Tracing Pharmaceuticals in South Asia: Key findings and implications for policy

April 2009

About the Project

Tracing pharmaceuticals in South Asia: regulation, distribution and consumption was an ESRC/DFID-funded research project carried out by researchers in Nepal at Martin Chautari, and in India at the Centre for Health and Social Justice, in collaboration with the University of Edinburgh, UK.

The main aim of the research was to provide governments and others with a better understanding of the contexts and causes of inappropriate pharmaceutical use in South Asia; information which will ultimately assist in the development of effective interventions to improve health outcomes and help countries in their efforts to reach Millennium Development Goals (MDGs). The research integrated diverse methodologies and approaches into the investigation and analysis of factors that determine how three pharmaceuticals—**oxytocin**, **rifampicin**, and **fluoxetine**—reach their end users.

Together, the analysis of these three drugs provides a number of key insights into the forces that affect pharmaceutical consumption in developing countries:

- They have emerged in previous research as having significant relationships to poverty;
- They play important roles in key health areas, and have broad implications for the achievement of the MDGs:
    - Inappropriate oxytocin can increase health problems for mothers and new-born children;
    - rifampicin misuse can lead to multi-drug resistance in TB; and
    - fluoxetine is potentially used to mask more serious problems
- They offer diverse insights into the production, distribution and prescription of drugs in developing economies;
- They are out of patent, in common with most of the medicines consumed by the poor.

Key policy issues and questions

In drug regulation, production, and supply:

The commercial promotion and marketing of drugs, and their easy availability over-the-counter at pharmacies, has significant implications for the use and misuse of drugs in Nepal, but this tends to be rendered invisible in most discussion around treatment programmes and access to medicines.

The drug distribution system in Nepal is highly complex, and allows for the movement of drugs between different channels at several points along the supply chain. Any intervention in the rational promotion of essential drugs should take into account an understanding of the local drug market, as well as the upstream forces that encourage the promotion of particular brands.

A key issue in both prescription and consumption of drugs is the 'trust' in brands and companies. It is important to understand how this trust is manufactured and its impacts on government services and distribution chains. Doctors often prescribe brands they trust (rather than generic versions) for reasons that may have little to do with the intrinsic quality of drugs available in the system.

There have been recent moves to apply Good Manufacturing Practice (GMP) standards to the regulation of drugs produced within South Asia. As currently practised, however, these regulations endanger local drug production, yet the degree to which this brings clear benefit in terms of improved safety or quality is unclear. GMP certificates show that a company can make products properly and consistently, not that the drugs produced do what they claim. Those who do not upgrade to GMP standards may eventually be driven out of the market entirely, while those who do upgrade must charge higher prices to offset their investment in new facilities. The reduced competition and rise in prices may have serious consequences for access to medicines.

The gaps between current international standards, local regulatory rules, and actual everyday practice are often huge: rather than act to reduce these gaps, the varied interests (producers, distributors, regulators and politicians) tend to blame each other for the shortcomings.

Improved regulatory capacity is essential for the safe and effective production and supply of locally produced drugs. How should donor agencies act? Can increased bilateral and other types of funding really promote capacity-building in regulatory agencies like the DDA?

In relation to the specific drugs considered in this research:

In reproductive health:

Major policy initiatives directed at Safe Motherhood often include recommendations for the use of oxytocin in the third stage of labour. However, these initiatives take little account of the widespread availability and use of oxytocin during childbirth that does not follow clinical guidelines.

Though there has been some decline in the maternal mortality ratios in South Asia, this seems to have plateaued. Declines in child and infant mortality are mostly due to declines in post-neonatal mortality, while neonatal mortality has scarcely shifted. These data imply that birthing conditions in South Asia are still seriously problematic, and our findings indicate that the misuse of oxytocin may be an important element in this situation.

There appear to be problems with oxytocin use in both institutional and informal settings, though systematic data is still lacking. The advocacy of institutional delivery remains unrealistic, as there is insufficient capacity to cope with increased demand, and timely physical access to an institution is not feasible in many rural areas. Attention must still be given to improved home delivery.

In mental health:

Though Global Burden of Disease estimates for depression are often cited to support further research and various initiatives in mental health, there is a significant lack of good epidemiological evidence for the burden of depression in developing countries; a situation which can lead to a diversion of resources away from the real health needs of these countries.

The WHO mental health strategy draws on epidemiological studies that are up to 25 years old and which do not consider the immense changes in the recognition and treatment of depression that have taken place since the late 1980s. Its exclusive focus on licensed prescribers, and its failure to notice how widely antidepressants are used in South Asia's private health markets render claims about the treatment gap invalid. An effective mental health strategy must properly take into account the cultural, economic, and historical changes in the diagnosis and treatment of depression.

Hundreds of generic brands of antidepressants, including fluoxetine, are on sale in India, and their easy over-the-counter availability allow "floating prescriptions," which carry knowledge about antidepressants from psychiatrists to GPs and further to untrained prescribers. Non-specialist prescribers are using antidepressants far more frequently than is assumed.

Clinical studies have shown the importance of behavioural therapy in addition to drug treatment. However, patients typically cannot afford behavioural therapy, thus the expansion of mental health services is limited to pushing drugs.

In TB control:

Policies regarding drug combinations for TB control, and the insistence on direct observation of patients taking these drugs, need to take much more account of practitioner perspectives and local practices – many of which undermine these programmes.

Evaluating the effectiveness of treatment programs such as DOTs could include regular evaluation of drug sales from sentinel sites, incorporating a range of access points (pharmacies located near DOTs clinics, for example).

Drug companies themselves should do more to encourage the promotion of DOTS from public clinics, rather than pushing their own combination therapies. The major suppliers to DOTS programmes through the GDF will benefit if DOTS drug consumption increases: there is scope for Medical Representatives to be harnessed to promote DOTS rather than private consumption.