Preface

The 2016 Vaccine Development Pipeline: A special issue from the World Health Organization Product Development for Vaccine Advisory Committee (PDVAC)

Infectious diseases are the leading cause of death among children and adolescents globally, and one of the primary causes of mortality in adults. Most of these deaths disproportionately burden low- and middle-income countries (LMICs) and are attributable to infectious diseases that include diarrheal illnesses, lower respiratory infections, human immunodeficiency virus, tuberculosis and malaria. Socio-economic gains have translated into improvements in sanitation systems, clean water supplies, early diagnosis and healthcare accessibility and delivery, with consequent reductions in infectious disease incidence and mortality. However, for the majority of the world’s population, large scale advancements in public health infrastructure are still far off. For these communities, high-impact, low-cost public health interventions remain a key strategy for driving down the preventable infectious disease incidence and mortality. Principal among these cost-effective measures is immunization; however, some vaccines are unavailable, inaccessible, and/or unaffordable for the populations most in need. Global national immunization programmes, partially financed through the Gavi vaccine alliance, are estimated to save 2–3 million lives per year with the existing vaccines – and these could be even more impactful if greater levels of coverage could be achieved. Investments into the research, development and deployment of vaccines and delivery technologies against the deadliest and most widespread pathogens are, therefore, likely to yield considerable dividends in global health.

There are approximately 600 vaccine candidates in development against an estimated 110 pathogens [1]. Considering the resource constraints in vaccine development, there is a need to rationally identify the approaches that are most likely to succeed and then prioritize among these candidates. Additionally, as the routine immunization schedule expands, it becomes increasingly important to have strong, evidence-based justifications for investing in the development of new vaccines with a high likelihood of success. Just as innovation should be applied to the domain of vaccines in the development pipeline, there is room for improvement of some licensed vaccines with respect to cost-effectiveness and coverage in order to maximize their public health impact. This special issue, however, focuses its review on the research and development (R&D) pipeline of vaccines against 25 pathogens for which no licensed vaccines currently exists but for which there is high public health importance, as identified by the World Health Organization (WHO) Product Development for Vaccines Advisory Committee (PDVAC). PDVAC is a body of independent experts that was established in 2014 to guide WHO and the vaccine development community along the pathway toward the goal of licensure and deployment in countries of highest disease burden. As such, PDVAC’s remit is to advise on the acceleration of vaccine candidates at Phase 2 of clinical evaluation or earlier and report its proceedings from its meetings to the WHO’s principal committee on immunization policy recommendations: the Strategic Advisory Group of Experts on Immunization (SAGE).

PDVAC also has a contributory role within the framework of the R&D Blueprint at WHO for R&D preparedness and emergency research response in the emerging pathogen area. When WHO declares a Public Health Emergency of International Concern (PHEIC), PDVAC may be tasked with forming a working group to facilitate development of guidance tools for the vaccine development community in the context of the emergency. For example, as this issue goes to press, a PDVAC Working Group is developing a WHO Zika vaccine Target Product Profile [2].

The landscape analyses in this issue are intended as structured overviews of the key considerations for vaccine development, not as exhaustive literature reviews. They are authored by independent subject matter experts in each field and follow a template set forth by the PDVAC committee. Each report summarizes the biological evidence for a vaccine’s feasibility, the data on proof-of-concept studies, existing knowledge gaps, the technical and regulatory hurdles to vaccine licensure, and the prospects for donor funding and procurement of the product. The compendium of pathogens highlighted in this issue was agreed upon by PDVAC in 2015 [3]. Each year, pathogens and diseases to be reviewed is modified to incorporate new areas where vaccine development activity is progressing, and in 2016, Zika will be discussed. In this way, PDVAC remains

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at the cutting edge of product development issues, with oversight across a broad spectrum of R&D activity, ensuring that its contributions are relevant and impactful to vaccine developers, regulators, donors and policy makers.

References


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