

Université de Montréal

Analysis of the Ethical, Social and Legal Issues Related to the Delivery of the
Prenatal Genetic Testing in Argentina

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Abstract

The introduction of new biotechnologies in any health care system is a complex process that is closely tied to economic, political and cultural factors and thus poses a host of challenging social and ethical issues. In the particular situation of Argentina – that is, a country characterised by significant social inequalities between citizens, a scarcity of resources in health care, limited access to needed services, and a lack of specific health policies – the introduction of new genetic technologies poses serious ethical and policy challenges that need urgent attention by policy-makers. This project examines the case of prenatal genetic tests in the context of the Argentinean health care system with the aim of illustrating how complex their introduction can be in a nation where equal access to health care still needs significant improvements. Attention must also be given to the legal restrictions and religious precepts that strongly shape the use of these technologies. This further highlights the necessity of developing an integrated framework for the process of technology assessment, in order to support coherent and innovative policy recommendations applicable to the particular Argentinean context.

Keywords

Genetics, prenatal tests, health technology assessment, bioethics, policy, Argentina

Résumé

L'introduction de nouvelles biotechnologies dans tout système de soins de santé est un processus complexe qui est étroitement lié aux facteurs économiques, politiques et culturels, et, par conséquent, demande de remettre en cause plusieurs questions sociales et éthiques. Dans la situation particulière de l'Argentine - c'est-à-dire: de grandes inégalités sociales entre les citoyens, la rareté des ressources sanitaires, l'accès limité aux services de base, l'absence de politiques spécifiques - l'introduction de technologies génétiques pose de sérieux défis qui doivent impérativement être abordés par les décideurs politiques. Ce projet examine le cas des tests génétiques prénataux dans le contexte du système de santé argentin pour illustrer comment leur introduction peut être complexe dans une nation où l'accès égale aux services de santé doit encore être amélioré. Il faut également examiner les restrictions légales et les préceptes religieux qui influencent l'utilisation des technologies génétiques, ce qui souligne la nécessité de développer un cadre de référence intégral pour le processus d'évaluation des technologies afin d'appuyer l'élaboration de recommandations pour des politiques cohérentes et novatrices applicables au contexte particulier de l'Argentine.

Mots-clés

Génétique, tests prénataux, évaluation des technologies de la santé, bioéthique, politiques, Argentine

Resumen

La introducción de nuevas biotecnologías en cualquier sistema de salud es un proceso muy complejo, el cual está estrechamente vinculado a factores económicos, políticos y culturales, y por lo tanto plantea toda una serie de desafíos y cuestiones ético-sociales. En la situación particular de la Argentina - esto es: la existencia de profundas desigualdades sociales entre los ciudadanos, la escasez de recursos en salud, el acceso limitado a servicios básicos, la inexistencia de políticas específicas, etc. - la introducción de tecnologías genéticas plantea serios retos los cuales necesitan urgentemente ser abordados por los responsables de diseñar políticas. En este trabajo se examina el caso de las pruebas genéticas prenatales en el contexto del sistema de salud argentino con el ánimo de ilustrar cuán compleja puede ser su introducción en una nación donde el acceso igualitario a los servicios de salud necesita todavía ser mejorado. Asimismo, deben examinarse las restricciones legales y los preceptos religiosos que influyen en la utilización de las tecnologías genéticas, todo lo cual hace necesario el desarrollo de un marco integral para el proceso de evaluación de tecnologías, con la finalidad de elaborar recomendaciones que contribuyan al diseño de políticas coherentes e innovadoras, aplicables al particular contexto de la Argentina.

Palabras clave

Genética, pruebas prenatales, evaluación de tecnologías sanitarias, bioética, políticas, Argentina

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List of Abbreviations

AETMIS	Agence d'évaluation de technologies et de modes d'intervention en santé
CENAGEM	Centro Nacional de Genética Médica
CHSRF	Canadian Human Sciences Research Foundation
CORD	Canadian Organization for Rare Disorders
DNA	Deoxyribonucleic Acid
ELSI	Ethical, Legal and Social Issues
EURASSES	Europe Assessment
FISH	Fluorescence in Situ Hybridization
FLACSO	Facultad Latinoamericana de Ciencias Sociales
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
IECS	Instituto de Efectividad Clínica y Sanitaria
IMF	International Monetary Fund
INAHTA	International Network Association in Health Technology Assessment
MSSS	Ministère de santé et des services sociaux
OTA	Office of Technology Assessment
PAHO	Pan American Health Organisation
PGD	Prenatal Genetic Diagnosis
PGT	Prenatal Genetic Tests
PMO	Programa Médico Obligatorio
UBA	Universidad de Buenos Aires
UNLP	Universidad Nacional de La Plata
WHO	World Health Organisation

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INTRODUCTION

CONTEXT

A wide array of genetic technologies is becoming available in both developed and developing nations. This situation is the cause of growing concern for health policy makers, who must evaluate the utility of these and other health technologies for inclusion in public health programs. Ideally, these policy makers would have the information necessary to rationally allocate scarce resources, prioritise technologies, and ensure fair access to necessary health care services. The reality, however, is that policy makers often do not have such information. In Latin America, and for my purposes Argentina, prenatal genetic tests (PGT) are a good example of a health technology that poses serious social and ethical challenges for policy makers. There is growing public demand for access at the same time that there are ongoing debates about the morality of assisted reproductive technologies, and concerns about the fair distribution of health care resources in a developing country where many people lack access to even basic health care services. In this situation, I argue that the field of health technology assessment (HTA), through the integration of ethical analyses, can provide an integrated framework for Argentinean policy makers to better assess and balance these various concerns. That is, an “ethical HTA” can help to clarify the importance and utility of new technologies, and so play a critical role in the “effective management” of modern health care systems (Hofmann, 2005 a).

ARGENTINEAN SOCIETY: A BRIEF PORTRAIT

The strong European immigration that took place at the end of 19th and beginning of 20th Centuries has left indelible marks on Argentinean society, not only in terms of language (Spanish) or architecture style, but also in terms of culture and social values. For example, as part of the Italian legacy, family ties are very close and friendship is highly valued; European influences are also evident in Argentinean legislation (e.g., the National Civil Code was inspired by the French Napoleonic Code). Catholicism is still the most representative religion in Argentina, and the Church exercises a strong influence over civil society, but also over the government; until it was amended in 1994, the National Constitution required that the President and Vice-president be practicing Catholics.

These European influences have shaped in important ways contemporary Argentinean society's approach to delicate matters related to reproductive health, such as contraception, abortion and the use of reproductive technologies and prenatal tests. Yet, only 20% of the current population of more than 38 million (WHO, 2005) claim to be practicing Catholics, and despite the apparent public prominence of Catholicism in terms of expressed social and family values, Argentina's birth rate – estimated in 2007 at 16.53 per 1000 (CIA World Fact Book, 2007) – is the lowest in Latin America. The total fertility rate for 2000 to 2005 was 2.4 births per woman (United Nations, 2007), thus following similar patterns in many European and North American countries. Paradoxically, there are still serious difficulties with debating these subjects in

public, even when some issues such as unsafe abortion have become a matter of public health concern that need to be urgently addressed; in Argentina, clandestine abortions are one of the most important factors implicated in maternal mortality (Luna, 2006; Penschaszadeh, 2009). As will be explained further, these kinds of paradox are reflected in the delivery of health services, resulting in profound inequities and inequalities, particularly with regards to access to sophisticated technologies such as prenatal genetic tests.

THE HEALTH CARE SYSTEM

In Argentina, the right to equal access to health care is recognised by the National Constitution following the 1994 reform¹. Despite such recognition, many people still experience difficulty in accessing needed health care services; the economic and social inequalities present in Argentinean society are clearly reflected in the way that its citizens access health care, and in the manner that services are provided. To better illustrate the nature of such inequalities, a detailed description of Argentina's intricate and complex health care system is necessary.

¹In the Argentinean National Constitution, Article 42 explicitly recognises health related to consumers' rights to public services; article 75 section 22 incorporates many International Covenants that Argentina has signed in which the access to health care is considered a fundamental human right. These Treaties have Constitutional authority and therefore they have supremacy over domestic laws: American Declaration of the Rights and Duties of Man (OAS 1948), Universal Declaration of Human Rights (OAS 1948), American Convention on Human Rights, Pact of San José Costa Rica, International Pact on Economic, Social and Cultural Rights, International Covenant on Civil and Political Rights, Optional Protocol to the Covenant on Civil and Political Rights, Convention on the Prevention and Punishment of the Crime of Genocide Convention on the Elimination of All Forms of Racial Discrimination, Convention on the Elimination of All Forms of Discrimination against Women, Convention against torture and other cruel, inhuman or degrading, the Convention on the Rights of the Child, Declaration of children's rights.

Since its very beginning, the provision of health insurance and delivery of health care services in Argentina has been fragmented and heterogeneous, and closely related to labour unions (Belmartino, 2001). During the first period of immigration in the 19th Century, each community of immigrants (Spaniards, Italians, French, etc.) provided health care to its members through communitarian organizations called “mutual societies”, based on member solidarity and contribution to a central fund to help those in need. These European immigrants also brought with them ideals about the importance of social insurance that were in “vogue” in their home countries (Shield, 2003). So it was the various labour organizations (*sindicatos*) – metallurgy workers, farmers, teachers, the army, etc. – that, at the beginning of the 20th Century, created a system of social security for the country. Each *sindicato* was charged to collect money from its workers and employers in order to contract health services for their employees and their families (Shield, 2003).

It was only in 1943, with the creation of the Department of National Hygiene (today the National Health Ministry), that public health was recognized as specific matter for government involvement in Argentina; so a public health care system was created, based on the ideal of free and universal access to services (Tobar, 2001). Between 1945 and 1955, a strong social policy was implemented under Juan Peron’s first government, and access to health care came to be recognized as a public value and a basic civil right. An extensive network of public hospitals was established during the 1940s, financed through general taxation (Belmartino, 2001; Tobar, 2001). The social security sector

was also strengthened with the creation of the *obras sociales* which functioned as health insurance funds and were administered by their respective labour unions (*sindicatos*). Later, in the 1950s, a private health care sector also emerged and expanded greatly. The Argentine health care system thus has three main components: the public health sub-sector, the social security sub-sector and the private sub-sector (Belmartino, 2001).

a) The public sub-sector

The public sub-sector is co-managed by the national, provincial and municipal governments. It includes universal health insurance – similar to that which exists in Canada – and is made up of approximately 1200 state hospitals and 600 medical clinics that provide a wide range of services, ranging from primary care (e.g., family and preventative medicine), to technologically complex interventions (e.g., haemodialysis and organ transplantation). This sub-sector is financed from general tax revenues, although funding has decreased dramatically in recent years due to the profound economic crises of 2001². Public hospitals are the only facilities accessible to the lower socio-economic classes and the unemployed, and serve the 12 million Argentines (approximately one third of the country's population) who are not insured by

²At the end of 2001, Argentina suffered one of the worst (if not the worst) economic crises in its history. In January 2002 the Argentinean situation at all levels – social, political and institutional – was in utter disarray: the currency was devaluated by 80%, many banks closed, the government defaulted on its international debts, the budgets of all state areas (education, health care services, public infrastructure) were drastically reduced; the unemployment rate grew rapidly to 20.7% putting 57% of the population into poverty. For a detailed description of the situation see: International Monetary Fund, Executive Board Concludes 2006 Article IV Consultation with Argentina, Public Information Notice (PIN) No. 06/93 available at: http://www.imf.org/external/np/sec/pn/2006/pn0693.htm#P30_355

their employers (Acuña and Chudnovsky, 2002) or do not have private insurance. However, people insured by *obras sociales* (social security) and private health plans can also access public services for free since the public sub-sector is accessible to the entire Argentinean population.

b) The social security sub-sector (*Obras sociales*)

The social security sub-sector is composed of the *obras sociales* which play the role of health insurance funds for workers and their families. Funded by mandatory contributions from workers and employers, the *obras* have been controlled and administrated by the labour unions which provide health care to their beneficiaries: the “blue-collar workers, employees and retired persons” (Penchaszadeh, 2009) access health care services through their own service providers, but also through facilities and services contracted from private service providers. However, the political nature and interests of the labour unions, and by extension the *obras*, combined with a lack of transparency in their administration (Moyano and Escudero, 2005), led to decisions that did not necessarily or always promote the general welfare of their members. For example, the monies collected from contributors were often employed to fund travel for retired people or to maintain privileges of the labour unions’ leaders (Belmartino, 2001).

c) The private sub-sector

The private sub-sector is made up of private health insurance organizations known as *empresas de medicina pre-paga* (pre-paid medicine companies), for-profit institutions that contract private services to cover their clients in exchange for a monthly fee (although some also operate their own facilities). But this sub-sector also includes private hospitals and physician associations. The *pre-pagas* offer a variety of private health insurance plans with different types of medical coverage, although some minimal services are compulsory (required by the state), as in the case for the *obras sociales*. There are nearly 170 private health care facilities across Argentina, although most are concentrated in the central part of the country. These facilities provide health care services to 8% of the population, that is, to those Argentines belonging to the middle- and upper-income groups of the population who can afford the fees and prefer to pay for private services (Arce, 2003). A primary driver for the purchase of private insurance is that many people consider the private sub-sector to provide higher quality care than that which is available in public facilities (Ucin, 2005).

As de Ortúzar notes (2003), one of the main characteristics defining private health insurance – beyond the ability to pay – is a system based on risk stratification. Private insurance is voluntary, and the fees variable; the cost of a policy will vary according to similarities and differences in a person's health risks. What is problematic with this private model of health insurance, is that the people in most need of health care are often excluded from coverage, not only

based on ability to pay, but also because they are considered “at too high risk” (de Ortúzar, 2003).

Financing

During the second half of the 20th Century, Argentina became a victim of successive internal economic and political crises, including the worst dictatorship in Argentina’s history (1976-1983)³. This turmoil resulted in profound institutional decadence, evidenced by inefficiency and corruption in all sectors of government, which was particularly noticeable in the organisation of the health care system and delivery of services. Since the 1960s, public health expenditure has been severely constrained which resulted in a failure in upkeep of public facilities and massive inefficiency (Shield, 2003). Simultaneously, as Belmartino argues (2001), the expansion of the *obras sociales* and the private sector has further deepened the inequities in access to and provision of services among the different sub-sectors of the health care system.

During the 1990’s, as a part of reforms introduced into the health care system, the *Programa Médico Obligatorio* (Mandatory Medical Program, PMO)⁴, was created to ensure that all employees covered by the social security system received a minimum set of health benefits, including basic primary care,

³Between 1976 and 1983, tens of thousands of people disappeared (*los desaparecidos*). This period known as the national reorganisation process (*Proceso de Reorganización Nacional*) was characterized by political repression and murder of many people that opposed the military government. During those years, appalling civil and human rights violations occurred: the National Constitution was suspended and all democratic institutions were suppressed; the trade unions, political parties, professional associations and all public assemblies were prohibited. For more information about this subject, see for example Avery, 2004.

⁴For a detailed information about this program see: República Argentina. Ministerio de Salud y Ambiente, (1996) Programa Médico Obligatorio available at: <http://www.isalud.org/documentacion/PMO2.pdf>.

secondary care (hospital stays), preventative care (e.g., pre- and post-natal care for mothers and children, breast cancer screening), mental health care, rehabilitative care, dental care, medications, palliative care, and also haemodialysis. This program was extended in 1997 to include family medicine as part of primary services (Belmartino, 2001; Shield, 2003). However, with the burden of the economic crisis and growing unemployment, the social security system lost much of its economic base: the *obras sociales* did not have enough revenue to pay for health care staff salaries or all insured health services.

Interdependence of the sub-sectors

Although each sub-sector of the health care system is funded by different sources and managed by different actors, they are still intimately connected. Thus, companies offering private health care services (either as part of pre-paid insurance, or direct purchase), are also some of the most important providers of subcontracted services for the *obras sociales* and the public hospitals. As mentioned previously, people insured by private companies can also access public health care services since these are open and available to the entire population.

There is great diversity in the medical plans offered by the *obras sociales* and private insurance providers: the medical services delivered to the population are heterogeneous, and quality varies substantially depending on the sub-sectors, and even within them. Services are usually very good and waiting times short or nonexistent in the private sector; by contrast, given the

lack of funding in the public sector, not all necessary health care services are offered, they may be of lower quality (e.g., older equipment, lack of supplies), and there are usually very long waiting lists. This then results in an extremely complex and intricate system which fosters many injustices: the wealthy have access to double insurance – i.e., public and private insurance and services – that can allow advantageous selection of service providers and the jumping of waiting lists. For many people, including the most vulnerable, the only access to health care services is through the public sector, which is not always easy, especially for those living in the poorest and most isolated regions of the country.

As already mentioned, the right to equal access to health care was recognised by the National Constitution in 1994; paradoxically, this occurred at the same time that Argentina's government tried to reform the health care system by applying the neoliberal policies of the World Bank and the International Monetary Fund (IMF) (World Bank, 1993). These policies aimed to reduce state funding for public health to a set of "essential clinical services", leaving the rest of medical assistance to be privately financed or covered through social insurance (Bertomeu, 2005; Iriart and Waitzkin, 2006).

Successive governments failed to reverse the situation – that is, heterogeneity in the delivery of services, inefficiency and increasing costs – which worsened significantly during the economic crisis of 2001; in 2009, system organization and rationalization is still urgently needed. The economic crisis had a tremendous impact on the public health sub-sector which was

particularly badly hit due the convergence of many factors: the State was extremely slow in transferring funds to hospitals which became almost completely unable to provide basic services; public hospitals in many areas were forced to close; and physicians and nurses went unpaid for months (Iriart and Waitzkin, 2006; Shield, 2003). In addition, as a result of the monetary devaluation, the costs of medicines and technologies imported from abroad (e.g., diagnostic reagents, disposable materials) increased considerably (Cetrángolo and Devoto, 2003), making their replacement almost impossible. High rates of unemployment reduced contributions to the social security sector, and many people who had private insurance cancelled their plans because they could no longer afford the monthly fees. There was thus a massive transfer of people from others sub-sectors to the public sub-sector, which then found itself completely overburdened (Iriart and Waitzkin, 2006).

In March 2002, with the health care system in almost total collapse, the government was compelled to declare a national sanitary emergency in order to ensure the provision of basic essential medical services to the entire population (República Argentina, *Emergencia Sanitaria Nacional*, Decreto no. 486/02). A basic basket of generic medicines was prepared (around 200) as well as a list of reference prices; drug prices had expanded greatly due to the monetary devaluation (PAHO, 2002). Importantly, the Ministry of Health also announced that it would be necessary to implement a formal process of technology evaluation in order to help rationalise decisions in health care funding and

delivery (República Argentina, *Programa Médico Obligatorio y Evaluación de Tecnologías Sanitarias*, Decreto no. 674/2003).

The health care system's diversification and lack of rationalization are still important challenges in need of resolution, if Argentina is to move towards a more equitable provision of health care services and meet the legal and ethical obligations enshrined in the National Constitution. The case of prenatal genetic testing (PGT) – whether provided through public or private health insurance – will serve as a focus for better understanding how to address these broader economic, social and ethical challenges.

RESEARCH PROBLEM

The use of genetic tests⁵, along with other medical genetics services such as genetic counselling, is spreading rapidly around the world, including to developing nations. In many countries – such as Canada, Australia or Cuba – the majority of people access genetic services through public health care systems, although private purchase is also an option in many jurisdictions. In this thesis, I focus on the case of prenatal genetic testing (PGT) and its introduction into the Argentinean health care system.

Prenatal genetic testing is the class of genetic tests designed to determine or predict whether a fetus has (or is at risk of having) an inherited

⁵Following Williams-Jones (2002), I here define 'genetic testing' as "The analysis of a particular gene in order to provide predictive or pre-symptomatic information – usually for high penetrance genes – about the nature or time of disease onset; or susceptibility information – for genotypes of low penetrance – about the potential or risk of developing a particular disease". This definition includes tests that can determine: carrier status for inherited recessive disorders (e.g.: Cystic fibrosis); for inherited dominant disorders (e.g.: Huntington's disease) and x-linked disorders (e.g.: hemophilia) and also for some inherited adult onset disorders.

disorder or other genetic condition. For the most part, these tests have been conducted following invasive measures such as amniocentesis, although there are emerging and much less invasive technologies that would allow for PGT using maternal blood samples (identification of fetal DNA in maternal blood).

PGT provides information that parents can use to make a decision about whether to continue with or terminate a pregnancy (Penchaszadeh, 2000). While some tests provide information about the risk of a fetus developing a disease later on in life (e.g., for some hereditary cancers), the more established and widespread use is to diagnose a condition or disorder (prenatal genetic diagnosis, or PGD). In addition, genetic tests (whether diagnostic or predictive) are characterized by varying degrees of accuracy (there may be false positive or false negative results) and clinical utility. As such, decisions about their inclusion for coverage in public health insurance programs (which genetic test and for whom?) necessitate both a technical or scientific evaluation, as well as an analysis of the ethical, policy and social implications.

In Argentina, the integration of PGT into the public health care and social security sub-sectors is still quite limited, due in part to the lack of resources but also because of their controversial nature (Penchaszadeh, 2009). Nor are there explicit public policies dealing with medical genetics services, which creates uncertainty about who can or should access genetic testing and under what conditions. As Penchaszadeh notes, this is due in large part to the illegal status of abortion. Genetic tests are, nevertheless, widely available through private

health clinics, but given their high costs,⁶ they are beyond the means of most of the Argentinean population. A national census conducted in 2004 (Liascovich, Rozental, Barbero, Alba and Ortiz, 2005) about access to genetic services showed that there are also some public institutions offering genetic services, but due to understaffing, under-funding and uneven geographical distribution, many people who might benefit from these services simply do not have access.

This situation thus raises important questions about fair access to appropriate genetic services. In particular, are these services (e.g., counselling, PGT) important enough to be covered by public health insurance? Should they be publicly insured in a country with major inequities in health and access to health care? These questions cannot, however, be answered without also paying attention to the serious public and policy disagreements about the application of genetic services (and specifically PGT) in Argentina. Given that the Catholic Church still has a strong influence over civil society and government, terminating a pregnancy remains a criminal offence; so this option is not available for prospective parents when they receive genetic information. Thus, it is necessary to also question what follow-on services (e.g., genetic counselling) are appropriate and/or should be available to help parents deal with the information resulting from genetic testing. The current situation in Argentina constitutes an important problem of social justice. These challenging

⁶Prices range from US\$240 for Fragile X testing, to US\$862 for testing for hereditary breast and ovarian cancer. Asociación Argentina síndrome frágil X available at: <http://www.detodounpocotv.com/prevencion/xfragil.htm>. Also, see: Asociación Médica Argentina available at: http://www.ama-med.org.ar/publicaciones_revistas3.asp?id=108

questions call, I suggest, for a deeper reflection and public discussion about the appropriateness of publicly funding expensive and contentious technologies.

This thesis examines and seeks to understand the ethical rationales for justifying the public coverage of PGT in the socio-cultural and economic context of Argentina. More specifically, I hope to contribute to the emerging Latin American Bioethics and HTA communities by examining two subjects – the possibility of developing an integrated ethical HTA, and the challenges of evaluating PGT for inclusion in public health insurance – that have not been well developed in the particular context of Latin American countries. I argue that Argentinean policy makers currently lack the relevant and necessary tools to analyse the consequences of incorporating (or not) health technologies such as PGT into public and private health insurance programs. In presenting an integrated model of ethical HTA, this thesis aims to contribute to enlightened decision making processes about the allocation of scarce resources in health care in Argentina.

LIMITATIONS

The limited development of HTA – both in terms of agencies and procedures – in Latin America and Argentina posed important challenges to gathering the necessary information to conduct my study. In general, government agencies and public institutions – such as hospitals, laboratories and universities – did not have much information available about their practices, and web sites were often not up-to-date. Nonetheless, through a

comprehensive review of scholarly databases (e.g., through the Université de Montréal, Google Scholar, and the Humgen database), I was able to access to some of the key policy documents from government agencies in Argentina, NGOs, ethics guidelines, and academic literature about the diverse implications raised by genetic technologies.

I also travelled to Argentina on two occasions (in March 2006 and then again in March 2007), where I met with bioethics scholars, HTA producers and policy-makers. In addition, I established regular email contact with several public and private institutions working in genetics (e.g., *Centro Nacional de Genética Médica*, CENAGEM) and HTA (e.g., *Instituto de Efectividad Clínica y Sanitaria*, IECS). Those contacts in Argentina supplied me with very helpful information about how things are currently being done in Argentina with regards to the provision of and access to prenatal genetic tests, and the integration of socio-ethical, legal and policy questions into the HTA process.

Given the limitations of space and time possible for a Masters thesis, I chose not develop some of the complex topics closely linked to the use of PGT, such as patent rights and their impact on the cost of genetic tests. Nor have I gone into the debate about whether or not people should terminate pregnancies for genetic reasons, nor how follow-on services such as genetic counselling should be provided to support people undergoing testing. The reality is that even in Argentina, people are using PGT and are terminating pregnancies, and these raise important issues that should be addressed and publicly discussed. So I have limited my analysis to presenting a model for an ethical HTA and

showing how it would be applied to these challenging issues, in order for Argentina to move towards a more equitable provision of health care, and specifically as concerns access to genetic services for those who are in need.

OUTLINE

The thesis is structured as follows: Chapter One begins with a brief history of the development of health technology assessment (HTA) in the developed world, and then explores approaches to integrating ethical reflection and analyses into HTA processes, as a way to analyze and clarify the importance of considering PGT for coverage under public health insurance. The Québec Agence d'évaluation de technologies et de modes d'intervention en santé (AETMIS) is presented as an example of such an integrated ethical HTA, and the basis for a framework with which to consider the current situation in Argentina. In Chapter Two, I apply this framework to the case of PGT in Argentina. This Chapter is divided in two parts (A and B): part A is devoted to examining the problem of social and economic inequalities and its impact on access to services, while part B discusses the practical challenges for producing an ethical HTA that can deal with the myriad ethical, legal and social implications of incorporating PGT into public health care insurance. In the Conclusion to this thesis, I present arguments that justify the claim for equal access to PGT, and suggest some directions for future research.

CHAPTER I

**TOWARDS AN INTEGRATED FRAMEWORK FOR ETHICAL HTA IN
ARGENTINA**

INTRODUCTION

Starting with a description of the history and development of health technology assessment (HTA)⁷, and the current state of the subject in Argentina, this chapter then focuses on the specific case of prenatal genetic tests (PGT). In Argentina, a large part of the population experiences many difficulties with access to health services and technologies. In addition, religious influences and restrictive legislation turn the application of PGT into a source of serious social and ethical dilemmas. In this context, the integration of ethics in the process of technology evaluation becomes necessary, albeit difficult to implement. At the end of this chapter, I present the case of the AETMIS in Québec, as an example to illustrate key elements for developing a preliminary model of ethical HTA in Argentina.

Implementing better HTA processes can, I suggest, contribute to more rational decision making and so also to more just and fair resource allocation decisions. It should be obvious, however, that many other actions are necessary in order to resolve the broader socio-political and economic challenges facing Argentinean society. Attention to the social determinants of health⁸ highlights the importance of social policy interventions such as poverty reduction, improvement of public education, enhancement of universal access to health and social services, control of tax evasion, etc. An ethical HTA can

⁷According to the Swiss Network for HTA, "Health Technology Assessment is the scientific evaluation of medical technologies regarding their effectiveness, appropriateness, efficiency as well as social and ethical aspects and implications".

⁸The "social determinants of health" are those social factors that affect the health of the population such as the socio-economic inequalities, poor education and housing, unemployment, etc. For more information see: WHO, 2003.

nonetheless help with these challenges, in so far as it enables better organisation and provision of essential services by providing a mechanism to determine priorities and so build realistic health policies adjusted to the particular Argentinean socio-cultural context.

However, as will be explained below, systematized analyses of ethical issues are rarely performed as part of HTA processes. Producing an ethical HTA requires at least some knowledge about (bio)ethics matters such as ethical principles and justice theories that would enlighten, for example, the process of fair allocation of scarce resources in health care. Such knowledge would allow for the building of frameworks and procedures to guide ethical analyses, something that is lacking in the international HTA community in general. The issues faced by Argentinean HTA producers are very challenging, and arguably go beyond the tools that they have in hand. Here, I argue that Argentina's Bioethics community, which has developed substantially during the last decade, can contribute in important ways to the production of better HTA.

HISTORY & DEVELOPMENT OF HTA

The assessment of health technologies is not a new subject, since medical scientists and health administrators have for years been evaluating new and existing technologies; but it was not until the 1970's that a systematized and empirical approach to HTA emerged, and eventually became both a professional practice and an academic discipline. Prior to the systematic use of HTA, decisions in the health policy arena were not well informed about diverse and important aspects (e.g., safety) of technologies. As Lehoux

explains (2006), analysts of health policies noted that some extremely expensive devices (such as the computerized tomography scanner), treatments and tests were promptly acquired by hospitals without the support of sufficient evidence about risks and benefits for patients. Policy makers lacked the technical knowledge and pertinent tools to analyse the consequences of implementing these new technologies. In 1974, the U.S. Senate Committee on Labour and Public Welfare requested the Office of Technology Assessment (OTA) to study the justifications for North American hospitals implementing expensive health technologies and procedures.⁹ The result of this inquiry was a series of documents, and the development of "...a new analytical tool for the health policy arena" (Lehoux and Blume, 2000).

Since the 1980's, the interest manifested by different stakeholders (e.g., governments, health care managers, the pharmaceutical industry, academics, patient associations, and policy makers) for HTA has been growing considerably, especially in the developed nations. Some challenges, such as the rapid and widespread introduction of new technologies, their increasing costs (in the context of limited health care budgets) and a lack of standardisation in practices, plus the uncertainty provoked by as yet unknown effects, are just some of the reasons that have contributed to this growing interest in HTA (Hofmann, 2005 b; PAHO, 1998; Valencia and Manrique, 2004)

⁹For a detailed discussion of the origins and development of HTA and the creation of OTA see for example: National Information Center on Health Services Research and Health Care Technology, available at: <http://www.nlm.nih.gov/nichsr/hta101/ta10103.html>

Thus, by mid-1990, the USA, Canada and most western European countries had implemented diverse health technology evaluation systems through the creation of public and/or private agencies (ministerial commissions, non-governmental organisations, universities research teams, etc.). These groups were given the mandate to evaluate the security, effectiveness and cost-efficacy of new biomedical technologies, but also their economic, legal and socio-ethical implications; in practice, however, socio-ethical analysis has been and is still rarely performed (Lehoux and Williams-Jones, 2007).

In addition, regional cooperation programs, such as the EURASSES Program created by the European Union in 1994, were established with the aim of defining assessment priorities, common guidelines and evaluation methods for the European States¹⁰. International HTA groups were also created, most notably the International Society of Technology Assessment in Health Care (now called Health Technology Assessment International, HTAi)¹¹ and the International Network of Agencies for Health Technology Assessment (INAHTA) that was established in 1993 and currently includes members from more than 40 national HTA agencies. According to its institutional website, the purpose of INAHTA is to “provide a forum for the identification and pursuit of common interests to health technology” (INAHTA, 2007). INAHTA also edits a newsletter

¹⁰EURASSES was a research project coordinated by Prof. D. Banta and funded by European BIOMED Programme; the project has built a framework for the future development of HTA in Europe and was later continued by another project called European Cooperation on Health Technology Assessment (Conde Olasagasti, 1998)

¹¹For more information about this professional organization and its work, see: <http://www.htai.org/>

with information about current trends in research on health policies, publications and future developments.

Although the majority of HTA is performed in order to assess specific new technologies (e.g., prior to the introduction of Positron Emission Tomography, PET Scanners) (Nauenberg, Flood and Coyote, 2006), it can also be used as an approach to evaluate the performance of health care systems and services. For example, some Canadian provinces (notably Québec and British Columbia) have implemented initiatives¹² to reorganise services in order to respond more efficiently to their populations' health needs. In Canada, the restructuring of health care systems has in part been necessitated by the “aging population, rapid development of medical technologies and increasing costs” (Battista and Hodge, 1999).

AN INTEGRATED FRAMEWORK?

According to Blancquaert and Caron (2003), the process of HTA can be described as a combination of two phases or stages: 1) *assessment*: in which epidemiological studies are performed, involving the collection of all available information (e.g., literature review, cost-effectiveness analyses) and then a subsequent analysis and synthesis; and 2) *appraisal*: in which contextualised studies are conducted and recommendations made (e.g., in the case of PGT, tests can be evaluated regarding “their utility, feasibility and acceptability” in a given context). As Blancquaert explain (2006), contextual analyses that are

¹²In the most important Canadian cities, notably Montréal, Toronto and Vancouver some hospitals are already performing their own evaluations (CHSRF, 2007)

broader or more comprehensive than the standard or traditional assessments are needed in order to produce clear and pertinent recommendations adjusted to the local reality. Thus, the *appraisal* phase aims to go beyond economic studies and literature reviews (e.g., about safety and risks), in order to also address socio-ethical questions, by taking into account the environment in which a technology emerges, as well as the different positions of the various stakeholders concerned by the use of such a technology (Blancquaert, 2006).

Yet despite the recognition in the HTA community of the need for broader evaluations that include socio-ethical issues – something that has been stressed since the very beginning of the field – the aforementioned *appraisal* phase is not yet performed in a systematized manner by HTA agencies. Furthermore, classical HTA processes usually do not result in formal recommendations; instead, they produce technical reports about some aspects of technologies (e.g., cost-effectiveness, safety) that are likely insufficient for decision-makers to be fully informed (Nauenberg et al. 2006). This gap between HTA mandate and practice has been highlighted by HTA producers and bioethics scholars, e.g., in a series of works published by *Poiesis and Praxis* in 2004 (issue 2) (cited in Lehoux & Williams-Jones 2007). Specifically, it is argued that even when HTA producers recognise the importance of and need to address socio-ethical matters (especially regarding questions raised by the application of new technologies) these analyses prove difficult because of the lack of specialised staff and economic resources to assess, in a timely manner, *all* aspects of a technology (Gallo, 2004; van der Wilt, 2004).

In addition, as noted by Lehoux and Williams-Jones (2007), the absence of adequate frameworks and procedures to guide such ethical analyses further complicates the situation. As a result, the formal integration of socio-ethical analyses is mostly conducted by “ad-hoc advisory groups” (Faulkner 1997, cited in Lehoux and Blume 2000), even in jurisdictions where HTA has been practiced for many years. It should not be surprising then, that if integrating socio-ethical analyses into HTA is difficult in industrialised nations, the situation will be even more challenging in developing countries, such as those in Latin America, in which this multidisciplinary field of study is just in its earliest stages of development (Valencia and Manrique, 2004).

HTA in Latin America

In 1998, a study was conducted by the Pan American Health Organization (PAHO) with the aim of determining the situation of HTA in “the Americas”. This study identified two major pitfalls for the Latin American nations regarding the implementation of technology evaluation procedures: 1) the “misunderstanding of decision-makers about the relevance of HTA in the development of health care systems”, and 2) the absence of specialised staff (PAHO, 1998). This study also determined that, as a consequence of the lack of evaluations, countries in Latin America were incorporating new health technologies into their health care systems without taking into account their own regional particularities, “resulting in a diffusion of the most sophisticated technologies in inverse relation to the populations’ health needs” (PAHO, 1998).

This then results in a waste of limited resources, the use of possibly inappropriate technologies, a population with unmet medical needs, and other unjust situations, subjects that will be analysed further on in this Chapter in the specific case of Argentina.

In developing countries, people often experience many difficulties accessing health care services, especially those of the lowest income (Peters *et al.*, 2007). This situation is worsened by institutionalised inefficiencies, unequal resource allocation and aging infrastructures. All of these are common patterns in Latin America, a region where despite there being a tradition of social aid for the poorest sectors of society, appropriate and timely access to health care is almost a privilege, available only for the wealthiest. In this context, more inclusive health policies which have the potential to improve access to essential services are necessary. I will argue that a more comprehensive and ethical HTA would help support the development of such policies.

HTA in Argentina

Although international organisations such as PAHO and World Health organization (WHO) have been working since the 1970's to promote the development of HTA across Latin America – organising diverse seminars and encouraging collaborative studies – (PAHO, 1998) it has taken almost 30 years to formalise the assessment process in Argentina. Until the beginning of 2000, Argentinean decision makers did not recognise HTA as a tool that could help with the rational allocation of resources (Rubinstein, Belizán and Disciaciatti, 2004). However following the severe economic crisis that affected the country in

2001, the demand for HTA has been growing considerably and its role in the decision-making process has also increased. Argentinean policy makers have noted that a formal process of technology evaluation can contribute to transparency and efficiency in health policy decision-making processes (República Argentina, *Programa Médico Obligatorio y Evaluación de Tecnologías Sanitarias*, Decreto no. 674/2003).

Decision makers are now more aware of the relevance of HTA, and so the development of local HTA studies is being encouraged (Pichon Riviere, Augustovski and Rubinstein, 2006). Such awareness is a very positive step in the right direction, yet as will be further explained below, the systematised production of contextualised studies and formal integration of ethical issues in HTA is still missing in Argentina.

Currently, one of the most active producers of HTA in Argentina is the *Instituto de Efectividad Clínica y Sanitaria* (IECS), which during the period 2003-2006 published 117 HTA documents¹³; their assessments consist primarily of a literature review and evaluation about the quality of the available scientific evidence. The IECS does not, however, conduct socio-ethical assessments, nor does it work in collaboration with other institutions or

¹³In 2002, the *Instituto de Efectividad Clínica y Sanitaria* (IECS), “the main HTA agency in Argentina”, was created as “an independent and non-profit organisation...in order to contribute to improve the efficiency, the equity, the quality and sustainability of the health policies and services”. According to the institutional website, its staff includes professionals from multiple disciplines such as physicians and social scientists, who are engaged in research and other academic activities. The Institute offers technical support to public and private institutions as well as non-governmental organisations in areas such as evaluation of health innovations, economic assessments, research methodologies, “data analysis and validation of questionnaires”. The principal aim of this support is to orient the use of appropriate technologies and decrease unnecessary expenditures. The Institute also coordinates the Ibero-American Cochrane Network, promoting systematic reviews of health interventions which are published in the Cochrane Library with the aim to improve the production of local scientific reviews. See: www.iecs.org.ar

professionals performing analyses about those matters. Its technical reports, albeit very helpful, only provide decision makers with information about specific (partial) aspects of technologies, such as costs and efficacy, which is arguably insufficient to enable the development of comprehensive and effective health policies¹⁴. Similarly, evaluations by the *Comision Nacional Salud, Ciencia y Tecnologia* (National Commission on Health, Science and Technology) – created by the Health Ministry in 2006 with the aim of institutionalizing HTA into the health care system and promoting the use of scientific evidence in the health policy decision making¹⁵ – consist basically of literature reviews and consultation with experts; the resulting short reports focus on economic information, e.g., about cost-effectiveness, but do not include contextualised studies.

One point that deserves particular attention is the fact that the documents resulting from HTA producers in Argentina are in general technical reports about the “effectiveness, safety and cost-effectiveness” of particular technologies; given the lack of the *appraisal* phase, these reports do not include formal recommendations (Personal communication, Buenos Aires, 7 March 2007). For instance, in a report produced by IECS in 2003 about prenatal diagnosis and genetic studies, it was concluded that given the criminal status of abortion in Argentina, the financing and coverage of such tests can be

¹⁴It is interesting to note that the IECS is the only Argentinean institution (and one of only a few in Latin America) affiliated with the international network INAHTA. As such, the IECS is directly linked with the international HTA community, which should facilitate the exchange of ideas, methodologies and reporting models, which could be adapted to the local context. This relationship provides precious opportunities for collaboration and shared learning to help improve and enlarge the production of HTA in Argentina.

¹⁵See: República Argentina Ministerio de Salud y Ambiente. *Comisión Nacional Salud, Ciencia y Tecnología*, available at: <http://www.saludinvestiga.org.ar/ets-solicitud.asp>

controversial. Thus invasive procedures, such as amniocentesis, cannot be indicated although they can be suggested (IECS, 2003). These types of conclusions (i.e., not indicated but suggested), without formal recommendations, can create uncertainty and ambiguity for the diverse actors involved (e.g., parents, physicians, other health care professionals, policy makers); without clear guidance, these actors will be hard pressed to make well informed decisions in what are very delicate situations. I argue that formal and comprehensive recommendations from HTA producers in Argentina are needed to improve efficiency and quality of services and to sustain coherent health policies and guidelines pertinent to the local context. Such recommendations necessitate enlarging the HTA process, that is, implementing the aforementioned *appraisal* phase as an integral part of HTA.

As has been mentioned previously, taking into account the environment in which a technology emerges, as well as the different positions of the various stakeholders concerned by the use of a given technology is needed to determine its appropriateness, utility and acceptability. Pursuing an agenda of inclusiveness and equal access to health services requires addressing many other factors besides clinical effects and cost-effectiveness. Contextualising the evaluation process would, in the case of PGT for example, allow HTA producers to make explicit the socio-ethical and legal concerns associated with access to PGT in its particular socio-cultural context. Specifically, in the Argentinean context, attention would need to be given to the injustices that arise from inequitable access to PGT (and other health care services) and its

impact on equality of opportunities (Daniels, 1985), as well as concerns related to the provision of testing, such as informed consent, confidentiality, discrimination, and how to deal with the resulting information (these issues will be examined in Chapter Two).

HTA in Québec: Lessons to be learned

In Québec, HTA is performed by the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS), which was created in 2000 to replace the Conseil d'évaluation des technologies de la santé¹⁶. AETMIS is an independent organisation but directly linked to the Ministry of Health and Social Services of Québec (*Ministère de la santé et des services sociaux*, MSSS), both working in collaboration and according to a "national strategy". AETMIS' goal is to support and counsel health decision makers in the development of scientific policy for the Québec government. AETMIS is strongly engaged in the promotion of evaluation, knowledge translation, teaching and "outreach activities" (AETMIS, 2008), similar to other Canadian HTA agencies and institutions in developed nations.

The most important evaluation requests to AETMIS come from the MSSS and the major Quebec hospitals, as well as other institutions or associations working in the health field. To start, a feasibility assessment is conducted in order to decide whether to proceed (or not) with a particular evaluation. Each assessment begins with an exhaustive literature review where

¹⁶For more information about the creation of the AETMIS see: décret 855-2000 from Québec Government (28 June 2000)

the pertinent information is assessed through meta-analyses, evaluating diverse parameters, including: cost, efficiency and security aspects, as well as ethical, legal and social repercussions (*appraisal*). If necessary, external expert advice is requested. A preliminary report is submitted to the AETMIS board, who give final approval (after corrections). Then, the report is communicated to those who commissioned the assessment, and finally it is made publicly available on the AETMIS website, among other venues.

AETMIS performs comprehensive analyses (*assessment and appraisal*), and so include, for example, the use of statistics, medical files and other scientific information – including ethical, social, economic and legal factors – about the Québec population (Blancquaert, 2006). Each evaluation results in a report that formulates pragmatic policy “recommendations directly applicable to the Québec health care system” (AETMIS, 2008). For example, in 2003, AETMIS produced a report about prenatal screening for Down syndrome during the first-trimester. After evaluating diverse parameters, the report concluded that even when the screening modalities were effective, more research was still needed before implementing “wide-scale first-trimester screening in Québec” (AETMIS, 2003).¹⁷

Even though it could be argued that the model of AETMIS is not perfect and the process of the contextualised HTA has limitations – for example, the evaluation’s methods are constantly evolving making it necessary to adapt them to the specific situation and technology – coherence, scientific rigour and at

¹⁷In January 2009, the Québec *Commissaire à la santé et au bien-être* (MSSS) published a report recommending the introduction of population screening for Down Syndrome (*Commissaire à la santé et au bien-être*, 2009).

least some degree of organisation are present in their works. What is particularly interesting for our purposes is the fact that AETMIS is one of the few agencies in Canada or internationally to have a research team working on evaluations of genetics technologies (a specific unit was created in 1996); further, AETMIS is one of the few to integrate ethical analyses, in a systematised manner, into their assessments.

The ethical implications of a technology are analysed within Québec's socio-cultural, economic and political context. Different methods are employed to achieve this integration: for instance, focus groups with stakeholders or inquiries to different actors (who are concerned by a given technology) depending on the particular circumstances of each evaluation. At this point, it is necessary to recognize the strong influence exerted by the various stakeholders involved in implementing such innovations in a given context (e.g., technology designers, health administrators, physicians, patient groups) as well as the existence of diverse perceptions, interests and expectations that each may have about the same technology. Considering these factors and integrating them as part of the HTA process allows the AETMIS evaluators to obtain more accurate information about the utility, feasibility and acceptability of a technology in the particular context of Québec.

CRITICAL CONCLUSIONS ABOUT AN INTEGRATED FRAMEWORK

As Blancquaert explains (2006), the analysis of the social context in which a technology is to be implemented "can change how one frames the

question and what evidence is collected”, and this can have an impact on the recommendations formulated. In the case of Argentina, as in other developing countries, the government does not consider genetic testing as a priority for the public health care system (Sommer, 2008); prenatal genetic tests are provided mostly by private institutions and thus are accessible only for the wealthiest. But there may be situations in which genetic tests are appropriate (e.g., for people belonging to at risk groups) and justifiable in relation to other important health needs. Yet without a comprehensive HTA process that takes such issues into consideration, policy makers will be unable to rationally defend their choices (e.g., to not include PGT in public health insurance). The development of an integrated framework for an ethical HTA and its application to PGT can thus serve to clarify the pertinence of PGT and justify (or repudiate) the claims for broader inclusion and equal access in the Argentinean health care system.

To produce contextualised studies, it is obvious that substantial human and material resources are needed; but so too is an awareness on the part of HTA producers of the importance of enlarging their studies beyond simply an analysis of clinical and economic considerations, to include ethical and social issues in order to make more accurate and pertinent recommendations. Unfortunately, chronic understaffing and a lack of sufficient financial resources at HTA agencies is a major part of the problem, although it can in some places be overcome by re-allocating local resources; more important, however, is developing a willingness on the part of HTA agencies to engage in broader analyses.

The development of adequate frameworks to assess socio-ethical issues remains an important challenge, because as Lehoux and Williams-Jones argue (2007), “individual, clinical, managerial, economic, commercial, political and social perspectives are concurrently active in the development of new medical technologies and the associated values and expectations”. PGT, as with other technologies, is designed with the aim of providing certain information that is valuable for various decision makers (Lehoux, 2006); but its application necessarily brings in other norms and values (e.g., ethical, cultural, spiritual) that directly impact how a technology will be accepted (or not) and used in a given society. Addressing the complexity of these issues – even with an integrated framework that seeks to facilitate the work of HTA producers – will remain a significant challenge.

However, I argue that important progress can be made if HTA producers in Argentina begin to integrate the aforementioned *appraisal* phase as an integral part of their HTA processes. A contextual analysis “implies a good understanding of the real world implications of the introduction, dissemination, and use of new technologies for a variety of stakeholders” (Blancquaert, 2006). The capacity to conduct such contextual analyses will necessitate important efforts in education about the ethical issues related to health care and genetic technologies. HTA producers should, for example, reflect on and assess the possible consequences of *not* considering sensitive issues. For example, the growing commercialization of genetic tests can lead to an early introduction into the market of services that physicians are not yet prepared to handle, and

provide information to patients and third parties which can have serious legal consequences, such as discrimination, or even malpractice suits in the context of “wrongful life” claims (Andrews, 1992). Similarly, the issue of patent protection may mean that some genetic tests are simply too costly to be considered for inclusion in public health insurance programs in developing countries like Argentina (de Ortúzar, 2004).

In practice, integrating contextualised studies and ethical analysis into HTA processes will require, amongst others, the development of strategic partnerships between diverse spheres in “academia, practice and policy” (Blancquaert, 2006). In Argentina, a recent report from the aforementioned *Comisión Nacional Salud, Ciencia y Tecnología* (2008) shows that those researchers working on human genetics and its clinical applications are disconnected from decisions about the provision of health services. Better collaboration with the medical genetics community is needed, as well as more fluid dialogue between practitioners and policy makers, to avoid any misunderstandings. For instance, in Argentina, the field of genetics is still closely associated in the public mind with eugenic practices, and this is arguably one of the principal reasons why PGT has not been included in public services (*Comisión Nacional Salud, Ciencia y Tecnología*, 2008; Kaminker, 2006; Penchaszadeh, 2009). Promoting dialogue among the different stakeholders would help enormously to eliminate such misperceptions and misinformation.

To address the complex social, ethical and economic challenges raised by technologies such as PGT, the integration of interdisciplinary teams is needed. Here, I suggest (and develop the argument more fully in Chapter Two), there is room for the participation of local Bioethics scholars who have been studying the numerous challenges raised by genetic technologies, but who have to date not been involved in HTA processes. These scholars can help to integrate the multiples perspectives of diverse stakeholders in the *appraisal* process, and stimulate dialogue between the different actors; they could also be instrumental in helping HTA producers and decision makers think more reflexively about their own values, as well as issues of fairness and equity, when considering who should have access to PGT.

A promising strategy would be to start with a small scale pilot project at a public or private institution in which bioethicists are employed, to develop the aforementioned *appraisal* phase of the HTA process. In collaboration with HTA experts, bioethics scholars could help gather the social and scientific information already available about PGT in Argentina. But they could also go a step further by consulting with key stakeholders: for example, scholars could interview physicians working in public hospitals in which genetic testing is provided in order to document existing selection criterion (if any); conduct focus groups with patients in need of PGT to learn about their concerns; or survey genetics laboratories to know what kinds of tests are in most demand. Finally, as seen in the case of AETMIS, the dissemination of study findings is an important part of the HTA process. So in the context of the proposed pilot study,

research results that enlighten other aspects of technologies – besides economic and clinical considerations – could be a way to move the issue of prenatal genetic tests onto the political agenda in Argentina. A survey conducted between 2006 and 2007 by the IECS, which sought to measure the impact of HTA reports in decision making, showed that in Argentina such reports are mainly employed (76%) to define health policies regarding the coverage of health technologies (IECS, 2008). It is not unrealistic, then, to think that with a more comprehensive, integrated ethical HTA process, PGT could also be evaluated for inclusion (or not) in the public health care system.

CHAPTER II

**APPLICATION OF THE INTEGRATED FRAMEWORK TO PGT IN
ARGENTINA**

INTRODUCTION

This Chapter explores how an integrated ethical HTA framework could be applied to an evaluation of prenatal genetic testing in Argentina. Divided into two parts, Part A sets the background context to genetic service provision, describes the socio-economic inequalities present in Argentinean society and its impact on equality in access to services and technologies, and concludes with an exploration of the major cultural, religious and political factors that make the PGT such a contentious subject. Part B examines some practical (e.g., institutional and structural) challenges for producing an ethical HTA that can deal with the myriad ethical, legal and social implications of implementing PGT into public health care insurance in Argentina, and concludes with some recommendations.

PART A - SOCIO-ECONOMIC INEQUALITIES AND THE PROVISION OF GENETIC SERVICES IN ARGENTINA

Genetic Services and Prenatal Tests: Evolution and Current Situation

Although in most Latin American countries genetic services and genetic testing have only had limited uptake or integration into health care systems (e.g., because they are too costly), in countries such as Argentina and Brazil the medical application of prenatal genetics tests has become quite widespread. Yet even in these countries, and for our purposes Argentina, the integration of genetic services into the public health care system is still quite

limited, due in part to a lack of resources but also because of its controversial nature (Penchaszadeh, 2009).

Genetic services began to develop in Argentina during the 1960s, when a medical genetics section was opened at the *Academia Nacional de Medicina* (National Academy of Medicine). In 1969, the *Sociedad Argentina de Genética* (the Argentina Genetics Society) was created as a civil non-profit association with the purpose of gathering genetics researchers and establishing links with foreign institutions (<http://www.sag.org.ar/>). Some years later, the *Centro Nacional de Genética Médica* (CENAGEM, National Centre of Medical Genetics) opened its doors with the aim of conducting genetics research, providing teaching and training in medical genetics, and offering genetic services to the public (<http://www.anlis.gov.ar/CeNaGeM/CeNaGeM.htm>). During the 1980's, a medical genetics department was opened at the Garrahan pediatric hospital, which is currently the main referral centre for complex pathologies for all of Latin America (Pechaszadeh, 1998). The incidence of congenital disorders and genetic anomalies in Argentina are similar to those in industrialised nations, constituting the second cause (27%) of infant mortality in Argentina in children younger than 1 year old; the mortality rate is 12.9 per 1,000 live births (*Comisión Nacional Salud, Ciencia y Tecnología*, 2008; Penchaszadeh, 2009).

At present, in most major cities – such as Buenos Aires, Cordoba and Mendoza – public hospitals and universities operate genetics departments and specialized laboratories (around 50 across the country) that perform medical

genetic assessments such as cytogenetic, molecular biology and biochemical testing to detect birth defects and genetic disorders. These facilities have infrastructure and communication networks that allow them to be connected and informed about the latest technical and scientific developments in the field. As is the case in most developed nations, a wide range of genetic services are available in Argentina, ranging from preconception to adult care¹⁸. For instance, it is possible to test prenatally for disorders such as Fragile X, Down syndrome, and neural tube defects as well as a number of monogenic diseases such as cystic fibrosis, thalassemia, or Duchenne muscular dystrophy among others.

Today, Argentina has approximately 80 medical professionals specialised in human genetics, a ratio of 1.77 physicians with formal genetics training per million inhabitants (Liascovich *et al.*, 2006), which is similar to other regional countries although much less than in Europe, where the ratio is 2.7 per million inhabitants; as Penchaszadeh argues (2009), “understaffing” is one of the reasons limiting access to genetic services in Argentina. In addition, the absence of government policies dealing with genetic services creates uncertainty about who can or should access genetic testing and under what conditions.

What is interesting, for our purposes, is that despite the existence of public facilities, many institutions providing genetic services in Argentina are private centres (more than 100). Due to their private sources of revenue (and the chronic under-funding of public institutions), the private clinics have the

¹⁸Personal communication, by e-mail, with Argentinean physicians working in the genetics field in public hospitals and private centres (during 2006-2008)

capacity to incorporate new technologies faster than public facilities. Thus, these private centres are able to apply the same techniques as those used in industrialised countries, such as amniocentesis and Fluorescence in Situ Hybridization (FISH) for genetic testing of embryos¹⁹. The fees that these private centres charge are paid directly by patients, even if they have private health insurance, as most insurance plans do not cover genetic tests²⁰. As such, they are a privilege for a wealthy minority: given the high costs of these technologies (in large part due to issues of patents), genetic tests and especially PGT (whose application is quite limited at a public level) are beyond the means of the vast majority of the Argentinean population, who already experience serious difficulties accessing services in public health facilities.

Beyond the impact of cost on access to genetic services and the aforementioned understaffing of public institutions, another important factor is the uneven geographical distribution of centres specialised in genetic medicine. In 2004, a nation-wide survey of medical genetic services was conducted with the aim of identifying resources, as well as diagnostic procedures and services used by patients. This survey, conducted by the aforementioned *Centro Nacional de Genética Médica* (National Centre of Medical Genetics) in collaboration with the *Centro de Investigaciones Epidemiológicas de la Academia Nacional de Medicina* (Epidemiological Investigation Centre of the

¹⁹The different diagnostic procedures and tests already available in Argentina are listed in the web site of some private institutions. For example: Primagen Diagnósticos Genéticos available at: <http://www.primagen.com.ar/diagnosticosprenatales.php>

²⁰The costs of genetic studies can be quite expensive for Argentineans, although they would be considered very affordable for people living in developed countries. For example, amniocenteses costs around US\$100, while the subsequent genetic tests, which will vary depending on the pathology, range from US\$240 for Fragile X (or the Martin & Bell's Syndrome) to US\$862 for BRCA testing for hereditary breast and ovarian cancer.

National Academy of Medicine) identified a total of 134 facilities, 50 of which were public centres, with most (70%) concentrated in the central part of the nation, especially in the province and city of Buenos Aires; the survey also determined that almost the half of the country's 23 provinces had no public medical genetics services (Liascovich *et al.*, 2006).

With respect to the diagnostic procedures offered, significant variability was detected between public facilities; while many centres performed clinical and cytogenetic diagnoses, only a few ones (6, all of them located in the central part of the country) also conducted molecular and prenatal diagnoses; 44 centres delivered services to 50-150 people per month, and 6 other institutions assisted more than 150 patients per month (Liascovich *et al.*, 2006). Thus, people living in the Capital City and the province of Buenos Aires are the most favoured regarding access to genetic services while inhabitants of Argentina's northern (the poorest region) and southern extremes have virtually no access to such services. It should be noted, however, that this concentration of medical facilities is not so different from that occurring in other countries, such as Canada, where there are no genetic services available outside the major metropolitan areas. Yet unlike Argentina, in Canada there exist mechanisms to help plan and coordinate service provision in areas without specialised genetics centres (e.g., genetic testing for residents of the Yukon is provided by centres in British Columbia)²¹.

²¹For a detailed list of genetic testing delivered in the provinces and territories of Canada see: CORD, 2008.

It is noteworthy that even when prenatal care is included within the Mandatory Medical Program (*Programa Médico Obligatorio*, PMO), and ultrasound is practiced routinely in Argentina, the development of prenatal genetic diagnosis has encountered many pitfalls in the public and social security sub-sectors. There are neither explicit public policies dealing with medical genetics, nor any regulations about genetic testing and this – as Penchaszadeh notes – is due in large part to the illegal status of abortion. By contrast, as mentioned previously, prenatal genetic tests are quickly incorporated in the private health care sub-sector and easily available for those who can afford them (Penchaszadeh, 2009; Sommer, 2008).

Socio-Economic Inequalities and (Un)equal Access

In Argentina, we find a fairly small and privileged portion of the population accessing, through private health insurance, the most sophisticated technologies and health services in a timely fashion, while the vast majority of citizens experience many difficulties accessing even primary health care. Such inequity in the access to health care services in general, is even more apparent in the case of specialised services, such as medical genetics. This inequity might be less problematic in countries where the population has equal opportunities to access needed medical services; but in the case of Argentina, where millions of people face many obstacles to having their health needs satisfied the uneven delivery of genetic services and its related technologies

arguably worsens existing inequalities, and undermines equality of opportunity, something that in a democracy every citizen should have.

In a developing country such as Argentina, unequal access to health care is a reality, but is nonetheless ethically unacceptable. Argentina is a social democracy that aspires to be a just society, and has even gone so far as to recognise in its Constitution a right to health care. The standard of access to health care should thus be determined by medical need, and not by capacity to pay. One way to understand this issue is to reflect on John Rawls' principle of equality of opportunity (1971), and its application by Norman Daniels (2001) to the case of health care resource allocation and policy making. This principle is arguably an important philosophical foundation of a right to health and health care.²²

As de Ortúzar notes (2004), Daniels relates health with opportunities through the concepts of "normal species functioning" and a "normal range of opportunities". Daniels describes health needs as basic goods required to "maintain or restore normal functioning between members of the same species" (Daniels, 1981). Disease becomes then a pitfall to the normal function of a person that reduces the aforementioned range of opportunities to self realization and social participation so fundamental to democratic society; "Protecting normal functioning contributes to protecting opportunity" (Daniels,

²²There are important differences between Rawls' and Daniels' conceptions of "equal opportunity". Rawls does not justify equal access to health care, but to be entitled to the opportunity: he supposes that all citizens are normal and then he limits the application of this principle to positions, jobs and careers. While for Daniels health care is important because of its impact on opportunity, it means that the important fact is the opportunity itself, which is determined by social factors; acting to promote social justice (e.g., improving socio-economic inequalities) is critical to achieve equality in health care. Then, access to health care is a social responsibility because limited access impacts directly on the "normal range of opportunities".

2001). Furthermore, as Williams-Jones and Burgess (2004) note, one of the goals of health care is to compensate those people who are below the level of “normal functioning”. When unmet health (and other) needs decrease normal functioning, and thus the normal opportunities available to an individual, then they should be considered priority needs that the health care system must work to restore, improve or compensate to ensure equality of opportunity. According to this, all citizens should have access to needed health (and social) services, because health is essential to the pursuit of individual life goals; in a pluralistic liberal democracy, equality of opportunity becomes a fundamental part of a just society.

Following Daniels (2001), I argue that matters concerning the entire society, such as health and health care – factors that are seriously affected by socioeconomic inequalities – necessitate public participation and social cooperation. In a democratic society such as Argentina, just access to health care (and other social) services is needed to enhance the possibilities of *all* citizens to fully participate and co-operate in social life. The State, as part of its duty to protect its citizens, arguably has a duty to ensure the same standard of health for all, not just because health is a basic right but because it is a condition that empowers people to exercise other rights and responsibilities necessary to the achievement of personal goals but also to the progressive development of any country.

The persistence of unequal access to genetic services can have negative repercussions on society by further exacerbating the marginalisation of

those who are in need and cannot afford private services, or do not have the chance to live in a region where a public facility is located. As Rivera López states (2002), this affects the “the social basis of cooperation”. That is, those who can and prefer to purchase private services, such as PGT, will have better health standards than the less affluent; this arguably contributes to a loss of cooperation and social solidarity with the rest of society, potentially further entrenching negative social behaviours such as tax avoidance (which is rampant in Argentina) that continue to undermine the funding of public health and social services.

It is also plausible that genetic tests – including PGT – can contribute to individual health and thus also to equality of opportunity (Williams-Jones and Burgess, 2004). At this point, however, it is necessary to make a distinction between the medical uses of genetic testing in the public health care sector, from its commercial and/or non-medical (or non-essential) use, usually pressured by market forces. In the first case, the application of PGT can respond to important medical needs, that is, serious genetic conditions for which the identification, prevention, or treatment can improve the quality of life of affected people. In the second case, one such application would be to satisfy desires or preferences that are not considered medically necessary (de Ortúzar, 2004). While it may be hard to neatly distinguish between health needs and desires or preferences, the fact is that health care systems can and do set criteria to prioritize access to health care services. It is thus all the more important that such distinctions be based on rational and transparent

arguments, the data for which should come from sustained ethical reflection, i.e., part of ethical HTA processes (Williams-Jones and Burgess, 2004).

Argentina already possesses some prestigious medical facilities (e.g., the previously mentioned Garrahan pediatric hospital is a public institution) where genetic services are provided. In an attempt to better organise the provision of genetic services and to reduce inequalities in access, Argentina's Ministry of Health announced in 2005 that there was a need to develop specific policies and regulations regarding the application of genetic technologies and their use to improve public health (República Argentina, *Resolución ministerial no. 149/2005*).

The government also noted that given the state of development that medical genetics has reached in recent years, and its impact on public health (i.e., a growing number of genetic anomalies are preventable or treatable if detected early), there was need for a detailed framework to guide research, diagnosis and treatment in the field of medical genetics (República Argentina, *Resolución no. 149/2005*). In a recent report by the aforementioned National Commission on Health, Science and Technology, it is stated that some recent indicators of epidemiological transition (e.g., infant mortality rate) mean that birth defects and monogenic diseases are becoming a major health problem in Argentina (República Argentina, *Foro de investigación en Salud*, 2008). So a government initiative to develop health policies and directives regarding genetic testing is a very positive step in the right direction; it might even be seen as a demonstration of a willingness to consider, in the near future, the broader public

provision of genetic services, including PGT (although it is probably still too early to predict the impact of this good will).

In a country such as Argentina, where there are tremendous social inequalities²³, public debate about what is important for coverage in public health insurance is essential. Such participation is necessary not only to provide guiding values and to make explicit what services and technologies the society considers acceptable and reasonable, but also to clarify the health needs of the population as a whole and not simply the desires or preferences of those who can afford to pay for services. Such debate should be encouraged in order to determine how significant or important PGT is when considered within the wide spectrum of health care services necessary for Argentinean society to be healthy, productive and just.

Cultural, Religious and Political Factors

Beyond the different economic, material or physical obstacles that people face in accessing genetic services (e.g., socio-economic inequalities, the complex structure of health care system, and a lack of services in some regions), it is also necessary to examine some of the cultural, religious and political factors particular to the Argentinean context. In particular, I argue that more attention must be paid to the (apparent) strong influence that the Catholic Church exercises over government and civil society, most evident in legislation

²³To better illustrate these inequities, it is enough to note that until 2001, per capita income in Buenos Aires province – the country's richest one – was US\$21,000, while in Formosa – the north-eastern and one of the poorest provinces – per capita income was only US\$3,700.

prohibiting access to abortion²⁴. For instance, regarding modern reproductive technologies – a subject closely linked to PGT – Latin American law-makers “have received specific mandates from the Vatican” (Zegers-Hoschschild, 1999) stating that since, from the moment of conception, the right to life is inviolable, the “manipulation and research” on the embryo and its “voluntary disposal is immoral”²⁵. This ecclesiastical position, added to already restrictive legislation, poses a number of delicate ethical dilemmas as well as raising legal issues about the application of prenatal testing and the utility of the resulting information, making the applicability of these technologies controversial.

In Argentina, prenatal diagnosis is one of the ethically most problematic applications of genetic technologies, because in some cases it may lead to selective abortion which is a criminal offence. Thus when a severe condition (which cannot be modified) is detected in the foetus and the parents do not desire to continue the pregnancy, they are placed in a very delicate situation. Who should make a decision? If it is assumed that the future parents will support the consequences of such decision, who can evaluate (better than themselves) if they will be able or not to parent a handicapped child? (Chaplin, Schweitzer, and Perkoulidis, 2005). How are medical professionals and parents to deal with the information obtained from those tests? Will there be a real benefit to using such a technology, and if so, for whom? And who decides who

²⁴The Argentinean Criminal Code (Código Penal) establishes in articles 85, 86, 87 and 88 the illegality of abortion except in the case of severe risk for the mother's life and in the case of rape but only when the woman raped is mentally disabled. Even in these situations for which the abortion is accepted, physicians usually request judges for authorization to proceed because of their fear for law suits.

²⁵For more information about those ecclesiastical mandates see: Ciudad del Vaticano (1987) *Congregación para la Doctrina y la Fe, Instrucción sobre el Respeto a la Vida Humana Naciente y la Dignidad de la Procreación* cited in Zegers- Hoschschild (1999).

should have access? These questions need to be addressed and discussed by decision makers if the government aims to improve access and plans to consider funding publicly genetic services, including diagnosis and treatments.

Providing PGT to the broader public opens new possibilities and choices, and can create both personal and professional ambiguity. PGT can allow people to make informed and autonomous reproductive decisions, but testing may also engender psychological and social risks for some people, particularly if a severe disorder is detected. It is necessary to recognise that PGT is an informational tool and not a solution in itself. How are prospective parents to deal with a wealth of genetic information that they many not comprehend? And what are they to do with such information, given that the possibility to terminate the pregnancy, should they desire, is not available because abortion is a criminal offence in Argentina?

Is it realistic to think that all people undergoing testing do so only because they want to be prepared to parent a handicapped child? If not, should policy makers acknowledge that couples will access PGT and then procure a clandestine abortion in the event of a detected genetic condition (which is currently the case in Argentina) (Penchaszadeh, 2009), or travel abroad to those jurisdictions where abortion is not criminalised? In societies where there is an important percentage of the population living below the poverty line, as in Argentina, many citizens will not have the means to obtain safe clandestine abortions; then, women are forced to use more risky methods.

Although there are no official statistics available in Argentina, there is some recent data showing that an important percentage of parents who have gone through genetic testing would consider the possibility of an abortion if serious anomalies are found in the foetus, even when this would imply assuming all the risks of a clandestine abortion (Gadow *et al.*, 2006). Assuming that many people will experience serious difficulties in making the decision to terminate a pregnancy, the illegality of abortion simply worsens matters. Discussion of this subject should no longer be postponed in Argentina. The fact of the matter is that clandestine abortions – which are widely practiced in that country (a detailed discussion of this delicate issue exceeds the scope of this thesis) – have harmful but preventable consequences for the population, making this subject a “major public health concern” (Dickens and Cook, 2007). In addition, health practitioners offering clandestine abortions as well as women who interrupt their pregnancy can face significant consequences under the Argentinean Criminal Code; punishment for a woman causing her own abortion ranges between 1 to 4 years in jail (art.88).

Patients undergoing prenatal genetic testing will thus clearly need some level of counselling, support, and objective information which would be best delivered by health care professionals, most likely through the public health care system. In the previously mentioned 2004 survey (by the National Centre of Medical Genetics) about genetic services in Argentina, there is no mention about genetic counselling, nor other kinds of support for prospective parents; what follow-on services are necessary to be implemented to help these people?

Who should have access to them? Which circumstances would justify such access? Certainly one could look to North American and European countries for guidance (e.g., where genetic counselling is common), but this would also then necessitate consideration of other resource and capacity issues, and in particular, whether there are sufficient health professionals trained in medical genetics and genetic counselling available in Argentina to meet demand.

Physicians in Argentina (and even in developed countries) may be unprepared for the introduction of genetic tests, or demands from patients for counselling, which may lead to serious medical-legal implications (e.g., malpractice suits). As Lori Andrews notes, the arrival of genetic tests in medical practice has arguably lead to more wrongful birth cases in the US – which could potentially also become an issue in Argentina – with resulting pressure on physicians to then use more prenatal diagnostic services, increasing the cost to the health care system and potentially affecting patient autonomy (Andrews, 1992).

In many developed countries, genetic counselling by professionals with expertise in clinical genetics plays an important coordinating role in the provision of genetic services; the counsellor can help people to understand the information provided by tests and plan follow-on care. Yet in the National Centre of Medical Genetics survey, there is no mention of genetic counselling being available in Argentina. Without such professional support, informed choice about undergoing genetic testing – a fundamental norm in contemporary medical practice – becomes virtually impossible (Sommer, 2008).

In Argentina there are some human and structural resources in medical genetics, but major obstacles remain that leave many people with unsatisfied health needs. By contrast, wealthy people who can pay for PGT also likely have the means of dealing with the consequences of testing. That is, they can contract private medical services for treatment (when available) or specialised devices that a disabled child may need. And if they decide to terminate a pregnancy, they can assume the costs of a safe although clandestine abortion (provided either in Argentina or aboard). As Penchaszadeh notes (2009), for those (middle-upper class) people accessing private services, “legal restrictions don’t seem to apply”. But even when couples accept the task of raising a disabled child, there are few specialised public services available in Argentina (e.g., educational services to improve social integration), nor is there enough government support (e.g., subsidies) for families. In this scenario, deciding not to terminate a pregnancy often results in even “more complex decisions to assume” (Blancquaert et al., 2002). Given that these issues are shaped by social “customs, traditions and values” (Luna, 2006), a comprehensive analysis of the socio-cultural environment (*appraisal*), in combination with detailed ethical reflection, becomes all the more important for the HTA process.

PART B - CHALLENGES TO IMPLEMENTING AN ETHICAL HTA

Molecular genetic tests have been in use since the 1960s in Argentina, primarily for the identification of rare heredity diseases, but also in the context of forensics to clarify familial links and to identify children of people who

disappeared during the last dictatorship (1976-1983)²⁶. However, as previously discussed, the medical application for prenatal diagnosis in the public health care and social security system is still quite limited, due largely to the criminal status of abortion and political pressure from the Catholic Church. Nor are there well developed public policies or regulations governing the use of these technologies (Penchaszadeh, 2009; Sommer, 2008). On the other hand, private access to such services and technologies is relatively easy (through private clinics) and Argentinean professionals employ the same techniques as their colleagues in developed countries²⁷. This shows that there is at least some degree of acceptability of these technologies by the Argentinean public, and by health professionals.

As an object of technology evaluation, genetics and its related technologies are a very complex matter; as Blancquaert et al. note (2002), many questions about HTA seem to be more delicate in the genomics era and a considerable number of these issues are narrowly linked to questions about appropriateness and acceptance of these new technologies in diverse societies. Although some concerns about PGT are shared by other branches of medicine (e.g., who will have access to the services and who will pay for them), there are other aspects which need to be taken into account when deciding whether to introduce them into a health care system. For instance, the use of prenatal genetic tests raise ethical and social issues as the right to reproductive

²⁶To this purpose, a national bank of genetic data was created by Argentina's Congress in 1987 (National Law no. 23.511)

²⁷For a detailed list of genetic services and tests already available in Argentina, see for example: Primagen Diagnósticos Genéticos available at: <http://www.primagen.com.ar/diagnosticosprenatales.php>

autonomy, the subject of respect for private life, the delicate matter of confidentiality of genetic information²⁸ and the potential risk of discrimination that people, families or even groups can suffer. In addition, predictive tests can in some cases lead to the stigmatization of particular patient or population groups (Hofmann, 2005 b); they also raise questions about how to address diverging personal convictions, values and religious beliefs, all linked to human reproduction. In the specific case of Argentina, the lack of regulations or guidelines dealing with genetic tests also allows the introduction of predictive genetic tests for commercial reasons, which may lack medical validation (Sommer, 2008). All these issues pose serious challenges for decision makers.

Probably one of the most important challenges for an effective HTA in Argentina with regards to PGT – or for health services more generally – is the fragmentation of the health care system in terms of structure and organisation of insurance coverage (discussed in the Introduction of this thesis). This disorganisation and fragmentation, along with a scarcity of information (e.g., there are no registries about congenital disorders and chromosomal anomalies, nor is there any official data about the number of abortions that occur following genetic testing)²⁹ mean that it is exceedingly difficult to develop the background in which to conduct HTA, to compare services for coverage, or even know

²⁸In Argentina, the Law 421/2000 (*ley de Garantías al Patrimonio Genético*) for the protection against genetic discrimination guarantees and protects the right to dignity, identity and integrity of everyone with respect to their genetic heritage. However, this law is only applicable in the capital city (Buenos Aires is an autonomous jurisdiction that has its own legislation) thus leaving unprotected citizens of the rest of the Nation. In Argentina, there is still a need for specific regulation regarding the proper use of human genetic information in biomedical research as well as in clinical practice.

²⁹As Rivera López (2002) notes, the lack of information about the number of abortions performed following genetic testing is due to the illegality of such procedures.

whether services currently being offered (or envisaged for inclusion in public health insurance) are cost-effective and meet (or not) population health needs. Even when HTA is conducted, the absence of formal recommendations following technology assessments does not allow Argentinean policy makers to be fully informed about the range of contextual issues associated with a particular technology, and thus they remain unable to “improve the efficiency, the equity, the quality and sustainability of the health policies and services”³⁰. This situation is made worse by the fact that, in Argentina, the links between the scientific and political spheres have been historically quite weak, and policies have often been built according to particular interests, which are rarely transparent.

The fact is, however, that Argentina, as with other neighbouring countries like Chile and Brazil, is rapidly incorporating new biomedical technologies such as molecular genetic tests (primarily into the private health sub-sector) that have been developed in industrialised countries (Valencia and Manrique, 2004; Zegers-Hochschild, 1999), but without appraising the social or political contexts relevant to their introduction. This tendency to adopt health technologies without detailed analysis is probably to some extent rooted in a fascination for technological progress, and a perception by many people (including policy makers and the general public) that access to these technologies is

³⁰Improving “efficiency, equity, quality and sustainability of health policies and services” is the goal of the aforementioned IECS. Efficiency is the ability to accomplish what is intended; is the most economical way of achieving a task and usually used to control costs. Equity is used as synonymous of impartiality (e.g., all citizens have the same rights and obligations). Quality is characteristic of excellence. Sustainability is something that may be maintained at a particular level, in a balanced situation, avoiding its reduction (e.g., health and social services).

synonymous with being at the vanguard of modern medicine, and living in a modern society. As Lehoux states (2006), “for several observers, health technology...cannot be (irrationally) resisted”, because “technology sounds modern... must be about the latest. It is also supposed to be better. But how and when do we know that an innovation is better?” To determine that, scientific evidence is needed, but also contextual and even historical evidence (e.g., about the patient) is required (Battista and Hodge, 1999). The absence of contextualised assessments – and integrated *appraisals* – impedes efforts to determine if prenatal genetic tests fit or not into Argentinean society.

Capacity Development for an Ethical HTA

Given the number of genetic services coming into clinical use, it is important to consider, as part of the HTA process, the diverse concerns associated with their introduction, particularly with regards to their importance for inclusion in the public health care system (discussed in Part A). Facing-up to these very real challenges will be a hard task. However, I suggest that progress can be made by observing how other countries assess medical (and genetic) technologies. This is not to argue that the North American or European models of HTA should be copied and directly implanted into the Argentinean context; the contextual (social, cultural, political) particularities of each country are relevant. Nevertheless, some lessons can be learned from abroad – as has been explained in Chapter One, with the example of AETMIS – that can help to improve the HTA process in Argentina.

Accepting the current inadequate or insufficient state of HTA in Argentina, and in an attempt to map out a preliminary idea of what an ethical HTA would look like in this country, I argue that the production of more extended and more comprehensive evaluations should be emphasized. As Giacomini, Miller, and Browman note, (2003) to assess efficiency, efficacy and ethics issues, HTA producers need to have a detailed image about the “technology purposes and functions, from a social as well as clinical perspective”.

There have been some recent initiatives in Argentina to evaluate socio-ethical aspects raised by genetic technologies, albeit still without formal integration into HTA processes (Personal communications with Bioethics scholars, HTA producers and decision-makers in Argentina, March 2007). The aim of such evaluations is to build specific analyses of the ethical, legal, and social issues (ELSI) of genetic technologies, as has already been done in other countries, most notably in the USA, Canada and in Western Europe. In Argentina, some National Universities – such as at the National University of La Plata (UNLP) and the National University of Buenos Aires (UBA)³¹ – have begun developing bioethics centres and programs. For example, while the first ELSI courses for law and medicine students were taught by invited international scholars, it is increasingly local bioethics scholars (many who received training

³¹The UNESCO Bioethics Chair was established at the University of Buenos Aires (UBA) in 1994.

abroad and participated in other ELSI courses offered in Latin America) who are engaged in both research and teaching in Argentina³².

More recently, several research ethics commissions were created and began participating in public and policy discussions about ethics and genetics. Thus, for example, the *Comision Nacional en Genética Humana* (the National Commission in Human Genetics) was created by the National Health Ministry with the mandate to analyze socio-ethical issues raised by the application of genetic technologies³³. Another example of such local initiatives is the creation of the *Observatorio de Bioética* in 2002 (functioning at the Facultad Latinoamericana de Ciencias Sociales, FLACSO)³⁴ with the aim of contributing to the “public and specialized debate” about health matters (FLACSO, 2008).

Even though these commissions and institutions are not themselves HTA agencies, their works can be helpful for HTA producers. The integration of ethics with HTA and the introduction of HTA into the policy sphere nonetheless remain major challenges (Oliver, Mossialos, and Robinson, 2004), especially in developing countries where HTA is still not a priority in government agendas. But progress can be made if Argentinean HTA producers begin to build links with institutions where technologies are analysed from an ethical and social perspective, as is the case of some public universities, ethics commissions and

³²The first ELSI course in Genetics, in 1998, was financing by the National Institute of Health and Dartmouth College and directed by Prof. Ronald Green; this allowed Prof. M. Graciela de Ortúzar to start the first courses on this subjects in Medicine and Law Faculty, in UNLP, CIF, followed by several research projects and doctoral theses.

³³Following a recommendation from PAHO (on the base of the data collected by the census about genetic services in 2004), this Commission was created by Ministerial Resolution no 149 in February 2005.

³⁴Following an initiative of UNESCO, the FLACSO -an intergovernmental organization- was created in 1957 with the aim to promote the development of social sciences in Latin America. For more information about this organization see: <http://www.flacso.org.ar>

NGO's. Another possibility is that HTA agencies follow the lead of AETMIS in Québec, and incorporate into their staff scholars trained in bioethics in order to conduct their own analyses and reports. Such recruitment would be an opportunity for HTA staff to build awareness about ethics matters, and for bioethicists to recognise the objectives and restrictions of current HTA processes (Hofmann, 2005 a, cited in Lehoux and Williams-Jones, 2007).

People trained in bioethics can contribute substantially to the HTA processes. Bioethicists can employ several approaches, both theoretical and empirical (Lehoux and Williams-Jones, 2007) and may be involved in conducting both qualitative and quantitative research to understand and measure what people feel or are concerned with, regarding a given technology. For instance, such research would be useful in building a better comprehension of the experience of those parents undergoing PGT in Argentina. But also by referring to ethical principles (e.g., autonomy, beneficence, justice) and identifying societal values, an ethical analysis can help to build relevant frameworks to better analyse genetic technologies, such as prenatal tests. Such research can help to clarify a technology's social acceptability, appropriateness and utility within the Argentinean health care system.

Expert advice is needed for the development (or at least appearance) of sound state policy. As Webster states: "Government is keen to give the impression that its decisions are rational, based on the best possible advice available" (Webster, 1991). One must clearly be realistic about the other political and economic interests at stake for policy makers, but I think we should

be positive and recognize that there is place for engaging in better, i.e., more ethical, reflection and policy making. Local bioethicists are, I would argue, legitimate sources of advice on ethics matters. They could contribute not only to the development of more fully informed recommendations (e.g., about consequences of adopting or not a given technology, such as PGT), but also to the development of greater transparency in the policy arena: HTA evaluations and subsequent recommendations can be used to make decisions on rational grounds, according to needs and not just according to particular interests or preferences. Yet one also needs to recognise – as Webster does – that an explicit attention to rational or bioethics-informed policy might also serve implicit (and non-transparent) political ends.

In addition, to do better HTA in Argentina, public participation is needed, and could be encouraged through the implementation of consultative mechanisms as have been used by some European agencies, e.g., the “Publiforums” implemented by the Swiss Technology Assessment Agency. Such integration of citizens panels and other consultative mechanisms (e.g., roundtables) that facilitate discussions about the socio-ethical questions raised by new technologies (Commissaire à la santé et au bien-être, 2009; Lehoux and Williams-Jones, 2007) would go some way towards reflecting the diversity of social values, and move beyond strict epidemiological analyses of current HTA processes.

While discussions between different stakeholders groups (e.g., patients groups, medical associations, health insurers) should be encouraged in order to

clarify the utility of including PGT in Argentinean health care, they are not without their challenges. The repeated economic crises and political confrontations, the pressure of the Catholic Church, and the subsequent interruptions of democracy have been important obstacles for the Argentinean population in exercising their rights, and developing their “civic virtues”, including the motivation and opportunity to participate in public discussions about health and public well being that are so vital in modern democracies (Kymlica and Norman, 1999).

The repression suffered during the last dictatorship, and the constant and direct interventions of the Church (e.g., lobbying in deliberative processes, specifically for reproductive health matters), have deeply undermined public participation. For an important part of the population who grew up under state oppression, public discussion of sensitive issues such as abortion for genetic reasons can still be a challenge; then, a “double moral standard” exists so that people claim to be Catholic but do not follow closely Catholic orthodoxy regarding reproduction, contraception and abortion (Luna, 2006).

The creation of spaces that facilitate and encourage public participation is still important; some progress is being made, despite historical reticence. A good example is the so called “Argentinean Roundtable”, a public forum implemented by the National Ministry of Health, where different sectors of society (government, labour associations, scientific societies, the Church, etc.) participated in discussions about various health problems and their possible solutions (PAHO, 2002). This sort of dialogue, albeit difficult (e.g., because of

the political power of the Church) can also be stimulated by those in academia – an area that is strongly developed in Argentina – searching for new avenues of collaboration with governmental and private institutions.

While I have here raised important concerns about the effectiveness of HTA and ethical analyses in Argentina, I do not mean to underestimate the progress that state agencies and private institutions have made in rationally assessing health technologies in Argentina. There is no doubt that many have conducted pioneering work and made an invaluable contribution to the development and management of the health care system. Nonetheless, given the significant social inequalities and inequity in access to necessary health care that remain in Argentina, and the lack of clear regulations and policy concerning genetic tests, it is fair to say that much more work still needs to be done. To that end, I argue that HTA in Argentina must engage in a broader or contextualized assessment that includes the *appraisal* of socio-ethical aspects. In particular, there is real need to move beyond short technical reports, and to formulate pragmatic policy recommendations, as is the case with the AETMIS reports produced in Québec.

CONCLUSION

In modern democratic societies, policy makers play a critical role in pursuing the well being of citizens through the design of nuanced and inclusive (health) policies, assigning resources where they are most needed, while at the same time working with restricted budgets. Since it is impossible to offer all possible beneficial services and technologies to all patients, choices must be

made and this often implies making a “trade-off between services and treatments” (Nauemberg, 2006). In order to be socially accepted, such decisions need to be ethically justifiable because allocating resources to a given service or technology invariably leads to reduced or limited funding for others areas. Distributive justice considerations oblige policy makers to find the best way of allocating those resources,³⁵ and thus there is the need to evaluate the usefulness of the services, such as genetic tests (Williams-Jones and Burgess, 2004). Transparency in decisions is needed to build public trust, which requires, as has been discussed, making public and explicit the rationales for particular decisions.

Argentina is a nation with some resources in medical genetics: it currently has 50 public centres (and many others in the private sub-sector) able to deliver the same services that are available in developed and wealthy countries. Given the rapid expansion of genetic technologies around the world and associated public demand, it would be unreasonable to discontinue their provision in Argentina. Nonetheless, a more rational prioritization and planning of service provision is essential. For example, it would be important to decentralise the current Buenos Aires centred operation of public medical genetics facilities, to improve access in the less populated regions of the country. For areas where this would not be feasible (e.g., because of remoteness and insufficient population), it will be important to develop mechanisms to help plan and coordinate service provision, as has been

³⁵Following de Ortúzar (2005), Rawls’ concept of distributive justice can be applied here to justify universal obligations to perform certain positive actions to offset inequalities and ensure the fair equality of opportunity.

developed in countries such as Canada which share the challenges of ensuring equitable access to health care across large geographical areas.

In many areas of policy, Argentina has taken as reference external models in order to create and develop its own. The same situation can be expected in the case of HTA, and hopefully also the possibility of integrating socio-ethical analysis into such processes. In this Chapter, it has been argued that the case of PGT has not yet been properly integrated in Argentina; it is a contentious subject that needs to be assessed within its own socio-cultural context. Therefore, the evaluation of such technology is something that needs to be explored, while recognising that its integration into the medical system is a delicate matter, strongly shaped by many socio-cultural, economic and political factors, and will have repercussions at different levels, implicating a great diversity of stakeholders.

Primary research is still necessary in Argentina in order to clarify how socio-ethical questions should be appraised; then, possible methods to achieve such integration can be explored. Here, I have made some suggestions about how such integration could occur. Specifically, an important first step should be creating awareness on the part of HTA producers and decision makers about the importance of conducting comprehensive assessments. Such analyses can contribute not only to more efficient technology integration (i.e., to produce the desired effect of improved public health), but also to a more efficient and equitable organisation of the health care system in Argentina (e.g., to address the challenges of understaffing and the chronic under-funding of public genetics

facilities). To achieve such awareness, public education and training in ethics matters is a good starting point, something that has been recognised as an important priority in many developed nations.

The academic sphere, and in particular bioethics, can make a valuable contribution to Argentinean policy making. Bioethics has been growing in South America during the past decade (Luna, 2006; Salles and Bertomeu, 2002), and this would be an excellent opportunity to stimulate the integration of ethical reflection into HTA and policy making, in order to cope with the local challenges posed by genetic technologies. Local bioethics scholars interested in the different socio-cultural and ethical issues generated by the introduction of reproductive technologies (a prominent focus in Argentina) can genuinely help in the identification of concerns and dilemmas. They can, through both theoretical and empirical research, help enlighten other aspects that probably would not be identified by physicians, economists or politicians, and thus improve the production of assessments.

Using an integrated model of an ethical HTA would provide the basis for determining whether or not there is a need for more equal access to PGT in Argentina (and its public insurance), in comparison with other important and pressing public health needs. Without such an analysis, PGT will remain a hotly contested issue for the Argentinean public and a challenge for policy makers; and it will leave parents without the professional or social support necessary to deal with the complex issues and decisions posed by genetic information.

CONCLUSION

In 1978, during the International Conference on Primary Health Care of Alma Ata (in Kazakhstan, former USSR), it was argued that health technologies must be appropriate and relevant to real population needs and affordable for the societies (Declaration of Alma Alta, 1978). Given that such appropriateness is strongly shaped by particular socio-cultural contexts, comprehensive assessments that are broader than traditional HTA processes are required. In the particular case of Argentina, those comprehensive analyses are still lacking, something that arguably contributes to the diffusion of the most sophisticated biomedical technologies through the health care system, but without the pertinent evidence that should support and justify such decisions.

Economic crises and political misrule have resulted in a profound institutional decadence and a subsequent impoverishment in the quality of State goods in Argentina; the fact is that health care is gradually becoming a privilege for which citizens have to pay instead of the fundamental right recognised by the National Constitution. This situation has worsened with the application of neoliberal policies during the 1990's which left the most vulnerable members of the population almost completely excluded from access to many basic health and social services. Furthermore, despite the reforms introduced during the 1990s, the health care system still needs to be reorganized in a rational way; the public provision of different services needs to be significantly improved since universal access to health care services – along with access to other social services, public education, as well as decent housing, formal employment, etc. – are crucial for a healthy population (WHO, 2003).

The existence of major inequalities between citizens accessing health services in Argentina is a matter of justice that needs political response (Daniels, 2001); in a just society, the population's health needs should be prioritized over access to health services that focus on meeting particular desires or preferences. Such a possibility simply worsens existing inequalities. Many people who might benefit from genetic services and technologies, but who cannot currently access them because of economic considerations, would have the opportunity if these services were included in public health insurance. Yet it should be clear that the suitability of a technology aimed to prevent transmittable diseases, such as PGT, will be questionable in a society where its application remains socially or religiously controversial. Thus alongside considerations of social justice, i.e., equity in access, it is important to also attend to issues of reproductive autonomy and the religious influence on legal restrictions, when evaluating the importance of genetic services and prenatal testing for coverage in public health insurance.

In a country with tremendous socio-economic inequalities, and where the provision of many basic services still need to be improved, introducing contentious technologies such as PGT into public health insurance coverage may seem foolish (Penchaszadeh, 2009). Yet, publicly funding PGT could help to reduce significant inequalities in health and access to health care, thus favouring the situation of the most vulnerable members of the population. Given the diversity of concerns raised by the application of PGT, the answer will not be easy. What is clear is that the health of some populations in less developed

countries such as Argentina will not be improved given the impossibility of accessing new tests and new drugs to treat illnesses with genetic origins, especially congenital defects (de Ortúzar, 2004).

Removing obstacles to universal access to health care services is critical. For that to occur innovative and more inclusive health policies are urgently required in Argentina; this poses challenges for policy makers who need good evidence to make decisions on rational grounds. Part of the solution to clarifying the pertinence of contentious technologies, such as PGT, can be found in the production of comprehensive ethical HTA. That is, a global *appraisal* of the context needs to be performed in order to enlighten policy recommendations about the reality in which a new technology, such as PGT, is going to be applied (Johri and Lehoux, 2003). Issues regarding the accuracy of PGT, its potential utility and benefits for the Argentinean socio-cultural context, and its governance must all be analysed before deciding on its implementation. Introducing PGT without addressing these questions will only contribute to further increasing the already dramatic inequalities that exist between fellow citizens. Integrating ethics and HTA processes can, I have argued, result in an effective tool – and even a method in itself – for addressing delicate issues raised by the introduction of medical technologies and other health innovations. Working towards such integration is essential.

The principal pitfalls for the production of HTA in Argentina – namely misunderstanding of decision makers about the roll of HTA in the organisation and management of the health care systems, and the absence of specialised

staff in the matter (PAHO,1998) – can be overcome. However the current situation is still far from perfect: although decision makers are becoming aware about the relevance of HTA for health care systems and there are currently trained people in the field, substantial efforts are still required to implement better and more ethical HTA. More interaction between these two multidisciplinary fields of study, that is, HTA and Bioethics, is needed. Local bioethicists are able to give useful advice on critical issues, such as better resource management, health promotion and ethical matters in research (PAHO, 2004). Specifically, Argentinean bioethics scholars can and should play an active role in HTA processes. Working in collaboration with HTA producers can genuinely contribute to the policy sphere in Argentina, by making explicit the socio-ethical questions that arise from the application of PGT in order to design coherent recommendations for nuanced and realistic health and public policies that can, hopefully, be implemented in more transparent fashion.

It is important to emphasise that the lack of comprehensive analyses is a major obstacle for the production of punctual and pragmatic recommendations (Blanquaert, 2006) that are so vital to the design of realistic health policies. For that, I suggest, that more empirical research in the social sciences (sociology, economics, etc.) and qualitative studies are necessary in Argentina in order to collect local and pertinent data to facilitate the production of contextualised assessments. In addition, much more public education in ethics matters is needed in Argentina, especially ethics related to genetics, something that would benefit patients, health professionals and policy makers (*Consultación Pública*

para un Sistema Nacional de Ética y Derechos Humanos en Investigación Biomédica, 2006).

At present, physicians and other health professionals do not receive “formal courses in clinical genetics, genetic counselling and/or public health genetics” as part of their medical curricula (Penchaszadeh, 2009). Remedying this situation, and incorporating ethics into the medical curricula, would go some way to ensuring that future health professionals are able to offer medical genetic services in a manner that is both clinically appropriate and sensitive to patient needs. Finally, policy makers have the duty to protect public health and welfare, thus they need to be conscious about the implications of deciding to allocate resource towards expensive and controversial technologies that may not be “in keeping with the local culture” (Declaration of Alma Alta, 1978).

In South America, Argentina is one of the most advanced nations in the fields of genetics: the country counts some of the most prestigious medical facilities, such as the aforementioned Garrahan hospital, and numerous public and private centres providing genetic services and testing. Planning and coordination between these facilities would be an important means of improving access to genetic services and prenatal testing. The current reality is that in Argentina, the use of genetic technologies is expanding despite the lack of regulations and public policies, and this situation is unlikely to change in the near future. Nevertheless, there are some government initiatives to improve access to genetic services and related technologies, thus it is all the more important that these genetic services be available to *all* in need. Equitable

access, accurate information and appropriate support are critical to facilitate prospective parents to make informed and autonomous decisions.

Hopefully, the case of PGT presented in this work has helped illustrate the fact that new technologies cannot be taken for granted; and maybe some lessons can be learned for the future. I have argued that unfair and unethical situations can be diminished or even prevented if decisions are taken on the basis of more comprehensive HTA analyses, performed at a local level. For that to be accomplished, it would be necessary to encourage the production of technology assessments at the provincial or regional level in Argentina, e.g., by dividing the country into regions to produce local evaluations following a national strategy (including defined assessment priorities, common guidelines and evaluation methods), as has already been done in other jurisdictions. The possibility of creating an Argentinean HTA Network should also be explored.

For many reasons which have been explained in this thesis, Argentina represents a fertile ground for the production of HTA, and the country has a real possibility to play an important role in the promotion of ethical HTA and its relevance for policy in South America. However the situation of vulnerability in which many people live in developing nations must be taken into account; the conditions required for the real exercise of a deliberative democracy (e.g., public discussions on health subjects) are currently far from perfect in Argentina. Education is required to create these conditions (Sommer, 2008) and to have informed people deliberating in fair conditions. As noted by Traynor and colleagues, “inadequate information is the most often cited impediment for

deliberations” (Traynor, Adonis, and Gil, 2007). On this aspect, there is still much need for bioethics research in Argentina and other neighbouring countries.

In 2010, Argentina will celebrate 200 years of autonomy from Spain; however, by that time, the country will have had only 26 years of continued and genuine democracy. Hopefully, as democracy continuous over time, civil society will take part more fully in open and inclusive deliberations about subjects such as health care, allowing Argentinians to reach at least a minimal consensus about sensitive matters such as PGT. Although it is obvious that many other actions would need to be implemented to solve the broader socio-political and economic challenges facing Argentinean society, I suggest that integrating ethics with HTA can be part of the solution. By giving policy makers some of the tools needed to reorganise and rationalise the country’s intricate and overly complex health care system, an ethical HTA can help ensure safer and more equitable access to services and technologies such as PGT.

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