More than regulatory challenges for genomic medicine in Latin America: Gaps, Barriers and Challenges

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Therapeutic potential of research and clinical applications of genetic technologies

Bio-economy

Regulatory uncertainty

Socio-cultural and historical factors

Policies that reflect social values
Absence of robust policy frameworks. Risk of abuse

International standards ¿policy convergence or policy transfer?

National home-keeping policies

At the intersection of the international and local governance of Genetic Medicine
More than regulatory challenges for genomic medicine

Policy frameworks and scientific infrastructures that are competitive globally

Robust regulatory and governance frameworks

Appropriate health care infrastructures

International collaboration

Good Governance

Not only rules

Social environment
Policy approaches in LA: Gaps

1. appropriate priority-setting measures

2. conflicts between stakeholders

3. restrictive approach to policy vs. bio-economy

Public Health Policies in Genetic
Policy approaches in LA: Barriers

1. moral and legal status of the human embryo
2. genetics applications used in the context of assisted human reproduction
3. equitable access, discrimination and misuse for non-medical purposes
In this context, how should policy be developed?

**Mechanisms for policy development**

- **Harmonization or policy convergence**
  - Convergence in to ethical principles and requirements governing research
  - mechanisms for oversight and compliance has not been empirically assessed and evaluated

- **Policy transfer effective tool to overcome legislative inertia**
  - national, international and regional stakeholders can motivate policy-makers to engage in normative action
What is the state of the art of regulation in LA

- **Barriers →** Biomedical research and clinical translation

- **Gaps →** There is no specific regulation for genetic research and medicine

- **Challenges →** Transition to an efficient regulatory model.
Challenges: how to overcome the barriers

In the absence of governments’ normative action, laissez faire approaches will prevail. Promote a market model. “Ethical arbitrage”

By regulations, 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 – much we have learned from history.
Challenges
Transition to an efficient regulatory model

- First step → Improve regulatory space

- Second step → Design and implement flexible, efficient and clear regulation with the participation of stakeholders
  (Scientists, Professional Societies, Patients’ Organization, Academic Organizations, Regulatory Agencies)
Between the first and second step it is necessary to create a regulatory culture.

- **The rights and health of patients and improve health care system are the keys**
- **Regulators need to work more closely with scientists**
- **Interactive discussions**
- **Accelerating regulatory science initiatives**
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Ecosystem
Innovation
in Medicine
Regenerative Medicine
Genetic Medicine
Clinical Research Ethics
Clinical Trial Design
Regulatory Agencies
Regulatory Support
Health Care System
Industry
Research
Infrastructure Clinical Resources
Gaps to effective transfer
Strengthening good regulatory practices
Regulation of Regenerative Medicine
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