

Reproductive Health and Research Ethics: Hot Issues in Argentina

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In this article I focus on two issues concerning bioethics in Argentina: reproductive health and ethics in research. Although these topics are quite dissimilar, they share a particular feature: their special relationship with context.

Argentina is a multifaceted and paradoxical South American country whose population is basically of European descent. It has a history of good public healthcare and education, and it can boast several Nobel Prize winners in science. Laboratories are working on new trends in genetic research and have managed to clone cows with special milk. Sophisticated medical technologies—from organ transplantations and assisted reproductive technologies (ART) to genetic and preimplantary testing—are quick to be adopted. The 2002 Human Development Index ranked Argentina thirty-fourth among the countries with the highest levels of human development. The same report points out that the 2000 survey shows a life expectancy of 73.4 years and a literacy rate of 96.8.

However, Argentina is a developing country. The report also reveals that the percentage of the population with ameliorated water is 79%, and the percentage of the population with access to essential drugs is between 50% and 79% (prior to the 2001 economic crisis). Hence, there are and had been wide gaps in and between the social classes, and the 2001 economic crisis deepened these gaps even further. According to a new United Nations report, indicators from 1999 to 2002 in Argentina's urban areas show that poverty rates almost doubled, going from 23.7% to 45.4%, and indigence grew threefold, from 6.7% to 20.9%.¹ The economic crisis devastated our traditionally large middle class and left the country poorer. Malnutrition and poverty are now part of our everyday life. Against this backdrop we face another factor: the Catholic Church and its strong political power. It shapes nearly all regulations and laws regarding sexual and reproductive rights, which institute a highly conservative legal framework with dramatic consequences on public health.

In this report I focus on these contextual factors and related bioethical concerns. Reproductive issues are associated with a lack of respect for women's rights and the broad political influence of the Roman Catholic Church. Many of the concerns over research ethics are related to the environment within which research is conducted: poverty and the possibility of exploitation.

Reproductive issues and ethics in research are hot topics in Argentina, though their impacts and the areas of discussion are quite different. Whereas the first—reproductive rights—implies legislation, public policies, and a public debate, the second—research ethics—has had a narrower discussion, mainly within academic and scientific circles. Both topics have generated literature,

workshops, and training. In this brief report I present some of the issues under discussion, their link to the context, and the activities that have ensued.

Reproductive Issues

I first consider some of the relevant problems concerning reproductive health, illustrating the strong barriers established by the Catholic Church and how embryo protection has restricted basic reproductive rights and led to high levels of hypocrisy and some absurd practices. I will focus on three points: (1) the lack of respect for reproductive rights and the first attempt to reverse some of these omissions; (2) the restrictive abortion laws and their consequences on pregnancies, for example, with the anencephalic fetus; and, (3) the incoherence of adopting techniques like preimplantatory genetic diagnosis or ART and of maintaining specific conceptions of embryos.

Contraception

The teachings of the Catholic Church are present throughout most of the legal framework. However, there is also the practice of a “double moral standard.” One thing is what religion says; another is what people do. The great majority of the population have had a Catholic upbringing (84.4% claim to be Catholic) but do not follow Catholic teachings. Nor are they truly devout. Abortion laws are highly restrictive. However, illegal abortions are carried out continuously. In Argentina, between 450,000 to 500,000 illegal abortions are performed every year. The problem with this double moral standard is how it impacts the vulnerable population, especially poor women and teenagers.

Forty-five percent of the beds in obstetric wards in public hospitals are occupied by women with postabortion problems. In fact, complications due to illegal abortions are the main cause of maternal death. The WHO indicates that Argentina has 38 maternal deaths per 100,000 live births, whereas Canada, for instance, has 4 per 100,000. Argentina does not fare well even when compared to Chile, 21/100,000, or Uruguay, 23/100,000. In some provinces of northern Argentina, the situation is even worse: Formosa shows 177/100,000.

Another pressing issue is the matter of teenage pregnancies. They are on the rise at a rate of 20% of all live births. In the city of Rosario, 30% of the deliveries occur with girls under age 19, and a high percentage are single mothers. Additionally, babies born to mothers under 15 years of age suffered double the average mortality rate.²

With respect to this dramatic public health situation, this is the first time that a political power such as the Ministry of Health has explicitly acknowledged the lack of reproductive rights as a problem. Consider that until 2003 no national law existed concerning sexual and reproductive rights. Law 25,673 created a national program that stipulated the provision of contraceptives in public hospitals, as well as the provision of information about sexual education, and the diagnosis and treatment of sexually transmitted diseases and ovarian and breast cancers. However, the proposal of the program generated strong criticisms from the Catholic Church. A prolife nongovernmental organization (NGO) interfered legally and obtained a judge’s support. Her extreme position reached the point that she tried to forbid all use and sale of contraceptives, even in cases of medical use for gynecological and fertility problems.

Although the case underwent various legal steps, it nevertheless could not stop the program.

Note that this is a program for reproductive health and responsible procreation—basic issues for a healthy reproductive life. It is one of the paths toward preventing abortions. It offers choices regarding when to have a child and helps prevent sexually transmitted diseases that in many cases cause secondary infertility. One concern to the Church was the possibility of its providing information to teenagers, so they opposed it on grounds of *patria potestas* or parental authority. What this legal battle did achieve was to foster a discussion in the media and bring about an awareness of the problems involved. However, this was merely the tip of the iceberg, and the polemic and legal barriers that arose illustrate how difficult it is to legislate this area in Argentina.

Abortion and the Anencephalic Fetus

If we consider abortion and its impact on certain problematic cases, here too we find problems concerning the position of the Catholic Church. The restrictive abortion laws have consequences on pregnancies, for example, with anencephalic fetuses.

In Argentina, Article 86 of the Penal Code bans abortion. Exceptions are considered ambiguous by many judges. There are three exceptions: (1) when the mother's health and life are in danger, (2) when the pregnancy is the consequence of rape, and (3) when the pregnancy is the result of a dishonest act on a demented woman. However, the current interpretation reads the exceptions as only two: the first rarely considers the mother's health and only a life-threatening condition is grounds for abortion; the second conflates the second and third exceptions and accepts abortion only when a demented woman is the victim of rape.

However, not even these extreme exceptions are respected. What is worse, physicians at public hospitals choose not to perform these accepted abortions³ and petition a judicial authorization even when the law does not require it. While judges and physicians deny their responsibility and refuse to perform the requested abortion, the pregnancy continues.

Cases of fetuses with serious genetic problems or illnesses that will result in the death of the newborn are ignored. During the past few years, some cases of anencephalic-fetus pregnancies have been taken up by the media. Women or couples wanting to end such pregnancies face endless legal battles. Because of these cases, legislation was passed for the City of Buenos Aires (the most "progressive" part of Argentina). This law sanctions an "early delivery" in cases of anencephalic fetuses or any analogous condition that is incompatible with life, only if viable after 24 gestational weeks.⁴

Note that the law does not speak of "abortion" but of "early deliveries." In no way does this legislation open the door to "eugenic/genetic abortions." Moreover, consider that this law is not a fitting solution: a woman may be diagnosed at week 16 or even earlier. Under this law, however she has to wait two painful months with the physical, psychological, and emotional costs this may imply.

However, the worst aspect of this law is that it impedes a better solution. If the three exceptions of the penal code are to be seriously and correctly interpreted, this is a case of nonpunitive abortion. It is implicit in the first

exception. If we consider health not only as merely biological functions but also psychological ones, a woman who does not wish to carry out the pregnancy of a deformed fetus that will die immediately upon delivery may have to endure great psychological suffering. This embraces the correct application of the first exception, owing to the psychological harm such a pregnancy can inflict on the woman. According to this interpretation, there is no need to wait until week 24. In fact, this was the position of the Ombudsman of the City of Buenos Aires, who participated in the legal resolution of several of these cases. Hence, even if the law was an attempt at a first step with the best of intentions, it fell short.

Embryos and Assisted Reproductive Technologies

The same pattern occurs in a related arena, ART. Religious background appears to play a role in the provision of treatment, as well as in treatment-seeking behavior. Embryos are considered “persons,” which, in turn, leads to problems with their manipulation. However, Argentina counts with quite sophisticated centers. These centers manipulate embryos—creating, selecting, and cryopreserving them. As no law regulates these practices, these centers face no legal impediments. However, because they do not wish to alter the status quo, or the approval and perception of their activities, they may ultimately prioritize embryos over the well-being of the woman and may limit the options a woman or a couple is offered.

Even if the importance and beneficial aspects of cryopreservation are recognized,⁵ Argentine ART centers limit the number of embryos that can be frozen. Hence, women may have to submit more frequently to hormones and medication, with their associated inconveniences and harms. There is an ongoing trend by which centers are cryopreserving fewer embryos.⁶ No option for discarding embryos is offered, and the *only* alternative available—when a person does not choose to transfer the remaining embryos to herself—is to donate the embryos to another couple. This “compulsive donation” is quite a strong obligation and can also have disturbing psychological effects. It may prove to be especially painful when the donor cannot achieve pregnancy.

A second consideration arises with the practice of “embryo donation” and its current denotation. Terminology carries weight; it implies a particular way of understanding facts. The term “prenatal adoption” is deceptive and conveys the idea of an “actual adoption.” It is not a neutral term, much less so in a region where embryos are sometimes more protected than women. I will not enter here into the controversy regarding the ontological or ethical status of embryos. However, with the current denotation, embryos are treated as “orphans,” an analogy that leads to paradoxes. If we were to grant embryos the condition of persons, the whole process of cryopreservation would, at least, be odd—how could we freeze persons? Moreover, *in vitro* fertilization could be seen as a massacre, owing to the losses of embryos when transferring them to the woman’s uterus. Additionally, the same practice of giving them up for adoption (with the obvious intention of protecting them) may imply their death and destruction.⁷

Another problem relates to the embryo’s health status and the prohibition against discarding embryos. Whereas the International Federation of Fertility Societies encourages screening for serious diseases that would be a potential

threat to the potential child's health,⁸ the majority of Argentine ART centers reject the discarding of embryos. However, genetic testing is offered.

This poses a paradox. Even if embryos are tested and proven to be genetically abnormal or to have severe genetic problems, they "must" be transferred (because they cannot be discarded). This transfer leads to the nightmare of a woman who has to accept the transference of an embryo and pregnancy with the knowledge that her future offspring will carry a serious or even fatal illness.⁹

Hence, if this conservative framework is to be followed, preimplantary prenatal diagnosis should be banned, and this might be harmful to the couple and the future offspring, especially if they are undergoing these procedures to avoid transmitting a genetic disease. Or, conversely, a preimplantary prenatal diagnosis could be made and embryos with genetic problems discarded. However, this is an option the majority of fertility centers deny doing—another example of hypocrisy and double standards, not to mention possible harm to the couple or the offspring, because of the embryo's status in the culture. The practical solution that many centers are finding is simply to avoid the problem and freeze the genetically disabled embryos. Instead of confronting the problems and paradoxes that an extreme respect for the embryos poses, ART centers and physicians ignore the issue and conceal the problem. The pattern of hypocrisy and double moral standards is once again replicated.

Latin America, Argentina, and Research Ethics

Research ethics is another heated topic in Argentina and Latin America. I focus here on the recent debates about the Helsinki Declaration and the proposal of amendments.

After the 2001 economic crisis, Argentina's health situation deteriorated dramatically. Public hospitals were in higher demand, and drugs and basic items were practically nonexistent. For many people, participation in a research protocol was their only chance to acquire a needed drug.

Meanwhile, since 1997, strong debates have arisen in the international research setting. Controversial clinical cases, such as Zidovudine (AZT) trials with pregnant women in Africa, have triggered different initiatives to change ethical codes. Since then, important ethical documents have come under scrutiny. For example, the Helsinki Declaration was updated after a series of discussions and disputes.

The two main points in the controversy over ethical codes, at that time, were the standard of care during the trial and the use of placebos. That is, what are research subjects entitled to during research, and what is the adequate comparator in a clinical research trial? The first issue considered (1) a single- versus double-standard discussion and (2) the level of treatment to be offered in a research trial (e.g., best proven, highest attainable and sustainable, standard of care, proven effective).

This discussion took place mainly during the redrafting of the Helsinki Declaration. At that time, different proposals were presented.¹⁰ The final version (Helsinki, 2000) in its "renowned" paragraph 29 refers to "the *best current* prophylactic, diagnostic, or therapeutic methods" endorsing a single standard.¹¹

Details about this controversy, which have been examined thoroughly, go beyond this article.¹² What I would like to point out is how various developing

countries reacted to this proposal and how Argentina participates in this context. When this discussion arose, UNAIDS conducted workshops regarding ethical issues of the human immunodeficiency virus (HIV) vaccine in Thailand, Uganda, and Brazil, and UNAIDS regional groups discussed the issues with great dissidence and controversy. For example, Thailand considered it acceptable not to offer antiretroviral treatment. The country said that the treatment of research subjects who became infected during the research (but not as a result of the research) was to be consistent with that of the rest of the country. There was no healthcare requirement like the one proposed by the sponsoring country. Uganda indicated difficulties in establishing the level of treatment to be given to their research subjects, but ultimately decided not to give antiretroviral treatment. It claimed that some treatment should be offered but the sponsoring country should decide on the appropriate kind and level of the treatment. It could include immune monitoring, physicians' visits, prevention and treatment of infections, and palliative treatment but not necessarily antiretroviral therapy.

In contrast, Brazil claimed it was unacceptable to not offer antiretroviral treatment and rejected not treating research subjects. It stated that infected participants should be treated like those in the sponsoring country. This was later backed by a resolution of Brazil's National Council of Health.¹³

UNAIDS reveals significant differences in the way the developing countries are trying to resolve the issue. Brazil strongly resisted and prioritized the condition of the research subjects. Thailand or Uganda privileged the urgency of the researchers and sponsors. Leaving the decision in the hands of the individual countries can also prove problematic. Social pressure and the lack of resources may force countries to accept disadvantaged positions, as Thailand and Uganda did.

At that time, Brazil took the lead in the region with the Resolution of their National Council. Argentina, as a country, did not take a stance. The standard of care and the placebo debate, at that time, was of personal concern to the author (having been invited to some of the international forums such as the CIOMS redrafting) rather than being a public or even academic debate. Even if justified exceptions might exist, I endorsed the region's position. I considered that, given the commercialization of drug research and socioeconomic problems, a double standard might be very dangerous. It could and can open the door to abusive research.¹⁴

The second point—use of placebos—was explicit, for the first time, in the latest version of the Helsinki Declaration (section 29). So strong were the debates and criticisms over the use of placebos in the Helsinki Declaration that the World Medical Association (WMA) issued a Note of Clarification in October 2001.

Months earlier, in February 2001, the Food and Drug Administration (FDA) had seriously been considering endorsing the design of a Surfaxin trial in Ecuador, Bolivia, Peru, and Mexico. This study proposed a control group of 325 premature newborn infants with potentially fatal respiratory distress syndrome (RDS) to be treated with placebos instead of a lifesaving and already FDA-approved surfactant drug.¹⁵ This study would have meant accepting the preventable death of 17 infants.¹⁶ Even more questionable was the fact that the same manufacturer was seeking approval for this drug in Europe, where infants would not be under placebo but would receive an FDA-approved surfactant drug.

The Surfaxin proposal was viewed as completely unethical by the majority of Latin America. It was considered to repeat a well-known pattern in the region: exploitative and abusive behavior.

The Note of Clarification of section 29 of the Helsinki Declaration has two clauses. If we require and consider only “compelling sound methodological reasons” (the first clause), the flexible use of placebos might be very dangerous mainly in resource poor countries. The main and truly relevant clause is the second one: It considers the use of placebos “for a minor condition and where the patients who receive placebo will not be subject to any *additional risk or serious or irreversible harm*.”¹⁷ This allows placebo use in studies with some analgesics, hypnotics, antihistamines, antiemetics, *provided that the condition is minor and will not entail additional risk or serious or irreversible harm*, for example, a temporary discomfort. However, no placebo is acceptable in the case of antiemetic drugs in a chemotherapy treatment. The second clause’s flexibility will allow for cases that are often deemed important,¹⁸ such as mild hypertension. It accepts the use of add-on treatments because it does not deny the research subject’s treatment. It implies close monitoring, adequate end points, rescue treatments, and so on.

The first and second clauses should be respected simultaneously—an issue that the Note of Clarification, unfortunately, does not require. In this sense, it was widely felt in Latin America that the Note of Clarification was problematic for developing countries and that it would not preclude abusive research like the proposed surfactant study.

As the international debate increased, Argentina’s awareness also grew. In contrast to other debates such as the standard of care and even the placebo debate, the latest attempt to amend the Helsinki Declaration raised concern in the academic and medical communities. In this case the discussion focused on the 2003 attempt to amend section 30. It covered new issues such as the posttrial obligations (though some people confused this with the double-standard debate). Argentina’s position, and the region’s, called for caution and a wider presence of developing countries. It was felt that they should have a voice in this international discussion.

This interest in and impetus on research ethics has had many manifestations in Argentina. Since 2000, a Fogarty Training Program has begun. It was originally intended as a collaborative effort to be conducted six months in New York and six months in Buenos Aires. It is now being fully conducted in Buenos Aires and has had its second year of trainees. There has also been networking, not only in the region, but also within Argentina, and this has led to the creation of an Argentine chapter of FLACEIS (a Latin American network of research ethics committees created in Mexico in 2000). Additionally, *Perspectivas Bioéticas*, the first Argentine journal wholly devoted to bioethics is preparing a special monographic issue on research ethics and on the recent debates. There have also been governmental initiatives, such as the creation of a Central Research Ethics Committee of the City of Buenos Aires that will have a voice in all public hospitals of the City of Buenos Aires (where most research in Argentina is conducted). The Ombudsman Agency of the City of Buenos Aires has made a survey regarding the situation of research ethics committees and is counseling the Ministry of Health about these organizations. The National Regulatory Agency, ANMAT, is preparing a new regulation with stringent ethical requirements. They are also trying to implement inspections of the

research ethics committees. Also, multiple seminars and workshops are being held (e.g., FLENI, University of Buenos Aires School of Medicine). Undoubtedly, research ethics is one of the relevant topics and one of the main concerns in Argentina today.

Notes

1. Economic Commission for Latin America and the Caribbean (ECLAC). Social Panorama of Latin America. Available at: <http://www.eclac.cl>.
2. Reporte Sombra on the Third Report by Argentina before the Human Rights Committee.
3. An example of the lack of respect of the accepted exceptions even within the more conservative framework is the dramatic case of a demented girl of 13 who had been raped but was denied an abortion in a public hospital.
4. Law 1,044.
5. Latin American Network for Assisted Reproduction. *Consenso Latinoamericano en aspectos ético-legales relativos a las técnicas en reproducción asistida*. Reñaca, Chile: ; 1996:13–7.
6. Personal conversations with directors of Argentine fertility centers.
7. Luna F. Assisted reproductive technology in Latin America: some ethical and socio-cultural issues. In: Vayena E, Rowe P, Griffin D, ed. *Current Practices and Controversies in Assisted Reproduction*. Geneva: World Health Organization; 2002:31–41.
8. Jones H, Cohen J. Surveillance 1998. *Fertility and Sterility* 1999;71(6):S18.
9. Also at stake here is the physician's responsibility and the couple or woman who is denied rights. A number of thorny questions arise: Can we knowingly seek a pregnancy resulting in a handicapped or severely ill offspring? What are our responsibilities toward this future human being? Should we avoid bringing "evitable suffering" into the world?
10. For details, see: Luna F. Is "best proven" a useless criterion? *Bioethics* 2001;15(4):273–88.
11. World Medical Association. *Declaration of Helsinki*. Edinburgh, Scotland. Oct 2000:section 29 (emphasis added).
12. See note 10, Luna 2001.
13. Conselho Nacional de Saúde (Brazil). Resolucao N 301 (16 Mar 2000).
14. See note 10, Luna 2001.
15. Lurie P, Wolfe S. Request to the Department of Health and Human Services to halt plans for unethical placebo-controlled study of drug for respiratory distress syndrome in Latin America unless it is redesigned to treat all patients: HRG publication 1558. 22 Feb 2001. Available at: <http://www.citizen.org/publications/release.cfm>.
16. This drug is shown to reduce neonatal mortality by 34%. See note 15, Lurie, Wolfe 2001.
17. World Medical Association. *Declaration of Helsinki: Note of clarification on placebo-controlled trials*. Edinburgh, Scotland. October 2000 (emphasis added).
18. Levine R. The need to revise the Declaration of Helsinki. *New England Journal of Medicine* 1999;341(7):531–4.