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Healthcare Interventions and Vaccines

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Rotavirus infections are ubiquitous. Where vaccines have been widely introduced, there has been an extraordinary positive impact on mortality and morbidity. There is much yet to be done in India to ensure full introduction of rotavirus vaccination in the national immunization program. There are many challenges in implementation of a new vaccine for a large birth cohort and new challenges will surely emerge, as with any effort on this scale. Our collective experience will deal with existing and emerging issues, and full deployment of the vaccine will save hundreds of thousands of lives and will greatly improve the health of children. On the science and technology front, the development and deployment of an indigenous vaccine is exemplary, and raises confidence that more such efforts will follow. The Indian vaccine industry, indeed all of India, should take great pride in what it did in the manufacture of vaccines in general and against rotavirus in particular. Two big cheers are due to India.

Yet, this is a time for introspection and self-criticism. We need to ask ourselves if we could have gone ahead faster and implemented faster. We also need to learn from the rotavirus experience what we need to do for immunization programs in general, and for specific vaccines as needed. While our vaccine and vaccination challenges are complex, our programs can be broken down into components in a pipeline. Each component can be analyzed and we can chart out where and how we can do better. Reality is far more complex, dynamic and unpredictable but such an approach and a constant self-appraisal can help in strategic development and implementation.

We can divide the components in the pipeline into research, the 'valley of death' that needs to be crossed to take vaccine development into trials, manufacture, implementation and monitoring. While a detailed analysis is needed, I outline aspects that need attention, and try and point to realistic routes to address these problems. In each of these components, we can analyze our strengths, weaknesses and, very important, the efforts needed to address the problem. These components and the current situation are broadly and qualitatively summarized in ***Table* I**. A constant and critical mapping of each cell in the table, for each vaccine candidate, is needed. As a research funder, not directly involved in deep-downstream implementation (a responsibility of central and state health ministries), this dynamic mapping could be anchored by a partnership of the Department of Biotechnology (DBT) and the Indian Council of Medical Research (ICMR). Such a 'landscaping' unit, organically connected with our reality is an effort which the DBT will put in place. Indeed, some such structures are already in place; learning from their successes and weaknesses, and

TABLE I THE COMPONENTS IN THE IMPLEMENTATION PIPELINE

Component	*Strengths*	*Weaknesses*	*How to address*
Research	Terrific Cell and Molecular Biology community	Disconnected with society	DBT can, and is developing better incentives to connect.
'Valley of Death'	Many leads globally	Disparate laboratories, uncertain funding, poor connect, little investment in research and development from companies for potential small volume markets.	Create a nimble global research fund.
Trials	Quality clinical researchers and industry	Foggy regulation. More training programs needed as trial requirements scale-up. Investment in surveillance to establish sites for efficacy trials.	ICMR-DBT proactively clarify regulatory routes in complex debates. This is happening, as also training programs and some surveillance efforts.
Manufacture	Excellent capacity	Market complexities and resources keep costs high. More vaccine candidates needed.	DBT-BIRAC should drive earlier steps more in partnership with public and private biotech industry. Industry incentives from regulators for 'public good' vaccines.
Introduction	NTAGI functional	Needs to be more nimble, proactive, forward looking to broaden scope.	Formal steps for improving NTAGI function.
Implementation	Steady and well-organized at each stage.Experience with large birth cohorts and campaigns	Coverage issues continue in certain regions.Costs and capacity are a challenge when deciding on introduction. Shortage of trained staff and resources are constraints on speedier national implementation.	Better alignment between centre and states. New strategies for implementation, which raise national and global resources and train delivery workers to scale. S&T can help here.
Monitoring	Outstanding experience with polio	Disease prevalence, surveillance and impact of introduction studies constrained due to costs and capacity	New strategies for monitoring, which raise national and global resources and link programs with independent monitors. S&T can help here.

DBT: Department of Biotechnology; ICMR: Indian Council of Medical Research; NTAGI: National Technical Advisory Group on Immunization; S&T: Science and Technology.

coordination with them can itself help develop a more effective aid to those who need to take decisions and monitor performance.

This simplistic table (***Table* I**) suggests that we have bottlenecks at every stage in the pipeline. This may lead us to the view that the pipe will have a poor flow rate or be clogged. This would be wrong. There are ways to clean pipes by addressing challenges, even as the pipeline continues to work as it does. Our being more active in being aware, in an integrated manner, of our strengths and weaknesses (columns 2 and 3), and using this awareness to address solutions (column 4) is the only way to bring vaccines to the Indian people. In this effort, the DBT has a special role. It is removed enough to be able to think unhurriedly and objectively, and it is connected enough to help develop and implement urgent solutions. The model was developed with the end-to-end engagement with the indigenous rotavirus vaccine. We have learned from the experience and need new challenges.

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