

It should be noted that once promising vaccine candidates have been identified, the main constraint on the rate of progress, if the other factors are favorable, is the availability of resources -- either public or private -- to expedite development. Furthermore, although the provision of resources for basic research cannot guarantee success in identifying feasible approaches to vaccines, delays in vaccine development -- and ultimately in disease control -- are certain to occur if the available resources are inadequate for following up on promising scientific opportunities or for promoting immunization.

ACCELERATING VACCINE DEVELOPMENT AND DISEASE PREVENTION

In the early 1980's, senior officials at the National Institute of Allergy and Infectious Diseases (NIAID) recognized that emerging technologies in molecular biology and immunology were about to open up almost unlimited opportunities for developing vaccines (see section VI). To prepare for using resources in the most productive way possible, they commissioned a study by the Institute of Medicine of the National Academy of Sciences to suggest ways of setting priorities for the accelerated development of vaccines, based on public health needs and scientific opportunity. The Institute identified the possibility of accelerating, in the ensuing decade, the development of vaccines for 14 of 35 diseases of importance in the United States and 19 of over 100 diseases of importance in developing countries. (The U.S. Agency for International Development joined NIAID in supporting the international phase of the study). The Institute also suggested certain priorities for vaccine development (Institute of Medicine, 1985a ; 1986).

Progress has been made on many of the priority candidates (see National Institute of Allergy and Infectious Diseases, 1993a). For example, vaccines have been licensed recently for hepatitis B (recombinant vaccine), *Haemophilus influenzae* type b meningitis, typhoid, and Japanese encephalitis; licensing has been requested for varicella (chicken pox) and hepatitis A vaccines. However, the overall rate of new product licensure has been lower than expected by the Institute of Medicine. The reasons for the lower-than-expected rate are both that the science has not evolved and that neither the Federal resources available to accelerate vaccine development nor private-sector development activity have reached the levels necessary to match scientific opportunities and public health needs.

ASSESSING PROGRESS TOWARD DISEASE PREVENTION

The number of human diseases caused by infectious agents is not known with certainty; new causative agents are continually being recognized. The number of infectious agents identified worldwide as causes of human disease probably well exceeds 200. For most of these agents, more basic research is needed to identify approaches to their prevention through immunization. A disease may be judged "potentially vaccine preventable" if enough is known from basic research to envision a vaccine candidate. The progress of a vaccine candidate toward licensure can be evaluated by determining what stage it has reached in the development "pipeline" of prelicensure activities. Where a vaccine is licensed, the extent to which it reaches the population for which it is recommended is a rough guide to its impact on the incidence of disease.

As of January 1994, vaccines have been licensed in the United States for 22 diseases (figure 3, section A), and roughly twice that number of diseases are now judged to be potentially vaccine preventable (figure 3, section B). Nevertheless, of the vaccines licensed in the United States, none fully reach the populations for which they are recommended, and many need to be improved so that they are more effective and result in fewer adverse effects.