A system framework for access to medicines – Implications for research and policy

Maryam Bigdeli
Alliance for Health Policy and Systems Research
World Health Organisation, Geneva
Hans V. Hogerzeil
Professor of Global Health
University of Groningen, Netherlands

Alliance for Health Policy and Systems Research

World Health Organization

Outline

1. Access 1-2-3-4-4-6-9
2. Access to Medicines in LMICs: current situation and future challenges
3. A multi-layer health system view of barriers to access
4. A system framework for access to medicines: the critical paradigm shifts
5. Implications for research and policy

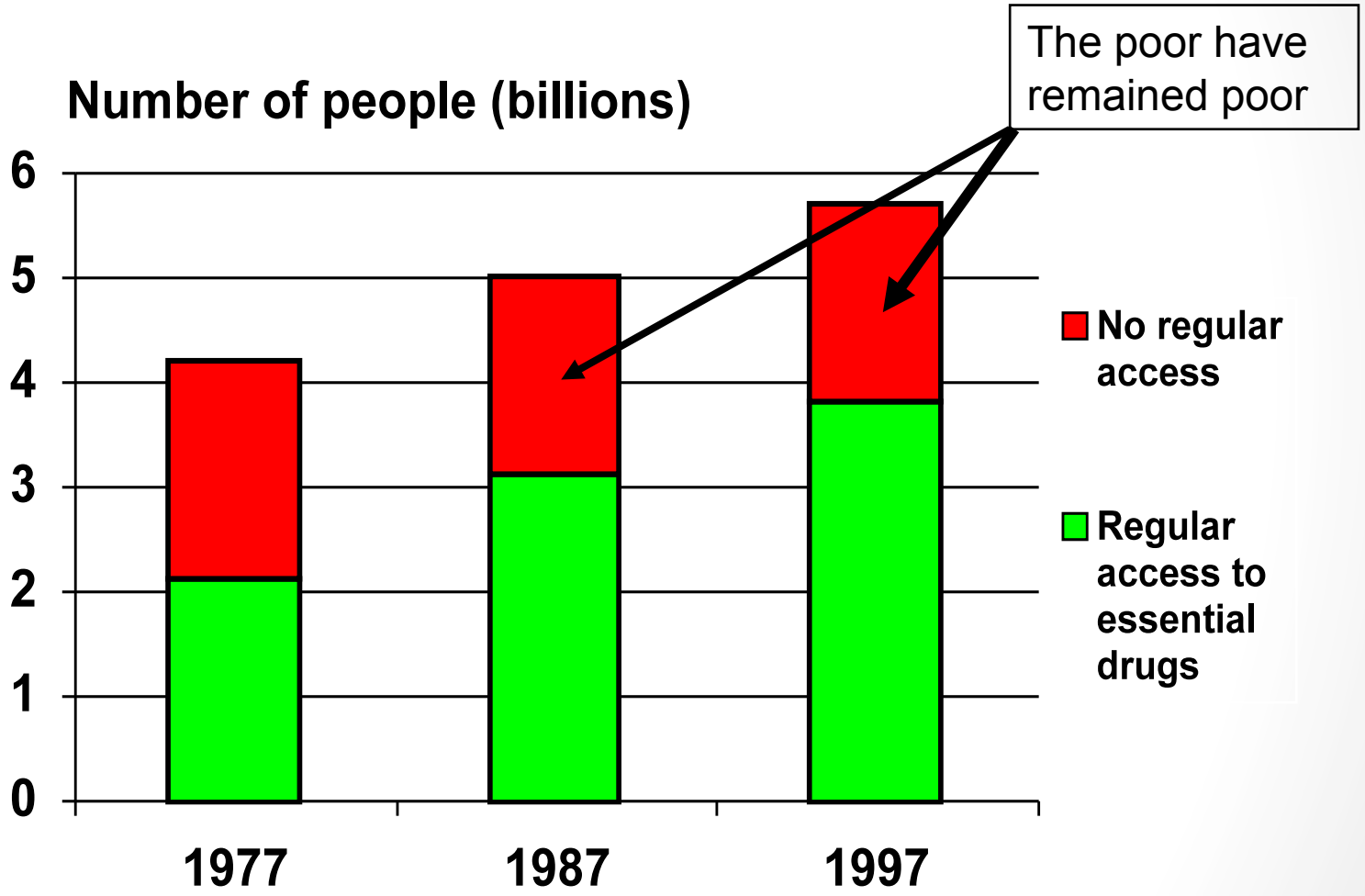
Access “1”

WHO, Lauridsen / Hogerzeil (1987-2002)

- Access to 20-30 essential medicines, within one hour’s travel from your home, at a price you can afford

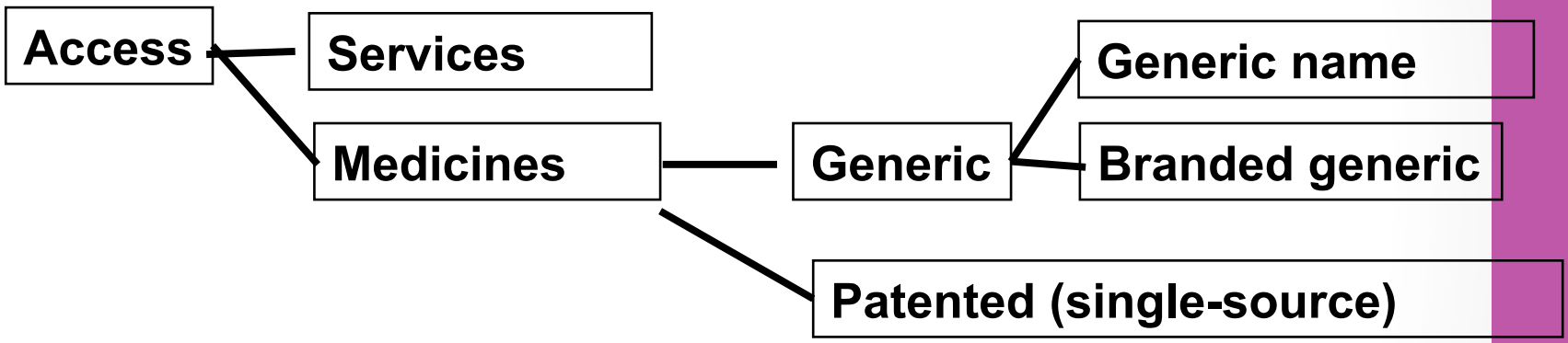
Access “1”

WHO, Lauridsen / Hogerzeil (1987 – 2002)



Access “2”

UN Millennium Project: patented vs generic (2002-)



- **98% of medicines on WHO Model List of EMs are off-patent**
- **85% of the access problem can be solved with generic medicines (UN)**
- **But: new essential medicines are expensive!**

Policy guidance:
There are many ways to reduce medicine prices

All medicines

- Reduced taxes, tariffs and margins
- Price monitoring, public price information, pricing policy

Multi-source products

- Generic competition, generic substitution
  - **Adapted legislation (includes TRIPS), assured quality, professional /public acceptance, economic incentives**
- Good procurement practices
  - **Price information, prequalification system, competitive tender**

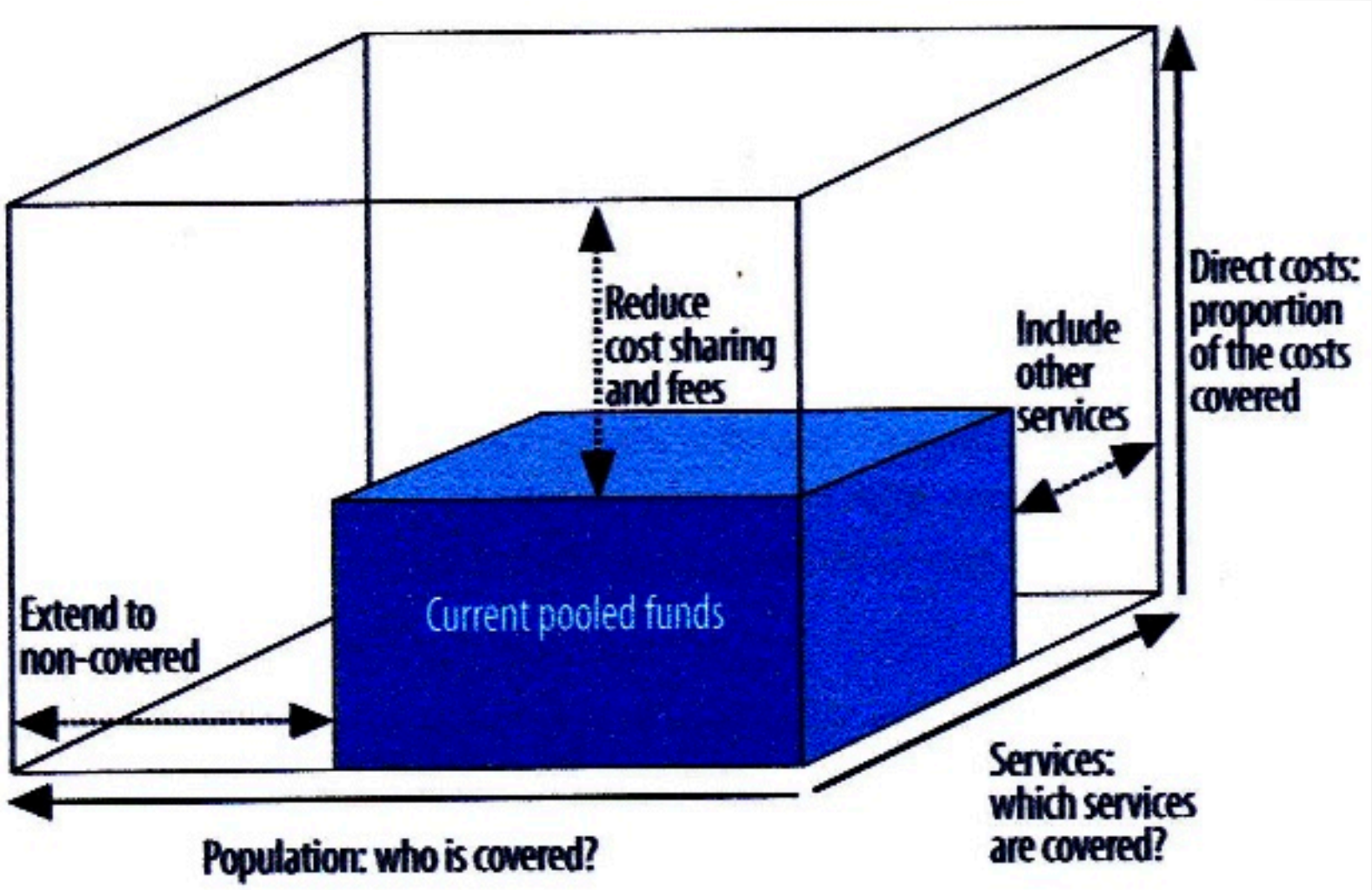
Single-source products

- Evidence-based clinical guidelines, therapeutic substitution
- Differential pricing, voluntary license, compulsory license

Compulsory licenses are a partial solution to part of the problem

Access "3"

WHO : Three dimensions of universal access (2010-)



Access “4”

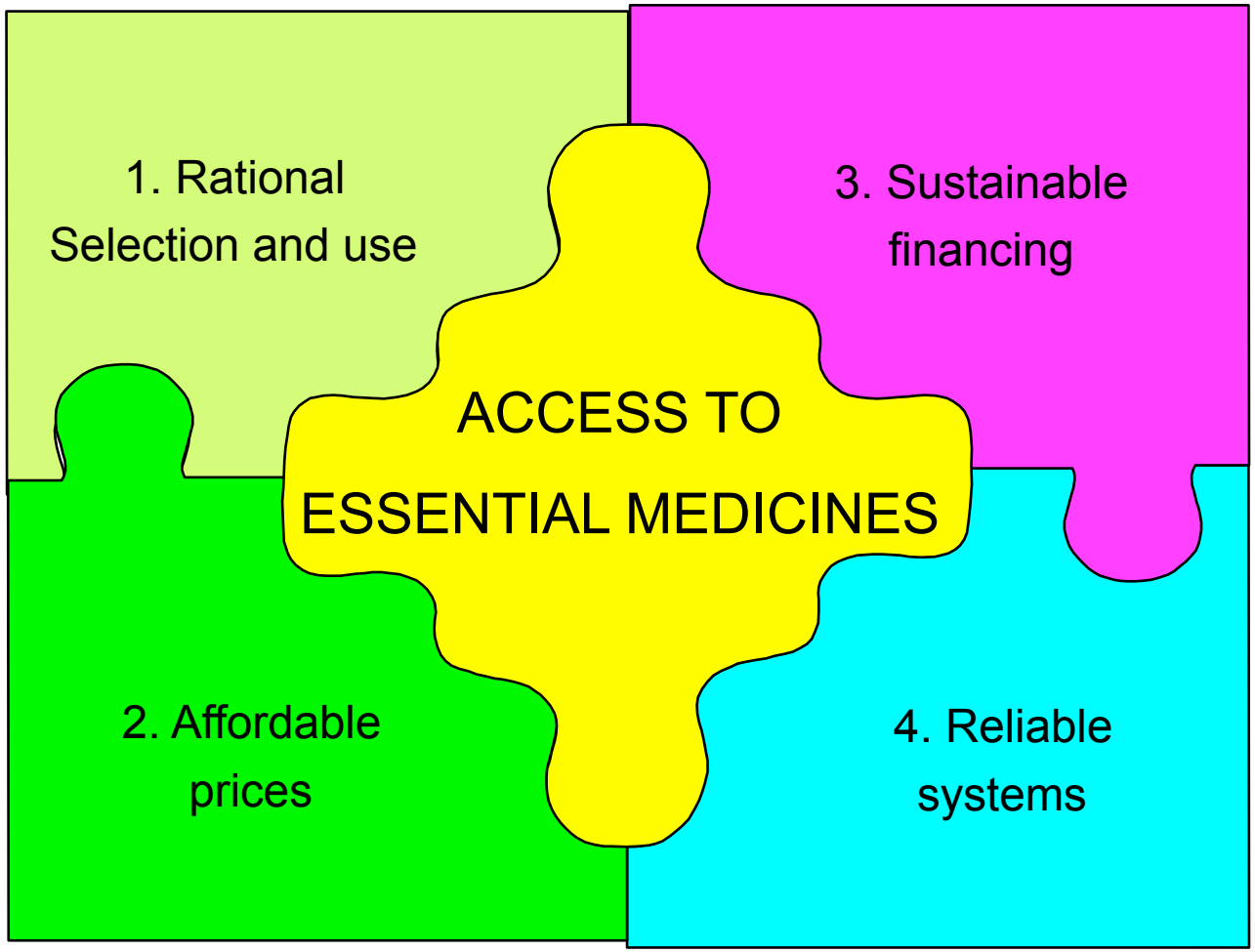
MSH “Ferney Voltaire (2000-); Human rights framework, Hunt (2004-)

AAAQ

- Available (medicine exists, has been developed)
- Accessible (physical access, financial access)
- Acceptable (right dosage form; culturally acceptable)
- Quality (of good quality)

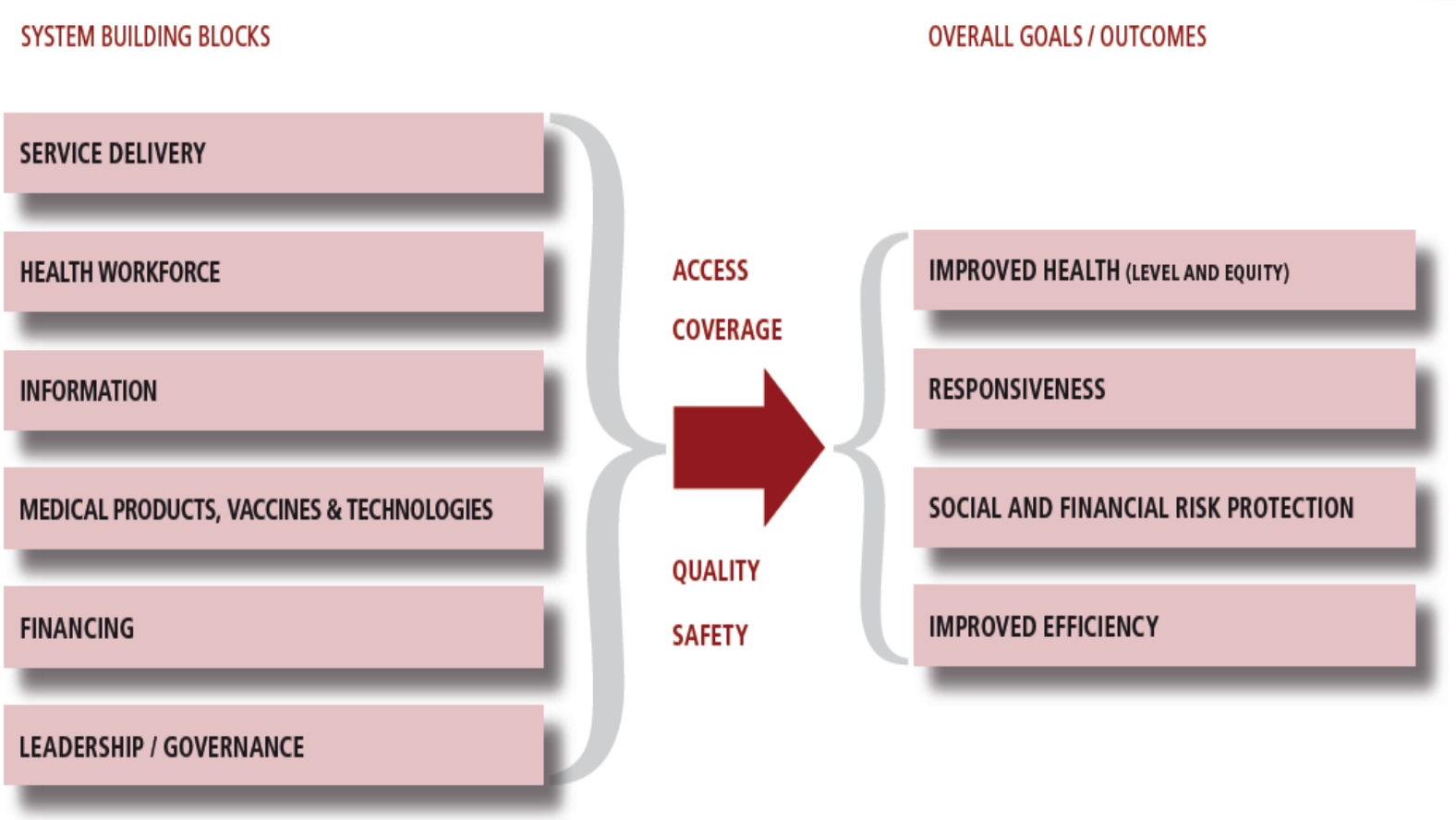
Access "4"

WHO, Quick (2002-2008)



"Access – 6"

Essential health system functions
WHO / Health Systems (2007-)



Source: WHO. *Everybody's Business: Strengthening health systems to improve health outcomes - WHO's Framework for Action*, 2007

Access "9"

WHO, Hogerzeil / Laing (2008-)

Government commitment:

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

Rational selection:

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

Affordable prices:

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

Sustainable financing:

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

Reliable systems:

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

Legenda: S=Structural indicator; P=Process indicator; O=Outcome indicator

Access to medicines in LMICs

Current situation

- Considerable improvement in access since late 70's
- **Significant problems persist**, especially for poor and vulnerable populations
  - Inadequate prescription and use
  - Poor quality of services and medicines
  - Unregulated informal sector
  - High proportion of health spending remains Out-Of-Pocket
- **Fragmented vertical approach to access to medicines**
- **Disconnect between the pharmaceuticals and other health system building blocks**

Access to medicines in LMICs

Challenges

- On-going challenges: : communicable diseases, neglected diseases, high burden of mother and child mortality and morbidity , constraints in system resources: human, financial etc.
- New challenges: non-communicable diseases, aging population, escalating costs, widening inequities
- Opportunities
  - Strong movement around universal coverage and social health protection
  - New IT capabilities and opportunities for health systems
  - Increased attention on the crucial role of human resources
  - Focus on national planning processes
  - Innovations in community participation and role of consumers
  - Increasing attention on evidence for decision making

"Multiple, dynamic relationships between building blocks are essential for achieving better outcomes"

Source: Alliance for Health Policy and Systems Research, WHO. *Systems Thinking for Health Systems Strengthening. 2009*

A multi-layer health system view of barriers to access **to medicines**

Level at which constraints to access operate
I. Individual, household and community
II. Health Service Delivery
III. Health Sector
IV. Public policies cutting across sectors
V. International and regional level

Source:
Adapted from Hanson, K. et al., 2003. Expanding access to priority health interventions: a framework for understanding the constraints to scaling-up. *Journal of International Development*, 15: 1-14.

Populated with access to medicines barriers identified in the literature between 2000-2010
[PubMed systematic search on access to medicines and access to health in LMICs]

Level of the health system	Barriers to access medicines
I. Individual, household and community	Physical barriers (geographical location, opening hours) Perceived quality of medicines and health services Inadequate health seeking behaviour and demand for medicines Inadequate use of medicines Social and cultural barriers (stigma related to poverty, ethnicity, gender, etc.)
II. Health Service Delivery	low quality of health services, including staff capacity and motivation, infrastructure etc. Competition between public and private health service delivery Low level of funding for service delivery Weak supply of medicines, low availability Inadequate prescription and dispensing Low quality / substandard medicines High medicine prices
III. Health Sector	Weak governance of the health sector affecting all building blocks: • Absence of stewardship over a pluralistic health system , including private and informal health sector • Absence of partnership with civil society or civil society participation in governance • Weak human resources planning and capacity development • Weak health information system and capacity for monitoring and evaluation • Low level of funding for health, inefficiency in the use of funds, low coverage of pre-payment and social protection schemes, over-reliance on donor funding Weak governance of the pharmaceutical sector affecting all functions: Registration, selection, procurement, distribution, licensing of pharmaceutical establishments, inspection, control of medicines promotion, etc.
IV. Public policies cutting across sectors	Low public accountability and transparency Low priority attached to social sectors High burden of government bureaucracy Conflict between trade and economic goals for pharmaceutical markets and public health goals
V. International and regional level	International donors agenda, including for medicines Weak regional development and economic cooperation mechanisms Unethical use of patents and intellectual property rights Research and development not targeting disease burden in LMICs

Level of the health system	Barriers to access medicines
I. Individual, household and community	Physical barriers (geographical location, opening hours) Perceived quality of medicines and health services Inadequate health seeking behaviour and demand for medicines Inadequate Social and
II. Health Service Delivery	Overa low Co Low ality High medic
III. Health Sector	Weak gove • Absence o • Absence of partnership with civil society or civil society participation in governance • Weak human resources planning and capacity development • Weak health information system and capacity for monitoring and evaluation • Low level of funding for health, inefficiency in the use of funds, low coverage of pre-payment and social protection schemes, over-reliance on donor funding Weak governance of the pharmaceutical sector affecting all functions: Registration, selection, procurement, distribution, licensing of pharmaceutical establishments, inspection, control of medicines promotion, etc.
IV. Public policies cutting across sectors	Low public accountability and transparency Low priority attached to social sectors High burden of government bureaucracy Conflict between trade and economic goals for pharmaceutical markets and public health goals
V. International and regional level	International donors agenda, including for medicines Weak regional development and economic cooperation mechanisms Unethical use of patents and intellectual property rights Distorted research and development, not targeting disease burden in LMICs

WHO-MSH 2000 "Ferney-Voltaire"
Address barriers mainly at service delivery level with consideration of user's perspective

Level of the health system	Barriers to access medicines
I. Individual, household and community	Physical barriers (geographical location, opening hours) Perceived quality of medicines and health services Inadequate health seeking behaviour and demand for medicines Inadequate use of medicines Social and cultural barriers (stigma related to poverty, ethnicity, gender, etc.)
II. Health Service Delivery	Overall low quality of health services, including staff capacity and motivation, infrastructure etc. Competition between public and private health service delivery Low level of funding for service delivery Weak supply of medicines, low availability Irrational prescription and dispensing Low quality High medic
III. Health Sector	Weak g ove • Abs e c • A • sche , ov Weak g ove procureme promotion,
IV. Public policies cutting across sectors	Low public accountability and transparency Low priority attached to social sectors High burden of government bureaucracy Conflict between trade and economic goals for pharmaceutical markets and public health goals
V. International and regional level	International donors agenda, including for medicines Weak regional development and economic cooperation mechanisms Unethical use of patents and intellectual property rights Distorted research and development, not targeting disease burden in LMICs

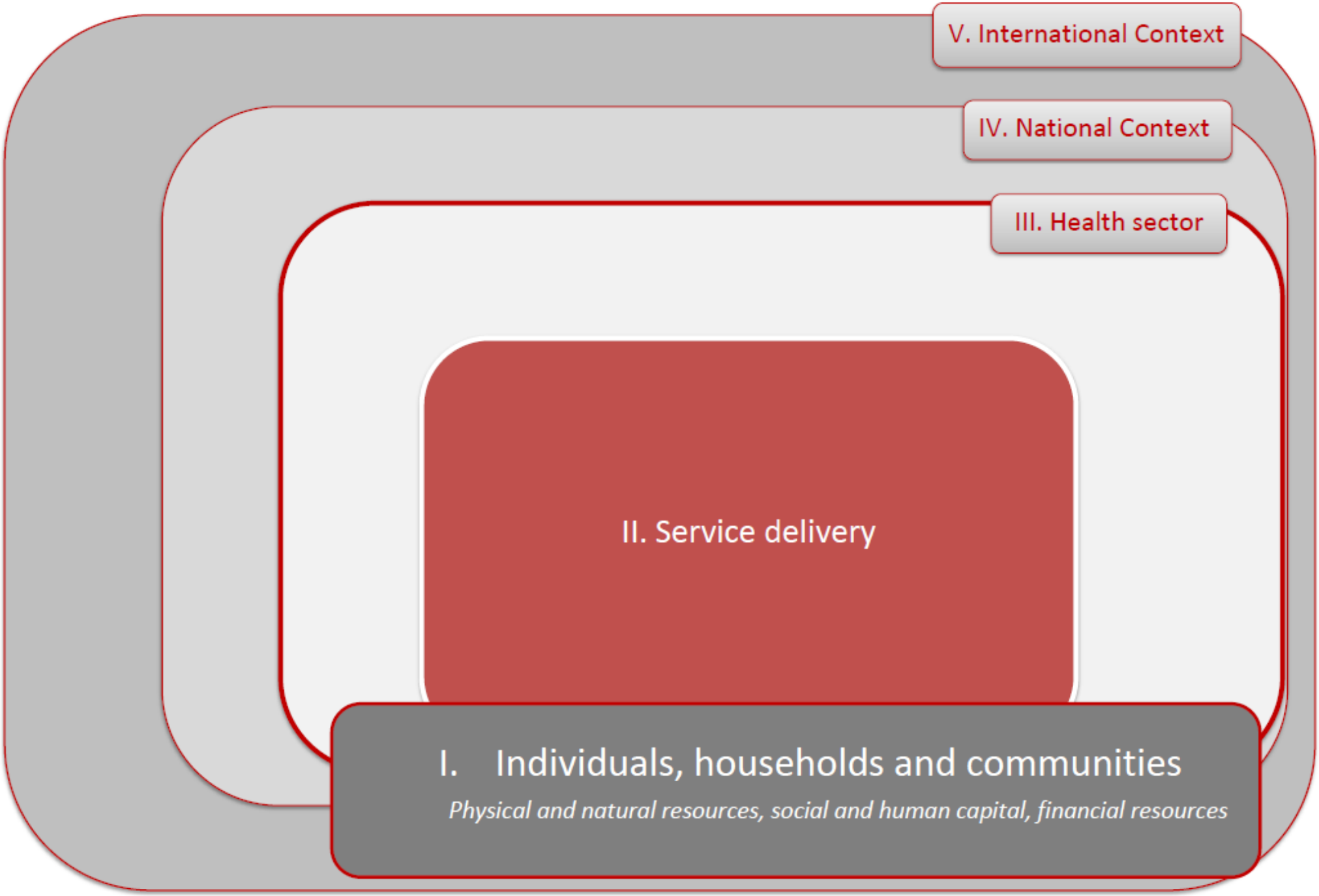
WHO-2004
Address barriers mainly at pharmaceutical and health sector levels

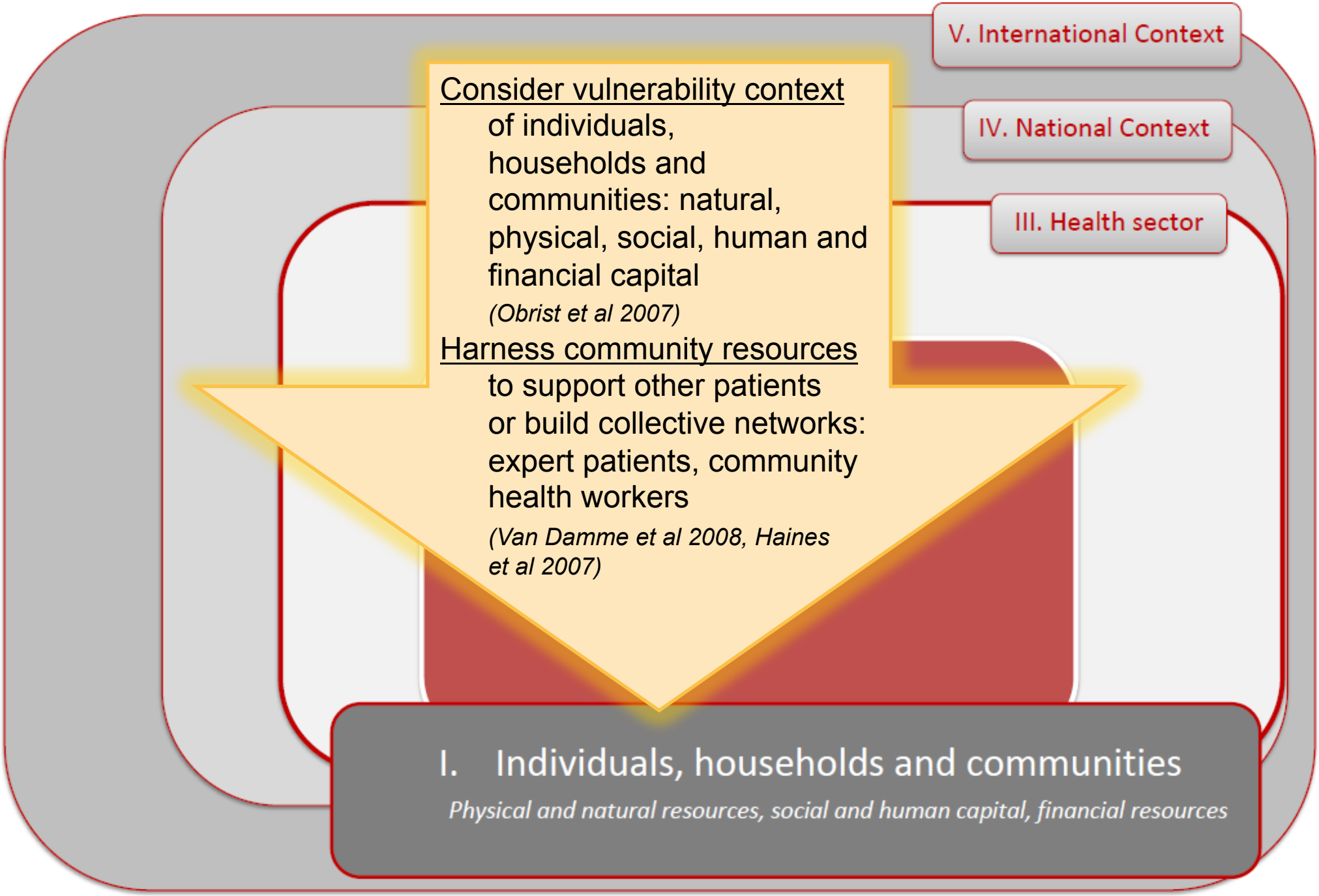
A system framework for access to medicines: the critical paradigm shifts

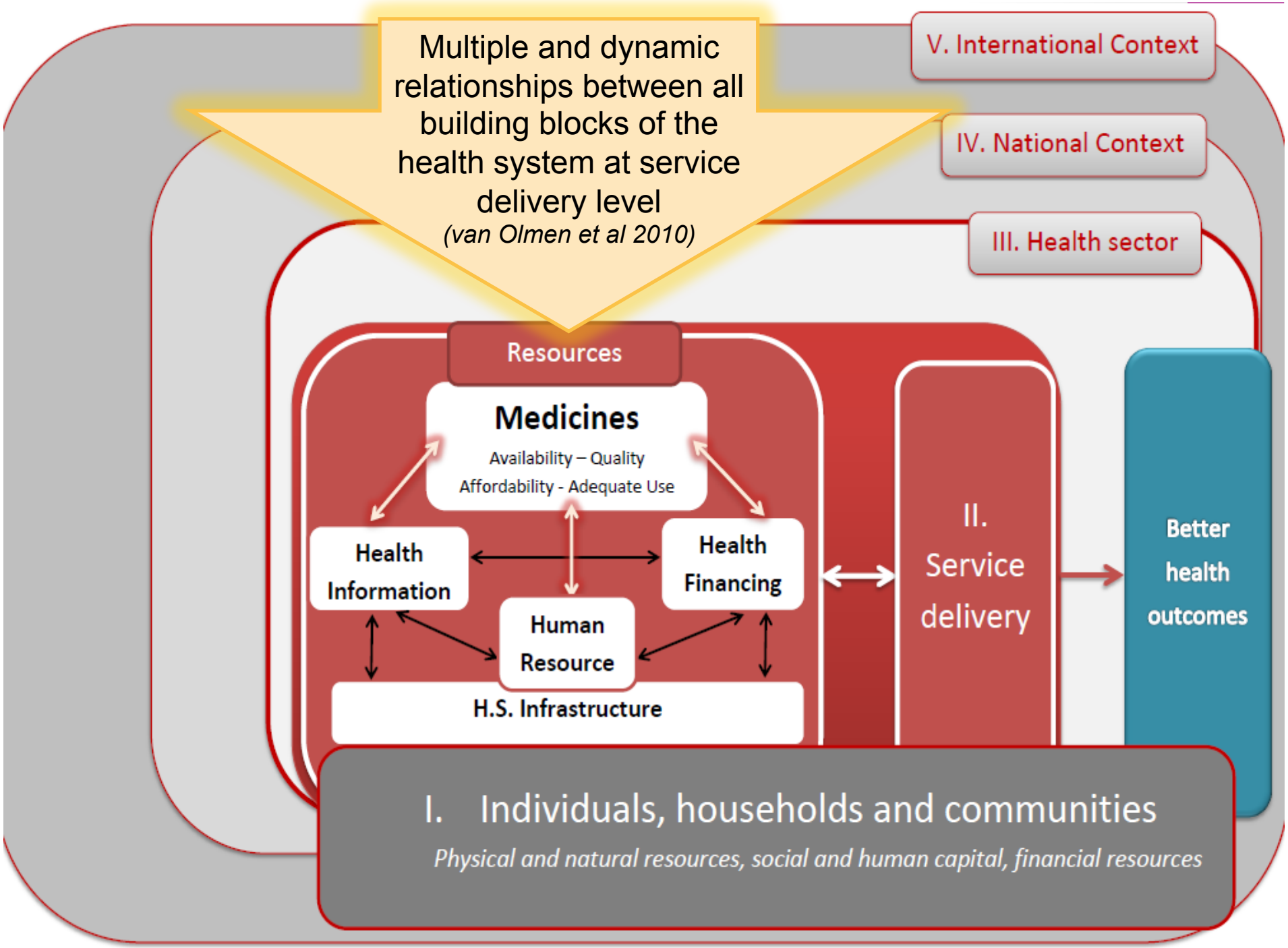
1. Adopt a holistic view on demand-side constraints:
   - Beyond the individual user
   - Inclusive of households and communities

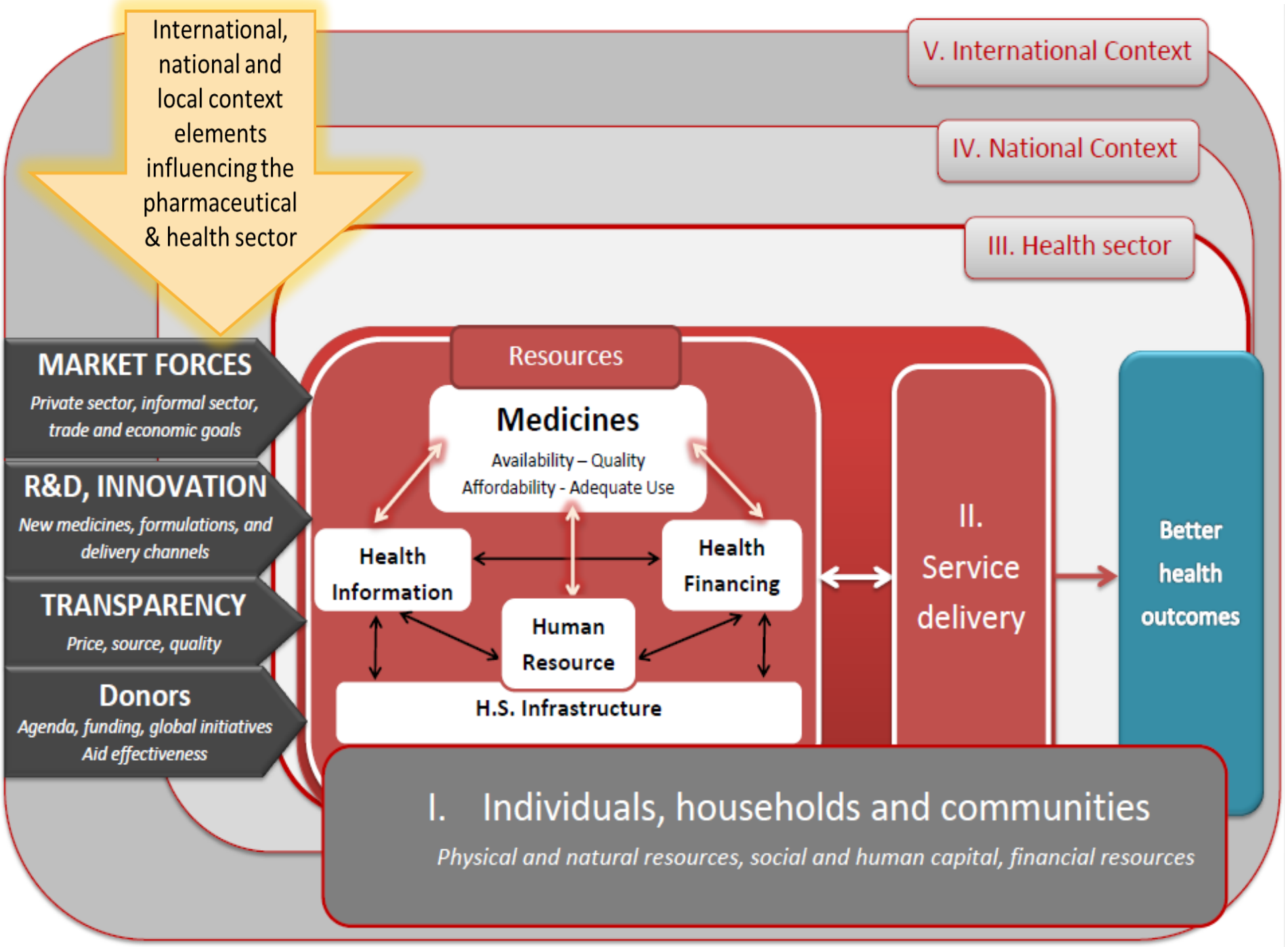
2. Consider the multiple and dynamic relationships between all building blocks of the health system at service delivery level

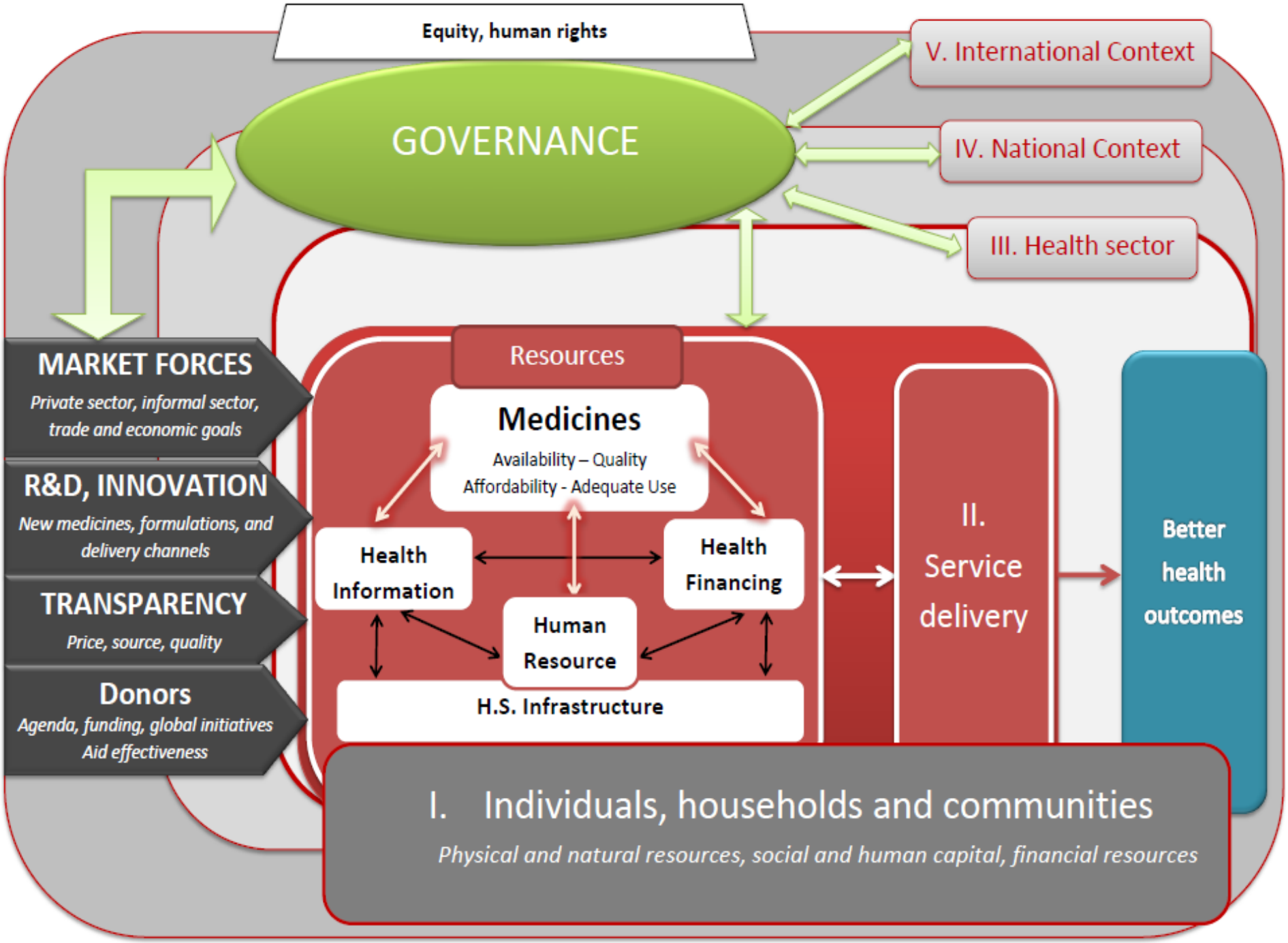
3. Consider multi-layer leadership and governance:
   - Beyond just health sector governance
   - Inclusive of local, national (above health sector) and international contexts


V. International Context
IV. National Context
III. Health sector
II. Service delivery
I. Individuals, households and communities
Physical and natural resources, social and human capital, financial resources


V. International Context
IV. National Context
III. Health sector
Consider vulnerability context of individuals, households and communities: natural, physical, social, human and financial capital
(Obrist et al 2007)
Harness community resources to support other patients or build collective networks: expert patients, community health workers
(Van Damme et al 2008, Haines et al 2007)
I. Individuals, households and communities
Physical and natural resources, social and human capital, financial resources


Multiple and dynamic relationships between all building blocks of the health system at service delivery level
(van Olmen et al 2010)
V. International Context
IV. National Context
III. Health sector
Resources
Medicines
Availability – Quality
Affordability - Adequate Use
Health Information
Health Financing
Human Resource
H.S. Infrastructure
II. Service delivery
Better health outcomes
I. Individuals, households and communities
Physical and natural resources, social and human capital, financial resources


International, national and local context elements influencing the pharmaceutical & health sector
V. International Context
IV. National Context
III. Health sector
MARKET FORCES
Private sector, informal sector, trade and economic goals
R&D, INNOVATION
New medicines, formulations, and delivery channels
TRANSPARENCY
Price, source, quality
Donors
Agenda, funding, global initiatives Aid effectiveness
Resources
Medicines
Availability – Quality
Affordability - Adequate Use
Health Information
Health Financing
Human Resource
H.S. Infrastructure
II. Service delivery
Better health outcomes
I. Individuals, households and communities
Physical and natural resources, social and human capital, financial resources

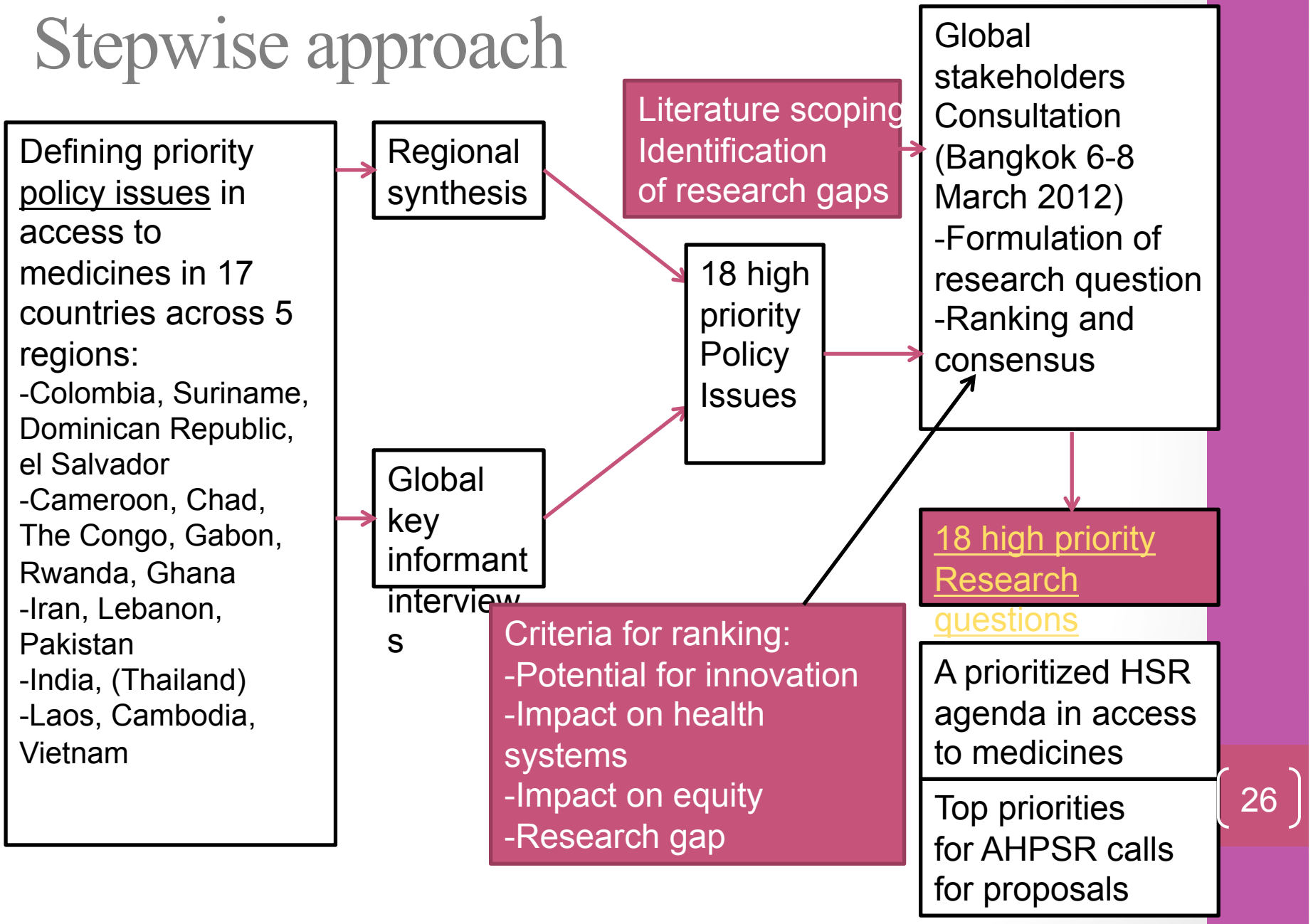

Equity, human rights
V. International Context
GOVERNANCE
IV. National Context
III. Health sector
MARKET FORCES
Private sector, informal sector, trade and economic goals
R&D, INNOVATION
New medicines, formulations, and delivery channels
TRANSPARENCY
Price, source, quality
Donors
Agenda, funding, global initiatives Aid effectiveness
Resources
Medicines
Availability – Quality
Affordability - Adequate Use
Health Information
Health Financing
Human Resource
H.S. Infrastructure
II. Service delivery
Better health outcomes
I. Individuals, households and communities
Physical and natural resources, social and human capital, financial resources

Stakeholders

Priority setting for health policy and system research agenda in access to medicines

- 17 Countries in 4 regions
  - Timeframe: September 2010 – September 2011
  - Grey and published literature search: local, regional and international databases
    - **Identify existing research and research gaps**
  - Key Informant Interviews at country and regional level (multi-level stakeholders)
    - **Identify priority policy concerns in access to medicines**
    - **Identify priority research questions in access to medicines**
- Global level Key Informant Interviews
  - International organizations
  - NGOs
  - Academia

Stepwise approach



Results of priority-setting exercise

Top 3 priority research questions

1. In risk protection schemes, which innovations and policies improve equitable access to and appropriate use of medicines, sustainability of the scheme, and financial impact on beneficiaries?
2. How do policies and other interventions into private markets impact on access to and appropriate use of medicines?
3. How can stakeholders use the information available in the system in a transparent way towards improving access and use of medicines?

Implications for research and policy -1

- **Policies and interventions can use any entry point, but should keep the wider picture in mind**:
  - ✓What are the contextual pre-requisites for a given policy or intervention?
  - ✓What are the wider system effects?
  - ✓How will the system react?

"*A systems perspective can minimize the mess; many of today's problems are because of yesterday's solutions*"

Dr. Irene Akua Agyepong, Ghana Health Service
Ministry of Health, Ghana, 2009

Implications for research and policy -2

- **A collective systems thinking exercise is required among an inclusive set of stakeholders**
  - ✓Revisit policies and interventions with a system-wide perspective:
    - How successful are they really ?
    - How could system-wide perspective help reach long-term sustainable results?
  - ✓Redesign

Anticipating relationships and reactions among the sub-systems and the various actors in the system is essential in predicting possible system-wide implications and effects.

Conclusions

- There are many ways to classify access (1-2-3-4-4-6-9)
- These classifications have become increasingly comprehensive and complex; but they present a solid basis for action
- Key research areas reflect key challenges and priorities:

  1. How to promote equitable access and rational use in health insurance schemes, and protect their sustainability?

  2. How do policies and other interventions into private markets impact on access to and appropriate use of medicines?

  3. How to make best use of the increasing amount of information?

Related papers

1. Bigdeli, M., Jacobs, B., Tomson, G., Laing, R., Ghaffar, A., Dujardin, B., & Van Damme, W. Access to medicines from a health system perspective.. Health Policy and Planning 2013

2. Bigdeli M, Javadi D, Hoebert J, Laing R, Ranson K and the AHPSr network of researchers on ATM. Health policy and systems research in access to medicines: a prioritized agenda for low- and middle-income countries. Health Research Policy and Systems 2013, 11:37

3. Zaidi, S., Bigdeli, M., Aleem, N., & Rashidian, A. (2013). Access to essential medicines in Pakistan: policy and health systems research concerns. PloS one, 8(5)

4. Rashidian A, Jahanmehr N, Jabbour S, Zaidi S, Soleymani F, Bigdeli M. Bibliographic review of research publications on access to and use of medicines in low-income and middle-income countries in the Eastern Mediterranean Region: identifying the research gaps. BMJ Open 2013;3:e003332