

Strategies for introduction of new vaccines

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Immunizations

- Most cost-effective health intervention
- <\$20/yr of life saved
- 2-3 million additional lives could be saved
 - Better use of under-used vaccines
 - ▶ Hib
 - ▶ HepB
 - Introduce new vaccines
 - ▶ Pneumo
 - ▶ Rota virus



Incidence of 9 harmful diseases in US reduced by >98% through vaccination

Disease	Max number of cases	Number of cases in 2002	Reduction (%)
Small Pox	48,164 (1901-04)	0	100
Polio	21,269 (1952)	0	100
Diphtheria	206,939 (1921)	1	99.99
Measles	894,134 (1941)	44	99.9
Rubella	57,686 (1969)	18	99.78
Mumps	152,209 (1968)	270	99.86
Pertussis	265,269 (1934)	9771	98.20
<i>H influenzae b</i>	20,000 (1992)	<100	98.79
Tetanus	1,560 (1923)	25	98.44

MMWR 48:577-581, 1994



Recommended Childhood and Adolescent Immunization Schedule UNITED STATES • 2006

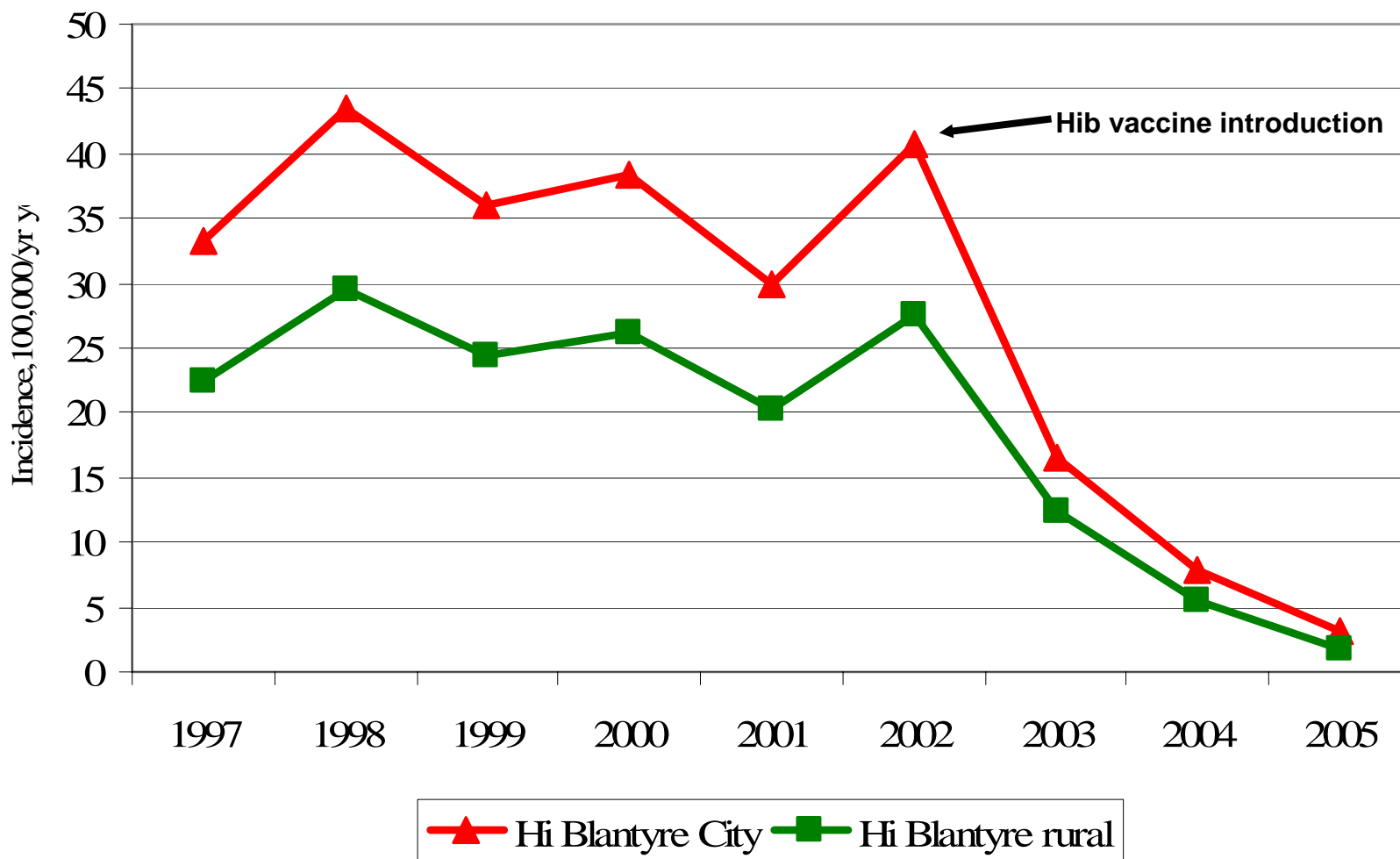
Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	24 months	4–6 years	11–12 years	13–14 years	15 years	16–18 years
Hepatitis B ¹	HepB		HepB	HepB ¹	HepB			HepB Series							
Diphtheria, Tetanus, Pertussis ²			DTaP	DTaP	DTaP	DTaP				DTaP	Tdap	Tdap			
<i>Haemophilus influenzae</i> type b ³			Hib	Hib	Hib ³	Hib									
Inactivated Poliovirus			IPV	IPV	IPV				IPV						
Measles, Mumps, Rubella ⁴						MMR				MMR	MMR				
Varicella ⁵						Varicella				Varicella					
Meningococcal ⁶								Vaccines within broken line are for selected populations		MPSV4		MCV4		MCV4	
Pneumococcal ⁷			PCV	PCV	PCV	PCV				PCV	PPV				
Influenza ⁸					Influenza (Yearly)			Influenza (Yearly)							
Hepatitis A ⁹									HepA Series						

US child: 13 antigens →

Indian child: 6 antigens →



Decline of Hib meningitis following introduction of Hib conjugate vaccines, children <5 yrs, Malawi 1997-2005



Source: Daza P, et al. Vaccine 2006

Division of Epidemiology and Communicable Diseases



Need for new vaccines

- Pathogens that have circulated for long but existence ignored
 - Hep B
 - Hib
 - Pneumococcal diseases
 - Rota virus
- Old pathogens have changed geographical habitat and introduced into newer areas
 - Chikungunya
 - West Nile
- New pathogens have emerged
 - SARS
 - Avian Flu
- Pathogens thought to be controlled have re-emerged
 - *M tuberculosis*



Framework for decision making on introduction of new vaccines

1. Is the disease a public health problem?
2. Is immunization the best control strategy for this disease?
3. Is the immunization programme working well enough to add a vaccine?
4. What would be the net impact of the vaccine?
5. Is the vaccine a good investment?
6. How will be the vaccine funded?
7. How will the addition of the new vaccine be implemented?



Is the disease a public health problem?

- Disease burden studies
- Other methods
 - Include new diseases in routine surveillance for which vaccines are available
 - Congenital rubella syndrome
 - Hep B
 - Special laboratory surveillance
 - Influenza
 - Rota virus
 - Measles
 - Community based sero-surveys
 - Rubella
 - Probe study (difficult to diagnose)
 - Hib



Is immunization the best control strategy for this disease?

● Management prolong and difficult

- JE: encephalopathy

- HepB: chronic hepatitis, cancer

- Rubella: congenital malformations

● Develop skills

- Cost-effective studies

- Immunological correlates of protection

- Duration of immunity



Programme related aspects of introduction of new vaccines

- Improve cost effectiveness of programme by reducing costs
 - More efficient mix of delivery strategies
 - Reduce vaccine wastage
 - Combination vaccines
 - ▶ DPT+HepB (Q-vac, SII) (Shantetra, Shantha Biotech)
 - ▶ DPT+HepB+Hib (Panacea + Chiron)
 - New routes of administration
 - ▶ Intradermal rabies
 - ▶ Aerosol measles
 - Review EPI schedule



Funding introduction of newer vaccines

● Newer Financial methods

- Innovative funding mechanisms put forward by Innovative Funding Mechanisms put forward by International Finance Facility for Immunization (IFFIm)
- Advance Market Commitments
 - Accelerated development of new vaccines
 - Ensure availability of new vaccines at affordable price



Evaluation of New Vaccines

■ Development of skills

- Disease burden estimation
- Large scale clinical trials
- Development of trial sites
- Cost-effective and cost benefit studies
- Quantify non-health benefits
- Studies on interference with other vaccines
- Adverse events following immunizations

■ Regulatory aspects

- Streamlining procedures for approvals
- Strengthening DCGI



Risk communication

- Movement against vaccines
 - Thimerosal controversy
 - Autism to MMR
 - Polio
 - Relation between Hib and diabetes

