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## *Vaccines and Vaccination Program Essentials*

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- **Vaccine:** “A preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease” – Merriam-Webster Dictionary, 2005



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*Section A*

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History of Vaccines

- **1000 AD:** first records of Chinese variolation
- **1721:** Lady Mary Wortley Montagu, wife of British ambassador to Turkey, has first variolation in England performed on her three-year-old daughter
- **1796:** Edward Jenner uses cowpox viruses to vaccinate a child against smallpox

- **1881:** Louis Pasteur, Emile Roux, and Charles Chamberland publicly immunize livestock against anthrax
- **1885:** Pasteur vaccinates a nine-year-old boy against rabies
- **1896:** Richard Pfeiffer and Almoth Wright independently develop heat-inactivated typhoid vaccine

## *Vaccine Timeline*

- **1921:** Camille Calmette and Alphonse Guerin develop attenuated BCG vaccine
- **1955:** Jonas Salk's inactivated polio vaccine
- **1960:** Albert Sabin's live attenuated oral polio vaccine
- **1963:** first measles vaccine licensed in United States

## *Vaccine Timeline*

- **1971:** live attenuated measles/mumps/ rubella (MMR) vaccine licensed in United States
- **1981:** recombinant DNA hepatitis B vaccine
- **1985:** first Haemophilus influenzae B (Hib)
- **1989:** conjugate Hib vaccine licensed
- **2000:** pneumococcal conjugate vaccine (PCV) licensed



## Morbidity Comparison

Comparison of 20<sup>th</sup> Century Annual Morbidity and Current Morbidity, Vaccine-Preventable Diseases

| Disease   | 20th Century Annual Morbidity <sup>†</sup> | 2003* (Provisional) | Percent Decrease |
|---|--|---------------------|------------------|
| Diphtheria  | 175,885                                    | 1                   | 99.99%           |
| Measles   | 503,282                                    | 42                  | 99.99%           |
| Mumps   | 152,209                                    | 197                 | 99.87%           |
| Pertussis   | 147,271                                    | 8,483               | 94.29%           |
| Polio (paralytic)                                     | 16,316                                     | 0                   | 100%             |
| Rubella   | 47,745                                     | 7                   | 99.99%           |
| Congenital Rubella Syndrome                           | 823  | 0                   | 100%             |
| Tetanus   | 1,314                                      | 14                  | 98.93%           |
| <i>H. influenzae</i> ,<br>type b and unknown (<5 yrs) | 20,000 <sup>‡</sup>                        | 213                 | 98.94%           |

<sup>†</sup> Source: CDC. *MMWR* April 2, 1999. 48: 242-264

<sup>\*</sup> Source: CDC. *MMWR* January 9, 2004. 52:1277-1300

<sup>‡</sup> Data are estimated.

Numbers in yellow indicate at or near record lows in 2003

▼ Notes Available

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This favorite slide of Walt's demonstrates continued success of the program in achieving and maintaining record lows in virtually all of the vaccine-preventable diseases listed as indicated in yellow





- <http://www.cdc.gov/nip/recs/child-schedule.htm#Printable>

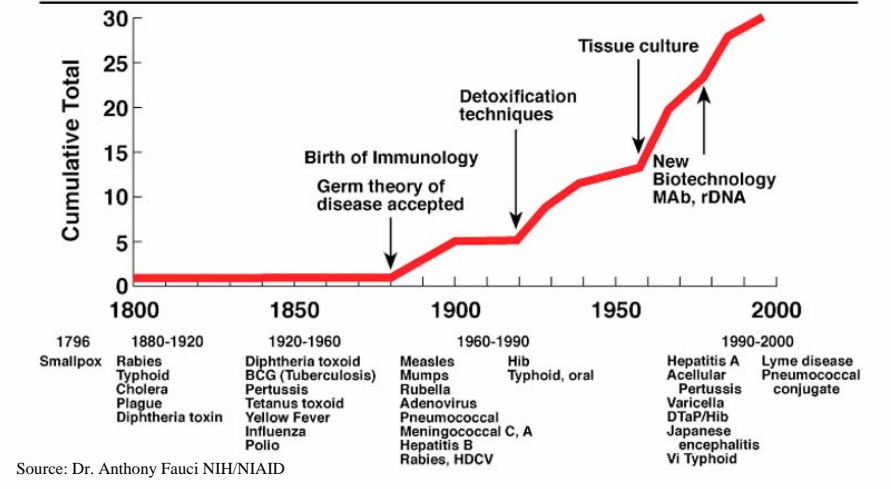
## WHO-Recommended Vaccination Schedule

| <i>WHO-Recommended Vaccination Schedule</i>                      |                                  |                 |                 |
|--|----------------------------------|-----------------|-----------------|
| <i>Age</i>   | <i>Vaccine</i>                   | <i>Scheme A</i> | <i>Scheme B</i> |
| Birth  | <b>BCG, OPV</b>                  | <b>HB1</b>      |                 |
| 6 weeks  | <b>DPT1, OPV1</b>                |                 |                 |
| 10 weeks   | <b>DPT2, OPV2</b>                |                 | <b>HB2</b>      |
| 14 weeks   | <b>DPT3, OPV3</b>                | <b>HB3</b>      | <b>HB3</b>      |
| 9 months   | <b>Measles</b>                   |                 |                 |
|  | Yellow fever (where risk exists) |                 |                 |
|  | Hepatitis B Vaccine**            |                 |                 |
| **According to perinatal transmission rates<br>From UNICEF, 1996 |                                  |                 |                 |

## Increased Demands



## Introduction of New Vaccines, Jenner to the Present Day



▼ Notes Available

Source: Bruce Gellin, MD, MPH, Executive Director, National Network for Immunization Information. May 31, 2001, National Immunization Conference

## *Live Attenuated Vaccines*

- Attenuated (weakened) form of the “wild” virus or bacteria
- Must replicate to be effective
- Immune response similar to natural infection
- Usually effective with one dose



## *Inactivated Vaccines*

- Generally require 3–5 doses
- Immune response mostly humoral
- Antibody titer falls over time
- Principal antigen may not be defined

## *Types of Vaccines*

- Inactivated
  - DPT, TT, DT
  - IPV
  - Hib
  - HepB
- Live attenuated
  - BCG
  - OPV
  - Measles, MMR

- There are no contraindications to simultaneous administration of any vaccines—except cholera and yellow fever vaccines
- Increasing the interval between doses of a multi-dose vaccine does not diminish the effectiveness of the vaccine
- Decreasing the interval between doses of a multi-dose vaccine may interfere with antibody response and protection
- It is not necessary to restart the series of any vaccine\* due to extended intervals between doses  
\* (except oral typhoid vaccine in some circumstances)

- Most routine childhood vaccines are effective for 85% to 95% of recipients

Source: WHO

## Vaccine Adverse Reactions

- Adverse reaction
  - Extraneous effect *caused by the vaccine*
  - “Side effect”
- Adverse event
  - Any event following a vaccine
  - May be true adverse reaction
  - May be only coincidental

Estimated Serious Adverse Events Rates  
Following Some Childhood Vaccines

| <i>Vaccine</i>           | <i>Estimated Rate</i>                          |
|--------------------------|--|
| BCG                      | 1 in 1,000 to 1 in 50,000 doses                |
| OPV (Oral polio vaccine) | 1 in 3 million doses for the first dose of OPV |
| Measles                  | 1 in 1 million doses                           |
| DTP                      | 1 in 750,000                                   |

Source: WHO

## *Contraindications and Precautions*

- **Contraindication**

- A condition in a recipient that greatly increases the chance of a serious adverse reaction

- **Precaution**

- A condition in a recipient that may increase the chance of an adverse event
- May compromise the ability of the vaccine to produce immunity

## *Contraindications and Precautions*

- Permanent contraindications to vaccination
  - Severe allergy to a prior dose of vaccine or to a vaccine component
  - Encephalopathy following pertussis vaccine
- In fact, serious adverse reactions to vaccination are rare, and the misdiagnosis of precautions and contraindications is a leading cause of missed vaccination opportunities





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*Section B*

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National EPI Programs: The Developing World  
and the United States

## Anatomy of an EPI Program



## *The World Bank's National EPI Program Checklist*

- 1.** Formally designated national EPI manager
- 2.** Multiyear plan of action with both coverage and disease-reduction goals
- 3.** MOH budget line item for immunization
- 4.** At least 80% vaccine coverage nationwide

▼ Notes Available

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Source: World Bank, 2002

| Integrated EPI Budget |              |                   |    |           |            |           |              |        |      |             |           |                |   |
|-----------------------|--------------|-------------------|----|-----------|------------|-----------|--------------|--------|------|-------------|-----------|----------------|---|
| Component             | Type of Cost | External—Partners |    |           |            |           |              |        | Gov. | Grand Total | Shortfall |                |   |
|                       |              | WHO               |    | Total WHO | E.g. USAID | E.g. JICA | E.g., UNICEF | Others |      |             |           | Total External |   |
|                       |              | Regional          | WR |           |            |           |              |        |      |             |           | \$             | % |
| Immunization Services | Inv.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Rec.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Tot.         |                   |    |           |            |           |              |        |      |             |           |                |   |
| Logistics             | Inv.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Rec.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Tot.         |                   |    |           |            |           |              |        |      |             |           |                |   |
| —                     | Inv.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Rec.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Tot.         |                   |    |           |            |           |              |        |      |             |           |                |   |
| —                     | Inv.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Rec.         |                   |    |           |            |           |              |        |      |             |           |                |   |
|                       | Tot.         |                   |    |           |            |           |              |        |      |             |           |                |   |

TYPE: Rec. = Recurrent; Inv. = Investment

## *Interagency Coordination*

- A single, multi-year work plan with major government, donor inputs specified
- Inputs by functional area (e.g., logistics, training, surveillance) and year
- Recurrent, capital costs shown separately

## *The World Bank's National EPI Program Checklist*

- 5.** Quality of vaccine used is assured
- 6.** Injection practices assessment conducted, auto-disposable syringes in use
- 7.** Vaccine management system (stock management, cold chain, use of cold monitors, etc.) adequate

▼ Notes Available

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Source: World Bank, 2002

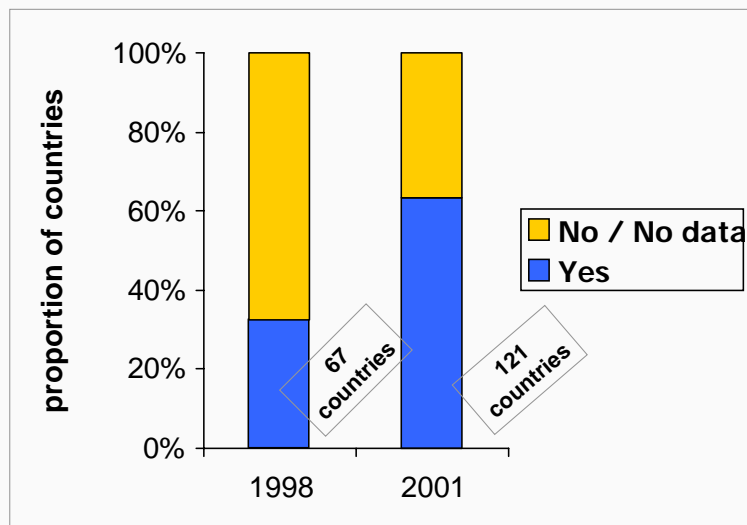
## *The World Bank's National EPI Program Checklist*

- 8.** EPI, other PHC services integrated at every opportunity
- 9.** Regular district-level staff training, retraining
- 10.** Communication strategy, public awareness plan implemented
- 11.** Country on track to eradicate polio

Source: World Bank, 2002

## Written Feedback on Immunization to District Level

- (At least every quarter, 1998–2001)



▼ Notes Available

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Source: WHO/UNICEF joint reporting form, 1998, 2001 data from 191 WHO member states



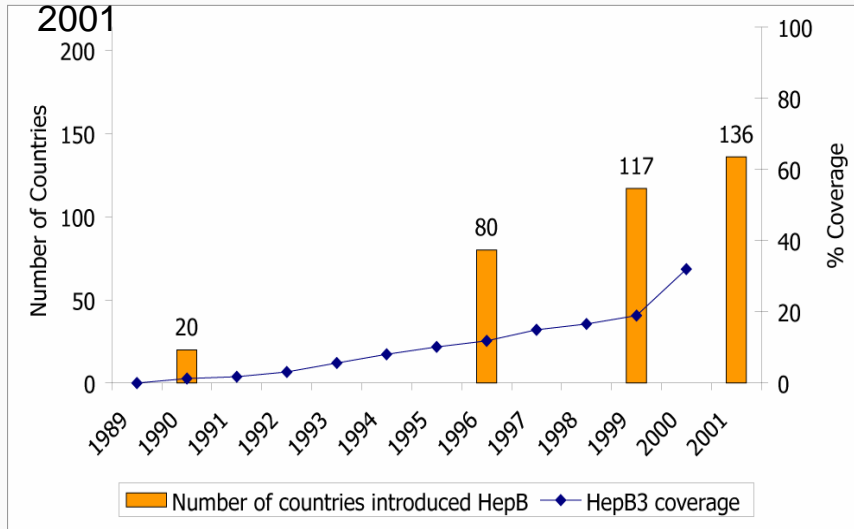
## *The World Bank's National EPI Program Checklist*

- 12.** Surveillance system functioning well
- 13.** Hepatitis B, yellow fever, H. influenzae b disease burdens estimated
- 14.** Multi-year plan budgets for introducing new vaccines

Source: World Bank, 2002

## Hepatitis B Vaccine

- Number of countries introduced Hepatitis B vaccine and global Hepatitis B3 coverage, 1989–



- What does the U.S. National Immunization Program look like?

## *U.S. National Immunization Program*

- A mix of federal, state, and local government—as well as private sector providers
- 60% of vaccinations given by private sector in 1999
- Increasing private sector share due to increasing coverage by Medicaid and Childhood Health Insurance Program

*Continued* 35

## *U.S. National Immunization Program*

- About 80% of all U.S. vaccines are publicly provided; 53% are purchased for states by CDC through the Vaccines for Children Program, begun in 1994
- Grants to states and territories to strengthen immunization programs
- Continuous epidemiological surveillance, vaccine monitoring, research
- Increasing international involvement

## *U.S. State and Municipal Immunization Programs*

- Manage public immunization sites
- Supervise both public and private providers
- Operate immunization registries
- Investigate local outbreaks
- Provide health education

## *U.S. National Vaccine Advisory Committee Standards*

- Immunization services are readily available
- No barriers or unnecessary prerequisites to the receipt of vaccines
- Immunization services free or for a minimal fee
- Providers utilize all clinical encounters to screen for needed vaccines
- Providers educate parents and guardians
- Providers question parents and guardians about contraindications, advise them of risks, benefits
- Providers follow only true contraindications
- Providers administer simultaneously all vaccine doses for which a child is eligible

*Continued* 38

## *U.S. National Vaccine Advisory Committee Standards*

- Providers use accurate, complete recording procedures
- Providers co-schedule immunization appointments with appointments for other child-health services
- Providers report adverse events
- Providers operate a tracking system
- Providers appropriately manage vaccines
- Providers conduct semi-annual audits

*Continued* 39



## *U.S. National Vaccine Advisory Committee Standards*

- Providers maintain up-to-date, easily retrievable medical protocols
- Providers practice patient-oriented and community-based approaches
- Vaccines are administered by properly trained persons
- Providers receive ongoing education and training



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*Section C*

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Evolution of Vaccination Programs

- **Circa 1900:** U.S., European governments begin routine smallpox vaccination of high-risk groups (port, transportation, health care workers, etc.)
- **1955:** Advent of IPV stimulates systematic mass polio vaccination campaigns in developed countries

## *Smallpox Eradication*

- **1956:** WHO calls for smallpox eradication
- **1967:** WHO effort begins; countries soon attain high vaccine coverage, develop active surveillance and case containment
- **1977:** Last smallpox case occurs in Somalia
- **1980:** WHO certifies smallpox eradication

## *Expanded Program on Immunization*

- **1974:** EPI launched; LDC coverage ~ 5%
- **1977:** WHO sets 1990 target for Universal Childhood Immunization (UCI)
- **1980:** All LDCs have national EPI programs; coverage ~ 20%
- **1990:** UCI achieved: 90% of LDC children 0–11 months immunized against the six EPI target diseases
- **2002:** 72% of LDC children 8–23 months receiving DTP3, 78% receiving OPV3 or IPV3

Source: WHO/UNICEF



- **1985:** PAHO sets 2000 polio eradication goal for Americas Region
- **1988:** WHO adopts 2000 global eradication goal; polio incidence ~ 350,000 cases/year
- **1991:** Last confirmed wild poliovirus case in the Americas

- **1994:** Polio eradication certified in the Americas region
- **2001:** 480 polio cases worldwide, confined to 10 LDCs
- **2005:** Revised target for certifying global eradication



## *Vaccination as an Organizational Accomplishment*

- Through UN, governments cooperate multilaterally to vaccinate, eradicate diseases
- Nations have developed EPI programs, disease eradication capabilities
- Donor agencies routinely coordinate inputs

## *Interagency Coordination*

- **1977:** WHO, UNICEF issue Alma-Ata Declaration, which incorporates EPI
- **1984:** UNICEF, WHO, UNDP, World Bank, and Rockefeller Foundation join forces for UCI—1990
- **1988:** WHO, UNICEF, Rotary International, U.S. Centers for Disease Control form Global Polio Eradication Initiative

*Continued* 49

- **1999:** Bill & Melinda Gates Foundation, WHO, UNICEF, World Bank, and other donor and technical agencies form the Global Alliance on Vaccines and Immunization (GAVI)  
<http://www.vaccinealliance.org/>

## *Vaccination as an Organizational Accomplishment*

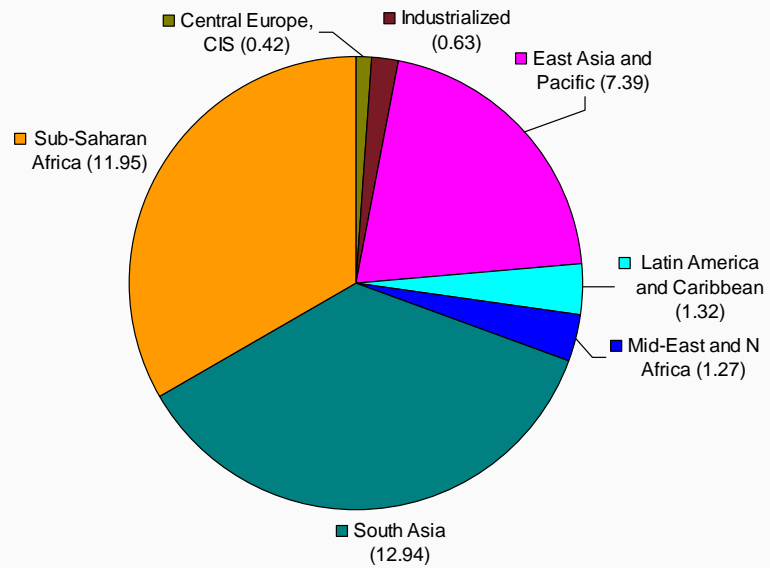
- Through UN, governments cooperate multilaterally to vaccinate, eradicate diseases
- Nations have developed EPI programs, disease eradication capabilities
- Donor agencies routinely coordinate inputs
- **Communities are educated, mobilized**



## *But Operational Problems Persist*

- Still 3 million deaths per year from EPI target diseases

## 36 Million Children Not Immunized (DTP3), 2001



▼ Notes Available

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Source: WHO/UNICEF estimates, 2002





## *But Operational Problems Persist*

- Still 3m deaths/yr from EPI target diseases
- Expanding vaccination schedule increases client-provider dependency

## *But Operational Problems Persist*

- Still 3m deaths/yr from EPI target diseases
- Expanding vaccination schedule increases client-provider dependency
- Increasingly complex delivery systems require more management support



## *But Operational Problems Persist*

- Still 3m deaths/yr from EPI target diseases
- Expanding vaccination schedule increases client-provider dependency
- Increasingly complex delivery systems requires more management support
- Populations still unvaccinated most difficult

*Continued* 59

*But Operational Problems Persist*



- Eradication efforts may weaken routine EPI
- LDCs unable to finance vaccination efforts
- AIDS decimating health manpower
- Global migration flows increase disease transmission, risk of reintroduction

## *If Community-Level Program Efforts Wane*

- Disease risks increase
- Stocks of health knowledge decrease
- Potential for other forms of collective action is lost

## *For Some Problems, There Are Effective Interventions*

- To increase community demand
  - Client reminder-recall methods
  - Mass media, community education
  - School immunization requirements

Source: Task Force on Community Preventive Services, 2000



## *For Some Problems, There Are Effective Interventions*

- To increase access to immunizations
  - Reduce out-of-pocket costs
  - Increase clinic hours, convenience
  - Link to other programs
  - Home visits

Source: Task Force on Community Preventive Services, 2000

## *For Some Problems, There Are Effective Interventions*

- To improve provider efficiency
  - Provider reminder-recall methods
  - Periodic assessment, feedback
  - Standing orders

Source: Task Force on Community Preventive Services, 2000

## *Less Is Known About Sustainability*

- Once attained, how does the community maintain high vaccine coverage?
- Some promising theories to build on
  - Collective action
  - Social learning
  - Trust

- Vaccines are a powerful public health tool
- Vaccination programs are multilevel collective action exercises
- Interventions exist to strengthen them
- More research is needed to understand how they are sustained