

# Setting Limits Fairly: International Experience and Colombia

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# Overview

- General Problem--limit setting happens everywhere
- Colombian Case
- Why Accountability for Reasonableness?
- International Experience
- Application to Colombia

## **Societies Can't Avoid Priorities, Limits and Tough Resource Allocation Choices in the Health Care Sector**

- New technologies: ↑ opportunities to spend
- Aging population: ↑ clinical needs to serve
- Internet/DTCA: ↑ expectations to meet

***Even in the wealthiest societies there are more potentially beneficial interventions than society is prepared to pay for! Priority setting is unavoidable.***

The problem is how  
to set limits!

# Fewer Resources: Mexico, Colombia

*Despite a right to health care*

- New technologies, aging, internet (as elsewhere)
- Less funding for lower tier insurance schemes
- Visible inequalities in access
- Not sustainable to eliminate inequalities immediately (perhaps as strategic goal *as in progressive realization of human rights*)

# Special Issue in Colombia: Tutelas

- Right to health care (in Constitution)
- Limits to care (however decided by insurers) challenged by tutelas, which have strong political support and *sometimes* a useful function
- If tutelas over-used, health system cannot meet population health needs
- Need fair process-- tutelas not a general remedy to assure fair allocation, can make things worse

# Why fair process?

- Justice requires limits
- No consensus on distributive principles, much controversy
- Just limits require fair process
- Fair process assures accountability for reasonableness
- Accountability for reasonableness necessary for legitimacy

## Two questions about legitimacy and fairness

- When should patients, clinicians, or concerned others, who believe an uncovered service is “medically necessary,” accept a health plan or public agency as a **legitimate** source of a limit setting decision?
  
- When should patients, clinicians, or concerned others, who believe an uncovered service is “medically necessary,” accept a health plan or public agency limit-setting decision as **fair**?

\* The entire project has been done in collaboration with James Sabin, Clinical Professor of Psychiatry, Harvard Medical School and Harvard Pilgrim Health Care

# Types of Limit-Setting Decisions Raising Questions of Fairness

- Treatment/Enhancement
- Proven/Experimental
- Practice Guidelines
- Cost-Worthiness



Patient Goals  
vs. Goals of  
Others

- Priorities
- Aggregation
- Fair Chances/Best Outcomes



Unsolved  
Problems

# Proven vs. Unproven (Especially Last Chance)

## Proven

- Stewardship
  - Conserve resources
  - Allocate them to meet needs fairly
- Only obligations of justice to provide effective treatments
- Obligations to determine effectiveness

## Unproven

- Urgency
  - Immediate need for identified victim
  - Individual variation
  - Possibility of trial?

# Why not just economic analysis?

- Standard tools (CEA) ignore important distributive and other issues
- CEA embodies unacceptable and extreme positions on some distributive issues
- IOM--"Valuing Health" recommendations

# CEA vs. Fairness (equity)

	CEA	FAIRNESS
<b>BO vs FC</b>	BO	Weighted chances
<b>Priority to worst off</b>	None	Some--varies
<b>Aggregation</b>	Any	Some

Any questions about  
why we need fair  
process?

# Accountability for Reasonableness (A4R)

- Publicity (transparency including reasons)
- Relevant reasons (as judged by appropriate stakeholders)
- Revisability (in light of new evidence, arguments, appeals)
- Enforceability (assurance that other conditions are met)

# A4R yields:

- Presumption of similar treatment for similar cases
  - Commitment to coherent use of reasons
  - “Similarity” defined by reference to reasons and principles
  - Rebuttal
    - Show relevant difference in cases
    - Show rationale for revising principle
- Public record of commitments - behavior matches pronouncements
- Similar to case law

# A4R--general alternative to tutelas

- Relevant reasons -- but still disagreement on weights
  - e.g. safety, efficacy, cost-effectiveness, some priority to those worst off, some concern for fair chances at significant benefit
- Improvement on “procedural democracy” where any reasons held by majority outweigh reasons advanced by minority, losers resentful
- In A4R (democratic deliberation), only relevant reasons play role in deliberation, so losers feel less that might makes right

Any questions about  
the features of A4R?

## **What has happened with the Accountability for Reasonableness Framework since 2002 (publication of Setting Limits Fairly)?**

- The framework itself was not new – it articulated what exemplary resource allocation processes were already doing
- The big picture, in international perspective:  
In the U.S., relatively little has happened  
In Europe, Scandinavia & and Latin America – a lot!
- Experience provides some guidance about the roles of government, civil society organizations, & academia

# International Experience

- WHO equity guidelines for 3 by 5, Canada, Norway, Sweden--adopting features
- UK--NICE
- Mexico
- NZ

# Some early uses

- WHO and equity in 3 x 5
- Canada--research agenda
- Norway-- Lonning Commission 1 vs Lonning Commission 2

# Accountability for Reasonableness in Sweden

- “The strategy...implies that priority setting involves the ability to make socially acceptable decisions, and that ***this bargaining process must be repeated again and again***. According to this strategy, we reach the best possible solution to the prioritization problem through transparency, participation of many different parties in the process, the ability to consider and analyze opposing arguments, and finally viewing the decision as being ‘reasonable’”

Garpenby P. The priority setting process: a macro perspective. National Centre for Priority Setting in Health Care, 2003.

# NICE and A4R

- NICE leadership explicitly appeals to A4R
- Citizen's Council as forum for social and ethical issues
- Consultation about integrating stakeholders and more specific decisions
- Existing structure still invites some public (and vested interest) resistance

# A4R in Mexico

- Initial effort: use A4R to determine benefits in catastrophic insurance scheme (possible model for other contexts)
- Current effort: use A4R to build capacity for ethically and socially sensitive priority setting across system

# Catastrophic Plan: What to Cover?

- Resource limits, global budget
  - Unavoidable problem
- Choices produce winners, losers
  - True for essential package--less controversy
  - True for catastrophic coverage
    - Choice of categories
    - Choice within categories
- Conflicting moral claims on resources--ethical controversy
- Vested interests lobby for coverage, some initial decisions out of priority

# Proposal for integrating working group outputs into fair process:

- Clinical and Economic Working Group taken as inputs into Ethics Working Group (and CSG)
- Ethics Working Group analyzes how the considerations addressed by the other groups should be evaluated; provides rationale to for rankings among candidates under consideration
- Commission makes preliminary proposalc and airs it before stakeholders consulted by Social Acceptability Group
- CSG makes final recommendation, with rationale, to SP Commission based on reevaluation

Figura 1. Propuesta para la Priorización de Intervenciones Alto Costo

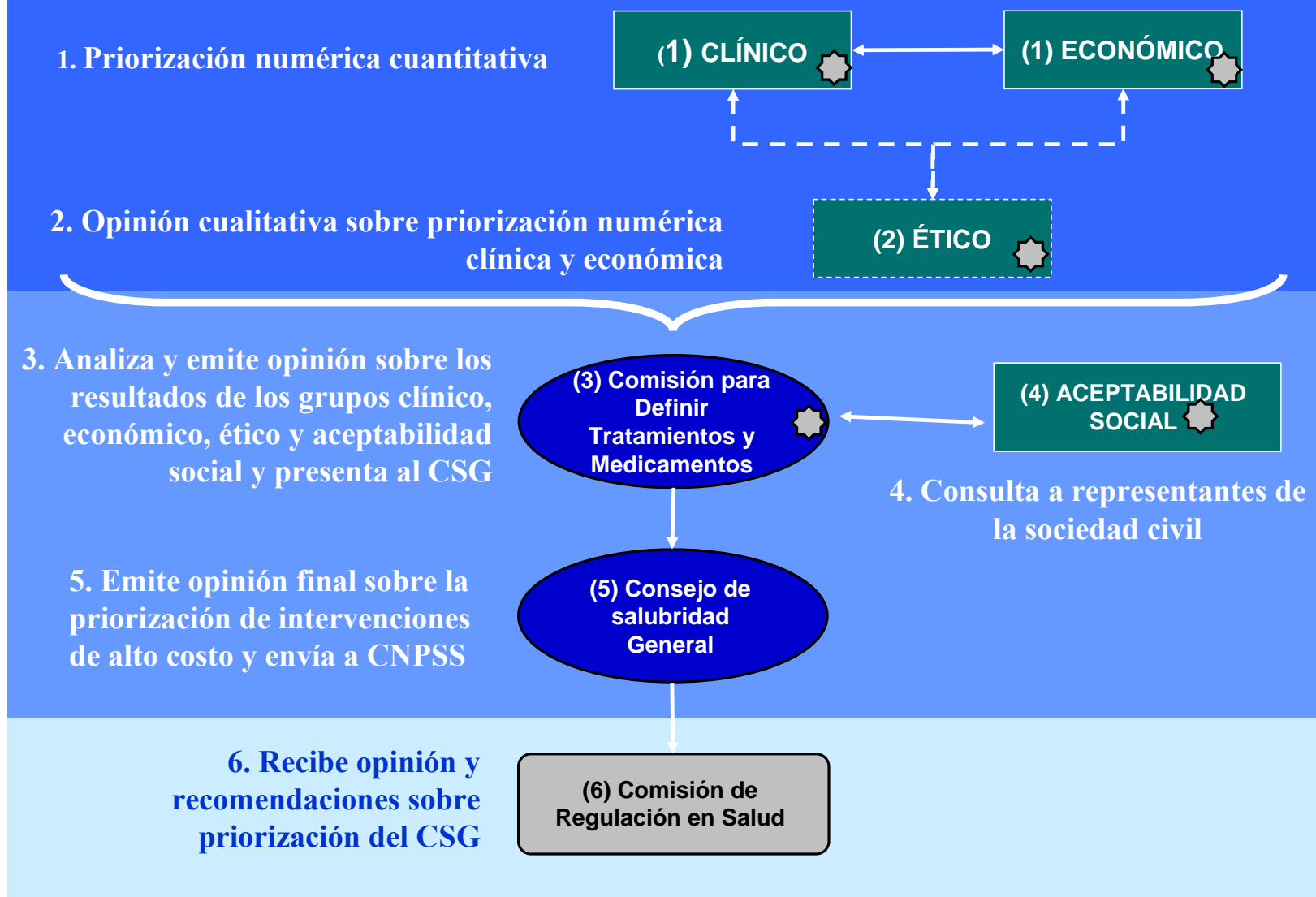
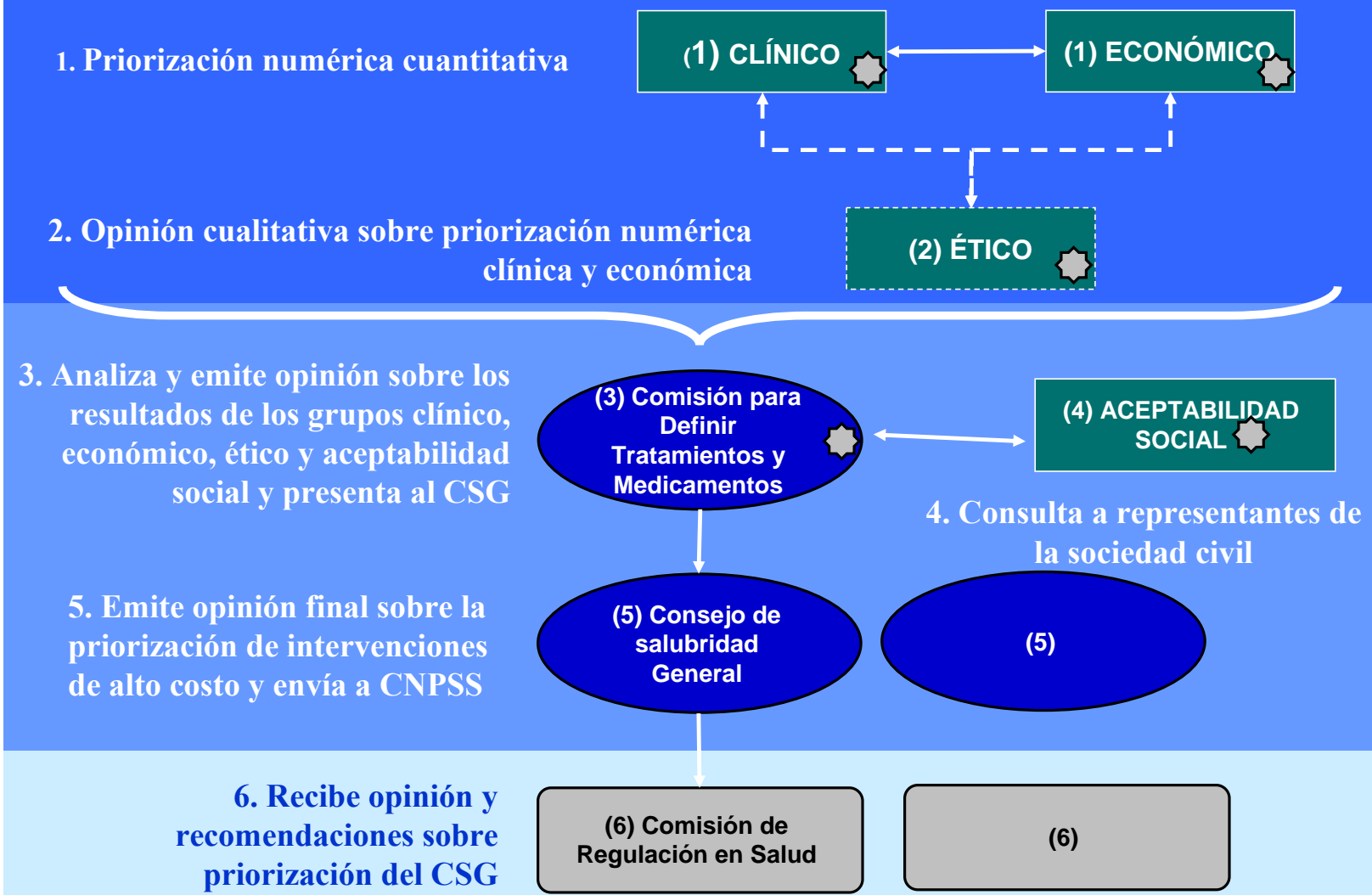


Figura 1. Propuesta para la Priorización de Intervenciones Alto Costo



# Mexico: Recent

- Economic Analysis Unit (EAU) and Preventive Services: HPV vaccine case study, pneumococcal vaccine
- EAU: Depression, dialysis
- CENETEC--work on dialysis, mobile units, incorporates A4R in HTA guidelines
- INSP-- courses and outreach teaching (other university settings)
- CARSO capacity building grant

# How New Zealand Improved Social Acceptability for Limit-Setting

- Several years ago, MoH initially denied unproven care to sick patient, but backed off after media blitz
- MoH undertook public education campaign (forums, media, local civic society meetings) to improve understanding of need to share resources and limit some coverage
- Similar case arose, and MoH was able to stand by decision because less public resistance

Any questions about  
international  
experience?

# **Societal Learning about Setting Limits – Some Conclusions (1)**

1. Dealing with health care limits confronts societies with the ultimate limits – disease, disability, & death
2. The first human impulse is to avoid the topic altogether
3. Some systems – like the fragmented U.S. health care “system” (and Mexico and Colombia?)– make it easier to avoid grasping the need for limits and in this way impede learning
4. Systems more clearly responsible for population health make it easier to understand the need for limits & harder to avoid the topic

## Societal Learning about Setting Limits – Some Conclusions (2)

- 5. Many societies and organizations have found the A4R account of fair process a useful framework for approaching the setting of limits:
  - Limits should be based on **relevant reasons** (clinical evidence, individual needs **AND** population needs)
  - Limit setting policies & rationales should be **public**
  - Limits (policies & decisions) should be **revisable** (new evidence, special patient needs, changed external circumstances)

## **Societal Learning about Setting Limits – Some Conclusions (3)**

6. A4R is inclusive and participatory & can be seen as threatening by those in power – it requires **support from leaders** to be applied
7. A4R requires **structured settings** for deliberation – Harvard Pilgrim Ethics Advisory Group, Seguro Popular Committees, Hutt Valley workshops & consultations, Swedish Priority Center

## **Societal Learning about Setting Limits – Some Conclusions (4)**

8. Conducting a deliberative process, like playing music, requires **practice over time**
9. Applying A4R requires **capacity building** (recall that sharing isn't natural for children – we have to learn it!)
10. Applying A4R requires collaboration among **civil society** (consumers and other stakeholders), **academia** (economics, ethics, & scientific expertise) and **government** (creating and enforcing the rules of the game)

## Reflections about the relevance of Accountability for Reasonableness for Colombia in response to tutelas and T-760 (1)

1. The Constitutional Court plays a remarkably active role in Colombia's health care system
2. Is the Court acting to **enforce** (condition # 4) **publicity** (condition # 1) , **relevance** (condition # 2) and **revisability** (condition # 3)?
3. Or is the Court in effect taking over resource allocation and limit-setting?

## Reflections about the relevance of Accountability for Reasonableness for Colombia in response to tutelas and T-760 (2)

4. The ideal role for courts is to ensure that the health system meets the publicity, relevance and appeals conditions – not to conduct those functions itself
5. In the U.S. almost all states have established a non-judicial system of independent external appeals to address circumstances that may generate tutelas in Colombia
6. Sentencia T 760 correctly acknowledges that the right to health is not absolute and can be limited

## Reflections about the relevance of Accountability for Reasonableness for Colombia in response to tutelas and T-760 (3)

7. Exactly *how* and *why* the right to health should be limited requires the same kind of deliberation the health system has to undertake to allocate resources and set limits – i.e., requires A4R
8. Thus the Accountability for Reasonableness framework can support the human rights approach
9. Courts are especially poorly suited to the complex task of guiding appropriate use of complex high cost treatments – their natural focus is the individual alone & they lack medical and epidemiological sophistication

# Right to Health Care & Entitlement to Treatment

Jack has moral and legal  
right to health care

- T1 offers Jack best chance at meeting his health need
- Jack has entitlement to T1 only if T1 part of reasonable array of services meeting population health needs fairly
- Priority setting problem at heart of specification of entitlements

Jill has human right to  
health care

- ◆ T1 offers Jill best chance at meeting her health need
- ◆ Jill has entitlement to T1 only if T1 included in services government agrees to provide in effort to progressively realize right to health
- ◆ Priority setting problem at heart of progressive realization

**THANK YOU!**  
**And time for discussion**