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Pediatric vaccine procurement policy: The monopsonist's problem

Matthew J. Robbins [a,*], Sheldon H. Jacobson [b]

[a] Department of Operational Sciences, Air Force Institute of Technology, 2950 Hobson Way, Wright-Patterson AFB, OH 45433-7765, United States
[b] Department of Computer Science, University of Illinois at Urbana-Champaign, United States

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ABSTRACT

Vaccination against infectious disease is an extremely important public health endeavor. Yet, in the past 40 years, the manufacture of pediatric vaccines has become less profitable due to rising costs and limited demand, inducing many pharmaceutical companies to leave the market. To ensure the safe, secure, and reliable provision of vaccines, the economic interests of the vaccine industry must be considered by public health policy makers. The monopsonistic market power of the federal government uniquely positions it to significantly influence the pediatric vaccine market by negotiating contractual agreements that increase the vaccine manufacturers' financial incentives to remain in the market. The Monopsonist Vaccine Formulary Pricing and Purchasing Problem (MVF3P) is introduced, which seeks pediatric vaccine prices and purchase quantities that ensure a birth cohort is fully immunized according to the recommended childhood immunization schedule at an overall minimum system cost while also ensuring that vaccine manufacturers each attain a reservation profit level. The practical value of MVF3P is demonstrated by analyzing and assessing pricing and purchasing policies that the Centers for Disease Control could adopt in attempting to actively manage the long-term provision of pediatric vaccines.

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1. Introduction

Vaccination is one of the most important and successful public health endeavors in human history, profoundly reducing the number of mortalities caused by infectious diseases [20,21]. In the United States, the incidence of many childhood diseases has dramatically decreased, even as the number of vaccine-preventable diseases has increased [20]. Yet, by some measures the pediatric vaccine industry is quite fragile [20]. To ensure the safe, secure, and reliable provision of vaccines, the economic interests of the vaccine industry must be considered by public health policy makers.

The United States pediatric vaccine industry consists of a relatively small number of pharmaceutical companies engaged in the research, development, manufacture, and distribution of pediatric vaccines. Participation in the vaccine industry is a difficult, costly, risky, and most importantly, *voluntary* enterprise. All pediatric vaccines distributed in the United States are manufactured by privately held companies, with no obligation to sustain or initiate the production of pediatric vaccines, regardless of the importance of such vaccines to public health [6,29]. Over the past 40 years, the manufacture of pediatric vaccines has become less profitable due to rising costs and limited demand, inducing many pharmaceutical companies to exit the market [6,19]. As of 2010, just six pharmaceutical companies manufacture vaccines for young children, three of which manufacture only one pediatric vaccine [5]. The contraction of the pediatric vaccine market negatively impacts the provision of vaccines. When a vaccine is produced by a small number of manufacturers, production problems create immediate, acute shortages [28]. In order to ensure adequate immunization coverage levels, a robust vaccine industry is vital to the nation's public health and well being.

A substantial number of public health policy experts have highlighted factors that would assist in sustaining the current supply of vaccines, as well as encourage the development of new vaccines [6,11,18–20,22]. Typically, recommendations concerning the vaccine industry's robustness involve financial incentives. For example, Hinman [11] suggests pricing a vaccine in advance based on its estimated social value. McGuire [18] offers an economic model to facilitate the determination of such prices, reporting that while vaccines have high social value (see Zhou et al. [29] for a full analysis concerning the economic benefit of vaccines to society), the vaccine manufacturers do not receive appropriate financial incentives for participation in the market. Many public health experts contend that vaccine manufacturers should earn higher returns on their investments in order to sustain and expand the production of vaccines [6,11,18–20,22].

The monopsonistic market power of the federal government uniquely positions it to significantly influence the pediatric vaccine market by negotiating contractual agreements that increase the

* Corresponding author. Tel.: +1 937 255 3636x4539; fax: +1 937 656 4943.
E-mail address: Matthew.Robbins@afit.edu (M.J. Robbins).

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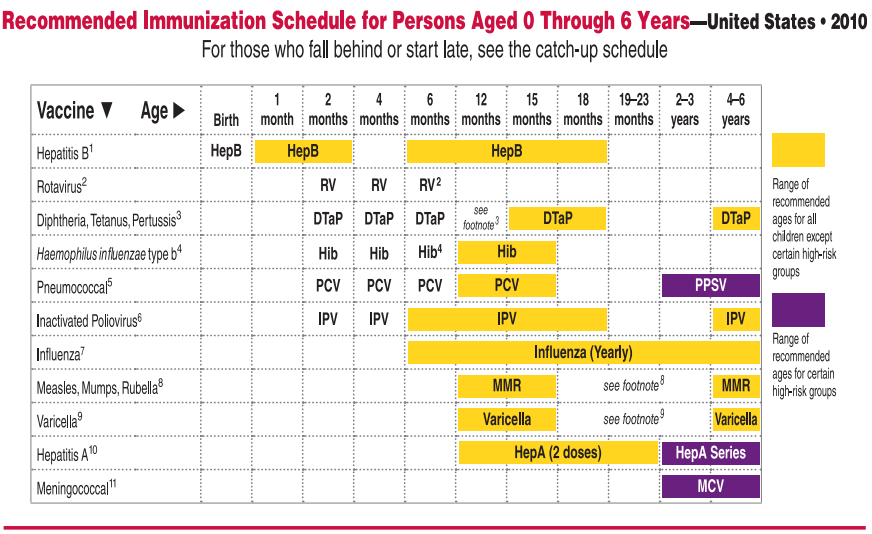

Fig. 1. United States 2010 Recommended Childhood Immunization Schedule (through age 6).

vaccine manufacturers' financial incentives to enter or remain in the market. Pediatric vaccines purchased at the public-sector price, as negotiated by federal government officials at the Centers for Disease Control and Prevention (CDC), account for approximately 57% (by volume) of total pediatric vaccine purchases [11,20]. In the United States, the CDC acts as the primary federal public health organization responsible for setting pediatric immunization policy. Based on recommendations from the Advisory Committee on Immunization Practices (ACIP), the CDC annually publishes a Recommended Childhood Immunization Schedule (RCIS) (see Fig. 1 from [4]) that provides specific guidance regarding the effective control of vaccine-preventable diseases, to include the appropriate periodicity and dosage requirements for each pediatric vaccine. The RCIS serves as the fundamental force driving market demand [6]; vaccine purchasers buy vaccines in order to fully immunize children in accordance with the RCIS. The CDC also maintains a list of acceptable pediatric vaccines (i.e., licensed by the Food and Drug Administration (FDA) [7]) and negotiates discounted prices at which federal, state, and local governments can purchase the vaccines. A model that addresses the short term need to satisfy the RCIS at minimum economic cost while accounting for long-term concerns regarding the vaccine industry's viability provides value to the public health community (specifically, the CDC) and is the focus of this research.

Operations research methods have been applied to the analysis of the United States pediatric vaccine market. Prior research has mostly addressed the selection of an optimal vaccine formulary (i.e., a set of vaccines stocked to satisfy the immunization needs for a population cohort, as defined by a given set of immunization requirements) that satisfies a RCIS at minimum cost [10,15,27] (from the perspective of a vaccine purchaser) or the determination of optimal vaccine prices [14,16,23–25] (from the perspective of a vaccine manufacturer). Weniger et al. [27] introduce an integer program (IP) model to aid health care decision makers in determining a vaccine formulary that minimizes the cost to fully immunize a child according to a given childhood immunization schedule. Jacobson et al. [15] present a full technical description of the model introduced by Weniger et al. [27]. Hall et al. [10] introduce the general vaccine formulary selection problem, providing fundamental insights into the structure of problems concerning minimum cost satisfaction of a childhood immunization schedule. Sewell et al. [25] adopt a "reverse engineering" scheme involving a bisection algorithm to compute a vaccine's maximum inclusion price (i.e., the maximum price at which a vaccine is selected to be part of the lowest overall cost formulary). Sewell and Jacobson [24] present a full technical description of the methods in Sewell et al. [25]. Similar efforts are seen in Jacobson et al. [14,16]. Robbins et al. [23] present a method to optimally price a pediatric vaccine so as to maximize a vaccine manufacturer's expected revenue given an uncertain cost parameter. While these efforts provide analysis tools to help one group of stakeholders in the pediatric vaccine market make decisions, no study has presented a comprehensive approach in which the interests of all stakeholders in the market are simultaneously considered.

This research effort addresses the issue of the pediatric vaccine industry's continuing viability from the perspective of the monopsonistic federal government. The fundamental premise of the analysis is the supposition that the altruistic CDC desires to negotiate pediatric vaccine prices and determine purchase quantities in order to minimize the vaccine system's delivery costs while ensuring that the pharmaceutical companies manufacturing the pediatric vaccines each earn a profit that induces them to remain in the market. The operations research approach presented in this paper defines the Monopsonist Vaccine Formulary Pricing and Purchasing Problem (MVF3P) mixed integer nonlinear program (MINLP) model, which minimizes the weighted sum of the cost to fully immunize a birth cohort according to a given childhood immunization schedule. The model determines optimal vaccine prices and purchase quantities while ensuring that each vaccine manufacturer earns at least a particular amount of profit, with vaccine production quotas, capacities, and price caps respected. The MVF3P MINLP model can be used to design a pricing and purchasing policy for the CDC that establishes a sustainable and stable capital investment environment in which the reliable provision of the pediatric vaccines (so essential to public health) can occur.

The paper is organized as follows. Section 2 presents the MINLP model formulation for the optimization problem MVF3P that determines the set of pediatric vaccine formularies and attendant component vaccine prices and quantities that should be used to satisfy a given childhood immunization schedule for an entire birth cohort. The model minimizes overall system cost while ensuring a sustainable market environment for vaccine manufacturers. Section 3 presents the computational complexity of MVF3P. Section 4 reports the computational results of applying the MVF3P MINLP model to the analysis of CDC pricing and purchasing policies; optimal pediatric vaccine prices and purchase quantities for the current United States pediatric vaccine market are reported. Section 5 provides concluding comments and directions for future research.