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
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”

- Access to 20-30 essential medicines, within one hour’s travel from your home, at a price you can afford
Access “1”

The poor have remained poor

Number of people (billions)

- No regular access
- Regular access to essential drugs

1977
1987
1997

The diagram shows a bar chart indicating the number of people (in billions) with no regular access to essential drugs and those with regular access. The chart highlights that the number of people remaining poor has increased over the years from 1977 to 1997.
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!

Diagram:
- Access
  - Services
    - Medicines
      - Generic
        - Generic name
        - Branded generic
      - Patented (single-source)
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”

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)

1. Rational Selection and use
2. Affordable prices
3. Sustainable financing
4. Reliable systems

ACCESS TO ESSENTIAL MEDICINES
“Access – 6”
Essential health system functions
WHO / Health Systems (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

**Source:**

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*
<table>
<thead>
<tr>
<th>Level of the health system</th>
<th>Barriers to access medicines</th>
</tr>
</thead>
</table>
| **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 |
<table>
<thead>
<tr>
<th>Level of the health system</th>
<th>Barriers to access medicines</th>
</tr>
</thead>
</table>
| 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 / 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  
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
<table>
<thead>
<tr>
<th>Level of the health system</th>
<th>Barriers to access medicines</th>
</tr>
</thead>
</table>
| 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  
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 |
| 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
I. Individuals, households and communities

Physical and natural resources, social and human capital, financial resources

II. Service delivery

IV. National Context

V. International 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)
Multiple and dynamic relationships between all building blocks of the health system at service delivery level (van Olmen et al 2010)
Individuals, households and communities

Physical and natural resources, social and human capital, financial resources

I. Individuals, households and communities

II. Service delivery

Resources

Medicines
- Availability - Quality
- Affordability - Adequate Use

Health Information

Human Resource

Health Financing

H.S. Infrastructure

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

International, national and local context elements influencing the pharmaceutical & health sector

V. International Context

IV. National Context

III. Health sector

Better health outcomes
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

Defining priority policy issues in access to medicines in 17 countries across 5 regions:
- Colombia, Suriname, Dominican Republic, el Salvador
- Cameroon, Chad, The Congo, Gabon, Rwanda, Ghana
- Iran, Lebanon, Pakistan
- India, (Thailand)
- Laos, Cambodia, Vietnam

Regional synthesis

Literature scoping
Identification of research gaps

Global stakeholders Consultation (Bangkok 6-8 March 2012)
- Formulation of research question
- Ranking and consensus

18 high priority Policy Issues

Global key informant interviews

Criteria for ranking:
- Potential for innovation
- Impact on health systems
- Impact on equity
- Research gap

18 high priority Research questions

A prioritized HSR agenda in access to medicines

Top priorities for AHPSR calls for proposals
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

• 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


