



Regulating human genetic research in Latin America: a race to the top or a race together?

Regulación de la investigación genética humana en América Latina: ¿una carrera para subir al pódium o una carrera entre todos?



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Abstract

Balancing the therapeutic potential of genetic science with the adoption of policies that reflect social values has proven to be a formidable task for Latin American countries. This essay presents some reflections on human genetics research policy in Latin America and explores a path forward for policy development.



Resumen

Equilibrar la potencialidad terapéutica de la genética con la adopción de políticas que reflejen los valores sociales, ha demostrado ser una tarea formidable para los países latinoamericanos. Este ensayo presenta algunas reflexiones sobre la política de investigación genética humana en América Latina y explora un camino para el desarrollo de estas políticas.



Keywords

Human genetics policy, ethics, governance, Latin America.

Políticas de genética humana, ética, gobernabilidad, latinoamerica.



Fechas

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Introduction

History provides us with an abundance of cases illustrating how societies have confronted enduring ethical and moral concerns elicited by disruptive scientific developments. Perhaps the most illustrative examples continue to reside in research and clinical applications of genetic technologies, particularly regarding the early stages of human development.

In the absence of robust policy frameworks, the sole condemnation of particular scientific field of study, such as human genetics (or of particular applications) has proven to be futile for preventing abuses.

Balancing the therapeutic potential that these technologies bring, with the adoption of proportional policy reflective of societal values, has proven to be a formidable task for Latin American countries. Influenced by economic, socio-cultural and historical factors, and shaped by the role of diverse stakeholders, Latin American genetic policy has been thwarted for decades.^{1,2} In the absence of robust policy frameworks, the sole condemnation of particular scientific field of study, such as human genetics (or of particular applications) has proven to be futile for preventing abuses³. As occurred in other regions of the world, these factors have enabled the emergence of an unregulated and dangerous reproductive “tourism” and medical research industry^{4,5} governed by unconstrained market forces, where commercial interests⁶

shape demand¹. At the same time, this policy inertia has impeded investments in scientific research and thereby, curtailed progress.^{7,8}

“Arguing against globalization is like arguing against the law of gravity”⁹. Genetic research is, indeed, by nature a global endeavour. Consequently, for Latin America to benefit from the promise genetics offers for individual and population health and wellbeing, it must start to develop policy frameworks and scientific infrastructures that are competitive globally. This entails not only developing robust regulatory and governance frameworks; together with appropriate health care infrastructures. It also requires establishing the necessary conditions to enable cross-jurisdictional research collaboration by fostering the sharing of resources (e.g. biological materials and data, local expertise, etc.).

- 1 Isasi, R. M., Knoppers, B. M., Singer, P. A., et al. (2004). Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa. *Journal of Law, Medicine and Ethics*, 32(4) 626-40.
- 2 Isasi, R. M., Knoppers, B. M. (2006). Mind the gap: policy approaches to embryonic stem cell and cloning research in 50 countries. *Eur J Health Law*. Apr;13(1) 9-25.
- 3 Aultman, J. M. (2013). Abuses and apologies: irresponsible conduct of human subjects research in Latin America. *J Law Med Ethics*. Spring;41(1) 353-68.
- 4 Smith, E., Behrmann, J., Martin, C., et al. (2010). Reproductive tourism in Argentina: clinic accreditation and its implications for consumers, health professionals and policy makers. *Dev World Bioeth*, 10(2) 59-69.
- 5 Connell, J. (2015). From medical tourism to transnational health care? An epilogue for the future. *Soc Sci Med*. (124) 398-401.
- 6 Annas, G. J. (1998). *Some Choice*. New York: Oxford University Press
- 7 Acevedo Rocha, C. G. (2013). Latin American science: sustainable careers. *Science* (2013) 339(6125) 1274.
- 8 Huete-Pérez, J. A. (2013). Latin American science: much work remains. *Science* 339(6125) 1274.
- 9 Kofi Annan (2006, 23 February). Secretary General Kofi Annan's Opening Address to the Fifty-Third Annual DPI/NGO conference. Accessed from www.un.org/dpi/ngosection/annualconfs/53/sg-address.html



This essay presents some reflections on human genetics research policy in Latin America and explores options for policy development in the field.

Regulating Genetic Research in Latin America

Genetic science bring us great prospects for humanity in terms of improving health and wellbeing and alleviating human suffering, but it also presents us profound socio-ethical implications that extend beyond individuals and communities, to humanity as a

Over the past few decades, in most parts of the world, human genetics policies have moved from an “embryo-centric”, right-to-life approach, to one that is focused on the globalization of research and the ensuing need for governance and policy interoperability. However, this has not been the case for Latin America.

whole. From real scenarios to hypothetical ones, these implications have been widely documented and analyzed in the scientific literature and have been the subject of contentious (and often acrimonious) policy debates at national and international fora¹⁰. Over the past few decades, in most parts of the world, human genetics policies have moved from an “embryo-centric”, right-to-life approach, to one that is focused on the globalization of research and the ensuing need for governance and policy interoperability¹¹. However, this has not been the case for Latin America.

Policy approaches to genetics research are quite heterogeneous in Latin America,^{12,1} reflecting the role and influence of stakeholders and the peculiarities of national institutional frameworks in each jurisdiction. Moreover, the region’s diverse socio-cultural, religious, economic and historical contexts have shaped and influenced public policy and its development. A distinctive aspect worth noting is the strong political power and lobbying pressure still possessed by Latin American religious organizations,

despite the fact that the legal principle of separation between church and state has been consistently upheld¹³.

Coherent and comprehensive policy frameworks governing human genetics research and clinical applications are sorely lacking in the region. Public health policies addressing the equitable provision of genetics services are also scarce (e.g. pre-natal and newborn screening, genetic testing and counselling, etc)¹⁴. There are many reasons for this legal vacuum. First, appropriate priority-setting measures call for attending to more pressing issues, such as socio-political stability, poverty reduction, improving literacy

10 Isasi, R. M., Annas, G. J. (2006). To clone alone: the United Nations’ Human Cloning Declaration. *Rev Derecho Genoma Hum.* (24) 13-26.

11 Isasi, R. (2009). Policy Interoperability in Stem Cell Research: Demystifying Harmonization. *Stem Cell Review and Reports* 5(2) 108-15.

12 Oliva Sánchez, P. F., García-López-De Llano, J., Zaga-Galante, J., et al. (2013). HumGen in Spanish: a comparative description of human genetics regulatory framework in Latin America. *Gac Med Mex.* 149(2) 168-74.

13 Morgan, L. M. (2014). Claiming Rosa Parks: conservative Catholic bids for ‘rights’ in contemporary Latin America. *Cult Health Sex.* 16(10) 1245-59.

14 Restrepo-Méndez, M. C., Barros, A. J., Requejo, J., et al. (2015). Progress in reducing inequalities in reproductive, maternal, newborn, and child health in Latin America and the Caribbean: an unfinished agenda. *Rev Panam Salud Publica.* 38(1) 9-16.



and public health care systems^{15,16} as well as achieving economic progress¹. Second, conflicts between stakeholders committed to conflicting interests and values are also factors responsible for the deferment or absence of policies. Finally, in countries that appeared ideologically or politically predisposed to a restrictive approach to policy¹⁷ (e.g. Brazil, Mexico and Chile), there has been hesitation in maintaining such status quo. The potential of genetic technologies to contribute to the creation of a bio-economy, this is situating the biotechnology sector as the cornerstone for socio-economic development¹⁸, appears to be at the central to such indecisiveness.

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Societal debates and policy-making activity in this area have been permeated by the politics of abortion¹⁹. Discussions about the moral and legal status of the human embryo are present in virtually every policy debate. Policy-makers across jurisdictions have struggled to address the fundamental issue whether the human embryo should be granted full personhood status, or, at minimum, be recognized as a potential person. For Latin American countries, constitutional frameworks appear to limit the policy responses available to legislators. The “right to life” enshrined in most of their national constitutions²⁰ and in the Declaration on Human Rights of the American States²¹, has been often interpreted as granting personhood status to the human embryo, and, therefore, has been used as justification for curtailing any research or manipulation of the embryo¹. Embryonic stem cell²² and cloning research are in consequence, either restricted by law or widely unregulated¹ across the region. A similar scenario has shaped the regulation of genetics applications used in the context of assisted human reproduction, as these tools and methods are inextricably entangled with research that uses or involves early-stage human embryos (e.g. pre-implantation genetic diagnosis and screening)²³.

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- 15 De Andrade, L. O., Pellegrini Filho, A., Solar, O., et al. (2015). Social determinants of health, universal health coverage, and sustainable development: case studies from Latin American countries. *Lancet* 385(9975) 1343-51.
- 16 Atun, R., de Andrade, L. O., Almeida, G., et al. Health-system reform and universal health coverage in Latin America. *Lancet* 385(9974) 1230-47.
- 17 Castilla, E. E., Luquetti DV. (2009). Brazil: public health genomics. *Public Health Genomics* 12(1) 53-8.
- 18 Organization for Economic Cooperation and Development (OECD) (2009). *The Bioeconomy to 2030: designing a policy agenda*. Accessed <http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/thebioeconomyto2030designingapolicyagenda.htm>
- 19 Richardson, E., Birn, A. E. (2011). Sexual and reproductive health and rights in Latin America: an analysis of trends, commitments and achievements. *Reproductive Health Matters* 19(38) 183-96.
- 20 See, e.g., Constitutions adopted in Chile, Costa Rica, Ecuador, Honduras, Nicaragua, and Peru.
- 21 Article 4 of the American Convention on Human Rights, “Pact of San Jose, Costa Rica”, Organization of American States (November 22, 1969).
- 22 Palma, V., Pitossi, F. J., Rehen, S. K., et al. (2015) Stem cell research in Latin America: update, challenges and opportunities in a priority research area. *Regen Med.* 10(6) 785-98.
- 23 Luna, F. (2002). “Assisted Reproductive Technology in Latin America: Some Ethical and Sociocultural Issues”. In “Current Practices and Controversies in Assisted Reproduction” Report of a Meeting on “Medical, Ethical and Social Aspects of Assisted Reproduction”, World Health Organization.



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Influential to the framing of policy has been fears over slippery-slope scenarios that could lead to exceptionally objectionable uses²⁴, such as human reproductive cloning and human genetic engineering. In some countries, these concerns have been advanced by arguments based on blanket protections of human dignity and integrity, however defined²⁵. The latter is illustrated by the fact that of the few genetics laws already adopted, virtually all impose criminal bans with hefty penalties or imprisonment terms (e.g. Argentina, Brazil, Chile, Colombia, Ecuador, Panama and Peru). The aims of criminal law are retribution, denunciation and deterrence. By using criminal law as a tool, Latin American legislators are sending an implicit message of condemnation of what they consider to be a particularly morally reprehensible behavior. The language adopted

in some laws reflects this view. The Colombian penal code, for instance, states as its main purpose respect for human dignity before criminalizing the “creation of identical human beings”²⁶. Similarly, legislation adopted in Ecuador^{27,28}, Panama^{29,30}, Peru³¹ and Chile explicitly prohibits human cloning in an effort to protect “genetic integrity”³² and human rights.

Amongst the chief socio-ethical concerns associated with genetic technologies are issues regarding equitable access³³, discrimination and misuse for non-medical purposes, including so-called “enhancements”³⁴. The latter has prompted hesitation in the adoption of genetic technologies because of their eugenic potential.^{35,36} The term “eugenics” evokes the intent to improve or eliminate the influence of certain presumed genetic characteristics. Across jurisdictions, its interpretation remains properly limited

24 Sequeiros, J., Gibbon, S., Clarke, A. (2015). Genetics and ethics in Latin America. *J Community Genet.* 2015 Jul. 6(3) 185-7.

25 Knoppers B. M., Özdemir, V. In: van Beers B, Corrias L, Werner WG, eds. *Humanity across International Law and Biolaw.* Cambridge: Cambridge University Press 223-243 (2014).

26 Colombia, Penal Code, Law 600 (2015).

27 Ecuador, Organic Health Law of December 22, 2006.

28 Ecuador, Ministerio de Salud Pública, Reglamento para uso del material genético humano en Ecuador, MSP, Dirección Nacional de Normatización y Programa Nacional de Genética, 2013, Quito, Ecuador.

29 Panama, Law No. 3 of 200.

30 Penal Code of the Republic of Panama Law 14 of 2007 (modified by Law 26 of 2008).

31 Peru, General Health Law No. 26842 (1997).

32 Chile, Law No. 20.120 on Scientific Research Involving Human Beings, their Genome, and Prohibition of Human Cloning (2006).

33 Almeida, G., Sarti F. M. (2013). Measuring evolution of income-related inequalities in health and health care utilization in selected Latin American and Caribbean countries. *Rev Panam Salud Publica* 33(2) 83-9.

34 Penchaszadeh, V. B. (2015). Ethical issues in genetics and public health in Latin America with a focus on Argentina. *J Community Genet.* 6(3):223-30.

35 Powell, R. (2015). In Genes We Trust: Germline Engineering, Eugenics, and the Future of the Human Genome. *J Med Philos.* 2015 Dec;40(6) 669-95.

36 Miller, P. S., Levine, R. L. (2013). Avoiding genetic genocide: understanding good intentions and eugenics in the complex dialogue between the medical and disability communities. *Genet Med.* 15(2) 95-102.



to state programs (e.g. USA, Germany) which continue to be morally condemned. This is reflected in legislation governing genetics research and clinical applications which explicitly proscribe “eugenic practices”³² and “any other procedure directed at the selection of the human race.”^{29,30} However, “eugenics” is also a much abused term that can serve as political trump card to shut down further social debate and ensuing policy action.

Nevertheless, Latin American policy still reflects a degree of optimism with respect to the prospects of genetics research and medicine.

Nevertheless, Latin American policy still reflects a degree of optimism with respect to the prospects of genetics research and medicine. Either intentionally, by cautiously included normative exceptions, or unintentionally, by means of legal loopholes, legislators across the region have created a space to allow for certain genetics applications in health care and biomedical research. As such, limitations on the applications of particular technologies (e.g. genetic testing, gene therapy, genetic manipulation of cells) are often overridden when conducted for research, preventive, diagnostic or therapeutic purposes if subject to governance and

ethical safeguards to protect research participants and patients (e.g. Chile, Ecuador, Panama)³⁷.

Thus, the potential of this field to improve health and health care, by providing effective interventions for disease prevention, improving diagnostic methods and developing new therapies for intractable diseases, has not escaped the legislators. The time is therefore ripe, for reflective and proportional policy.

Drafting Latin American Genetics Policy: A Race Together?

Perhaps last in the list of government priorities, policy and funding for innovation in the provision of health services and biomedical research has stagnated for decades. At the same time, thanks to the Latin American “genetic heritage”^{38,39,32} we can witness a slow increase in the participation of local researchers in international consortia as well as a continuously growing interest in the region by the international scientific community^{40,41,42}. Obstacles to increasing these efforts are undoubtedly formidable; they go beyond providing sufficient financial investments and building the necessary

37 Acosta, A. X., Abé-Sandes, K., Giugliani, R., et al. (2013). Delivering genetic education and genetic counseling for rare diseases in rural Brazil. *22(6)* 830-4.

38 Ecuador, Organic Health Law of December 22, 2006.

39 Mexico, General Health Law (1984) (last amendment, 2015).

40 Homburger, J. R., Moreno-Estrada, A., Gignoux, C. R., et al. (2015). Genomic Insights into the Ancestry and Demographic History of South America. *PLoS Genet.* 11(12) e1005602.

41 Garcia, C. R., Parodi, A. J., Oliva, G. (2012) Growing Latin American science. *Science* 30;338(6111) 1127.

42 Hermes-Lima, M., Alencastro, A. C., Santos, N. C., et al. (2007). The relevance and recognition of Latin American science. Introduction to the fourth issue of CBP-Latin America. *Comp Biochem Physiol C Toxicol Pharmacol.* 146(1-2) 1-9.



foundational expertise. They also encompass political will, which includes but is not limited to the building of robust regulatory frameworks.

In this context, how should policy be developed? Which lessons could be learnt from other jurisdictions? There are two mechanisms for policy development that are often neglected and should be considered as guiding posts. One is harmonization or policy convergence⁴³ and the other is policy transfer.

In countries in which genetics research and clinical applications are well advanced, policy convergence or the harmonization of scientific and normative ethical standards⁴⁴ has successfully occurred, the European Union provides a good example. As in other

contexts, strong economic and institutional links between and among countries is leading to increasingly similar policies across jurisdictions⁴⁵. The globalization of genetics science has further contributed to this convergence. Harmonization does not require similarity in legislative approaches but rather, complementarity⁴⁶, so it remains possible even though national policy frameworks remain quite heterogeneous. There are substantial incentives for countries to adopt mechanisms that foster harmonization, such as to reduce transaction costs, promote their scientific infrastructures and strengthen their competitiveness⁴⁷. Most importantly, harmonization of policies could facilitate the timely realization of the therapeutic potential of genetics research.

Across Latin America, a degree of policy convergence is reasonably present in the context of genetics research, despite that most countries have shied away from genetics-specific norms.

Such convergence is evident with regards to fundamental ethical principles and requirements governing research with human participants and for the donation of tissue and reproductive materials (e.g., respect for autonomy and confidentiality; respect for the human body by restricting the use of monetary payments and financial incentives for donation; ethics review and oversight; etc.). As such, requirements for informed consent, safeguards related to privacy and confidentiality of genetic information and measures against the commodification of the human body have been adopted, reflecting widely accepted international ethical standards⁴⁸. As adherence to such standards in

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43 Knill, C. (2005). Introduction: Cross-national policy convergence: concepts, approaches and explanatory factors. *Journal of European Public Policy* 12(5) 764-774.

44 Isasi, R. (2012). Alliance, Collaborations and Consortia: The International Stem Cell Forum and its Role in Shaping Global Governance and Policy. *World Stem Cell Report*, Reg. Med 7(6 Suppl.) 84-8.

45 Knill, C. (2005). Introduction: Cross-national policy convergence: concepts, approaches and explanatory factors. *Journal of European Public Policy* 12(5) 764-774.

46 Boodman, M. (1991). The Myth of Harmonization of Laws. *The American Journal of Contemporary Law* 39 699-724.

47 The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). Accessed <http://www.ich.org/home.html>

48 Lamas, E., Ferrer, M., Molina, A., et al. (2010). A comparative analysis of biomedical research ethics regulation systems in Europe and Latin America with regard to the protection of human subjects. *J Med Ethics*. 36(12) 750-3.



the conduct of scientific research is of paramount importance, many countries –albeit with a high degree of difference among normative provisions– foresee ethics review by a local, regional or national ethics committee or equivalent institution.

However, the stringency of governance mechanisms for oversight and compliance has not been empirically assessed and evaluated in the context of human genetics research⁴⁹. Neither has the impact of the wide range of international clinical trials conducted in the region been documented. Given the history of past abuses, substantial ques-

tions remain to be addressed. Are current structures centralized, independent and transparent enough to meet good governance criteria?⁵⁰ Is there enough expertise to deal competently with the complexities of genetics science? Are enforcement mechanisms effective? Are there similarities in policies and policy outcomes? Are there parallels between policies adopted by governments and their actual effects in terms of goal achievements?

With the power to provide an institutional foundation for the development and dissemination of policies and best practices, the standing and role of Latin America's professional and funding organizations in the field of genetics (and related areas) should be carefully evaluated.

Another mechanism for policy development is policy transfer, which can be an effective tool to overcome legislative inertia. Conducted by national, international and regional stakeholders (e.g. professional organizations, funding agencies, etc.) acting in a multidisciplinary and multidimensional manner^{51,52}, these actors' legitimacy can motivate policy-makers to engage in normative action.⁵³ They also have great power to foster scientific progress by promoting best practices and policy innovation, and therefore, their influence should not be underestimated⁴⁴. More-

over, these stakeholders' knowledge and experience in adapting best practices to local contexts, given them additional authority to serve as true "policy agents". As such, they mediate cross-jurisdictional policy transfer and innovation while promoting governance of research⁵⁴.

With the power to provide an institutional foundation for the development and dissemination of policies and best practices, the standing and role of Latin America's professional and funding organizations in the field of genetics (and related areas) should be carefully evaluated. They are essential actors capable of promoting scientific integrity⁵⁵

49 Rivera, R., Ezcurra, E.(2001). Composition and operation of selected research ethics review committees in Latin America. *IRB*. 23(5) 9-12.

50 Rivera, R., Ezcurra, E.(2001). *Ibid*.

51 Newmark, A.J. (2002). An integrated approach to policy transfer and diffusion. *The review of policy research* 19(2) 151-180.

52 Stone, D. (2012). Transfer and translation of policy. *Policy Studies* 33(6) 483-499.

53 Rosemann, A., Chaisinthop, N. (2016). The pluralization of the international: Resistance and alter-standardization in regenerative stem cell medicine. *Soc Stud Sci*. 46(1) 112-39.

54 Rojas-Martínez, A., Giraldo-Ríos, A., Jiménez-Arce, G., et al. (2014). RELAGH - The challenge of having a scientific network in Latin America: An account from the presidents. *Genet Mol Biol*. 37(1 Suppl) 305-9.

55 Bostiancic, M. C. (2012). Latin American bioethics committees: tools for the prevention of medical and legal conflicts. *Med Law*. 31(2) 325-34.



while accelerating scientific progress and fostering international cooperation⁵⁶. Despite their limited enforcement or accountability powers, professional and funding organization could still have effective authority by virtue of their power of persuasion. Accountability, foresight and global approach to scientific innovation should thus be characteristics of their activities.

Conclusion

Scientific developments in the field of human genetics research will undoubtedly continue to emerge at incredible speed and so too the contentious debate surrounding their broad implications. Perhaps in order to manage competitive pressures, Latin American

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countries will end adopting or adjusting policies and regulatory standards in order to best integrate with the international community. The more these countries attempt to be competitive and seek integration into the global community, the most likely that their policy frameworks would achieve a degree of convergence⁵⁷. The issue therefore is whether given such pressures, Latin American countries will move together as a community, and, whether, the direction of such race would be towards the top or the bottom of ethical and scientific standards.

What is clear is that in the absence of governments' normative action, laissez faire approaches will prevail. This will promote a market model in which the chief principle is the economic one of supply and demand. In such context, "ethical arbitrage" or forum shopping practices would inevitably transform the region into un-

desirable havens for biomedical research and medical interventions. Conversely, there is also the risk of falling into "juridification" or the dangers of uncritical and unreflective appeal to legislation, which in turn could hamper scientific progress. The great challenge for Latin America is, therefore, to develop policy frameworks that are both ethically and politically consistent while remaining socially equitable.

Political compromises and trade-offs would be necessary in order to achieve consensus in pluralistic, democratic societies. By setting political and ethical boundaries in the governance of genetics research and its clinical applications, governments would be able to demonstrate that they are capable of making ethical assessments, encouraging regulatory consistency and establishing priorities. Regulatory vacuums and the lack of adequate procedural and substantive safeguards undeniably lead to abuse -- that much we have learned from history.

56 Giugliani, R., Baldo, G., Vairo, F., et.al. (2015). The Latin American School of Human and Medical Genetics: promoting education and collaboration in genetics and ethics applied to health sciences across the continent. *J Community Genet.* 6(3) 189-91.

57 Holzinger, K., y Knill, C. (2005). Causes and Conditions of cross-national policy convergence". *Journal of European Public Policy* 12(5) 775-796.