



Health Reform and the Rule of Law

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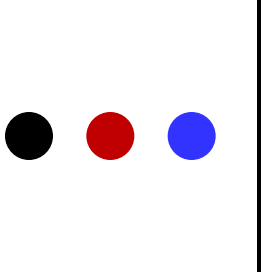
Southwestern University

Chongqing, China December 2009



Is it comprehensive?

- Apply the public health science and public health best practices
- Legislative checklists to ensure comprehensive body of law
 - Core functions of health system – primary purpose is health
 - Subunits , DRA, Pharmacy law, Others – hospitals, professionals,
 - Functions of other ministries and stakeholders
- Test – is it comprehensive?
 - Rule of law indicators
 - Accountability and fairness
 - Branches of legal epidemiology - distal, proximal and systems approach.
 - Coherence and interrelationships



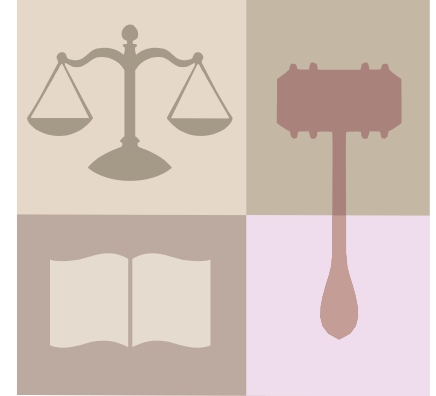
ROL Universal Principles and Results



1. The government, its officials and agents are accountable.
2. The laws are clear, publicized, stable and fair, and protect fundamental rights, including the security of persons and property.
3. The process by which the laws are enacted, administered and enforced is accessible, fair and efficient.
4. The laws are upheld. Access to justice is provided by competent and independent judiciary and law enforcement officials and attorneys who are of sufficient number with adequate resources and competencies.



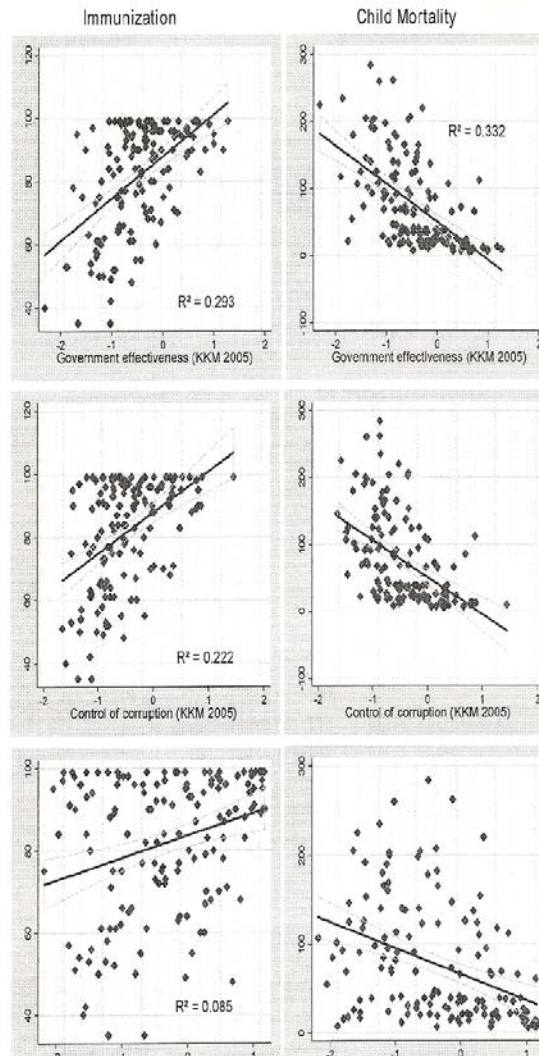
Essential Institutions



- Institutions
 - Well-functioning independent courts
 - Effective law enforcement agencies
 - Legal professionals
 - A comprehensive body of laws
- Why is rule of law important to health?
 - Rule of law → economic growth
 - ▲ improved health
 - Essential to fight corruption
 - Essential to cost control and quality
 - Fundamental to good regulation



Figure 1. Relationship between corruption indices and health outcomes





Performance and Reform

Core functions

- Service provision
- Resource generation
- Financing
- Stewardship
- *Ensure Coherence*

Reform strategy

- Evidenced based policy
- Based on patient needs and demands
- Disease burden
- Social determinants of health
- Integrate basic functions



Legal Epidemiology

- Three aspects

- 1. Proximal – direct

- Protect human, animal and property rights
 - Behaviors and powers - immunizations, quarantine
 - Contracts

- 2. Distal – remote

- Trade, environment, customs, traffic laws, sanitation.

- 3. Describes and defines structure and function

- The government and
 - The health system



Health system legislation

- National law – executive function
- Ministry of health
 - Sub units
 - Drug Regulatory authority
 - Pharmacy Law
 - Other sub-units
 - Licencing
 - Hospitals
- Other ministries and sectors



Functions of medicines system

- Selection
 - Marketing approval
 - QA
 - Pharmaco vigilance
- Registration
- Procurement
 - International procurement – business transactions – customs – CISG, procurement models
 - Domestic – basic business law and procurement rules
- Distribution – retail, wholesale, intermediaries
- Inspection and market control
- Promotion
- Licensing of pharmaceutical establishments
- Clinical trials



Medicines Legislation

Checklist

- Purpose
- Products and activities covered
- Establish and structure of DRA
- Define roles responsibilities, rights and functions of all
 - Issue regulations – process
- Qualifications for all who handle medicines
- Quality norms and standards
- Licenses – grants and revocations
- Prohibitions and penalties
- Transparency and accountability
- Oversight

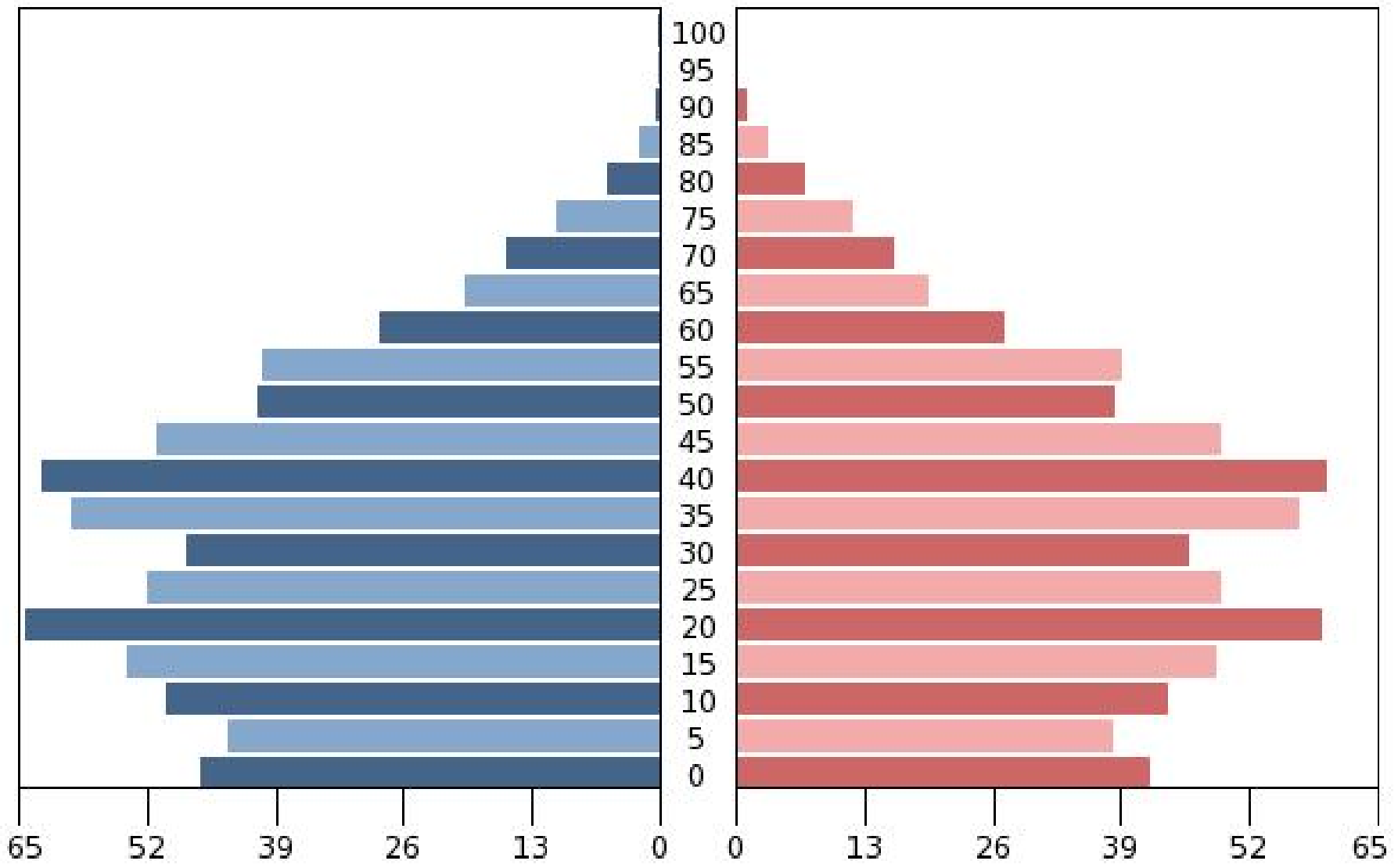


Population Demographics and Health Status

- Gains in health status
 - Increased longevity
 - Decreased maternal and childhood mortality
- Gains in chronic diseases means more costly and daily care
 - Disability
 - Mental health
 - Diabetes, cancer, hypertension, +

DEMOGRAPHIC INDICATORS	2050	2025	2015	2010
Population				
<u>Midyear population</u> (in thousands)	1,424,162	1,453,124	1,393,417	1,347,563
<u>Growth rate</u> (percent)	-0.3	.02	0.6	0.7
Fertility				
<u>Total fertility rate</u> (births per woman)	1.7	1.8	1.9	1.8
<u>Crude birth rate</u> (per 1,000 population)	10	11	14	14
<u>Births</u> (in thousands)	13,672	15,432	19,271	19,216
Mortality				
<u>Life expectancy at birth</u> (years)	81	77	75	74
<u>Infant mortality rate</u> (per 1,000 births)	6	11	16	19
<u>Under 5 mortality rate</u> (per 1,000 births)	7	13	19	23
<u>Crude death rate</u> (per 1,000)	13	8	7	7
<u>Deaths</u> (in 1000's)	18,172	12,090	10,172	9,568

Male China - 2010 Female

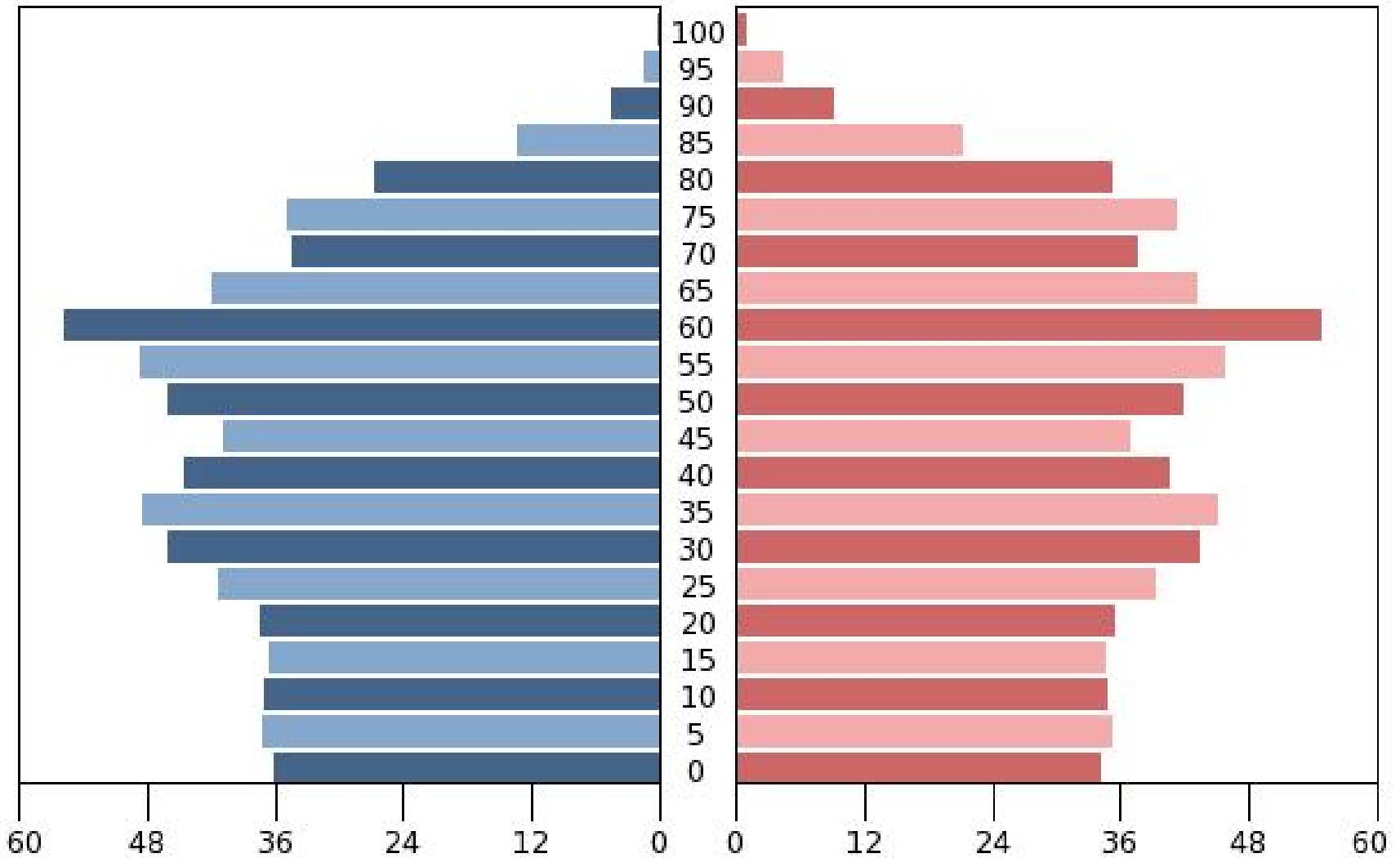


Population (in millions)

Male

China - 2050

Female



Population (in millions)



The evidence: Health Access, Costs, Regulation

- Low rates of health insurance coverage
 - Both rural and urban
- High rates of out of pocket costs
 - Of total in 1978 20%, 2005 52%
- Annual drug bill \$73 B & 45% of NHE
 - International average 20%-30%
- Inadequate regulatory infrastructure



China Health Reform

- Overarching Goal 2010-2015
 - Build a basic health care system
 - Safe, effective, convenient, affordable
- Goals 2009 – 2011- Opinions CPC
 - Basic medical security system
 - Essential medicines system
 - Improve rural health care services
 - Pilot projects for hospital reform
 - Reduce disparities urban/ rural



China National Essential Medicines System

- Medicines in public welfare sector
- Elements to secure supply
 - Selection of EML
 - Rational utilization
 - Supply chain
 - Price controls
 - Procurement practices and standards
 - Safety and security of supply



WHO suggested elements of a medicines strategy

- 1. National policies on medicines and traditional medicines
- 2. Financing mechanisms
- 3. Supply Chain
- 4. Norms and standards for drugs
- 5. Regulation and quality assurance
- 6. Rational use



Selection

- Formulate selection and management methods for national list
- Readjust and update regularly
- Publicize



Selection and rule of law

- Formulate selection and management methods for national list
- Readjust and update regularly
- Publicize
- Require essential medicines list and concept in all aspects of the laws and regulations.



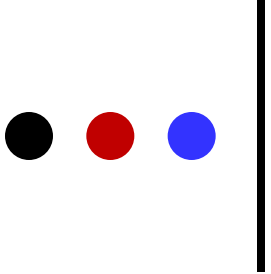
Rational utilization

- All retail pharmacies and health care institutions store, use and sell national essential medicines.
- Health departments should formulate treatment guidelines and prescription formularies
- Patients allowed to purchase drugs in retail pharmacies with prescription.



Rational utilization and rule of law

- .Scope of practice
 - Disassociate prescribing from dispensing
- Scheduling of drugs
- Drug promotion laws – details
- Licensing and training of informal sellers and traditional healers
- Qualifications on who can handle drugs
- Prohibitions



Supply chain Price controls

- Central gov sets retail prices based on tender results.
- Provincial govt. set purchase prices within range of govt. set- prices, distribution included in purchase price.
- Public health care institutions zero mark up.
- All essential medicines in drug reimbursement list of basic medical insurance: reimbursing rate higher than that of non-essential medicines.



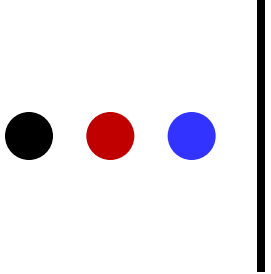
Price controls and rule of law

- Regulations prescribe ownership, staffing, acceptable medicines and sources, quality standards, pricing and prescription practices.
- Remove tariffs on imported drugs
- Parallel imports and compulsory licensing
- Franchise laws
- Contract and insurance laws



Supply Chain and Procurement

- Open tenders for purchase and distribution of essential medicines
- Good procurement laws and practices
- Contracts executed by both parties and strictly implemented.
- Pre-bid prequalification of manufacturers distributors



Procurement and rule of law

- National procurement law
 - Elements
 - Bidder prequalification
 - Monetary limits
- Commercial and contract laws.
 - Convention on Int'l Sale of Goods
 - Other international standards, Incoterms
 - WTO laws – non-discrimination



Supply Chain Safety and security

- Improve national reserve system
- Strengthen supervisions over drug quality, and conduct sampling inspection
- Publicize results.
- Improve retail pharmacies, certified pharmacists and who consult and guidance purchase decisions.



Safety and security and rule of law

- Adequate drug regulatory agency and \$
 - Sufficient staff in number and capacity
 - Counterfeit defined
 - Quality standards: GMP, GDP
 - Licensing process
 - Transparency
 - Trained and paid inspectors
 - Disposal unwanted, confiscated or expired drugs



Thank You

For questions, comments or further information
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