THE NATIONAL BUREAU of ASIAN RESEARCH
Center for Health and Aging

IMPACT & INNOVATION SERIES

Immunization Effectiveness in India: The Less Understood Dimensions

Health System Preparedness, Capacity, and Program Errors

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In the field of immunization, the manner in which vaccines are stored, transported, and used in the field can adversely affect immunization effectiveness, resulting even in good vaccines with high levels of efficacy not achieving the desired results. The commonly held notion is that vaccine effectiveness is largely due to cold chain issues, and as such, a lot of money and effort has gone into addressing cold chain elements in the delivery system. However, this has only partly addressed the issue.

Like the proverbial slip between the cup and the lip, vaccine effectiveness in the field can be completely lost even when good cold chain elements are in place. There are several reasons for this loss, and based on my experience so far in this arena, they are critical and truly mar immunization campaigns. These reasons have been identified broadly as "program errors," often resulting from ineffective health delivery systems, which relate to the capacity and preparedness of the health providers in carrying out immunization programs.

> *"Vaccine delivery needs as much attention as the vaccines themselves. The horse should be in front of the cart!"*

In a developing country setting, health delivery is most often carried out by governments or government agencies. It is common knowledge that the government-led health delivery infrastructures in many countries are grossly inadequate. To illustrate, I cite several examples of critical steps that were missing from a recent measles vaccination campaign in India, which led to serious adverse events. Quoting an August 2009 investigative report on this campaign[1]:

- "…cold chain maintenance for the vaccines was by and large found to be satisfactory. However, storage of measles diluents was not proper. They were kept near the window in a polythene bag and were exposed to the light/sunlight throughout the day…"
- "…there was gross mismatch between the number of measles vaccine and measles diluents…"
- "…record keeping of diluents was not found to be in place…even syringe distribution practice was also found to be improper…"
- "… almost no preparedness for the management of serious adverse events following immunization (AEFI) at the immunization session sites."
- "…an urgent need for training of auxiliary nursing midwives (ANMs) and medical officers in routine immunization with special focus on prevention of program errors."

[1] "Report of Investigations by Central Team of Ministry of Health, Government of India, into reported deaths following immunization in Lucknow District, Uttar Pradesh, 22-24 August 2010."

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Pakistan, 2010 - An infant is vaccinated at a newly established clinic in Kyber Pakhtunkhwa province, a region that has suffered considerable insecurity, which has weakened the health system and disrupted national vaccination campaign goals.

In the past two years, there have been at least six such measles vaccine-related AEFI cases in India involving the tragic deaths of four children, all attributed to "program errors." The investigative report posits that the most likely cause of death in these cases resulted from a mix-up between diluent ampoules (ampoules contain drugs such as muscle relaxants) and vaccines. Diluent ampoules are normally stored separately from the vaccines.

Program errors are not limited to measles vaccinations alone. They were also reported around immunization using the Diphtheria, Pertussis, and Tetanus (DPT) vaccine; India's DPT immunization campaign reported 83 AEFI cases in the past two years alone. Note that none of these cases were linked to the quality of the DPT vaccine.

> *"Unless concerted efforts are taken to address these issues, we will continue to have good vaccines developed but poor overall results in immunization coverage and effectiveness…this outcome serves no one."*

Following such adverse reports, mothers are naturally reluctant to bring their children for vaccination, and overall vaccination coverage suffers.

While much effort has gone into building appropriate, quality-controlled cold chain systems that improve vaccine effectiveness, there has not been significant investment in addressing these "program voids." There are several program voids that we can identify from some of the investigations conducted into recent adverse events in India, chiefly:

- Inadequate training of field staff on immunization practices that are appropriate "in the field" (outside traditional hospital and clinic settings), as well as the basic do's and don'ts in vaccination;
- Low levels of motivation among field staff, who are mostly low-paid government employees;
- Overburdened primary health workers who are employed for standard health service duties but who also end up deployed for immunization programs;
- Improper medical supervision by qualified medical doctors and a lack of lifesaving medicines for use in the rare case of an adverse event;
- Improper storage and distribution practices, recordkeeping, and stock reconciliation;
- Inadequate maintenance of cold chain equipment and power backup, leading to a loss of vaccine potency;
- Inadequate adverse event reporting and investigation; and
- Lack of concerted efforts to make immunization programs successful by adequate extension efforts and communication.

These program voids manifest in some form or another in many developing countries. Unless concerted efforts are taken to address these issues, we will continue to have good vaccines developed but poor overall results in immunization coverage and effectiveness. This outcome means that we miss out on opportunities to prevent disease and death; it also means that large amounts of money and time are wasted. This outcome serves no one.

India, 2007 – Healthcare workers gather at a clinic in Mumbai on polio immunization day. The instructor points out the vaccine vial monitor on the vaccine to the group.

While we vaccine manufacturers are rightly called upon to follow stringent regulatory norms set by the WHO, there are no similar norms specified by the WHO, governments, or funding agencies for the *delivery* of vaccines. For example, why do we not have norms in place for "Good Storage and Delivery Practices" for service providers, similar to the "Good Manufacturing Practices (GMPs)" requirements that manufacturers must meet? Alternatively, similar to the WHO's Six Function Test, which addresses regulatory oversight of vaccine manufacture and supply, could there not be a similar "Function Test" to oversee the health delivery systems used for immunization? In short, we must introduce standards of quality for service delivery in immunization.

Funding agencies committed to safe, effective immunization would increase their impact by earmarking funds to improve the quality and diligence of the vaccine delivery component of health delivery systems. Vaccine delivery needs as much attention as the vaccines themselves. The horse should be in front of the cart! It is here that I believe public-private partnerships can be of help.

In summary, immunization effectiveness "in the field" within the developing world is beset with numerous challenges to effective delivery. These issues are not restricted to cold chain aspects alone; rather, they connect to far more serious systemic issues around the organization of health delivery systems. Without a concerted effort to address these issues in a holistic manner with the development of appropriate standards of performance and globally accepted systems for oversight, we will continue to face serious adverse events, loss of precious lives, and attrition in immunization coverage.

Published in the United States of America by The National Bureau of Asian Research (NBR)

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