GAVI Full Country Evaluation 2013
Annual Progress Report

January 2014

Evaluation Team

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Acronyms

Acronym	Definition
AAR	After-Action Review
ABCE	Access, Bottlenecks, Cost, And Equity
ACADEMIC	A Comprehensive Assessment Of Diarrhoea And Enteric Disease Management In Children
AIS	Aids Indicator Survey
CES	Coverage Evaluation Survey
CHERG	Child Health Epidemiology Reference Group
CHTWG	Child Health Technical Working Group
CHU	Child Health Unit
CIDRZ	Centre For Infectious Disease Research In Zambia
CISM	Manhiça Center For Health Research
CRO	Country Responsible Officer
DAH	Development Assistance For Health
DBS	Dried Blood Spot
DHS	Demographic Health Survey
DSS	Demographic Surveillance Site
DTP	Diphtheria, Tetanus, And Pertussis
EAT	EPI Expenditure Tracking
EEA	EPI Expenditure Accounts
EPI	Expanded Program On Immunization
EPITWG	EPI Technical Working Group
ERC	Ethical Review Committee
EVMA	Effective Vaccine Management Assessment
FCE	Full Country Evaluations

FDC	Fundação Para O Desenvolvimento Da Comunidade
FGD	Focus Group Discussion
FMA	Financial Management Assessment
GBD	Global Burden Of Disease
GPR	Gaussian Process Regression
GSK	GlaxoSmithKline
HAI	Health Alliance International
HMIS	Health Management Information System
HPV	Human Papillomavirus
HSS	Health Systems Strengthening
ICC	Inter-Agency Coordinating Committee
Icddr,b	International Centre For Diarrhoeal Disease Research, Bangladesh
IDRC	Infectious Diseases Research Collaboration
IEC	Information, Education, And Communication
IFMS	Integrated Financial Management System
IHME	Institute For Health Metrics And Evaluation
INE	National Institute Of Statistics
INS	National Institute Of Health
IPD	Invasive Pneumococcal Disease
IRB	Institutional Review Board
IRC	Independent Review Committee
ISO	International Organization For Standardization
ISS	Immunization Services Support
KAP	Knowledge, Attitudes, And Practice
KII	Key Informant Interview

LCMS	Living Conditions Monitoring Survey
LIST	Lives Saved Tool
MCDMCH	Ministry Of Community Development, Mother And Child Health
MCHIP	Maternal And Child Health Integrated Program
MIS	Malaria Indicator Survey
MMR	Measles, Mumps, Rubella
MOH	Ministry Of Health
MOHFW	Ministry Of Health And Family Welfare
MCPA	Malaria Control Policy Assessment
MPM	Multi-Partner Meeting
MR	Measles-Rubella
MSD	Measles Second Dose
NCC	National Coordinating Committee
NHA	National Health Accounts
NIP	National Immunization Program
NITAG	National Immunization Technical Advisory Group
NMS	National Medical Stores
NVS	New Vaccine Support
OECD	Organization For Economic Cooperation And Development
PAED	Programme For Awareness And Elimination Of Diarrhoea
PBF	Post-Bachelor Fellow
PCV	Pneumococcal Vaccine
PETS	Public Expenditure Tracking Survey
PHFI	Public Health Foundation Of India
PIE	Post-Introduction Evaluation

QSS	Quality, Safety, Standards
RRC	Research Review Committee
RT	Resource Tracking
SIA	Supplemental Immunization Activities
TA	Technical Assistance
TOC	Theory Of Change
TOT	Training Of Trainers
TT	Tetanus Toxoid
TWG	Technical Working Group
UEM	University Of Eduardo Mondlane
UNZA	University Of Zambia
UW	University Of Washington
VIG	Vaccine Introduction Grant
WHO	World Health Organization
XRP	Radiologically (X-Ray) Confirmed Pneumonia
ZISSP	Zambia Integrated Services Strengthening Program

Executive Summary

This document describes the progress of the GAVI Full Country Evaluations (FCE) project in 2013. The GAVI Full Country Evaluations is a prospective evaluation study in five countries (Bangladesh, India, Mozambique, Uganda, and Zambia) covering the 2013 – 2016 period. The overall goal of the GAVI FCE is to understand and quantify the barriers to, as well as drivers of, immunization program improvement, including the contribution of the GAVI Alliance. The scope of the GAVI FCE includes GAVI's support for new and underused vaccines as well as GAVI's cash-based support to countries.

The GAVI FCE is a mixed-methods evaluation, involving qualitative, semi-quantitative, and quantitative methods to understand the full results chain. An additional feature is that the GAVI FCE not only collects data and conducts analyses at the national level, but also at subnational levels wherever possible. The key study methods include:

- a process evaluation to understand the process by which countries implement GAVI support;
- health facility surveys that measure constraints to immunization delivery from both the supply and demand side;
- household surveys to measure key population-based indicators, including measuring vaccine antibodies;
- resource tracking study to identify how GAVI Alliance resources are used and its relationship to resources from other donors and domestic resources; vaccine effectiveness studies;
- outcome and impact analyses, which include the use of novel statistical methods to estimate trends over time in key indicators at the subnational level.

An important aspect of the mixed method approach is to allow triangulation of data and findings across methods, and across the five GAVI FCE countries where relevant.

Based on consultation with stakeholders, the GAVI FCE in India will focus on the ongoing introduction of pentavalent vaccine. In Bangladesh, Mozambique, Uganda, and Zambia, we are broadly tracking all relevant vaccine and cash-based support over the evaluation period. This will allow a holistic examination of multiple support streams and how they interact; for example, how the presence or absence of HSS contributes or detracts from new vaccine introductions.

Implementation of the GAVI FCE commenced in 2013 in Bangladesh, Mozambique, Uganda, and Zambia; the main phase evaluation activities in India will commence in 2014. Much of the focus of the GAVI FCE in 2013 has been on the development of project infrastructure including study protocols, data collection instruments, institutional review board (IRB) applications and approvals, and capacity strengthening. Data collection and subsequent analysis has been limited to the third and fourth quarters of 2013.

The primary focus of this first year's work was the process evaluation of pneumococcal vaccine (PCV) introduction in Uganda, Zambia, and Mozambique. The process evaluation was primarily based on qualitative data from document review, participant observation, and key informant interviews (KIIs). Findings from the process evaluation of PCV introduction are provided in a separate report.

In addition to the process of PCV introduction, GAVI FCE activities were also focused on an evaluation of the Measles Rubella (MR) campaign in Bangladesh. This includes pre-and-post campaign surveys, facility assessments and process evaluation methods. For other evaluation components, in 2013 the evaluation focused on preparation for data collection in 2014 for resource tracking, household surveys, health facility surveys, and vaccine effectiveness studies.

In 2014, the evaluation will involve the continuation of qualitative data collection, with new areas of focus in each country. These include:

- **Bangladesh:** Implementation of the measles-rubella (MR) campaign beginning at the end of January 2014; introduction of PCV; implementation of HSS; application for HPV.
- **India:** Ongoing pentavalent vaccine introduction; although other streams of support exist such as HSS, the GAVI FCE will focus on the pentavalent introduction.
- **Mozambique:** HPV demonstration project; implementation of HSS; and application for rotavirus vaccine introduction.
- **Uganda:** Ongoing PCV introduction; reprogrammed HSS; and application for HPV national introduction.
- **Zambia:** Rotavirus introduction that launched in November 2013; and reprogrammed and/or new applications for HSS.

In addition to the qualitative areas of focus listed above, the main focus of 2014 work will be the quantitative elements. Baseline resource tracking, household, and health facility surveys will be conducted in each country. Additionally, outcome and impact evaluations will measure sub-national estimates of key indicators, including child mortality and vaccination coverage.

1 Introduction

The GAVI Full Country Evaluation (FCE) is a prospective evaluation study in five countries (Bangladesh, India, Mozambique, Uganda, and Zambia) covering the period 2013 to the end of 2016. This is the first of four annual progress reports on the GAVI FCE. The report covers the period January 1, 2013 to December 1, 2013.

The GAVI FCE began in the fourth quarter of 2012 with an inception phase involving detailed consultations with key stakeholders in each of the five countries. These consultations aimed to identify key areas of focus in each country and incorporate feedback into the evaluation design, such that evaluation activities are aligned with countries' information needs and avoid duplication of existing monitoring and evaluation activities. A report of the inception phase is available on request.

This report summarizes the design, implementation progress in 2013, and planned 2014 activities of the GAVI FCE. A separate report, *Process evaluation of pneumococcal vaccine introduction in Mozambique, Uganda and Zambia*, presents findings from the process evaluation of pneumococcal vaccine introductions in Mozambique, Uganda, and Zambia. This report provides: a brief description of the GAVI Alliance and the types of support to countries it provides; baseline characteristics and approved GAVI Alliance funding for the five GAVI FCE countries; the rationale, goals, and principles of the GAVI FCE; the evaluation framework and research questions; and evaluation methods and activities.

This report also describes the implementation of evaluation activities in 2013 in Bangladesh, Mozambique, Uganda, and Zambia including lessons learned to date. The main phase evaluation activities in India will commence in 2014 and will be reported in subsequent reports. An extended planning phase was required in India to ensure non-duplication of monitoring and evaluation efforts. It is important to note that much of the focus of the GAVI FCE in 2013 has been the development and scaling up of project infrastructure and country teams, study protocols, data collection instruments, and obtaining local institutional review board (IRB) approval. As a result, data collection and analysis began midway through the 2013 reporting period, described in more detail in the implementation progress section.

This report concludes with a description of evaluation activities scheduled for 2014, including the key areas of focus of the GAVI FCE for the coming year. These activities include but are not limited to: In Bangladesh, the implementation of the measles-rubella campaign, the pneumococcal conjugate vaccine (PCV) introduction, Health Systems Strengthening (HSS) activities, and the application for human papillomavirus (HPV) support; In India, the ongoing rollout of pentavalent vaccine; In Mozambique, the HPV demonstration project, HSS support, and rotavirus application; In Zambia, the recent introduction of rotavirus vaccine and new applications or re-programming of HSS funds; and in Uganda, the ongoing introduction of PCV and HSS, and application for HPV. We will also cover the decision-making and application phases for new support such as inactivated polio vaccine (IPV).

2 Description of the GAVI Alliance and types of country support

The GAVI Alliance was launched in 2000 in response to declining rates of vaccination in developing countries. The GAVI Alliance is based on a public-private partnership model and brings together the World Health Organization (WHO), UNICEF, the World Bank, the Bill & Melinda Gates Foundation, donor governments, developing countries, international development and finance organizations, and the pharmaceutical industry. The GAVI Alliance is governed by the GAVI Alliance Board, whose membership is made up of partner organizations and experts from the private sector. The GAVI Alliance Board is responsible for strategic direction and policy-making, oversees the operations of the Alliance, and monitors programme implementation. The GAVI Secretariat, based in Geneva, Switzerland, is responsible and accountable for the day-to-day operations of the GAVI Alliance.

The mission of the GAVI Alliance is "to save children's lives and protect people's health by increasing access to immunization in poor countries". The alliance has four strategic goals (SG), as outlined in the 2011-2015 strategy and business plan:

- **SG 1:** Accelerate the uptake and use of underused and new vaccines by strengthening country decision-making and introduction;
- **SG2:** Contribute to strengthening the capacity of integrated health systems to deliver immunization;
- **SG3:** Increase the predictability of global financing and improve the sustainability of national financing for immunization; and
- **SG4:** Shape vaccine markets to ensure adequate supply of appropriate, quality vaccines at low and sustainable prices for developing countries.

GAVI offers support to countries with a GNI per capita below or equal to US $1,570. 53 countries are presently eligible. Proposals for support are submitted by countries and are reviewed by the Independent Review Committee (IRC). The IRC provides recommendations to the GAVI Alliance Board, who decide whether to approve the funding for new country grants. The alliance offers support across the following areas:

- ***New and underused vaccine support (NVS):*** NVS supports countries to accelerate introduction and use of: Human papillomavirus vaccine; Inactivated polio vaccine; Japanese encephalitis vaccine; Measles vaccine, second-dose; Measles-Rubella vaccine; Meningitis A vaccine; Pentavalent vaccine; Pneumococcal vaccine; Rotavirus vaccine; and Yellow Fever vaccine. There is a co-financing requirement for all countries receiving NVS support, with the exception of measles second dose and preventative campaigns for yellow fever and meningitis.
- **Immunization services support (ISS):** Immunization services support is performance-based financing, with cash provided based on increases in immunization coverage. Funds are intended to be flexible, with governments deciding how to spend ISS funds. This type of GAVI support is being phased out. The Health systems strengthening (HSS) window incorporates an element of performance-based financing.

- **Health systems strengthening (HSS):** The objective of GAVI HSS funding is to address bottlenecks or barriers in the health system to increase the delivery of immunization and other child and maternal health services. The latest HSS window includes an element of performance-based financing.
- **Civil society organization support:** The objective of this stream is to support stronger engagement of civil society organizations (CSOs) at the country level, including immunization service delivery. Support was previously provided through two pilot windows of support. Support to CSOs can be requested as part of the HSS window.

3 Rationale, goals, and principles of the GAVI FCE

It is critical to show that past and continuing investments in health are making an impact, and that resources devoted to health programs are effective. Past evaluation studies of GAVI Alliance support have primarily been retrospective, focused on specific streams of funding, and with limited country ownership of evaluation results. This evaluation effort represents an important shift toward focused, forward-looking, and in-depth monitoring and evaluation, which takes into account the needs of country-level immunization programs. This will better inform policy implementation and strengthen local capacity to conduct monitoring and evaluation activities.

The overall goal of the GAVI FCE is to understand and quantify the barriers to, as well as drivers of, immunization program improvement, including the contribution of the GAVI Alliance. The scope of the GAVI FCE includes GAVI's support for new and underused vaccines as well as GAVI's cash-based support to countries. These four-year prospective evaluations are being undertaken in five countries (Bangladesh, India, Mozambique, Uganda, and Zambia) from 2013 to 2016.

A number of important principles underlie the GAVI Full Country Evaluations. These are: harmonizing monitoring and evaluation activities in each country by leveraging available data; working collaboratively with partners to conduct targeted primary data collection; strengthening country ownership and capacity, by partnering with in-country institutes and undertaking shared learning activities; and providing timely, regular, and systematic feedback to countries and the GAVI Alliance.

4 GAVI FCE Countries

The five countries included in the GAVI FCE represent a broad array of GAVI Alliance support (Table 1). This includes new vaccine support for pentavalent, measles second dose, measles-rubella vaccine, pneumococcal, rotavirus, and HPV. The five countries have also received a range of cash-based support including ISS, HSS, and cash-based support through the new HSS window.

Table 1: GAVI Alliance support by country and year of vaccine introduction

Components	Country				
	Bangladesh	India	Mozambique	Uganda	Zambia
PCV	2014		April 2013	April 2013	July 2013
Rotavirus					2013
Pentavalent	2009 (GAVI support active until 2015)	Sequential roll-out, 2011-2014	2009 (GAVI support active until 2013)	2002 (GAVI support active until 2015)	2005 (approved until 2015)
HPV (demo or national)			Demo in 2014		
Measles second dose	2012 (approved until 2016)				2013
Measles-rubella campaign	2014				
Health systems strengthening (HSS)	2009-2012 (funds re-programmed to 2013)	2013-2015	2014 - 2018[1]	2008-2013 (funds re-programmed to 2015)	2007-2013 (funds re-programmed)
Immunization services support (ISS)	2001-2004, 2006, 2009, 2011, 2012		2001-2003, 2006-2008, 2011-2013	2001-2004, 2009, 2011	2001, 2002, 2004, 2006, 2007, 2009, 2011, 2012
Injection safety support (INS)	2004-2006		2003-2005	2002-2004	2002-2004
Vaccine introduction grant (VIG)	2002, 2008, 2012, 2014	2002-2011, 2010-2012	2002, 2008, 2012, 2013	2002, 2012	2002, 2012, 2013

[1] At the time of writing this report, the Government of Mozambique is still awaiting final approval for this HSS funding award

The five GAVI FCE countries represent different levels of demographic and economic indicators, health spending and development assistance for health, vaccine coverage levels as well as child, and adult and vaccine preventable disease mortality (Table 2). These countries also reflect different levels of geographical inequalities in vaccine coverage (See Annex section 10.1: Sub-national estimates of antigen coverage).

Table 2: Country characteristics

Characteristic	Bangladesh	India	Mozambique	Uganda	Zambia
Demographic and economic indicators					
Total Population (2013)	156,594,962	1,252,139,596	25,833,752	37,578,876	14,538,640
Birth Cohort (2013)	3,317,681	25,595,238	1,005,489	1,625,654	624,919
World Bank Index, IDA (2012)	3.48	3.74	3.74	3.77	3.44
Gross National Income per capita (US$, 2013)	840	1,530	510	440	1,350
GDP per capita (2010)	$1,244	$2,867	$739	$1,028	$1,191
Health spending and development assistant for health*					
Government Health Expenditure as Source	$1.39B	$22.2B	$213M	$266M	$643M
Development Assistance for Health, channeled through Government	$72.6M	$726M	$138M	$119M	$592M
Development Assistance for Health, channeled through Non-Government Entities	$208M	$208M	$296M	$334M	$369M
Total DAH	$281M	$739M	$434M	$453M	$4.28B
GAVI disbursements	$305.5M	$131.6M	$77.0M	$175.7M	$83.4M
Vaccine coverage					
*DTP3 coverage***	93.4%	71.5%	76.2%	71.5%	80.6%
*BCG coverage***	87.8%	86.9%	91.1%	93.7%	90.3%
*Polio3 coverage***	93.4%	70.4%	73.2%	62.9%	77.0%
*Measles coverage***	87.5%	74.1%	81.5%	75.8%	84.9%
*Percent of fully immunized children****	86.0%	61.0%	64.1%	51.6%	67.6%
Child, adult, and vaccine-preventable disease mortality**					
All-cause mortality (risk per 1,000)					
Infant Mortality ($_1q_0$)	38.4 (34.5-42.6)	44.5 (39.2-50.3)	81.4 (66.8-99.0)	43.7 (35.7-52.4)	57.7 (44.8-73.0)
Under-5 Mortality ($_5q_0$)	47.0 (43.0-51.8)	55.5 (49.2-62.2)	113.6 (91.9-138.1)	62.8 (51.2-76.8)	93.1 (69.6-121.2)
Female adult mortality ($_{45}q_{15}$)	149.7 (124.4-176.5)	169.6 (133.3-208.6)	388.5 (330.9-448.9)	293.7 (251.3-341.8)	347.6 (298.6-403.1)
Male adult mortality ($_{45}q_{15}$)	202.1 (168.8-	261.2 (205.0-	489.2 (415.6-568.6)	369.9 (309.2-434.2)	407.0 (341.7-

Characteristic	Bangladesh	India	Mozambique	Uganda	Zambia
	238.3)	328.7)			484.0)
Cause-specific mortality: Children under 5 *(rate per 100,000)*					
Measles	2.4 (0.7-6.1)	46.0 (13.7-105.9)	9.0 (2.6-22.9)	17.9 (5.7-43.0)	15.8 (5.2-38.0)
Diphtheria	0.1 (0.0-0.6)	0.3 (0.0-2.3)	1.2 (0.0-9.9)	0.5 (0.0-4.1)	0.6 (0.0-5.1)
Tetanus	5.3 (2.4-11.1)	10.1 (4.4-19.9)	4.3 (0.2-13.4)	13.9 (6.2-26.1)	1.9 (0.6-5.3)
Pertussis	3.4 (0.0-17.1)	17.2 (0.0-84.7)	25.4 (0.1-124.6)	13.1 (0.0-64.4)	8.5 (0.0-41.8)
Meningococcal infection	0.4 (0.1-0.8)	2.1 (1.2-3.2)	7.5 (4.4-11.9)	9.8 (5.8-16.1)	12.3 (7.8-18.4)
Diarrheal Disease	65.4 (48.9-86.4)	117.2 (76.1-165.8)	193.3 (131.9-276.2)	59.0 (37.7-89.0)	215.8 (153.6-296.1)
Lower respiratory infections	93.0 (66.6-124.4)	154.6 (115.8-202.9)	261.0 (177.0-373.1)	122.6 (84.2-175.9)	278.4 (205.0-365.9)
Cause-specific mortality: All ages *(rate per 100,000)*					
Cervix uteri cancer	9.6 (2.6-14.9)	6.6 (4.3-10.0)	10.6 (6.8-21.5)	10.1 (5.2-15.2)	15.9 (7.9-25.6)
Acute hepatitis B	4.0 (1.6-6.3)	4.5 (2.9-7.0)	4.7 (2.3-7.8)	2.1 (0.9-3.6)	2.0 (1.0-3.2)
Cirrhosis of the liver secondary to hepatitis B	8.5 (6.9-10.1)	5.4 (3.8-6.8)	4.5 (3.0-8.3)	3.2 (2.1-4.9)	5.8 (4.5-8.0)
Liver cancer secondary to hepatitis B	0.8 (0.6-1.3)	1.1 (0.8-1.3)	2.6 (1.3-3.4)	0.9 (0.7-1.1)	1.5 (1.1-1.9)

* Health expenditure is explained in terms of government health expenditure as source (GHE-S), DAH channeled through government (DAH-G), and DAH channeled through non-government entities (DAH-NG). GHE-S + DAH-G gives the total government health expenditure, GHE-S + Total DAH gives total spending on health in the country. Health expenditure estimates 2011; GAVI disbursements 2001 – 2012.

** Vaccination coverage for each country comes from survey estimates: 2009/10 India Coverage Evaluation Survey; 2011/12 Bangladesh DHS; 2011 Uganda DHS; 2011 Mozambique DHS and 2007 Zambia DHS.

*** BCG, measles and three doses each of DPT and polio vaccine (excluding polio vaccine given at birth).

**** All-cause mortality based on GBD2010 estimates for 2011; cause-specific mortality based on GBD2010 estimates for 2010.

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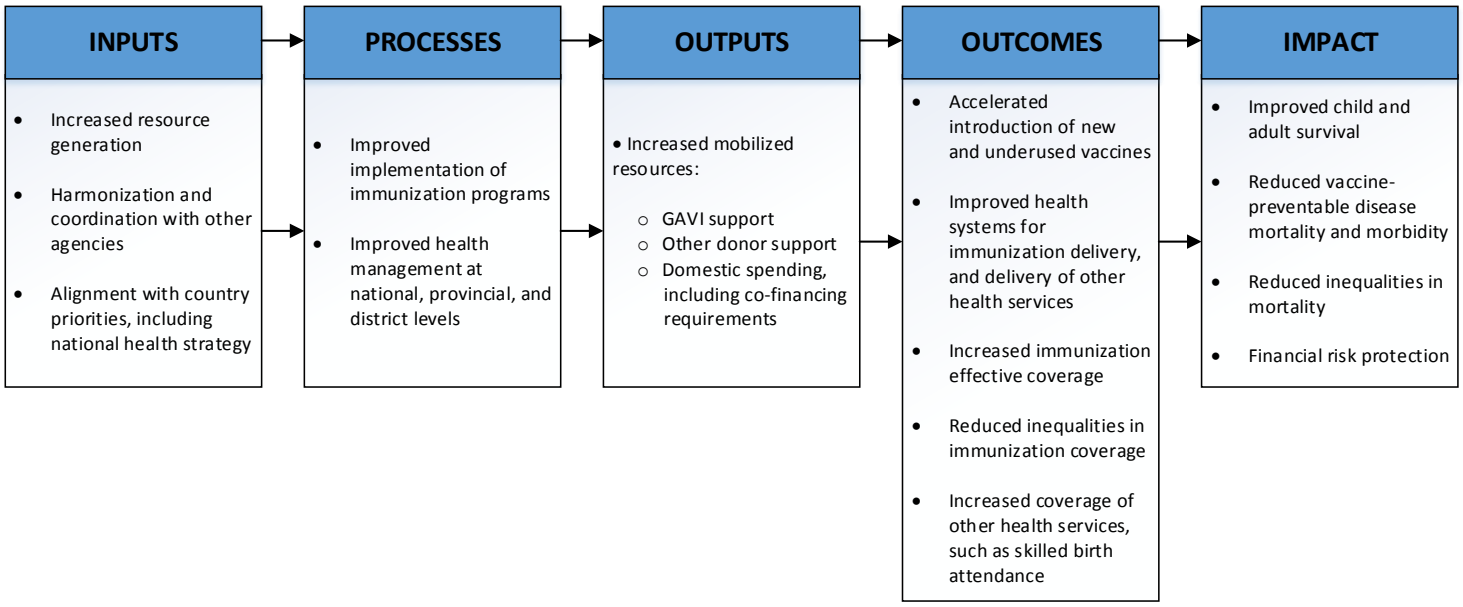
5 Evaluation framework and evaluation questions

The evaluation framework is shown in Figure 1.

Figure 1: The evaluation framework



The GAVI FCE is assessing a range of inputs, processes, outputs, outcomes, and impact with corresponding indicators including, but not limited to, those endorsed by the GAVI Alliance Board 2011-2015 strategy (selected key indicators are shown in Table 3).

Table 3: Selected key indicators for the GAVI FCE and endorsed indicators by GAVI Alliance Strategic Goals (SG)

Goal-level indicator	Measure
Country introductions of new and underused vaccines (SG1)	We will determine the year of introduction of each vaccine from program documents.
DTP3 immunization coverage, coverage of new and underused vaccines, the number of children fully immunized, and timely immunization coverage (SG1 and SG2)	We will measure the fraction of children by birth cohort (in surveys, using children aged 12-23 months) who received three doses of DTP, who received other relevant new and underused vaccines, and the number of children fully immunized. We will also measure timely immunization coverage. This will be done using all possible data sources, such as household surveys and immunization registry data collected through HMIS and the WHO/UNICEF Joint Reporting Form. We will use validated approaches for estimating national time trends, correcting for bias in immunization registry data. We will also produce subnational estimates of immunization coverage using validated statistical models.
DTP1-DTP3 drop-out rate (SG2)	We will measure the fraction of children who receive the first dose but not the third dose of DTP from an analysis of household surveys. We will use validated approaches for estimating national time trends and subnational estimates.
Equity in immunization coverage (SG2)	We will measure the distribution of immunization coverage against wealth index, education, gender, and geography using household surveys.
Vaccine cold chain integrity and vaccine stock	We will use health facility surveys to estimate the fraction of health facilities with functioning vaccine cold chains and the fraction of health facilities with adequate vaccine stocks.
Country investments in vaccines per child (SG3)	We will measure the average amount spent from national health budgets on vaccines, per surviving infant. This will be measured through a resource tracking study utilizing information from sources including National Health Accounts and other budget documents described in the resource tracking section.
Fulfillment of co-financing commitments (SG3)	We will measure the proportion of countries that meet their co-financing commitments in a timely manner, based on the resource tracking study.

Goal-level indicator	Measure
Child and adult mortality	We will estimate the probability of dying between birth and age five (child mortality) and the probability of dying between age 15 and age 60 (adult mortality) by analyzing all available data sources (census, household surveys, vital registration, Demographic Surveillance Sites). We will use validated approaches for estimating national time trends, and we will produce subnational estimates of child mortality.
Vaccine-preventable mortality	We will measure the mortality rate from vaccine-preventable diseases through a systematic analysis of all available cause of death data using cause of death models.
Number of future deaths averted	We will estimate the number of future deaths averted as a result of pentavalent, pneumococcal, rotavirus, yellow fever, meningitis A, Japanese encephalitis, HPV, typhoid, and rubella vaccination, building on existing natural history models, and by triangulating this with data collected from the vaccine effectiveness and mortality studies.

This evaluation will generate knowledge along the five dimensions proposed by the Organization for Economic Co-operation and Development (OECD) for the evaluation of development assistance: relevance, effectiveness, impact, efficiency, and sustainability. Table 4 provides the full list of evaluation questions for the GAVI FCE; these are based on an adaptation, in conjunction with the GAVI Monitoring and Evaluation team, of the original set of evaluation questions included in the request for proposals (RFP) for the GAVI FCE.

Table 4: Evaluation questions and measurement strategy for the GAVI Full Country Evaluation

Evaluation question	Measurement strategy
Relevance	
1. To what extent is the design of GAVI support and its implementation aligned with GAVI priorities and principles?	We will use process evaluation methods including desk review and key informant interviews with individuals at all levels of decision-making and implementation to understand the alignment of GAVI support with GAVI's priorities and principles.
2. To what extent is the design of GAVI support and its implementation at the country level relevant to the country's needs and aligned with the country's priorities and systems?	We will use process evaluation methods such as desk review and a resource tracking study to understand the design of GAVI Alliance support and how it is budgeted, disbursed and used. We will also examine whether resources are being directed to the areas of greatest need. We will use linked household and facility surveys to quantify the major supply and demand constraints to increasing immunization coverage and determine the alignment with priorities using process evaluation methods such as key informant interviews.
3. How do GAVI's process, products, and resources work at the country level to influence immunization-related outcomes? Are they improving over time? What are the intended and unintended consequences?	As this is essentially the fundamental question for the evaluation we will use all described methods in a mixed-method approach c.
Effectiveness	

Evaluation question	Measurement strategy
1. In the five target countries, how do achieved outputs at each phase align with goals and objectives outlined in the 2011-2015 GAVI Alliance Strategy and Business Plan and contribute to SG1, SG2 and SG3?	A resource tracking study will be conducted to examine how GAVI support has been disbursed and used. This will be combined with the necessary process, outcome, and impact evaluation methods to understand how this contributes to the GAVI Alliance's Strategic Goals.
2. How do achieved outputs at each phase contribute to meeting the specific objectives for the corresponding window of support (cash-based support versus new vaccine support)?	A resource tracking study will be conducted to examine how GAVI support has been disbursed and used. This will be combined with process, outcome, and impact evaluation methods to understand how this contributes to the corresponding window's objectives.
3. To what extent does the GAVI funding mechanism at the country level (e.g., HSS, ISS, NVS) and its implementation contribute to attainment of the country's stated goals (National Health Strategy/cMYP)?	A resource tracking study will be conducted to examine how GAVI support has been disbursed and used. This will be combined with process, outcome and impact evaluation methods to understand how this contributes to national health strategies and plans.
4. At both the global and country level, how do the GAVI Partnership inputs (from different partners) contribute to results achieved at the country level?	We will use process evaluation methods such as stakeholder network analysis and key informant interviews to understand the added value of the GAVI Alliance as a partnership.

Evaluation question	Measurement strategy
5. To what extent does the GAVI funding mechanism at country level (e.g., HSS, ISS, NVS, and including technical assistance) and its implementation reflect country-level ownership, alignment, harmonization, managing for results, and mutual accountability?	We will use process evaluation methods such key informant interviews to understand the alignment of GAVI Alliance support with aid effectiveness principles.
Impact	
1. What is the immunological evidence of effective vaccination?	To assess the immunological evidence of effective vaccination, we will conduct dried blood spots (DBS) analysis of vaccine antibodies in household surveys.
2. To what extent have reductions in morbidity and mortality of vaccine preventable diseases occurred? To what extent has the GAVI Alliance contributed to such reductions?	To measure the decline in morbidity and mortality of vaccine-preventable diseases, and the extent to which the GAVI Alliance contributed to such reductions, we will conduct community-based verbal autopsy studies to prospectively estimate national time trends in vaccine-preventable disease mortality. We will supplement this with an analysis of existing health system data (hospital death records and vaccine preventable disease case notification), correcting bias in incomplete reporting, to provide population-level estimates. We will use methods developed as part of the GBD 2010 study to estimate national trends in vaccine-preventable disease mortality over time. We will use the resource tracking study to understand the extent of GAVI's immunization support in comparison to other donors and domestic resources.
3. To what extent have reductions in child and adult mortality occurred in GAVI supported countries? To what extent has the GAVI Alliance contributed to such reductions?	To measure trends in child and adult mortality, we will undertake systematic data identification and compilation of all available sources on child and adult mortality, and will estimate national level trends over time. For child mortality we will also estimate trends at the district-level using validated small-area estimation methods. We will apply the same small-area estimation methods for immunization program indicators (e.g., the coverage and effective coverage of different vaccines), as well as trends in the coverage of other key health services (e.g., malaria control) and other determinants of child mortality (e.g., education). By estimating district-level trends in these indicators, we will employ difference-in-differences evaluation methods to examine how changes in child mortality relate to changes in immunization program indicators.

Evaluation question	Measurement strategy
4. To what extent has GAVI support contributed to social and financial risk protection for populations in countries supported by GAVI?	To understand the impact of catastrophic household payments related to vaccine-preventable diseases, we will embed an assessment of health care spending for each vaccine-preventable case compared to controls in the case-control study.
5. To what extent does GAVI support contribute to improved equity between and within countries, including, but not limited to, gender equity and equity between the poor and the non-poor?	We will examine GAVI's contribution to improved equity between and within countries by examining changes in geographic inequalities over time and their relationship with GAVI Alliance support using small area models. In addition, we will examine individual-level socioeconomic inequalities in immunization and health outcome indicators, by gender and between the poor and the non-poor, using asset-based measures of household wealth from household surveys.
6. Across all phases (decision to apply, application, preparation, implementation) what positive or negative unintended consequences have occurred as a result of GAVI support?	To analyze positive or negative unintended consequences as a result of GAVI support, we will examine whether GAVI support leads to improved coverage through health system strengthening activities or whether increased resources for immunization programs diverts limited resources (e.g., health workers) away from the provision of other health services. In addition, we will conduct a resource tracking study to examine to what extent GAVI support is additional to a government's own spending on health. We will also use process evaluation methods to identify more broadly positive or negative unintended consequences.
Efficiency	
1. To what extent is GAVI support cost-effective?	To study whether GAVI support is cost-effective, we will use economic evaluation and natural history models and triangulate this with evidence collected through the vaccine effectiveness and mortality studies to determine the number of deaths averted through immunization delivery. We will examine the extent of GAVI support in comparison with other donors and domestic resources through the resource tracking study. These two pieces of information will be combined to determine the cost per death and cost per case averted.

Evaluation question	Measurement strategy
2. To what extent have the following occurred in a timely manner: **a)** approval of cash support from GAVI, **b)** disbursement of money from GAVI to countries, **c)** utilization of funds and implementation of activities by countries, and **d)** achievement of objectives?	We will use process evaluation methods and the resource tracking study to examine how GAVI support has been implemented in each of the five countries, including how timely resources have been disbursed and used and whether the objectives have been achieved.
3. To what extent have the following occurred in a timely manner: **a)** approval of new and underused vaccine support from GAVI to countries, **b)** shipment and delivery of GAVI-supported vaccines, **c)** utilization of supply and implementation of immunization programs, and **d)** achievement of objectives?	We will use process evaluation methods and the resource tracking study to examine how GAVI support has been implemented in each of the five countries, including how timely resources have been disbursed and used and whether the objectives have been achieved.
Sustainability	
1. Considering the people, processes and structures that GAVI has invested in, what elements are likely to continue after direct support ends and what is the level of commitment by government to provide ongoing support?	We will use process evaluation methods and the resource tracking study to assess commitments, strategic health plans, sources of financing, financial sustainability, to understand to what extent the benefits to countries are likely to be maintained after the end of GAVI support.
Program implementation and context	

Evaluation question	Measurement strategy
1. What are the most important factors that affect program implementation, effectiveness, efficiency, and sustainability?	We will use process evaluation methods to identify the most important factors that affect immunization program implementation, effectiveness, efficiency and sustainability. Through estimating subnational-level indicators of immunization program performance, we will also examine both quantitative and qualitative correlates of immunization program performance.
2. To what extent has GAVI support been responsive to changes in context? In other words, to what extent have GAVI stakeholders used an adaptive management approach to learn from experience where appropriate?	We will use process evaluation methods such as key informant interviews to assess the extent to which GAVI support has been responsive to changes in context, whether GAVI stakeholders have used adaptive management approaches, and whether in-country stakeholders have contributed to the planning, implementation, monitoring, and evaluation of GAVI support.
3. To what extent do the main stakeholders at the country level contribute to the planning, implementation, monitoring, and evaluation of GAVI support? To what extent are their activities coherent and complementary?	We will use process evaluation methods such as stakeholder network analysis to understand how key stakeholders work together and whether their activities are complementary.

6 Synopsis of 2013 progress

This section briefly highlights the progress of the FCE in the 2013 period; a more detailed description of the evaluation progress is described in section 8: GAVI Full Country Evaluation Progress. The majority of work in 2013 was focused on the process evaluation, and preparing for the quantitative data collection of 2014. It should also be noted that, as the FCE involves a flexible and adaptive research design, the specifics of the evaluation methods outlined below represent a significant achievement from the first year's work.

In Uganda, Zambia, and Mozambique, the FCE team carried out detailed process evaluations of the introduction of PCV vaccine. This involved various methods of qualitative data collection, document review, and secondary data analysis.

In Bangladesh, as the introduction of pneumococcal vaccine was postponed, the FCE team focused efforts on a targeted evaluation of the Measles Rubella campaign. This evaluation specifically measured the campaign's impact on increasing MR coverage, and captured the campaign's effects on routine immunization services.

With regard to quantitative components, the FCE team developed master household and health facility instruments and protocols. These instruments and protocols were then tailored to each country, and adapted to reflect the emerging findings of the process evaluation. For example, in a country where poor community sensitization was identified in the process evaluation, an expanded section on maternal knowledge and sources of information is included in the household survey.

The vaccine effectiveness study in Mozambique has continued in hospital-based surveillance, and begun recruiting controls for the case-control study of invasive pneumococcal disease (IPD) and radiologically-confirmed pneumonia (XRP).

Lastly, outcome and impact evaluations have leveraged previous models used for the GBD2010 study[1]. This has included the generation of sub-national estimates of child mortality, immunization coverage, and other key indicators in some countries. Work is ongoing to systematically collect and incorporate datasets from all countries to further develop and update these estimates moving forward.

The following section outlines the detailed evaluation methods used for the FCE. These methods have grown and adapted since the inception of the project, and represent a more targeted and responsive evaluation. The findings of the first year's activities have shaped the approach of the evaluation, and resulted in more applicable, contextual, and country-driven activities in 2014.

7 Evaluation methods

A defining feature of the GAVI FCE is the use of a mixed-method approach including qualitative, semi-quantitative, and quantitative methods to understand the full results chain. An additional feature is that the GAVI FCE not only collects data and conducts analyses at the national level, but also at subnational

levels wherever possible. This approach permits a more nuanced examination of the factors that influence successful program implementation, and a better understanding of the factors that moderate the relationship between GAVI Alliance support and downstream indicators such as immunization coverage and child mortality.

Table 4 provides a mapping of the evaluation questions and methods used. The key study methods include:

- a process evaluation to understand the process by which countries implement GAVI support;
- health facility surveys that measure constraints to immunization delivery from both the supply and demand side;
- household surveys to measure key population-based indicators, including measuring vaccine antibodies;
- resource tracking study to identify how GAVI Alliance resources are used and its relationship to resources from other donors and domestic resources; vaccine effectiveness studies;
- outcome and impact analyses, which include the use of novel statistical methods to estimate trends over time in key indicators at the subnational level.

An important aspect of the mixed method approach is to allow triangulation of data and findings across methods as well as across the five GAVI FCE countries where relevant.

Based on consultation with stakeholders, the GAVI FCE in India will focus on the ongoing introduction of pentavalent vaccine. In Bangladesh, Mozambique, Uganda, and Zambia, we are broadly tracking all relevant vaccine and cash-based support over the evaluation period. This will allow a holistic examination of multiple support streams and how they interact; for example, how the presence or absence of HSS contributes or detracts from new vaccine introductions. This higher level process tracking will be complemented by more in-depth studies of specific streams of support in these four countries.

In 2013, the focus of the GAVI FCE has been on the introduction of pneumococcal vaccine in Mozambique, Uganda, and Zambia, and preparations for the measles-rubella campaign and PCV introduction in Bangladesh. Anticipated focus areas for the 2014 evaluation include, but are not limited to: In Bangladesh, the implementation of the measles-rubella campaign, the PCV introduction, HSS activities, and the application for HPV support; In India, the ongoing rollout of pentavalent vaccine; In Mozambique, the HPV demonstration project, HSS support, and rotavirus application; In Zambia, the recent introduction of rotavirus vaccine and new applications or re-programming of HSS funds; and in Uganda, the ongoing introduction of PCV and HSS, and application for HPV. We will also cover the decision-making and application phases for new support such as IPV.

Table 5 provides a summary of the components being implemented in each country and how they are being implemented. We undertook a highly consultative approach to the development of the evaluation plan for each country, which is reflected in the components. During the inception phase, informal and formal consultations were held with key stakeholders including the Ministry of Health,

technical partners, non-government organizations, and academia. It is important to note the evaluation approach and methods described in this report are based on information available to us at this time, and are intended to be flexible to changing circumstances. We have developed an evaluation plan that addresses the immunization activities that are currently planned for each country; however, implementation plans may be delayed, and/or new streams of funding may come on board over the course of the evaluation. With this in mind, details of the end line activities, in particular, will be more fully developed over the course of the GAVI FCE and will be described in subsequent reports. Further details on each of the key methods are described in the section below.

Table 5: Country-specific implementation of evaluation components, 2013-2016

Component	Country status of implementation
Process evaluation	**Bangladesh, Mozambique, Uganda, and Zambia** Conduct ongoing process tracking of immunization-related activities through participant observation of key meetings, trainings, and events, key informant interviews, and document review of the key processes surrounding new vaccine introduction and cash-based support such as HSS as well as interactions between the different streams of support implemented in each country. Conduct targeted studies using (1) after action reviews (AAR) to conduct rapid evaluations of key milestone events occurring in-country, and (2) implement contingent studies beginning in 2014 based on developed protocols and on-going throughout evaluation. Conduct analysis of partnership by gathering data through key informant interviews, direct observation, and focus group discussions to further contribute to the qualitative evaluation.

Component	Country status of implementation
Household data collection	**Bangladesh** Baseline (2014): Leveraging pre- and post-campaign, nationally-representative MR campaign evaluation household coverage surveys with collection of DBS in a subsample of children to measure HepB and tetanus antibodies. End-line (2016): Leveraging annual Coverage Evaluation Survey (CES). **India** Baseline (2014): Implementation of a stand-alone household coverage survey in two states (Madhya Pradesh and Odisha). DBS will be collected from a subsample of children to measure HepB and tetanus antibodies. End-line (2016): Follow-up survey of similar sample size and key indicators. **Mozambique** Baseline (2014): Vaccine coverage and related questions will be added to the nationally representative AIDS Indicator Survey/Malaria Indicator Survey (AIS/MIS); DBS will also be collected from a subsample to measure HepB and tetanus antibodies. End-line (2016): Leveraging planned Demographic and Health Survey (DHS). **Uganda** Baseline (2014): Implementation of a stand-alone household coverage survey; verbal autopsies will be collected from households where a death of a child under 5 occurred in the last year, and DBS will be collected from a subsample of children to measure HepB and tetanus antibodies. End-line (2016): Leveraging planned DHS 2015-2016. **Zambia** Baseline (2014): A short household survey will be conducted to follow up on a subsample of households surveyed during the 2014 Demographic Health Survey; in addition, DBS samples will be collected from a subsample of children to measure HepB and tetanus antibodies. End-line (2016): Leveraging planned Living Conditions Monitoring Survey (LCMS), 2015-2016.

Component	Country status of implementation
Health facility data collection	**Bangladesh, India, and Mozambique** Baseline (2014): Implementation of a nationally representative Access, Bottlenecks, Costs, and Equity (ABCE) Health Facility Survey to collect key indicators including: finances and revenue, personnel, services, and outputs. This will include the administration of a vaccine module to capture data on vaccine services, cold chain capacity, and stock availability. End-line (2016): Conducting follow-up to 2014 ABCE survey, gathering data on changes in key indicators related to vaccine service delivery and GAVI support. **Uganda and Zambia** Baseline (2014): Follow-up of the previously conducted ABCE facility surveys. This will include the administration of a vaccine module to capture data on vaccine services, cold chain capacity, stock availability, and coverage. End-line (2016): Conducting follow-up to previous ABCE surveys, gathering data on changes in key indicators related to vaccine service delivery and GAVI support. **All partner countries** Conduct patient exit interviews of caretakers exiting facilities after visiting to receive vaccination services to understand drivers of patient demand, satisfaction, and perceptions of quality.
Resource tracking study	**Bangladesh, Mozambique, Uganda, and Zambia** Collect data from in-country EPI Expenditure Accounts (EEA) and EPI Expenditure Tracking (EAT) studies by leveraging ongoing National Health Account, the ABCE health facility surveys and other expenditures tracking activities. These data and analyses are targeted annually, beginning in 2014.
Vaccine-effectiveness study	**Bangladesh** Baseline (2014): Pneumococcal carriage survey of households within an urban and rural site in 2014. End-line (2015-2016): Follow-up household survey in the same sites. **India** Baseline (2014): Hib carriage study integrated into the household surveys conducted in two states. End-line (2016): Follow-up carriage study integrated into the household surveys conducted in two states. **Mozambique** Ongoing surveillance of invasive pneumococcal disease (IPD) and X-ray confirmed pneumonia (XRP) within a demographic surveillance site (DSS) Baseline (2014) and follow-up nasopharyngeal carriage study in three sites, and case-control studies of IPD and XRP.

Component	Country status of implementation
Measles-rubella campaign evaluation	**Bangladesh** *Household surveys* Baseline (2013): Implementation of rounds of household coverage surveys, prior to the roll-out of the measles-rubella vaccine campaign. DBS samples collected from subset of children and analyzed for the presence of MR antibodies to measure population susceptibility to MR. Follow-up (2014): Nationally representative household coverage survey, following implementation of the campaign. DBS samples collected from subset of children and analyzed for the presence of MR antibodies to measure population susceptibility to MR. *Health facility assessments* 2014: In addition to the ABCE facility survey mentioned above, during the month-long measles-rubella campaign, conduct facility assessments through direct observation, exit interviews of caregivers during campaign days and facility records review. *EPI service provider interview* 2014: After the MR campaign implementation is complete, conduct interviews with EPI service providers to gather further information on campaign implementation.

7.1 Process evaluation

The process evaluation examines the interface between the GAVI Alliance and countries, as GAVI inputs (including financial and technical assistance) are applied for, received, and implemented. The intent is to answer the following three questions.

1. To what extent is the process of providing GAVI Alliance support to countries improving over time? What has improved, what has not improved, and why?
2. What are intended and unintended consequences of GAVI Alliance support across different levels of the immunization system, and why have these consequences occurred?
3. To what extent is the design of GAVI Alliance support and its implementation relevant to the country's needs and aligned with the country's priorities and systems?

The process evaluation will involve two broad categories of data collection activities, reflecting different levels of depth of investigation:

- Process tracking, a suite of continuous and high-level monitoring activities, and
- Targeted studies, including milestone event studies and contingent studies, which are intended to collect more in-depth information on targeted topics.

7.1.1 Process tracking

Process tracking will monitor the implementation and timing of planned and unplanned activities, facilitate identification of key stakeholders and decision-making processes, and document outputs. Process tracking will cover cash-based GAVI support and new vaccine support. It will also cover overall

immunization program activities that are directly linked to GAVI support. Depending on the types of active or anticipated GAVI Alliance support during the evaluation period, the number of processes being tracked may be different in each country. Specifically, the process tracking will contribute to assessment of the following four elements of the process:

1. Comprehensiveness: to what extent have the activities necessary for successful implementation been included in work plans? Or conversely, to what extent are unplanned activities been conducted in order to complete tasks?
2. Completeness: to what extent are planned activities completed?
3. Timeliness: to what extent are activities started, sequenced, and completed in a timely manner?
4. Partner/relationships: for each task, which stakeholders are involved and what roles do they play? How do they interact?

Data from process tracking will be collected through participant observation, key informant interviews (KIIs), and focus group discussions (FGDs).

7.1.2 Targeted studies

Two types of targeted studies – planned studies of milestone events and contingent studies – are designed, for three purposes:

1. To provide opportunities to answer country-specific priority evaluation questions relevant to GAVI Alliance support.
2. To address in greater depth evaluation questions that arise from process tracking and from quantitative studies.
3. To document the intended and unintended consequences of GAVI assistance to routine immunization programs and health systems, and to identify causal factors that influenced these consequences.

Planned studies of milestone events

Planned studies of milestone events consist of shorter-term, qualitative evaluation studies that explore specific factors that may have influenced outcomes related to GAVI Alliance support, such as the new application form and submission process for GAVI Alliance support.

Milestone events are investigated using in-depth key informant interviews, focus group discussions, and/or the after action review (AAR) methodology. The AAR focuses on a key process or milestone event, and is designed to clarify what was originally intended, what actually happened, what went well and why, and what can be improved and how. The AAR engages participants in the process to compare the actual output of a process with its intended outcome. Through a facilitated workshop that explores in-depth how the process unfolded, participants identify strengths and weaknesses, and together decide how to improve the performance of GAVI-sponsored programs. As a result, the method explicitly links the process evaluation to process improvement, as well as provides a means for in-depth documentation and verification of processes.

Contingent studies

Contingent studies are in-depth qualitative or mixed-method research studies with the flexibility to address country-specific research questions. These questions may be identified through global or local stakeholder consultation, process tracking, or through quantitative studies such as facility surveys, household surveys, and resource tracking studies. The number of contingent studies per country will be determined by the availability of financial and technical resources, the level of interest from country stakeholders, and the number of priority research questions identified by countries (Table 6). Contingent studies will utilize a range of research methods.

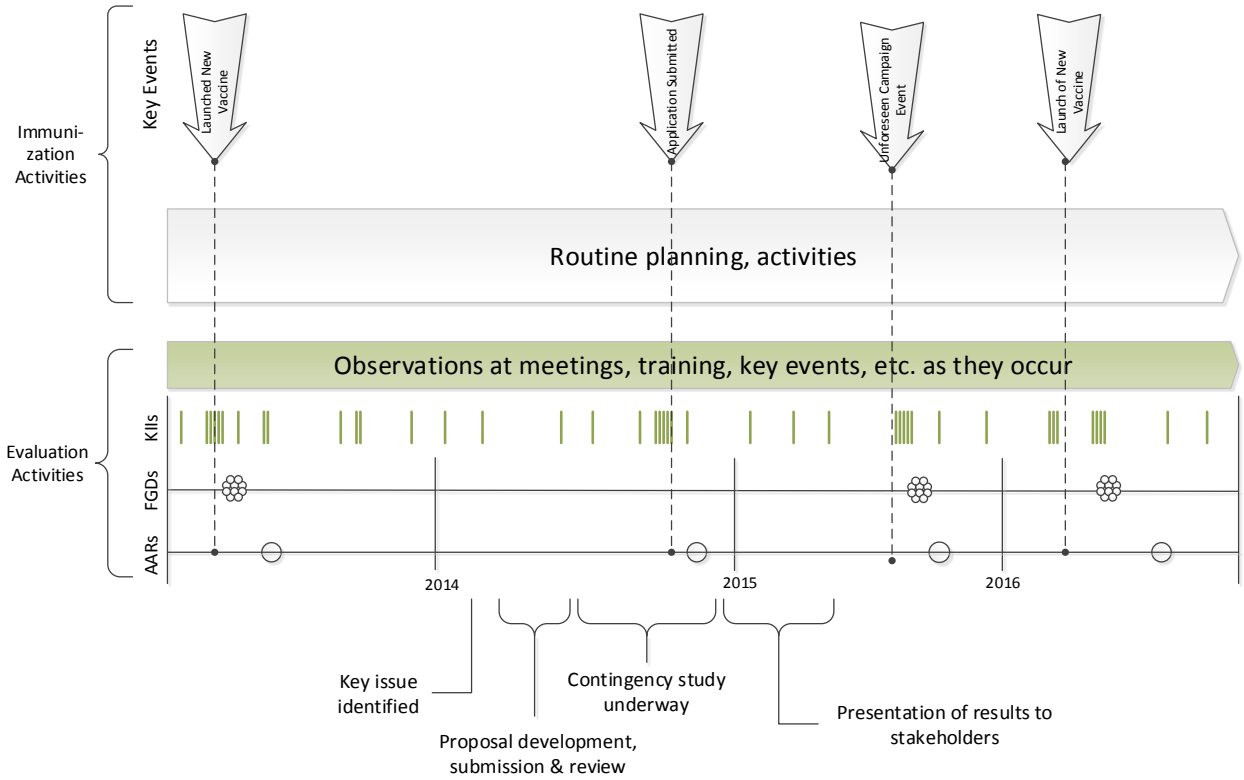
Table 6: Potential contingent study topics

Country	Potential Contingent Study Topics
Bangladesh	• Assessing the effectiveness of alternative strategies for improving uptake and immunization coverage in hard-to-reach areas of Bangladesh • Evaluating the role of community clinics in strengthening immunization system in Bangladesh • Historical and prospective case studies on the vaccination program in Bangladesh, as well as broader assessments of MNCH program policies and strategies • Assessing the contribution of political discontents in immunization service delivery
Uganda	• Community awareness and preparedness for the PCV vaccine, and identification of sources of knowledge • Quality of immunization services in the private health sector, compared to the public health sector, including health worker perspectives • Impact of IFMS on the PCV introduction, including analysis of structure and policies of IFMS, compared to previous system
Mozambique	• Quality of Data and identification of causes for poor data quality • Temperature monitoring throughout the vaccine cold chain, and the use of VVMs for vaccine management • Evaluation of cost-effectiveness of outreach campaigns (brigadas moveis), and comparison of outreach campaigns to static vaccination services • Evaluation of the donor coordination and support in the development of GAVI applications provided to the NIP • Evaluation of training quality, and identification of key decisions, processes, bottlenecks, and constraints that affected training outcomes
	• Study of the intended and unintended consequences of simultaneous introduction of

Country	Potential Contingent Study Topics
Zambia	PCV and MSD, combined with the Rotavirus vaccine and HPV introductions during the same year • Evaluation of the consequences surrounding the abolition of immunization activities from Child Health Week • Evaluation of the realignment of MCDMCH, and study of the effects on EPI programs, funding flows, monitoring, and supervision

These data collection mechanisms are geared toward the prospective evaluation of the application (both decision to apply, as well as development of the application), preparation, and implementation processes. They are intended to be complementary and implemented over the course of the evaluation period, as illustrated in Figure 2.

Figure 2: Illustrative flow of process evaluation activities



7.1.3 Partnership analysis

A key principle of the GAVI Alliance is partnership. As relates to the process of applying for and implementing GAVI support, core members of the Alliance partnership include the GAVI Secretariat, WHO, and UNICEF. The GAVI Secretariat is based in Geneva, and each country has a designated Country Responsible Officer (CRO) assigned to be the primary point of contact for the country. WHO and UNICEF have in-country offices and, often with other supporting partners, provide technical assistance to the country immunization program.

In theory, partnership adds efficiency, effectiveness, and legitimacy to the implementation of GAVI assistance through collaboration and shared resources. The evaluation team is undertaking a partnership analysis that includes a set of questions to be integrated into process tracking activities including observation and KIIs. Information about roles, responsibilities, and interactions between partners will inform a stakeholder network analysis, designed to answer questions such as:

- To what extent are GAVI's Country Responsible Officers integrated into the country stakeholder network, and what roles do they play?
- To what extent do in-country Alliance partners interact throughout the process of GAVI assistance, from application through implementation?
- How is key information related to GAVI assistance disseminated among in-country Alliance partners?
- To what extent do Alliance partners effectively interact to provide necessary assistance to the government?
- What are priority issues for key stakeholders concerning new vaccine introductions and GAVI Alliance support in the country?
- How do the roles of key stakeholders change over time?

This analysis will provide important insights into the functioning and effectiveness of the partnership model in the evaluation countries, the structure of those partnerships at different phases of the GAVI Alliance support (decision to adopt, application, preparation, implementation), and their evolution during the evaluation.

7.2 Resource tracking

The focus of the resource tracking (RT) component of this evaluation is to shed light on the flow and use of resources (financial, commodities, and technical assistance) for immunization programs. The RT component will investigate the following questions:

- What GAVI Alliance support (by type of support) is spent on immunization and other related activities, such as health system development?
- What is the contribution of other external donors' spending on immunization and other related activities?
- What is the impact of GAVI Alliance and other external donor support on the national budget, i.e., domestic resources, for immunization and health systems?

We are implementing the resource tracking study by adapting and applying existing RT tools like the National Health Accounts (NHA) framework and the Public Expenditure Tracking Survey (PETS) methodology. This will also be done by integrating efforts with other resource tracking studies that are being conducted in each of the five countries. Furthermore, the RT activities are closely linked with the health facility surveys, which function as an important data collection mechanism for the resource tracking work by providing expenditure estimates at the implementation and district levels.

7.3 Health facility surveys

In order to examine how GAVI Alliance support has led to stronger health systems, such as through the HSS window of support, we must collect information on their ability to deliver immunizations and health services more generally. Factors that affect these components include properly functioning vaccine cold chains, availability of health workers, and the location and accessibility of health services.

In each of the GAVI FCE countries, health facility data collection will be undertaken as part of the Access, Bottlenecks, Costs, and Equity (ABCE) Project, led by IHME. The ABCE project includes a multi-country facility survey, conducted in a select set of facilities within a representative sample of districts. The ABCE survey captures characteristics of health facilities across a number of dimensions: facility inputs and finances; management; laboratory characteristics and supplies; medical consumables and medical equipment; facility capacity; pharmacy characteristics and pharmaceutical stocks; and facility outputs. In addition to collecting information at the facility level, the project also collects key information from District Health Offices (or their equivalent) including expenses, human resources, and infrastructure. The ABCE study also collected information from patient exit interviews on user fees, patient perceptions of quality, and patients' health care experience.

A key research question is whether GAVI Alliance support is being directed toward those areas that have the greatest effect in increasing immunization coverage and improving health outcomes. Constraints to increasing effective immunization coverage include supply-side factors, such as maintenance of vaccine cold chains, and demand-side factors, such as seeking health care. Data to support answering these questions are collected though the patient exit interviews administered at health facilities during ABCE data collection.

Resource allocation would be most efficient if it were directed toward addressing the constraints that are the biggest impediments to increasing effective immunization coverage. We will use geo-located facility and household surveys to analyze supply and demand side constraints to increasing immunization effective coverage.

7.4 Household surveys

Population-based household health surveys are a critical source of information, and—due to underdeveloped health information systems—are considered the gold standard for many of the indicators in the GAVI FCE, including immunization coverage and child mortality. Household health surveys also provide an avenue for assessing and correcting routine health information system data; for example, household survey data will be used as part of the GAVI FCE to examine and correct for

inaccuracies that arise in administrative data estimates of immunization coverage. The usual approach for measuring immunization coverage in surveys is to use vaccine card documentation and maternal recall when vaccine cards are not present. Literature has shown, however, that maternal recall may have limited accuracy[2–7]. Even when a child has been documented on a vaccine card to have received a particular vaccine, this does not mean that the child is effectively immunized— a breakdown in the cold chain, for example, may mean that the vaccine delivered is no longer efficacious. Given that a core part of the assistance provided by the GAVI Alliance is to strengthen systems and improve vaccine cold chains, it is critical to know if these investments translate to higher rates of immunization in the population.

As part of the GAVI FCE, we are implementing biomarker-based approaches using dried blood spots (DBS) to provide a way to examine population-level immunization coverage in each country. Dried blood spots will be analyzed to measure antibody responses to hepatitis B and tetanus vaccines to estimate effective vaccine coverage. To help minimize the cost of data collection we are limiting data collection to a subsample; we will then use statistical models that can be applied to correct vaccine card and maternal recall responses in the full survey sample to estimate population-based effective immunization coverage. One exception is India where we will implement a larger sample of DBS to measure antibody responses based on stakeholder feedback.

Assays for the following markers will be developed:

- Anti-Hepatitis B Virus surface antigen total antibody titer (a-HBs total)
- Anti-Hepatitis B Virus core antigen total antibody titer (a-HBc total)
- Hepatitis B Virus surface antigen (HBsAg)
- Anti-Tetanus toxin IgG antibody titer (a-TT IgG)

These assays will be standardized at a reference laboratory (University of Washington Department of Laboratory Medicine). Once developed, local laboratory capacity will be strengthen to test DBS samples in-country. If sufficient quality can be achieved by the local laboratory, analysis of samples will proceed there; if local labs do not meet quality assurance standards, testing will be done at the reference laboratory. Quality control procedures will be implemented by the reference laboratory through re-testing of a random 10% of samples.

7.5 Vaccine effectiveness studies

The introduction of pneumococcal, rotavirus, and pentavalent vaccines represent sizeable GAVI Alliance support streams. There are known limitations of current observational methods for measuring vaccine effectiveness. For the GAVI FCE, we have chosen to focus the vaccine effectiveness studies on three sites, paying careful attention to known sources of bias. Given the relative advantages and disadvantages of the evaluation methods, we will also be triangulating across different study design methods (such as nasopharyngeal carriage studies, before-after surveillance and case-control designs) where possible. Vaccine effectiveness studies will be conducted in Mozambique, Bangladesh, and India. In Zambia, we will rely on an ongoing study to evaluate the effectiveness of the rotavirus vaccine. We are not presently planning a vaccine effectiveness study in Uganda.

In Mozambique, the primary site for the vaccine effectiveness work is the Manhiça District, with work led by CISM. The Manhiça site is a highly advantageous location as it is within a well-defined and studied demographic surveillance site (DSS). This facilitates the implementation of multiple methods and the presence of the DSS helps to address the limitations of denominator estimation, and facilitates unbiased control selection for case-control studies. The following vaccine effectiveness components are being implemented in this site:

1 **Surveillance of invasive bacterial disease and pneumonia at the Manhiça District hospital**. This is an established surveillance system for invasive bacterial disease and pneumonia dating back to 2001 and 2004, respectively. The surveillance site covers the DSS population as well as the remaining population in Manhiça District.
2 **Nasopharyngeal carriage study of S. pneumoniae and serotype distribution of colonizing isolates in children under 5 years of age.** A baseline cross-sectional survey prior to introduction of the pneumococcal vaccine and follow-up surveys one and two years after the introduction are being implemented in Manhiça, Maputo City, and Nampula Province.
3 **Case-control study for invasive pneumococcal disease**. This leverages the surveillance system described above and, based on sample size calculations, there will be sufficient cases from the Manhiça DSS population during the evaluation period. As the case-control study would be embedded within the DSS, this would address the principle biases around control selection and would allow a more precise control of potential confounders by accessing the detailed items available as part of the DSS.
4 **Case-control study for X-ray confirmed pneumonia (XRP)**. This also leverages the existing surveillance system. The limitation, however, is that it is anticipated there will be insufficient cases for XRP among the Manhiça DSS population. As a result, the DSS is being expanded to include the rest of the Manhiça District population, and additional cases and controls are being collected in Maputo City.

In Bangladesh, we plan to implement a pneumococcal nasopharyngeal carriage survey both before and one and two years after the introduction of PCV in sites to be determined. We are in the process of identifying sites for the nasopharyngeal carriage study in Bangladesh and intend to align this work with other related work that is planned and ongoing in Bangladesh. We intend to implement the nasopharyngeal carriage surveys in existing surveillance sites so that the results from the nasopharyngeal carriage surveys can be compared to, for example, changes in mortality or disease incidence in the population from these other data sources.

In India, we will assess the impact of pentavalent immunization on reducing Hib nasopharyngeal carriage rates in children as part of the household survey that will be implemented in each of two states. The Hib carriage rate at baseline will be compared with a similar assessment in the end-line survey after two years to assess the reduction in the Hib nasopharyngeal carriage rates, and its association with immunization coverage and other socio-demographic variables. The assessment of *Streptococcus pneumoniae* serotypes in the nasopharyngeal swabs in the population-based sample of children will also provide useful baseline data that would inform the ongoing discussions in India about the value and timing of including pneumococcal vaccine in the national immunization program. As part of the study, will be conducting a pilot study to assess field data collection including the field-based LAMP method of

Hib The pilot study will be done in Hyderabad on a sample of 100 children 6-59 months of age visiting a tertiary hospital, and another 100 children 6-59 months of age sampled from the population.

The Programme for Awareness and Elimination of Diarrhoea (PAED), implemented by the Centre for Infectious Disease Research in Zambia (CIDRZ), is a demonstration pilot of comprehensive diarrhea control, including the introduction of rotavirus vaccine, in 4 districts in Lusaka Province. An assessment of the impact of PAED, including rotavirus vaccine, is being implemented - A Comprehensive Assessment of Diarrhoea and Enteric Disease Management in Children or ACADEMIC study. The ACADEMIC study will assess impact of PAED on morbidity and mortality rates using community and health facility surveys. Given this ongoing study which will inform the likely local impact of the rotavirus vaccine introduction in Zambia and consistent with the principle of non-duplication, we have not planned to conduct as part of the GAVI FCE, a vaccine effectiveness study of rotavirus in Zambia. We will, however, consider, future rotavirus vaccine effectiveness studies pending introduction of the vaccine in other GAVI FCE countries.

7.6 Outcome and impact evaluation analysis

The outcome and impact evaluation analysis will involve the following:

- National and subnational estimation of trends in key indicators (Table 3) by combining all available data
- Socioeconomic-related inequalities analysis
- District-level difference-in-differences analysis
- Lives saved analysis

7.6.1 Estimating national- and subnational-level trends in outcome and impact indicators

Another aspect of the evaluation is the compilation of all available data on key indicators and application of validated statistical methods to understand how these indicators have changed over time. Where sufficient data are available, we will apply statistical models to understand the extent of variation in key indicators at the district level or other subnational level. Table 3 provides a list of the key outcome indicators that we will measure.

Using the data sources, including household surveys and administrative data, that we will continuously identify we will undertake the following steps:

- **Assess the general quality and completeness of data.** As the data will come from many different sources, collection platforms, and years, there will undoubtedly be large variation in their quality. We will systematically assess the data by looking at standard measures of missing data. For example, for administrative data on immunization coverage we will examine completeness of district reporting. Data visualization tools will be used to visualize discrepancies between different sources over time at both national and sub-national levels.

- **Apply statistical methods to data to produce unbiased measurements of health indicators.** For HMIS data we will use appropriate imputation techniques to adjust for incomplete

reporting. We will, for example, apply new methods for analyzing summary birth histories to measure child mortality and sibling survival methods to measure adult mortality.

- **Establish trends for health indicators using validated statistical models for time-series data.** Methods developments in global health and other disciplines are improving the estimation of time trends in health indicators with the use of new modeling methods that have been applied to systematic assessments of child, adult, and maternal mortality. These new approaches have been shown to produce dramatically better predictions than previous approaches. We will use validated methods such as spatiotemporal regression, Gaussian Process Regression (GPR) and small-area statistical models to establish trends for health indicators at the national and sub-national levels.

The methods described above are ideally situated for advancing the vaccine coverage data quality agenda. The approach we are proposing begins with the compilation of all data sources (household surveys, administrative data), data visualization tools to visualize discrepancies over time at both national and sub-national levels and then statistical models such as the spatiotemporal/GPR approaches to triangulate across sources. With this approach, we are able to identify districts where there are large discrepancies that could be targets for further investigation. Further investigations will leverage the health facility surveys to collect and assess facility-level administrative data and may also be the topic of additional contingent studies.

7.6.2 Analysis of inequalities in immunization program indicators and related factors

In addition to a geographic analysis of inequalities produced through the small area analysis, we will also assess inequalities in key areas such as immunization coverage. We will use available household survey data to examine the distribution of these indicators against household wealth indices[8,9], education and gender using the collected household survey data as well as other household survey datasets that collect this information.

7.6.3 Subnational level difference-in-differences analysis

One of the key research questions to answer in an evaluation is the counterfactual; in this case, what would have happened in the absence of GAVI Alliance support. This is not possible to answer by looking at national-level measures, so we will conduct a difference-in-differences analysis at the district level to examine the relationship between outcomes and indicators of immunization system performance. A difference-in-differences analysis compares the differences in changes in a given outcome—such as immunization coverage—over time between two districts; that is, it examines the variation in change between two areas, which serves to minimize sources of unknown bias. This approach, which has been used successfully in previous studies, can provide a more nuanced understanding of the relationship between inputs, process, outputs, outcomes, and impact and the contribution of GAVI Alliance support. To do this, we will estimate district-level trends in child mortality or other health outcomes where possible; estimate district-level trends in immunization system performance (through, for example, immunization coverage); estimate trends in the coverage and effective coverage of other key health services, such as malaria control; and use appropriate statistical analysis to examine changes in health

outcomes against changes in immunization system indicators controlling for potential confounders at the district level.

7.6.4 Estimation of lives saved and cost effectiveness of GAVI Alliance support

This component will estimate the likely benefits of GAVI Alliance support and immunization programs more broadly, by year of impact and vaccinated cohort. To compute lives saved, we will build on existing models such as those developed as part of the Global Burden of Disease study as well as other estimation efforts such as WHO, Lives Saved Tool (LIST), or Child Health Epidemiology Reference Group (CHERG). We will triangulate the input parameters and results from models with the results from the studies on vaccine effectiveness and mortality. We will estimate the number of deaths likely averted through immunization programs generally which reflects contributions from multiple agencies, i.e. country EPI programs, GAVI, other donors. In addition, we will use the resource tracking study to determine the fraction that GAVI Alliance support contributes to this overall reduction in deaths. This analysis will involve multiple scenario or sensitivity analyses to reflect different perspectives as well as underlying models and data.

7.7 Mixed-method analysis and cross-country analysis

An important feature of the GAVI FCE is maximizing linkages and triangulation among the evaluation components described above. During the course of the evaluation we will use results from one evaluation component to inform the approach of other evaluation components. For example, if the results of the process evaluation highlights that distribution of vaccines from district to outlying facilities is a major impediment, we will use this understanding to target questions in the health facility survey surrounding vaccine distribution and delivery. The connection may also work the other way; for example, the resource tracking study may identify that the resource distribution to certain districts is inadequate. These findings can then be supplemented by the process evaluation, which may provide a more nuanced understanding of why resource distribution was inadequate, or identify the causes of disbursement delays.

We will use a case study design to combine the information across the different evaluation components for each country as well as facilitate comparisons across countries. The case study design allows for the triangulation of qualitative and quantitative methods. Cross-country comparison will offer insights such as similarities and differences in how GAVI Alliance support is implemented, roles played by GAVI Alliance partners, and contextual factors influencing the outcomes of GAVI Alliance support.

7.8 Measles-rubella campaign evaluation

One of the objectives of the GAVI FCE is to serve as a platform for targeted or special studies that complement the proposed scope of work of the assessment. An example of this is an additional evaluation component, developed at the request of the GAVI Alliance, to examine the measles-rubella (MR) campaign in Bangladesh. The Ministry of Health and Family Welfare (MOHFW) of the Government of Bangladesh will implement the MR campaign in 2014, targeting more than 52 million children aged 9 months to 15 years.

The MR campaign evaluation is integrated with and builds upon the GAVI FCE evaluation activities and has two specific objectives:

1. Assess the impact of the MR campaign on improving MR coverage
2. Assess the impact of the MR campaign on the routine EPI program, including key functions of the immunization system

As with the GAVI FCE, the MR campaign evaluation uses a mixed-method approach at various levels of the health system, as described below.

7.8.1 Vaccine coverage survey

To assess the primary objective of measuring how the MR campaign has increased vaccine coverage, we are implementing a pre- and post-campaign vaccine coverage survey. A pre-campaign survey was necessary in Bangladesh because the Measles, Mumps, Rubella (MMR) vaccine has been provided through the private sector in Bangladesh for the last few years, and the MR vaccine was introduced as part of the routine EPI program of Bangladesh in 2012; therefore, it was not reasonable to assume that vaccine coverage against measles or rubella would be zero. DBS collected from a subsample of children will allow a measurement of measles and rubella antibodies to determine how population-level susceptibility to measles and rubella has changed as a result of the MR campaign. The coverage survey also allows us to measure how knowledge, attitudes, and practices of primary caregivers of the target population has changed as a result of the MR campaign.

To minimize costs, the pre-campaign survey will focus on four selected geographies, stratified by low-performing/high-performing immunization coverage and urban/rural. The pre-campaign survey involves interviewing the primary caregiver of children aged 9 months to 15 years. Data collected include: status of MR vaccination among children aged 9 months to 15 years, respondents' knowledge, attitude, and practices (KAP) regarding the MR vaccine, and demand-side constraints to vaccination.

To allow the measurement of overall population-level vaccine coverage, the post-campaign survey is designed to be representative at the division and national level. We will purposefully sample the same geographies included in the pre-campaign survey to allow measurement of change in vaccine coverage and measles and rubella susceptibility as a result of the campaign. The same instrument from the pre-campaign survey will be utilized, with additional modules added to capture perceptions about the campaign. For example, we will examine whether the campaign has motivated caregivers to vaccinate children previously excluded, or whether it has motivated caregivers to vaccinate their children with other vaccines besides MR. Also, we will capture details of the registration process to determine the target population, and whether the campaign influenced caregivers to seek other healthcare services from the local facilities.

7.8.2 Facility assessment

A facility assessment will be conducted during the implementation of the MR campaign in Bangladesh. This will allow us to understand how the MR campaign has affected routine EPI services and measure performance of the campaign in real time by observing actual immunization sessions across the country.

The facility assessment will use the following data collection methods: observations of vaccination sessions during the MR campaign at routine EPI centers and educational institutes, review of facility-level records, and exit interviews of mothers. A total of 100 facilities from high-performing upazilas and wards and 100 facilities from low-performing upazilas and wards will be selected randomly for the assessment.

7.8.3 EPI service provider survey

In addition to the facility assessment, we will also conduct a survey with EPI service providers (health assistants in rural areas and vaccinators in urban areas) following the completion of the MR campaign. EPI service providers of the sampled clusters of the post-campaign survey will be included in the sample for EPI service provider survey. Data from the service providers will be collected on change in work load, adequacy of supply of required logistics, training on MR campaign, incentives for extra work, interruption of routine EPI activities, and interruption of other health program activities.

7.8.4 Process evaluation

In addition to the vaccine coverage surveys, facility assessments, and EPI service provider surveys, we will evaluate the process of implementing the MR campaign through qualitative methods. This component will be integrated into the process evaluation component of the GAVI FCE study as described earlier. The objectives of the process evaluation are to understand the key decisions made by stakeholders related to the design and operation of the MR campaign and EPI program implementation during the campaign and identify factors that have influenced the implementation of the MR campaign and EPI program during the campaign period at the national, subnational, facility, and community levels. This will be based on document review, observation, key informant interviews, and focus group discussions.

7.8.5 Review and analysis of secondary data

Lastly, we will compile and analyze available secondary data. This includes facility-level service statistics including routine EPI coverage data, the annual Coverage Evaluation Survey (CES), information related to MR coverage and other health care utilization data from the selected facilities, and EPI surveillance data including measles and rubella cases reported before and after introduction of MR vaccine.

8 GAVI Full Country Evaluation Progress 2013

This section of the report describes achievements and progress towards implementing the evaluation methods described and associated evaluation activities such as dissemination and capacity strengthening. We also describe lessons learned to date. As noted earlier, implementation commenced in 2013 in Bangladesh, Mozambique, Uganda and Zambia; the main phase evaluation activities in India will commence in 2014. As Figure 3 outlines, much of the focus of the GAVI FCE in 2013 has been on the development of project infrastructure including study protocols, data collection instruments, institutional review board (IRB) applications and approvals, and capacity strengthening. As can be seen it Figure 3, data collection and subsequent analysis has been limited to the third and fourth quarters. It should also be noted that the official contract for the main phase of the evaluation between the GAVI Alliance and the GAVI FCE team was formally signed on August 7, 2013. Prior to this the GAVI FCE team was able to support many of the planned activities; however, several were delayed or scaled back due to a lack of available funding at the time. The remainder of this section describes in further detail progress toward implementing the methods described in the previous section of the report.

Figure 3: Progress of evaluation activities for 2013, by quarter

Evaluation component and country	Q1	Q2	Q3	Q4
Process evaluation				
Master protocol and instrument development				
Development of global theory of change and evaluation questions				
IRB application and approval				
Engagement and interviews with international personnel (GAVI and partners)				
Uganda				
Country adaptation of master instruments and protocols				
Country IRB approval				
Document review and embedded observation				
Key informant interviews				
Analysis and reporting				
Zambia				
Country adaptation of master instruments and protocols				
Country IRB approval				
Document review and embedded observation				
Key informant interviews				
Analysis and reporting				
Mozambique				
Country adaptation of master instruments and protocols				
Country IRB approval				
Document review and embedded observation				
Key informant interviews				
After Action Review Workshop				

Evaluation component and country	Q1	Q2	Q3	Q4
Analysis and reporting				
Household survey				
Development of master instruments and protocols				
Country adaptation of instruments and protocols				
DBS assay development and standardization				
Literature review and identification of methodology				
Identification of vendors and products required				
Testing vendors and products with known blood samples (control samples)				
Health facility survey				
Development of master instruments protocols				
Country adaptation of instruments and protocols				
Data collection in Madhya Pradesh, India				
Resource tracking study				
Development of master instruments protocols				
Country adaptation of instruments and protocols				
Data collection				
Vaccine effectiveness studies				
Development of country-specific instruments and protocols				
Data collection: Mozambique				
Targeted study: measles-rubella campaign evaluation in Bangladesh				
Consensus on study aims and desired outcomes				
Protocol development				
Stakeholder engagement and facilitation of stakeholder feedback				
Pre-campaign survey: instrument and protocol finalization, IRB approval				
Pre-campaign survey: data collection				
Pre-campaign survey: data analysis				
Facility assessment: instrument and protocol finalization				

8.1 Process evaluation

In 2013, the GAVI FCE has focused on the development and scale-up of the process evaluation component by developing the following:

- A general framework for the planning and implementation processes associated with GAVI streams of support;
- A framework for evaluating the partnership principle of the GAVI Alliance;
- Process evaluation protocols, including methods, tools, and topic guides;
- Process evaluation data collection mechanisms, including document review, participant observation, key informant interviews, and AARs;

The process evaluation activities in 2013 have also included analyzing data and synthesizing results on the pneumococcal vaccine introductions in Mozambique, Uganda, and Zambia.

The initial focus of the process evaluation activities was on the introduction of PCV in Mozambique, Uganda, and Zambia in early 2013. Although the focus in Bangladesh was intended to be on the PCV introduction, originally scheduled for mid-2013, this introduction has been delayed until 2014 due to global PCV supply constraints. Our approach to prospectively track the implementation process of these vaccine introductions was built around process tracking as the central mechanism for data collection, as it provides a way to monitor the process of implementation in real time. Key to the success of the process tracking approach is the establishment of working relationships between the GAVI FCE team and country stakeholders to allow for participant observation, access to documents, and willingness to participate in key informant interviews (KIIs).

In each country, the evaluation team sought and received formal approval from the appropriate stakeholders, such as the Ministry of Health, to attend relevant meetings and observe. These ranged from EPI technical working group meetings and subcommittee meetings focusing on cold chain management, to national immunization technical advisory group meetings and inter-agency coordinating committee (ICC) meetings. The GAVI FCE team also attended other relevant events, such as the official launch of the pneumococcal vaccine, trainings, and supervisory visits at national and subnational levels. Participant observation has been established in Bangladesh, Mozambique, Uganda, and Zambia.

As a complement to participant observation, we also implemented key informant interviews focused on pneumococcal vaccine introduction in Mozambique, Uganda, and Zambia. In addition, KIIs in Zambia have also begun to collect information on the rotavirus vaccine introduction; the findings from these and future KIIs will be included in subsequent reports. Data collection through participant observation and KIIs has also been buttressed by document review, which provides a means of triangulating to confirm that reports from respondents fill information gaps for meetings not attended, or capturing information about events that happened prior to the evaluation period.

In addition to process tracking activities, another important and innovative method used for the process evaluation is the AAR. The first AAR was conducted in September in Mozambique with results used in the process evaluation of the PCV introduction. A separate report on the AAR in Mozambique is also available on request from the GAVI FCE team.

8.2 Resource tracking

The focus of the resource tracking study has been aligning work with other resource tracking efforts, soliciting feedback, identifying potential data sources, and developing data collection instruments. In Mozambique, the evaluation team is working closely with the Department of Planning and Health Economics at the MoH's National Directorate for Planning and Cooperation to implement the resource tracking work, which will consist of the National Health Accounts survey with an additional subaccount

review of child health and immunization. In Zambia, the GAVI FCE team is integrating resource tracking work with ongoing national health account activities, led by the University of Zambia Department of Economics in partnership with the MoH and the MCDMCH. In Uganda, we have held a stakeholder consultation meeting intended to seek views of stakeholders in immunization programs; we have also developed data collection instruments for gathering expenditure and resource flow data from key donors, partners, and the ministry.

8.3 Health facility survey

The health facility work of the GAVI FCE leverages the work done by IHME and partners on the Access, Bottlenecks, Costs, and Equity (ABCE) project. Taking advantage of this existing and field-tested ABCE instrument, the GAVI FCE team has developed an additional survey module to capture immunization-system data, especially as it relates to HSS indicators. This module incorporates a comprehensive set of immunization-specific indicators, described below:

- Vaccine supply chain: frequency of supply, supply constraints and stock-outs, and supply-chain infrastructure, and newly acquired equipment
- Personnel capacity and training: personnel inventory, personnel training and oversight, awareness of adverse events protocol, availability of promotional materials, supervision practices, and knowledge of proper disposal process
- Secure waste procedures: inventory and management of contaminated waste containers, availability of contaminated specimen handling materials, process observation of vaccine administration and disposal
- Vaccine availability: inventory of current stock of vaccines and supplies, documentation of recorded stock-outs, stock-out recall by health worker, quality assessment of supply chain, and country-specific indicators surrounding new vaccine introduction
- Vaccine storage: cold chain capacity assessment, observed adherence to storage guidelines, temperature recording of vaccine storage equipment, and assessment of vaccine viability, e.g. observation of sampled vaccines being stored/administered at the facility
- Vaccine output: delivery of vaccines by antigen for multiple years through routine immunization (number of years varies by country) and supplemental immunization activities, and adverse events reporting and procedures

This updated instrument has been piloted and incorporated into the ABCE facility survey for Madhya Pradesh, India. Data collection began at the end of 2013. This first implementation of the vaccine module in India will also allow valuable experience prior to implementation in the other FCE countries.

The GAVI FCE team is in the process of adapting the master health facility survey instrument, protocols, and sampling frames for the remaining countries, as well as preparing IRB applications where required. Country adaptation of the instrument involves consultation with key stakeholders, discussions with experienced health-sector workers, and visiting facilities to field test the instrument.

8.4 Household survey including dried blood spot-based measurement of vaccine antibodies

The evaluation team has developed the master household survey, which incorporates the following key indicators:

- Household roster and birth history
- Household characteristics: demographics and household assets
- Health of women ages 15 to 49: exposure to risk and reproductive health (including live birth roster)
- Immunization practices of children: maternal recall of vaccination, knowledge and attitudes about immunization, demand-side constraints such as travel time and cost of transportation to nearest health facility, cost of facility visit including user fees, wait time, experience and satisfaction with health workers, and reasons for non-immunization including vaccine availability
- Health card transcription of vaccination records of children in the household
- Dried blood spot samples to measure presence of vaccine antibodies
- Health of children ages 0 to 5 years: current health status, past treatment for vaccine-preventable diseases, and vaccination status

Contextualizing the master instrument, sampling frames, and protocols to each country is ongoing along with finalizing agreements to leverage ongoing or planned household surveys where relevant. The instrument contextualization is also largely informed by themes identified through the 2013 process evaluation; issues identified through qualitative research will be further explored through the household surveys in each country. In Uganda, the focus of the household survey work has been on the contextualization of the instruments in preparation for IRB submission and the development of sampling frames for a stand-alone survey.

In Mozambique, the GAVI FCE team is finalizing agreements with the National Institute of Statistics (INE) and National Institute of Health (INS) to include a vaccination module of the combined AIS and MIS household survey. This includes a combination of vaccine coverage questions, knowledge, attitude, and practice indicators and other key demand-side constraints. DBS will also be reserved for measuring vaccine antibodies. In Zambia, we are working on the contextualization of instruments and discussions with the Central Statistics Office to subsample the 2013/2014 Demographic and Health Survey. In Bangladesh, household survey data collection is leveraging the targeted MR campaign evaluation activities as part of the nationally representative post-campaign survey module which will be implemented in 2014. Lastly, in India the household survey contextualization will begin in 2014 with implementation scheduled for later that year.

Assay development and standardization at the UW Department of Laboratory Medicine is ongoing. Assay development will be finalized for two assays in 2013: anti-Hepatitis B Virus Surface Antigen (a-HBs) and anti-Hepatitis B Virus core antigen (a-HBc); the remaining two—Hepatitis B Surface Antigen (HBsAg) and anti-Tetanus toxin IgG—will be finalized in the first quarter of 2014. Optimization of the assays, development of standard laboratory operating procedures, and trainings of local laboratories will occur in early 2014.

8.5 Vaccine effectiveness studies

In Mozambique, the surveillance of invasive pneumococcal disease and X-ray confirmed pneumonia is an ongoing activity. The baseline nasopharyngeal carriage samples have been collected in Manhiça District, Maputo City, and Nampula Province. The case-control studies have received IRB approval and data collection has been initiated. In Bangladesh, we are currently in a planning process to choose the study sites for the nasopharyngeal carriage survey, which is to be implemented in 2014. The nasopharyngeal carriage study in India is currently in the protocol finalization stage.

8.6 Outcome and impact analysis

The evaluation team is in the process of systematically reviewing and compiling data sources to develop estimates of key indicators, such as immunization coverage and child mortality, at the subnational level in each of the GAVI FCE countries. As part of work that IHME and UNZA are implementing (the Malaria Control Policy Assessment), we have finalized district-level estimates for Zambia from 1990 to 2010 as well as a causal analysis of drivers for child mortality. A full report is available on request. Examples of district-level estimates for Zambia for child mortality and pentavalent vaccine coverage are shown in Figure 4 and Figure 5. We are also attempting to resolve issues with the immunization coverage administrative data in Zambia to allow inclusion of more recent estimates, e.g. 2013 or 2014. Preliminary results from these activities were presented as part of the GAVI Alliance Mid-Term Review in November 2013.

Figure 4: District-level Pentavalent Vaccine Coverage Estimates (%)

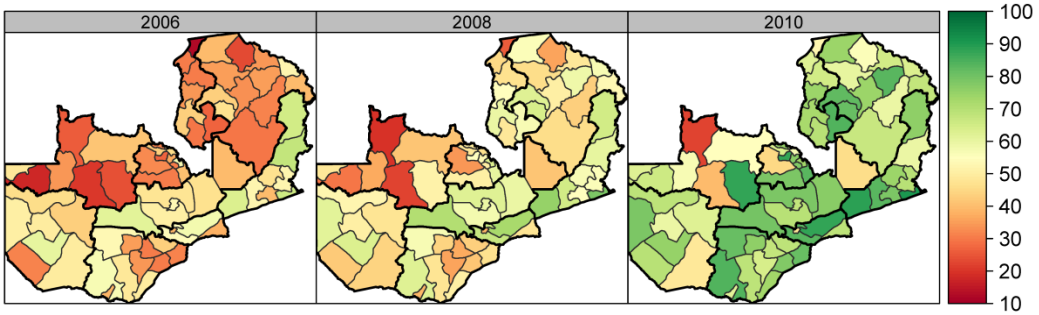
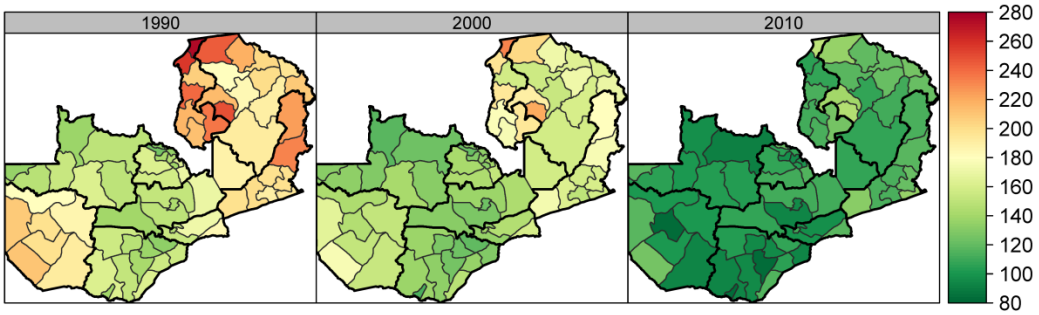


Figure 5: District-level Under-5 Mortality Estimates (deaths per 1,000 live births)



Similar sub-national estimates for Uganda are planned for dissemination in 2014. In Bangladesh we have begun compiling and analyzing available survey data; in India, small area estimation models have been applied to existing survey data, while in Mozambique data compilation is underway.

8.7 Measles-rubella campaign evaluation

From September to November 2013, the GAVI FCE team completed data collection of the pre-campaign survey in two of Bangladesh's seven divisions: Rajshahi (high-performing) and Sylhet (low-performing). Within each division, two districts were visited – one rural and one urban. Of the targeted 1,920 households, 1,736 households completed an interview; this yields at 90.4% response rate. Of the 616 children randomly selected for DBS for measles and rubella antibody testing, 550 DBS samples were collected, an 89.3% response rate. Final analysis of the pre-campaign survey is underway and will be reported in subsequent reports. The DBS will be analyzed for Measles and Rubella antigens, as well as HepB and Tetanus assays as with all other countries; this analysis is anticipated for completion in 2014.

In addition to the pre-campaign survey, the GAVI FCE team is finalizing instruments and preparing for data collection during and shortly after the MR campaign—including health facility assessments, exit interviews, and EPI service providers' surveys. The campaign is scheduled to be implemented starting January 25, 2014.

8.8 Dissemination and stakeholder consultation

Consistent with the key principles of the FCE, the consortium has prioritized timely and targeted dissemination efforts. As the first year of the evaluation phase of the FCE, many of the dissemination activities in 2013 were focused on sharing the research goals and design with national and international stakeholders. In each of the GAVI FCE countries, we conducted stakeholder consultations, both formal and informal, at the beginning of the evaluation to describe the evaluation design and solicit feedback. These country-level consultations are scheduled annually or on an as-needed basis. In the interim we have continued informal updating stakeholders in-country and at the global level. At the global level, the FCE team has engaged with the scientific and policymaking community through forums such as the GAVI partners meeting. This first annual progress report and the accompanying PCV case reports represent the first written, public means of dissemination of early term findings from the GAVI FCE. These reports will be accompanied by in-country dissemination events in the first quarter of 2014.

Given the prospective nature of the evaluation, the GAVI FCE team with the GAVI secretariat has also recognized the potential for key actionable findings from the GAVI FCE that warrant rapid dissemination. This needs to be balanced against preserving the ability of the FCE to inform implementation of GAVI Alliance support in other countries by allowing the implementation process to fully unfold. The evaluation team, in conjunction with the GAVI secretariat, is piloting criteria and standards to help determine and guide dissemination of real-time information collected prospectively.

8.9 Capacity strengthening

Key principles of the GAVI FCE are that the work is driven by country teams and that shared learning and capacity strengthening occurs. A particular focus is on strengthening capacity in the GAVI FCE countries. The evaluation work has been driven by teams who have led the implementation of the evaluation activities in-country. To strengthen capacity, there has been a focus on developing junior researchers on each of the country evaluation teams who are trained, supervised, and supported by senior staff from the country teams, IHME, and PATH.

As part of an annual multi partner meeting, two full days and multiple other sessions were focused on strengthening capacity among country teams. This included a particular focus on process evaluation methods including conducting key informant interviews, focus group discussions, and after action review workshops.

8.10 Lessons learned

In this section, we highlight a series of lessons learnt during the year 1. We have divided these lessons learned into three main areas: research design and methodology; positioning of the GAVI FCE in the overall monitoring and evaluation context; and project implementation.

8.10.1 Research design and methodology

Prospective evaluation design: The first year of data collection has highlighted the value of the prospective evaluation design, particularly with respect to the process evaluation activities. The collective experience in the collection of process evaluation in the GAVI FCE countries has highlighted the difficulties of retrospective assessment due to the reliance on sparse documentation and the recall of key informants. In several cases, turnover in key positions has meant that there is limited institutional memory about past events or decisions. The prospective design has allowed the evaluation team to better identify key issues as they arise through the participant observation approach, and resulted in better design of the subsequent retrospective data collection approaches such as key informant interviews and document review. The prospective design, when coupled with the participant observation approach, also means that there is direct visual verification of what has happened rather than relying on recall via key informant interviews or documentation which may not be present.

Mixed and multiple method approach: The GAVI FCE experience to date has also emphasized the value of the mixed method approach in terms of the various evaluation components described above. Triangulation between these components will allow richer detail to be collected on the key issues identified. The value of multiple data collection mechanisms is also highlighted in the process evaluation component which has been the focus in 2013. Each of the process evaluation methodologies vary in terms of the nature of data gathered and implications for evaluation activities and stakeholders (see Table 7). For example, embedded observation has proven well-suited for tracking the real-time progress and planning of activities but have a limited ability to uncover underlying issues. Conversely, key informant interviews proved valuable in obtaining an in-depth understanding of key issues. KII are limited, however, due to the challenges of scheduling, and respondent fatigue—especially as there are a limited number of key stakeholders in each country.

One particular methodology worth highlighting is the AAR. The AAR methodology explicitly links the evaluation to process improvement in a timely fashion. In-depth information was able to be collected and a series of recommendations for improvement developed by stakeholders within a single day. This also demonstrates the value of the GAVI FCE to stakeholders in an explicit way. A potential risk is if AARs implemented as part of the GAVI FCE replace usual EPI program and partner evaluation activities; this would represent weakening of local processes. A positive development would be if EPI programs and partners choose to utilize the AAR methodology independently moving forward.

The following table outlines the evaluation team's assessment of the advantages and disadvantages of the various process evaluation mechanisms employed in 2013.

Table 7: GAVI FCE assessment of advantages and disadvantages of process data collection mechanisms

Data collection mechanism	Advantages	Disadvantages
Document review	• Poses no additional burden on key stakeholders, policymakers, or program implementers • If events/decision were documented well, can assist with in-depth understanding of past events, processes, or decisions • Low-cost	• Relies on how well issues are documented, and can be limited if previous events, processes, or decisions were not documented well • Access to documents may be challenging, if poor record keeping or document-management or limited publicity of documents occurs • Provides less timely information, this is a largely retrospective evaluation activity
Participant observation	• Limited additional burden on stakeholders, policymakers, and program implementers • Allows for timely collection of key processes and decisions • Allows for direct visual verification of what actually occurred, and when • Provides opportunity to understand context with more depth, as observer is present • Enhances the ability to identify consequences, as they occur	• Has potential for subjective assessments, as evaluation team members are interpreting decisions and events as they occur • Has potential for the Hawthorne effect (being less willing to raise issues or adjusting behavior when observers are present at meetings) • Limited to meetings, events, or key activities, and observers may not have access to informal communications, such as telephone or email • Challenging to consider in-depth issues, as data gathered is limited to observation of activities or events

Data collection mechanism	Advantages	Disadvantages
Key informant interviews and focus group discussions	• Allows one to capture individual or small group perspectives in a safe environment • Has high potential for in-depth understanding of reasons behind key decisions or actions, as interviewers can probe on key issues to obtain the underlying factors and sources of influence • Provides an opportunity to obtain insight or pieces of information from key individuals who are most knowledgeable of the subject	• Presents considerable potential for respondent fatigue, especially if a limited number of individuals have the necessary information • Subject to scheduling challenges and have proven to be difficult to ensure enough time with respondents
After action review (AAR)	• Directly links evaluation to process improvement, and encourages key stakeholders to turn results into actionable items • Has proven valuable to stakeholders, who see immediate value of the evaluation; stakeholder support for this methodology is so high there is potential for a demand-driven process in some countries	• Involves a potential for interfering with usual implementation process, as the evaluation may affect how the implementation would have otherwise occurred • Potentially risks replacing pre-existing feedback and process improvement mechanisms

Flexible and adaptive research design: The implementation of the GAVI FCE to date has emphasized the importance of maintaining a flexible and adaptive research design. As the FCE is dependent on other data collection exercises, changes in plans by other institutions—such as the delays in the implementation of the Zambian DHS—can have effects on the FCE evaluation activities. A major example of changing external factors that require a flexible and adaptive research design was the changing launch dates for PCV introductions, most notably in Bangladesh where the introduction has been postponed until 2014.

8.10.2 Positioning of the GAVI FCE in the overall monitoring and evaluation context

Potential for leveraging ongoing data collection efforts: A key principle of the GAVI FCE is to not duplicate existing efforts, but rather to integrate data collection efforts with other ongoing or planned data collection. A positive aspect of the GAVI FCE implementation in 2013 has been the integration of data collection with other efforts. For example, rather than conduct a standalone household survey we were able to integrate an immunization module into the 2014 AIDS Indicator Survey/Malaria Indicator Survey in Mozambique. It should be noted that the process to integrate with other data collection activities has not been without its complications given the need to coordinate between multiple objectives, institutions and funding sources. Thus far, however, the experience of leveraging existing data collection efforts has been very positive, and we firmly believe the advantages of non-duplication and efficiency outweigh the efforts required to integrate primary data collection across multiple partners.

GAVI FCE as a platform for targeted studies: Another key motivation in the establishment of the GAVI FCE is the evaluation's role as a platform for identifying and conducting separate, targeted or special studies. Through the GAVI FCE we are identifying emerging themes and areas of key interest by stakeholder that can be topic of these studies. The contingency studies are one example of an internal mechanism the evaluation team uses to implement targeted studies. In 2013, we have also used the GAVI FCE as a platform for the measles-rubella campaign evaluation in Bangladesh.

8.10.3 Project implementation

Stakeholder engagement: In order to maintain a country-driven evaluation approach, ongoing stakeholder engagement and feedback has proven invaluable. The evaluation plan reflects in-depth consultation with key stakeholders during the planning and main phases of the GAVI FCE. This engagement allowed stakeholders to provide active feedback to the FCE evaluation team, and play an integral role in shaping the focus and direction of evaluation activities. For example, the AAR workshop in Mozambique focused on topics that were chosen by key stakeholders; consequently the AAR participants were engaged during the workshop and invested in the results. In Bangladesh, stakeholders provided instrumental feedback regarding the Measles-Rubella Campaign Evaluation, which resulted in stronger stakeholder buy-in, and an evaluation design that better aligns with other upcoming data collection activities in Bangladesh. Relationship building has therefore been a primary focus of the GAVI FCE team to date, and it will be critical to the success of the GAVI FCE that these are maintained through ongoing consultation. It should be noted that the stakeholder consultation process has added to the time required to implement GAVI FCE activities; however, we believe the advantages of a stakeholder consultation and ownership outweigh this additional time required.

Central role of dedicated country teams: The country evaluation teams have played an essential role to the success of the GAVI FCE to date. The importance of the country teams is evident through multiple facets. First, a clear understanding of the in-country political landscape and strong relationships with country stakeholders have been critical for formal approval of the GAVI FCE, engendering country ownership of the evaluation. This understanding and relational capital has facilitated access to key information and data for the evaluation, including the ability to establish novel data collection mechanisms such as participant observation and the after action review. Lastly, country teams have been central in capitalizing on opportunities for leveraging existing or planned data collection efforts.

Strengthening and maintaining country team capacity: In order to maintain this essential role and to undertake the evaluation work at the country level, a clear focus of the GAVI FCE is country team capacity strengthening. Strong evaluators at the country level are scarce, and when available, often have limited availability due to competing demands. As part of the GAVI FCE, we have paid particular attention to ensuring that the next generation of in-country evaluators is being trained. We will be increasing this emphasis over the course of the GAVI FCE, including through formal mechanisms as well as more structured procedures for the evaluation work, particularly around the process evaluation.

9 Activities scheduled for 2014

This section describes scheduled activities for 2014 in each of the five GAVI FCE countries. It is important to note that these activities reflect expectations of current GAVI-supported implementation activities scheduled in each country in 2014. These include:

- **Bangladesh:** Implementation of the measles-rubella (MR) campaign beginning at the end of January 2014; introduction of PCV; implementation of HSS; application for HPV.
- **India:** Ongoing pentavalent vaccine introduction. As noted above, although other streams of support exist such as HSS, the GAVI FCE will focus on the pentavalent introduction.
- **Mozambique:** HPV demonstration project; implementation of HSS; and application for rotavirus vaccine introduction.
- **Uganda:** Ongoing PCV introduction; reprogrammed HSS; and application for HPV national introduction.
- **Zambia:** Rotavirus introduction that launched in November 2013; and reprogrammed and/or new applications for HSS.

It is important for the GAVI FCE to be flexible and adaptive to changing implementation plans, including applications for new support, accelerated or delayed implementation of currently approved support, and new GAVI policies or procedures that are being implemented. New support streams may include applications through GAVI's new window for IPV. In 2014, GAVI will also be implementing a new grant application, monitoring, and review (GAMR) process, as approved by the GAVI Alliance board in mid-2013. This will be an important area of focus for the process evaluation in particular, as a comparison to the previous GAMR.

Baseline quantitative data are expected to be completed in 2014. While some of the extensive analyses of data may continue into 2015, preliminary results and emerging themes are expected by the end of 2014. Complete impact analysis cannot be completed until end-line data are collected, which is planned for completion by 2016. We expect these baseline findings from the FCE data collection, when compared with previous estimates and studies, to provide a useful snapshot of immunization system performance in each country with triangulation of indicators and results across multiple evaluation methods and components.

The anticipated GAVI FCE activities by each evaluation component are outlined below.

9.1 Process evaluation

In 2014, we will continue conducting observation, key informant interviews, and after action review (AAR) workshops in Mozambique, Uganda, and Zambia, and scale-up in Bangladesh with regard to the streams of support identified above. Additional process evaluation activities in these countries will include contingent studies that are targeted, in-depth studies of key themes or processes.

The process evaluation in each country will have a different focus. In Uganda, given the delayed rollout, the process evaluation will continue to focus on the PCV introduction as well as the reprogrammed HSS funds, and new HPV application. In particular, the evaluation will examine the relationship between HSS

funds and aspects of the PCV introduction. In Zambia, the process evaluation will focus on the introduction of rotavirus vaccine and reprogrammed and/or new applications for HSS. As is the case of Uganda, the relationship between HSS funds and the recent PCV and rotavirus introductions will be a high-priority area for examination. Upcoming priorities in Mozambique include the HPV demonstration project, HSS, and application development for rotavirus introduction. As in Zambia and Uganda, the intersection between HSS and the previous PCV introduction will be an important area of focus, particularly as this is the first HSS window of support in Mozambique. In Bangladesh, the process evaluation will primarily focus on the introduction of PCV vaccine, the forthcoming implementation of the measles-rubella immunization campaign, HSS support, and the new application for HPV support. In all countries we will also track the decision making and application phases for new support such as IPV. A particular focus in 2014 will also be on examining the relationship between different types of GAVI support.

9.2 Household survey

Baseline household survey data are scheduled to be collected in 2014 in all five evaluation countries. An advantage of the timing of data collection in 2014 is that the primary target age group for household surveys (children aged 12 to 23 months) corresponds to the children vaccinated in the 2013 as part of the three PCV introductions. This will allow us to triangulate qualitative or other quantitative data, such as administrative data collected in 2013, with household survey data collected in 2014.

In Uganda, the standalone household survey of approximately 5,000 households will seek to complement the 2011 DHS data collection and systematically overlap with the health facility survey. In Zambia, the evaluation team will be conducting a targeted follow-up of the Demographic and Health Survey (DHS), to gather DBS from children. While in the household, we will also gather data on a sub-sample of questions from the master survey, to complement DHS data with more targeted immunization indicators. Preparations for the joint AIS/MIS in Mozambique are already well underway, and data collection is targeted for the second quarter of 2014. We will collect data on immunization coverage, KAP of immunization, and key demand-side constraints; and DBS. In Bangladesh the household coverage survey will be undertaken as part of the MR campaign evaluation post-campaign survey. In India the baseline household surveys in two states is anticipated to begin in 2014, involving over 5,000 children in each of two states with data collection scheduled for the last quarter of 2014. .

9.3 Health facility survey

Similar to the household surveys, we anticipate conducting health facility surveys in each country in 2014. In Uganda and Zambia this will be undertaken as a follow-up to the ABCE survey conducted in 2010 and 2011. The survey will gather updated information on the last two years of key indicators for expenditure; the previous ABCE survey gathered data on five years, so this will create a seven-year complete time-series for each facility. The immunization module will also be conducted to allow for in-depth knowledge of vaccination in the facility. As with the household survey, collecting the most recent two years of key indicators will allow for a triangulation of 2013 qualitative data with 2014 quantitative data.

In Bangladesh, India, and Mozambique, the health facility surveys will be a part of the baseline ABCE data collection. This baseline data collection will begin at the end of 2013 or in early 2014 in India, and will be completed in 2014. In Bangladesh and Mozambique, it is anticipated the surveys will be conducted in the latter part of 2014. The entire ABCE survey module will be conducted, as well as the GAVI FCE immunization module. Data will be gathered for the past five years, as is standard with the ABCE questionnaire. Again, this will allow for triangulation of qualitative and quantitative data.

Preliminary findings from the health facility survey will be reported in 2014, with detailed analysis in subsequent years.

9.4 Resource tracking study

In 2014, the resource tracking work will largely be a continuation of what was started in 2013. With lists of targeted data sources in hand in each country, 2014 will largely focus on compiling and analyzing budget and expenditure data for the resource tracking exercise. Also, the resource tracking work and health facility surveys are complementary data collection exercises; that is, as field teams travel to conduct health facility surveys, other evaluation team members will conduct interviews at the district or provincial level to gather resource tracking–related data. The health facility data will also feed into the resource tracking study, especially as it relates to funding flows from the national, provincial, and district levels. The results of the resource tracking studies will be reported in 2014.

9.5 Vaccine effectiveness studies

Vaccine effectiveness studies in Mozambique will largely be a continuation of previous work in 2014. This will involve the continued hospital-based surveillance at Manhiça, NP carriage studies, and ongoing enrollment of cases and controls. In Bangladesh, baseline nasopharyngeal carriage studies will be conducted within an established DSS site, pending the introduction of pneumococcal vaccine. The GAVI FCE team is currently identifying precisely which DSS site is most appropriate to support this work, and anticipate rolling out data collection in the third quarter of 2014. In India, we will assess the impact of pentavalent immunization on reducing Hib nasopharyngeal carriage rates in children. This will be part of the surveys described above.

While many of the samples from the vaccine effectiveness studies will be collected in 2014, the time needed for laboratory analysis will lead to these results being reported in 2015. In Mozambique, however, we anticipate reporting on the progress of the ongoing hospital-based surveillance, and the case-control recruitment progress.

9.6 Outcome, impact and mixed-method analysis

Systematic analysis of national and subnational trends in key indicators, such as immunization coverage and child mortality, is ongoing and we expect to have a set of preliminary results for GAVI FCE countries in 2014. Subnational trends in indicators will also provide a basis for the analysis of impact using causal attribution models. As described above, the evaluation team will also begin the mixed-methods analysis by overlapping results from the various components to provide a fuller assessment of the baseline situation in the GAVI FCE countries.

9.7 Measles-rubella campaign evaluation

The Government of Bangladesh is currently planning to implement the measles-rubella immunization campaign in January 2014. We will conduct evaluation activities as the campaign is happening and after the campaign is completed. During the campaign, we will conduct health facility assessments and exit interviews. Health facility assessments will serve to observe vaccination sessions and identify how health workers implement the campaign and how campaign activities affect routine immunization services. We will also conduct exit interviews with caregivers who have just vaccinated their children, which will provide a unique opportunity to assess maternal knowledge with effectively no recall bias.

After the campaign implementation is complete, there are three remaining components of the MR campaign evaluation: EPI service providers' interviews, post-campaign coverage survey, and multiple process evaluation methods. Evaluation team members will interview EPI service providers (those who deliver vaccinations) to assess the campaign's impact on routine immunization activities. The post-campaign coverage survey will be nationally representative, with intentional sampling in the districts evaluated during the pre-campaign survey to directly evaluate changes in coverage due to the campaign. The process evaluation will be integrated with the broader FCE process evaluation, involving key informant interviews, focus group discussions, embedded observation, and targeted studies. This qualitative research will complement the quantitative findings and allow for a deeper understanding of the reasons behind certain results. Results from the MR campaign evaluation study will be reported in a separate report in 2014.

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10 Annexures

10.1 Sub-national estimates of antigen coverage

10.1.1 Uganda

Region level estimates of antigen coverage (2011 DHS)

Regional coverage estimate	BCG	DPT 3	Polio 3	Measles
Central 1	85.2	66.4	51.1	75.0
Central 2	94.5	61.7	54.0	70.7
Kampala	94.6	73.5	71.6	82.0
East Central	95.5	52.8	54.3	71.4
Eastern	97.5	74.2	62.3	76.8
West Nile	98.5	82.0	64.3	77.7
North	94.0	73.4	59.5	72.0
Karamoja	99.8	89.5	65.4	90.6
Western	95.4	77.6	72.2	81.7
South West	85.9	79.2	78.1	71.4
National average	93.7	71.5	629	75.8

10.1.2 Mozambique

Region level estimates of antigen coverage (2011 DHS)

Regional coverage estimate	BCG	DPT 3	Polio 3	Measles
Niassa	92.7	82.8	83.5	87.9
Cabo Delgado	95.1	67.8	76.2	80.4
Nampula	88.4	75.1	69.2	83.4
Zambezia	84.0	60.3	56.8	71.5
Tete	88.7	79.9	72.0	75.8
Manica	97.0	76.6	77.2	80.3
Sofala	95.3	85.3	85.1	87.4
Inhambane	96.2	81.8	76.6	86.4
Gaza	92.7	89.0	85.9	85.6
Maputo Provincia	99.4	96.7	90.9	98.1
Maputo Cidade	96.4	90.1	80.7	95.4
National average	91.1	76.2	73.2	81.5

10.1.3 Zambia

Region level estimates of antigen coverage (2007 DHS)

Regional coverage estimate	BCG	DPT 3	Polio 3	Measles
Central	93.0	83.6	78.1	91.6
Copperbelt	94.8	86.5	81.2	87.0
Eastern	98.0	88.4	83.9	89.0
Luapula	84.1	68.4	71.4	75.8
Lusaka	94.1	91.9	79.7	91.9
Northern	81.9	63.0	69.1	71.1
North-Western	93.7	60.5	58.5	78.0
Southern	97.8	87.9	81.3	92.0
Western	97.4	86.3	86.1	93.1
National average	92.3	79.7	77.0	84.9

10.1.4 Bangladesh

Divisional level estimates of antigen coverage (2011/12 Bangladesh DHS):

Divisional coverage estimate	BCG	DPT 3	Polio 3	Measles
Barisal	98.5	91.4	92.0	86.1
Chittagong	96.9	90.9	92.0	83.9
Sylhet	96.0	88.9	87.9	82.9
Dhaka	98.4	93.9	93.5	86.6
Khulna	99.1	97.2	97.2	94.2
Rangpur	98.4	96.1	96.0	92.9
Rajshahi	97.4	95.3	94.5	90.7
National average	97.8	93.4	93.4	87.5

10.1.5 India

State level estimates of antigen coverage (2011/12 Annual Health Survey)

State coverage estimate	BCG	DPT 3	Polio 3	Measles
Andhra Pradesh	98.6	89.9	75.9	90.4
Arunachal Pradesh	66	45	41.3	48.2
Assam	86.3	67.5	67.5	80.1
Bihar	82.3	59.3	61.6	58.2
Chhattisgarh	84.8	66.5	66.5	73.1
Delhi	89.1	79.5	76.9	83.3
Goa	92.8	92.4	91.2	91.5

State coverage estimate	BCG	DPT 3	Polio 3	Measles
Gujarat	84.9	68	71	78
Haryana	84.4	75	76.9	79.9
Himachal Pradesh	98.4	93.4	79.4	96.2
Jammu & Kashmir	85.2	77	74.9	77.2
Jharkhand	87.4	68.7	69.5	67.5
Karnataka	97.1	88.2	87.1	89.9
Kerala	94	88.7	89.2	86.2
Madhya Pradesh	81.4	50.6	51.7	61.9
Maharashtra	94.7	85.8	84.2	91.2
Manipur	69.2	62.7	61.5	60.3
Meghalaya	81.8	69.3	74.6	74.1
Mizoram	87.5	77.8	78.1	81.1
Nagaland	59	45.9	35.8	52.2
Orissa	87.3	70.5	74	71.9
Punjab	96.6	91.4	92	87.3
Rajasthan	82.6	60.1	64.3	65.6
Sikkim	97	85.3	86.7	87.8
Tamil Nadu	88.9	78.6	79.6	88.4
Tripura	74.2	70.6	71.3	68.8
Uttar Pradesh	76.4	58.1	53.9	52.8
Uttarakhand	88.3	78.1	78.9	75.8
West Bengal	89.4	72.8	74.2	77.2
UTs combined	92.1	82	81.2	83.3
National average	86.9	71.5	70.4	74.1