New Vaccines in the Pipeline 2019

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Before clinicians can administer a vaccine in the United States, the FDA must approve and license it. Investigators conduct extensive research leading up to this process, typically testing a vaccine in thousands of patients over 6 to 7 years or longer.\(^1\) Even with large sample sizes and rigorous study designs, rare adverse effects may be missed. For example, RotaShield, the first vaccine for rotavirus, was withdrawn from the market in 1999, despite being tested in more than 10,000 patients. Postmarketing surveillance demonstrated that a rare, yet serious, risk of intussusception was linked to the vaccine, and the FDA determined that the vaccine’s risks outweighed its benefits.\(^2\)

Once the FDA approves a vaccine, the CDC’s Advisory Committee on Immunization Practices (ACIP) can make a recommendation for its use. Although the FDA focuses on the safety and efficacy of the vaccine, the ACIP can consider more aspects, such as the epidemiology of the disease, health economic impact, and implementation challenges, when making its recommendation.\(^3\) In addition, the US Department of Defense advocates for expedited development, review, and emergency use authorization of medical products that may benefit the US military forces or the general public.\(^4\)

According to the World Health Organization, 240 vaccines were in development for 25 infectious diseases.\(^5\) Topping the list for most candidate vaccines are HIV/AIDS, malaria, pneumococcal infections, tuberculosis, and Ebola.

Vaccines of interest in development include those for the following conditions listed in the table.\(^6^-19\)
**New Delivery Systems**
Combination vaccines are advantageous because they mitigate the burden of multiple injections, reduce the number of visits, and save on costs for storage and shipment. In 2018, the FDA approved a new hexavalent vaccine, DTaP5-HB-IPV- Hib (Vaxelis, Merck) for primary and booster vaccination in infants and toddlers against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and invasive disease caused by Haemophilus influenzae type b.

Vaccine adjuvants are important for eliciting desired protective and sustained immune responses against target pathogens. In recent years, investigators have studied many novel adjuvants for clinical development, such as the oil-in-water emulsion MF59, which is currently being used in Fludan, an influenza vaccine, as well as ASO1B (eg, Shingrix, GSK) and CpG 1018 (eg, Heplisav-B, Dynavax).

**Novel Vaccines**
Vaccine technology has also been applied to the treatment of noninfectious disease conditions and areas such as cancer, smoking cessation, and hypertension. Vaccines that target tumor-associated antigens have been shown to prolong the survival of patients with metastatic melanoma with minimal toxicity. An angiotensin II vaccine is also in development for hypertension.
CONCLUSION
The challenges that investigators face while developing a vaccine are unique, from infectious
diseases that mutate at varying rates to efforts to develop a safe vaccine that not only targets the
correct strain but also elicits an adequate immunologic response. Although this article has
discussed a handful of vaccines in the pipeline, investigators are evaluating many others on a
global scale. Despite the obstacles for vaccine development, FDA vaccine approvals have
accelerated over the past 2 decades, making the prevention of even more human diseases in the
future a realizable prospect (figure).²⁸

![Figure: Number of Vaccines Approved by the FDA Over Time in the United States](image)

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