Annex 6: The Monitoring and Evaluation/ Accountability Framework

Background

The Monitoring and Evaluation/Accountability Framework is a critically important element of the Global Vaccine Action Plan (GVAP). Recognizing the importance to closely monitor the GVAP implementation progress, the World Health Assembly (WHA) resolution called for annual reports on progress at each Regional Committee meeting and at the WHA, through the WHO Executive Board (EB).

IN DEFINING THE SCOPE OF THE M&E/A FRAMEWORK, THE GVAP REFERS TO THE NEED:

TO FINALIZE a complete set of GVAP indicators with the appropriate methodology and data sources for each indicator defined and baselines established, where required.

TO INVEST in improving data quality and developing more robust in-country monitoring and evaluation systems.

TO SECURE commitments aligned with the GVAP from different stakeholders, including countries, civil society organizations, multilateral agencies, private foundations, development partners, and vaccine manufacturers.

TO DEVELOP a mechanism for coordinating the implementation of these commitments at global, regional and national levels.

TO ENSURE annual reporting of progress at each Regional Committee meeting and at the WHA, through the WHO EB.

The Accountability Framework for the United Nations (UN) Secretary General's Global Strategy for Women's and Children's Health

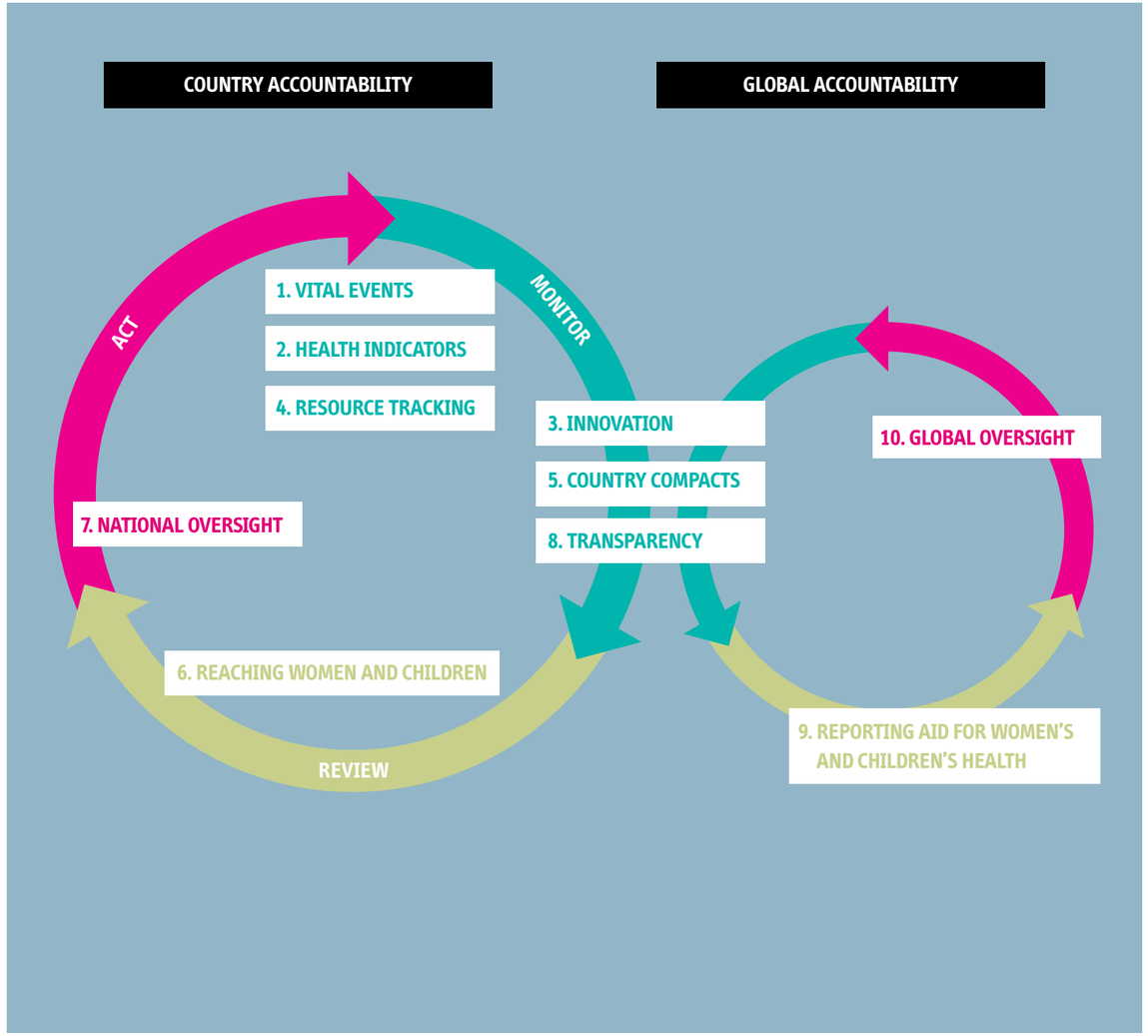
The GVAP calls for leveraging the recommendations of the Commission for Information and Accountability for Women's and Children's Health and aligning work, wherever possible, with other accountability efforts.

The Accountability Framework of the UN Secretary General's Global Strategy for Women's and Children's Health refers to a cyclical process of monitoring, review and remedy/action to assess progress, document success, identify problems that need to be rectified and take prompt action as and where needed. This process needs to occur at the country and global levels as illustrated in Figure 1.[6] To have a better oversight of progress an independent Expert Review Group (iERG)[7] reports annually to the UN Secretary General on the results and resources related to the Global Strategy and on progress in implementation of the Commission's recommendations. The Decade of Vaccines annual report that will be submitted to the WHA will also be shared with the iERG as information for their annual report to the UN Secretary General.

6 Commission on Information and Accountability for Women's and Children's Health. Keeping Promises, Measuring Results. World Health Organization 2011 (http://www.who.int/woman_child_accountability/en/)

7 iERG members http://www.who.int/woman_child_accountability/ierg/members/en/

FIGURE 1:
THE ACCOUNTABILITY FRAMEWORK FOR THE UN SECRETARY GENERAL'S GLOBAL STRATEGY FOR WOMEN'S AND CHILDREN'S HEALTH



Proposed Process for the GVAP Monitoring and Evaluation / Accountability Framework

A similar cyclical process of monitoring, review, and recommendations for action is proposed for the GVAP M&E/A Framework. In addition to the national and global levels, another level of GVAP M&E/A at the regional level is required to accommodate the requirement of reporting annually to the WHO Regional Committees.

Using a similar framework allows for complementarity with the accountability process for the UN Secretary General Global Strategy for Women's and Children's Health and provides opportunities to leverage and/or use these processes for tracking and reporting on some of the aspects of GVAP. This applies in particular to the process to monitor commitments and resources as described in the related documents for this session. Figure 2 illustrates the proposed GVAP M&E/A Framework process. Guidelines for making immunization commitments under the UN Secretary General Global Strategy for Women's and Children's Health framework can be found on each Decade of Vaccines (DoV) Collaboration Leadership Council website.

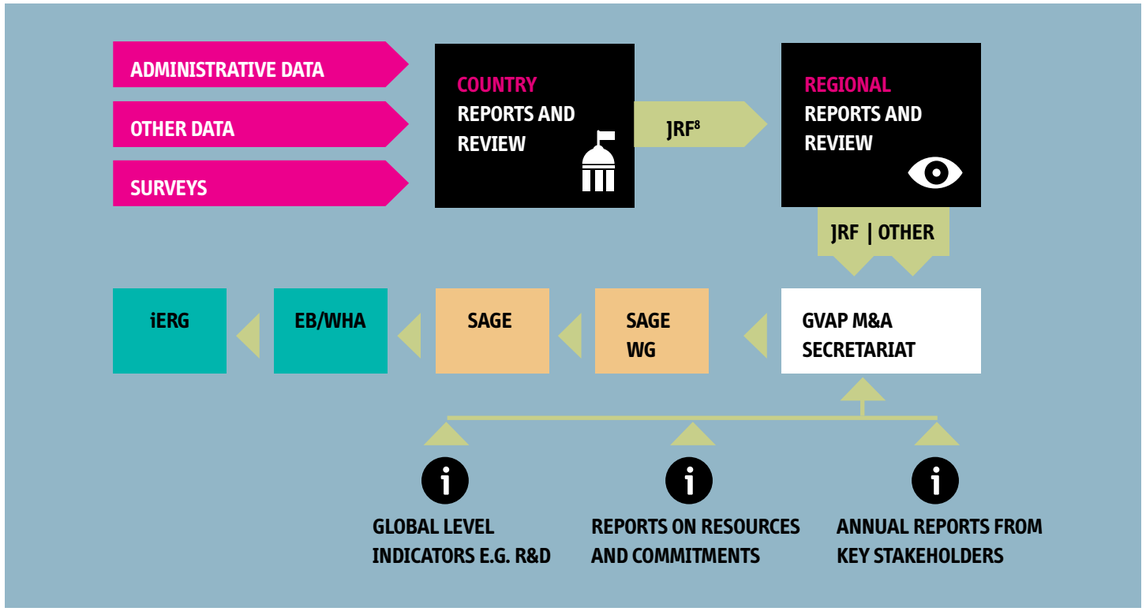
The GVAP M&E/A Framework will be applied to: (1) monitoring results (defined as progress against the GVAP Goals' and Strategic Objectives' indicators); (2) documenting and monitoring stakeholder commitments to GVAP and DoV; (3) tracking resources invested in vaccines and immunization; and (4) inclusion of independent oversight and review of progress, through the World Health Organization Strategic Advisory Group of Experts (SAGE) on Immunization, in the reporting to the governing bodies.

A final set of GVAP indicators (see Table 12 and Table 13) was reviewed and approved by SAGE during their 6-8 November 2012 meeting, and will be presented to the WHO EB in January 2013 and the WHA in May 2013.

MONITORING COMMITMENTS AND RESOURCES:

The M&E/A Framework will also document and monitor stakeholders commitments to GVAP and track resources invested in vaccines and immunization.

FIGURE 2:
PROPOSED GVAP MONITORING AND EVALUATION/ACCOUNTABILITY FRAMEWORK



GLOBAL LEVEL: The annual review process will go through SAGE, the WHO EB and the WHA. The report will also be shared with iERG for their women's and children's health annual report to the UN Secretary General.

REGIONAL LEVEL: The WHO Regional Offices are developing their mechanisms for review and reporting to the Regional Committees. Regional Technical Advisory Groups on Immunization may take on that role, similar to the SAGE role at the global level.

COUNTRY LEVEL: The National Immunization Technical Advisory Groups (NITAGs) and the Interagency Coordination Committees (ICCs) could also assume roles of monitoring commitments and resources at the country level. This will be determined as countries continue to develop their national plans.

8 JRF is the WHO and UNICEF Joint Reporting Form.

TABLE 12: PROPOSED EXTENDED GOALS INDICATORS

	1. ACHIEVE A WORLD FREE OF POLIOMYELITIS		2. MEET GLOBAL AND REGIONAL ELIMINATION TARGETS		
INDICATORS	**1.1.** Interrupt wild poliovirus transmission globally	**1.2.** Certification of poliomyelitis eradication	**2.1.** Neonatal tetanus elimination	**2.2.** Measles elimination	**2.3.** Rubella/CRS elimination
OPERATIONAL DEFINITION	No wild poliovirus isolated globally for at least 1 year, in the presence of certification quality AFP surveillance (annual non-polio AFP rate of at least 1/100,000 population < 15 years at national and sub-national level, with adequate stool specimens collected from at least 80% of AFP cases)	No wild poliovirus isolated globally for at least 3 years in the presence of certification quality AFP surveillance	< 1 NT case/1,000 live births in each district and maintenance of elimination based on annual WHO/UNICEF District Data Spreadsheet	Number of regions with 100% of countries having declared interruption of endemic measles virus transmission for a period of > 12 months in the presence of high quality surveillance The surveillance quality will be assessed as described in criteria for verification of elimination	Number regions with 100% of countries having declared interruption of endemic rubella virus transmission for a period of > 12 months without occurrence of CRS cases associated with endemic transmission in the presence of high quality surveillance
DATA SOURCE/COLLECTION	National AFP surveillance systems + supplementary surveillance data where available (environmental surveillance or enterovirus surveillance through national lab networks)	Final national documentation on polio-free status submitted by NCCs and accepted by RCCs	WHO/UNICEF District Data Spreadsheet, and WHO validation report (based on LQA in worst performing district)	Each region has a verification commission which annually reviews the status of all countries	Each region has a verification commission which annually reviews the status of all countries
BASELINE	2011: 650 WPV-confirmed cases reported from 16 countries	2011: National documentation on polio-free status accepted by RCCs in 168 out of 194 WHO member states (87%)	2010 (40 countries still to achieve elimination)	2010 (0/5 regions - AMRO, WPRO, EMRO, EURO, AFRO)	2010 (0/2 regions - AMRO, EURO)
TARGET	2014	2018	2015	2015: 4 WHO regions 2020: 5 WHO regions	2015: 2 WHO regions 2020: 5 WHO regions
MILESTONES		Track number of countries with national documentation of polio-free status, accepted by RCCs	10 countries eliminated NT by 2012; 22 countries eliminated NT by 2013; 36 countries eliminated NT by 2014; 40 countries eliminated NT by 2015	Monitor # and % of countries in each region that are verified as having eliminated diseases	Monitor # and % of countries in each region that are verified as having eliminated diseases

3. MEET VACCINATION COVERAGE TARGETS IN EVERY REGION, COUNTRY AND COMMUNITY

INDICATORS	**3.1.** Reach 90% national coverage and 80% in every district or equivalent administrative unit with three doses of diphtheria-tetanus-pertussis containing vaccines	3.2. Reach 90% national coverage and 80% in every district or equivalent administrative unit for all vaccines in national programmes, unless otherwise recommended
OPERATIONAL DEFINITION	WHO UNICEF Estimates of National Immunization Coverage (WUENIC)* for national coverage; District data: - accept JRF admin data if WUENIC based on administrative coverage; missing district reports =indicator not met, encourage reporting; - if WUENIC not based on administrative coverage, repeated measure (at least two surveys or special studies to document district coverage); early measure (2009 to 2015) and later measure (2016 to 2020) - countries may choose to conduct surveys in selected "high risk" districts likely to have low coverage - surveys should be conducted at least twice in the decade (baseline and one other time) but countries should aim for more frequent surveys	Determination of national and district level coverage as defined above Indicator applies to all vaccines being used for country-wide, universal immunization (exception of HPV, where country-wide universal immunization of girls would be included) Coverage refers to coverage with primary series of vaccine For pneumococcal and rotavirus vaccines, this will be coverage with primary series by 12 months of age. For other vaccines, the exact measurement of coverage needs to be defined, but will be as reported in the WUENIC
DATA SOURCE/COLLECTION	WUENIC, JRF, surveys or special studies	WUENIC, JRF
BASELINE	2010 or early measure	2010 or early measure (for district data)
TARGET	2015 – all Member states	2020: All Member States
MILESTONES	Monitor trends in coverage	Monitor trends in coverage

	4. DEVELOP AND INTRODUCE NEW AND IMPROVED VACCINES AND TECHNOLOGIES			MDG4 5. EXCEED THE MILLENNIUM DEVELOPMENT GOAL 4 TARGET FOR REDUCING CHILD MORTALITY
INDICATORS	**4.1.** Licensure and launch of vaccine or vaccines against one or more major currently non-vaccine preventable diseases	**4.2.** Licensure and launch of at least one platform delivery technology	**4.3.** Number of low-income and middle-income countries that have introduced one or more new or underutilized vaccines	**5.1.** Reduce under-five mortality rate
OPERATIONAL DEFINITION	Licensure relates to registration by a functional National Regulatory Authority (NRA) Launch is defined as addition of the vaccine to the national immunization schedule in one or more low or middle income countries (WB definition) and sustained for a period of at least 12 months. Excludes use only in the private sector. Includes vaccines in national schedule that may be selectively used in "at risk" populations	Licensure relates to registration by a functional NRA New platform delivery technology is defined as a new mechanism for delivering vaccines to individual recipients that facilitates coverage, improves performance, or reduces cost of vaccine or delivery, e.g. jet injectors, microneedles, aerosol etc. Launch as defined for new vaccine introduction (see above indicator)	Low- and middle-income countries= world bank classification 2012 Vaccine is added in national immunization schedule and used for a sustained period of at least 12 months (excluding those used only in the private sector and not in national immunization schedule; includes vaccines included in national schedule but for selective use at risk populations, e.g. seasonal influenza) New and underutilized vaccines refers to all vaccines that were not previously in national immunization schedule	Under-five mortality rate per 1000 live births
DATA SOURCE/COLLECTION	Annual surveys with NRA's; JRF for launch of vaccine; WB for definition of low and middle income countries	Annual surveys with NRA's; JRF for launch; WB for definition of low and middle income countries	World Bank, JRF	United National Interagency Group on Mortality Estimates (IGME)
BASELINE	0	0	2010	
TARGET	2020: one or more	2020: one or more	2015: at least 90 2020: all low and middle income countries	2015:2/3 reduction compared to 1990 2020: exceed 2015 target
MILESTONES	Incremental progress (i.e. number of products in phase 1, 2 or 3 clinical trials) on development to be reported and assessed by SAGE	Incremental progress on development (i.e. number of products in phase 1, 2 or 3 clinical trials) to be reported and assessed by SAGE	Monitor trends in vaccine introduction	Monitor trends

* WUENIC= WHO UNICEF Estimates of Nactional Immunization Coverage

TABLE 13: PROPOSED EXTENDED STRATEGIC OBJECTIVE INDICATORS

1	INDICATORS		2	INDICATORS	
ALL COUNTRIES COMMIT TO IMMUNIZATION AS A PRIORITY	**1.1.** Domestic expenditures for immunization per person targeted	**1.2.** Presence of an independent technical advisory group that meets defined criteria	INDIVIDUALS AND COMMUNITIES UNDERSTAND THE VALUE OF VACCINES AND DEMAND IMMUNIZATION BOTH AS A RIGHT AND A RESPONSIBILITY	**2.1.** Percentage of countries that have assessed (or measured) the level of confidence in vaccination at subnational level**	**2.2.** Percentage of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision**
OPERATIONAL DEFINITION	Immunization expenditure from national domestic resources, as reported in the JRF Size of target populations as reported in JRF	National Immunization Technical Advisory Groups meeting all WHO criteria of functionality Criteria of functionality are as described in the WHO/UNICEF JRF	**OPERATIONAL DEFINITION**	Vaccination confidence: Trust in the usefulness and safety of vaccines and in the system that delivers them. Vaccination confidence exists on a continuum and is one of the factors that influences behavior ranging from acceptance to refusal. Determination, whether there been some assessment (or measurement) of the level of confidence in vaccination at subnational level.	Vaccination confidence: Trust in the usefulness and safety of vaccines and in the system that delivers them. Vaccination confidence exists on a continuum and is one of the factors that influences behavior ranging from acceptance to refusal. Determination of % of un- and under-vaccinated in whom lack of confidence was a factor that influenced their decision (this applies to all vaccines)and whether this % was measured or estimated.
DATA SOURCE/COLLECTION	JRF	JRF	**DATA SOURCE/COLLECTION**	JRF	JRF
BASELINE	Reported expenditure for 2010	2010	**BASELINE**	TBD	TBD
TARGET	Increasing trend in country allocation to national immunization programmes	Functional National Immunization Technical Advisory Groups in all countries	**TARGET**	Increasing trend in the % of countries having assessed the level of confidence in vaccination at subnational level	Decreasing trend in the distribution of % of un- and under-vaccinated in whom lack of confidence is a factor at the national level.
MILESTONES	Monitor and report trends	Increasing trend in number of countries with functional NITAGs	**MILESTONES**	Monitor and report trends	Monitor and report trends

** Provisional indicator to be finalized based on outcomes of pilot assessment in selected regions.

3	INDICATORS		4	INDICATORS	
THE BENEFITS OF IMMUNIZATION ARE EQUITABLY EXTENDED TO ALL PEOPLE	**3.1.** Percentage of districts with 80% or greater coverage with three doses of diphtheria-tetanus-pertussis-containing vaccine	**3.2.** Reduction in coverage gaps between wealth quintiles and other appropriate equity indicator(s)	STRONG IMMUNIZATION SYSTEMS ARE AN INTEGRAL PART OF A WELL-FUNCTIONING HEALTH SYSTEM	**4.1.** Dropout rate between first dose (DTP1) and third dose (DTP3) of diphtheria-tetanus-pertussis-containing vaccines	**4.2.** Sustained coverage of diptheria-tetanus-pertussis-containing vaccines 90% or greater for three or more years
OPERATIONAL DEFINITION	Same process for determining district level coverage as for Goal 3	Determination of wealth index as defined in DHS and UNICEF Multi-indicator cluster surveys (MICS); If wealth quintile is used should report coverage across all quintiles and not just lowest and highest quintile; Data collection by repeated measure (special study or survey), with at least two measurements, early measure (2009-2015) and late measure (2016-2020)	**OPERATIONAL DEFINITION**	((DTP1-DTP3)*100)/DTP1	Countries sustaining coverage of 90% or higher for three consecutive years, based on WUENIC
DATA SOURCE/COLLECTION	JRF annual, or special studies/surveys for repeated measures	Household survey or special study representative of entire population	**DATA SOURCE/COLLECTION**	WUENIC	WUENIC
BASELINE	2010 or early measure	Early measure	**BASELINE**	2010	2010
TARGET	All countries with all districts ≥ 80% DTP3 coverage by 2020	Increasing trend in equity in immunization coverage; Proposed target to align with GAVI targets: proportion of countries with < 20% difference in coverage between wealth quintiles 60% by 2015 and 75% by 2020	**TARGET**	Decreasing trend in drop out rate	All countries by 2020
MILESTONES	Monitor trends in number of countries meeting the target	Increasing trend in equity in immunization coverage	**MILESTONES**	Trends in drop-out rates	Increasing trend in number of countries sustaining coverage of 90% or higher

4 CONTINUED ON PAGE 140

4 CONTINUED	INDICATORS			5 IMMUNIZATION PROGRAMMES HAVE SUSTAINABLE ACCESS TO PREDICTABLE FUNDING, QUALITY SUPPLY AND INNOVATIVE TECHNOLOGIES***	INDICATOR
	4.3. Immunization coverage data assessed as high quality by WHO and UNICEF	**4.4.** Number of countries with case-based surveillance for vaccine-preventable diseases			5.1. Percentage of doses of vaccine used worldwide that are of assured quality
OPERATIONAL DEFINITION	Use qualitative assessment of data quality in WUENIC, based on nationally reported data, consistency in data on estimates of size of target population, and consistency between estimates from administrative and other data sources (surveys and other programmatic information)	# countries reporting that they have established surveillance in the JRF and whose reports are included in WHO databases Vaccine preventable disease surveillance will contain, at a minimum: - country-wide surveillance for poliomyelitis, measles and neonatal tetanus; - hospital-based sentinel site surveillance for invasive bacterial diseases and rotavirus diarrhoea with laboratory confirmation of cases Established WHO quality standards will be used for assessing surveillance quality; a analysis of surveillance quality will be included in narrative report on this indicator		**OPERATIONAL DEFINITION**	Number of doses of vaccines of assured quality used in a country / total doses of vaccines used in national immunization programme Vaccines of assured quality include: - Vaccines produced in a country with a functional national regulatory authority - Vaccines prequalified by WHO
DATA SOURCE/COLLECTION	WUENIC Grade of Confidence	JRF and surveillance reports to WHO		**DATA SOURCE/COLLECTION**	JRF; Assessment by by the WHO team on quality, safety and standards for vaccines
BASELINE	2010			**BASELINE**	2010
TARGET	All countries to have high quality immunization coverage data by 2020	100% of countries for polio and measles surveillance by 2015	75% of low and middle income countries for sentinel site surveillance by 2020	**TARGET**	100% of doses vaccines by 2020
MILESTONES	Monitor trends in number of countries meeting the target	Increasing trend		**MILESTONES**	Increasing trend

***The report on progress will also include a narrative report on progress with vaccine supply, pricing and procurement.

6	INDICATORS				
COUNTRY, REGIONAL AND GLOBAL RESEARCH AND DEVELOPMENT INNOVATIONS MAXIMIZE THE BENEFITS OF IMMUNIZATION.	**6.1.** Progress towards development of HIV, TB, and malaria vaccines	**6.2.** Progress towards a universal influenza vaccine (protecting against drift and shift variants)	**6.3.** Progress towards institutional and technical capacity carry out vaccine clinical trials	**6.4.** Number of vaccines that have either been re-licensed or licensed for use in a controlled-temperature chain at temperatures above the traditional. 2-8 °C range	**6.5.** Number of vaccine delivery technologies (devices and equipment) that have received WHO pre-qualification against the 2010 baseline
OPERATIONAL DEFINITION	Number of HIV, TB, and malaria vaccine clinical trials assessing clinical efficacy completed and with results reported	Number of influenza clinical trials assessing clinically the breadth of protection completed and reported	Number of countries per WHO region having reported conduct of a vaccine clinical trials that meet quality standards (to be specified)	As defined in indicator	Four categories of equipment would be tracked: - Refrigerators and freezers - Cold boxes and vaccine carriers - Coolant packs - Temperature monitoring devices
DATA SOURCE/COLLECTION	WHO, NIH and other clinical trial registries	WHO, NIH and other clinical trial registries	WHO, NIH and other clinical trial registries	Reports from NRAs	PQS data base
BASELINE				Incremental above 2010	Incremental above 2010
TARGET	Proof of concept for a vaccine that shows greater or equal to 75% efficacy for HIV/AIDS, tuberculosis, or malaria vaccines	At least one vaccine providing broad spectrum protection against influenza A virus licensed	Every Region has a solid base of countries competent in hosting and managing vaccine trials		
MILESTONES	Narrative report on progress in development of these vaccines	Narrative report on progress in development of these vaccines		Increasing number of vaccines	Increasing number of technologies

The SAGE Decade of Vaccines Working Group that will review the annual GVAP progress report will also consider the development and addition of indicators that measure equity in access to vaccines between countries, and an indicator to monitor integration of immunization systems into broader health systems.