Editorial

Vaccines, Social Mobilization, or any Other Game Changer: Polio Eradication is an Unfinished Narrative

With the fatal attacks on frontline workers in Pakistan and Nigeria and a programmatic emergency, mainly caused by funding deficit, the global polio eradication efforts are passing through a critical phase where the impact of its outcome is going to be felt all across public health programs. Wandering in time and historicizing polio eradication is a lesson in public health. Polio vaccination was integrated to routine immunization (RI) world-wide in early 70s. This was consequent to a series of the lameness surveys conducted in many high income countries. The Global Polio Eradication Initiative (GPEI) started in 1988 when over 3.5 lacks cases were reported annually and the distribution of cases was across the globe. Major arms of this enormous program were supplementary immunization activities (SIA); establishment of a vertical system of acute flaccid paralysis (AFP) surveillance; and community mobilization on a scale that has been unprecedented in human history. The criticality of the last component was to be realized a bit later though, more so with the endgame strategies for the last frontiers and the hotspots. Since then, we have witnessed a phenomenal progress in eliminating polio from almost the entire globe. Today, we have only 3 endemic countries (Afghanistan, Nigeria and Pakistan) and 3 countries with re-established transmission (Angola, Chad and Democratic Republic of Congo). No case of wild poliovirus type 2 (WPV2) has been reported since 1999. For the other 2 WPV types (WPV1 and WPV3), the last decade has been very eventful and interesting.

Before taking the polio narrative forward, it may be relevant to spare a thought about measles here. After the eradication of variola, GPEI was the second world-wide effort of comparable nature. How measles lost out to polio at this stage remains an "unknown," but surely the reasons were unlikely to be scientific or technical. Going by scientific rationale, measles should have stayed at the center of the agenda, even if it was crowded, as a candidate disease after smallpox. Very much like the case of variola, measles does not have any extra-human reservoir, has no sub-clinical cases and has an easily identifiable clinical syndrome. The disease burden of measles was and continues to be comparable to any major pediatric health problem, even though, we had a potent vaccine available against the virus. In all likelihood, measles lost out to polio because of some extrinsic reasons.

Coming back to polio, the global picture has never looked better. A total of 223 WPV cases have been reported in 2012. This is in contrast to 650 and 1352 WPV cases in 2011 and 2010, respectively. Barring 6 cases from Chad and Niger, all of these cases were from 3 endemic countries: Nigeria-122; Pakistan-58; and Afghanistan-37. No case has been reported from Angola, Democratic Republic of Congo, or rest of the world.[1] In spite of this encouraging epidemiological trend, there are certain serious stumbling blocks in the way of the final push. The two major impeding factors are funding gap and sub-optimal progress in the endemic countries.[2] A large number of SIAs have been cancelled globally and many others downscaled because of funding deficit or non-availability of appropriate vaccine type. The irony is that the "financial" benefit of polio eradication is estimated to be 50 billion USD,– and everyone knows about it. Specter gets worrisome when global ruling classes are unable to convince themselves that investing in polio is a sound venture.

On the other arm, slow progress in the three endemic countries is further confounded with weak RI. In fact, the coverage is abysmal in certain pockets with the social and the cultural resistance to immunization. Although program managers and academics concentrate on vaccine innovations, microbiological issues, supplies and financial crunch, the critical pathway to eradication may lie in resolving social and cultural resistance to available interventions.[3] The overall coverage at the district level might look good in spite of harbouring less visible clusters of perpetually un-immunised children located in extremely poor sanitary conditions. Such clusters, though miniscule when seen at the macro level, may

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sustain low level of WPV circulation, particularly among densely populated communities. Despite 97% coverage in Netherlands, several outbreaks of poliomyelitis occurred in the last three decades, among clustered unvaccinated persons.[4] Marginalised communities, across religions and social groups, in areas of poor development and primary health-care services remain sceptic clients of this repetitive population-based intervention. Analysis of contents of some of the rumours generated during the SIAs indicated that the phenomenon also had a strong share of religious and geopolitical constructs.[5] Another serious threat is the global buildup of 'never exposed' young adults in polio eliminated areas. This is swelling with every new birth cohort. If these areas have a weak RI coverage, added with no or downscaled SIAs, introduction and establishment of transmission of WPV would not be outside the realm of possibility. This would have devastating consequences. Much more than polio related morbidity, such an event may generate a mass fatigue and cynicism against many other public health programs, and is likely to put the peripheral health workers under tremendous pressure.

Choice of Vaccine in the SIAs

Since the beginning, Sabin's trivalent oral polio vaccine (tOPV) was used for SIA. It was only around the middle of the last decade that monovalent oral polio vaccine type 1 (mOPV1) was deployed in the program on a massive scale - for WPV1 transmission was difficult to contain in certain areas. Trivalent vaccine was still there in the RI. This switch from tOPV to mOPV1 in some of the SIAs yielded good results in bringing down WPV1, but was also temporally associated with the unprecedented outbreaks of WPV3 in the areas where mOPV1 was deployed. The emergent situation prompted selective use of mOPV3 in some SIAs and this reduced the number of WPV3 cases as well. Nonetheless, overall program strategy continued to focus primarily on WPV1 for its higher paralytic rate and its likelihood to spread to polio free areas. Selection of vaccine for SIAs has been a matter of calculated, epidemiologically guided considerations– and this has generated some contesting arguments. Severity of paralysis caused by WPV3 is no lesser than the one caused by other types. Knowing well that RI with tOPV is quite dismal in the endemic areas, the risk involved in targeting a single virus type in SIAs was sizeable. In several areas, the trivalent vaccine was not used for over a year in SIA rounds, which had exclusive reliance on mOPV1. This rendered under-fives vulnerable to WPV3. Some professional bodies took a strong position on this and stated that the surge of WPV3 cases in 2008 and 2009 in India and elsewhere globally could be termed as "iatrogenic outbreak", and also that indigenous expert advice was being ignored in critical decisions.[6] Although evidence to support the monovalent vaccine was gradually emerging,[7] the processes and methods were exposed to criticism. A newer, high potency vaccine that had already been given to children on a massive scale should have been supported by a more robust evidence base, instead of *post hoc* rationalizations. The best way would have been to target both WPV1 and WPV3 concurrently, which was ultimately carried out with the bivalent oral polio vaccine (bOPV). The introduction of bOPV in 2009 to replace mOPVs in the SIAs marked the turn of a tumultuous decade and proved to be a major breakthrough.

The Endgame, Interface, and the Post-Eradication Era

On the global scenario, we are struggling to achieve what should have been achieved during the last decade, and this is showing a cascading effect on subsequent phases. We are already late by half a decade in achieving a complete world-wide cessation of all WPV transmission. Meanwhile, we need to simultaneously create an "endgame-post eradication interface" while preparing for the post-eradication era. Such an interface would involve a series of actions, starting with a switch from tOPV to bOPV in SIAs as well as RI. Introduction of inactivated polio vaccine (IPV) in the RI should be the second step, and a precondition to the third one: Simultaneous global cessation of all oral polio vaccines (OPV). In many countries, these steps may be synergized with the planned roll out of pentavalent vaccine, having IPV. Equally, critical would be our response to circulating vaccine-derived polioviruses (cVDPV) emerging as a major concern, with 68 confirmed cases in 2012 and 3 cases in the first 2 months of 2013. Barring 2 cVDPV3 cases, all of them were cVDPV2, and for the first time they appeared to be evenly distributed.[8] Intensified AFP surveillance and downscaling of the program for horizontal integration with the primary care delivery would be the other parallel arms of action.

To minimize the risk of re-introduction of WPV and to check the emergence of cVDPV, the immediate technical and logistical challenges are to be surmounted with urgency. Priority areas are to develop affordable IPV, appropriate bio-containment of all polioviruses and to explore the role of antivirals. Managing risks associated with OPV cessation would also involve stockpiling of monovalent oral vaccines. Immediate risks associated with OPV cessation is the emergence of cVDPV while medium and long-term risks are re-introduction of poliovirus from a vaccine manufacturing unit, diagnostic lab or research facility. For these reasons, global OPV cessation has to be a critically studied decision, which should be acted upon by all the nations simultaneously. The type of IPV and the cost and capacity for its mass production in low and middle income countries are also

emerging as significant issues, and there are unsettled debates around the technology transfer amongst nations and future roles of conventional Salk-inactivated polio vaccine (Salk-IPV), enhanced inactivated polio vaccine (eIPV), IPV using attenuated Sabin poliovirus strains (Sabin-IPV) and combined eIPV/OPV vaccination during this phase.[9,10] Since, the IPV would prevent paralysis, but may not stop poliovirus shedding, the role of antiviral drugs is also being explored by GPEI. Two categories of antivirals - capsid inhibitors and protease inhibitors are being developed to address possible resistance issues. They may be deployed to prevent, reduce or stop poliovirus shedding in subjects given OPV; among immunodeficient people who are chronically shedding poliovirus; and for unintentional laboratory exposures. The antivirals may also be used, along with the IPV, in the communities exposed to cVDPV outbreaks.[11]

Besides all these technical considerations, there are certain realities which are largely beyond our control. Civil unrest and war like situation in many of the remaining polio hotspots have always been serious impeding factors for the program. In some of the areas of these last frontiers, microplanning, social mobilization, and implementation of SIAs are extremely difficult and considerably risky for the health functionaries. To confound the situation, the quality of information for RI and SIA coverage, and sensitivity of AFP surveillance from these areas would remain suspect. Quantum of civil aviation that we have today may also pose some problems. Although surface movement of migrating people may be the major concern for poliovirus spread in pre-eradication scenario, civil aviation will also need to be factored during the post-eradication phase.

Polio narrative has taught us again that population-based disease control activities are much more than a technical mission. It is being argued that the phenomenal social mobilization and energized health machinery of polio campaigns should be exploited for measles agenda as well. Under the pressure of international advocacy and the culture of verticality among national experts, we may continue to ignore the voices of the most peripheral health workers and people. This may push us toward another top-down program of mammoth magnitude, with a dedicated surveillance system, at the cost of other core programs for human development. We may force a program on people and give it a community-based façade, but it would take an interminably longer period to deliver unless it is community-owned as well. Reversals are punctuations in any global program, but responding to them would depend on our capacity to bridge the global divide between people and programs. As of now, on the polio front, the big picture looks good. Well, almost!

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