

**INFORMED CONSENT AND
LIABILITY – CONTEXT IN THE
CLINICAL CARE FRAMEWORK
WITHIN LAC EXPERIENCES**

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**Workshop on Ethical, Legal and Social Aspects
(ELSA) Related to Personalized Medicine
November 17-18th, 2020
EULAC PerMed**

LATIN AMERICA & THE CARIBBEAN CONTEXT

2020 656,103,025 persons
8.42% of total world population
Density 32-84/km²
82.5% urban
Median age 31.0 years
Fertility rate 2.04, 50-94%
professional coverage of births
53% jobs in the informal
sector, 50% women

Indigenous population – 50M, 500 ethnic
groups – 8% region's population
14% poverty, 17% extreme poverty, 43%
material poverty
48% urban, lack of environmental protection
Schooling 20-65%, higher education 0.5-15%
Poor access to health services : diseases
markers of inequality. Development of
biomedical research using health services

COVID-19, September
28% cases, 34% deaths, 5.3% GDP contraction
20-40% lost of employment
Gender gap and increase in child labor
3.5% increase in poverty, 2.3% extreme poverty

- Challenges
- ✓ Continuous improvements in competitiveness and productivity
 - ✓ Poor quality of education and slow transfer of knowledge
 - ✓ Excessive inequality and lack of social protection

<https://www.worldometers.info/world-population>

<https://www.latinamerica.undp.org>

<https://blogs.imf.org/2020/10/22>

<https://www.american.edu/centers/latin-american-latino-studies>

<https://en.unesco.org/courier/2020-3>



**Equality
Justice
10**

**Liberty
Autonomy
5**

**Benefices
4, 15**

**Dignity
3**

**Informed Consent
6**

**Solidarity and
cooperation
13, 21**

**Privacy
Confidentiality 9**

**No
discrimination
11**

**Respect for
cultural diversity
13**

**Respect of
vulnerability
7, 8**

**Social
Responsibility
14**

**Protecting future
generations and
the environment
16, 17**

**Risks
assessment and
management 20**

**Bioethics
Committees 19**



INFORMED CONSENT - LAC INITIATIVES

| | | |
|-----------------------------|--|--|
| Clinic | Cartagena's Declaration 2004 Ibero-American Web of Data Protection Recognition of UDHR, ACHR | National law on Patient Rights: Argentina, Chile , Costa Rica, Ecuador, El Salvador, Uruguay Specific Laws and Norms on IC: all except Brasil and Haiti |
| Research | Declaration of Helsinki, UDHR, CIOMS, GCP | National laws and norms ERC |
| Biological materials | | National Law: Ecuador, Costa Rica, Panama National guidance: Argentina, Brazil, Chile, Colombia, Haiti, |
| Privacy of Data | | National law: all but El Salvador Habeas Data: all but El Salvador, Panama, Venezuela |
| Genetic research | WMA Declaration of Reykjavik 2005-2019 WMA declaration of Yaipai on Ethical Considerations regarding Health Databases and Biobanks 2002-2016 Universal Declaration on the Human Genome and Human Rights, 1997 International Declaration on Human Genetic 2003 | National Law: Ecuador, Costa Rica National guidance: Argentina, Brazil, Chile, Colombia, Uruguay, Venezuela |

INFORMED CONSENT – PROBLEMS IN LA & C

| | | |
|-------------------------|--|--|
| Clinic | Contractual defensive medicine or paternalism Poor participation and forced co-responsibility Poor access to sanitary care | Autonomy |
| Research | Medical and institutional power Understanding and education Induced consent Out of benefits post-research Extraterritoriality and compensation | Autonomy Beneficence No maleficence Justice |
| Genetic research | Discrimination: poor, Indigenous and Afro-American groups Donors: obligation of solidarity and altruism? Withdrawal Extraterritoriality and patents Lack of genetic counselling | |

INFORMED CONSENT FOR GENETIC SERVICES AND BIOBANKS

- “Pharmacogenomics sub studies” involved in biomedical researches: deviation of the objectives, violation of dignity and informed consent process: partial information on the commercial aspect and patent and loss of property, symbolic violence against population confidence in science, structural violence deepening inequalities and differences (Justo).
- Global Alliance to Enable Responsible Sharing of Genomic and Clinical Data, 2013
- Private biobanks
- World Bank: the major beneficiaries of IPRs are the developed countries (USA annual gain of USD 20 billion), while developing countries face an annual loss of 7.5 billion on royalties and license fees

- Informed consent for genetic services and biological material
- DNA paternity testing: IC or legal mandate
- NBS programs in 14 countries: mandatory; congenital hypothyroidism, phenylketonuria, G&P deficiency, Hbp, CF, galactosemy

Revista Redbioética/UNESCO, Año 4, 1 (7): X-XX, Enero - Junio 2013

www.eubios.info/index.htm

WHO 2004 Community genetic services in Latin America and regional networks on medical genetics

eJIFCC2015Vol26No4pp326-331

INFORMED CONSENT FOR BIOBANKS IN LA


| IC | Social impact | Confidentiality | Security | Contact |
|----------|--|-----------------------------|---------------------|--------------------------------------|
| Broad | Lack of information Inequity Donor as object | Codification Free access | No physical risks | Individual information Withdrawal |
| Specific | Rare diseases | None | Genetic counselling | Feasibility |

INFORMED CONSENT AND BIOBANKS

- ✧ Quality of life in the future
- ✧ Respect of dignity
- ✧ Veracity
- ✧ Professional responsibility
- ✧ Social, legal and relational context

- ✧ Word meaning: confusion, antagonism and lack of confidence in science
- ✧ Rights of children and persons not able to consent

ETHICS REFERENCES FOR INFORMED CONSENT

- ✓ Universal Declaration on Human Rights, 1948
 - ✓ The Declaration of Inuyama, CIOMS 1990
 - ✓ Universal Declaration on the Human Genome and Human Rights, 1997
 - ✓ Convention on Human Rights and Biomedicine · Oviedo, 1997
 - ✓ International Declaration on Human Genetic Data, 2003
 - ✓ Universal Declaration on Bioethics and Human Rights, 2005
 - ✓ Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights, 2015
 - ✓ WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, 2002-2016
 - ✓ WMA Declaration of Reykjavik – Ethical Considerations Regarding the Use of Genetics in Health Care, 2005-2019
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PERSONALIZED MEDICINE ?

Personalized medicine = clinical relation = dialog between the patient and the doctor for the best treatment within the current scientific knowledge

Precision medicine = invasive procedures and robotics

Specialized medicine = focused on a defined group of patients, diseases, skills, or philosophy

Personalized/precision/specialized Medicine ?

FDA, 2000: Precision medicine, sometimes known as "personalized medicine" is an innovative approach to tailoring disease prevention and treatment that takes into account differences in people's genes, environments, and lifestyles.

UE, 2015: personalized medicine included in a large concept of patient centered sanitary attention. Cooperation and interchange of the best practices

Necessity of biobanks and big data for research, development and applications of results

PROPOSALS

- “Decolonial thinking” for a fair use of concepts
- Dynamic informed consent: control and democratic participation of donors
- Genomic sovereignty and regional bioethics answer to the new technologies with social participation
- Equitable and sustainable international collaboration
- Ethics requirements for patent jurisprudence and intellectual property

<https://www.who.int/bulletin/volumes/93/2/14-138420>

<http://revistas.fuac.edu.co/index.php/grafia/article/view/547/582>

<https://www.redalyc.org/pdf/3438/343845607012.pdf>

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Revista Grafia 2015, 12(2):50-72

THANK YOU
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