Medicines in Health Systems: 
*The AHPSR Flagship Report*
AHPSR Flagship Reports

2004

2007

2009

• Available at: [www.who.int/alliance-hpsr](http://www.who.int/alliance-hpsr)
Essential medicines “should be available at all times in adequate amounts, be affordable, and have a proven efficacy, quality and safety.”
1
WHY A HEALTH SYSTEMS APPROACH?
• A systems approach is one that situates medicines within the full complexity of a health system

Using a systems approach enables an understanding of:

– how medicines interventions influence the rest of the health system and vice versa
– the strong links between access to medicines and equity
– how medicines contribute to stronger health systems and the goals of universal health coverage
Six Components of a Health System
Chapter 1: Why a Health Systems Approach?

1. Access to, affordability, and use of medicines affect (and are affected by) decisions in other parts of the health system.

- **Service delivery processes** affect medicines distribution, prescription; dispensing; uptake.
- **Well-trained health care providers** must appropriately prescribe/dispense, and support adherence to prescribed use.
• **Information systems** support medicines use, supply management, pricing and payment.

• **Financing systems** ensure equitable access and affordability of medicines.

• **Good governance** is essential to registration, selection, quality assurance, procurement, financing, prescribing and dispensing.
Access to medicines from a health systems perspective – adapted Bigdeli et al 2013
Chapter 1: Why a Health Systems Approach?

2. Medicines much more than goods in a series of interactions between patients and public health services.

Access to medicines is influenced by multiple factors at the patient, household, community and systemic levels.
Chapter 1: Why a Health Systems Approach?

3. It is essential to map out, analyse and involve actors of influence.

Major pharmaceutical actors, their linkages, and positions related to the supply and demand of medicines as demonstrated on the next slide...
2
Evolving Concepts in Essential Medicines and Health Systems
Chapter 2: Evolving Concepts in Essential Medicines and Health Systems

a historical perspective on the development of essential medicines and health systems.

- Essential Medicines Lists (EML) originated with WWII military medicine; adopted by some LMICs in the 1970s

- EML evolved beyond just lists and today includes issues around quality, sustainable supply chains, equity in access, efficiency, appropriateness and affordability
WHA Resolution 28.66: WHO to assist country selection, procurement of affordable, quality essential drugs

Alma Ata identifies the provision of essential drugs as a key PHC component

1975

WHO publishes first EML of 205 items

1977

1978

WHO launches Action Programme on Essential Drugs. First publication of “Managing Drug Supply”.

1981
Nairobi conference results in WHO Revised Drug Strategy: emphasis on procurement, distribution, rational use, quality assurance

1987

1985

Implementation of Bamako Initiative: establishment of revolving drug funds (user fees for medicines)

INRUD established to design, test, disseminate effective medicines strategies in LMICs

1989

1994

WTO’s TRIPS agreement sets 20-year patent protection for medicines
Pharmaceutical companies sue South Africa over policies that improve citizens’ access to low-cost HIV medicines.

First ICIUM conference

1997

World Health Report identifies medicines as key input for functioning health systems.

1998

MDG 8 specifically targets access to medicines in cooperation with pharmaceutical companies.

2000
WHO introduces prequalification service to assess quality, safety, efficacy of medicines for HIV, TB, and malaria.

Global Drug Facility for TB medicines is created

Most GHIs include activities to improve medicines procurement, distribution, and use

Doha declaration creates flexibility for countries to protect public health under TRIPS

2001

2002

2003
Commission on Intellectual Property Rights, Innovation and Public Health publishes report with recommendations for creation of new medicines that disproportionately affect LMICs

WHO publishes *Everybody’s Business*: equitable access to essential medicines becomes one of six health system building blocks

ReAct – a network for concerted action on antibiotic resistance – is created
Medicines Transparency Alliance (MeTA) is launched

World Health Report highlights 3 of top 10 sources of health system inefficiency involve medicines

The UN NCD meeting also recommends improving access and affordability of medicines for NCDs.
The Lancet Infectious Disease Commission publishes a report with policy recommendations for coordinated efforts to curb antibiotic resistance

WHA 67 adopts resolution on access to essential medicines; includes refs to complexity and inter-relation of system components

AHPSR releases *Medicines in Health Systems*
Essential Medicines

Satisfy priority health needs: Efficacy – Safety – Cost-effectiveness (WHA 1975)

- **Selected Rationally**
  - Essential Medicines Lists
  - Formularies

- **Available**
  - Public sector: 57%
  - Private sector: 65%

- **Affordable**
  - 30% of total health spending– up to 68%
  - ~50% of out-of-pocket expenditures

- **Quality Assured**
  - 15-50% of drugs are counterfeit
  - Lack of data on extent of substandard medicines
  - Treatment according to guidelines: 40% in the public sector; 30% in the private sector
  - Up to 50% dispensing events are inadequate

- ** Appropriately Used**

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Pluralistic Health Systems: multiple providers, often unregulated
3
THE ROLE OF MEDICINES IN ACHIEVING UNIVERSAL HEALTH COVERAGE
Chapter 3: The Role of Medicines in Achieving Universal Health Coverage (UHC)

A systems approach to medicines can contribute to UHC.

- **UHC**: to ensure that all people obtain the health services they need without suffering financial hardship when paying for them.
In an ideal world ATM in UHC would mean that:

| All patients **access** the medicines they need |
| Products of proven **quality** |
| Appropriately **prescribed/dispensed** medicines available where/when needed and **taken appropriately** by patients |
| Households and health systems have the **resources** to pay for medicines |
| **Legitimate commercial interests** of generic and research pharmaceutical companies taken into account |
| Stakeholders adhere to **good governance** and **ethical business** practices |

Moving towards UHC means engaging stakeholders with often competing objectives and interests
Ensuring Availability of Quality Generic and Innovative Products

• Monitoring product quality
• Prequalifying supplies, products
• Negotiating prices, quality, volume, supply-chain security
• Promoting fair competition
• Engaging in risk-sharing agreements
• Establishing patient access programs

Improving Equitable Access

• Understanding socioeconomic angiographic disease and utilization profiles
• Assessing of household care-seeking and barriers to care
• Expanding provider networks
• Targeting policies and programs to improve access for vulnerable populations

Encouraging Appropriate Use

• Implementing and updating standard treatment guidelines (STGs)
• Matching essential medicines and reimbursements lists to STGs
• Assessing provider performance
• Managing care comprehensively
• Implementing and monitoring policies to encourage clinically appropriate and cost-effective use

Keeping Costs Affordable

• Monitoring routine medicines expenditures by therapeutic area
• Evaluating health technologies, budget impact
• Assessing household medicines expenditure burden
• Implementing and monitoring policies and programs to reduce waste, inappropriate use.

Approaches to balance competing medicines policy objectives
Managing these competing objectives requires policymakers to put in place:

• Mechanisms to select *what medicines* to provide or subsidize

• *Procurement and reimbursement* strategies

• Provider *payment* strategies

• Strategies to improve appropriate *utilization*

• Systems for monitoring *prices*, prescribing *behaviour*, and *user satisfaction*. 
• However, policy interventions are more complex than balancing objectives.

• This is because one policy can influence the behaviours of multiple actors and affect expenditures, quality of care, and patient outcomes in numerous ways.

• Programs that seek to move countries towards UHC, illustrate this well, Ghana example on next slide....
Stakeholders in Ghana’s pharmaceutical sector
• A systems approach, identifies:
  • where policies have the greatest potential to advance UHC and medicines objectives
  • how those policies might lead to unintended consequences
Moving towards UHC requires:

• Explicitly considering *ethical dimensions* of policy decisions to guide decisions about resource allocation. Important to develop a *process* to do this (A4R).

• *Routine information* from administrative data on medicine spending, utilization, quality and fraud and from household surveys to understand access barriers and how to overcome them.
4
INNOVATION TO ENSURE BETTER ACCESS TO MEDICINES
Chapter 4: Innovation to Ensure Better Access to Medicines

Innovation required to bring new and existing medicines to people in novel ways.

Innovation at systems level, much broader than invention or developing new products or technology:

`process to create or improve products, processes, technologies or ideas to generate positive changes in efficiency, value and quality’
Three types of innovation:

• Innovative models of R&D: to develop *new products* for NTDs; new antibiotics

• Innovations in expanding markets for high-quality, lower-cost generics: leading to *substantial savings* for LMICs (generics estimated to have saved US health system over 1000 billion USD 2002-11)

• Innovations in expanding access to specialty medicines: to enable *wider access* to new and expensive *life saving drugs* for conditions such as cancer and hepatitis
Innovative Models for R&D need:

- Creating *product development partnerships* and R&D models
- *Balancing* industry profit with treatment needs

- India’s Open Source Drug Discovery Initiative (OSDD)
  - Publicly and privately financed initiative to *develop new medicines* for neglected diseases
  - Collaboration of scientists through *online platform* and *offline lab-work*; partnership with generic manufacturers
  - Mechanisms to *share financial and non-financial rewards* at individual and collective levels
Innovations in expanding access to generics need to:

• Expand *availability*
• Build *public trust* in generic quality
• Create *incentives* for prescribers, dispensers, and patients to use generics

Brazil’s approach to generic medicines

• Generics Law set *standards* for production, bioequivalence, registration, prescription and dispensing
• *Multiple stakeholders* including pharma companies, provider groups and drug retailers engaged in *policy development* to enable effective implementation
• *Mass education* campaigns for prescribers, dispensers and users; resultant *high awareness* of generics and *increased usage*
Innovation in expanding access to specialty medicines need to:

- Make these **affordable** to individuals, households and health systems
- **Restrict access** to those for whom these medicines are intended and administered in specialty settings
- Maintain **incentives** for continued innovation

The E2 Access programme for high-cost specialty medicines in Thailand

- List of **high cost medicines** covered by insurance programs
- Uses mix of pharmaceutical company patient access programs, compulsory licensing regulation, centralized procurement and distribution
- Demonstrates how combination of **regulatory, managerial** and **economic** measures with **stakeholder involvement** can balance competing objectives
5
MAKING HEALTH MARKET SYSTEMS WORK FOR MEDICINES
• **Market factors** are crucial to LMIC health systems:
  • *To develop* medicines and other technologies
  • *To deliver* health-related goods and services

Improving access and ensuring appropriate use of medicines requires an understanding of **health market systems**

LMIC policy-makers have not given health market systems sufficient attention
• However, **markets on their own do not produce efficient** or equitable health systems

• **Market failures** including information asymmetries and moral hazard can result in unneeded or harmful treatments; high costs; counterfeit/substandard products; antibiotic resistance

• **Market failures must be offset by government action;** policies bringing **together public and private sectors** are crucial to this
Framework for understanding health market systems (adapted Bloom et al 2014)
• Systems approaches to analysing health care markets should take *supply and demand* at their core (provider-client transactions)

Examples of systems approaches to analysing health care markets

• **Tanzania**: Accredited Drug Dispensing Outlet initiative, increased access to high quality, affordable medicines in rural areas by engaging retail drug shops

• **Cambodia**: MoPoTsyo peer educator program for diabetes patients to enable access to diabetes care through task shifting, combined with improved access to drugs and services
Case Study Lessons

• Successful interventions to improve health system markets require:
  • *Continuous revision*, policy-makers must plan for an intervention changing over time;
  • Involving *multiple components* addressing different aspects of the market system and mapping consequences of their interaction
  • Engagement of *multiple stakeholders*
  • A balanced application of *incentives, controls and capacity building*
  • The use of *data* to monitor intended and unintended consequences, and to enhance accountability
6
USING A SYSTEMS PERSPECTIVE TO INNOVATE IN ACCESS TO MEDICINES
A Framework for Moving Forward

1. Include access to medicines and their appropriate use as an explicit focus in health system strengthening and efforts towards universal health coverage (UHC).

Attempts to strengthen health systems or achieving UHC must include a primary focus on medicines.
A Framework for Moving Forward

2. Recognize the need for transparency and governance in the medicines sector; strengthen governance capacities.

There are multiple authorities and governance structures for essential medicines.
A Framework for Moving Forward

3. Build more *robust connections* between information, medicines and decision-making.

Innovations are needed in:

- *generating information* for data;
- *connecting* information and medicines policies;
- *connecting actors* who gather, shape, control, and make decisions based upon that information.
Medicines in Health Systems: An Agenda for Action

To act on the recommendations in this report, health system decision-makers should:

1. Incorporate policy-making principles that advance the availability of quality-assured products, the equitable access to medicines, their appropriate and efficient use, and ensure household and system affordability.

2. Include diverse stakeholders in medicines policy and program design, implementation, monitoring and evaluation.
Medicines in Health Systems: An Agenda for Action

3. Implement innovative stewardship arrangements for the multiple private and public channels through which medicines reach people

4. Use the convening power of UHC to integrate multi-pronged medicines policies and pharmaceutical management strategies into health care delivery and financing systems

5. Connect fragmented information on medicines, and also the stakeholders who collect and use this information
6. Include core medicines-focused *indicators* in assessments of health systems and UHC performance.

7. Enable continuous learning through *implementation research* on changes concerning medicines in systems.
Thank You!!

For a copy of the Report, visit: www.who.int/alliance-hpsr