

Background

Increasing fiscal burdens related to vaccine purchase costs pose major challenges to the ongoing success of public immunization efforts, because over 50% of childhood vaccine doses are purchased with government financing. The Institute of Medicine has recently examined how the prices of new vaccines may relate to the costs of their development and commercialization by private-sector vaccine manufacturers, but much information about the development process remains proprietary. Importantly, the success of immunization in the US rests on continued vaccine production by a small group of major private manufacturers, who – to sustain their business interests and satisfy their shareholders in this small sector of the vast market for pharmaceuticals – must continue to make profits on their existing products and also have expectations of profits on future vaccine products as well.

For these reasons, there is a clear imperative to create a tool for public immunization officials to understand more completely the investments that vaccine manufacturers make in developing their products, and for vaccine manufacturers to understand how the public sector anticipates the prices they will face for newly recommended vaccines. The investigators believe that greater mutual understanding about the processes and costs of vaccine development and commercialization will yield an even stronger public-private partnership regarding ongoing efforts to safeguard health in the US through child, adolescent, and adult vaccination.

Objectives

The research team, comprised of some of the leading vaccine policy experts in the US and experienced as well regarding health economics and processes related to approval and regulation of biologicals, will create and refine a model of childhood vaccine development and commercialization that will subsequently inform a tool for use in partnership of the CDC with vaccine manufacturers.

Specific aims of the research project include:

- (1) To inform and evaluate a conceptual model of observable factors that contribute to the costs of vaccine development, commercialization, and pricing, using expert primary sources and an array of complementary, publicly available secondary sources;
- (2) To translate the conceptual model into a working model of development/commercialization costs and pricing for vaccines, based on input from confidential primary industry sources and ongoing iterative analysis of secondary sources;
- (3) To convert the working model of vaccine costs and pricing into a practical, user-friendly tool with observable inputs that can be used in the future by federal immunization program staff at CDC and vaccine manufacturers.

The product of this research – a practical vaccine cost/price estimation tool – will be of great value in the ongoing partnership between public health and vaccine manufacturing interests in the US.

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