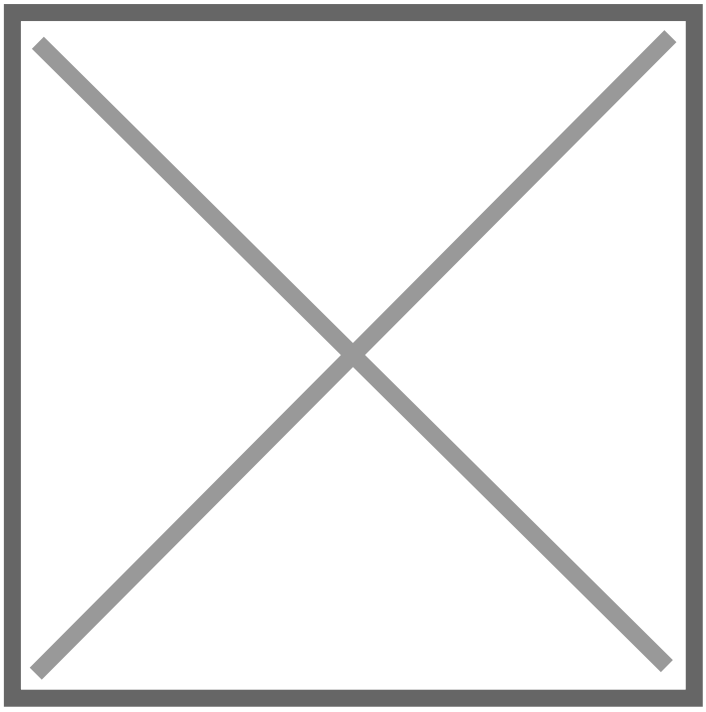
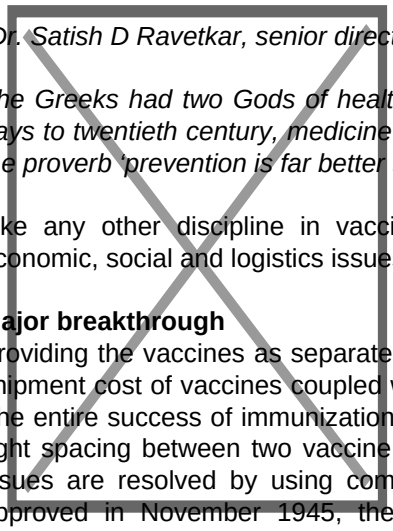
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Combination Vaccines Boost Immunization

10 March 2009 | News



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-Dr. Satish D Ravetkar, senior director, Serum Institute

The Greeks had two Gods of health, Aesculapius and Hygieia, meaning therapy and prevention respectively. From ancient days to twentieth century, medicine is revolving around these two points. Vaccines belong mainly to second category proving the proverb 'prevention is far better than cure'.

Like any other discipline in vaccinology, which continuously kept developing, more novel vaccines posed substantial economic, social and logistics issues.

Major breakthrough

Providing the vaccines as separate injection is not only expensive but also leading to distressed parents and providers. The shipment cost of vaccines coupled with cold storage and administration cost many a times exceeds the cost of vaccine itself. The entire success of immunization program can be jeopardized with missed vaccination schedules. With the acute need for right spacing between two vaccine injections and the need for booster, even best vaccine fails in field. All these complex issues are resolved by using combination vaccines. Even though the first combination vaccine licensed in the US was approved in November 1945, the combination vaccine concept has caught up in the last decade with the dramatic consolidation in vaccine development; one of the peculiar situation during this period was newer vaccines were developed and mainly at affordable cost by developing world. More need was felt to revisit the concept of combination vaccine to innovate further.

A combination vaccine as name suggests consists of two or more separate antigens that have been physically combined in a single preparation. One must remember to differentiate between simultaneous vaccines which are administered concurrently but are physically separated. In fact this very concept partly gave stimuli for the development of more combined vaccines.

Issues

There are however lot of issues in production of combined vaccines. Chemical or physical interactions among the vaccine components being combined can result in alteration of immune response to different antigens mixed together. The factors like type of gel suitable for individual antigen or no gel required can also alter the immune response to antigens being mixed together. In addition to this buffers, excipients and salts, which are good for one antigen can be harmful in terms of immunogenicity of other antigen. Circumventing all these issues to produce effective combination vaccine is real challenge to modern vaccinologist. In spite of this the world vaccine market is having lot of combination vaccines like DtaP/IPV, Tdap/IPV, DtaP/Hib, DtaP/IPV/Hib, DtaP/HepB/IPV, DtaP/HepB/IPV/Hib, HepB/HepA, HepA/Typhoid, Mnc/Hib, DtaP/Hib, DtaP/Hep/IPV, HepB/Hib, DT/IPV, Td/IPV, DtaP/IPV, DtaP/IPV/Hib, DTwP/IPV, DTwP/Hib, DTwP/HepB, DTwP/HepB/Hib, DTwP/IPV/Hib and list continues to grow.

The need for huge investment for the clinical trails pose challenge while developing combination vaccine. More funding for combination vaccine particularly for those being developed in developing countries is essential. The cost of combination vaccine against the cost of individual vaccines and their relation to development cost is very sensitive and critical. It's also a case many a times that single manufacturer may not have all the antigens being manufactured by himself. In that case consolidation of various manufacturers becomes rule of the industry, which luckily seems to be working well. This synergy is also benefiting in terms of exchange of knowledge between various companies. Combination vaccine trials should also be prospective, randomized and as fully blinded as possible and should have appropriate and ample control groups. Number of subjects should also be enough to confirm to Good Clinical Practices (GCP). Common practice in vaccine industry is to conduct non-inferiority trials which provides statistical assurance that the investigational product is not inferior compared to standard product. The candidate vaccine may also be superior or equivalent but not inferior to the standard product available in the market.

Future trend

The future trend will be to develop combination vaccines depending on the need of that part of world considering various factors. By reducing number of injections, combination vaccines help to facilitate immunization against more and more diseases with lesser cost and better coverage, which will certainly benefit mankind.

It's up to international agencies like GAVI, UNICEF, WHO and PATH to have co-ordinated efforts to make these costly vaccines available to developing countries where majority of infant population resides. The opportunities, possibilities and market potential are so encouraging that new players will enter the field to leverage advantage of growing market of combination vaccines.

Market potential

The market potential for combination vaccine is huge. In 2007, combination vaccines generated $850 million in revenues. The combination vaccine are slated to cross $2 billion mark in 2013, which implies annual compound growth of more that 17 percent.