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Access to Medicines

Reorienting the research agenda

Von Mary Ann D. Lansang

While just and fair economic and social policies are critical for improved drug access, much more needs to be done. Health research must contribute to solutions to the multifactorial and multidimensional problem of drug (in)access. We will first discuss the broad goals of health research as a tool for equity in health and health care. We will then outline some important areas of research in relation to access to medicines, based on the expanded mandate for health research. We will end by suggesting some critical steps for moving forward on the health research agenda of access to medicines.

"It is a crime against humanity for poor people to die because lifesaving medicines are too expensive." This was part of a strong statement issued by the Ministers of Health of South Africa and Belgium, just before last year's World Trade summit in Doha, Qatar. There are many examples of such crimes, where sterling products of research are rendered ineffective because of poor access for the people most in need. There are now around 25 million people with HIV/AIDS in Africa, and yet it is estimated that only 1 in 1,000 receives antiretroviral treatment. There are very efficacious antiretroviral drugs to prevent pediatric HIV infection at birth, but there is no end in sight for many poor countries because public health care programs for mothers cannot afford nor sustain what research evidence has proclaimed as "best practice".

Some of the most elegant clinical and field trials on the effectiveness of hepatitis B vaccine were done in African countries. Yet as of December 2000, of the 130 countries with hepatitis B vaccine incorporated into their Expanded Program of Immunization, few are found in the continent of Africa.

Multi-drug resistant tuberculosis is a growing concern, raising the specter of an unaffordable super-cocktail in place of the old multi-drug regimen – already beyond the reach of many poor HIV/TB patients.

A new antimalarial drug, malarone, has been launched for prophylaxis and treatment especially in areas with chloroquine-resistant malaria, but it is unaffordable for most of malaria endemic countries in Africa.

On the other hand, the same pharmaceutical giant that produces malarone, has forged an agreement with the World Health Organization to develop a more affordable antimalarial drug combination, LAPDAP. Novartis has also agreed to reduce the price of its new combination drug, Coartem, to only $1 - $2 for a full treatment in Africa, as against $40 - $50 in developed countries.

However, price reductions do not provide the full answer to the problem of drug (in)access. When the Philippine government arranged for the parallel shipment of PhP 20 million (US$400,000) worth of off-patent branded drugs from India, initial surveys showed poor sales and utilization of these lower-priced drugs for common illnesses. In addition, concessions to patent laws, although a major breakthrough for developing nations, do not necessarily translate to better drug access. A recent study by Attaran and Gillespie-White (2001) showed that a median of only 3 out of 53 African countries surveyed had patents for antiretroviral drugs, indicating that patent coverage, by itself, was not the major impediment to AIDS treatment in Africa.

Stretch Goals for Health Research

The Organisation for Economic Co-operation and Development OECD and the United Nations Educational, Scientific and Cultural Organization UNESCO have defined research and health research as "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society; and the use of this knowledge to devise new applications."

Although this concept of health research encompasses the full spectrum of knowledge and its management, it serves to reinforce the traditional view of research as a producer of knowledge, new products and technology.

For health research to effectively contribute to equity in health in the world, health research, in addition to generating knowledge for "proof of principle", must extend to becoming a global public good, particularly for those in the developing countries where 90% of the global burden of illness is found. "Stretching" the goals of health research also means:

- active involvement of stakeholders in the planning and implementation of research and its application;
- sharing and communication of research results and best practice;
- translation of research findings to policy and practice, where appropriate;
- study, monitoring and evaluation of the health systems where new knowledge, products and tools are to be applied;
- and finally, evaluating the impact of health research.

Access to Medicines

In this broad paradigm of health research, improving access to medicines becomes a priority research area for many "E" reasons: equity, the epidemiology of the diseases of the poor, the economics (or efficiency) of health care interventions for the poor, and the ethics of post-research availability of effective drugs and tools.

The Global Forum for Health Research, whose primary mission is to "help correct the 10/90 gap" has helped to draw attention to the development of affordable drugs for the neglected diseases by facilitating the establishment of a number of product development public-private partnerships (PPP) and drawing new finances for these. To name a few:

International AIDS Vaccine Initiative (IAVI) – aimed to discover and develop vaccines against HIV for use throughout the world. This is a multi-partner effort involving various foundations, AIDS organizations, research institutes, and supported by World Bank, UNAIDS, bilateral agencies, philanthropic foundations, and pharmaceutical companies.

Medicines for Malaria Venture (MMV) – aimed to discover and develop new antimalarial drugs for use in developing countries. Some partners involved are: WHO, the International Federation of Pharmaceutical Manufacturers Association (IFPMA), Bayer, GlaxoSmithKline, and Roche.

Global Alliance for TB Drug Development (GATB) – aimed to discover and develop cost-effective anti-TB drugs. Involves WHO, industry partners and additional infusion of funds from large philanthropic foundations.

There have also been other forms of public-private partnerships focusing on systems issues or product donations, for example, the Global Alliance for Vaccines and Immunization GAVI, Roll Back Malaria, the Stop TB Initiative, the Global Program to Eliminate Filariasis, the Malarone Donation Program, the Accelerating Access Initiative for HIV/AIDS, Secure the Future, the Diflucan Partnership Program, etc., but less focused on research and development.

All these efforts, while laudable, need to be expanded. Between 1975 to 1996, nearly 1,240 new drugs were licensed in the United States, and only 13 were for diseases of the poor and tropical countries (Garrett, 2000) – still another indication of the 10/90 gap in health care, or more accurately, the 1/99 gap in drugs for the poor. These product development PPPs also need to grow and evolve as mutually beneficial collaborations and partnerships in the face of issues like differences in values, potential conflict of interest, governance, and what has been called "cherry-picking" of countries and products.

Collaboration with the potential users

Perhaps more importantly, there must be collaboration with the potential users of these new drugs from the very beginning. This reorientation involves a shift from a linear relationship with the potential beneficiaries and users, to a relationship where the users are central or the most

critical pathways to research decision-making.

In practical terms, the research agenda for drug access would include:

- involving the developing countries and their stakeholders in setting researchpriorities, including their expressed needs and demands;
- carrying out basic behavioral and other social science research related to potential health interventions (Why, for example, there was low utilization of the parallel drug imports in the Philippines despite the lower prices);
- working with the communities and decision-makers at the onset of the clinical trial phase of research and development efforts on such matters as policy implications and "buy-in", drug access issues such as post-trial availability and pricing, or even redirecting the research and development effort;
- working with policymakers in selecting health interventions, drawing up essential drugs lists, and crafting policies and programs using the best evidence;
- working with decision-makers and control program managers on health systems research issues involving financing, supply and procurement, quality control, and equitable distribution;
- working with health care practitioners and providers on improving rational use of drugs and monitoring adherence to recommendations;
- educating the patients and public on rational use of drugs and monitoring of compliance/adherence.

Strategies

Lastly, three critical strategies are needed for success in reorienting the research agenda to include the priority issue of access to medicines:

First, successfully reorienting the research agenda requires an absolute increase in research financing, both for global and country-based research devoted to this issue. One very recent and exciting research consortium is now being established, the European Clinical Trials Platform for Povery-Related Diseases, which promises to bring on at least 200 ECUs as well as other resources into drug research and development for HIV/AIDS, malaria and TB. Other such new initiatives, coordinated through an organized forum for drug research and development, will continue to be needed and accelerated. The proposed G-8 global health fund should have a healthy allocation for research on the prevention and treatment of the great neglected diseases. And such a fresh infusion will need a rational and just mechanism for research agenda setting and implementation, with the developing countries and their research capacities as the prime focus.

Second, the effort needs building of strong research coalitions to improve drug access. Product-based public-partnerships must continue to be strengthened and expanded. But they should not be allowed to dominate the research agenda and financing to the exclusion of research needed on the ground. WHO has led the research effort in drug access and rational

use of drugs. Other networks like INRUD (International Network for Rational Use of Drugs) and the INCLEN Trust (International Network for Clinical Epidemiology) can join forces with WHO, national health systems and the pharmaceutical industry in formulating and implementing a strong and coordinated research agenda for improving drug access.

Third - the most critical and most challenging – is to build and strengthen the capacity of developing nations for research and development. Without indigenous scientific and technological capacity for innovative health research, few efforts in improving drug access -- and improving health care in general -- can be sustained by developing countries. This is a major investment that few funding agencies and national governments have been prepared to commit for the long haul, much less, to plan systematically and strategically. WHO and the Council on Health Research for Development should step up their efforts to support countries in building and strengthening their national health research systems. Without this, begging bowls and benevolent benefactors will be the paltry and unsustainable answer to the 10/90 gap in drug access and health care for the poor.

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