

Changes in bioethics

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Bioethics, since its beginnings in the 1970s, has changed in many different ways. In this short commentary I will only focus on its shift from a local view of problems to an international analysis. I will take as an example the evolution of research ethics. I wish to signal (a) a turn away from the first emphasis on the principle of autonomy to a revalorization of the idea of justice; and (b) the inclusion of problems not only present in the industrialized world but also in countries with scarce resources. I would like to suggest that this is not just the reaction to the “globalization trend” but that it implies a deeper commitment to justice and the avoidance of inequalities that go beyond the slogan of “globalization.”

Interestingly, this shift in bioethics is present in the International Association of Bioethics’ (IAB) creation and growth. Established in 1992, several years after bioethics was introduced, the IAB began this focus on international ethics. Its purpose was to be truly international: The constitution and election of the Board members reflect this, as does its intention to hold Congresses in different parts of the world.¹

Even if IAB includes such key issues as clinical ethics, research ethics, health policies, animal rights, and environmental ethics among others, its main concern focuses on its international commitment to global bioethics –the topic of the Tokyo Congress. Secondly, we should outline its deep concern for injustice, global inequalities, and the imbalance of power in the world. (Luna in press A)

I believe this second set of problems constitutes a central part of the IAB’s concerns today. If we consider the Congresses and Presidential Addresses of this Association, we can also follow this trend. Power and injustice was a topic that warranted an entire conference, such as the Brazil conference. Similar concerns regarding inequalities were presented in Dan Wikler’s 1996 Presidential Address when he strongly pointed out the social responsibilities of bioethicists regarding the lack of access to health care in the world (Wikler 1997). In a similar vein was Ruth Macklin’s Presidential Address at the 2000 Conference. There she presented data about inequalities in the world and the unjust situation of women (Macklin 2001). And the last Presidential Address’s title “Poverty and inequality: challenges to the IAB” exhibits the same line of thought. Some theoretical tools regarding the conceptualization of global justice are presented and explored there. (Luna, in press A) Hence, justice and inequality are one of the main worries of the leading association on bioethics.

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¹ Amsterdam (1992), Buenos Aires (1994), San Francisco (1996), Tokyo (1998), London (2000), Brazilia (2002), Australia (2004).

Research ethics also reflects this path. Just as bioethics emphasis initially was on autonomy and individual rights, and recently on questions about public health, justice and social rights, research ethics has also turned from problems of autonomy and informed consent to more general ones that embrace obligations to research subjects and the community, such as non-exploitation. The situation of societies with vulnerable and marginal populations is now central. Informed consent is merely the first step in a far more complex and problematic process. This shift in the focus of interest is related to the problems that developing countries brought to the international debate.

If we consider cases that brought about the ethical debate in research ethics, we can also see this shift. Classic cases that prompted the need for research ethics were basically infamous situations mainly taking place in industrialized countries. Such cases were unthinkable abuses of prisoners during World War II. Experiments were perpetrated during the wartime by the Nazis. (Annas and Grodin 1992). Variations of these kinds of abuses in times of peace and prosperity are the cases that were conducted during the so-called 'gilded age of research' in the United States. These cases were revealed by the anesthesiologist Henry Beecher in 1966. For example, in a study about cancer immunity live cancer cells were injected into twenty-two human subjects as part of a study of immunity to cancer. According to a recent review, the subjects (hospitalized patients) were 'merely told they would be receiving "some cells"—...the word cancer was entirely omitted' (Rothman 1991). All of these cases risked the lives and health of the individuals without their consent or approval. Beecher reported that only two of the original fifty protocols mentioned obtained consent (Rothman 1991).

Research ethics' response initially focused on informed consent. It assumed that informed consent would protect research subjects. However, informed consent quickly lost its privileged place as the main role in the Nuremberg Code. It was the first article in that document; in the Declaration of Helsinki it was found in Art. I.9 (World Medical Association 1996). Informed consent is unquestionably one of the fundamental factors in research ethics. Based on the principle of respect for persons (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979), it implies the recognition of the autonomy of research subjects and their authorization to participate in a clinical trial.²

However, consent alone cannot serve as the sole condition for acceptable research ethics. Other fundamental elements –even at that time– have begun to play important roles. One is the risk-benefit ratio. Another factor is the need for independent review, for example, through research ethics committees. At that time, there seemed to be a consensus on how to

² Note, however, that despite the long tradition in implementing informed consent, it still poses problems. For example, we have to consider the amount and kind of information that must be presented (some consents appear to overwhelm the research subjects rather than inform them). Respect for voluntariness appears to escape the rules in the cases of research subjects who are so needy that the trial is their only access to treatment; or in the cases of rural or very isolated communities where certain members have no decision-making power, for example, women.

protect a research subject (Luna, in press B) based on the experience of industrialized countries. There was a great emphasis on informed consent and other safeguards that tried to complement and strengthen the process.

Recent cases are related to research in developing countries. In late 1997 and 1998 a fierce international polemic followed controversial placebo use in pregnant women with AIDS (Lurie and Wolfe 1997; Angell 1997; Varmus and Satcher 1997; Mbide 1998). The studies were conducted in Sub-Saharan Africa, Thailand, and the Dominican Republic. The purpose was to find a more economic and effective treatment to prevent the vertical transmission of AIDS. The study proposed giving pregnant women short AZT treatments against placebo. The problem arose for an effective treatment had already been available since 1994. The original controversy focused on use of placebo with the control group and further questioned the ethics of withholding proven treatment in clinical trials (Schüklenk 1998, Luna, 2001 B).

In February 2001, the FDA seriously considered approving the design of a test for Surfaxin to be conducted in Ecuador, Bolivia, Peru, and Mexico. It proposed a control group of 325 premature newborn children with Respiratory Distress Syndrome (RDS). This potentially fatal condition was to be treated with placebo while other surfactants existed. These surfactants had FDA approval and could save their lives (Lurie and Wolfe, 2001). More questionable yet was the fact that the same laboratory was seeking approval for the drug in a European trial in which the children would not receive placebo but an FDA-approved surfactant.(Luna, in press B)

The main problem in these cases was not informed consent. With the increase of research in developing countries, new issues have become the focus of international debate: standard of care, placebo use, analyses about the obligations during the trials and once they have concluded, about the vulnerability of some populations, or about access to the benefits of the research. All these issues are clearly related to the question of justice.

Undoubtedly research in developing countries generates new problems and discussions. We can see how the current analysis brought forward by developing countries goes far beyond informed consent, as well as beyond the first framework of early ethical safeguards. Informed consent is a necessary condition for research, but it is not sufficient. Developing countries' problems show that ethics does not end with the acceptance of a contract –such as some conceptualizations of informed consent seem to imply- (Luna, 2001 A). The conditions under which it is accepted are also relevant. Individuals with no other choice may find it difficult to refuse to participate in research. They are not acting as contractors, and they may reflect the characteristics of “victim”. The situation of the Swedish research subject, who enjoys a public, efficient, and accessible healthcare system, is a far cry from the subject in Mozambique or in Bolivia, who has no access to vital medication. It is not enough just to have a clear initial contract. A clear initial contract is merely a first step, other substantial issues should be considered: obligations to research subjects during and after research, and the benefit to the populations.

The problems associated with increased research in developing countries have not been solved. They are difficult and complex. In the past, vulnerability, exploitation, and justice were not perceived in their true

dimension. At present, they cannot be ignored and they imply new challenges. I think bioethics is heading in that direction. Part of the task of bioethics today is to avoid the moral and legal validation of unfortunate burdens on the vulnerable populations of the world. It seems that the first concerns of bioethics are –even if not fully solved- far from these other new challenges.

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