Medical Device Innovation – South Africa as a Case Study

MLADEN POLUTA¹ & TONY BUNN²

¹ Universities of Cape Town & Pretoria
² South African Medical Research Council
In the year 2000, more than 533 thousand women died due to pregnancy-related causes. The map shows that most of these maternal deaths were in Southern Asian and African territories. The fewest maternal deaths were in Western Europe and Japan.

The highest rate of maternal deaths was in Sierra Leone, where 2 mothers die per 100 births. At the other extreme, Malta and Iceland reported no maternal deaths in 2000. The world average is 401 maternal deaths for every 100,000 births.

Territory size shows the proportion of deaths of women worldwide while pregnant or within 6 weeks of pregnancy and partly due to it, that occur there.

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“I was worried during my pregnancy. It is a very stressful time and there are not many resources here. I could not have afforded hospital if something bad had happened.”

Jariatu Sesay, undated
HIV, or Human Immunodeficiency Virus Infection, attacks the immune system. It eventually causes AIDS, which stands for Acquired Immune Deficiency Syndrome. With cases first recognised in the United States in 1981, AIDS increases the risk of many infections and tumours.

In 2003, the highest HIV prevalence was Swaziland, where 38%, or almost 4 in every 10 people aged 15 to 49 years, were HIV positive. All ten territories with the highest prevalence of HIV are in Central and Southeastern Africa.

Transmission of HIV is through sex, using infected needles and in the womb. Infected children are not shown here. HIV/AIDS often has an acquired social stigma.

 Territory size shows the proportion of all people aged 15-49 with HIV (Human Immunodeficiency Virus) worldwide, living there.

“I have come to the conclusion that HIV/AIDS is not entirely about death. People die and will continue to die for one reason or the other. AIDS is also about the living.”

Kiiza Ngorzi, 2004
Public Health Spending

Public health spending is all government spending on health care, plus money from grants, social insurance and non-governmental organisations. Public health spending reduces, or even eliminates, the direct cost of health care to an individual.

The highest public health care spending per person is in the regions of Western Europe, North America and Japan. Luxembourg, Norway and Iceland are the territories with the highest per person spending. As this map of spending is adjusted for purchasing power parity, the size of a territory compares more directly what can actually be funded by this spending. However costs will still vary.

 Territory size shows the proportion of worldwide spending on public health services that is spent there. This spending is measured in purchasing power parity.

“...I brought my little girl to the health center in my district in the south of Bujumbura. But the nurse wouldn’t see us as I didn’t have any money to pay for the consultation.”

Simeon, 2004

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Health Worker Shortages
>90% Fail in the First 5 years

95% of all medical equipment in resource-limited settings are donated

Health Technology Assessment – Methodologies for Developing Countries
Panerai & Mohr (PAHO, 1989)
• 2001: In value terms ~90% MD consumed in RSA are imported and MD represents ~5% of all SA imports.
• Approx. 600-700 MD companies in SA, approximately 80% of which are SA owned.
  – highly fragmented, competitive and unstable
  – high turnover of companies, with 50-70 firms p.a. entering or abandoning market
  – 75% employ <50 people
  – 30-50 firms have annual revenues >R20M
• Approx. 40% MD consumed are consumables
• 2001: MD exports were 0.14% of all exports

(C Landsberg – MDI Summit 2008)
Figure 7: Some of the challenges faced by medical device players
Why and when are funds necessary?

What are investors funding?
- Risk-reward ratio change along the way

Technology risk

Market risk
Figure 4: Stakeholder map – medical device industry RSA

Medical Devices Centre of Competence - Business Plan for Start-up Phase
MDI SIG & Cape Biotech Trust 2008
Figure 5: Stakeholder matrix indicating each stakeholder’s level of influence over MD innovation activity and its interest in such activity.
<table>
<thead>
<tr>
<th>CAPABILITY</th>
<th>RATING</th>
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<tbody>
<tr>
<td>Applied/translational research (i.e. market-led)</td>
<td></td>
</tr>
<tr>
<td>Needs- and market assessment (dedicated units)</td>
<td></td>
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<tr>
<td>Systems engineering</td>
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<tr>
<td>Engineering</td>
<td></td>
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<tr>
<td>Legal: IPR; licensing; agreements</td>
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<tr>
<td>Regulatory/Quality Management Systems</td>
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<tr>
<td>Clinical trials/evaluation</td>
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<tr>
<td>Production/manufacturing: Electronic assembly; Injection moulding</td>
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<tr>
<td>Production/manufacturing: Injection moulding (clean room)</td>
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<tr>
<td>Production/manufacturing: Tool making</td>
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<tr>
<td>Business skills (medical device context) / Entrepreneurial skills</td>
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<tr>
<td>Specialist/innovation Skills: Tech Transfer</td>
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<td>Specialist/innovation Skills: Project management</td>
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<td>Funding</td>
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Table 2: RSA Medical device innovation capabilities mapping
SA 2007 Biotech audit data
Barriers/problems: Biotech commercialisation in RSA

Rating

- Time required for regulatory approval
- Access to Capital
- Cost of regulatory approval
- Access to International markets
- Size of Domestic market
- Access to human resources
- Limited international harmonization
- Distribution & marketing channels
- Information about markets
- Access to technology/information
- Public perception/acceptance
- Lack of protection for intellectual property
- Patent rights held by others

Rating scale from 0 to 4.5
... some of the dots ...

- MD Centre of Excellence ⇒ MD2M (Medical Devices 2 Market)
- National MD Innovation Platform (MRC/Universities)
- Technology Innovation Agency (DST)
- SHIP
  - MRC-PATH Collaborative Agreement
  - Medtronic Global Innovation Fellowship Programme (Oct/Nov 2013): Developing an ecosystem to support the local medical device & diagnostics industry in South Africa - A landscape analysis
**Recommendation 1:** Obtain alignment of government departments on core areas of strategic health care device and technology focus

Step 1: Department of Health
- Translate strategic direction into a list of focus diseases
- Identify MDD which pertain to the focus diseases

Step 2: Department of Trade and Industry
- Analyze import and export data to identify specific MDD
- Analyze the list of MDD and assign priority

Step 3:
- Compare the outputs of steps 1 & 2 above to identify areas of overlap

Step 4: Department of Economic Development
- Estimate local employment creation potential of each opportunity and prioritize the list developed in step 3.

Step 5: Department of Science & Technology
- Target research and product development investments towards areas of focus listed in step...
Recommendation 2: Hold a medical device development stakeholder summit
Recommendation 3: Ensure that the strategy remains stable over long-term with strong leadership and oversight

Recommendation 4: Effectively communicate the aligned strategy and available financial supports

Recommendation 5: Use the health care and device strategy to provide focus along the innovation pipeline

Recommendation 6: Incentives should be modified to drive research through to the marketplace and maximize its commercial protection

Recommendation 7: Establish partnerships across the medical device development industry

Recommendation 8: Capitalize on South Africa as a gateway to Africa and consider novel partnership models
• Coming up:
  ○ Medical Device Local Manufacturers Workshop with key stakeholders, hosted by SAMED: 4 December 2013

• Contact:
  ○ mladen.poluta@uct.ac.za
  ○ tony.bunn@merc.ac.za