Going beyond price: Impact and value analysis of quality-assured medicines

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The environment is changing (albeit slowly)

- Increasing recognition of the difficulty of producing for low- / middle-income markets
  - regulatory burden at national / international levels (but move → harmonization, reliance)
  - (perceived) low returns on investment (WHO fair pricing initiative; Global Fund multi-year agreements & faster payment)
  - demand not predictable (better data)
• Quality is ultimately measured as patient outcomes (e.g. life years, quality of life, ability to work or care for the family)
• Cost should be overall cost, including direct and indirect medical cost, in addition to patient and societal cost
• ....and more is expected by governments and donors of investments in (global) health.
Cost should be measured across stakeholders, silos and budgets

Measure total value

Medicines budget
Diagnostics budget
Hospital budget
Outpatient budget
Patient out-of-pocket spend
Ability to work: patient impact
Ability to work: societal impact
Time and cost of caregivers
Transportation: cost and time
Compliance, loss to follow up
Other

Investment in one health care component may decrease cost in another, and may reduce overall cost
There are many different types of quality-driven value

• Value due to improved clinical outcome (success rate of treatment, reduced length of treatment)
• Value arising from innovative, external feature of a product (e.g. packaging or formulations) resulting in better patients outcomes through e.g., improved compliance
• Regulatory value (a prequalified product, eligible for collaborative procedure) helps ensure patient receive (the value of) quality-assured products
Value should be viewed in in a broad environment with many stakeholders, but with the patient in the centre…

The core principle of value-based health care is to align health care system stakeholders towards value delivered to patients.

Mostly today… *Separate functions*

Moving towards… *Considering the patient*

Future… *Integrated patient-centric*

A cost-efficient health care system needs to reduce waste and align all stakeholders involved in the delivery of health care.
The value of generic medicines is valued

• Generics have increased access:
  o 17 million people were accessing life-saving antiretroviral medicines at the end of 2015; AIDS-related deaths reduced from 1.5 million in 2010 to 1.1 million in 2015
  o 217 million life-saving antimalarial treatments procured in 2016 through Global Fund’s pooled procurement mechanism; 90% of the medicines concerned = WHO-prequalified
• And can continue to increase access:
  o “Competitive large-scale generic manufacture could allow supplies of treatment for 5-10 times more MDR-TB cases within current procurement budgets”\(^1\)
  o hepatitis C: \(^1\)st generic sofosbuvir API & \(^1\)st generic sofosbuvir FPP PQed in 2017; 3-month treatment / US$ 260; market entry price of sofosbuvir FPP in late 2013 = US$ 84,000 / 3 months’ treatment
• Prequalified generics are trusted

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The value of generic medicines is valued…but insufficiently

• “Value” still often defined as “fewer $ spent” in single silos, not as value across stakeholders and silos
• Highest value often considered to be the lower (than innovator) price
• Contributing to a race to the bottom, i.e. lowest (price)
• Manufacturers may pull out, market becomes unstable and “unhealthy”
What are the options for generic medicines manufacturers?

• Provide the lowest priced commodity

Or

• Demonstrate you are the best value alternative — the key word being value
Quantifying value means taking a broad view of the health care environment & stakeholders
What is impact or value analysis

- Diseases
- Medicines, formulations, etc.
- Clinical practice
- Healthcare structure
- Payers, donors, procurers

How will current practice change with the new medicine?

Data sources

Communicate:
- Publish
- Present
- White papers...

Impact on:
- Patient outcomes
- Cost
- Budgets
- Overall outcomes per invested $$

Difference in Impact
Current practice
New practice
What are the benefits of value or impact analyses? How can generic medicines manufacturers use it?

- Help enable value-based pricing
- Help understand the clinical practice and market dynamics
  - Current clinical practice
  - How practice will change
  - New product impact on the market
- Quantify the value of quality or innovation
- Determine value to key stakeholders
- Guide marketing strategies
- Quantify the budget impact for key stakeholders
- Publish and communicate the value of products
Economic and clinical value: treating TB in sub-Saharan Africa

- Hospitalization usually makes up the highest portion of total disease cost
- A range of direct medical cost and indirect cost may also be impacted by various interventions
- Interventions with potential highest impact on overall cost are medication (12% of total cost in this example) and diagnostics (5%)
  - Potential reduction in hospitalization cost, cost of caregiver and lost income

Economic and clinical value: treating TB in sub-Saharan Africa (2)

- By adding an additional medicine to background regimen for treating of MDR TB, the cost of drug treatment and monitoring more than doubled, but hospitalization cost was reduced by one-third
- Overall cost reduction = 10%
- Should the benefit of overall cost reduction from the new medicine benefit both payers and manufacturers?

The value(s) of local production

- Shorter lead times
- Accessibility to markets
- No import regulations to navigate
- Reduced storage capacity (warehouses) when not import dependent
- Employment creation
- (Greater) national self-sufficiency in medicines

But…we must remember to keep patient / healthcare "value" separate from "industrial value". One may create more jobs from local manufacturing but it may be less expensive to buy medicines from manufacturers in another country. If so, the risk would be that resources are being taken away from patient care to subsidize industry. The benefits of local production should be balanced by the cost difference between locally-produced and imported medicines, as lower-cost imported medicines could benefit more patients.
The added value of a prequalified product

• Less national regulatory time required for assessment
  ▪ saves regulatory resources
• Under collaborative registration:
  ▪ gets to patients more quickly: especially important for new products
What skills are needed to carry out value and impact analysis? Who can do it? An integrated team.
**Impact & value analysis: when?**

*The analysis should be a continuous and iterative process…*

| Before product development (e.g. new formulation) – simple model | Understand value / impact of the new product features for key stakeholders and an approximate value-based price |
| Late stage of product development, refine models and communicate with key stakeholders | Quantified value should help value-based pricing |
| Post-launch (modelling and / or outcomes studies) | Continuous evaluation of real-life impact for refinements of product profiles, pricing support and new generations |

*Quantified value needs to be believable and communicated well*  

*Payers or procurers need to listen and understand the value, and ultimately be willing to pay for value*
Impact and value of quality-assured medicines: Key take home messages

• Quality-assured generic medicines have facilitated access and increase coverage – thus contributing to Universal Health Care
• The value of quality-assured generic products should be seen beyond reduction in product price – but includes:
  • increased access and coverage
  • reduction of cost of non-compliance & cost of deviations, recalls, patient harm, loss of reputation to manufacturer & healthcare system
  • increase in confidence in health system and health system efficiency
  • reduction in financial waste, morbidity, drug resistance
  • increase life years, quality of life, ability to work or care for the family
• The core principle of value-based health care is to align health care system stakeholders towards value delivered to patients
• We need better models to measure value across the health care system – this requires integrating different skills.