Policies and approaches to increase access essential medicines to treat major NCDs in both public and private facilities

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Overview

• Global action plan: targets and indicators
• Tools to measure
• Approaches
• Sri Lanka: Where are we?
• Policy interventions
Global Monitoring Framework on NCDs Negotiations

9 global targets and 25 indicators

“What gets measured, gets done”
WHO DG, Margaret Chan
Tools to measure 80% coverage?
WHO/HAI Joint Activity on Essential Medicine, Prices and Affordability

Summary price data is expressed as the Median MPR - calculated as the median local unit price divided by the international unit reference price in local currency using the exchange rate on the first day of data collection. Most surveys use Management Sciences for Health (MSH) International Drug Price Indicator Guide as the source of the reference price.

Availability of individual medicines is reported as the percentage of medicine outlets in which the medicine was found on the day of data collection. Summary data for availability is presented as either the median or mean availability of the medicines in the selected basket.

Affordability is the cost of treatment in relation to peoples’ income. In the WHO/HAI methodology, the measure is number of days of work by the lowest-paid unskilled national government worker to purchase a defined course of treatment for a specific condition.

Drug utilization research

• ATC/DDD system is a tool for presenting drug utilization statistics
• Important for initiating and modifying drug policy at both national and local levels
• Data can be from a variety of sources - wholesale data at a national, regional or local level/Dispensing data either comprehensive or sampled.
• Used to describe the present state, and trends in drug prescribing and drug use at various levels of the health care system

TOOLS
• ATC classification system
• Defined daily dose

http://www.whocc.no/
ATC classification system

• Drugs are classified in groups at five different levels.
• Classification of glibenclamide illustrates structure of the code.
• A Alimentary tract and metabolism (first level, main anatomical group)
  • A10 Drugs used in diabetes (second level, main therapeutic group)
    • A10B Oral blood-glucose-lowering drugs (third level, therapeutic/pharmacological subgroup)
      • A10B B Sulfonamides, urea derivatives (fourth level chemical/therapeutic/pharmacological subgroup)
        • A10B B01 Glibenclamide (fifth level, subgroup for chemical substance)
      • A10B B01 Glibenclamide (fifth level, subgroup for chemical substance)
• All plain glibenclamide preparations are given the code A10B B01.
Defined Daily Dose (DDD)

• Defined daily dose is a unit of measurement
• DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults.
• Does not necessarily reflect the recommended or Prescribed Daily Dose.
• Drug consumption data presented in DDDs gives a rough estimate of consumption to assess trends
• Examples of DDS
  – Glibenclamide = 10mg
  – Atorvastatin = 20mg
  – Enalapril = 10mg
Drug consumption data

• Presented as
  – numbers of DDDs/1000 inhabitants/day or,
  – when in-hospital drug use is considered, as DDDs per 100 bed days.

• Sales or prescription data presented in DDD/1000 inhabitants/day may provide a rough estimate of the proportion of the population within a defined area treated daily with certain drugs.

• For example, 10 DDDs/1000 inhabitants/day indicates that 1% of the population on average gets a certain treatment daily.
Eight key approaches and the specific solutions to increase access to essential cardiovascular medicines in Low- and Middle-Income Countries.


<table>
<thead>
<tr>
<th>Approach:</th>
<th>Specific Solutions:</th>
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<tbody>
<tr>
<td>1. Enhancing capacity for generic substitution</td>
<td>Expand disease scope of WHO prequalification project</td>
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<td>Build capacity of local Medicines Regulatory Authorities to fast track generic drug</td>
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<td></td>
<td>registration</td>
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<td>Linkages of ACC and AHA with local cardiology societies to jointly develop guidelines</td>
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<td></td>
<td>on use of generics</td>
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<td>2. Expediting generic availability by overcoming legal barriers</td>
<td>Increase use of Compulsory Licenses (Article 31 of TRIPS)</td>
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<td>related to patents and licenses</td>
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<td>3. Optimizing local procurement practices in the public sector</td>
<td>Recruit political, ministerial and civil society support for supply chain management</td>
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<td>Use of mobile and information technology to map “stock-outs” for targeted remediation</td>
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<td>4. Broadening global procurement via third-party price negotiations</td>
<td>Establish an international procurement body for CVD and related NCD medicines</td>
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<td>Augment pooled purchasing to reduce costs</td>
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<td>5. Engaging the private sector to differentially price CVD medicines in</td>
<td>Offer rebates to working poor to afford branded drug</td>
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<td>LMICs</td>
<td>Establish responsible price indicators for each country or region</td>
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<td>6. Regulating retail mark-ups in the supply chain</td>
<td>Use of government controls to restrict mark-ups</td>
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<td>Fixing maximum end-user price</td>
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<td>7. Eliminating tariffs on medicines</td>
<td>Adhere to international treaties to eliminate import tariffs</td>
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<td>Eliminate national sales taxes</td>
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<td>8. Developing a fixed-dose combination (FDC) for CVD (the “Polypill”)</td>
<td>Simplify forecast and delivery needs</td>
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<td>Reduce overall cost of multi-drug regimen</td>
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<td>Add to WHO Essential Medicines List pending data</td>
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</table>
Sri Lanka: National initiatives
Country Background (2008)

- Total population = 20.2 million
- Both state sector and private sector provide health care services
- State sector provides free services to ~60% of the population
- Life expectancy at birth
  - Males = 71.7
  - Females = 76.4
- Adult literacy rate = 90.7%
- Age index (ratio between the 65y and over to 0-14y population) = 24
Sri Lanka: Burden of NCDs 2008

NCDs are estimated to account for 65% of all deaths. CVDS account for almost 50%.
National Initiatives

• Assess situation

• Expected outcomes
  – Efficient spending
  – Improve accessibility
  – Efficient procurement practices to ensure continuous availability of essential medicines for NCD
  – Affordability in private sector

• Policy recommendations
Methodology for public sector

• **Study design:** Cross sectional descriptive study.
• **Study period:** 2002 - 2006 and 2007-2011
• **Study setting:** Medical Supplies Division (MSD), Ministry of Healthcare and Nutrition, Sri Lanka
• **Source of data:**
  – Computerized records of annual data on medicines supplies maintained in the MSD on four key NCDs; diabetes, cardiovascular diseases, cancers, and chronic respiratory diseases, supplied to the entire public sector during the study period
  – Captured complete data on medicine supplies to the Public sector except locally purchased by individual hospitals
• Medicines were classified according to 2012 Anatomical Therapeutic Chemical (ATC) classification /DDD system
Results 2002 - 2006

• 71% of this money was spent on essential medicines.
• Anti-asthma medicines totalled 13.7 DDDs/1000/day
• Selection of medicines was inappropriate
  – symptom relievers accounted for 86%
  – preventers accounted for only 14 %
  – Beta 2 agonists: 51.2% oral vs 4.8%. inhaled
  – proportion of inhaled salbutamol to systemic salbutamol to inhaled steroids was 1: 11 : 3 in 2006.
• Issues of statins not in proportion with the DDDs for antihypertensive and ant diabietic medicines
Fig 1: Comparison of DDDs of statins, antidiabetics and antihypertensive medicines; 2006.
Outcome: Low public sector availability?

- Lack of updating MSD list
- Procurement not in keeping with NEML
- Lack of prioritizing medicines procurement with disease burden
- Inaccurate forecasting
- Inefficient procurement / distribution / storage
- Quality failures
Essential medicines List

• Sri Lanka: Frequent updating of NEML
• Developed a list of essential medicines in keeping with WHO pen for primary care
Results in 2007 - 2011

2011: Supply of inhaled asthma dosage forms markedly increased by 575% as opposed to a 2.65% increase with the salbutamol tablet. The percentage increase observed for beclometasone inhale dosage form was 129%. A 70% drop was observed in the supplies of theophylline.
Expenditure on CVS medicines
2007-2011
## Medicines for cancers

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>C + B01</th>
<th>L</th>
<th>A10</th>
<th>R03</th>
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</thead>
<tbody>
<tr>
<td>2007</td>
<td>747</td>
<td>88</td>
<td>80</td>
<td>7</td>
<td>22</td>
</tr>
<tr>
<td>2008</td>
<td>759</td>
<td>83</td>
<td>81</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>2009</td>
<td>738</td>
<td>82</td>
<td>80</td>
<td>9</td>
<td>22</td>
</tr>
<tr>
<td>2010</td>
<td>738</td>
<td>80</td>
<td>93</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>2011</td>
<td>783</td>
<td>83</td>
<td>113</td>
<td>9</td>
<td>24</td>
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<tr>
<td>Mean</td>
<td>753</td>
<td>83.2</td>
<td>89.4</td>
<td>8.6</td>
<td>22.6</td>
</tr>
</tbody>
</table>

### Notes
- **Mean** values are percentage change from the previous year.
- **Total** includes all categories of medicines for cancers.
- **C + B01** represents the combined cost of selected medicines.
- **L** denotes the specific category of medicines.
- **A10** and **R03** are distinct cost categories.
Medicine prices, availability and affordability in Sri Lanka: 2009

• Innovators were five to six-times the IRP at privately owned pharmacies and four to seven-times at the Rajya Osu Sala.

• The prices of generics were ≤1 the IRP during 6 years in privately owned and Rajya Osu Sala pharmacies.

• Cheapest generics were high in availability (>80%) throughout the study period.

• Innovators cost more than a day’s wage of the lowest-paid government worker; in contrast, generics were always less than one day’s wage.

• There seems to be no difference in affordability between privately owned or semi government pharmacies.
On going research

• Availability of essential medicines for management of clinic patients with cardiovascular diseases in selected primary level health institutions in the Kalutara district

• Medicine availability prices, and affordability of medicines used for NCDs in Sri Lanka 2013
Availability of generics
Strengths 1

- Most products on the market are registered products
- Innovators are registered without patent
- **Generic version of a medicine that is still protected by a patent available with no legal issues so far**
- CDDA does not ask generic companies to sign statements on patent status
- Preferential registration procedures, e.g. fast-tracking, lower fees
- Tax exemptions for medicines
- Concessions for local manufactures
- Price regulation for medicines on NEML
Strengths 2

• Prescribing of generics (branded) high >70%

• Procurement of medicines under INN or generic name and world wide tenders

• High availability of generic products for NCDs but should pay more attention to quality

• Local manufacture of NCD medicines in place but few compared to imported medicines. Eg. Atorvastatin (1 vs 96), enalapril, losartan, glibenclamide, metformin
Weaknesses

• **Local production of allopathic medicines** accounts for only $\approx 10\%$ of the total medicines used in the country

• Never manufactured any NCEs

• No instances of compulsory licensing and manufacture

• At present Sri Lanka is totally dependent upon imports of essential medicines

• Substandard medicines undermining confidence in the health drug delivery system at present

• Generic substitution by pharmacists not permitted

• Inadequate training on IPR: Patent office, CDDA. Health care professionals
Policy interventions

• Prioritize medicine budget, i.e. target widespread access to a reduced number of essential generic medicines for NCDs.
• Affordable medicines for cancer
• Timely procurement, equitable distribution, better storage facilities
• Targeted local manufacture
• Sustain generic use:
  – ensure the quality of generic products
  – build confidence and educate doctors/consumers on availability and acceptability of generics
  – permit generic substitution
AN ACT TO PROVIDE FOR THE ESTABLISHMENT OF A
REGULATORY AUTHORITY WHICH SHALL BE
RESPONSIBLE FOR THE REGULATION AND CONTROL OF
THE MANUFACTURE—IMPORTATION, SALE, STORAGE,
DISPOSAL, TRANSPORTATION AND DISTRIBUTION OF
MEDICINAL DRUGS IN A MANNER COMPATIBLE WITH THE
NATIONAL DRUG POLICY, AND FOR THE REGULATION
AND CONTROL OF THE MANUFACTURE, IMPORTATION,
SALE, STORAGE, DISPOSAL, TRANSPORTATION AND
DISTRIBUTION OF DEVICES AND COSMETICS AND TO
PROVIDE FOR THE ESTABLISHMENT OF THE MEDICINAL
DRUGS REGULATORY DIVISION, DEVICES REGULATORY
DIVISION AND COSMETICS REGULATORY DIVISION; TO
REPEAL THE COSMETICS, DEVICES AND DRUGS ACT NO.
27 OF 1985 AND FOR MATTERS CONNECTED THERewith
OR INCIDENTAL THERETO.

Bill is enacted by the Parliament of the Democratic Socialist Republic
of Sri Lanka as follows:—

This Act may be cited as the National Medicinal Drugs,
Devices and Cosmetics Regulatory Authority Act, No. 21 of 2013
and shall come into operation on such date as the Minister may
appoint by order published in the Gazette (hereinafter referred to as
"the appointed date").

PART I

ESTABLISHMENT OF THE NATIONAL MEDICINAL DRUGS,
DEVICES AND COSMETICS REGULATORY AUTHORITY
Conclusions

• Methodology available for measuring effectiveness of policies
• Policy Interventions to target
  – Outcome of research
  – Address weakness in the system
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