



Vaccine Costs and Manufacturer Profits: What is the Right Balance?

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Vitality of United States Pediatric Vaccine Market

- Vaccination is an important public health endeavor
- Despite overall success (e.g., smallpox and polio), the market remains fragile
- Over the past 40 years, pediatric vaccine manufacturing has become less profitable, due to rising costs and limited demand
- Many pharmaceutical companies have exited the market (just six remain; three of which produce just one vaccine)



Market Description

- An interdependent system of stakeholders
- Government (Purchaser, Regulator)
- Congress
 - Centers for Disease Control and Prevention
 - Advisory Comm. on Immunization Practices
 - Food and Drug Administration
 - Local and state public health organizations

- Industry (Supplier)
- Limited number of companies research, develop, manufacture, and distribute vaccines
 - Participation is risky, costly, and *voluntary*
 - No obligation to sustain/initiate production of pediatric vaccines
 - Profit is the primary motivation

Robustness of the Pediatric Vaccine Market

Factors that would assist in sustaining the current supply of vaccines

- Proper financial incentives
- Pricing vaccines based on societal value
- Allow vaccine manufacturers to earn higher returns on their investments in order to sustain and expand production of vaccines

This research addresses the pediatric vaccine industry's continuing viability from the perspective of the federal government

Monopsonistic market power of the federal government place it in a unique position

- Negotiate contractual agreements that increase the manufacturers incentives to enter and/or remain in the market
- Responsible for approximately 57% (by volume) of total pediatric vaccine purchases
- Manage trade-off between minimizing cost and maximizing industry profit

Previous Operations Research Analyses

Addresses the selection of an optimal vaccine formulary or a vaccine's optimal inclusion price

- Encompasses various perspectives
 - Vaccine purchaser – satisfy the RCIS at minimum cost (Hall et al. 2008; Jacobson et al. 1999; Weniger et al. 1998)
 - Vaccine manufacturer – determine optimal vaccine prices (Jacobson et al. 2003; Jacobson et al. 2005; Robbins et al. 2010; Sewell et al. 2003; Sewell et al. 2001)

RCIS

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2010
For those who fall behind or start late, see the catch-up schedule

Vaccine	Age	Birth	1	2	4	6	12	15	18	18-23	2-3	4-6	
		months	months	months	months	months	months	months	months	months	years	years	
Hepatitis B ¹			HepB										
Rotavirus ²				RV	RV	RV ³							Range of recommended ages for all rotavirus vaccines
Diphtheria, Tetanus, Pertussis ⁴			DTaP	DTaP	DTaP	DTaP	DTaP	DTaP					DTaP
Hemophilus influenzae type b ⁵				HiB	HiB	HiB ⁶	HiB						
Pneumococcal ⁷				PCV	PCV	PCV	PCV						PPSV
Inactivated Poliovirus ⁸				IPV	IPV								IPV
Influenza ⁹									Influenza (Yearly)				Range of recommended ages for all influenza vaccines
Mumps, Measles, Rubella ¹⁰					MMR	see footnote ¹¹							MMR
Varicella ¹²					Varicella	see footnote ¹³							Varicella
Hepatitis A ¹⁴									HepA (2 doses)				HepA Series
Meningococcal ¹⁵													MCV

Methodology

Define the Monopsonist Vaccine Formulary Pricing and Purchasing Problem (MVFP3P)

- Mixed Integer Non-Linear Program (MINLP) model
- Determines the set of pediatric vaccine formularies, vaccine prices, and vaccine quantities that satisfy the RCIS for a birth cohort
- Minimizes overall system cost while ensuring a sustainable market environment for vaccine manufacturers (i.e., a given reservation profit level is satisfied)

Model Inputs:

- Number of children in the birth cohort
- RCIS requirements
- Pharmaceutical companies: Reservation profit levels, and vaccines manufactured
- Vaccine production costs
- Minimum production quotas, maximum capacity limitations, and price caps for each vaccine

Results

- Two different CDC pediatric vaccine procurement scenarios (public sector) are examined
 - Scenario 1 – no constraint is placed on the minimum number of doses that must be purchased
 - Scenario 2 – at least 500,000 doses of each vaccine must be purchased
- Examine trade-offs between minimizing costs and increasing robustness of vaccine supply.

Fundamental Insight

Relative low cost of establishing minimum purchasing volume requirements to reduce the risk of vaccine supply interruption that could negatively impacting immunization coverage levels

Period	Formulary 1	Formulary 2	Formulary 3	Formulary 4
1	RECOMBIVAX Hib ^a	RECOMBIVAX Hib ^a	ENCRIBX Hib ^a	RECOMBIVAX Hib ^a
2	Pediasix ^b	RECOMBIVAX Hib ^a	Infanrix ^c	RECOMBIVAX Hib ^a
	PediasixHib ^b	Pentacel ^d	COMVAX ^e	Asstrix ^f
			IPOL ^g	IPOL ^g
3	Pediasix ^b	Pentacel ^d	Infanrix ^c	Tripedix ^h
			PentacelHib ^d	Asstrix ^f
			IPOL ^g	IPOL ^g
4	Pediasix ^b	RECOMBIVAX Hib ^a	Infanrix ^c	RECOMBIVAX Hib ^a
		Pentacel ^d	ENCRIBX Hib ^a	Tripedix ^h
			IPOL ^g	Asstrix ^f
			Asstrix ^f	Asstrix ^f
5	Triaxix ⁱ	Triaxix ⁱ	Infanrix ^c	HiHex ^j
			HiHex ^j	Tripedix ^h
6	Kiixa ^k	Kiixa ^k	Kiixa ^k	Tripedix ^h
			IPOL ^g	IPOL ^g

Conclusions

CDC's vaccine pricing and purchasing policies are critical to the long-term success of public immunization programs

CDC challenge: balance the division of the net benefit

- Improve immunization coverage levels (facilitated by lower purchase costs)
- Appropriate investment in research and development (facilitated by higher prices)

MVFP3P model provides a mathematical framework for analyzing and assessing numerous policies.

- Assist public health policy practitioners to achieve the appropriate balance
- Results presented are a small sample of the different policies that can be evaluated

Limitations

Vaccine purchases are driven by state public health agencies and providers

CDC does not have direct control over specific pediatric vaccine purchases

CDC can not dictate which formulary an agency or provider should use to satisfy the RCIS

Economic factors that may impact overall immunization cost are not included:

- vaccine efficacy, shelf life, storage requirements, reduced handling costs

Results

Scenario 1—vaccine system cost and formulary purchase quantities.

Mfg. profit	Sys. cost	Formulary 1	Formulary 2
Base	\$662.8M	1,993,900	306,100
+25%	\$763.3M	1,474,300	825,700
+50%	\$863.6M	1,150,000	1,150,000
+75%	\$962.9M	1,429,900	880,100

Scenario 2—vaccine system cost and formulary purchase quantities.

Mfg. profit	Sys. cost	Formulary 1	Formulary 2	Formulary 3	Formulary 4
Base	\$703.1M	1,362,700	270,600	500,000	167,700
+25%	\$803.1M	1,171,400	461,900	500,000	167,700
+50%	\$903.2M	980,000	653,300	500,000	167,700
+75%	\$1002.8M	1,088,300	545,000	500,000	167,700