution of ethical problems arising from research involving human subjects." Durable and ever-present, the *Belmont Report*, which is the foundational document that reset the ethics of human subject research, must now reckon with all-important novel issues of the day that could not have been foreseen by its drafters. (*Am J Public Health*. 2018;108:1345–1348. doi:10.2105/AJPH.2018.304580)

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On September 30, 1978, a month before its disbandment, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Commission) issued the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Report).[1] Conveying the sense of the Commission, Chair Kenneth J. Ryan, MD, recommended that the Report "be adopted in its entirety" as a statement of "policy on the conduct of research involving human subjects."[1(p11)] Pithy yet foundational, this final study of the Commission proved to be a touchstone proclamation of the ethical tenets of responsible human subject research.[1] The outgrowth of a retreat held at the Smithsonian Institution's Belmont Conference Center, the Report laid out a principled analytical framework to "guide the resolution of ethical problems arising from research involving human subjects."[1(p10)] It was a watershed moment in the annals of biomedical and behavioral research in which US moralism featured prominently. We considered the ethos and substance of the Report, discussed its legacy, and reviewed its relevancy on the occasion of its 40th anniversary.

GENESIS

Calls for the establishment of the Commission were triggered by a string of widely denounced medical experiments, culminating in the infamous Tuskegee Syphilis Study.[2,3] Rising from a crucible of public outrage and congressional indignation, the Commission, the subject of numerous congressional hearings, was enabled by The National Research Act of 1974.[4,5] The brainchild of Senator Edward M. Kennedy, the Commission was to "find the critical balance required to satisfy society's demands for the advancement of knowledge while abiding by its strictures to protect the dignity, privacy, and freedom of its individual members."[4(p92)] This was to be a federal commission unlike any other. Never before was a federal commission convened to define the ethical moorings of public policy.[6] No previous federal commission of this stature was obliged to conduct all of its deliberations in public.[7] In addition, no previous federal commission was granted action-forcing authority to render its recommendations binding (absent public accounting to the contrary).

PRIMACY OF RESEARCH SUBJECTS

Upon commencing its deliberations, the Commission embraced the premise that "investigators should not have sole responsibility for determining whether research involving human subjects fulfills ethical standards. Others, who are independent of the research, must share this responsibility, because investigators are always in positions of potential conflict."[8(p5)] In addition, the Commission took the view that risk-laden, albeit promising research, may not be justified merely on the strength of its potential social benefits.[8] In adopting this decidedly nonutilitarian stance, the Commission rejected the notion of "for the greater good of the greater number" as an ethical rationale for the conduct of risk-encumbered, if auspicious, research. In subscribing to the foregoing positions, the Commission reflected widely held sentiments of its time according to which "scientific research must be supported. It must be encouraged. But it must go forth with the minimal possible risk to research subjects."[4(p96)]

RESEARCH VS PRACTICE OF MEDICINE

Addressing its first mandated task, the Commission drew a sharp line between "biomedical or behavioral research involving human subjects and the accepted and routine practice of

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medicine."[5(p7)] Research was defined as "an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge."[1(p20)] The routine practice of medicine, in turn, was defined as "interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success."[1(p20)] To do away with any residual ambiguity, the Commission took pains to add that "if there is any element of research in an activity, that activity should undergo review for the protection of human subjects."[1(p21)] This crisp demarcation of the research–practice interface endorsed the notion of conceptually distinct, segregated, activities, which, in the view of the Commission, were not to be conflated.

ETHICAL PRINCIPLES OF HUMAN SUBJECT RESEARCH

Addressing its main task, the Commission undertook to "conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects."[5(p7)] In addition, the Commission set out to "develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles."[5(p7)] It was here that the Commission left its mark in the nature of 3 equally weighted fundamental ethical principles: respect for persons, beneficence, and justice.[1] The corresponding guidelines were to consist of informed consent, assessment of risks and benefits, and selection of subjects.[1] Combined, these prima facie precepts and the guidelines for their implementation were considered to be both necessary and sufficient to govern the moral conduct of human subject research.

RESPECT FOR PERSONS

In framing the principle of respect for persons, the Commission treated it as a dual moral requirement to "acknowledge autonomy" and to "protect those with diminished autonomy."[1(p22)] By so doing, the Commission endorsed age-old Judeo-Christian convictions regarding the inherent "moral worth" of each and every person. The Commission further surmised that respect for autonomy will accord "weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others."[1(p22)] To ensure compliance with the principle of respect for persons, the Commission required the derivation of a nonexculpatory voluntary "informed consent."[1(p28-35)] This consent was to constitute a process, not a form, requiring valid, enlightened permission "free of coercion."[1(p31)] In circumstances when "comprehension is severely limited," consent was only to be granted by an authorized third party "most likely to understand the incompetent subject's situation and to act in that person's best interest."[1(p30)]

BENEFICENCE

In crafting the principle of beneficence, the Commission understood it to constitute an ethical obligation to the "well-being" of persons by way of an appropriate risk-benefit ratio.[1] To assure such outcome, the Commission took to formulate the axioms "do not harm" and "maximize possible benefits and minimize possible harms" as "complementary expressions" of beneficent actions.[1(p24)] The implementation of risk–benefit assessment would require the investigator to "examine whether the proposed research is properly designed." A "review committee," for its part, would need to determine "whether the risks that will be presented to subjects are justified."[1(p32)] It was only through the responsible discharge of these responsibilities that prospective subjects would be empowered to make the "determination whether or not to participate."[1(p32)] In the eyes of some commentators, the notion of avoiding harm would have been better served by the supplementary ethical principle of nonmaleficence.[9]

JUSTICE

In wrestling with the principle of justice, the Commission framed the central question as "who ought to receive the benefits of research and bear its burdens?"[1(p26)] To resolve this quandary, the Commission settled on the Rawlsian notion of distributive justice, the key pillars of which are fairness and equity in the allocation of burdens and benefits.[10] By so doing, the Commission characterized the principle of justice as one that "gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects."[1(p35)] In keeping with this outlook, research, a social enterprise for the public good, must be broadly inclusive and participatory. What is more, its benefits must accrue to all. In taking this stance, the Commission interpreted individual justice to require the selection of subjects to be free of all biases. Social justice, in turn, required that a "distinction be drawn between classes of subjects that ought, and ought not, to participate in any kind of research, based on the ability of members of that class to bear burdens."[1(p36)] Contingent on these strictures, vulnerable subjects such as "racial minorities, the economically disadvantaged, the very sick, and the institutionalized" deserved the utmost attention.[1(p37)]

LEGACY

The legacy of the Report is substantial and enduring. Topping the list is the inculcation of the Report "in its entirety" in government policy overseeing human subject research.[1] Four decades later, this legacy manifests itself in the reality that the Report and the federal regulations governing human subject research ("Common Rule") are inextricably linked.[11] Similar laudatory conclusions were arrived at by an Institute of Medicine committee, which asserted that "The ethical foundations of research protections in the United States can be found in the three tenets identified in the Belmont Report."[12(p92)] Apart and distinct from the foregoing, the Report stands out as a defining moment in the history of bioethics as a scholarly and applied discipline.[13] This conclusion was buttressed by the realization that the principles enunciated by the Report evolved to constitute some of the key precepts of contemporary bioethics.[14] Whether the

Report has had an impact on the practice of medicine remains debatable. However, in the eyes of some, the Report "dramatically reworked the relationship between doctor and patient."[13(p12)] Another impact of the Report on related international documents, such as the *Ethical Guideline of the Council for International Organizations of Medical Sciences*, has also been acknowledged.[15]

REAPPRAISAL

In further assessing the legacy of the Report, an accounting of its exceptional notoriety appears to be in order. The report was but 1 of 11 diverse reports issued by the Commission during its tenure. Many of these reports have left their own distinguished mark. That said, there is no doubting the fact that the Report remains hands down the most visible contribution of the Commission. No single explanation of the uncontested primacy of the Report will likely suffice. Much of the notoriety of the Report can be assigned to its seminal role as the conceptual progenitor of the "Common Rule" and thereby of contemporary ethical human subject research.[11] In addition, unlike some of the other tome-like reports of the Commission, the Report stands out for its brevity and conceptual clarity. These attributes have been the subject of celebration by countless institutional review boards the world over. Finally, there is the all-important matter of the readership, which, in the case of the Report, consists of any and all members of institutional review boards wherever they might be. Apart and distinct from the preceding considerations, the Report, along with other output elements of the Commission, was precedent setting in validating the usefulness of federally sanctioned committees, in which the public exercise of bioethics was front and center.[6] In so doing, the Report paved the way for the establishment of future constructs in its own image. Examples include but are not limited to The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, The Biomedical Ethics Advisory Committee, The Advisory Committee on Human Radiation Experiments, and The National Bioethics Advisory Commission.[6] Finally, the Report all but single-handedly launched a new principled era in public health research in which sound bioethical principles reign supreme. Often overlooked, this legacy of the Belmont Report can hardly be overestimated. Improved public health through principled human subject research would not have been realized were it not for the Report. Indefensible experimental undertakings such as the Tuskegee Syphilis Study must never be allowed to recur.

The Report has been the subject of ongoing constructive reappraisal almost from its outset. Headlining these concerns is the adequacy of 3 unordered abstract principles to resolve ethical dilemmas.[16] Anticipating these concerns, the Report cautioned that its principles are best viewed as "an analytical framework" more akin to a compass than to a checklist or a formula.[1] Related concerns regarding the optimal delineation, exploration, and analysis of the "Belmont Principles" remain the subject of ongoing active scholarship.[9] More recent reservations have centered on the necessity of "updates" impelled by evolving societal and scientific norms that could not have been foreseen by the Commission. Some of the more penetrating questions that have been raised concern the judgement of the Commission in placing protectionism ahead of utilitarianism and individualism ahead of communitarianism.[17] These concerns, first illustrated by the HIV/AIDS epidemic, fault the Report for excluding marginalized, often disempowered and resource-poor communities that are now desirous of participation in research.[18,19] Additional concerns have focused on the lack of emphasis on transparency, the relevance of which to the commercialization of present-day research is self-evident.[20] The absence of the all-important feminist perspective has been similarly lamented.[21] Lastly, it has been noted that the research–practice distinction in present-day learning health care systems is disappearing, for which a novel framework was originally proposed.[22,23]

Although the Belmont Report as such may not be a candidate for revision, serious consideration should be given to an addendum in recognition of the emerging issues of our time. Although expandable and interpretable, the Report never claimed timelessness. Much has changed that would benefit from the kind of piercing scrutiny that characterized the deliberations of the Commission. Novel moral principles such as "solidarity" and "transparency" may well be just what the doctor ordered.[20,21,24] AJPH

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