Pharmacovigilence and Risks of Expanded Access to Essential Medications for Noncommunicable Diseases

Gene Bukhman, MD, PhD
Harvard Medical School and Partners In Health

Rémy Pacifique Ntirengaya, BPharm, MPhil Sd (UR)
Partners In Health-Inshuti Mu Buzima

International Symposium on Medicines and Patient Safety,
Kigali, Rwanda, 5 November 2014

Categories of NCD Medicines
Expanding access to essential (NCD) medicines is not a new idea.
Millennium Development Goal (MDG) 8

**Target 17.** In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries

**Indicators**

46. Proportion of population with access to affordable essential drugs on a sustainable basis (WHO)

But still far from achieved

Initial Drafts of Global Monitoring Framework for NCDs did not include any health system targets
Indicators and targets for 2025 for the global monitoring framework for NCDs

<table>
<thead>
<tr>
<th>Indicators with targets</th>
<th>Mortality between ages 30 and 70 due to CVD, cancer, diabetes, and chronic respiratory disease</th>
<th>25% reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td></td>
<td>25% reduction</td>
</tr>
<tr>
<td>Tobacco</td>
<td></td>
<td>30% reduction</td>
</tr>
<tr>
<td>Salt</td>
<td></td>
<td>30% reduction</td>
</tr>
<tr>
<td>Physical inactivity</td>
<td></td>
<td>10% reduction</td>
</tr>
</tbody>
</table>


Final Monitoring Framework added two health system targets
<table>
<thead>
<tr>
<th></th>
<th>Reduction Target</th>
<th>Age of Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Death from CVD, Cancer, Diabetes, Lung Disease</td>
<td>25% age 30-70</td>
</tr>
<tr>
<td>2</td>
<td>Harmful Alcohol Use</td>
<td>10% 15+</td>
</tr>
<tr>
<td>3</td>
<td>Physical Inactivity</td>
<td>10% 10-19; ≥ 18</td>
</tr>
<tr>
<td>4</td>
<td>Salt</td>
<td>30% ≥ 18</td>
</tr>
<tr>
<td>5</td>
<td>Tobacco</td>
<td>30% 10-19; ≥ 18</td>
</tr>
<tr>
<td>6</td>
<td>High Blood Pressure</td>
<td>25% ≥ 18</td>
</tr>
<tr>
<td>7</td>
<td>Diabetes and Obesity</td>
<td>≥ 0% 10-19; ≥ 18</td>
</tr>
</tbody>
</table>

### National System Response

<table>
<thead>
<tr>
<th></th>
<th>Treatment for Cardiovascular Risk</th>
<th>Age ≥ 40 + 10-yr risk ≥ 30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>50% coverage</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Medicines and Technologies</td>
<td>80% availability</td>
</tr>
</tbody>
</table>


**Implications of Essential Medicines Target**
Meeting the Challenge of NCD: We Cannot Wait

Agnes Binagwaho
Kigali, Rwanda

A decade ago, the world prepared to confront one of the greatest public health and moral challenges in human history. The pages of medical journals were filled with debates about whether it was possible to act on anything close to the scale that was needed to tackle the scourge of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome. Many years and many lives were wasted as researchers and policymakers with the best of intentions invented a conflict between prevention and cure and pointed to countless reasons, including high fixed costs, as well as human resources and infrastructural deficits, why the time-quently prevent, treat, and monitor this group of complex chronic conditions, which together account for more than 60% of all deaths. The complexity of this task is enormous and its urgency fierce, but there is no question of whether we possess the tools to meet it head on. Political will and unimpaired vision—not some kind of inherent shortcomings on the part of developing country policymakers, clinicians, or patients—are the greatest threats to our success.

I believe that health is a human right. In Rwanda, this understanding is enshrined in our constitution, and we do not miss opportunities to improve
The next generation of global solidarity must be more strategic, more efficient, and more country-driven. The dialogue begun many years ago, globally recognized at the United Nations High-Level Meeting on Non-Communicable Diseases, and carried on in these pages is a wonderful start, but we have much work to do in creating a future in which the greatest risk factor for dying of a non-communicable disease is not where one is born. My vision for Rwanda is for our country to become a place where cardiology and cancer patients are referred from around the region and where our doctors can harness all the tools of science—not just those currently considered appropriate for Africa—in treating our people in the most dignified way possible. Such a future is within our grasp, and history will judge us by our efforts to meet the challenge.

Risks of Increased Distribution
• Poor Quality Medications
  – Counterfeit
  – Poor Bioavailability
  – Poor Storage
• Excessively Costly Medications

• Adverse Medication Events
  – Prescribing Errors
  – Distribution Errors (pharmacy and nurse)
  – Patient Adherence Errors
• Risk Poisoning of (Children)

No prequalification system
WHO prequalification (PQ)

WHO product quality, safety and efficacy evaluation

• List of PQ medicinal products:
  - HIV/AIDS (338)
  - Tuberculosis (72),
  - Malaria (35)
  - Reproductive health (23)
  - Influenza (7)
  - Diarrhoea (2)
  - Neglected tropical diseases (1)

• Other WHO prequalification programs
  - Prequalification quality control labs (26)
  - Prequalification vaccines
  - Prequalification diagnostics
  - Prequalification insecticide treated bed nets

Courtesy Michiel de Goeje, IDA Foundation

Many NCD medications have a narrow therapeutic window
Urgent to strengthen pharmacology systems