Description of WHO and UNICEF estimates of national immunization coverage

compliance with GATHER criteria

1. **Define the indicator(s), populations (including age, sex, and geographic entities), and time period(s) for which estimates were made.**

Since 2001, WHO and UNICEF have annually updated single-year estimates of national routine infant vaccination coverage for select vaccine dose combinations for all Member States of the World Health Assembly and the State of Palestine. As of this writing, estimates are produced for 195 countries and territories. Estimates are published each July and cover the period from 1980 through the most recent calendar year (January through December). For example, estimates produced and published in July 2020 reflect the period 1980 through 2019. National vaccination coverage estimates reflect the percentage of infants vaccinated with a given vaccine dose combination without regard to demographic characteristics.

For each country (C), vaccine dose (V), year (Y) combination, WUENIC coverage estimates (WUENIC$_{CVY}$) are presented as a percentage of the target population receiving the vaccine dose during year (Y). Estimates are currently made for the vaccine dose combinations listed in Table A1. Target populations vary by vaccine and by national immunization schedule (Table A1). In general, the target population is the total number of births for vaccines recommended at birth and is the total number of surviving infants (children aged < 12 months) for vaccines recommended during the first year of life. The target population for PCV3 is either the total number of surviving infants or children aged 12–23 months, depending on the national immunization schedule. Similarly, the target population for MCV1 and RCV1 is the total number of surviving infants or children aged 12–23 months, depending on the national immunization schedule. The target population for MCV2 is the total number of children at the recommended age in the national immunization schedule. The target population for YFV is the total number of surviving infants in countries where recommended, even if only recommended subnationally. The estimated total number of children vaccinated with a specific vaccine dose for each year is obtained by multiplying estimated vaccination coverage by the estimated total number of births or surviving infants, depending on vaccine and country for each country for a given year. Data obtained from the United Nations Population Division (UNPD) (https://population.un.org/wpp).

In addition to global, population-weighted average coverage estimates, averages are produced for WHO regions (www.who.int/about/regions), UNICEF regions (www.unicef.org/where-we-work), The World Bank income groupings (www.worldbank.org) and by eligibility for support from Gavi, the Vaccine Alliance (www.gavi.org) . Global and regional averages are calculated by multiplying estimated country-specific coverage values by a country-specific population weight, computed as the country-specific proportion of the global (or regional) total population, and aggregating across countries. Global and regional average calculations utilize the aggregated total number of estimated births or surviving infants (as appropriate) for the region as obtained from UNPD. The global estimated total number of children vaccinated with a specific vaccine dose is obtained by multiplying estimated vaccination coverage for the region by the relevant estimated target population from UNPD. And, the estimated total number of children *unreached* with a specific vaccine dose in a given year is obtained by subtracting the percentage of children vaccinated in the country for that year from 100 and multiplying by the estimated total number of surviving infants for the same year. For example,

$$\text{estimated total number of children unreached} = (100 - \text{WUENIC}_{CVY}) \times \text{SI}_{CY},$$

where WUENIC_{CVY} is the estimated vaccination coverage for country (C), vaccine dose (V), and year (Y) and SI_{CY} is the estimated total number of surviving infants for a specific country-year dyad.

2. List the funding sources for the work.

WUENIC estimate production is a core activity of both UNICEF and WHO, which are mandated to monitor and assess trends in the health and well-being of populations worldwide. Historically, immunization data activity, including WUENIC, has been financially supported through operating budgets that are derived from assessed contributions (i.e., dues countries pay as members of the World Health Assembly and United Nations) and voluntary contributions (i.e., contributions from Member States and other partners). Over time, voluntary contributions have accounted for increasing shares of each organization's operating budget [A1].

Following the launch of Gavi, the Vaccine Alliance, financing has largely shifted away from a model relying on core agency funds and funds received directly from bi-lateral donors (i.e., voluntary contributions from member states) towards a model that relies on coordination through Gavi, the Vaccine Alliance and the Gavi Secretariat. Since 2011, the production of WUENIC has been funded, in part, through Gavi, the Vaccine Alliance. The Bill and Melinda Gates Foundation, which is one of the largest contributors to Gavi, the Vaccine Alliance, is also an important contributor to WUENIC. However, while outside partners have been increasingly interested in the WHO and UNICEF estimates, partners have not directly engaged in the production of the estimates.

3. Describe how the data were identified and how the data were accessed.

Each year, WHO and UNICEF jointly review annual reports of national vaccination coverage from national authorities for the antigens noted in Table A1; most often, coverage is reported using the WHO and UNICEF Joint Reporting Form on Immunization (JRF). Survey data from the published and grey literature are also assessed. A detailed description of the data collection process is available in Brown and Gacic-Dobo [A2].

The data inputs include administrative and official coverage, national vaccination schedules (e.g., vaccine dose recommendations by age and indications for use), vaccine stockouts (e.g., occurrence and length of national stockouts and whether they affected supply at the subnational level), vaccine preventable disease surveillance, and additional contextual information garnered through general comments.

Administrative coverage data are derived from routine administrative health service delivery reports and reflect the aggregated number of doses of a vaccine dose administered to a specified target population during a specified time period divided by the total number of persons in the same target population. Official coverage reflects a national authority's assessment of their most likely coverage based on any combination of administrative coverage, survey-based estimates or other data sources or adjustments. Approaches used to determine official coverage differs across countries. Administrative and official coverage data are available at: http://bit.ly/WUENIC-input-coverage-data [A3].

Table A1. WUENIC are produced for vaccine dose combinations listed below

VACCINE DOSE	TARGET POP	ESTIMATE DESCRIPTION	NOTES
BCG Bacille Calmette-Guérin	Births	Percentage of births that received a dose of BCG vaccine	Estimates produced for 160 countries with a high disease burden and for high-risk children in countries with low disease burden.
HepBB Birth dose of hepatitis B vaccine	Births	Percentage of births that received a dose of hepatitis B vaccine within 24 hours of delivery	Estimates produced for countries with a universal birth dose policy. Estimates are not produced for countries recommending a birth dose only for infants born to HepB virus-infected mothers or where information is insufficient to determine whether vaccination occurred within 24 hours of birth.
DTP1, DTP3 1st and 3rd dose diphtheria–tetanus–pertussis containing vaccine	Surviving infants (SI)	Percentage of SIs who received the 1st & 3rd dose of DTP containing vaccine, respectively	
Pol3 3rd dose polio containing vaccine	Surviving infants	Percentage of SIs who received 3 doses of polio vaccine	
IPV1 1st dose inactivated polio vaccine	Surviving infants	Percentage of SIs who received a 1st dose of IPV	
MCV1 1st dose measles containing vaccine	Surviving infants	Percentage of SIs who received a 1st dose of MCV	
MCV2 2nd dose measles containing vaccine	Depends on national schedule	Percentage of children who received a 2nd dose of MCV	Estimates are produced for countries according to the nationally recommended schedule.
RCV1 1st dose rubella containing vaccine	Surviving infants	Percentage of SIs who received a 1st dose of RCV	Estimates based on the dose of MCV that corresponds to the 1st measles-rubella combination vaccine. If given with MCV1, the target population is SIs; if given with MCV2, the target population is children 12–23m. RCV coverage and other data are not considered.
HepB3 3rd dose hepatitis B vaccine	Surviving infants	Percentage of SIs who received a 3rd dose of HepB containing vaccine after a birth dose, as applicable	
Hib3 3rd dose Haemophilus influenzae type b containing vaccine	Surviving infants	Percentage of SIs who received a 3rd dose of Hib containing vaccine	
RotaC Final dose rotavirus vaccine	Surviving infants	Percentage of SIs who received the final recommended dose of rotavirus vaccine	Final dose may be either the 2nd or the 3rd dose depending on the vaccine.
PCV3 3rd dose pneumococcal conjugate vaccine	Surviving infants	Percentage of SIs who received a 3rd dose of PCV	When 2 doses during infancy and a booster dose at 12m or later is recommended based on disease epidemiology, coverage estimates may reflect the percentage of SIs who received 2 doses of PCV prior to 1st birthday.
YFV Yellow fever virus vaccine	Surviving infants	Percentage of SIs who received 1 dose of YFV	Annualized estimates for the national cohort of SIs are produced for countries where YFV is part of the national childhood immunization schedule or is recommended in at risk areas.

A vaccine is a biological substance that stimulates an organism's immune system to protect that organism from a particular disease or pathogen. Antigens are molecules from the pathogen against which an immune response is desired. Except for diphtheria-tetanus-pertussis containing vaccine (DTP), which is a combination vaccine targeting three distinct antigens, WHO and UNICEF produce estimates of antigens. Due to historical terminology usage, reference is often made to vaccines rather than antigens alongside attempts to deal with loose language using constructions like measles containing vaccine (MCV). For consistency sake, one should refer not to Hib vaccine but rather Hib containing vaccine, Hepatitis B containing vaccine, etc.

In addition to reported administrative and official coverage, WHO and UNICEF review estimated vaccination coverage levels obtained from nationally representative, population-based household surveys. Survey results are most often obtained from USAID-supported Demographic and Health Surveys (DHS), UNICEF-supported Multiple Indicator Cluster Surveys (MICS), World Bank supported Living Standard Monitoring Surveys (LSMS) and Expanded Programme on Immunization (EPI) cluster coverage surveys. Reports are submitted by national authorities. WHO and UNICEF also search national and agency websites for survey reports and information. A database of surveys is available at: http://bit.ly/WUENIC-survey-data [A4].

Age-specific population estimates from the UNPD are used to estimate regional and global coverage rates and to inform the Grade of Confidence (GoC) that describes uncertainty in coverage estimates. Population data are obtained from UNPD's World Population Prospects site at: https://population.un.org/wpp.

Finally, WHO and UNICEF obtain additional information from the JRF and through consultation with regional and national immunization and monitoring experts who are able to provide otherwise unreported information, such as changes in immunization policies and insight into the functioning of the immunization system and quality of reported data.

4. Specify the inclusion and exclusion criteria. Identify all ad-hoc exclusions.

Reported vaccination coverage data are included if they meet at least one inclusion criterion and do not meet any exclusion criterion. Likewise, data are excluded if they do not meet any inclusion criteria or meet at least one exclusion criterion.

Administrative coverage: National authorities must report administrative coverage data to WHO or UNICEF in writing and may update prior years' data at any time through written communication to WHO or UNICEF. For all antigens, reported coverage levels >100% are excluded. For all antigens, coverage levels that suggest large (≥10%-points) year-to-year changes (either increases or decreases) in vaccination coverage and that are not accompanied by an explanation (e.g., vaccine supply disruption, natural disaster that impacted health service delivery) are excluded. If an explanation is provided, administrative coverage data involved in a large coverage swing may be included. Dramatic increases or decreases in coverage are also allowed for vaccines being newly introduced in recent years such as pneumococcal conjugate vaccine, inactivated polio vaccine and rotavirus vaccine.

Official coverage: Official coverage estimates must be reported in writing to WHO or UNICEF by the relevant national authorities. Prior estimates may be updated at any time through written communication. For all antigens, coverage levels >100% are excluded. For all antigens, coverage levels that suggest large (≥10%-points) year-to-year changes in vaccination coverage (either increases or decreases) and that are not accompanied by an explanation (e.g., vaccine supply disruption, natural disaster that impacted health service delivery) are excluded. Dramatic swings in coverage for new vaccines are included during periods of introduction.

Survey coverage: Survey reports must be finalized before results are included and must provide a sufficient description of the survey methods, including sampling methodology. Survey results are excluded if they are not nationally representative; are derived from a survey of small size (i.e., <300 observations) or no sample size is reported; are not accompanied by the methods used to

obtain the coverage estimates; or derived from samples of children with documented evidence only, unless the survey reports evidence that nearly all children in the country maintain documented evidence. Survey results may also be ignored if the reported coverage estimates are not for single year cohorts (e.g., children 0–11 months, 12–23 months, 24–35 months). Crude, rather than valid (e.g., refers to doses of vaccine administered in a manner that respected the earliest recommended age and minimum interval between doses [A5]) vaccination coverage estimates are considered. Finally, survey results may be ignored in the presence of evidence that coverage estimates are compromised by survey design, implementation or analysis issues. In 2018–19 a survey checklist (available upon request from vpdata [at] who [dot] int) was developed by WHO and UNICEF and surveys from 2016 are verified against the checklist criteria.

All nationally reported immunization performance data noted above are publicly available on the WHO website (https://www.who.int/immunization/monitoring_surveillance/en/) and updated in June and December.

> **5. Provide information on all included data sources and their main characteristics. For each data source used, report reference information or contact name/institution, population represented, data collection method, year(s) of data collection, sex and age range, diagnostic criteria or measurement method, and sample size as relevant.**

Countries report immunization system performance data annually using the WHO and UNICEF JRF. These data include administrative and official vaccination coverage data, national vaccination schedule information, vaccine stockouts, and vaccine preventable disease surveillance data. These are complemented by population survey-based coverage data and by population data from the UNPD.

Administrative coverage: Administrative coverage reflects the percentage of a target population receiving a vaccine dose during a given time period based on aggregated administrative reports of the number of vaccinations administered from health service providers (numerator data) and reported target population data (denominator data). Administrative numerator and coverage data are reported annually to WHO and UNICEF by national authorities, most often using the WHO and UNICEF JRF (http://bit.ly/WHO-UNICEF-JRF) [A6]. See also http://bit.ly/WUENIC-coverage for additional information.

Official coverage: Official coverage estimates reflect the percentage of a target population receiving a vaccine dose during a given time period, but are based on national authorities' own assessment of the most likely coverage level based on any combination of administrative coverage, survey-based estimates or other data sources or adjustments. For example, official coverage estimates provide national authorities an opportunity to account for instances when private sector services are not included in administrative reported systems. Approaches to determine official coverage may differ across countries and over time. Data are most commonly reported annually using the WHO and UNICEF JRF (http://bit.ly/WHO-UNICEF-JRF).

National vaccination schedule: National vaccination schedules provide standardized information regarding the vaccines and number of doses of vaccine that a population should receive and the recommended ages at which the vaccine doses should be received, inclusive of minimum ages and intervals between doses. Vaccination schedules also provide information on whether a vaccine is recommended for an entire population or targeted to specific risk groups. Schedule information is important for guiding whether estimates should be produced for a country/vaccine/year combination. The quality of vaccination schedule data varies in quality and availability across countries and over

time. Data are most commonly reported annually by national authorities using the WHO and UNICEF JRF (http://bit.ly/WHO-UNICEF-JRF).

Vaccine stockouts: The occurrence and duration of vaccination stockouts at the national and subnational levels are reported for selected antigens. The quality of vaccination stockout data are of unknown and varying quality across countries and over time. Data are reported annually most commonly using the WHO and UNICEF JRF (http://bit.ly/WHO-UNICEF-JRF).

Survey coverage: Vaccination coverage is also obtained from survey results based on nationally representative population-based household surveys, usually among children 12–23 months or 24–35 months of age. Evidence of vaccination is based on any of several sources: documented evidence from home-based records (immunization cards) or health facility records or recall of vaccination history by the child's caretaker. Survey results are referenced to the appropriate birth cohort based on the period of data collection. Survey results are abstracted from finalized survey reports. Data are available at: http://bit.ly/WUENIC-survey-data [A4].

Population estimates: Age-specific population estimates from the UNPD are used to estimate regional and global coverage rates, and to inform the GoC that describes uncertainty in WUENIC estimates. Population data are obtained from UNPD's World Population Prospects at: https://esa.un.org/unpd/wpp.

> ## 6. Identify and describe any categories of input data that have potentially important biases (e.g., based on characteristics listed in item 5).

WUENIC estimates of national immunization coverage are based solely on country-specific data, which may be of unknown and varying quality. We are aware of the following potential biases in the input data:

Administrative coverage: Both the reported number of administered vaccine doses (numerator) and the target population (denominator) may be biased, leading to biased coverage. Biases affecting numerator data include, but are not limited to incomplete and untimely reporting (e.g., absent reports from private sector providers), as well as data recording and reporting errors. Biases affecting denominator data include, but are not limited to, population estimates based on an outdated census, a poorly implemented census or poorly implemented census projections.

Official coverage: Official coverage is a country's estimate of vaccination coverage. The methods and sources used to produce official estimates are not always described or available. Methods may also change over time without documentation or notice. In instances where a country bases official coverage on administrative coverage, biases in the administrative coverage carry over to official coverage.

Survey coverage: Survey-based coverage estimates are subject to sampling and non-sampling error. Sampling error may result from areas that were purposively excluded from the sampling frame. For example, areas with limited access may also have limited health services; exclusion of these areas would lead to an upward bias. Misclassification of vaccination status may result in non-sampling error due to inaccurate respondent recall, errors transcribing information from documented evidence, inaccurate recorded history or data entry errors.

WHO and UNICEF use nationally reported data on immunization schedules, new vaccine introductions, vaccine stockouts, the occurrence of mass vaccination events (e.g., national immunization days, campaigns, child health days) and vaccine preventable disease surveillance. Data for each of these domains are obtained as part of an annual immunization system data collection exercise.[3] New vaccine introductions are carefully monitored by the WHO and complemented using information derived from UNICEF Supply Division and Gavi, the Vaccine Alliance. Data on the occurrence of national vaccine stockouts, length and whether the stockout affected supply at the subnational level are collected for most of the antigens noted in Table A1. All of these data inputs are publicly available at http://www.who.int/immunization/monitoring_surveillance/data.

WHO and UNICEF make all input data publicly available at http://www.who.int/immunization/monitoring_surveillance/data. The complete time series data of official country reported coverage estimates are available in multiple electronic formats (e.g., HTML and MS Excel, Microsoft Corporation, Redmond, Washington, USA) available at http://www.who.int/entity/immunization/monitoring_surveillance/data/coverage_series.xls, and the complete time series of country reported administrative coverage data are available in MS Excel format at http://www.who.int/immunization/monitoring_surveillance/data/administrative_coverage.xls. Abstracted results from population-based survey reports are available in MS Excel format at http://www.who.int/immunization/monitoring_surveillance/data/Coverage_survey_data.xls.

WUENIC, the supporting data, information, heuristics, and working group decisions are characterized in a formal knowledge representation and reasoning system using computational logic as described in Burton et al 2012 (https://doi.org/10.1371/journal.pone.0047806). Data, information, and working group decisions are represented as facts described as predicates; heuristics are represented as rules in "if conditions then conclusion unless exception" form. The estimates may be derived using formal inference rules from the data and working group decisions.

WUENIC are based on a country-by-country, vaccine-by-vaccine, year-by-year assessment. A complete time series is produced for each country; that is, an estimate is made for every country/vaccine dose/year combination from 1980 to present. Estimates, which cannot exceed 99%, are country-specific: each country's data are reviewed individually and there is no "borrowing" of data from other countries in the absence of information. And, there are no ad hoc quantitative adjustments to input data based on subjective judgements. While general trends frequently exist in

immunization coverage, no attempt is made to fit data points with smoothing techniques or time series methods.

Under specific conditions, empirical values may be modified in a formal, rule governed manner. For example, survey coverage for multi-dose vaccines (e.g., DTP3) informed by a respondent caregiver's recall of her child's vaccination history is modified when information is available to warrant doing so. The modification is based on the dropout in coverage between the first and third dose vaccination coverage based on documented evidence applied to vaccination coverage for the first dose coverage informed by caretaker recall and documented evidence. Although there are known differences between persons who retain documented evidence and those that do not, it is generally believed that respondent caregivers are more likely to accurately recall the type of vaccines a child received better than the number of doses of that vaccine the child received. Thus, the justification for a recall bias adjustment to the third dose vaccination coverage. The modification may raise or lower the unmodified coverage value.

We distinguish between when data reported by national authorities accurately reflects immunization system performance and when the data are likely compromised and misleading. Unless challenged, the nationally reported estimate constitutes the WUENIC. If reported data are supported by independent survey results, then WUENIC will reflect the reported data. When reported data are challenged by survey results, WUENIC may diverge from the reported data.

The estimates are not the product of a formal modelling exercise. No statistical or mathematical models are used with one exception: estimates of the first dose of diphtheria-tetanus-pertussis containing vaccine. Data from different sources are not averaged to arrive at a final estimate. The approach does not borrow information from data rich countries to fill in gaps among data poor countries. Attempts to identify exogenous, macro-level covariates such as income level, development status, population size or geographical characteristics that provide sufficiently sensitive and robust covariates to immunization services delivery have proven unsuccessful.

WUENIC are informed and constrained by the following heuristics, expressed as rules and exceptions in the form *conclusion IF condition UNLESS exception* (Nota bene: In formal logic UNLESS(x) is usually represented as AND (NOT[x])). For example, an informal expression may look like the following:

WUENIC = nationally reported coverage

IF *there is nationally reported coverage* AND

nationally reported coverage is < 100% AND

there was no year-to-year increase/decrease > 10 percentage points AND
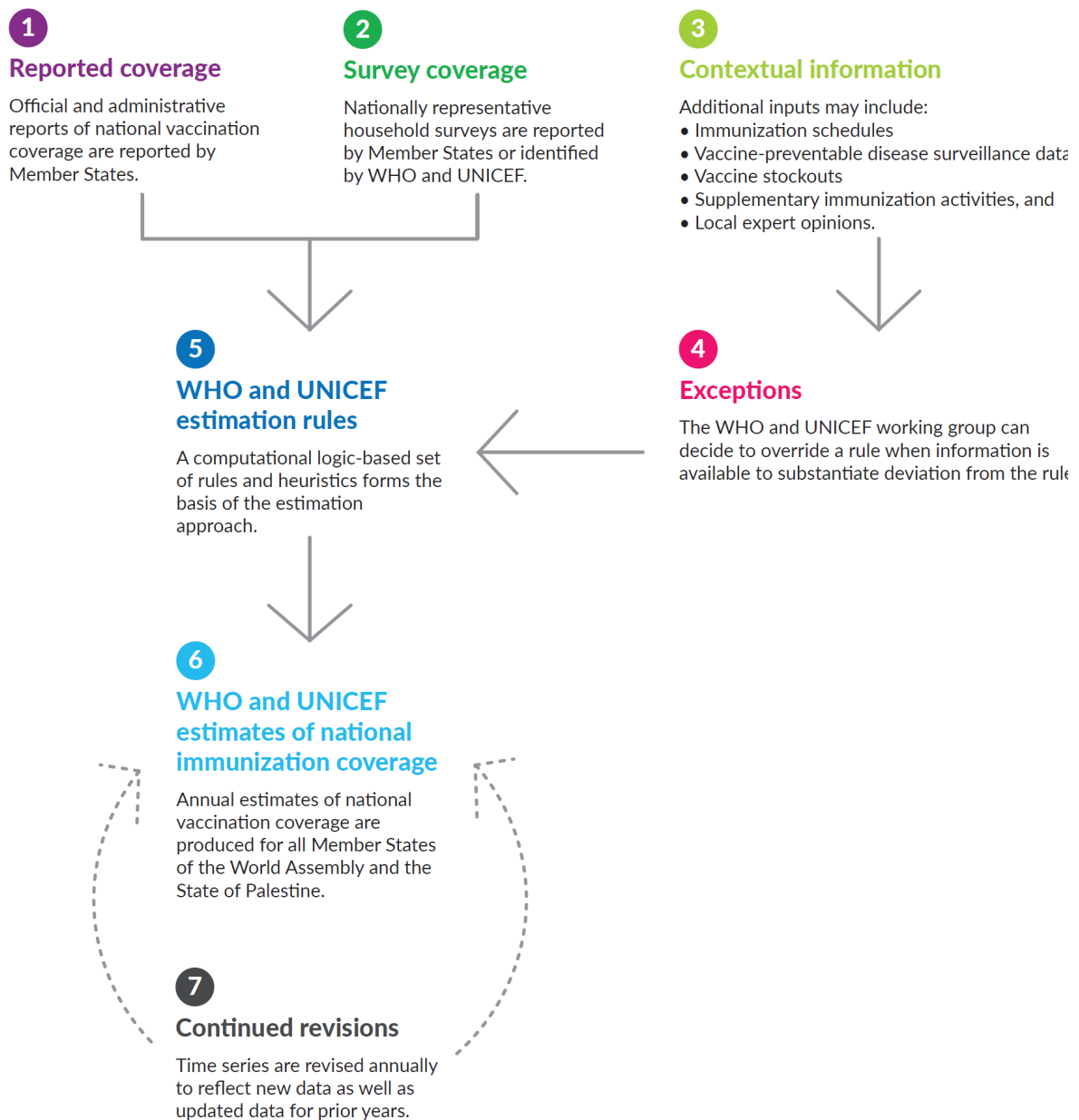
there are no survey data for that country/vaccine/year UNLESS

the working group has a reason why the rule should not apply.

The WHO and UNICEF working group uses exceptions to override rules if information is available suggesting a rule application is inappropriate. Working group decisions are documented and included in the operational database.

Figure A1. Summary process flow for the WHO and UNICEF estimates of national immunization coverage

1 Reported coverage

Official and administrative reports of national vaccination coverage are reported by Member States.

2 Survey coverage

Nationally representative household surveys are reported by Member States or identified by WHO and UNICEF.

3 Contextual information

Additional inputs may include:
- Immunization schedules
- Vaccine-preventable disease surveillance data
- Vaccine stockouts
- Supplementary immunization activities, and
- Local expert opinions.

5 WHO and UNICEF estimation rules

A computational logic-based set of rules and heuristics forms the basis of the estimation approach.

4 Exceptions

The WHO and UNICEF working group can decide to override a rule when information is available to substantiate deviation from the rule.

6 WHO and UNICEF estimates of national immunization coverage

Annual estimates of national vaccination coverage are produced for all Member States of the World Assembly and the State of Palestine.

7 Continued revisions

Time series are revised annually to reflect new data as well as updated data for prior years.

10. Provide a detailed description of all steps of the analysis, including mathematical formulae. This description should cover, as relevant, data cleaning, data pre-processing, data adjustments and weighting of data sources, and mathematical or statistical model(s).

The WHO and UNICEF estimation process generally proceeds as follows: Reported official coverage estimates, administrative coverage and available survey coverage estimates are assessed independently. Reported data are reviewed with regards to consistency over time and between antigens as well as for face validity. As a general principal, reported coverage data >100% are ignored as they have no face value. In addition, there is a general belief that vaccination coverage is unlikely to change rapidly overtime; actual or real sudden changes are likely to be the results of "shocks" to the system and thus should be accompanied by an explanation (e.g., vaccine arrived at national warehouse frozen). Apparent changes may also be artefacts of changes in data collection or reporting (e.g., estimates of the size of the target population change suddenly due the availability of a new census), errors in recording or reporting, or errors in calculating coverage. If changes in coverage from year-to-year exceed 10 percentage points in any direction, the reported value is ignored and is replaced by interpolation (or extrapolation if at the end of a time series) from surrounding years. If available information suggests that the sudden change accurately reflects immunization system performance, then an exception to the rule is made and the reported data point is accepted. Exceptions are documented in the operational database.

With the exception of diphtheria-tetanus-pertussis containing vaccine (DTP), WUENIC are presented by antigen. (Nota bene: Because antigens may be combined into a variety of vaccines, estimates are presented by antigen. The exception, for historical reasons, is that estimates are made for the combination diphtheria-tetanus-pertussis containing vaccine as a single "antigen".) Because combination vaccines contain multiple antigens, the WHO and UNICEF estimates for the antigens delivered in the same combination vaccine are equal. If survey results or nationally reported estimates for antigens known to be part of a combination vaccine are not the same, relevant contextual data is reviewed—either referencing data reported by the national authorities through the JRF or by direct correspondence—to reconcile or explain the difference. Likewise, it is expected that coverage for vaccine doses recommended at the same age should be similar. If there are meaningful differences between vaccination coverage for vaccine doses given at the same age, efforts are made to reconcile or explain the differences. Finally, for multi-dose vaccines, it is expected that the coverage for each successive dose will be less than or equal to the coverage for the preceding dose in the series. For example, the second dose of DTP should be less than or equal to the first dose and the third dose should be less than or equal to the second.

Survey coverage estimates are assessed and considered if they are the result of a nationally representative, population-based survey of sufficient size (currently is a minimum sample size of 300 observations) for which the methods are available for review and the results have been finalized. Ideally, survey results reflect coverage for a single annual cohort, such as children aged 12–23 months or 24–35 months. Survey results spanning multiple cohorts, such as 12–59 months, are not considered. While survey coverage obtained from documented evidence only and from respondent caregiver recall are referenced, primary attention is focused on coverage derived from the combination of vaccination history based documented evidence and recall from respondent caregiver (in the absence of documented evidence). Issues of vaccine to vaccine consistency within survey coverage are taken into account. For example, if survey estimates suggest national vaccination coverage of 75% for the third dose of DTP (DTP3) and 90% for the third dose of oral polio vaccine (OPV3), and there is evidence of polio campaigns that align with the estimation year, then the survey

results for OPV3 are likely to be ignored vis-à-vis those of DTP3 based on vaccine-to-vaccine consistency and the focus on routine vaccine doses rather than campaign delivered doses.

If reported data are available from a single source, the WHO and UNICEF estimates are based solely on that source, supplemented with linear interpolation to impute values for years for which data are not available. If no reported data are available for the most recent estimation period, the estimate remains the same as the previous year using extrapolation. If new data or information subsequently become available, the relevant portion of the time series is updated.

When multiple sources of information are available for a given country/vaccine dose/year combination, the sources either provide support for a given coverage level or they diverge and judgements must be made as to which source most likely reflects actual coverage levels. Anchor points constitute years where vaccine dose/year coverage values are available from multiple sources (e.g., officially reported coverage and survey-based coverage). If estimates from both sources are similar (e.g., the survey data supports the nationally reported data), then evidence suggests the nationally reported data are correct. If the survey data challenges the nationally reported estimate (i.e., does not support), the presumption is that the survey estimates are more likely to be correct. (Nota bene. A principle justification for this assumption is that administrative coverage estimates are commonly biased due to errors in the coverage denominator. Survey coverage estimates are not affected by such problems.) If survey coverage results are $\leq\pm10$ percentage points different from the officially reported coverage, the anchor point value for that country/vaccine dose/year is the value of the reported data. If survey coverage results are $>\pm10$ percentage points different from the officially reported coverage, the anchor point value for that country/vaccine dose/year is the value of the survey coverage estimate. Survey coverage levels are adjusted to compensate for maternal recall for multi-dose antigens (i.e., DTP, polio vaccine, hepatitis B vaccine and Hib vaccine) by applying the dropout between the first and third doses observed in the documented data to the vaccination history reported by the child's caregiver [A7].

Once coverage estimates at all anchor points have been established, estimates between anchor points are made. For years between two anchor points, if both anchor point vales are based on nationally reported coverage, then WHO and UNICEF estimates between the two anchor point years are based on the nationally reported data for each year. However, if at least one anchor point is not based on nationally reported data, then the WHO and UNICEF estimate becomes the nationally reported data calibrated to the anchor point values. If an anchor point value is based on a nationally reported estimate, then WHO and UNICEF estimates for years beyond the anchor point(s) are based on nationally reported data. If an anchor point value is not based on nationally reported data, then the WHO and UNICEF estimate is the same as the most recent anchor point value or based on a calibrated value based on the anchor point.

A stepwise visual description of the WUENIC estimation process is provided for several scenarios in Annex 2.

<h2>11. Describe how candidate models were evaluated and how the final model(s) were selected.</h2>

The WUENIC estimation process and methods have evolved since their initial release in 2000. Periodic, independent, external expert reviews have been conducted by: the WHO Quantitative Immunization and Vaccines Related Research (QUIVER) Advisory Committee (2009), the WHO QUIVER Advisory Committee (2011), the WHO Strategic Advisory Group of Experts on

Immunization (SAGE; 2011), and the WHO Immunization and Vaccines Related Implementation Research Advisory Committee (2019). Reviews have supported the approaches taken and provided useful advice for improvements, emphasizing the importance of improving the quality of input data alongside national immunization programmes. While the current methods have not been formally evaluated against other approaches, WHO is working with the Institute for Health Metrics and Evaluation (IHME) (http://www.healthdata.org), which produces vaccination coverage estimates through a space-time Gaussian process regression model utilized in the context of the Global Burden of Disease Project, to describe differences, and similarities, between estimates from the two methods.

> ## 12. Provide the results of an evaluation of model performance, if done, as well as the results of any relevant sensitivity analysis.

The results of an independent, external expert review completed in 2009 are available at:http://bit.ly/QUIVER2009. The results of additional independent reviews completed in 2011 are also available at:http://bit.ly/QUIVER2011 and http://bit.ly/SAGE2011. And, the results of a 2019 review are available at:http://bit.ly/IVIRAC2019.

> ## 13. Describe methods for calculating uncertainty of the estimates. State which sources of uncertainty were, and were not, accounted for in the uncertainty analysis.

WUENIC are based on data and information, including reports of vaccination coverage from national immunization programmes and survey data from the published and grey literature that are of varying, and, in some instances, unknown quality across countries and over time. Uncertainty is communicated through a GoC, which was introduced to WUENIC with the 2011 revision (completed July 2012) [A8].

Because there is no underlying probability distribution for the WUENIC estimates, classic measures of uncertainty such as confidence intervals are not used. The GoC reflects the accumulation of endorsements, or sources of supporting information, that may influence certainty about an estimated value. Currently, three levels of endorsement are possible in the GoC: 1) supported by coverage data reported by national authorities; 2) supported by (i.e., < 10%-points away from) coverage levels recomputed using the number of children vaccinated as reported by national authorities and the number of births or surviving infants obtained from the UN Population Division; and 3) supported by (i.e., < 10%-points away from) survey results within a two-year window (before or after).

A GoC value of three (3) reflects high confidence in an estimate and is assigned if an estimate is supported by all three endorsements. A GoC of two (2) indicates an estimate is supported by at least one endorsement and there is no challenge to the estimate by a data source. A GoC of one (1) reflects low confidence in an estimate and indicates the estimate is challenged by at least one data source.

The GoC does not reflect an assessment of the quality of the underlying input data. All WUENIC estimates carry a risk of being incorrect—even estimates which carry multiple supporting endorsements—given potential deficiencies in the input data (e.g., reported data from national authorities may be inaccurate or incomplete; survey-based estimates of coverage are subject to sampling and non-sampling errors).

14. State how analytic or statistical source code used to generate estimates can be accessed.

A computational logic-based representation of rules, data and decisions for WUENIC is provided in Burton et al [A9]. Currently, data and information (administrative coverage, official coverage, survey coverage and working group decisions) are maintained in a Microsoft Access (Redmond, WA, USA) production database. Rules are implemented in XSB Prolog, and an R script extracts data from the Access database and creates a country-specific file of Prolog predicates of the data, as well as information and working group decisions. XSB Prolog then executes the rules using the country-specific file of data and information and produces a file of estimates with the accompanying supporting data and working group decisions. Finally, an R script reads this file and outputs graphs and LaTex (https://www.latex-project.org) source code of a country-specific summary which is used to produce country-specific Portable Document Format (PDF) formatted reports. The formal representation and Prolog code are available upon e-mail request from vpdata [at] who [dot] int.

15. Provide published estimates in a file format from which data can be efficiently extracted.

The complete time series of country-specific, regional and global coverage estimates are available electronically (HTML, MS Excel, and PDF) at: http://bit.ly/WUENIC-coverage [A10].

16. Report a quantitative measure of the uncertainty of the estimates (e.g., uncertainty intervals).

The GoC, a qualitative measure of uncertainty used by WUENIC, is published alongside the WUENIC time series for 1997 through the most recent release and available at: http://bit.ly/WUENIC-coverage [A10].

17. Interpret results in light of existing evidence. If updating a previous set of estimates, describe the reasons for changes in estimates.

Annual estimate production involves a revision of the time series to reflect new data as well as updated data for prior years. As such, coverage levels for the current revision are not comparable to those from previous revisions. New or updated data may include reports by national authorities, estimates from surveys, contextual information, methodological updates, and updated population estimates from UNPD, which occurs every two years.

WUENIC aims to identify the most likely coverage level reflective of a country's immunization delivery system given the available data and data quality while ensuring the consistency and comparability of estimates within and across countries over time. Estimates are limited by the quality of the underlying empirical input data. Reported data from national programmes are of unknown and varying quality. Inaccuracies may exist within the reported numerator data as well as denominator data. For example, although the time series of reported data is complete for many countries, missing data may exist for *1)* one or more vaccine doses or years within reported administrative or official coverage, *2)* the reported number of doses administered or *3)* the reported number of children in the target population (often due to poor census quality, outdated census results, or poor population projections from a census).

Vaccination coverage estimates from population-based, household surveys may be limited by the quality of the planning and implementation of the field work and the availability of documented evidence of vaccination history in home-based or facility-based records. Additionally, coverage indicators from survey reports do not always conform to standard definitions due to errors therein, analysis or presentation of results (e.g., reporting coverage for multiple birth cohorts rather an than single year cohorts) thereby impacting interpretation and usefulness. And, because of time lags in the release of survey results following completion of field work, survey results are often lacking for the most recent two years of the estimates, which are thereby subject to an information bias. For countries with infrequent survey-based coverage estimates, the availability of new survey coverage data can lead to substantial changes in the historical time series of coverage estimates to the extent that differences exist between reported administrative or official coverage levels and estimated coverage levels from surveys.

WUENIC estimates are also constrained by the underlying rules and heuristics utilized in the estimation approach itself. For example, as a system, the reach of immunization service delivery does not tend to change dramatically from one year to the next. With this in mind, a threshold of $>\pm10$ percentage points is used to identify outlier year-to-year changes in coverage. Recent observations of WUENIC have demonstrated there are problems with a fixed threshold as coverage in countries reaches high levels. Similarly, a fixed threshold of ≤10 percentage points when comparing survey coverage to reported coverage data to determine whether survey results support, or not, is problematic at high levels of coverage. Efforts are underway to implement coverage-dependent thresholds that change as coverage levels increase. Currently there is no functional relationship between estimated coverage for the first and third doses of DTP beyond the constraint that DTP3 must be less than or equal to DTP1; efforts are underway to consider dropout between DTP1 and DTP3 more formally. Finally, there is no sunset provision in place to limit the influence of survey coverage results. That is, vaccination coverage survey results from 2005 could influence the levels of coverage (vis-à-vis reported data) in 2018 in scenarios where WUENIC are calibrated to reported data at the levels of the survey-based coverage. Again, efforts are underway to explore alternative approaches to implementing a sunset provision.

Annex References

A1. World Health Organization. The WHO Programme Budget Portal. Available at:
http://open.who.int/. Accessed 2020 October 12

A2. Brown DW, Gacic-Dobo M. Reported National Level Stock-Outs of Home-Based Records—A
Quiet Problem for Immunization Programmes That Needs Attention. World J Vaccines. 2017;7(1):1-
10. doi:10.4236/wjv.2017.71001.

A3. Complete URL:
http://www.who.int/entity/immunization/monitoring_surveillance/routine/coverage/WUENIC_input_t
o_PDF.xls

A4. Complete URL:
http://www.who.int/immunization/monitoring_surveillance/data/Coverage_survey_data.xls

A5. World Health Organization. 2018 WHO Vaccination Coverage Cluster Survey Reference
Manual. WHO: Geneva, Switzerland. Available at:
https://www.who.int/immunization/documents/who_ivb_18.09. Accessed on: 2020 October 12.

A6. Complete URL:
http://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting

A7. Brown DW, Burton AH, Gacic-Dobo M. An examination of a recall bias adjustment applied to
survey-based coverage estimates for multi-dose vaccines. White Paper. May 2015. doi:
10.13140/RG.2.1.2086.2883

A8. Brown DW, Burton A, Gacic-Dobo M, Karimov RI. An Introduction to the Grade of Confidence
Used to Characterize Uncertainty around the WHO and UNICEF Estimates of National Immunization
Coverage. Open Public Health J. 2013;6:73–76.   dx.doi.org/10.2174/1874944501306010073

A9. Burton A, Kowalski R, Gacic-Dobo M, Karimov R, Brown D. A formal representation of the
WHO and UNICEF estimates of national immunization coverage: a computational logic approach.
PLoS One. 2012;7(10):e47806. doi: 10.1371/journal.pone.0047806.

A10. Complete URL:
http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index4.html

Graph your data

- For each province and vaccine, graph coverage results from administrative data (admin) and survey vaccination coverage results (survey) on a graph. For survey data collected during two years assign the survey data to the year in which most of the data were collected.
  - The y-axis of the graph is coverage level between 0-120% (sometimes coverage greater than 100% are reported. The y-axis is the years of the data and estimates.
  - Use dots to represent the admin data. Use bars to represent survey results.

Place 1, Vaccine/dose
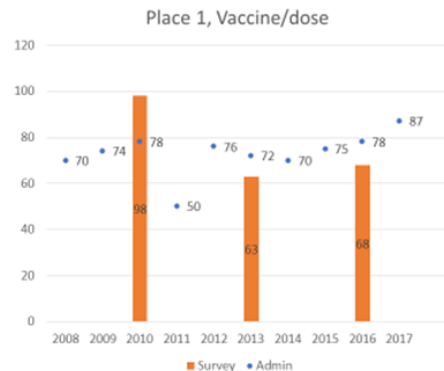
Move survey results back to reflect the child's birth year

- For survey data collected for children 12-23 months of age, survey results are moved back one year to reflect the child's birth cohort.
  - Data collected for children 12-23 months of age in 2013 are moved to 2012.
  - Data collected for children 12-23 months of age in 2016 are moved to 2015.

Place 1, Vaccine/dose
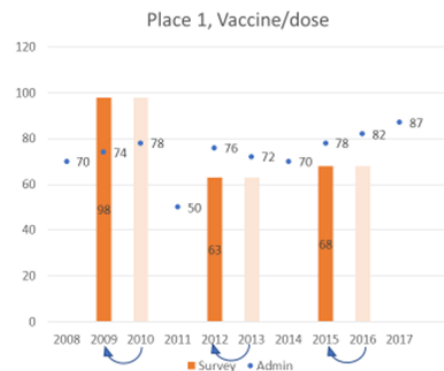
Survey data may be excluded

- Survey data should be exclude if there is no report of methods and findings, the sample size is unknown or too small (n < 300), it is not for a standard age group (12-23m or 24-35m), or the evidence is not based on both card and caretaker recall.
- Document WHY the data were excluded.
  - The 2009 survey data point is exclude because the sample size is not reported.

Place 1, Vaccine/dose
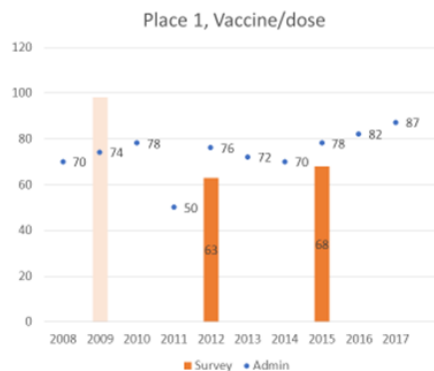
Admin data may be excluded

- Admin data should be exclude if it is greater than 99% or if there are year-to-year changes greater than +/- 10%.
- Document WHY data were excluded.
- The excluded point is replaced with the interpolation between the closest remaining points.
  - The 2011 admin point of 50% is replaced by interpolation between 2010 (78%) and 2012 (76%) or 77%

Place 1, Vaccine/dose
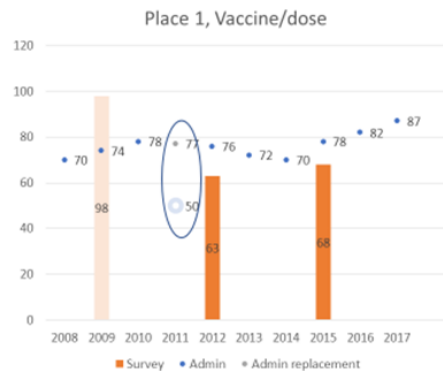
Identify anchor points

- Anchor points are years where there are data from two independent sources; usually admin and survey results.
  - 2012 is an anchor point.
  - 2015 is an anchor point.

Place 1, Vaccine/dose
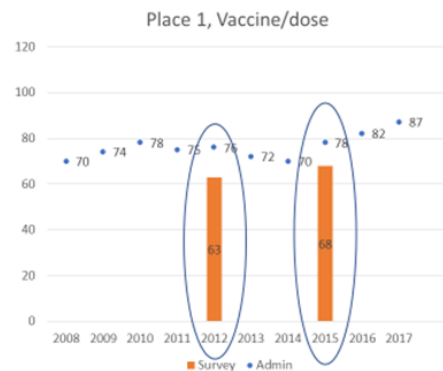
Decide estimate value at the anchor points: scenario 1a.

- If the difference between admin and survey data is <= +/- 10 percentage points, the estimate is the value of the admin data.
- If the difference is > +/-10% points, the estimate is the survey results.
- Document which anchor point values you assigned and WHY.

  - 2012; estimate = 63%. The different between survey (63%) and admin (76%) = 13% or more than 10%. Estimate = survey value
  - 2015: estimate = 78%. The different between survey (68%) and admin (78%) = 10% or <= than 10%. Estimate = admin data

Place 1, Vaccine/dose
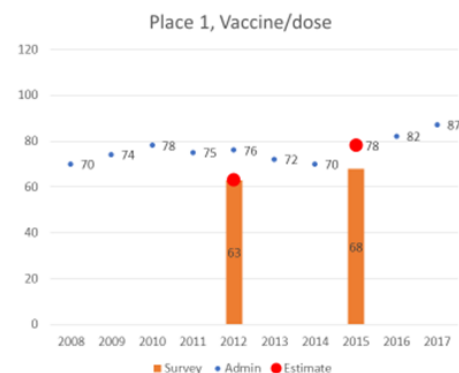
Decide estimate values <u>between</u> the anchor points - interpolate: scenario 1b.

- Since the value for at least one anchor point (2012) is based on survey data, ignore the admin data and interpolate between the 63% anchor point in 2012 and the 78% anchor point in 2015.

- *For years between two anchor point where the survey supports the admin data in both years, use the admin data as the estimate.*

- Document WHAT you did and WHY.

  - 2013; estimate = 68% (interpolation)
  - 2014; estimate = 73% (interpolation)

Place 1, Vaccine/dose
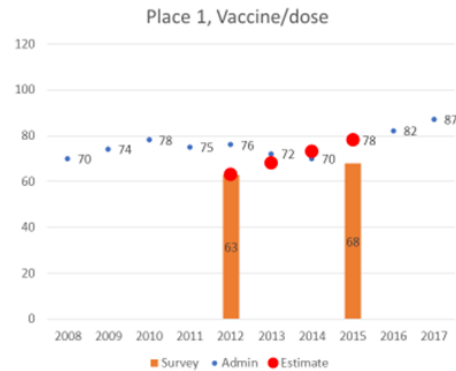
Decide estimate values <u>before</u> the earliest anchor point – nearest neighbor (NN): scenario 1c.

- *If the earliest anchor point value is based on the admin data, the admin data are the estimates.*

- If the earliest anchor point value is not based on admin data, the earliest anchor point value is the estimate for those years.

- Document WHAT you did and WHY.

  - 2011; estimate = 63% (NN)
  - 2010; estimate = 63% (NN)
  - 2009; estimate = 63% (NN)
  - 2008; estimate = 63% (NN)

Place 1, Vaccine/dose
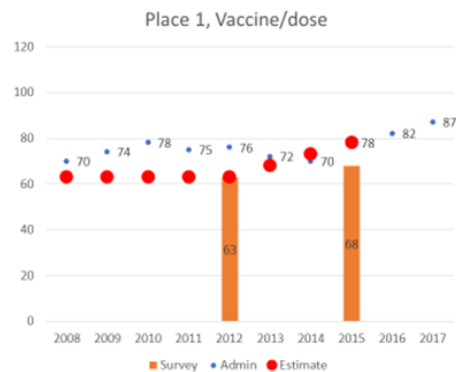
Decide estimate values <u>after</u> the latest anchor point – admin: scenario 1d.

- If the latest anchor point value is based on the admin data, the admin data are the estimates.

- *If the earliest anchor point value is not based on admin data, the latest anchor point value is the estimate for those years.*

- Document WHAT you did and WHY.

  - 2016; estimate = 82% (admin)
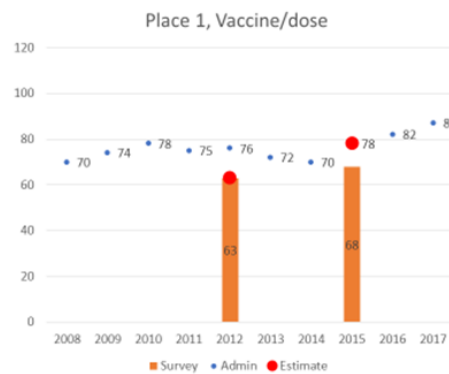 - 2017; estimate = 87% (admin)

Place 1, Vaccine/dose
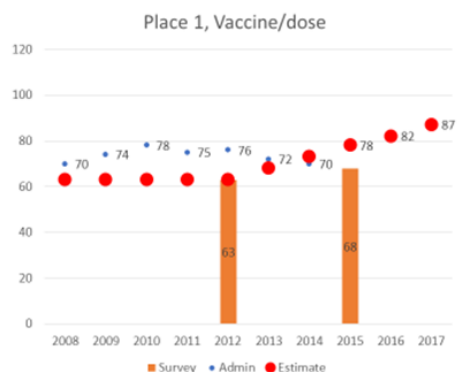
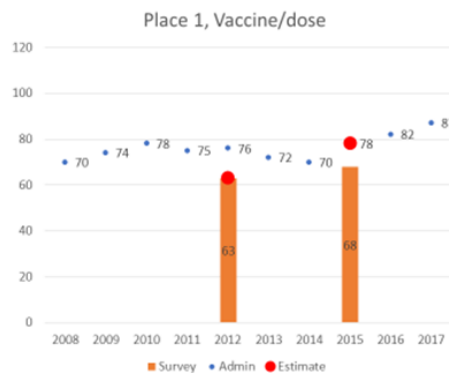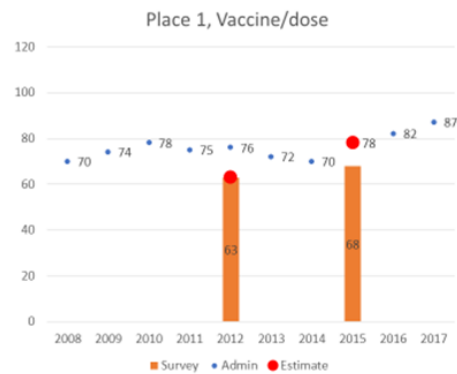## Estimated coverage: scenario 1.
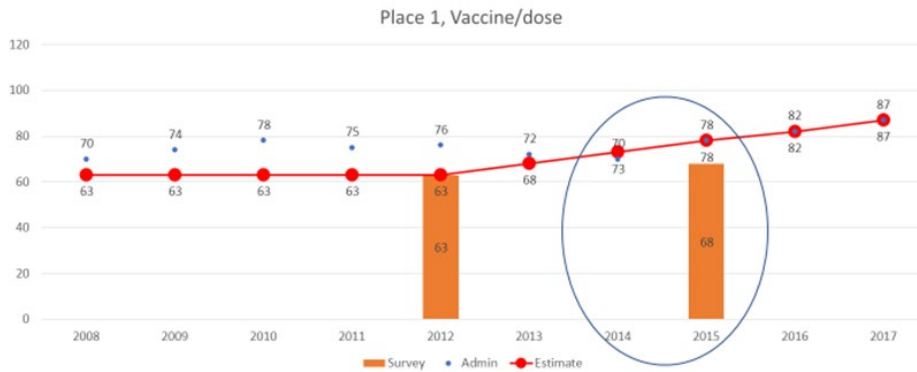
Decide estimate value at the anchor points: scenario 2a.

- The increase in admin coverage from 70% in 2014 to 78% in 2015 is quite high.
- The difference between 78% admin coverage in 2015 and the survey result of 68% is on the +/- 10% difference threshold.

Decide estimate value at the anchor points: scenario 2a.

- The increase in admin coverage from 70% in 2014 to 78% in 2015 is quite high.
- The difference between 78% admin coverage in 2015 and the survey result of 68% is on the +/- 10% difference threshold.
- Is an 8% increase in coverage reasonable. What would explain it?

Decide estimate value at the anchor points: scenario 2a.

- The increase in admin coverage from 70% in 2014 to 78% in 2015 is quite high.
- The difference between 78% admin coverage in 2015 and the survey result of 68% is on the +/- 10% difference threshold.
- Is an 8% increase in coverage reasonable. What would explain it?

- The cold chain was reviewed and some equipment was replaced in late 2014 and early 2015.
- A program to hire additional vaccinators was announced in the third quarter of 2015.
- A DQA documented about 10% over counting.

Decide estimate value at the anchor points: scenario 2a.

- Suppose we decide to use the 2015 survey results of 68% as our 2015 threshold value because nothing happened between 2014 and 2015 to cause such a large increase in coverage.
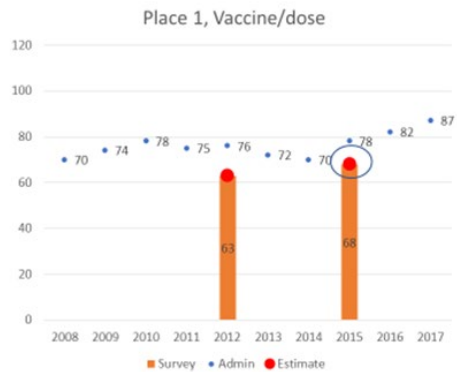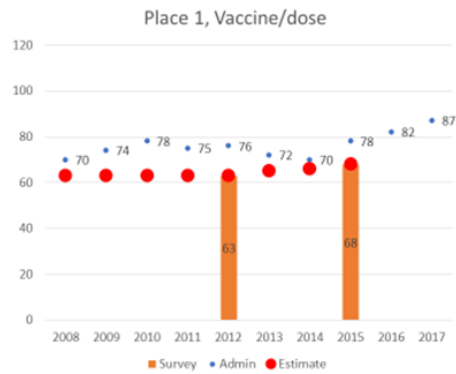

Decide estimate values <u>between</u> the anchor points - interpolate: scenario 2b.

- This time we estimate values between anchor points.
- Since the value for both anchor points are based on survey data, ignore the admin data and interpolate between the 63% anchor point in 2012 and the 68% anchor point in 2015.
- Document WHAT you did and WHY.

  - 2013; estimate = 65% (interpolation)
 - 2014; estimate = 66% (interpolation)
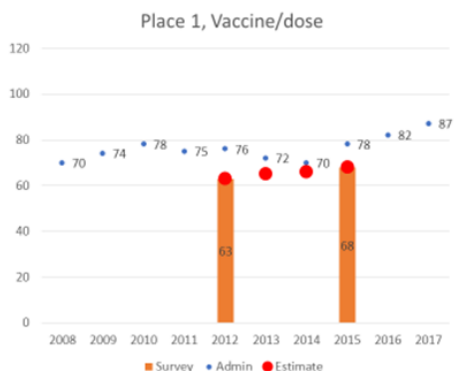
Decide estimate values <u>before</u> the earliest anchor point – nearest neighbor (NN): scenario 2c.

- The earliest anchor point value is not based on admin data, the earliest anchor point value is the estimate for those years.
- Document WHAT you did and WHY.

  - 2011; estimate = 63% (NN)
  - 2010; estimate = 63% (NN)
  - 2009; estimate = 63% (NN)
  - 2008; estimate = 63% (NN)


Place 1, Vaccine/dose

Decide estimate values <u>after</u> the latest anchor point – nearest neighbor: scenario 2d.

- Now the latest anchor point is based on the 2015 survey results.
- If the latest anchor point value is not based on admin data, the latest anchor point value is the estimate for those years.

- Document WHAT you did and WHY.

 - 2016; estimate = 68% (NN)
  - 2017; estimate = 68% (NN)

Place 1, Vaccine/dose
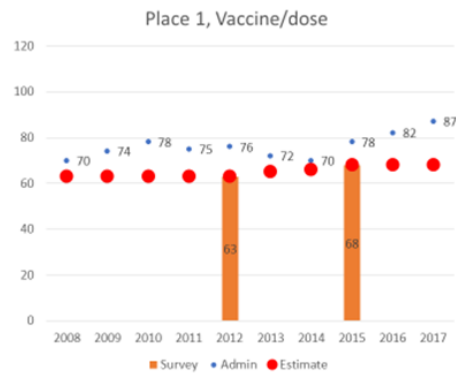
Look at Results, Scenario 2

# Estimated coverage: scenario 2.

Place 1, Vaccine/dose
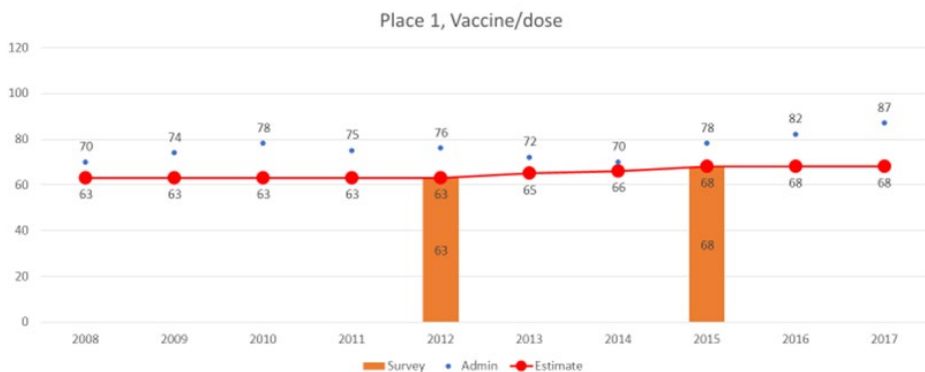
Decide estimate values <u>after</u> the latest anchor point – calibration: scenario 3d.

- The additional vaccinators have been hired, trained and deployed. They are conducting additional out reach in rural areas and vaccinating from temporary post in urban settings. Vaccination post opening days/times have been extended in many areas.

- It is reasonable that these activities have improved coverage (upward trend) but the level is too high due to the uncorrected over reporting.

- We can following the trend between 2015 (68%) and 2017 established by the admin data but at a lower level.

- In 2015 the difference between survey (68%) and the admin (78%) is 10% points. Subtract 10% points from the admin data for 2016 and 2017 for an estimate.

- Document WHAT you did and WHY.

  - 2016; estimate = 82%-10% = 72% (calibration)
  - 2017; estimate = 87%-10% = 77% (calibration)

Place 1, Vaccine/dose
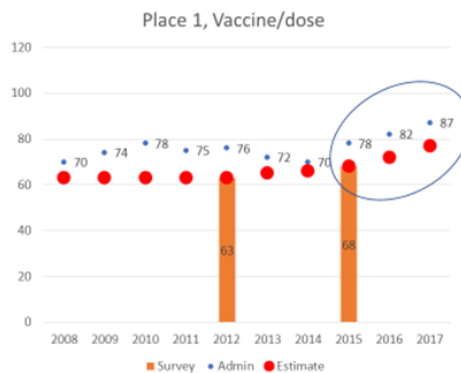
Estimated coverage: scenario 3.

Place 1, Vaccine/dose
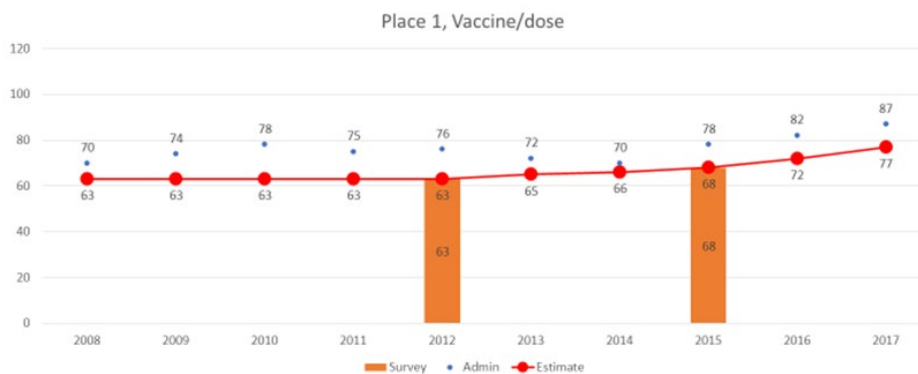
Do the data reflect programme performance or are their problems with the data?

- Estimates are based on data. Not all data are equal.

- Judgement and information on programme performance are used to determine which data most likely reflect programme performance.

- Consider not only the percent coverage but also the number of children and the target number to be vaccinated. These may reveal problems with the admin data.

- Survey quality, methodology and report completeness is important in determining whether the survey results can be used.

- Document WHAT judgements you made and WHY.