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NEW VACCINES AND BIOTECHNOLOGY

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Introduction

A number of new vaccines with major potential for controlling infectious diseases have just been licensed or are at advanced stages of development. Among the illnesses targeted are rotavirus diarrhoea, pneumococcal disease, and cervical cancer (as caused by human papillomavirus), which together kill more than a million people each year, most of them in developing countries. In addition to these efforts against diseases of global importance, progress is being made on a vaccine for the regional menace posed by meningococcal meningitis serogroup A, which causes frequent epidemics and high rates of death and disability in African countries south of the Sahara.

These advanced candidate vaccines are the focus of the information provided below. However, it should be noted that continuing, intensive efforts are under way to develop effective vaccines for AIDS, malaria, tuberculosis, dengue, leishmaniasis, and enteric diseases, among others and to adapt new technologies to improved formulation and delivery.

Vaccine development proceeds through discovery, process engineering, toxicology and animal studies to human Phase I, II, and III trials. The process can take more than 10 years, depending on the disease. The human trials focus initially on safety, involving small groups of people (I); then progress to moderate-sized "target" populations (persons close to the age and other characteristics for whom the vaccine is intended) to determine both safety and the stimulation of immune response (II); and finally to large target populations to establish whether a vaccine actually prevents a disease as intended (efficacy) (III).

WHO Initiative for Vaccine Research

The WHO Initiative for Vaccine Research was established in 2001 to streamline the various vaccine research and development projects being carried out by different departments of WHO (including the Special Programme for Research and Training in Tropical Diseases: TDR) and UNAIDS. IVR is an international team of scientists, managers, and technical experts whose task is to facilitate the development of vaccines against infectious diseases of major public health importance, to improve existing immunization technologies, and to ensure that these advances are made available to the people who need them the most. IVR will achieve these objectives using a three-pronged approach:

1. Management of knowledge and provision of guidance and advocacy through effective partnerships to accelerate innovation for new and improved vaccines and technologies;
2. Support to research and product development for WHO priority new vaccines and technologies; and
3. Conduct of appropriate implementation research and development of tools to support evidence-based recommendations, policies and strategies for optimal use of vaccines and technologies.

Vaccines under development

Numerous new vaccines with major potential for improving health in developing countries are in the research and development pipeline. They include vaccines for rotavirus diarrhoea, which kills 300 000 to 600 000 children under age five every year; human papillomavirus, a leading cause of cervical cancer, which afflicts some 500 000 women each year, 80% of them in developing countries; and pneumococcal disease, which causes a large fraction of the world's approximately two million annual deaths from childhood pneumonia. In addition, a conjugate vaccine now in development should be much more effective against Group A meningococcal disease (Men A), a frequently fatal form of meningitis that causes recurring epidemics in a number of countries in sub-Saharan Africa. Several of these vaccines — those against rotavirus, pneumococcal disease, and Men A — may be available in developing countries by 2008-2009.

Types of vaccines

Vaccines come in different forms. The injected polio vaccine is a killed, intact virus; the oral polio vaccine is a live, weakened virus. The vaccine for typhoid is a killed, intact bacteria. Vaccines for measles and the other standard "childhood" diseases — mumps, chickenpox, and rubella — are live, attenuated (or weakened) viruses. Vaccines for diphtheria and tetanus consist of toxins that have been "inactivated." Influenza vaccines often consist of killed, "disrupted" viruses (that is, the proteins on the coat of the virus have been released into a solution by solvents). Vaccines against Hib, pneumococcal disease, and

meningococcal disease consist of highly purified complex sugars taken from bacterial coats or capsules.

Vaccines are frequently administered as combinations of antigens. The most widely used combinations are diphtheria-tetanus-pertussis (DTP); diphtheria-tetanus-pertussis-hepatitis B (DTP-HepB); pentavalent vaccine: diphtheria-tetanus-pertussis-hepatitis B-Hib; and measles-mumps-and rubella (MMR).

Effectiveness and safety

All vaccines used for routine immunization are very effective in preventing disease, although no vaccine attains 100% effectiveness. More than one dose of a vaccine is generally given to increase the chance of developing immunity.

Vaccines are very safe, and side effects are minor — especially when compared to the diseases they are designed to prevent. Serious complications occur rarely. For example, severe allergic reactions result at a rate of one for every 100 000 doses of measles vaccine. Two to four cases of vaccine-associated paralytic polio have been reported for every one million children receiving oral polio vaccine.

New vaccines licensed by FDA, 2005-2009

Vaccine	Manufacturer	BLA submitted to FDA
DTaP/IPV (KINRIX)	GlaxoSmithKline (GSK)	Jun-2007
Hib/DTaP/IPV (PENTACEL™)	sanofi pasteur	Jul-2005
Hepatitis A (VAQTA®)	Merck	Supplement to original BLA
Hepatitis A (HAVRIX®)	GlaxoSmithKline (GSK)	Supplement to original BLA
Hepatitis A and Hepatitis B (TWINRIX®)	GlaxoSmithKline (GSK)	Supplement to original BLA: accelerated dosing
Herpes zoster vaccine (ZOSTAVAX®)	Merck	Apr-2005
HPV (GARDASIL®)	Merck	Dec-2005
		Supplement to original BLA
HPV (Cervarix™)	GlaxoSmithKline (GSK)	Mar-2007
Influenza vaccines	varies	n/a
Influenza - LAIV-T (FluMist®)	MedImmune	Supplement to original BLA
Japanese Encephalitis (IXIARO)	Intercell Biomedical	Dec-2007
MCV4 (Menactra®)	sanofi pasteur	Dec-2003
		Supplement to original BLA March 2005
MCV4 (Menveo™)	Novartis	Aug-2008
MMRV (ProQuad®)	Merck	Aug-2004
PCV7 (Prevnar 13®)	Wyeth	Mar-2009
Rotavirus (ROTATEQ®)	Merck	Apr-2005
Rotavirus (ROTARIX®)	GlaxoSmithKline (GSK)	Jun-2007
Tdap (BOOSTRIX®)	GlaxoSmithKline (GSK)	Jul-2004
		Supplement to original BLA
Tdap (ADACEL™)	sanofi pasteur	Aug-2004
Varicella virus second dose (Varivax®)	Merck	Supplement to original BLA: second dose

Potential New Vaccine 2009

1. Vaccines for Cocaine Abuse
2. Vaccines to Treat Methamphetamine Addiction
3. Vaccines against Nicotine
4. Neglected Tropical Disease Vaccines
    a. Vaccine against Human Hookworm
5. Malaria Vaccines
6. New Generation of Inactivated Poliovirus Vaccines for Universal Immunization after Eradication of Poliomyelitis
7. Inactivated Rotavirus Vaccines
8. First Generation Leishmaniasis Vaccines
9. DNA Vaccines: Developing New Strategies to Enhance Immune Responses
10. New Horizons in Adjuvants for Vaccine Development
11. Group B Streptococcal Conjugate Vaccine
12. New generation of Tuberculosis Vaccination
13. Novel Vaccines: Bridging Research, Development and Production
14. Measles Vaccination: New Strategies and Formulations
15. Recent Progress in the Development of Plant Derived Vaccines
16. Reducing Post-Traumatic Anxiety by Immunization
17. Immunization in Alzheimer's Disease
18. Cancer Vaccines:
19. HIV/AIDS Vaccines
20. Vaccines against Pandemic Influenza