Access to Medicines in Low and Middle Income Countries: Goals and Challenges

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The World Bank and its clients

Overall goal: reduce poverty, increase equity
Health Systems focus

Access to Quality Health Care

- Governance (laws, regulations, standards)
- Human Resources
- Financing and payment systems
- Medicines, supplies, infrastructure, technology
Core challenges for policy makers

Low income
- Availability
- Quality
- Affordability
- Adherence
- Lack of resources requires prioritization of life-saving treatments with high public health impact

Middle income
- Equitable access
- Rational use
- Perception of quality
- Financial protection
- Affordability of innovative treatments
Systemic issues

Market failure
- Fragmented buyers
- Uninformed consumers
- Biased professionals
- Conflict between public health and private incentives

Weak governance and management
- Lack of accountability
- Outdated HR policies
- Fragmented decision making
- Corruption
- Lack of business skills
- Lack of technical skills
- Lack of data and transparency
Innovation dilemma

• Novel, potentially life saving medicines developed by large multinational companies come at a high cost
• Insurance funds and other payers with pooled funding are interested in offering new technologies but need to contain costs, the relevant factor being budget impact
• Individual patients from low-income households may not be able to afford new medicines even if they are priced far below the developed country price level
• Manufacturers of such products face an ethical dilemma between shareholder interests (cost recovery, profit) and patient interest (access for all who could benefit from a new medicine)
Drug budget overruns are the norm...

Pharmaceutical Expenditure and Cost Drivers

- Better access to care, higher utilization
- Sense of entitlement; “more is better” attitude
- Aging populations, more chronic diseases
- Fraud, cheating and collusion among providers, suppliers and beneficiaries
- Financial incentives for providers favor overuse and use of expensive medicines
- Innovation creates new options and demands
- Increasing patient literacy and demands for certain types of drugs
- Courts ordering coverage of costly biologics

Year 1 Year 2 Year 3 Year 4

Real Budget
Once established, bad habits are not easy to break

Payers often find it hard or impossible to crack down on abuse and enforce restrictions against the combined political power of healthcare professionals, patients and a well organized industry
Rationale for Price Regulation

- Protecting consumers (vulnerability in the case of illness)
- Staying within limited budget
- Getting more value/volume for the money
- Improving access for the poor
- Protecting domestic industry, stimulating R&D investment (?)

- But price regulation alone is not sufficient to achieve any of these objectives!
Standard Pricing Tools

- Reference pricing (innovator, generic)
- Reimbursement ceilings (internal referencing)
- Pooled purchasing/contracting
Self-limiting concept? What happens once all countries are referencing to each other?
Drug Pricing “Mind Map”

Volume competition

Ceiling or fixed

Generics in reference to originator

Country of origin

Distribution margins

Taxes and tariffs

For non-reimbursable

For all drugs

For OTC

External referencing Single-source

Cost plus

Regulation

Free pricing

Drug Pricing

Reimbursement caps for HIF*

Value based (HTA)

Innovative drugs

Volume caps

Package deals

Payment for outcomes

HIF/hospital buying

Generics

Tendering for defined volume

Contracting with manufacturer

Contracting with wholesaler

Innovative drugs

Preferred brand for reimbursement

Framework Contract

*Health Insurance Fund
Core areas for policy innovation – Low income
Supply chain integration

• So far, procurement and supply chain logistics are often treated as separate system components
• Fragmentation is the rule
• Establish “Good Practices” for supply chain management as integral part of development cooperation?
Financing systems

• Public, top-down funding systems often ineffective, strangled by bureaucracy
• “Money-follows-patient” principle with focus on the poor
• Opening the door for more participation of private sector (combined with better regulation)
Strengthen regulators

- Current procurement systems potentially undermine regulators
- Patients using private providers exposed to significant risks due to weak enforcement
- Long-term solution has to rely on competent regulators to ensure quality of medicines in the market
What about rational use?

• Any evidence for successful, cost-effective, sustainable strategies to change provider and patient behavior..

• .. in the absence of a strictly managed pharmaceutical benefit provision with third party payment mechanism?
Core areas for policy innovation – Middle income
Universal Coverage...

Typically includes coverage for a range of pharmaceutical products:

“Pharmaceutical Benefit Management” or “Pharmacy Benefit Management” is the set of rules, controls and enforcement tools that define how eligible beneficiaries can obtain third party payment for prescription medicines under a public budget or insurance funded healthcare program.
Defining rules and developing tools upfront...

- **Restrictive** – stay on the safe side; later more benefits can be added
- **Enforceable** – have all management tools in place before benefit is implemented
Setting parameters for a pharmaceutical benefit

- Reimbursement list: which medicines are covered
- Patient eligibility (sub-population, condition, age, gender etc.)
- Reimbursement rates, prices, discounts, budget caps etc.
- Patient co-payment; exemptions, limits
- Compensation for distributor, pharmacist; substitution rights
- Assessment and decision making on inclusion of new technologies
- Case management for high-cost patients
- Negotiation strategies for deals with industry
Countries that cannot afford a full scale Health Technology Assessment body still need a mechanism to assess available information on new medicines/technologies and make rational decisions on spending priorities for a pharmaceutical benefit package.

**Medical and economic assessment**

- Publicly available data & analysis (example NICE)
- Decisions made by other countries
- Manufacturer provided data

**Considering**
- Health priorities
- Applicability of data
- Available funds
- Economic impact
- Subjective suffering
- Delivery capacity
- Other relevant factors

**Rejection** or **Go-ahead for negotiations with supplier**
Negotiation goals and strategies

Optimizing “value for money” requires different negotiation strategies for dealing with manufacturers of innovative (patented) versus generic medicines. Price regulation or fixed reimbursement rates alone will lead over time to sub-optimal outcomes. This issue can be tackled after a benefit scheme is implemented.
Investing into data collection and management

- Provider and patient level data on utilization are needed to manage the main cost drivers.
- Transaction monitoring produces lots of data every day; significant computing power is needed to process data and generate meaningful reports.
- Confidentiality of personal data is an issue that needs to be addressed and communicated well.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Product</th>
<th>Service Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique identifier</td>
<td>Unique identifier</td>
<td>Unique identifier</td>
</tr>
<tr>
<td>Diagnosis (code)</td>
<td>Dosage form, dosage</td>
<td>Date of transaction</td>
</tr>
<tr>
<td>Eligibility criteria (example age, gender)</td>
<td>Units dispensed</td>
<td>Units prescribed</td>
</tr>
</tbody>
</table>
Using data to adjust rules and inform negotiations

(Examples)

- Expenditure tracking against budget
- Performance against agreed goals for rational use
- Identifying patterns of abuse, overuse
- Measuring cost-effectiveness of prescribing
- Flagging potential fraud
- Enforcement of price-volume agreements
Options for a frugal approach

In a low income environment or if political will for upfront investment is missing, a benefit package under a defined budget cap could be implemented as follows:

• **Coupon system**
  – Offering coupons for eligible beneficiaries and specific products; coupons are handed out by providers and can be cashed in by pharmacists
  – Data collection at payer level, based on reimbursed coupons

• **Budget holding at health facility level:**
  – Each facility gets a defined budget allocation for reimbursement through a single contract pharmacy. Once budget is used up, patients pay out of pocket
  – Pharmacy keeps record and informs health facility management of remaining budget

**Downsides:** Benefit may be captured by people with “connections” or higher literacy levels, who learn how to play the system
Ensuring access for the poor

• Manufacturers should make a commitment to working with their national counterparts on a solution that maximizes access to novel medicines for which the need exceeds ability to pay

• Different medicines and different countries will require a range of strategic options to optimize access without eroding profitability in the high-income segment, such as
  – Compassionate need programs
  – Collaboration with service providers that treat mainly poor patients and offering the medicine for free
  – Voluntary license to a generic drug company
Technology offers innovative solutions

Management of the provider-patient transaction with a smartphone app, that

• Verifies patient eligibility
• Guides the provider through the intervention based on a defined protocol
• Verifies identity with a photo and barcode reader
• Transmits transaction based data to a central server for analysis
• Pays the provider through an “m-pesa” like service as soon as transaction is complete

In this setting, the type and number of transactions can be pre-defined and controlled server-side. Each type of service has its own app. The risk of budget overruns is minimalized.