# Annex 10A Methodologies Used for Impact of EPI Vaccines and New Gavi-Supported Vaccines

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## Measles

Using a dynamic population-based Markov model developed by Pennsylvania State University and WHO (Chen, Fricks et al. 2012; Simons, Ferrari et al. 2012).

## Hepatitis B

Because disease develops over many years, impact of vaccination programs are modeled over the lifetime of birth cohorts. Numbers of expected hepatitis B deaths averted were estimated using a static cohort model based on the natural history of hepatitis B disease developed by the US Centers for Disease Control and Prevention (Goldstein, Zhou, et al 2005). Underlying rates of hepatitis B infection in the model were based on pre-vaccination seroprevalence studies (Goldstein, Zhou, et al 2005).

## Hib

Estimates of deaths averted by Hib vaccination were calculated using the Lives Saved Tool (LiST) developed by Johns Hopkins University (Winfrey, McKinnon et al. 2011). Consistent with the approach used to estimate global Hib pneumonia disease burden (Watt, Wolfson et al. 2009; Theodoratou, Johnson et al. 2010) estimates of the proportion of under-five pneumonia deaths due to Hib pneumonia were derived by applying the proportionate reduction in radiologically confirmed pneumonia cases observed in Hib vaccine probe studies to WHO/CHERG country-specific estimates of the proportion of under-five deaths due to pneumonia in 2000 (Bryce, Boschi-Pinto et al. 2005; Liu, Johnson et al. 2012).

## Pneumococcus

Estimates of deaths averted by pneumococcal vaccination were calculated using the LiST tool developed by Johns Hopkins University (Winfrey, McKinnon et al. 2011). The same approach was used to estimate pneumonia deaths due to pneumococcus as described above for pneumonia deaths due to Hib.

## Rotavirus

Estimates of deaths averted by rotavirus vaccination were calculated using the LiST tool developed by Johns Hopkins University (Winfrey, McKinnon et al. 2011). To estimate the number of deaths caused by rotavirus, WHO country-specific estimates of under-five deaths due to diarrhea were multiplied by an estimated 39 percent of cases of severe clinical gastroenteritis caused by rotavirus based on 41 hospital-based surveillance studies (Parashar, Gibson et al. 2006; Fischer Walker, Munos et al. 2013). In 2008, it was estimated that 453,000 deaths occurred due to rotavirus worldwide (Tate, Burton et al. 2012), although a more recent estimate using a different methodology and diarrhea mortality envelope estimated 193,000 rotavirus deaths in 2010 (Walker, Rudan et al. 2013).

## Rubella

Estimates of CRS disease burden are based on surveillance data, serologic surveys of childbearing-aged women and mathematical modeling. Review of worldwide data on CRS in developing countries suggested incidence of 0.6 to 2.2 cases per 1000 live births, similar to rates seen in developing countries before universal vaccination (Reef and Plotkin, 2013). Estimates of the number of CRS cases averted by vaccination were calculated using a dynamic transmission model developed in 2011 by the UK Health

Protection Agency and extended from previous modeling work (Cutts and Vynnycky 1999; Vynnycky, Gay et al. 2003). This model projects the number of women of childbearing age susceptible to rubella infection by country and year through the lifetime of each vaccinated cohort. Estimates of CRS deaths averted were calculated assuming a proportional case fatality ratio of 30 percent in all countries (De Owens and De Espino 1989; Lawn, Reef et al. 2000; Al-Awaidy, Griffiths et al. 2006; Lanzieri, Pinto et al. 2007).

### Meningococcus

To calculate these figures, estimates of 1.04 deaths averted per 1,000 persons vaccinated through mass vaccination campaigns and 0.08 deaths averted per 1,000 infants vaccinated through routine vaccination were applied to projected numbers of persons vaccinated. These rates were based on an analysis conducted by PATH using a generalized static cohort model to estimate the impact of a WHO and UNICEF investment case (LaForce and Okwo-Bele 2011). Underlying *Neisseria meningitidis* serogroup A incidence used in the model was based on a prospective hospital-based surveillance study of meningitis in Niger conducted during 1981–1996 (Campagne, Schuchat et al. 1999). The model assumed a ten-year inter-epidemic interval and a 12 percent case fatality ratio.

### Yellow Fever

An estimate of 0.2 epidemic yellow fever deaths averted per 1,000 persons vaccinated, derived from a 1993 study that modeled the impact of routine infant yellow fever vaccination in Nigeria (Monath and Nasidi 1993), was applied to projected numbers of persons vaccinated to estimate deaths averted during 2000–2020. The reference study utilized a static cohort model based on the assumption that, on average, epidemics occur at 17-year intervals, 4 million persons are affected in each epidemic, there is an epidemic infection rate of 20%, and 20 percent case fatality ratio.

### Japanese Encephalitis

Estimates of Japanese encephalitis deaths averted were calculated using a static cohort model developed by PATH, modified from models developed for Cambodia and India (Suraratdecha, Jacobson et al. 2006; Touch, Suraratdecha et al. 2010). Underlying incidence rates used in the model estimates were based on a recent review of population-based surveillance studies (Campbell, Hills et al. 2011). Country-specific proportional case fatality ratios were based on a review of published and unpublished surveillance data and ranged from 10 to 25 percent (Sohn 2000; Solomon, Dung et al. 2000; Kari, Liu et al. 2006).

For the new vaccines, we used a methodology recently adopted through an expert process with leading modeling groups co-convened by Gavi, The Vaccine Alliance and Bill and Melinda Gates Foundation to estimate impact of vaccinations administered in the 73 Gavi-supported countries (table 10A.3). The methods and results from the first round of modeling were published (Lee, Franzel et al. 2013), covering vaccinations forecasted to be administered in Gavi-supported countries from 2011-20. Numbers of deaths averted were calculated as the difference in deaths expected to occur over the lifetime of vaccinated cohorts compared to the number of deaths expected to occur in those cohorts without vaccination. We provide an update of this analysis covering vaccinations administered from 2000-2012 and updated forecasts of vaccinations expected to occur between 2013 and 2020 based on the Gavi, The Vaccine Alliance Strategic Demand Forecast version. Similar evidence on the projected impact of new vaccines in non-Gavi eligible countries would also be valuable to decision-makers in those countries and globally, but at present no systematic and standardized demand forecast exists that projects vaccination uptake and use in such countries.

**Table 10A.1** Models Used To Estimate Averted Cases and Deaths from Administration of Original EPI Vaccines and New and Underutilized Vaccines Supported by Gavi

| Vaccines | Vaccination strategies | Model source | Model structure | Underlying disease burden |
|---|---|---|---|---|
| Measles | routine and campaign | Chen, Fricks et al. 2012; Simons, Ferrari et al. 2012 (Pennsylvania State University and WHO) | Dynamic population-based Markov model informed by surveillance data | Case-fatality ratios for children <5 years and 5-9 years applied to age distribution derived from case-based surveillance data, using first dose coverage and region as covariates |
| Hepatitis B | Routine | Goldstein et al, 2005 (U.S. Centers for Disease Control and Prevention) | Static natural history population-based cohort | Pre-vaccination hepatitis B surface antigen (HBsAg) serosurvey data |
| Haemophilus influenzae type b (Hib) | Routine | Lives Saved Tool model (Johns Hopkins University) | Static cohort | Pneumonia deaths <5 years (WHO) x Hib vaccine preventable burden of radiographic pneumonia |
| Pneumococcal | Routine | Lives Saved Tool model (Johns Hopkins University) | Static cohort | Pneumonia deaths <5 years (WHO) x pneumococcal conjugate vaccine preventable burden of radiographic pneumonia |
| Rotavirus | Routine | Lives Saved Tool model (Johns Hopkins University) | Static cohort | Diarrhea deaths <5 years (WHO) x proportion of severe gastroenteritis due to rotavirus infection |
| Rubella | campaign & routine | UK Health Protection Agency Centre for Infections, CDC, WHO | Dynamic cohort | Pre-vaccination rubella serosurveys to determine age-specific incidence |
| Meningococcal serogroup A | campaign & routine | Long Range Cost and Impact model (Gavi) | Deaths averted per 1,000 vaccinated | Pre-vaccination prospective hospital surveillance study in Niger, 1981-1996 |
| Yellow fever | Routine | Long Range Cost and Impact model (Gavi) | Deaths averted per 1,000 vaccinated | Model based on disease burden studies in Nigeria |
| Japanese encephalitis | campaign & routine | PATH | Static cohort | Population based surveillance studies |

Table 1 HepB = Hepatitis B; Hib = Haemophilus influenza type b; JE = Japanese encephalitis; PCV = pneumococcal conjugate vaccine; MenA = Meningococcus serotype A; MSD = measles second dose; Rota = rotavirus; YF = Yellow Fever.

**Table 10A.2** Characteristics of Common Childhood Vaccines

| Vaccine (common abbreviations) | Type of vaccine | Diseases prevented | No. countries with routine vaccination, 2012 | No. (%) of 73 GAVI countries with routine vaccination, 2012 | Schedule | Vaccine efficacy | Duration of immunity | Estimated deaths in children < 5 years, rounded to thousands (2012 unless indicated) | Source for deaths |
|---|---|---|---|---|---|---|---|---|---|
| *Recommended vaccines for national immunization programs in all low- and middle-income countries* | | | | | | | | | |
| Bacille Calmette-Guérin (BCG) | Live-attenuated *Mycobacterium bovis* | Disseminated disease and meningitis caused by *M. tuberculosis* | 159 | 69 (95%) | 1 dose at birth | 75-86% | Unknown | 55,000 | WHO 2014 |
| Diphtheria, Tetanus, Pertussis (DTP, DTwP or DTaP) | Diptheria toxoid, tetanus toxoid, killed whole cell (wP) or acellular (aP) *Bordatella pertussis* | Diphtheria, tetanus, pertussis | 194 | 73 (100%) | 3 doses age ≤6 months + boosters | 70-90% pertussis; >95% tetanus; >87% diphtheria | 5-10 years; more waning with acellular vaccine | Diphtheria 1,000; pertussis 63,000, tetanus 56,000 | WHO 2014 |
| Oral Polio (OPV) | Live-attenuated Sabin poliovirus type 1, 2, 3 (monovalent, bivalent [1,3] or trivalent) | Poliomyelitis | 159 | 73 (100%) | At birth + 3 doses age ≤6 months + boosters | ~90% | Lifelong | <1 | Global Polio Eradication Initiative |
| Inactivated Polio (IPV) | Inactivated wild poliovirus type 1, 2, 3 (trivalent) | Poliomyelitis | 66 | 1 (1%) | 3 doses age ≤6 months + boosters | 80-90% | | <1 | Global Polio Eradication Initiative |

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|---|---|---|---|---|---|---|---|---|---|
| Measles, Measles-containing vaccine (M, MR, MMR) | Live-attenuated measles virus | Measles | 194 | 73 (100%) | 9-15 months, 1st dose; 15+ months 2nd dose | 85-95% | Lifelong in most; some waning after one dose | 101,000 | WHO, 2014 |
| Haemophilus influenzae type b conjugate (Hib) | Hib polysaccharide-protein conjugate | Hib diseases (meningitis, pneumonia) | 180 | 68 (93%) | 3 doses age ≤6 months | >85% invasive disease | | 203,000 (2008); 197,000 (2010) | Watt, 2009;WHO, 2013c |
| Hepatitis B (HB) | Recombinant hepatitis B surface antigen | | 181 | 71 (97%) | At birth + 2 or 3 doses age ≤6 months | 75-95% | >15 years | 5,000 | WHO, 2014 |
| Pneumococcal conjugate (PCV) | Pneumococcal polysaccharide-protein conjugate (10- or 13-valent) | Pneumococcal diseases (meningitis, pneumonia) | 88 | 23 (32%) | 3 doses age ≤6 months, or 2 or 3 doses ≤6 months + booster 9-15 months | >70% vaccine-serotype invasive disease | At least 5 years | 541,000 (2008); 411,000 (2010) | O'Brien 2009;WHO, 2013b |
| Rotavirus (RV) | Live-attenuated (RV1) reassortment or bovine-human (RV5) | Rotavirus gastroenteritis | 41 | 11 (15%) | 2 or 3 doses age ≤6 months (different vaccines) | 50-77% severe gastroenteritis | Waning in 2nd year of life | 453,000 (2008); 193,000 (2010)* | Tate 2012; Walker 2013 |
| Rubella, Rubella-containing vaccine (R, RCV) | Live-attenuated rubella virus | Rubella, congenital rubella syndrome | 132 | 20 (27%) | 1 dose age ≥9 months | 95% | Lifelong in most; rare waning after one dose | 30,000 (no year) | Cutts 1999; Lee 2013 |

*Recommendations for certain regions or high-risk populations*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Mening-ococcal serogroup A conjugate (MenA) | Polysaccharide-protein conjugate | Meningococcal meningitis and disease due to serogroup A | 12 of 25 high-risk countries | 12 of 25 high-risk countries | Under evaluation | > 95% | unknown | 10,000/year (all ages, 1993 to 2012) | WHO 2013a |
| Yellow Fever (YF) | Live-attenuated yellow fever virus | Yellow fever | 37 of 48 high-risk countries | 24 (33%) | 1 dose age ≥9 months | 90-98% | Lifelong | 29,000-60,000 | WHO 2013c |
| Japanese Encephalitis (JE) | Live-attenuated Japanese encephalitis virus | Encephalitis | 10 | 5 (7%) | | 90% | unknown | 10,000/year(ages 0-14) | Campbell, Hills et al. 2011 |
| Oral Cholera (OCV) | Killed, whole cell *Vibro cholerae* | Cholera | N/A | N/A | 2 doses age ≥1 year | 67-80% | Effective-ness shown for 6 months to 2 years | 45,000 | Ali et al. 2012; Sack 2014 |

*Note that the 2008 and 2010 estimates used different methodologies and overall diarrhea mortality envelopes.

**Table 10A.3** New and Underused Vaccines Introduced into Routine Immunization Programs in 73 Gavi Countries through the End of 2014

| Country | Region | HepB | Hib | PCV | JE | YF | MSD | Rubella | Rotavirus |
|---|---|---|---|---|---|---|---|---|---|
| Afghanistan | EMRO | X | X | X | | | X | | |
| Angola | AFRO | X | X | X | | X | | | X |
| Armenia | EURO | X | X | X | | | X | | X |
| Azerbaijan | EURO | X | X | X | | | X | | |
| Bangladesh | SEARO | X | X | X | | | X | X | |
| Benin | AFRO | X | X | X | | X | | | |
| Bhutan | SEARO | X | X | | | | X | X | |
| Bolivia | AMRO | X | X | X | | X | | X | X |
| Burkina Faso | AFRO | X | X | X | | X | X | | X |
| Burundi | AFRO | X | X | X | | | X | | X |
| Cambodia | WPRO | X | X | X | X | | X | X | |
| Cameroon | AFRO | X | X | X | | X | | | X |
| Central African Republic | AFRO | X | X | X | | X | | | |
| Chad | AFRO | X | X | | | X | | | |
| Comoros | AFRO | X | X | | | | | | |
| Congo, Democratic Republic | AFRO | X | X | X | | X | | | |
| Congo, Republic | AFRO | X | X | X | | X | | | X |
| Côte d'Ivoire | AFRO | X | X | X | | X | | | |
| Cuba | AMRO | X | X | | | | X | X | |
| Djibouti | EMRO | X | X | X | | | X | | X |
| Eritrea | AFRO | X | X | | | | X | | X |
| Ethiopia | AFRO | X | X | X | | | | | X |
| Gambia | AFRO | X | X | X | | X | X | | X |
| Georgia | EURO | X | X | X | | | X | X | X |
| Ghana | AFRO | X | X | X | | X | X | X | X |
| Guinea | AFRO | X | X | | | X | | | |
| Guinea-Bissau | AFRO | X | X | | | X | | | |
| Guyana | AMRO | X | X | X | | X | X | X | X |
| Haiti | AMRO | X | X | | | | | X | X |
| Honduras | AMRO | X | X | X | | | | X | X |
| India | SEARO | X | X | | X | | X | | |
| Indonesia | SEARO | X | X | | | | X | | |
| Kenya | AFRO | X | X | X | | X | X | | X |
| Kiribati | WPRO | X | X | X | | | X | X | |
| Korea, Dem. People's Republic | SEARO | X | X | | | | X | | |
| Kyrgyzstan | EURO | X | X | | | | X | X | |
| Lao People's Democratic Republic | WPRO | X | X | X | X | | X | X | |
| Lesotho | AFRO | X | X | | | | X | | |
| Liberia | AFRO | X | X | X | | X | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Madagascar | AFRO | X | X | X | | | | | X |
| Malawi | AFRO | X | X | X | | | | | X |
| Mali | AFRO | X | X | X | | X | | | X |
| Mauritania | AFRO | X | X | X | | | | | X |
| Moldova | EURO | X | X | X | | | X | X | X |
| Mongolia | WPRO | X | X | | | | X | X | |
| Mozambique | AFRO | X | X | X | | | | | |
| Myanmar | SEARO | X | X | | | | X | | |
| Nepal | SEARO | X | X | X | X | | | X | |
| Nicaragua | AMRO | X | X | X | | | X | X | X |
| Niger | AFRO | X | X | X | | X | | | X |
| Nigeria | AFRO | X | X | X | X | | | | |
| Pakistan | EMRO | X | X | X | | | X | | |
| Papua New Guinea | WPRO | X | X | X | | | X | | |
| Rwanda | AFRO | X | X | X | | | | X | X |
| Sao Tome and Principe | AFRO | X | X | X | | X | X | | |
| Senegal | AFRO | X | X | X | | X | X | X | X |
| Sierra Leone | AFRO | X | X | X | | X | | | X |
| Solomon Islands | WPRO | X | X | X | | | X | X | |
| Somalia | EMRO | X | X | | | | | | |
| Sri Lanka | SEARO | X | X | | X | | X | X | |
| Sudan | EMRO | X | X | X | | | X | | X |
| South Sudan | EMRO | X | X | | | | | | |
| Tajikistan | EURO | X | X | | | | X | X | X |
| Tanzania | AFRO | X | X | X | | | | X | X |
| Timor-Leste | SEARO | X | X | | | | | | |
| Togo | AFRO | X | X | X | | X | | | X |
| Uganda | AFRO | X | X | X | | | | | |
| Ukraine | EURO | X | X | | | | X | X | |
| Uzbekistan | EURO | X | X | | | | X | X | X |
| Vietnam | WPRO | X | X | | X | | X | | |
| Yemen | EMRO | X | X | X | | | X | X | X |
| Zambia | AFRO | X | X | X | | | X | | X |
| Zimbabwe | AFRO | X | X | X | | | | | X |
| **Total Countries** | | 73 | 73 | 50 | 6 | 24 | 40 | 26 | 35 |

*Note*: The estimates were produced through an expert modeling process convened by Gavi and the Bill and Melinda Gates Foundation, in partnership with the World Health Organization, which updated the estimates described in Lee and others (2013). The source for forecasted dates and coverage levels for future vaccine introductions is Gavi's Strategic Demand Forecast, version 9. The methods for estimating future DALYs averted are described in Ozawa and others forthcoming.

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