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Controversies and Challenges in Pediatric Vaccination Today

Editor:

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EDITORIAL

Controversies and Challenges in Pediatric Vaccination Today

Vipin M. Vashishtha¹ and Puneet Kumar²

Vaccines are among the greatest achievements of modern medicine, leading to the eradication of naturally occurring smallpox and the near elimination of polio [1]. The first virus vaccines against smallpox and rabies proved their effectiveness even before the ultra microscopic viruses had been identified as a new world of infectious agents [2].

Vaccination has a short history when measured against the centuries during which man has sought desperately to rid himself of various plagues and pestilences. Only in the 20th century did the practice flower into the routine vaccination of large populations [3]. Despite its relative youth, since the time of Edward Jenner, vaccination has controlled the following 12 major diseases, at least in parts of the world: smallpox, diphtheria, tetanus, yellow fever, pertussis, *Haemophilus influenzae* type b disease, poliomyelitis, measles, mumps, rubella, typhoid and rabies “in industrialized countries” [3].

The infectious disease community can now turn attention to hepatitis B. War has been declared on pandemic influenza but with this zoonotic virus containment is key, with vaccines used alongside antivirals and social distancing. Undoubtedly “we have the guns, and now we can finish the job [1]”.

To date most antibacterial and antiviral vaccines have not been designed but rather built step by step. Today, purification of microbial elements, genetic engineering and improved knowledge of immune protection allow direct creation of attenuated mutants, expression of vaccine proteins in live vectors, purification and even synthesis of microbial antigens, and induction of a variety of immune responses through manipulation of DNA, RNA, proteins and polysaccharides. Both noninfectious and

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infectious diseases are now within the realm of vaccinology. The profusion of new vaccines enables new populations to be targeted for vaccination, and requires the development of routes of administration additional to injection [4]. However, with all this come new problems in the production, regulation and distribution of vaccines.

Challenges in front of pediatric vaccination today:

Despite making big strides in to the stronghold of infectious diseases and successfully demolishing many of them, there are still many challenges in front of vaccination today. Effective vaccines against common infections such as HIV, Malaria, TB, and Hepatitis-C remain an unmet medical need. These gaps, together with the threat of resurgence of

eradicated diseases, contribute to the growing need for the development of new vaccines and the improvement of existing ones [1].

Another challenge is posed by the high investments and ever increasing cost of developing a new vaccine that has resulted in shrinkage of vaccine manufacturer pool globally. Today, the expense of developing a new vaccine is now upwards of \$500,000,000 [3]. This high cost is a major disincentive for companies to develop new and improved vaccines. Furthermore, more stringent requirements for proving safety and effectiveness can lengthen the time necessary to bring vaccines from initial ideas to licensed product. The requirement by major pharmaceutical companies for large markets to justify the expense of development means that many needed vaccines for geographically localized infections are not available. This is a problem that can only be solved by expansion of smaller vaccine companies or by increasing available capital for manufacturing facilities [3].

Another problem that clouds the otherwise bright picture of vaccinology is the deleterious effect of misinformation campaigns that vaccines cause a variety of adverse events, among them that autism is caused by MMR vaccine or by the preservative thimerosal, despite the scientific evidence against causation [1]. One is reminded of Jonathan Swift's aphorism: "Falsehood flies and the truth comes limping after." The situation is worse in developing countries that may be badly affected by suspension of mass immunization activities. The problem is compounded further when literate medical professionals join ill-literate laymen in opposing introduction of a new antigen in the national immunization programs or boycotting ongoing mass vaccination drives against an old disease [5,6].

All this notwithstanding, the vaccine enterprise is growing handsomely due to increased demand, appearance of new vaccine manufacturers in developing countries, availability of generous funding to many mass vaccination programs in poor developing countries by organizations such as Gates Foundation and GAVI, and to new knowledge of genetic engineering and immunology, and shows no signs of flagging as the 21st Century continues.

Vaccination scenario in developing countries of Asia:

Vaccination schedules and coverage rates vary widely across Asia. Some countries only provide free EPI vaccines (such as DTP, BCG, polio and hepatitis B), while others have a basic schedule of free EPI vaccines supplemented on a national basis with additional vaccines. Still others operate through independent, self-funded national schedules. World Health Organization prequalification, followed by distribution of pediatric vaccines through Unicef, is still the method of choice for vaccine distribution in many Asian countries. Some countries (such as India) have a two-tiered system with co-existing private and public markets for vaccination. Coverage rates for basic vaccines such as DTP vary widely from almost 100% in places like Japan, Malaysia or Thailand to as little as 45% in Laos and Papua New Guinea [7, 8]. Rather than introducing additional immunizations to national schedules, many countries' primary objective is to improve the coverage for existing vaccines by improving affordability of and access to these products.

Key diseases to target for the East and South East Asian markets include Hib, hepatitis B, meningitis, pneumococcal disease, HPV, rubella, Japanese encephalitis and dengue. Other changes that are due are the switch from the whole-cell pertussis to the acellular pertussis vaccine and from oral to injected polio immunization. Targeting the portfolio of therapies to the local disease burden is another key step to success, though this is not an easy task in the absence of good disease surveillance data for many Asian countries. International organizations, politicians and vaccine manufacturers need to support surveillance efforts, particularly in poorer countries [9].

Controversies in pediatric vaccination today:

Controversies against vaccination range from being over the morality, ethics, effectiveness, or safety of vaccination to their schedules, mode of delivery, optimum dosage, need of boosters, use of adjuvants and preservatives, suitability of available vaccines for a particular geographical regions, and so on. The medical and scientific evidence is that the benefits of

preventing suffering and death from infectious diseases outweigh rare adverse effects of immunization [10, 11]. Since vaccination began in the late 18th century, opponents have claimed that vaccines do not work, that they are or may be dangerous, that individuals should rely on personal hygiene instead, or that mandatory vaccinations violate individual rights or religious principles [12]. Of late, critics have accused the vaccine industry and international agencies of misrepresenting the safety and effectiveness of vaccines, covering up and suppressing information, and influencing health policy decisions for financial gain [5, 12].

Controversies are part and parcel of every budding and flourishing enterprise. And vaccination is no exception. In a way it is good for any evolving subsidiary of science and ultimately paves the way for further improvement, new inventions, refined products and better utilization of available resources and technology.

Just to conclude, the impact of vaccination on the health of the world's peoples is hard to exaggerate. With the exception of safe water, no other modality, not even antibiotics, has had such a major effect on mortality reduction and population growth [3]. Though, vaccination has got its share of challenges, and dogged with controversies that surround almost every aspect of it, the future of vaccination is bright and hopefully, it will continue to create many new milestones in the history of modern Medicine.

About this issue:

In this special issue devoted entirely to pediatric vaccination, many of the technical issues related to general immunization as well as individual vaccines are discussed in detail. We have not touched the controversy surrounding the vaccine safety and misinformation, but rather concentrated on scientific issues. The first few articles address the broad issues related to general aspects of vaccination such as how to make vaccines more affordable and accessible to the section of society needing them the most, reexamines the relevance, utility and effectiveness of current EPI schedules especially in developing countries, discusses issues/modus operandi of introduction of a new antigen in to national immunization program (NIP) of a country, newer routes of vaccine administration like mucosal

vaccination, a significant and user friendly administration in context of developing countries.

Issues related to individual vaccines/vaccination include certain old vaccines such as BCG, new and conventional Typhoid vaccines, Rotavirus, Human Papillomavirus vaccine (HPV), Hepatitis A, Influenza both seasonal and pandemic, issues related to polio eradication particularly with post-eradication scenario and IPV, need for dev a new generation of IPV, Pneumococcal vaccination and the need to establish efficient disease surveillance system not only to gather critical info on currently prevailing serotypes thus deciding upon the type of conjugate vaccine but more importantly to monitor community impact of mass vaccination and the shortcomings of currently available pneumococcal conjugate vaccines.

Hopefully, this special supplement on vaccination should provide an insight to few of the contentious issues related to both old and new pediatric vaccines, particularly in context of developing countries of Asia. The effort should also provide a food for thought for those in charge of devising and implementing vaccination policy in a country. The main focus is on practicing fraternity in developing world who may draw some useful inferences from this supplement.

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