# research snapshot

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# Research and Development of Drugs for Developing Countries Faces Many Barriers

## What is this research about?

Research and development (R&D) of new medicines is driven by the market – for the most part, large numbers of people with chronic diseases who live in first world countries. Drug companies are willing to invest in R&D because they can make a substantial profit from this pool of potential patients. The market-driven model for R&D, however, has failed when it comes to dealing with neglected diseases in developing countries (Type III diseases). Drug companies devote very little of their resources to creating medicines for these diseases. And when drugs are created, they tend to be of low value because they don't address the specific conditions in these countries. A drug may need to be administered in a hospital setting to which people don't have access. Or it may simply be unaffordable.

The problem is not just that companies aren't focusing on neglected diseases. Developing countries also share many diseases with first world countries. Type I diseases, like diabetes, afflict large numbers of vulnerable people in both developing and developed countries, while Type II diseases tend to afflict a greater proportion of people in developing countries. But there is little market incentive to invest in medicines that are tailored to the specific resources, conditions, and needs of people in the developing world.

### What you need to know:

R&D for neglected diseases faces a number of barriers. In order to expand R&D, all of the actors – governments, companies, and NGOs, among others – need to work together on solutions. The limitations of the prize fund model and PPPs need to be addressed.

## What did the researcher do?

Joel Lexchin, a Professor at York University, looked at the systematic barriers that impede research into diseases that afflict developing countries. He also considered the strengths and weaknesses of three specific proposals aimed at increasing R&D for these diseases.

## What did the researcher find?

There are five barriers to expanding research capacity for health problems facing the developing world: Priority Setting; Coordination of Research Efforts; Intellectual Property Rights and Publicly Funded Research; Intellectual Property Rights and Patent Thickets; and Clinical Trial Capacity. Donors who give money to fight particular diseases often set the priorities for research. But donor funding does not always address the actual needs of particular countries. Health care workers, on the ground in developing countries, need to be involved. So, too, do the people who will be on the receiving end of

any new research initiatives. In general, research efforts in and between donor countries often lack coordination. Governments do not necessarily know where they are allocating their research dollars. This can result in redundant work, gaps in policy, and a general lack of coherence. Universities often have exclusive rights to drugs they develop with public money. As a result, they tend to restrict access to the results of their research in the hopes of making money through licensing their patents to large drug companies. The rapid increase in patents – resulting in "patent thickets" – can inhibit research. Valuable biomedical knowledge may be left unused because multiple patent owners can exclude one another from access to the knowledge. Clinical trials, which test the effectiveness and safety of new drugs, should be carried out in the developing countries that need the drugs. But developing countries tend to lack the capacity for clinical trials.

It has been suggested that a prize fund be set up to pay those who develop drugs for neglected diseases. But it is hard to assess the therapeutic benefits of medicines in a timely, independent, and valid way. (Most clinical trials of drugs are done by the companies that produce them.) Clinical trial registries might help by making data more available to the public. Drug companies could also be required to hand over money for clinical trials to a neutral organization. It has also been suggested that a voucher system might help reduce barriers to research. Companies that work on neglected diseases could be given a "voucher" entitling them to a priority review for another product. But the voucher system is not without problems and should probably be abandoned. It is more a model of corporate welfare than a system for dealing with the needs of developing countries. Ultimately, public-private partnerships (PPPs) may be the most promising route for increasing R&D for neglected diseases. PPPs don't conduct drug development themselves. But they do integrate and coordinate different industry and academic partners. That said, PPPs tend to have a narrow funding base.

## How can you use this research?

This research may prove especially useful to policymakers, non-governmental organizations (NGOs), researchers, and health care workers who want to lower the barriers to research on neglected diseases.

## About the Researcher

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## Keywords

Developing world, Research capacity, Pharmaceutical company, Patent thicket, Public-private partnership (PPP), Social determinants of health

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