Evidence on Access to Essential Medicines for the treatment of HIV/AIDS

October 5th, 2011
Project overview

• IFPMA asked CRA to develop evidence on the improvement in access to anti-retroviral medicines (ARVs) over the last 10 years and the degree to which this can be attributed to different policy instruments

• The project involved a number of key steps:
  – Conducted a review drawing on publicly available data and the existing literature
  – Undertook interviews with a range of stakeholders including government representatives, international donors, procurement agencies, NGO and industry
  – Evaluated the extent to which the increase in access can be attributed to different mechanisms
    • By investigating seven case-study countries (Brazil, Botswana, India, Mexico, Rwanda, South Africa, Thailand)
    • By performing a statistical analysis to identify the determinants of access and prices of ARV
  – Produced a report presenting the empirical evidence produced and interpreting the implications of the analysis
Innovation has increased treatment options

- There has been a continuous stream of innovative ARV medicines being launched over the last two decades.
  - Increased tolerability, reduced side-effects, simplified dosages
  - Expanded the number of alternative treatments available when resistance to first-line treatment develops
  - WHO recommended combinations of ARV drugs to be used as first- and second-line treatments have changed three times

Launch of new ARV drugs over time, by class

Source: CRA
Overall improvement in access to ART in low and middle income countries over the last ten years

- There has been a dramatic improvement in access to ART during the last decade

- The number of patients treated with ARVs has increased more than ten-fold in ten years

- The increase has been even larger in sub-Saharan Africa, which concentrates more than three quarters of all patients being treated

Source: WHO
Weaker data exists on other dimensions of access but progress still observed

• ART coverage rates are the best measure of access available:
  – Well defined
  – Available for a wide range of countries
  – Easily comparable across countries

• However, there are relevant dimensions of access which ART coverage rates do not include:
  – Early initiation of treatment (CD4 cell count at initiation)
  – Access to the most appropriate ARV combination for the condition of each patient, including second line treatments
  – Retention of patients on ART after initiation

• Scarcity of data on complementary dimensions of access to ARV, but all available data suggests that these dimensions have also improved together with ART coverage rates

Source: WHO
A range of interventions are commonly suggested as important in improving access

- Political will
- Domestic health systems
- International funding and aid
- Innovative industry initiatives
- Generic supply
- The use of compulsory licensing and paragraph 6
A look at case-study countries to identify the factors that might explain the observed improvement in access to ART

- We have investigated the experience of seven case-study countries: Botswana, Brazil, India, Mexico, Rwanda, South Africa and Thailand

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**Incidence and prevalence rates in 2009**

- **Botswana**: Incidence 1.56%, Prevalence 17.90%
- **Brazil**: Incidence 0.45%, Prevalence 0.04%
- **India**: Incidence 0.30%, Prevalence 0.30%
- **Mexico**: Incidence 0.30%, Prevalence 0.02%
- **Rwanda**: Incidence 1.49%, Prevalence 2.90%
- **South Africa**: Incidence 1.30%, Prevalence 24.00%
- **Thailand**: Incidence 0.03%, Prevalence 0.03%

**ART coverage rates in 2004 and 2009**

- **Botswana**: 2004 - 0%, 2009 - 80%
- **Brazil**: 2004 - 0%, 2009 - 80%
- **India**: 2004 - 0%, 2009 - 80%
- **Mexico**: 2004 - 30%, 2009 - 60%
- **Rwanda**: 2004 - 0%, 2009 - 80%
- **South Africa**: 2004 - 10%, 2009 - 70%
- **Thailand**: 2004 - 0%, 2009 - 80%

Source: UNAIDS and WHO
An analysis of the relation between improvement in access to ART and local factors in the case study countries

Rwanda: an example of the descriptive analysis conducted on regulatory change and market performance

- 2002-2006 Strategic Plan attempts to align Rwanda with the MAP Program (2001)
- Government, in partnership with the William J. Clinton Foundation, rolled out the HIV/AIDS Treatment and Care Plan 2003-2007 to provide access to ARVs (2003)
- First national procurement tender process run by CAMERWA (2004)
- Rwanda receives shipment of Apo Trivar from Apotex in Canada under compulsory licensing arrangement (2008)

Source: CRA
Identification of the main factors that have played a role in determining access in each of the case-study countries

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<tr>
<th>Factor</th>
<th>Rwanda</th>
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<th>Thailand</th>
<th>Brazil</th>
<th>Botswana</th>
<th>Mexico</th>
<th>South Africa</th>
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<td>Political will</td>
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<td>Overcoming stigma</td>
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<td>Negotiation and procurement</td>
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<td>Generic manufacturers</td>
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<td>Compulsory licensing</td>
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<td>Partnerships</td>
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*** represent a significant factor in raising access to the current level, * represent a minor factor in raising access to the current level

Source: CRA
Lessons about the interventions that have contributed to increase access to ART in the case-study countries

• The date when the universal ARV programmes were initiated is clearly important.

• The speed at which it has been possible to improve access depends on development in the domestic health infrastructure and associated programmes to address stigma

• The substantial increase in resources from the international community has contributed to change the trajectory of the HIV/AIDS epidemic in the poorest countries

• The innovative industry has contributed to the affordability of ARVs through differential pricing and voluntary licensing

• Generic manufacturers have been important in nearly all of the case studies increasing competition and contributing to lower prices

• The use of compulsory licensing or provision of generics through using paragraph 6 have not directly played a significant part in improving access.
Statistical analysis to disentangle the contribution of different factors to increase access to ART

• We have used statistical analysis to try to identify the separate impact of different factors and to quantify their relative importance.

• Two types of analysis focusing on:
  – The factors determining access to ART
  – The factors determining the price of common ARV drugs
Results from the statistical analysis on determinants of access to ART and prices of ARV medicines

• The analysis of the factors determining access to ART show that this increases depending on a number of factors. In particular, the level of access is positively correlated with:
  – per capita income in the country;
  – the inequality in the distribution of income within the country;
  – the prevalence rate;
  – the country being outside of the sub-Saharan African region;
  – the time since large-scale ART programmes were started;
  – the expenditure on prevention, treatment and management of HIV in total;
  – the weight of foreign aid in HIV programs;
  – the lower cost of ARV treatment.

• We found that the average price of the ARV drugs is lower:
  – the lower is the per capita income in the country;
  – when the country is in the sub-Saharan African region;
  – the more generics are in the market;
  – the more recent is the observation
Conclusions

• There has been substantial progress in providing access to HIV patients over the last ten years

• This is due to many different factors working together in often complex ways:
  – Political commitment to HIV/AIDS has played a significant role
  – International funding is a key part of increased access for the lowest income countries
  – Holistic programs are needed allowing the different components to reinforce each other
  – The generic industry and the innovator industry contribute in different ways to addressing the epidemic, and both contributions are needed
  – Innovating companies should compete to develop new medicines and where appropriate collaborate to make sure there is access to their medicines
  – Existing IP mean that prices in middle income countries are likely to be higher than in low income countries, as generics are not able to compete there. This is compatible with the idea that contribution to innovation should be correlated with ability to pay

• Many other challenges clearly remain, there is a large under-served population, there are types of patient that are still particularly badly served

• A major source of uncertainty which hangs over all future policy formulation is the speed at which mutations will create resistant strains of HIV. Continued innovation is key to address these concerns