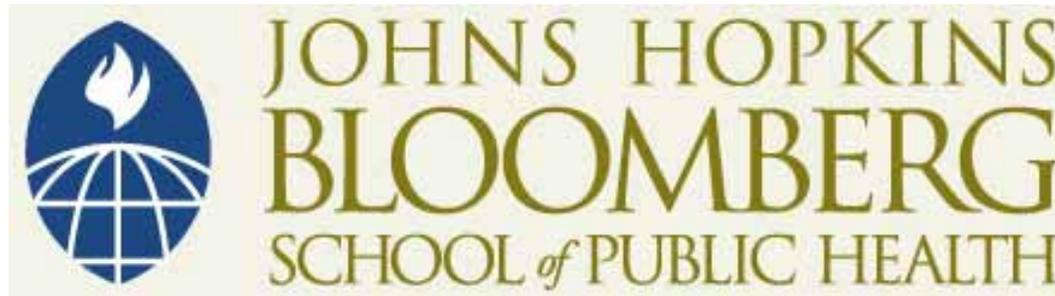


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## *Sustaining Immunization Supply*

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- After listening to, viewing, and studying the lecture materials in this course, you will be able to do the following:
  - Understand key issues affecting sustainable vaccine delivery worldwide
  - Identify and analyze policy problems that determine sustainability



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*Section A*

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Global Immunization Update

- By 1997, 80–95% of children in the U.S. and other **developed countries** were being fully immunized against up to 12 vaccine-preventable diseases
- The incidence of those diseases in the developed world is now virtually nil
- In 1990, the **developing world** reached a high-water mark: around 80% of children were immunized against the six core EPI target diseases (UCI 1990)
- Since then, vaccine coverage has dropped in many countries
- Developing countries still suffer 3 million cases of vaccine-preventable diseases annually
- Gap between rich/poor continues to grow

## *The Sustainability Problem*

- The rising inequality suggests developing-country EPI programs are unsustainable
- UCI 1990 succeeded thanks to prolonged, large-scale, external funding for routine EPI
- As donor inputs decreased, countries stopped investing
  - Many could not meet recurrent costs

## *Sustainability and Eradication*

- The countries continue to receive sizable inputs to eradicate polio, measles—but this will not solve the sustainability problem
- Eradication follows different logics
  - **Economic**: intrinsically cost-beneficial
  - **Pragmatic**: not necessarily dependent on routine program performance
  - **Political**: polities readily organize, support, participate
- In what ways can the polio eradication investments strengthen routine EPI?
- A high-level WHO official identified these specific areas:

*Continued* 6

## *The Sustainability Problem*

- Polio will probably be eradicated in the next few years
- New vaccines, perhaps other eradication efforts may induce more external inputs
- However, long-run, large-scale external funding for EPI programs is not assured
- Conclusion
  - Countries must eventually assume their own immunization costs



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*Section B*

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Global Alliance for Vaccines and Immunization  
(GAVI)

- An important new actor for global immunization is The Global Alliance for Vaccines and Immunization (GAVI)
- **GAVI** consists of counterpart staff from WHO, UNICEF, the World Bank, the Gates Foundation, other non-governmental organizations, and vaccine manufacturers
- **The Vaccine Fund** receives and disburses donor funds to meet GAVI's goals

- Fast track: GAVI began in 2000
- Donors matched an initial US \$750 million grant from the Bill and Melinda Gates Foundation, bringing total Vaccine Fund commitments to US \$1.3 billion by 2004
- GAVI targets the world's 75 poorest countries
- As of July, 2004, GAVI had committed US \$1.08 billion to 70 of them in the form of five-year grants
- As of 2004, GAVI had spent US \$236 million, saving over 500,000 lives
- “Any way you look at it the results are fantastic. Best investment I ever made.” (Bill Gates)

## *Eligibility Criteria*

- Annual per capita GNP less than U.S. \$1,000
- Functioning Interagency Coordinating Committee
- Recent EPI program assessment
- Multi-year plan incorporating assessment recommendations
- A strategy to improve, maintain injection safety

- GAVI awards include a combination of:
  - Funds for plan preparation
  - Vaccine funds
  - Immunization Support Funds to buttress EPI infrastructure
  - Funds for immunization safety
  - Accelerated development of new vaccines (ADIPs)



- Brugha et al (2002) analyzed the initial experiences of GAVI grantees Ghana, Mozambique, Tanzania, and Lesotho
- The GAVI inputs included:
  - Stronger donor coordination
  - Introduction of hepatitis B vaccine and new safe injection equipment
  - Additional operational funding

- Interviews with senior Ministry of Health staff, donor counterparts
- Reviews of interagency coordinating committee minutes
- Rapid assessments of 25 health facilities in one problematic region per country

- GAVI application process too rapid and time-consuming
- Coordination committees ineffectual
- Cold chain, injection safety, outreach, and supervision weak
- Routine service data unreliable
- National budgets for future vaccines nonexistent

## *GAVI in Africa: Positive Results*

- GAVI inputs rapidly reached the countries
- Auto-destruct syringes and other innovative equipment were introduced
- Meeting GAVI's expectations made managers realize routine EPI functions were under-resourced
- Recommendations
  - District, provincial, hospital managers, other senior staff must participate in planning for GAVI support
  - Many more resources needed to buttress EPI delivery systems before GAVI vaccine procurement support can have impacts
  - Start activities on a pilot basis

- In response, GAVI is:
  - Helping the countries improve their data collection and reporting systems
  - Helping the countries prepare and revise EPI financial sustainability plans
  - Working with vaccine suppliers to reduce costs and make multiple-antigen vaccines more available

- Awards tied to performance
  - Countries are expected to show increased DPT3 coverage within three years in order to remain eligible for more funding
- Exit strategy
  - After five years, countries are expected to find alternative funding sources
- Technical inputs
  - Data Quality Assessments (DQAs), Financial Sustainability Plans (FSPs)

- Each grantee country must perform at least one DQA
  - 2001: 6 performed, 1 country passed
  - 2002: 15 performed, 8 passed
  - 2003: 8 more passed
  - 2004: 16 new, 5 second-round DQAs planned
- Reported data are compared, validated from local to national level

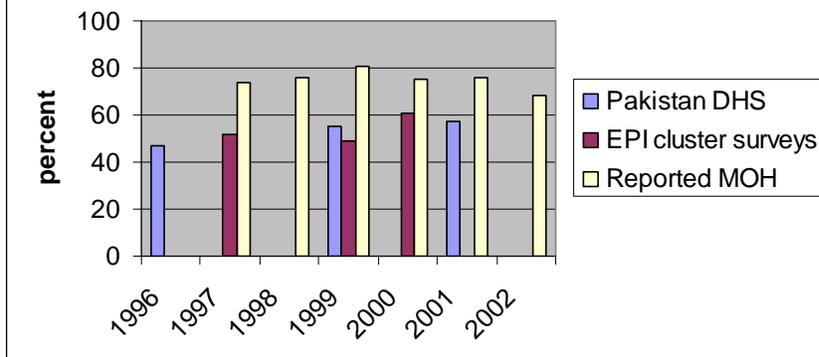
- Verification factor
  - A benchmark for reported data quality
  - Data quality must be at least 80% of expected level
- Quality of the System Index
  - Recording practices
  - Storage and reporting practices
  - Monitoring and evaluation
  - Denominators
  - System design

## DQA Example: Afghanistan 2003

### QSI of Provinces and of their Health Units

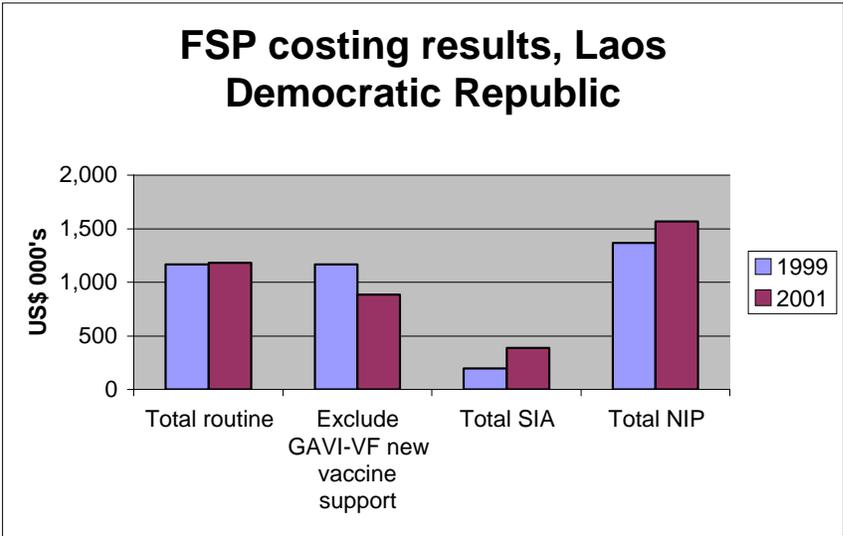
<i>Provinces</i>	<i>Health Units</i>			
	<i>QSI(%)</i>	<i>Average QSI(%)</i>	<i>Lowest QSI(%)</i>	<i>Highest QSI(%)</i>
Kabul	79.4	55.7	46.4	60.7
Ghazni	66.7	58.9	46.4	71.4
Herat	67.6	68.5	46.4	85.7
Bagh lan	31.6	58.9	28.6	82.1
Average QSI	61.3	60.5	28.6	85.7

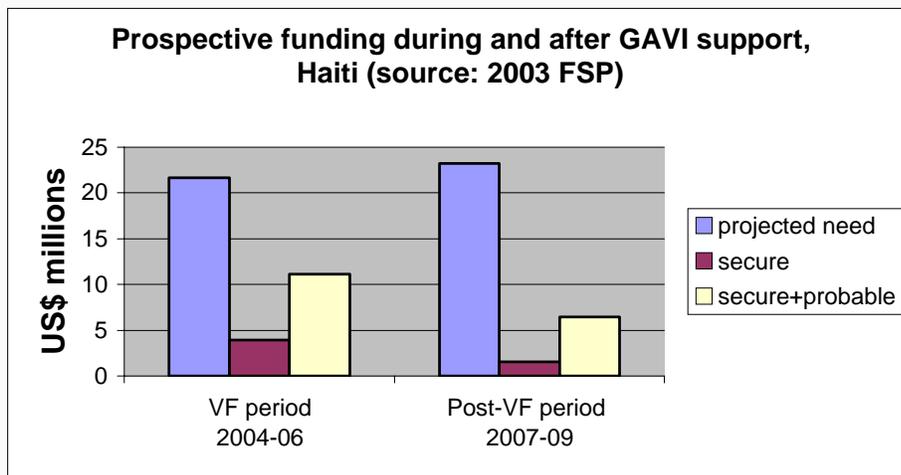
**Percent children 12-23m fully immunized, by year and data source, Pakistan (Source: GAVI 2003)**



- Financial sustainability plans
  - 12 countries in 2002
  - 16 countries in 2003
  - 43 countries total by mid-2004
- Host governments, donor agencies jointly analyze EPI costs, program strategies
- Costs are projected for coming five years
- Sources of funding, funding gaps are identified

FSP costing results, Laos (Source: Laos Ministry of Health)				
Costing	1999	(%)	2001	(%)
1. Operational costs	\$ 956,856	82	\$ 1,020,932	86
Vaccines	\$ 322,920	28	\$ 571,771	48
traditional 6	\$ 322,920		\$ 276,971	
new, underused	\$		\$ 294,800	
Injection supplies	\$ 21,565	2	\$ 43,817	4
Personnel	\$ 170,493	15	\$ 119,600	10
Central level	\$ 10,022		\$ 11,307	
Provincial level	\$ 34,481		\$ 40,722	
District level	\$ 95,331		\$ 109,768	
NID (per diems)	\$		\$	
Transportation	\$ 154,211	13	\$ 86,557	7
Cold chain maintenance	\$ 30,976	3	\$ 19,058	2
Short-term training	\$ 64,581	6	\$ 34,636	3
IEC/social mobilization	\$ 41,904	4	\$ 18,975	2
Monitoring and surveillance	\$ 88,134	8	\$ 91,001	8
Other	\$ 62,073	5	\$ 35,517	3
NID outreach	\$ 53,103		\$ 28,480	
2. Supplemental Immunization Activities	\$ 196,927		\$ 386,539	
3. Capital costs	\$ 211,292	18	\$ 160,696	14
Vehicles	\$ 130,482	11	\$ 110,679	9
Cold chain eqpt	\$ 65,735	6	\$ 42,452	4
Injection equipment	\$ 15,075	1	\$ 7,565	1
Total routine	\$ 1,168,148	85.6	\$ 1,181,627	75.4
Exclude GAVI-VF new vaccine support	\$ 1,168,148	85.6	\$ 886,827	56.6
Total SIA	\$ 196,927	14.4	\$ 386,539	24.6
Total NIP	\$ 1,365,075	100	\$ 1,568,166	100





## *Multiple-Antigen Vaccines*

- New, combined vaccines: GAVI funds their testing, introduction in grantee countries
  - DTP-HepB, DTP-Hib, DTP-HepB-Hib combinations
  - Monovalent HepB, Hib
  - Meningitis AC, rotavirus, pneumococcus
  - Malaria? HIV?

- GAVI is pursuing an intersectoral strategy, working closely with the vaccine industry to ensure availability
- Let's use the problem-solving paradigm to analyze this aspect of the GAVI experience and how it relates to sustainability

## *Problem Definition: Financial Sustainability*

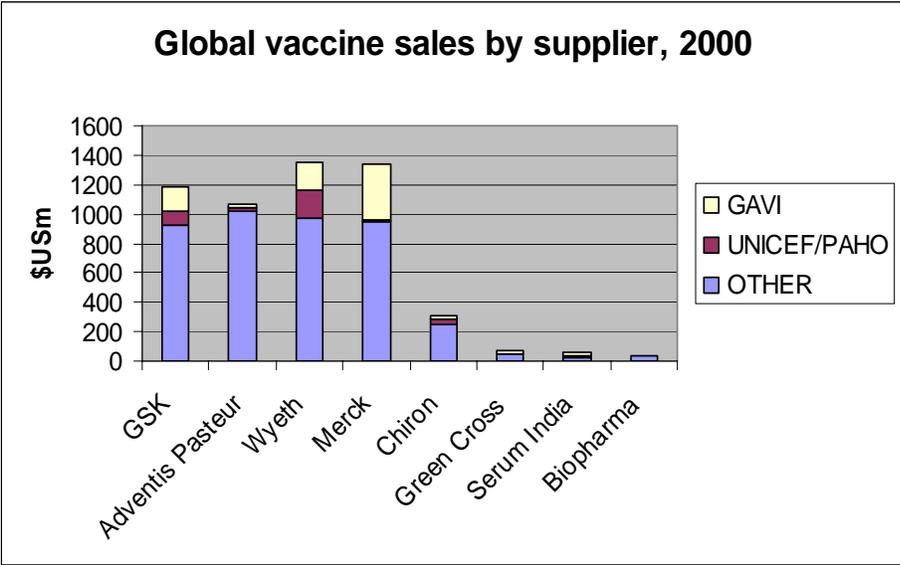
- “Although self-sufficiency is the ultimate goal, in the nearer term, sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety, and equity.”

Source: GAVI Financial Task Force, 1999

## *Magnitude of the Global Marketing Problem*

- A recent report to the GAVI Board (Mercer Management Consulting 2002) showed:
  - The global vaccine market grew from U.S. \$2.9 billion in 1992 to \$6 billion in 2000
  - Industrialized countries represent 82% of revenue, 12% of volume
  - The five largest manufacturers spent an estimated \$750 million on research and development in 1992

Global vaccine sales by supplier, 2000



Notes Available

Source: Mercer Consulting, 2002

## *Conceptualize Determinants*

- For multinational firms, vaccine profitability has risen since 1992, driven by proprietary products and technology substitution in high-income markets
- As industrialized countries' vaccine schedules diverge from those of developing countries, there are fewer opportunities to offset vaccine costs for the latter by charging higher prices in the former (tiered pricing)

## Vaccine Market Segments and Profits

Vaccine Market Segments and Profits (2000)			
<i>Basic Pediatrics</i>	<i>Enhanced Pediatrics</i>	<i>Proprietary Pediatrics</i>	<i>Adult / Travel</i>
OPV	IPV	Pneumococcal, meningococcal conjugates	Hepatitis A
BCG	DTaP	Varicella	Yellow fever
TT	Hepatitis B		Typhoid
DTP	Hib		Influenza
Measles	MMR		
<b>US\$680m</b>	<b>\$2.0b</b>	<b>\$1.7b</b>	<b>\$1.7b</b>

## *Strategy A: Develop LDC Vaccine Suppliers*

- In the past decade, more developing-country firms have become vaccine producers
- These emerging suppliers can produce basic vaccines more cheaply than the multinationals
- However, only the multinationals can profitably produce the newer vaccines
- Developing countries need both sources

## *Strategy B: Develop the New Vaccine Market*

- Developing countries are important to the emerging producers but have little leverage with the multinational producers
- Recommended GAVI procurement strategies:
  - Assure appropriate returns to suppliers
  - Create credible, predictable demand
  - Work closely and openly with multinational producers

## *Implementation and Evaluation*

- In CY2000, vaccine producers received only 18% of the vaccine orders GAVI had forecasted and funded in project countries
- The countries could not move fast enough, nor could their programs deliver that much vaccine
- Conclusion: performance problems are prior to financial problems

Source: Mercer Consulting, 2002

- **More funding needed:** current funds will last only two more years
  - By 2011, the need will be US \$1.037 billion per year compared to current \$400 million annual expenditures
  - Equivalent to half of what men in developed countries spend on Viagra (*The Washington Post*)



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*Section C*

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Decentralization and Privatization

## *Decentralization and Privatization*

- While GAVI addresses financial sustainability, many EPI programs must adjust to structural health sector reforms
  - Decentralization
    - ▶ Move decision making over public goods from central to peripheral levels
  - Privatization
    - ▶ Permit NGOs, commercial providers to offer immunization (economic liberalization)

- In heavily indebted poor countries, immunization and other health programs have been decentralized over the past two decades as part of structural adjustment policies

- A more generalized decentralization trend has affected most developing countries over the past two decades
- Countries are shifting both the authority to raise revenues and the responsibility for delivering services to lower governance levels
- With decentralization comes market liberalization
  - Private sector providers are encouraged to give immunizations, too

- As decentralization progressed during the 1990s, vaccine coverage fell in many countries
- Some of the coverage losses were due to reduced donor inputs and the failure of national governments to provide adequate funding
- Another component was technical
  - Most districts did not have enough adequately trained managers or the administrative agility to deliver immunization programs on their own

## *Implications of Decentralization for Immunization*

- Azfar et al (2000) identify three rationales for decentralization
  - Improve allocative efficiency by increasing demand-responsiveness of public goods and services
  - Increase accountability, cut corruption
  - Promote cost-recovery

## *Implications of Decentralization for Immunization*

- They compared immunization performance following decentralization in the Philippines and Uganda
- Among their conclusions:
  - Despite decentralization, hierarchy remains and there is little local input
  - Local information on program performance is scarce, enabling local elites to divert resources for other uses

- Gallardo et al (2002) studied immunization performance in Bogotá, Colombia, following structural reform
- Colombia's EPI and other public health services were decentralized and privatized in 1990–93
- Vaccine coverage dropped in Bogotá over the 1997–2000 period
- The authors analyzed why this happened

- Colombia's decentralization plan included:
  - Vaccine purchased with national funds, delivery costs paid with local resources
  - Universal insurance through private insurers with immunizations mandatory
  - Immunization delivered through:
    - ▶ Private providers (for those with contributory or subsidized insurance)
    - ▶ Government clinics (for the uninsured)

## *Bogotá: Private Providers and Public Hospitals*

- Private providers
  - Competed for patients
  - Received capitated payments that included immunization fees
- Public hospitals
  - Reimbursed for immunizations from departmental and municipal sources
  - Could not immunize insured individuals
- Bogotá
  - 72% insured
  - 28% uninsured

## *Bogotá: Falling Coverage Levels*

- Responding to the falling coverage levels:
  - Central MOH was unable to compel private providers or public hospitals to implement demand-generating efforts
  - It could only implement remedial vaccination days through public clinics
  - Coverage failed to increase

- The authors attributed the failure to:
  - Vaccine shortages due to delays in central vaccine procurement caused by an economic crisis
  - Divided responsibilities, uncoordinated administrative procedures across private and public sectors
  - Reduced immunization access as providers cut sites to minimize costs

- Khaleghian (2004) studied the effects of decentralization on immunization coverage in 140 lower- and middle-income developing countries from 1980 to 1997
- He used DPT3 and measles vaccine coverage data from the WHO/UNICEF joint reporting system
- Decentralization was indicated by whether states, provinces, or municipalities had taxing, spending, and regulatory authority
- His time-series model controlled for other factors, including GNP, degree of democratization, ethnicity, and external EPI donor involvement

- Findings
  - In low-income countries, decentralization was associated with higher coverage levels
  - In middle-income countries, decentralization was associated with lower coverage levels
  - The cut-point is at about US \$1400 GNP per capita
- In poor countries, the decentralization effect on immunization coverage was equivalent to a 20% increase in literacy levels
- In middle-income countries, decentralization had the effect of a 15% decrease in literacy

- These results raise difficult conceptual issues about immunization sustainability
  - If an immunized population is a public good, what incentives are there for the private sector to help provide it?
  - Without budgetary and legal authority, how can a ministry of health ensure that peripheral health actors follow norms, report, and coordinate efforts?

- A district-level EPI manager facing decentralization will probably have to deal with several kinds of problems
  1. A new “principal-agent” problem: the manager is now the agent, the communities are the principals
    - ▶ Before decentralization, the district manager was the agent of the national EPI manager

2. Provider heterogeneity: how can the manager gain compliance and cooperation from independent-minded private providers?
  - ▶ Meeting technical standards
  - ▶ Reporting and outbreak investigation
3. New advocacy responsibilities
  - ▶ Ensuring local political leaders provide resources
  - ▶ Maintaining public awareness of the need for immunization



- A national EPI manager also faces new roles and responsibilities
  - Ensuring that all districts perform and that none “free ride” (i.e., fail to maintain high vaccine coverage and strong surveillance systems)
  - Providing ever higher quality feedback to peripheral actors
  - Ensuring that public and private providers have adequate performance incentives

- There is no alternative to building public sector capacity for delivering immunization programs
- With decentralization, many more bureaucratic, political, and community actors require technical inputs
- A strong national immunization program is still needed

- In the following sections, we will address the sustainability issue from the demand side
- Later, we will return to the financial and programmatic implications of immunization decentralization



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*Section D*

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Update: U.S. Vaccine Supply

## *U.S. Immunization Situation*

- The U.S. has maintained childhood vaccine coverage levels over 75% since the early 1990s
- Indigenous transmission of the vaccine-preventable childhood diseases eliminated
- Influenza still kills over 20,000 Americans yearly, mainly adults over 65
- Let's trace the evolution of the U.S. immunization program

## *U.S. Immunization Milestones: 1955–1962*

- 1955
  - Federal government helps states buy inactivated polio vaccine (IPV)
- 1960
  - One-time bulk purchase of an OPV stockpile for states to stop polio epidemics
- 1962: Vaccination Assistance Act (**Section 317** of the Public Health Service Act)
  - Aimed to equalize vaccine coverage
  - Provided technical support (surveillance, management) to states
  - Federal government negotiated vaccine prices

## *U.S. Immunization Milestones: 1965–1986*

- 1965–1989
  - Five inexpensive vaccines in use: smallpox, DPT, IPV, OPV, measles
  - Half of vaccinations were given in private, half in public sector
- 1986: National Childhood Vaccine Injury Compensation Program instituted
  - Federal government indemnifies vaccine manufacturers from legal liability for vaccine adverse events

## *U.S. Immunization Milestones: 1989–1991*

- 1989–1991: U.S. measles epidemic
  - Over 55,000 cases, 123 deaths, mainly preschool children
  - Revealed urban, rural inequities
  - Following the epidemic, Section 317 amended allowing funding for vaccine administration

## *U.S. Immunization Milestones: 1990s*

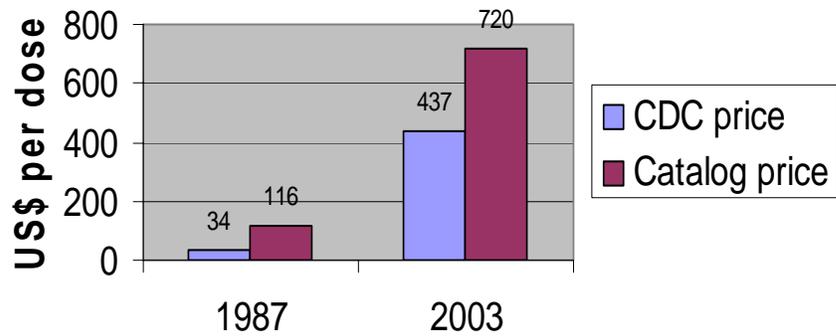
- 1990s
  - Costs increased dramatically as new and combined vaccines were added to the schedule
  - Section 317 funding varied from U.S. \$220 million to \$150 million annually
  - Private providers increasingly refer uninsured, underinsured to public immunization clinics
  - High-risk, under-immunized populations grew

## *U.S. Immunization Milestones: Vaccines for Children Act*

- 1993: Vaccines for Children Act
  - Federal entitlement to free vaccines for uninsured, underinsured, poor children
  - Government purchases vaccines directly on recommendations from CDC's Advisory Committee on Immunization Practices, not subject to annual Congressional approval
  - Allowed privatization: vaccinations in "medical home"
  - By 1996, VFC providers covered >75% U.S. children
  - In 2002, the private sector purchased 43% of all children's vaccines; VCA purchased 41%; and state/local governments purchased the rest<sub>66</sub>

- Positives
  - Vaccine coverage at an all-time high
  - No measles circulating since 2000
  - Registries reaching 44% of children
- Negatives
  - Just 65% of adults age 65 and over receive influenza and pneumococcal vaccines
  - Persistent racial, ethnic disparities in coverage
  - Vaccine shortages since 2000

### Public and private sector costs for US childhood vaccines



## *Case Study: Pneumococcal Vaccine*

- Hinman et al (2004) analyzed the impacts of introducing pneumococcal vaccine (PCV7) to the U.S. schedule in 2000
- PCV7 doubled public sector vaccine costs
- By 2003, Section 317, other public funding, were inadequate to meet costs
- 19 states turned to a two-tier system
  - VFC-eligible children continued to receive PCV7; others could not

## *Conceptualize Determinants*

- 53% of children under five have private insurance immunization benefit (Institute of Medicine, 2003)
- Fluctuations in Section 317 funding reduce public sector immunization delivery for the remainder of children
- Section 317 funding cannot be used to reimburse private immunization providers
- Even costlier vaccines are on the way

- As out-of-pocket costs rise, providers shift patients to public facilities, parents abandon the schedule
- To remedy the situation, the IOM (2003) recommended:
  - A government-subsidized mandate to all public and private health plans to provide all recommended vaccines
  - Subsidies to cover these additional costs, based on the societal benefits and costs of each vaccine (“value-based pricing”)
  - Vouchers for uninsured populations
- The federal government has yet to implement these IOM recommendations

- Global inequities in the availability and affordability of immunizations persist
- The advent of new vaccines has dramatically increased costs
- The poorest countries have little prospect of meeting these costs themselves
- Market incentives for vaccine manufacturers are weak