Newer vaccine

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- The Global Immunization Vision and Strategy (GIVS) was developed by WHO and UNICEF as a framework for strengenthing national immunization programs and protect as many people as possible against more diseases by expanding the reach of immunization, including new vaccines, to every eligible person.
- The introduction of new vaccines poses challenges to the existing logistics and cold chain requirement due to their current presentations. In particular, the prefilled glass syringes is exceeding the central cold chain storage capacity of some countries and the safe use and disposal of glass syringes poses the waste management challenge. These challenges seek more suitable formulation and presentation of new vaccines

NEWER VACCINES FOR INDIA

- Newer vaccine means any vaccine outside traditional EPI schedule. New and under utilized vaccines have overlapping definations. What is new vaccinesfor India may not be new vaccines for developing country. Definition iscontext specific and subjective. New vaccine for immunization program canbe called new vaccines in general

CLASSIFICATION OF VACCINES12

Pathogenes that have circulated for long but existance ignored:

- Hepatitis B virus
- Hemophilus influenzae type B (Hib)
- Pneumoccus
- Rota virus.

Old pathogens have changed geographical habitats and introduced in newer areas:

- Chickungunya virus
- Westnile virus

New pathogenes have emerged:

- Swine flu virus
- SARS
- Avian flu virus

Pathogenes thought to be controlled have re-emerged:

- M tuberculosis
- Polio virus
- Diphtheria, pertussis, tetanus and measles virus

NEW LICENSED VACCINES15

Several new vaccines and new vaccine formulations have become available since the year 2000. These include:

- T**he first pneumococcal conjugate vaccine,** PCV7 was licensed in early 2000. Ten years later in 2010, a new pneumococcal conjugate product PCV13 was licensed and replaced PCV7 for use in routine vaccination of children against the pneumococcus—a bacterium, which according to
- WHO estimates of the year 2000, cause more than 14.5 million episodesof serious pneumococcal disease and more than 800,000 deaths annually among children under five years

old, as well as high rates of meningitis related disability among children who survive (including mental retardation, seizures, and deafness).

- **Two new oral, live attenuated rotavirus** vaccines are available internationally (replacing a previous vaccine withdrawn from the market because of adverse events)—a virus which, according to WHO 2004 estimates, accounts annually for an estimated two million hospitalized cases of severe diarrheal disease in children and kills an estimated 527,000 children a year. WHO has recommended the rotavirus vaccine into the national immunization program in United States and Europe. WHO now recommends that rotavirus vaccine should be included in all national immunization programs
- **Currently two HPV vaccines** are marketed internationally using recombinant technology, both are prepared from purified L1 structural proteins that self assemble to form HPV type specific empty shells or vaccine like particle (VLP). Neither of the vaccines contain live biological products or viral DNA, so they are non infectious. WHO recommend the use of HPV vaccines in female as young as ten years of age to prevent cervical pre-cancer. It is not recommended for males. Diseases caused by HPV include cancer of cervix, vagina, vulva, penis, anus, a subset of head and neck cancer, and ano-genital wart. In 2005, there were about 500,000 cases of cervical cancer and 260,000 related deaths world-wide.16
- The first DTP combination vaccines specifically formulated for adolescents and adults.•• Live Intranasal and injectable H1N1 (flu shot) vaccine is available in India. •• An internationally licensed oral cholera vaccine (OCV) is currently available in the market and is suitable for travelers. It has a good efficacy (85–90% after six months in all age groups, declining to 62% at one year among adults). However, newer candidate vaccines which are effective,safe and can be orally administered for mass vaccination are still elusive.17
- The other vaccines include, DTaP, Hib, IPV, Bivalent OPV, MMR,Varicella, Hepatitis A, Typhoid, Tdap, and Td.

VACCINES IN THE PIPELINE9

VACCINES IN CANCER

- Vaccines initially thought of as preventing infectious diseases, but now are emerging as a new tool of treatment of various diseases viz cancers etc. Experimental therapeutic vaccines are under trial in various cancers including melanoma, renal cell carcinoma, colorectal, breast, ovarian, and lung cancers

FUNGAL VACCINES

- There is no fungal vaccine approved or currently undergoing advanced clinical trials for active immunization in human beings.20 However, several vaccine manufacturers have fungal antigens under development as candidate vaccines. Two vaccine formulations have undergone limited phase I and phase II trials; the first against vulvovaginal candidiasis by a candida ribosomal preparation, and the second against cryptococcosis by the tetanus toxoidconjugate of the capsular polysaccharide. A more extensive efficacy trial was done with a vaccine against coccidiomycosis

ANTIOBESITY VACCINES

- Antiobesity vaccines are also under trial in the western world. Treatment of obesity by a therapeutic vaccination approach includes world's first immunization-based growth hormone (GH) and insulin like growth factor-1 (IGF-1) treatments using novel second-generation somatostatin vaccines

CHIKUNGUNYA VACCINE

- The world could soon have an effective vaccine against Chikungunya—the viral disease characterized by high fever lasting between seven and 10 days and excruciatingly painful joints for over three months. India has been seeing explosive outbreaks of this mosquito-borne disease which came to the country in 2006 after a gap of 32 years

SCHISTOSOMIASIS AND HOOKWORM VACCINES

- Over the next decade, a new generation of vaccines will target the neglected tropical diseases (NTDs) *Necator americanus*-glutathione-*S*-transferase-1 (*Na*-GST-1) vaccine to prevent human hookworm infection. A multivalentanthelminthic vaccine for hookworm infection and schistosomiasis would represent an important new tool for combating disease and poverty

ORAL RABIES VACCINE

- Oral rabies vaccination (ORV) represents a socially acceptable methodology that may be applied on a broad geographic scale to manage the disease in specific terrestrial wildlife reservoirs, as well as in free-ranging or feral dog (Canis familiaris) populations, where parenteral vaccination is impractical. This may help in integration of ORV into variant of gray fox (Urocyon cinereoargenteus) rabies in west Texas and preventing the reemergence of canine rabies from Mexico

NEW VACCINE FOR TUBERCULOSIS

- The new vaccine, called MVA85A/AERAS-485, is given to children after the BCG and is designed to boost the body's immune response to the vaccine, improving the level of protection.25

FUTURE VACCINES IN INDIA

Dengue Virus Vaccines

- Dengue fever is caused by dengue virus of which there are four serotypes (DV 1 to 4). Infection induces long lasting protective immunity only to the specific serotype and thus a person can not suffer from the same serotype infection again but is liable to be infected by another serotype. Thus an effective dengue vaccine should be tetravalent and should induce simultaneous immunity against all the four serotypes. Multipronged efforts are underway to produce effective, safe and affordable vaccine and may be a reality in foreseeable future.

Hepatitis E Virus Vaccine

- Hepatitis E virus (HEV) is one of important agent causing water borne hepatitis. It mainly affects adults with low mortality rate but is cause of high mortality in pregnant women and cirrhotic patients. Several studies are in progress to produce an effective vaccine that can provide a long lasting immunity against HEV. Currently, there is no commercially available vaccine which is cost effective and simple to use as the disease is common in developing countries like ours. Human Immunodeficiency Virus Vaccine HIV infection/AIDS is a global pandemic, with cases being reported from virtually every country. The disease is caused by two serotypes HIV - 1 and HIV -

2. The Hall mark of HIV disease is a profound immune deficiency which is characterized by severe opportunistic infections and unusual neoplasms at one end of a spectrum of disease and healthy seropositive individuals at the other end.

Leishmania Vaccine

- Leishmaniasis is transmitted by sand flies. There are three major forms of leishmaniasis in human viz: cutaneous (CL), mucocutaneous and visceral leishmaniasis (VL). Leishmaniasis is endemic in 88 countries and India is one of the country where visceral leishmaniasis is prevalent. Without specific treatment VL is always fatal. The available drugs are expensive and toxic. Therefore safe, effective and economical vaccines are need of the hour.

Leprosy Vaccine

- Leprosy is a chronic infectious disease caused by acid fast bacilli *Mycobacterium leprae*. Despite success in reducing the prevalence of the disease in our country, the transmission of disease is continuing in some areas. Therefore, there is urgent need for a safe and effective immuno prophylaxis in moving towards ultimate eradication of the disease

Malaria Vaccine

- Malaria in humans is caused by four species of Plasmodium. It is one of the major causes of mortality and morbidity worldwide. Wide spread resistance of the parasite to common and easily available drugs has made the malaria situation very alarming. Therefore much emphasis is being on the development of antimalarial vaccines. Malaria research field has been active and there are as many as 80 vaccine constructs which are either at preclinical or clinical development stage. If Phase 3 trials of the RTS, S/AS01 candidate vaccine against malaria go well, this vaccine could be licensed by 2012. If successful, it would be the first vaccine against a parasite that causes disease in humans. The vaccine consist of P.falciparum circum sporozoite protein (CSP) fused to Hepatits B virus surface antigen, expressed in Saccaromyces cerevisial yeast shells.31,32

Recent Antitubercular Vaccine

- Tuberculosis still remains a major health problem worldwide especially in developing countries. The presently available BCG vaccine against Tb has been largely ineffective in controlling the disease, particularly among adults. Emergence of drug resistant strains is posing serious threats to the human race. The present scenario of tubercular infection has triggered the development of newer vaccine against Tb. The evolving vaccines at present comprise of recombinant BCG vaccine, DNA vaccine and fusion proteins with novel adjuvant and delivery systems. It is hoped that in near future one of the vaccines under trial may prove effective in controlling tuberculosis

Bird's (Avian) Flu

- The Avian influenza is cause by H5N1 subtype of influenza A. The influenza spreads from one bird to another bird and is highly infective. Most humans suffer after exposure to infected poultry. Transmission from human to human is rare. Distinguishing avian influenza from regular influenza is difficult, but avian influenza leads to respiratory failure much more frequently and children are predominantly infected. Disease is diagnosed because of exposure to birds. Leptospirosis Vaccine The leptospirosis vaccine model, designed in the Indian Council for Medical Research (ICMR) Regional Centre, Andamans, is ready for trials this year.34 *H. pylori* Vaccine *H. pylori* is leading cause of gastritis, peptic ulcer disease, gastric adenoma and lymphoma in human. Due to decreasing efficacy of anti *H. pylori* antibiotics therapy in clinical

practice, there is a renewed interest in discovery of *H. pylori* vaccine. Helico Vax is an epitope based therapeutic helicobacter pylori vaccine in a mouse model is currently going on.35