

The World Bank is finally embracing science

The World Bank has been criticised ever since its creation in 1944. Liberals and conservatives alike have charged the Bank with many sins: from being an unmanageable inefficient bureaucracy with a bloated staff of more than 10 000, to having a mission that is ideologically confused. One of the commonest complaints is that billions of dollars are thrown at aid projects with little if any evidence of efficacy. To counteract these charges the Bank has invested heavily in public relations, but it has so far avoided asking the question: does its approach really work?

The Bank's initial focus was on lending money to developing countries for projects aimed at stimulating economic development, often through large-scale infrastructure creation, with the goal of turning resource-poor countries into productive economies. But over the years its scope has expanded to include projects in health care, education, and law. Although these areas are important, their relation to economic growth is not always clear.

A crucial question, which extends beyond the World Bank, is whether aid of any kind is really better than debt forgiveness. So-called structural adjustment programmes are plans that call for repayments of debts that poor countries have accumulated as a result of various trade restrictions, protectionism, and shifting financial policies. The billions that these governments, especially those in Africa, spend yearly on repaying their debts to rich countries might logically be much better spent on AIDS treatments and other health services. The Bank—and the public—should ask first, whether aid works at all, and second, whether aid projects are the best way to improve the lives of people most in need of donor support.

There are recent signs that the Bank is taking long-needed steps to answer the first question, at least in part. This summer it is initiating a series of randomised trials to determine whether its aid projects are doing any good. Whereas "success" at the Bank has sometimes been calculated by the number of loans made, now more rigorous methods should replace that simplistic measuring stick. Impact evaluations being undertaken by the Bank and its collaborators, including the Massachusetts Institute of Technology's Poverty Action Lab, are a novelty for the Bank, where, astonishingly, only 2% of the projects it has funded for

the last few years have been critically appraised. This is an appalling statistic: such evaluations are public goods, and public accountability surely demands them. Without evidence, how can one know whether to modify, delete, or expand an existing programme?

Randomised trials in policy settings have certainly not been as common as they are in medicine. And staff at the Poverty Action Lab rightly point out that, while impact evaluation is in its infancy in international aid projects, there are plenty of domestic policies that have never been tested in randomised trials, not to mention the scarcity of an evidence base for most practices in medicine. In recent years, there has been growing interest within the social-science community in these methods of evaluation. As the Poverty Action Lab's Esther Duflo, a professor of economics at MIT, has written, "Creating a culture in which rigorous randomised evaluations are promoted, encouraged, and financed has the potential to revolutionise social policy during the 21st century, just as randomised trials revolutionised medicine during the 20th".

One such trial is examining the question of whether HIV/AIDS education works in schools in Kenya. Schools have been randomly divided into four groups, in a two-by-two design that will examine, alone and in combination, the influence of training teachers in the government's HIV/AIDS curriculum and of paying for the required school uniforms (which could help students stay in school longer and in turn help them to avoid sexual activity). HIV-infection rates would be the ideal outcome measure, of course, but a shorter-term surrogate in these underage students is pregnancy rates.

Researchers and policy makers will always have to grapple with the generalisability and replicability of the findings: what works in one country in Africa may not work elsewhere. But research like this, in addition to providing hard data about effectiveness, may yield surprises and unexpected connections that can be fed back into new projects. Furthermore, the trials are being constructed so as to provide experimental designs for prospective evaluation, a logical and important next step.

We welcome this long overdue undertaking. However, several important questions remain. For



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example, how independent are the researchers, including those in the World Bank itself? What steps have been taken to ensure an appropriate relation between the Bank and those evaluating its work? Which projects are chosen for evaluation, and what is the rationale for choosing some and not others? How will the data be used in planning future projects? Is there, as there should be, a requirement to build an evaluation component into all future projects?

Most crucially, how will the findings be disseminated? As a start, we strongly urge those involved in these evaluations to establish a mechanism for publishing all of its findings, including those from trials that turn out to be negative—just as we have called for the pharmaceutical industry to disclose the results of all its trials. Only a transparent and open process will serve the needs of the donor communities, the public, and, above all, those who so desperately need our assistance. ■ *The Lancet*

Paediatric research should take centre stage



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Last week, UK Health Minister Lord Warner announced a new initiative to encourage the development of more medicines designed specifically for use in children. “Off-label” use is common in paediatrics, which can mean that drugs have not been tested at all in children or in a particular age group, or are given by an unlicensed route, for an unlicensed indication, or at an unlicensed dose. As Patrina Caldwell and colleagues explain, conducting clinical trials in children is difficult for many reasons and requires specific expertise and extraordinary commitment by all those involved. With drug companies generally uninterested because of low market value and with harsh competition from adult studies for funding by the public or charity sector, research grants for clinical trials in children are very hard to come by. So any special attention to, and encouragement for, paediatric research is very welcome. But what does this new initiative entail?

The government says that “it wants to strongly encourage companies to provide much better paediatric clinical trial data for new and current medicines”. Yet the US Food and Drug Administration’s experience with the “Pediatric Exclusivity” clause and the so-called “Pediatric Rule”, which requires manufacturers to study their products in children, is discouraging. Without legislation, companies will not voluntarily undertake paediatric trials because they are politely encouraged to do so. The carrot of a 6-months’ patent extension

guaranteed by the exclusivity clause has led to some labelling changes but generally in drugs, such as antihypertensives, that are not a priority in paediatric medicine. The “Pediatric Rule” was struck down in a 2002 ruling by the US court for the District of Columbia, which held that the FDA lacked sufficient statutory authority to require paediatric studies. Only the additional legislation of the Pediatric Research Equity Act of 2003, passed by Congress at the end of last year, gave the FDA the necessary authority to demand paediatric studies unless conditions for a full or partial waiver apply and with the exemption of orphan drugs. The development of proposed EU legislation in this area is painfully slow and not expected before 2006.

Another part of the UK Government’s initiative is the investment of part of additional £100 million announced in April, 2004, into a new research network on medicines in children. In addition to medicines in children, research networks will initially cover cancer, mental health, diabetes, stroke, and Alzheimer’s disease. An effective research network for paediatric trials with a wider remit, rather than just for medicines in children, would be an extremely valuable step forward in an area where data are lacking and disease prevention, diagnosis, treatment, and care are all too often based on no more than anecdotal evidence. As presented, this new initiative falls a long way short of what children deserve: centre stage for acquiring research-based evidence. ■ *The Lancet*