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Published on *GiveWell* (http://givewell.org)

Program: Expanding immunization coverage for children

In a nutshell

- **The Problem:** Diseases that cause death and disability, such as yellow fever, measles, diptheria, tetanus, and pertussis. Further information on these diseases can be found here.
- **The Program:** Expanding immunization coverage for basic vaccines to reach more children in the developing world.
- **Track record:**. There's strong evidence that (a) the set of vaccines reviewed below provide protective immunity against the targeted diseases and (b) that vaccination delivery programs have succeeded when implemented across large geographic areas.
- **Cost-effectiveness:** Expanded vaccine coverage is among the most cost-effective programs we've considered. In Sub-Saharan Africa, available estimates claim that it costs approximately $14 to fully vaccinate a child and $200 to save a life with this program.
- **Bottom line:** This is a proven, cost-effective method for saving lives in the developing world.

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Basics of the program

What is the program? What problem does it target?

Immunizations protect against childhood, communicable diseases, which can result in death and severe debilitation. In this report we consider the nine vaccines that are recommended

by the WHO for national use:[1]

- **Vaccines originally included in the Expanded Immunization Program,** the World Health Organization's basic vaccination campaign: Diphtheria, Tetanus, Pertussis, Polio, Measles, and the BCG vaccine to prevent tuberculosis in infants and young children.[2]
- **Vaccines added to campaigns:** Haemophilus influenzae Type b (Hib), Hepatitis B, and Yellow Fever. [3]

What are the components required to implement this program - how does it work?

The Expanded Immunization Program, the WHO's initiative to improve immunization coverage, focuses on the following four items:[4]

- Standardizing immunization schedules
- Promoting safe injection technologies
- Improving the stocking and availability of vaccines
- Protecting vaccines' potency through cold chain management

How many doses of each vaccine should a child receive?

Some vaccines require only one dose while others require more. Here, we provide current WHO recommendations:[5]

- DTP3: 3 doses
- BCG: 1 dose
- Measles: 2 doses
- Polio: 3 doses
- Yellow Fever: 1 dose
- Hepatitis B: 3 doses
- Haemophilus influenzae Type b (Hib): 3 doses

Program track record

Micro evidence: Has this program been rigorously evaluated and shown to work?

We have not reviewed the initial clinical trials for all the vaccines included below because they are well accepted in the medical community as effective. Below we provide brief quotes taken from the WHO's Vaccine Position Papers, with more context in the footnotes and links to the full papers.[6] Some of the quotes below use the term "seroconversion." Seroconversion refers the "the development of detectable antibodies in the blood directed against an infectious agent," a sign that an immunization is effective.[7]

- **DTP, for diphtheria, tetanus and pertussis:** We present evidence for each vaccine individually.
  - *Diptheria*: "95.5% protective efficacy among children.... Protection increased to 98.4% after 5 or more doses."[8]
  - *Pertussis*: "Despite major differences in the contents, mode of preparation and efficacy among both wP and aP vaccines, comprehensive clinical trials have demonstrated that the most efficacious vaccines of either category will protect 85% of the recipients from clinical disease"[9]

    - *Tetanus*: "efficacy and the effectiveness of tetanus toxoid are well documented. In most clinical trials, efficacy has ranged from 80% to 100%."[10]
- **BCG**: "BCG ... provides protection against TB meningitis and the disseminated form of the disease in infants and young children. ... Thousands of lives have thus been saved through BCG vaccination over the years. The vaccine is relatively safe, inexpensive and requires only one injection."[11]
- **Measles:**""In most developing countries, children are vaccinated against measles at 9 months of age, when seroconversion rates of 80–85% may be expected."[12]
- **Polio:** "If IPV is administered in a WHO/EPI schedule (6, 10, 14 weeks of age), seroconversion to IPV has varied from 67% to 99% against type 1, 65% to 99% against type 2, and 91% to 100% against type 3."[13]
- **Yellow Fever:**"Highly efficacious... following immunization, up to 99% of vaccines show protective levels of neutralizing antibodies, and the immunity is likely to last for decades."[14]
- **Hepatitis B:** "The complete vaccine series induces protective antibody levels in >95% of infants, children and young adults."[15]
- **Haemophilus influenzae Type b (Hib):** "Randomized controlled trials using different formulations in different population groups have demonstrated remarkably consistent efi¬cacy."[16]

Macro evidence: Has this program played a role in large-scale success stories?

Immunization coverage in the developing world has significantly increased this decade.[17] Levine (2007) reports on the impact of two major programs that increased immunization coverage.

- **Hib:** There are two separate success stories, one in Chile and one in The Gambia.
    - *Chile:* Chile's Ministry of Health introduced the Hib vaccine into the routine immunization program for babies in 1996. The incidence of Hib meningitis in Chile fell by 91 percent and that of pneumonia and other forms of Hib disease fell by 80 percent.[18]
    - *Gambia:* The Gambia began administering the vaccine routinely as part of the national immunization program in 1997. The number of children developing Hib meningitis dropped from 200 per 100,000 to 21 per 100,000 in the 12-month period after the start of routine immunization. [19]
- **Measles:** In 1996, seven southern African countries implemented a strategy against measles consisting of routine immunization for babies at nine months, a nationwide campaign to provide an opportunity for immunization to all children aged 9 months to 14 years and campaigns addressing follow-up for young children every three to four years. Additionally, the countries organized surveillance for cases of measles. Between 1996 and 2000, the number of cases decreased from 60,000 to 117.[20] The number of reported measles deaths fell from 166 to 0. [21]

Recommendations and concerns

Do expert reviews of the comparative merits of interventions endorse this one?

- Jamison et al. (2006a) states, "Vaccination against childhood communicable diseases through the Expanded Program on Immunization (EPI) is one of the most cost-effective public health interventions available (UNICEF 2002;World Bank 1993)."[22] DCP2"); ?>

- The Copenhagen Consensus ranks "Expanded immunization coverage for children" as its 4th most cost-effective intervention.[23]
- The Copenhagen Consensus disease paper, Jamison, Jha, and Bloom (2008), lists expanded immunization coverage as its 4th most cost-effective disease intervention.[24]

What are the potential downsides of the intervention?

- **Adverse reactions to the injection.** Some portion of those immunized may have a reaction to the injection. The vaccines reviewed here are generally safe but those who receive them may present some, relatively mild, adverse reaction (see the notes on individual vaccines above).
- **Potential for disease transmission from lack of needle safety.** Needles used on individuals infected with a disease and then reused on others can significantly contribute to disease transmission.[25]

Cost-effectiveness

The cost effectiveness of the program vary by region, delivery strategy and level of scale, as reported in Jamison et al. (2006a).[26] Jamison et al. (2006a) estimates the following ranges of cost-effectiveness of a traditional immunization program (DTP, measles, polio, and BCG):[27]

- Cost per fully immunized child: $14.21 (in Sub-Saharan Africa) to $24.12 (in Europe and Central Asia)
- Cost per death averted: $205 (in Sub-Saharan Africa) to $3,540 (in Europe and Central Asia)
- Cost per disability-adjusted life-year (DALY): $7 (in Sub-Saharan Africa) to $438 (in Latin America and the Caribbean). More on the DALY metric here.

Additional vaccines (such as those for yellow fever, Hib, and Hepatitis B) could increase the cost significantly (for example, close to $15 per immunized child in Sub-Saharan Africa), depending on the delivery strategy used and the specific vaccines administered.[28] Jamison et al. (2006a) breaks this down in more detail on page 403. DCP2"); ?> The measles program (described above) cost an estimated $26.4 million, with the average cost per immunized child at $1.10.[29]

Sources

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1. "These remain the only vaccines recommended by the WHO for national use, and the recommendation presupposes that a disease burden of public health importance is present (see table 72.1)." Jamison et al. 2006a, Pg 1325.
2. "WHO initiated the EPI in 1974 to provide countries with guidance and support to improve vaccine delivery and to help make vaccines available for all children (Hadler and others 2004;Turk 1982; WHO 1974). A standard immunization schedule was established in 1984 on the basis of a review of immunological data for the original EPI vaccines: BCG, diphtheriatetanus- pertussis (DTP), oral polio, and measles vaccines (Halsey and Galazka 1985)." Jamison et al. 2006a, Pg 397
3. Jamison et al. 2006a, Pg 403
4. "Since 1974, WHO's Expanded Program on Immunization (EPI) has provided guidance and support for expanding coverage by standardizing immunization schedules, promoting safe injection technologies, improving the stocking and availability of vaccines, and protecting vaccines' potency through cold chain management." Jamison et al. 2006b, Pg 77
5. World Health Organization, "Table 2: Recommended Routine Immunizations for Children - Summary of WHO Position Papers."
6. World Health Organization, "Vaccine Position Papers."
7. Definition for seroconversion from MedicineNet, an online medical dictionary. See MedicineNet, "Definition of Seroconversion."
8. "The majority of evidence used to establish the effectiveness of diphtheria toxoid immunization comes from outbreak settings. During the epidemic in the 1990s in countries of the former Soviet Union, case-control studies showed that 3 or more doses of Russian-manufactured toxoid induced 95.5% (92.1–97.4%) protective efficacy among children aged <15 years. Protection increased to 98.4% (96.5–99.3%) after 5 or more doses of this vaccine." World Health Organization, "Weekly Epidemiological Record (January 20, 2006)," Pg 29. "Diphtheria toxoid is one of the safest vaccines available. Severe reactions are rare, and to date no anaphylactic reactions attributable to the diphtheria component have been described. However, local reactions at the site of injection are common, although reported rates differ remarkably (<10 to >50%)." World Health Organization, "Weekly Epidemiological Record (January 20, 2006)," Pg 30.
9. World Health Organization, "Weekly Epidemiological Record (January 28, 2005)," Pg 35.
10. "Both the efficacy and the effectiveness of tetanus toxoid are well documented. In most clinical trials, efficacy has ranged from 80% to 100%. The introduction of tetanus vaccination in the United States during the 1940s resulted in a decline in the overall incidence of tetanus from 0.4 per 100 000 population in 1947 to 0.02 per 100 000 population at the end of the 1990s. In a double-blind, controlled study in rural Colombia, neonatal tetanus did not occur among infants born to mothers who had received 2 or 3 doses of the vaccine, whereas among unvaccinated controls the mortality rate was 78 per 1000 live births." World Health Organization, "Weekly Epidemiological Record (May 19, 2006)," Pg 203.
11. "BCG, which is currently the only available TB vaccine, provides protection against TB meningitis and the disseminated form of the disease in infants and young children. However, it does not prevent the establishment of primary infection or reactivation of latent TB...Thousands of lives have thus been saved through BCG vaccination over the years. The vaccine is relatively safe, inexpensive and requires only one injection. Despite its shortcomings, BCG vaccination is considered a life-saving and important part of standard TB control measures in most endemic countries." World Health Organization, "Weekly Epidemiological Record (January 23, 2004)," Pg 33. "BCG vaccination should be offered to all unvaccinated, tuberculin-negative persons in non-endemic areas who are exposed to multiresistant Mtb." World Health Organization, "Weekly Epidemiological Record (January 23, 2004)," Pg 38.
12. "In most developing countries, children are vaccinated against measles at 9 months of age, when seroconversion rates of 80–85% may be expected. These figures are lower than seroconversion rates and vaccine effectiveness

estimates found in countries where measles immunization can be delayed until all children have lost maternal antibody (i.e. after 12 months of age), at which time seroconversion rates as high as 98% may be achieved. Several studies have demonstrated that higher effectiveness occurs in children vaccinated at 15 months compared with those vaccinated at 12 months, but that the protection conferred does not seem to improve further if the first dose is given at beyond 15 months of age." World Health Organization, "Weekly Epidemiological Record (April 2, 2004)," Pg 137

"The original IPV was evaluated in field trials in 1954 in the United States and found to be 80–90% effective in preventing paralytic manifestations. The immunogenicity of IPV in high-income countries has been confirmed by a large number of trials. When IPV was administered using the schedules outlined below (see IPV schedules, formulations and safety), nearly 100% of study infants seroconverted." World Health Organization, "Weekly Epidemiological Record (July 11, 2003)," Pg 245 "If IPV is administered in a WHO/EPI schedule (6, 10, 14 weeks of age), seroconversion to IPV has varied from 67% to 99% against type 1, 65% to 99% against type 2, and 91% to 100% against type 3. The lowest seroconversion rates were reported from a WHO-sponsored trial in Thailand (67% to type 1, 65% to type 2, and 94% to type3)." World Health Organization, "Weekly Epidemiological Record (July 11, 2003)," Pg 246

"A highly efficacious, live attenuated vaccine (17D) has been available for 60 years. One month following immunization, up to 99% of vaccines show protective levels of neutralizing antibodies, and the immunity is likely to last for decades. Adverse events following YF vaccination are usually minor, although hypersensitivity to vaccine components may occasionally occur, and very rare cases of viral encephalitis or multiple organ failures have been reported. The rare adverse events should not deter the appropriate use of this highly valuable vaccine." World Health Organization, "Weekly Epidemiological Record (October 3, 2003)," Pg 350.

"In countries of high disease endemicity (HBsAg prevalence >8%), HBV is mainly spread from mother to infant at birth or from child to child during early childhood (<5 years). In this epidemiological setting, schedules providing the first vaccine dose at birth are recommended. This approach prevents HBV transmission from HBsAg-positive mothers to their offspring in >90% of cases. The vaccine should be given as soon as possible (<24 hours) after birth." World Health Organization, "Weekly Epidemiological Record (July 9, 2004)," Pg 262 "The complete vaccine series induces protective antibody levels in >95% of infants, children and young adults. After the age of 40 years, protection following the primary vaccination series drops below 90%; by 60 years, protective antibody levels are achieved in only 65–75% of vaccinees." World Health Organization, "Weekly Epidemiological Record (July 9, 2004)," Pg 258

"The efï¬cacy of Hib vaccines is generally described in terms of the reduction in incidence of invasive Hib disease among vaccinated children when compared with unvaccinated controls. Randomized controlled trials using different formulations in different population groups have demonstrated remarkably consistent efï¬cacy. The observed efï¬cacy in such trials was 100% in northern California using PRP–CRM197 (95% conï¬dence interval (CI), 68–100%), 95% in the Navajo population in the United States using PRPOMP (95% CI, 72–99%), and 95% in the Gambia using PRP–T (95% CI, 67–100%). Only PRP–OMP was highly efï¬cacious after a single dose; the point estimate of efï¬cacy following a single dose of PRP–CRM197 was 26% and of PRP-T was 44% (both statistically non-signiï¬ cant). Since the etiology of childhood pneumonia is difï¬cult to deï¬ne using microbiological methods, several studies have evaluated the effectiveness of Hib vaccine in reducing the incidence of clinically or radiologically diagnosed pneumonia, irrespective of etiology. Studies that used radiologically diagnosed pneumonia as the outcome measure after Hib vaccination have observed a reduction of approximately 20% in the incidence of serious pneumonia; the reduction in the incidence of clinical pneumonias was in the order of 4–5%." World Health Organization, "Weekly Epidemiological Record (November 24, 2006)," Pg 450

Data available at World Health Organization, "WHO Vaccine Preventable Diseases Monitoring System."

Levine 2007, Pg 147.

Levine 2007, Pg 147

Levine 2007, Pg 127

Levine 2007, Pg 127

Jamison et al. 2006a, Pg 389

Copenhagen Consensus Center, "Copenhagen Consensus 2008 - Results."

Jamison, Jha, and Bloom 2008, Pg 51.

"The reuse of disposable syringes and needles is widespread and contributes significantly to the transmission of hepatitis B and C and HIV. The autodisabled syringe prevents reuse, and disposal in safety boxes reduces the risk to health staff and the general public from contaminated syringes and needles." Jamison et al. 2006a, Pg 1335

Jamison et al. 2006a, Pg 408

Jamison et al. 2006a, Pg 401

Jamison et al. 2006a, Pg 403, Table 20.6

Levine 2007, Pg 127

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320 7th Ave #232 - Brooklyn, NY 11215

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