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What the case of Guatemala has taught us

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What the Case of Guatemala Has Taught Us

UNIVERSITY
OF MIAMI
ETHICS PROGRAMS



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Panamerican
PABI
Bioethics
Initiative



Disclaimer

- The views provided in these slides are solely the opinions of the presenter and are not meant to represent any group or organization.

Questions for the International Research Panel- U.S. Presidential Commission for the Study of Bioethical Issues

- What occurred in Guatemala between 1946 and 1948 involving a series of STD exposure studies funded by the U.S. PHS?
- To what extent were U.S. Government officials and others in the medical research establishment at that time aware of the research protocols and to what extent did they actively facilitate or assist in them?
- What was the historical context in which these studies were done?
- How did the studies comport with or diverge from the relevant medical and ethical standards and conventions of the time?

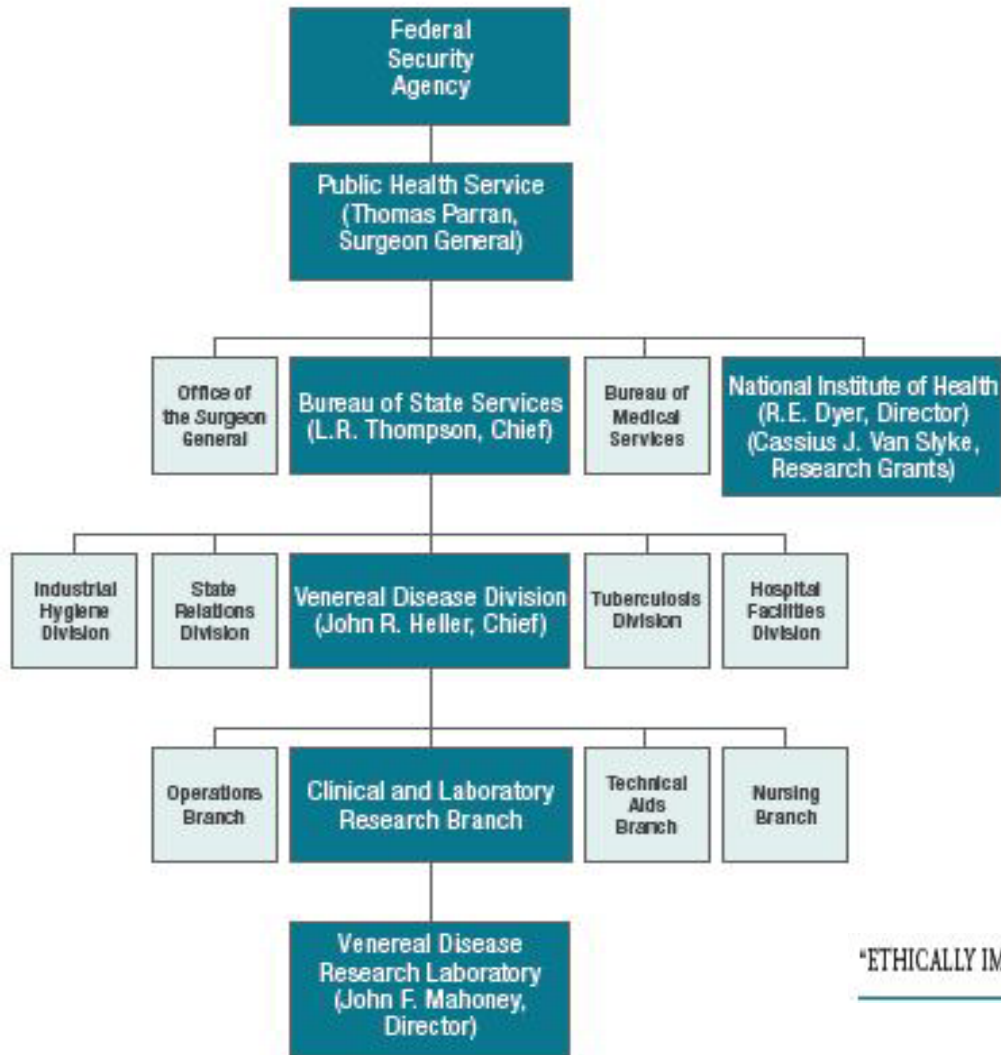
Normal exposure, Guatemala

- The primary purpose of the studies was to develop human models of transmission of *Treponema* by sexual transmission and cutaneous and mucous membrane inoculation in order to assess the effectiveness of potential chemo prophylactic regimens
- Additional studies were conducted to:
 - Assess the potential for re-infection of persons with untreated, latent syphilis or of those with recent treatment of syphilis with penicillin
 - Compare performance of various serologic tests for syphilis
 - Develop human models of transmission and chemoprophylaxis of the agents of gonorrhoea (*Neisseria gonorrhoeae*) and chancroid (*Hemophilus ducreyi*).

Context

- 350,000 fresh infections with gonorrhoea will account for 7,000,000 lost man days per year (in the Armed Forces)
 - Dr Joseph Earle Moore, Chairman of the National Research Council
- President Franklin D. Roosevelt established the Office of Scientific Research and Development (OSRD). The Committee on Medical Research provided unprecedented funding to the STD research

Organizational Chart PHS



ETHICALLY IMPOSSIBLE STD Research in Guatemala from 1946-1948

Table 1: Overview of the USPHS STD Inoculation Study, 1946–1948, Based on Review of Summary Reports and Experimental Lo Archived Papers of John Cutler, MD

Study characteristic	Syphilis	Gonorrhea	Chancroid
Source of subjects	Commercial sex workers, mental hospital patients, prisoners	Commercial sex workers, prisoners, soldiers, mental hospital patients	Soldiers (presumed), mental hospital patients
Type of exposure*			
--sexual contact with commercial sex workers**	12	93	0
--cutaneous or mucous membrane inoculation**	656	679	142
--intravenous inoculation	13	0	0
--intra-CSF inoculation (via cisternal puncture)	7	0	0
--oral ingestion	6	0	0
Total number of subjects exposed**	696	772	142
Number of subjects judged to be infected**	427 (61%)	234 (30%)	138 (97%)
Type of treatment considered to be adequate	Penicillin (≥ 3.4 million units)	Penicillin 300,000 units	Sulfathiazole (1 g PO qid X 5 days)
Number (%) of subjects with indication of adequate treatment**	369 (86%)	233 (99.5%)	129 (93%)

*Numbers include exposure to both infected and uninfected experimental materials (e.g., heat-killed bacteria, uninfected rabbit tissue)

**Numbers are totals summed from numbers of subjects in specific experiments.

Secrecy

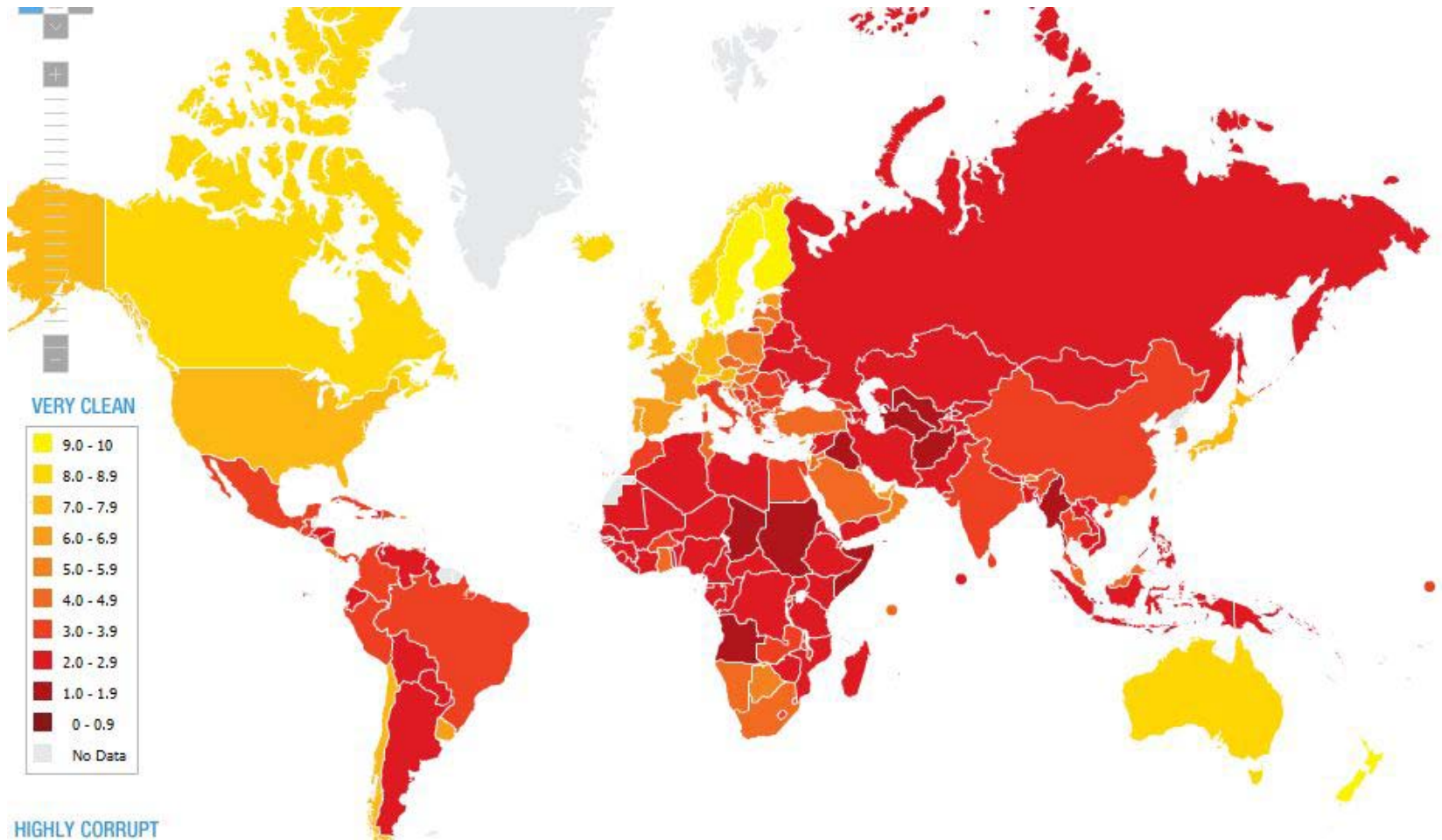
“...it is becoming just as clear to us as it appears to be to you that it would not be advisable to have many people concerned with this work in order to keep down talk and premature writing. I hope that it would be possible to keep this work strictly in your hands without necessity for outside advisors or workers other than those who fit into your program and who can be trusted not to talk....”

- Letter from Dr John Cutler to Dr John Mahoney, Director of the Venereal Diseases Research Laboratory, May 1947

Contemporaneous Standards for Ethical Research (1946-1948)

- Nuremberg Code (1947)
 - The American Medical Association accepted the report of Andrew Ivy and Leo Alexander and published that voluntary and informed consent is essential, as well as avoidance of inappropriate risk (1946)
- President's Advisory Commission on Human Radiation Experiments (1944)
 - Consent for experiments with healthy subjects
 - Not clear about consent when doing research with patients
- Experiments like the one in Guatemala were not “ethically permissible” in the U.S.

Corruption Perception Index 2010 (Transparency International)



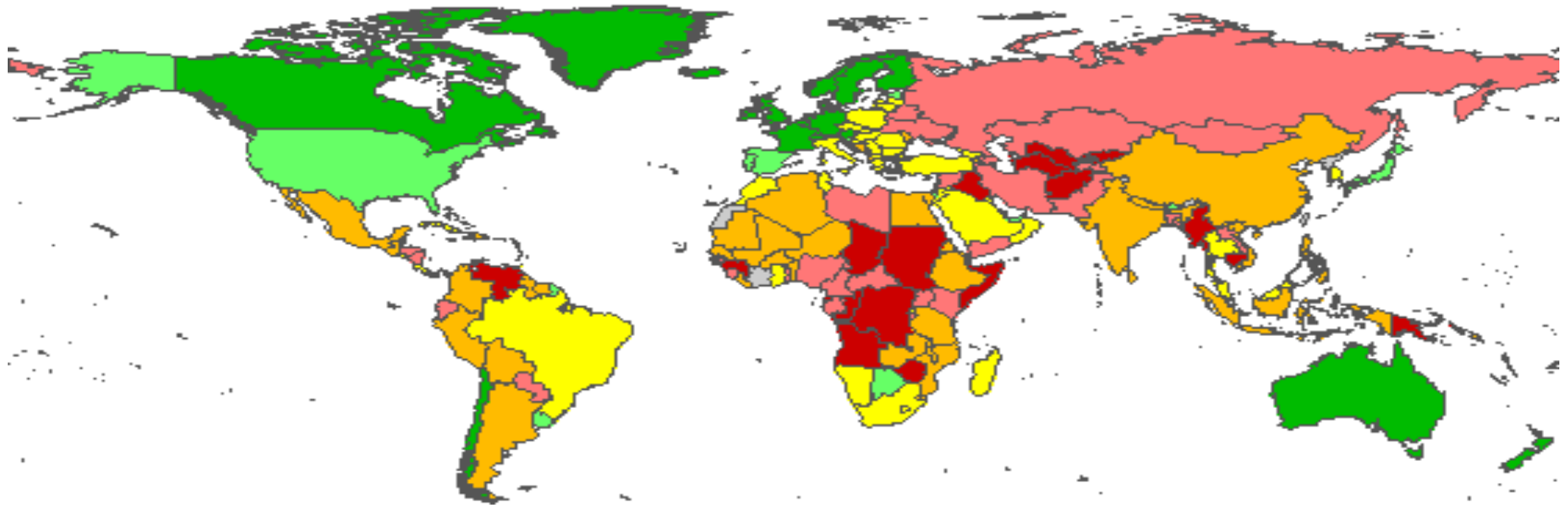
Governance

Traditions and institutions by which authority in a country is exercised (Kaufmann D, Kraay A, Mastruzzi M. Global Economy and Development. Brookings Institutions. September 2010 www.govindicators.org)

- Process by which governments are selected, monitored and replaced
 - Voice and accountability
 - Political stability and absence of terrorism/violence
- Capacity of a government to effectively formulate and implement sound policies
 - Government effectiveness
 - Regulatory quality
- Respect of the citizens and the state for the institutions that govern interactions among them
 - Rule of law
 - Control of corruption

Worldwide Governance Indicators

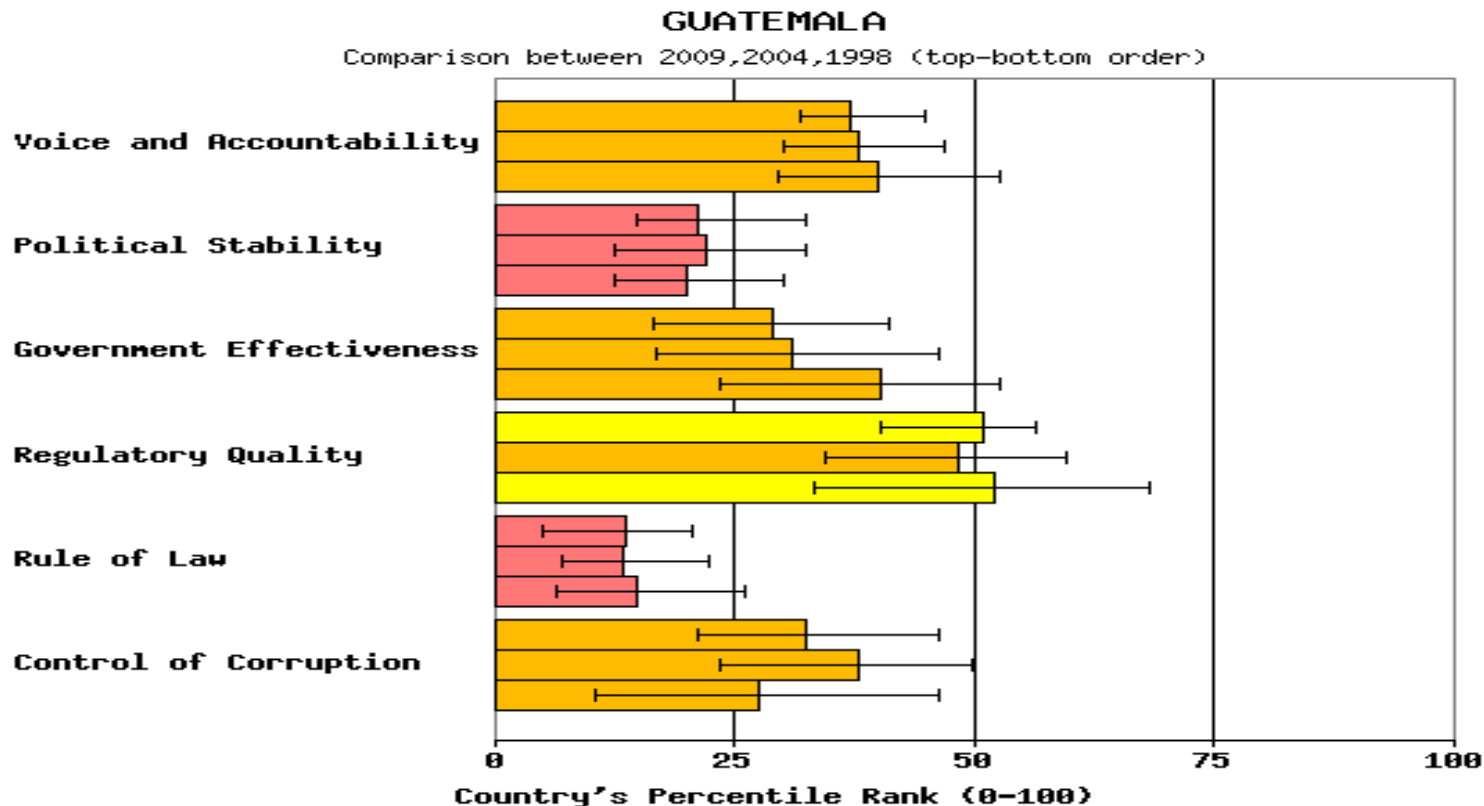
Control of Corruption (2009)



Source: Kaufmann D., A. Kraay, and M. Mastruzzi (2010), The Worldwide Governance Indicators: Methodology and Analytical Issues

Note: The governance indicators presented here aggregate the views on the quality of governance provided by a large number of enterprise, citizen and expert survey respondents in industrial and developing countries. These data are gathered from a number of survey institutes, think tanks, non-governmental organizations, and international organizations. The aggregate indicators do not reflect the official views of the World Bank, its Executive Directors, or the countries they represent. The WGI are not used by the World Bank Group to allocate resources.

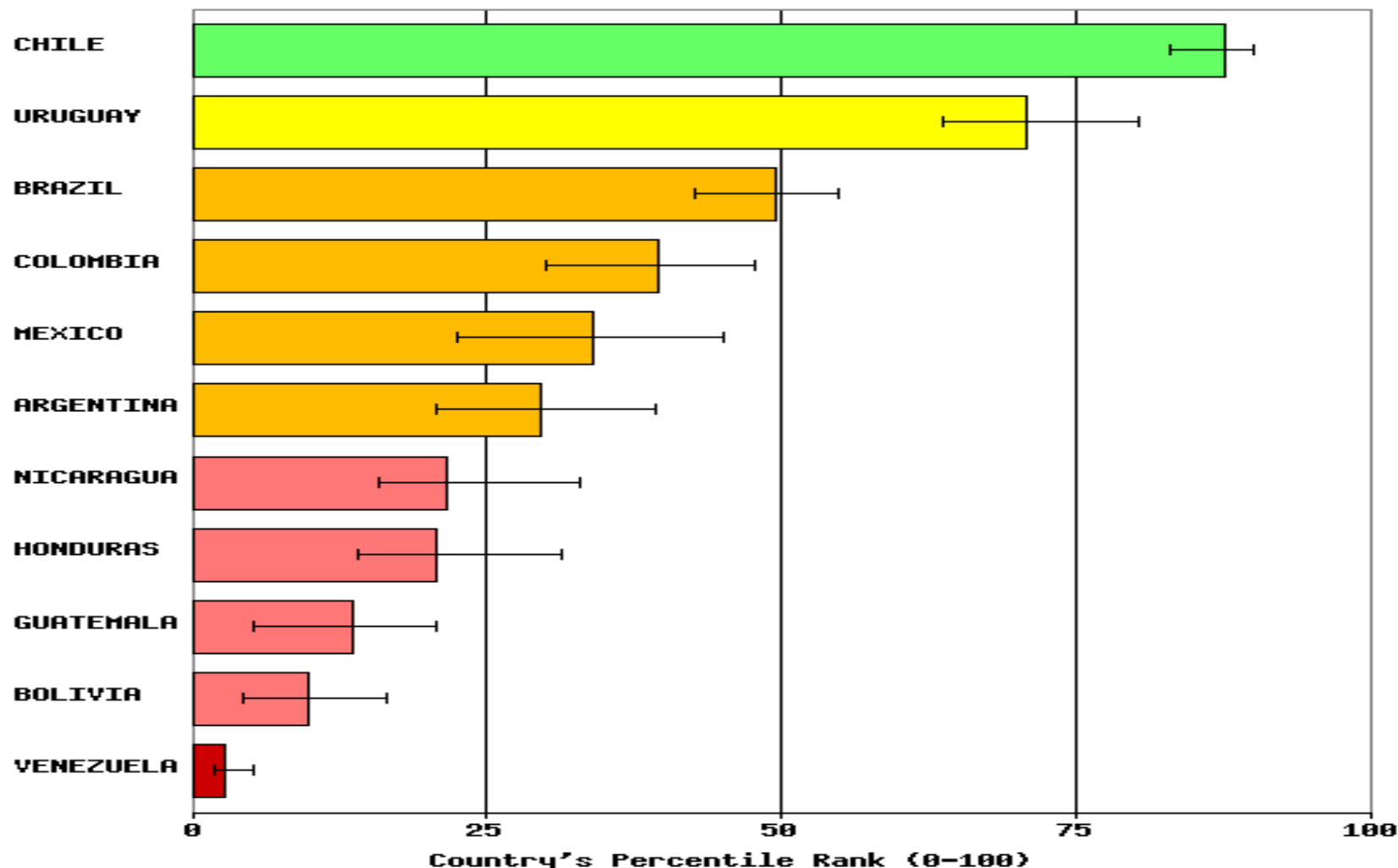
Worldwide Governance Indicators (World Bank)



Source: Kaufmann D., A. Kraay, and M. Mastruzzi (2010), *The Worldwide Governance Indicators: Methodology and Analytical Issues*

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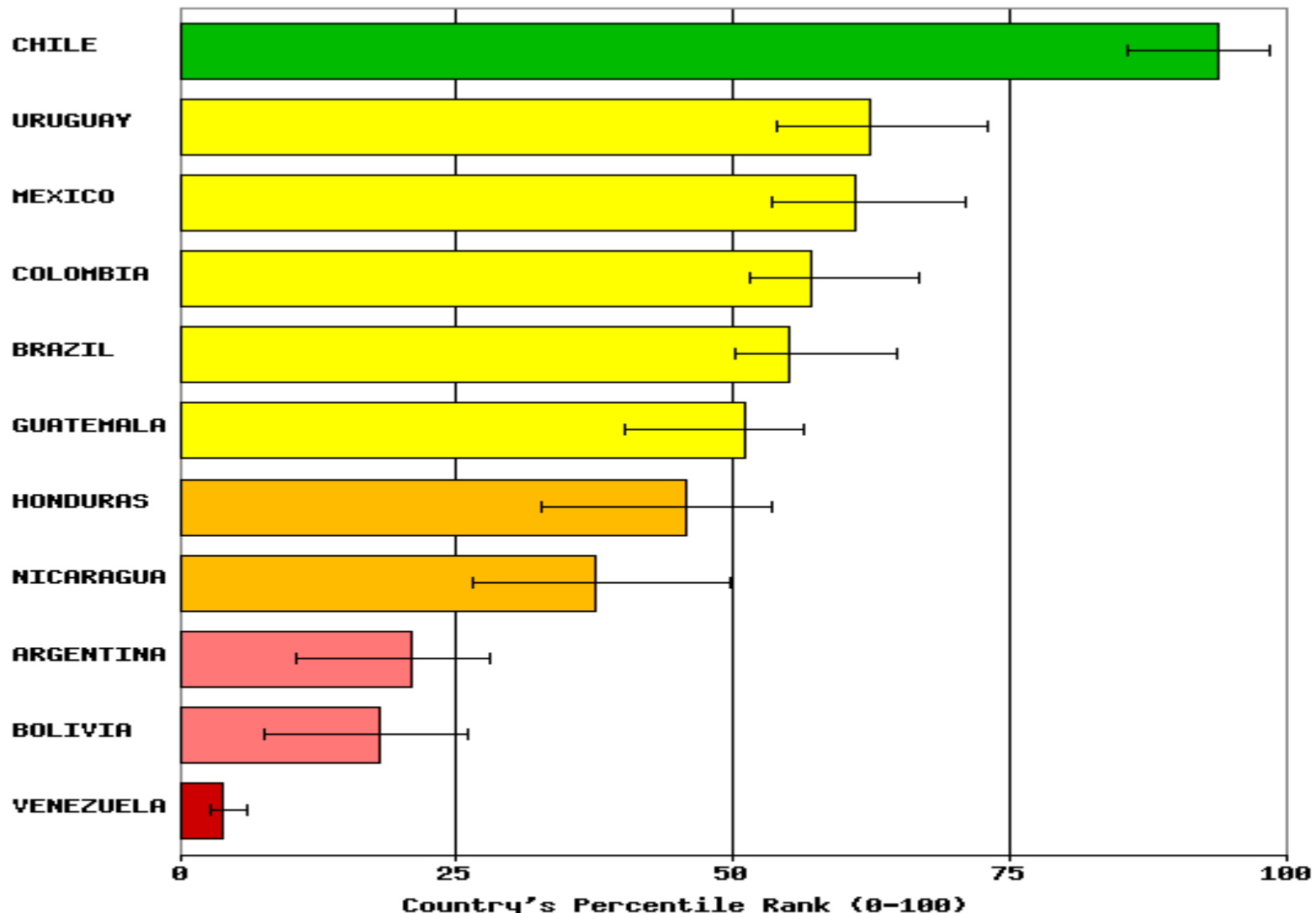
Rule of Law (2009)



Source: Kaufmann D., A. Kraay, and M. Mastruzzi (2010), The Worldwide Governance Indicators: Methodology and Analytical Issues

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Regulatory Quality (2009)



Source: Kaufmann D., A. Kraay, and M. Mastruzzi (2010), *The Worldwide Governance Indicators: Methodology and Analytical Issues*

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Lessons?

- The concept of “vulnerable population” should be revised in countries with structural corruption
- Guidelines and regulations cannot replace moral reasoning and personal and institutional integrity
- Politics, ideology and scientific research are (almost) always related
- Transparency and accountability are “sine qua non” requirements for mitigating potential abuses for subjects of biomedical research
- We are creative in our corruption, but transparency and accountability are essential if we seek to reduce or mitigate abuses of biomedical research subjects
- Education is a key component for assuring research ethics
- *No new rules are needed, rather greater efforts are needed to implement existing rules and make the process (research) more transparent*