
Human rights approach to health policy: the case of essential medicines



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Overview of the presentation

- n The Right to Health: principles and legal instruments**
- n Is access enforceable through the courts?**
- n Rights-based approach in medicine programmes:
Five practical points to check**
- n Practical recommendations to governments**

The way forward:

- n Access to essential medicines as indicator for
government commitment to the Right to Health**



Human Rights:

- n concern the **relation the between state and the individual**
- n lead to **state obligations and individual entitlements**
- n are **interdependent** and interrelated
 - à **Examples in recent UN assessment: Right to: life, liberty/security of person, food, health, freedom from torture, participate in public affairs, education, housing, social security, work, freedom of expression, fair trial**
- n are based on **freedom from discrimination**
- n Rights imply duties, **duties demand accountability**

Promotion of human rights is a **principle purpose of the UN**



First expression of the right to health: The WHO Constitution (1946)

“The States parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples.

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition (...)”

The right to the highest attainable standard of health = "Right to Health"



Universal Declaration of Human Rights (1948)

Art.25.1

“Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services”



The "Right to Health" is also recognized in numerous other legal instruments

1961 European Social Charter

1966 International Covenant on Economics, Social and Cultural Rights (most detailed; Article 12.1 and 12.2)

1978 Declaration of Alma Ata

1981 African Charter on Human and People's Rights

1988 Additional Protocol to the American Convention on HRs in the Area of Economic, Social and Cultural Rights

1989 Convention on the Rights of the Child



International Covenant on Economics, Social and Cultural Rights (ratified by 157 countries)

Legally binding

Article 12 recognizes the

- n ***“right of everyone to the enjoyment of the highest attainable standard of physical and mental health”***

Article 12.2 illustrates a number of

- n ***steps to be taken by States parties to achieve:***
 - ä a. maternal, child and reproductive health
 - ä b. healthy natural and workplace environments
 - ä c. prevention, treatment and control of disease
 - ä d. health facilities, goods and services



Committee on Economic, Social and Cultural Rights
General Comment nr.14 (May 2000)

Highly authoritative

Art.12.2.c:

Right to prevention, treatment and control of diseases includes creation of a system of urgent medical care in case of accidents, epidemics; and disaster relief and humanitarian assistance

Art 12.2.d:

Right to health facilities, goods and services includes appropriate treatment of prevalent diseases, preferably at community level;

**and the provision of essential drugs as defined by the WHO
Action Programme on Essential Drugs**



Committee on Economic, Social and Cultural Rights
General Comment nr.14 (May 2000)

Violations

- n **Adoption of retrogressive measures, repeal, suspension**
- n **Failure to take all steps to ensure the right to health; e.g.**
 - ä failure to adopt and or implement a **national health policy** designed to ensure the right to health for anyone
 - ä **insufficient expenditure** or misallocation of public resources
 - ä **failure to monitor** the realization of the right to health in the country
 - ä **failure to reduce inequitable distribution**

**Important: distinguish inability
from unwillingness of the State**

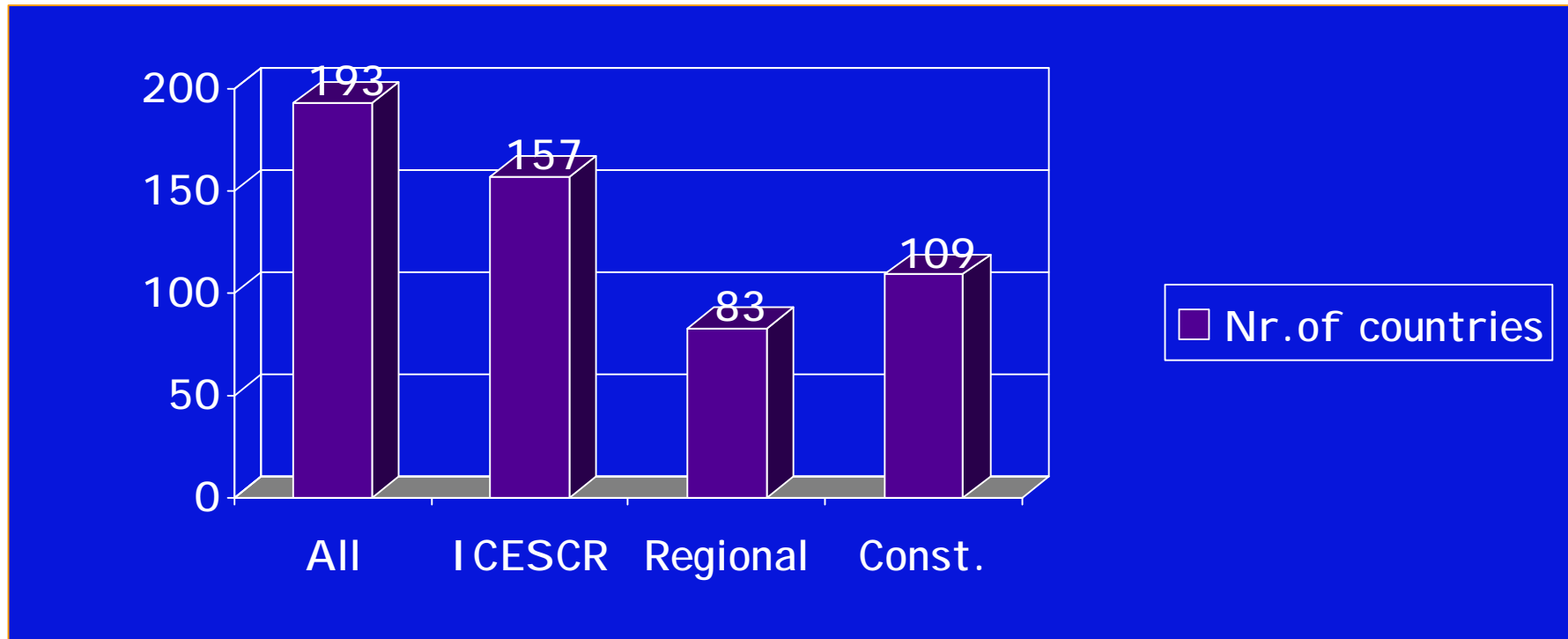


Access to essential drugs as a Human Right: Where are we now?

- n Health is a human right (WHO 1946, Univ. Decl. Human Rights 1948).
- n The right to health care includes the right to emergency care and health facilities, goods and services (Intern.Covenant, 1966)
- n The right to facilities, good and services includes the provision of essential drugs as defined by WHO (GCom.14, 2000)
- n **State parties are under immediate obligation to guarantee that the right to health care is exercised without discrimination, and that concrete steps are taken towards full realization, with emphasis on vulnerable and marginal groups**



All governments have signed at least one international human rights treaty or have a Constitution recognizing the Right to Health



Source: Eleanor D. Kinney: The International Human Right to Health: What does this mean for our nation and world? Indiana Law Review, 200; 34: 1465. Quoted in: 25 Questions and answers on health and human rights, WHO, 2002





So what?



Is access to essential medicines as part of the Right to Health enforceable through the courts?

Hogerzeil HV, Samson M, Vidal Casanova J, Rahmani L (*Lancet* 2006)

Objective

To identify and analyze court cases from low- and middle income countries, in which individuals/groups have claimed access to essential medicines on the basis of human right treaties signed by the State

Results

71 cases from 12 countries • 59 won, 12 lost • half deal with HIV/AIDS; others with leukemia, diabetes, renal dialysis • 38% public interest cases • 20% supported by NGOs • 93% of successful cases from Latin America (rest from India, S.Africa, Nigeria)



Main findings in 59 successful cases

(Argentina, Bolivia, Brazil, Colombia, C.Rica, Ecuador, India, S.Salvador, S.Africa, Venezuela)

- n Success often linked to:**
 - ä Constitutional provisions supported by human rights treaties
 - ä Link between right to health and right to life (66% life-savings EMs)
 - ä Legal, financial and advocacy support by public interest NGOs
- n Individual cases have generated group rights**
- n Right to health is not restricted by limits in social security**
 - ä Acquired rights, time restrictions in coverage
 - ä Essential medicines not (yet) included in social security
- n Government policies can successfully be challenged in court**
 - ä Discrimination, lack of progress
- n Court decisions on selection of EMs for reimbursement**
 - ä Missing essential medicines, expensive EMs, branded/new products



Good or bad?

Human rights and essential medicine lists

- n C.Rica: ARVs which were not on EML / Social Security**
- n C.Rica: Branded product (while generic in Social Security)**
- n C.Rica: Leukemia medicine, excluded (too expensive)**
- n Colombia: Medicines not included in Social Security**
- n Brazil: 3500 court cases pending for medicines not included in Social Security; just registered; not registered in Brazil**
 - ä Nearly always awarded; MOH funds immediately blocked**
 - ä MOH now loses about 25% of medicine budget**
 - ä Toll-free number to call for toll-free lawyer**



Conclusion of WHO study

- n Many governments have made international and/or constitutional obligations on the right to health. Skilful litigation can provide an additional mechanism towards ensuring that these obligations are fulfilled. Success is possible and this should encourage others.**
- n Health policy makers and the public health community should be aware of the increasing trend towards litigation. Rather than the judiciary deciding over who should have access to which medicines, policy makers should ensure that human rights standards guide their health policies and plans from the start.**



Rights-based approach in medicines: What makes it better than a good essential medicines programme?

Hogerzeil HV, WHO Bulletin, May 2006

General approach:

- n Check the WHO publication "25 Questions of the Right to Health" for practical implications in the case of essential medicines

General recommendation:

- n Human rights should **define the framework** for development in the medicines area. The attainment of the highest attainable standard of health must be the stated objective of the national medicine policy



1: Which medicines are covered by the right to health?
What are essential drugs? (Exp.Cee, April 2002)

Definition: Essential medicines are those that satisfy the priority health care needs of the population

Selection criteria: Disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness

Purpose: Essential medicines are intended to be available at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

Implementation: The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility. **The WHO Model List of Essential Medicines is a model product and a model process**



1: Which medicines are covered by the right to health?

Practical implications

- n **Does the constitution guarantee the right of everyone to the enjoyment of the highest attainable standard of health?**
- n **Do national laws/regulations further define the Right to Health, social security, services and medicines covered?**
- n **Has the national list of essential medicines been updated in the last two years?**
- n **Outside scope of national governments (refugee camps, ships): WHO/UN lists apply**

**Discussion question:
Is the WHO Model List a Moral Minimum?**



2: Have all beneficiaries of the medicine programme been consulted?

- n In developing a national medicine policy and implementation plan, the usual partners are the Ministry of Health, government departments, missions, academia, industry, professional associations**
- n What about:**
 - ä Rural communities, local governments**
 - ä Public interest NGOs**
 - ä Patient and consumer groups**
 - ä Representatives of vulnerable groups, ethnic minorities?**



3. Are there mechanisms for transparency and accountability?

- n **Transparent statement on government obligations, in line with international treaties**
- n **National medicine policy with clear identification of roles and responsibilities of government departments and other stakeholders**
- n **Indicators, baseline date and targets identified and used to monitor progressive realization of access to essential medicines**
- n **Mechanisms to hold stakeholders accountable**



4. Do all vulnerable groups have equal access to essential medicines? How do you know?

- n **Vulnerable groups**: children (girls), women, people living in poverty, rural communities, indigenous populations, national (ethnic, religious, linguistic) minorities, internally displaced persons, elderly, disabled, prisoners
- n **First step**: collect disaggregated statistics on access
 - ä Awareness among policy makers
 - ä Identify vulnerable groups which need special attention
 - ä Monitor progress towards universal access
- n **Absolute minimum**: gender-disaggregated statistics and incidental surveys aimed at specific vulnerable groups



5. Are there safeguards and redress mechanisms in case human rights are violated?

- n Access to essential medicines is best achieved and guaranteed by the rights-based approach in national medicines policies and programmes**
- n In case of slow progress, regression, discrimination: redress and appeal mechanisms are needed as last resort**
- n Careful litigation has been helpful to encourage governments to fulfil their constitutional and international obligations (WHO study in 12 developing countries)**



Practical recommendations to governments

- n **Ensure constitutional endorsement of the right to health, the right to life and the right to non-discrimination;**
- n **Specify government obligations in social welfare, provision of health care services and access to essential medicines, with emphasis on vulnerable groups; endorse selection of essential medicines by social security**
- n **Incorporate rights-based approach in national medicine policies**
- n **Collect disaggregated statistics, monitor access by gender and vulnerable groups**
- n **Create legal instruments for enforcement and redress**
- n **Report regularly on progressive realization of right to health**



Update 2009 / way forward

DG/WHO: What gets measured, gets done

- n **WHO assessment questions used for Philippines**
 - ä Main challenge: translate a legal concept into practical policy
 - ä Human right lawyers need to get used to pragmatic compromises
 - ä Health policy makers need to get involved, see the benefits, start acting
- n **Access to essential medicines becomes an indicator for government commitment to the Right to Health**
- n **WHO/EMP access indicators used for UN MDG-8 "Gap-analysis" reports in 2008, 2009 and 2010**



Access to Essential Medicines becomes an indicator for government commitment

- n WHO includes country constitutional commitment towards right to health in Medium Term Strategic Plan indicators**
- n WHO/EMP includes country constitutional commitment as indicator for access to essential medicines**
- n UN publishes set of 12 Human Right indicators, as model for country reporting on**
 - ä Political and civil rights (e.g. freedom of association)**
 - ä Economic, cultural and social rights (e.g. right to education, right to housing, right to health)**
- n Lancet publishes independent assessment of country progress towards the right to health (Nov 2008)**

Source: United Nations, HRI/MC/2008/3



Example 1:

Standard set of indicators for measuring access, as defined for WHO/MTSP, UNDP/MDG8 Gap Analysis, and Lancet assessment

Government commitment:

- n Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation (S)**
- n Existence and year of a published national medicines policy (S)**

Rational selection:

- n Existence and year of a published national list of essential medicines (S)**

Affordable prices:

- n Legal provisions to allow/encourage generic substitution in private sector (S)**
- n Median consumer price ratio of 30 selected EMs in pub/private facilities (P)**
- n Percentage mark-up between manufacturers' and consumer price (P)**

Sustainable financing:

- n Public and private per capita expenditure on medicines (P)**
- n % of population covered by national health service or health insurance (P)**

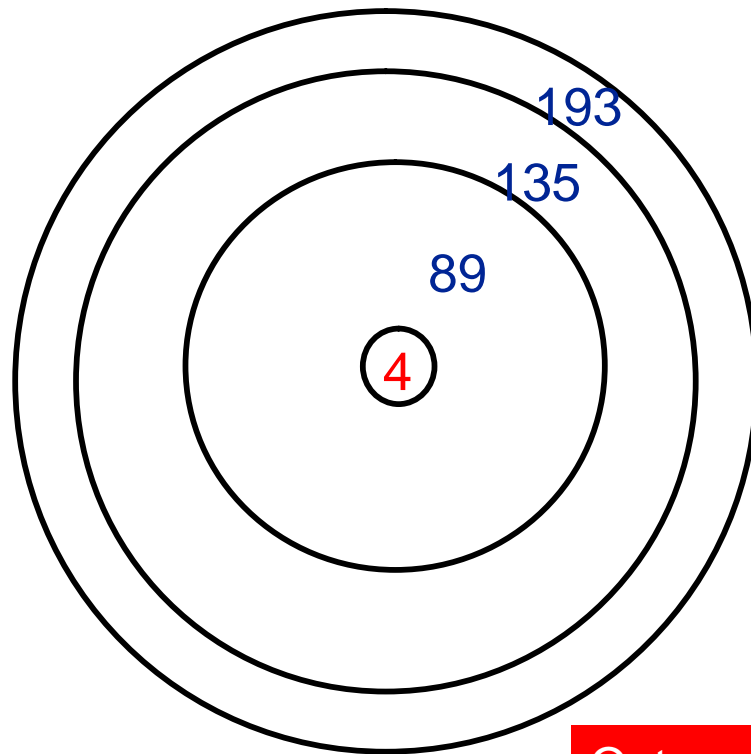
Reliable systems:

- n Average availability of 30 selected EMs in public/private health facilities (O)**



Example 2: (June 2008, S.K.Perehudoff)

Legal indicators for national commitment



Constitutions, 187 can be accessed

Include the Right to Health

Mention health facilities, good and services

Include (essential) medicines

Peru (1972, 1994)
Philippines (1987)
Syria (1973)
Mexico (1917)

**Outcomes: WHO/MTSP baseline and indicator;
Checklist and "Best practice" text for future use**

Example 3:

Access to Essential Medicines within the overall assessment of the Right to Health

New set of UN Right to Health indicators (June, 2008)

n Five areas of health:

- ä Sexual and reproductive health
- ä Child mortality and health care
- ä Natural and occupational environment
- ä Prevention treatment and control of diseases
- ä **Access to health facilities and essential medicines**

n Four different dimensions to collect and assess data:

- ä Obligation to respect, to protect, to fulfil
- ä Measuring commitment, efforts, results
- ä Structural, process, outcome indicators
- ä Routine statistics, surveys, event monitoring

Source: United Nations, HRI/MC/2008/3



***Saving lives
with the right (to) medicines***



[www.who.int / medicines](http://www.who.int/medicines)