GATHER Compliance: WHO/UNICEF Estimates of National Immunization Coverage (WUENIC), 2018

In 2016, a working group convened by the World Health Organization (WHO) issued "Guidelines for Accurate and Transparent Health Estimates Reporting: the GATHER statement". GATHER defines best practices for documenting studies that report global health estimates and recommends a checklist of 18 items to be reported in every publication of health estimates. The aim of presenting this methodological information is to allow both expert and non-expert audiences, including decision-makers, to assess the quality of the estimation methods, data used and the resulting health estimates. Additional information is available from the GATHER web site: http://gather-statement.org/

Even though the GATHER guidelines were not designed for health service delivery coverage indicators, such as vaccination coverage, they provide a useful framework for documenting the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) Estimates of National Immunization Coverage (WUENIC).[1]

WHO/UNICEF estimates of national immunization coverage are available at: http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index4.html and https://data.unicef.org/topic/child-health/immunization/.

WHO and UNICEF Estimates of National Immunization Coverage

1. **Definition of indicators, populations (including age, sex, and geographic entities), and time period(s) for which estimates were made.**
   a. Since 2000, WHO and UNICEF have updated annually single year estimates of national immunization coverage for selected vaccine and dose combinations for each of 195 countries and territories, including each of the 194 Member States of the World Health Assembly plus the State of Palestine unless otherwise noted.
   b. For each country, year and vaccine/dose combination estimates are presented as a percentage of the target population receiving the vaccination. Estimates are currently made for vaccine/dose combinations[2] listed below; target populations vary by vaccine and by national immunization coverage.

   Bacille Calmette-Guérin (BCG) vaccine coverage: percentage of births who received one dose of Bacille Calmette-Guérin vaccine. BCG vaccination coverage estimates are produced

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[1] NB. Immunization refers to the process whereby a person is made immune or resistant to an infectious disease, either due to administration of a vaccine or by natural exposure to an infectious agent or other antigen by the body. Vaccination refers to the act of introducing a vaccine into the body to produce immunity to a specific disease. For a period of time, loose language allowed immunization to also refer to the process of getting vaccinated. Technically speaking, however, WHO and UNICEF produce estimates of vaccination coverage. Due to historical use, reference to "immunization" continues in spite of the technical inaccuracy.

[2] 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.

for 160 countries with a high-disease burden and for high-risk children living in countries with low-disease burden.

First and third dose diphtheria–tetanus–pertussis containing vaccine (DTP1 & DTP3) coverage: percentage of surviving infants who received the 1st & 3rd dose, respectively, of diphtheria and tetanus toxoid with pertussis containing vaccine.

Third dose polio vaccine (Pol3) coverage: percentage of surviving infants who received three doses of polio vaccine.

First dose inactivated polio vaccine (IPV1) coverage: percentage of surviving infants who received at least one dose of IPV.

First dose measles containing vaccine (MCV1) coverage: percentage of surviving infants who received a first dose of MCV.

Second dose measles containing vaccine (MCV2) coverage: percentage of children who received a 2nd dose of measles containing vaccine according to the nationally recommended schedule.

First dose rubella containing vaccine (RCV1) coverage: percentage of surviving infants who received the 1st dose of rubella containing vaccine. Coverage estimates are based on WHO and UNICEF estimates of coverage for the dose of measles containing vaccine that corresponds to the first measles-rubella combination vaccine. Nationally reported coverage of RCV is not taken into consideration nor are the data represented in the accompanying graph and data table.

Birth dose of hepatitis B vaccine (HepBB) coverage: percentage of births which received a dose of hepatitis B vaccine within 24 hours of delivery. Estimates of hepatitis B birth dose coverage are produced only for countries with a universal birth dose policy. Estimates are not produced for countries that recommend a birth dose to infants born to HepB virus-infected mothers only or where there is insufficient information to determine whether vaccination is within 24 hours of birth.

Third dose hepatitis B vaccine (HepB3) coverage: percentage of surviving infants who received the 3rd dose of hepatitis B containing vaccine following the birth dose.

Third dose *Haemophilus influenzae* type b containing vaccine (Hib3) coverage: percentage of surviving infants who received the 3rd dose of *Haemophilus influenzae* type b containing vaccine.

Final dose rotavirus vaccine (RotaC) coverage: percentage of surviving infants who received the final recommended dose of rotavirus vaccine, which can be either the 2nd or the 3rd dose depending on the vaccine.

Third dose pneumococcal conjugate vaccine (PcV3) coverage: percentage of surviving infants who received a 3rd dose of pneumococcal conjugate vaccine. In countries where the national schedule recommends two doses during infancy and a booster dose at 12 months or later based on the epidemiology of disease in the country, coverage estimates may reflect the percentage of surviving infants who received two doses of PcV prior to the 1st birthday.

Yellow fever virus vaccine (YFV) coverage: percentage of surviving infants who received one dose of YFV in countries where YFV is part of the national immunization schedule for children or is recommended in at risk areas; coverage estimates are annualized for the entire cohort of surviving infants.

As seen in the indicator definitions, the target population for each coverage indicator varies by age and national immunization schedule. In general, the target population is the total number of births for BCG and HepBB and the total number of surviving infants (children aged < 12 months) for DTP1, DTP3, Hib3, HepB3, Pol3, IPV1 and RotaC. The target population for PcV3 is either the total number of surviving infants or of 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 of 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 recommended only sub-nationally.

c. Estimates are produced for each country at the national level. Global population weighted averages of estimates for each coverage indicator are produced each year as well as regional averages 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 obtained by multiplying the country-specific coverage estimate and a population weight for each country where the weight is the country-specific proportion of the global (or regional) total population. The estimated number of births and surviving infants for each country is obtained from the United Nations Population Division [https://population.un.org/wpp/]. The global number of children unreached with DTP3 is obtained by multiplying the value (1 – coverage level; e.g., 0.85) for each country and the estimated number of surviving infants for each country obtained from the United Nations Population Division and summing across countries.

d. Estimates, published each July, cover the period from 1980 through the most recent completed calendar (January to December) year.

e. Estimates are produced without regard to child sex or other sociodemographic characteristic.

2. **Funding sources for the work.**

a. The production of the WHO and UNICEF estimates of national immunization coverage are core activities of the respective agency's mandates to monitor and assess trends in the health and well-being of populations worldwide. As core activities, the production of WUENIC and related immunization data activity historically has been financially supported through operating budgets that are ultimately derived from assessed contributions (i.e., dues countries pay as members of the 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 [citation: World Health Organization. The WHO Programme Budget Portal. Available online at http://open.who.int/. Accessed 2019 February 6.]

b. Following the launch of Gavi, the Vaccine Alliance (www.gavi.org), the financing of WHO's and UNICEF's programme of work around vaccine preventable disease as a whole has largely shifted away from a model funded by core agency funds and funds received directly from bi-lateral donors (i.e., voluntary contributions from member states) to a model where activities are funded through programmes of work coordinated through Gavi, the Vaccine Alliance and the Gavi Secretariat. Since 201x, the production of WUENIC has been an activity funded through the coordinated agency body of work with Gavi, the Vaccine Alliance. The Bill and Melinda Gates Foundation, which is one of the largest contributors to Gavi, the Vaccine Alliance, also is an important contributor to the work of the WHO and UNICEF in the area of vaccine preventable disease and beyond.

3. **Data identification and access.**
   a. Administrative coverage: Reported by national authorities to WHO and UNICEF. Data are most commonly reported annually by national authorities using the WHO and UNICEF Joint Reporting Form (JRF)
   https://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting/en/
   b. Official coverage: Estimated coverage reported by national authorities to WHO and UNICEF that reflects their assessment of the most likely coverage based on any combination of administrative coverage, survey-based estimates or other data sources or adjustments. Approaches to determine official coverage may differ across countries. Data are most commonly reported annually by national authorities using the WHO and UNICEF JRF. Data are available at:
   http://www.who.int/entity/immunization/monitoring_surveillance/routine/coverage/WUENIC_input_to_PDF.xls?ua=1.

   For a and b, data are available at:
   http://www.who.int/entity/immunization/monitoring_surveillance/routine/coverage/WUENIC_input_to_PDF.xls?ua=1.

   c. Survey results: Estimated vaccination coverage levels of nationally representative, population-based household surveys are included. 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. National and agencies websites are accessed for survey reports and survey information and reports are submitted by national authorities. The database with the surveys is available here: http://www.who.int/immunization/monitoring_surveillance/data/Coverage_survey_data.xls?ua=1
   d. Population estimates: Age-specific population estimates from the United Nations Population Division (UNPD) are used to estimate regional and global coverage rates, and to inform the Grade of Confidence that describes WHO and UNICEF's confidence in the agencies' coverage estimates. Population data are obtained from UNPD's World Population Prospects site https://population.un.org/wpp/Download/Standard/Population/.
   e. Contextual data: WHO and UNICEF obtain additional information from the WHO and UNICEF JRF or through consultation with regional and national immunization and monitoring experts who are frequently 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. Such information includes:

  i. National vaccination schedule: vaccines recommended and age at which they are recommended in the country, as well as other indications for use (for example seasonal influenza vaccine for persons with chronic disease, health workers, etc).

  ii. Vaccine stock-outs: reports of national vaccine stock-outs, length and whether they affected supply at the sub-national level.

  iii. Vaccine-preventable disease surveillance data.

  iv. Contextual information given as general comments.

4. **Inclusion and exclusion criteria.** 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 do meet at least one exclusion criterion.

   a. Administrative coverage: Administrative coverage estimates must be reported in writing by the relevant national authorities to WHO and/or UNICEF. The national authorities may update prior years' data at any time through written communication to WHO and/or UNICEF. For all antigens, reported coverage levels >100% are excluded. For all antigens, coverage levels that suggest large ($\geq$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, etc.) are excluded. Another exception is allowing increases for vaccines being introduced in recent years such as PCV, IPV and rotavirus.

   b. Official coverage: Official coverage estimates must be reported in writing by the relevant national authorities to WHO and/or UNICEF. The national authorities may update prior years' estimate at any time through written communication to WHO and/or UNICEF. For all antigens, coverage levels >100% are excluded. For all antigens, coverage levels that suggest large ($\geq$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, etc.) are excluded. As for administrative coverage, new vaccines are an exception as it is expected that coverage will increase.

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

vaccination coverage estimates are considered. Finally, survey results may be ignored in the presence of evidence in the survey report that coverage estimates are compromised by survey design, implementation or analysis issues.

In 2018-2019 a survey checklist was developed by WHO and UNICEF and surveys from 2016 will be checked against the criteria established in the checklist. It can be requested at vpdata@who.int

The nationally reported immunization performance data are then made publicly available on the WHO website https://www.who.int/immunization/monitoring_surveillance/en/ and updated on the website twice per year (June, December).

5. **Provide information about 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.**

   a. Administrative coverage: Reported by national authorities to WHO and UNICEF and based on aggregated administrative reports from health service providers on the number of vaccinations administered during a given period (numerator data) and reported target population data (denominator data). Data are most commonly reported annually by national authorities using the WHO and UNICEF Joint Reporting Form (JRF) http://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting/en/. See also http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index1.html.

   b. Official coverage: Estimated coverage reported by national authorities to WHO and UNICEF that reflects their assessment of the most likely coverage based on any combination of administrative coverage, survey-based estimates or other data sources or adjustments. Approaches to determine official coverage may differ across countries. Data are most commonly reported annually by national authorities using the WHO and UNICEF JRF http://www.who.int/immunization/monitoring_surveillance/routine/reporting/reporting/en/.

   c. Survey results: Immunization coverage survey results from nationally representative population-based household surveys, usually among children aged 12-23 months or 24-35 months of age. Evidence of vaccination is based on any one of documented evidence from home-based records (immunization cards) or health facility records, or the child's caretaker's recall. Survey results are referenced to the appropriate birth cohort based on the period of data collection. For example, coverage from a survey conducted in 2017, collecting data on children 12-23 months of age will refer to vaccinations for the 2016 birth cohort.

   Survey results are abstracted from finalized survey reports. Data are available from http://www.who.int/immunization/monitoring_surveillance/data/Coverage_survey_data.xls?ua=1

   d. Population estimates: Age-specific population estimates from the United Nations Population Division (UNPD) are used to estimate regional and global coverage rates, and to inform the Grade of Confidence that describes WHO and UNICEF's confidence in the agencies' coverage estimates. Population data are obtained from UNPD's World Population Prospects site: https://esa.un.org/unpd/wpp/Download/Standard/Population/.

6. **Potentially important biases (e.g., based on characteristics listed in item 5).**

The WHO and UNICEF estimates of national immunization coverage are based solely on country-specific data, some of which are reported by countries and are of unknown and varying quality.

a. Administrative coverage data: For all antigens, administrative vaccination coverage is the result of dividing aggregated administrative reports from health service providers on the number of vaccine doses administered during a given period (numerator data) by an appropriate target population data (denominator data). Both the reported number of administered vaccine doses and the target population may be biased. Biases affecting numerator data include, but are not limited to, issues of incomplete and untimely reporting, absent reports from private sector providers to name a few. Biases affecting denominator data include, but are not limited to, population estimates based on an old census, a poorly implemented census and/or poorly implemented census projections.

b. Official coverage data: As noted above, reflects the country's estimate of what they believe vaccination coverage to be in the country. The methods and sources used to produce official estimates are not always described and available. The methods may also change over time, again without documentation or notice.

c. Survey coverage data: Survey-based estimates are subject to bias, both sampling and non-sampling error. Sampling error may result from areas that were purposively excluded from sampling frame, perhaps to accessibility issues (areas with access limitation may also be subject to health service limitations; exclusion would lead to an upward bias); sampling of children currently alive only (children that died may have been vaccinated, but also possible that children who died prior to survey may have been unvaccinated and thus died from vaccine preventable disease) among others. Non-sampling error may result due to misclassification of vaccination status perhaps due to inaccurate respondent recall, interviewer error, inaccurate recorded history; data entry error; among other reasons.

7. **Describe and give sources for any other data inputs.**

a. National routine immunization schedule: Nationally reported immunization schedules to WHO are obtained as part of an annual immunization system data collection exercise described elsewhere [World Health Organization. WHO/UNICEF Joint Reporting Process. Available: http://www.who.int/immunization/monitoring_surveillance/routine/reporting.; 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 Vaccine. 2017;7:1–10.]. Information is publicly available at http://www.who.int/immunization/monitoring_surveillance/data/en/.

b. New vaccine introductions: New vaccine introductions are carefully monitored by the WHO using both information reported by national authorities and information derived from UNICEF Supply Division and Gavi, the Vaccine Alliance Secretariat (www.gavi.org). Updated information on vaccine introduction is available at: http://www.who.int/immunization/monitoring_surveillance/en/ under highlights.

c. Vaccine stock-outs: Nationally reported data on occurrence of vaccine stock-outs (data reported by country available at: http://apps.who.int/immunization_monitoring/globalsummary). Information reported as part of an annual immunization system data collection exercise described elsewhere [World

Health Organization. WHO/UNICEF Joint Reporting Process. Available at: http://www.who.int/immunization/monitoring_surveillance/routine/reporting; 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 Vaccine. 2017;7:1–10.].

    d. Surveillance data: Vaccine preventable disease surveillance is the ongoing systematic collection, analysis, and interpretation of vaccine preventable disease event data (e.g., case report, hospitalization), closely integrated with the timely dissemination of these data to those responsible for preventing and controlling vaccine preventable diseases. Care is must be taken when interpreting due to issues of timeliness and completeness of surveillance data reporting. Nationally reported disease incidence information is available at http://www.who.int/immunization/monitoring_surveillance/data/en/

8. **Provide all data inputs in a file format from which data can be efficiently extracted (e.g., a spreadsheet rather than a PDF), including all relevant meta-data listed in item 5. For any data inputs that cannot be shared because of ethical or legal reasons, such as third-party ownership, provide a contact name or the name of the institution that retains the right to the data.**

    a. All data inputs are publicly available at http://www.who.int/immunization/monitoring_surveillance/data/en/. Time-series data of official country reported coverage estimates are available in HTML and MS Excel (Microsoft Corporation, Redmond, Washington, USA) files at http://www.who.int/entity/immunization/monitoring_surveillance/data/coverage_series.xls?ua=1. Time-series data of country reported administrative coverage are available in MS Excel file at http://www.who.int/immunization/monitoring_surveillance/data/administrative_coverage.xls?ua=1. Abstracted results from survey reports are available in MS Excel file at http://www.who.int/immunization/monitoring_surveillance/data/Coverage_survey_data.xls?ua=1.

    b. Information on immunization system indicators and immunization schedules are also publicly available online at http://www.who.int/immunization/monitoring_surveillance/data/en/.

    c. Information on survey and extraction of survey data are available here: http://www.who.int/immunization/monitoring_surveillance/data/Coverage_survey_data.xls?ua=1

The input data are compiled in a MS Access (Microsoft Corporation, Redmond, Washington, USA) database. This database contains the JRF information, the survey estimates obtained from various reports and the rule exceptions made by the working group which can be considered as input to the estimation method.

9. **Provide a conceptual overview of the data analysis method. A diagram may be helpful.**

    a. The WHO & UNICEF estimates of national immunization coverage are based on a country-by-country, vaccine-by-vaccine, year-by-year assessment of the data described above. We distinguish between situations in which data reported by national authorities accurately reflect immunization system performance and those in which the data are likely compromised and misleading.

b. The estimates are not the results of a formal modelling exercise and no statistical or mathematical models are used. While there are frequently general trends in immunization coverage levels, no attempt is made to fit data points with smoothing techniques or time series methods. We have been unable 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.

c. Metalevel rules:

    i. Country-specific: Each country's data are reviewed individually and are not "borrowed" from other countries.

    ii. An estimate is made for an appropriate country/vaccine/year.

    iii. Unless challenged, the nationally reported estimate constitutes the WHO & UNICEF estimate.

    iv. Selection: The WHO & UNICEF estimates are based on the selection of sources of coverage values – either reported by national authorities or survey results. Results from different sources are not "averaged".

    v. Modification: Under certain conditions empirical values may be modified in a formal, rule governed manner. For example, survey coverage for multi-dose vaccines (e.g., DTP3) based on the child's caretaker's recall is be modified by applying the dropout between the first and third dose of vaccinations confirmed by documented evidence to the first dose of vaccinations based on caretaker recall for a modified coverage of the third dose of vaccinations based on maternal recall. Modification may raise or lower the unmodified coverage value.

    vi. No "*ad hoc*" quantitative adjustments are made. For example, we do not make assign ad hoc quantitative adjustments based on subjective judgements. For example, "we believe coverage has increased but we have no recent empirical data to suggest by how much so we'll add 5% to the previous year's estimate" is not a proper inferential method in the WHO & UNICEF method.

    vii. No estimate greater than 99% is made.

d. Heuristics – Rules and Exceptions: The WHO and UNICEF estimates are informed and constrained by the following heuristics expressed as rules and exceptions in the form *conclusion IF condition UNLESS[3] exception*. For example,[4]

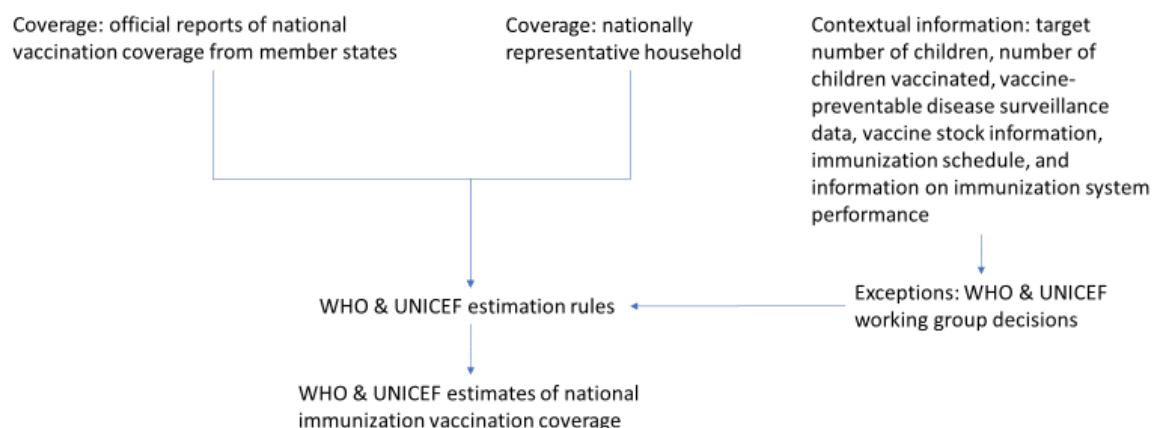   *WHO & UNICEF estimate = nationally reported coverage* IF

        there is nationally reported coverage AND

        nationally reported coverage is < 100% AND

        there was no increase/decrease > 10% AND

        there are no survey data for that country/vaccine/year UNLESS

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

    Exceptions are used by the WHO and UNICEF working group to "override" rules if information is available suggesting rule application is inappropriate. Working group decisions are documented and included in the operational database.

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[3] In formal logic UNLESS(x) is usually represented as AND (NOT(x)).

[4] The example is expressed in an inform fashion to facilitate interpretation.

National, regional and global estimates are updated annually for vaccinations delivered through routine services for children under one year of age (the second dose of measles vaccine is estimated for children xxxx) for a dose of Bacillus Calmette–Guérin (BCG), Hepatitis B administered within 24 hours of birth, the first and third dose of diphtheria, tetanus and pertussis (DTP) containing vaccine, the third dose of polio vaccine (either oral or inactivated polio vaccine), *Streptococcus pneumoniae* conjugate vaccine (PCV), *Haemophilus influenzae* type b (Hib), Hepatitis B, the final dose (either second or third depending on the manufacturer) of rotavirus vaccine, the first and second dose of measles containing vaccine, a dose of rubella containing vaccine and inactivated polio vaccine. Estimates are based on annual reports by member states of national vaccination coverage, nationally representative household surveys and local information. A set of formal rules are applied to these data. Where deemed appropriate the WHO & UNICEF working group may override and document exceptions to the rules.

Coverage: official reports of national vaccination coverage from member states

Coverage: nationally representative household

Contextual information: target number of children, number of children vaccinated, vaccine-preventable disease surveillance data, vaccine stock information, immunization schedule, and information on immunization system performance

WHO & UNICEF estimation rules

Exceptions: WHO & UNICEF working group decisions

WHO & UNICEF estimates of national immunization vaccination coverage

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).

   a. Consistency over time: The nationally reported coverage estimates and the WHO and UNICEF estimates rely on the believe that immunization coverage is likely to change overtime in a limited fashion; real sudden changes are likely to be the results of "shocks" to the system (e.g., vaccine arrived at national warehouse frozen),or an artefact effect due to changes in methods of data collection and reporting (e.g., estimates of the size of the target population change suddenly due the availability of a new census), or error in recording, reporting or calculating estimates. If changes in coverage from year-to-year are > plus/minus 10% point the reported value is set to a missing vale and is replaced by interpolation from surrounding years. If the WHO and UNICEF working group have information to suggest that the sudden change accurately reflect the immunization system performance an exception to the rule is made and the reported data point accepted. Exceptions are documented in the operational data based.

   b. Consistency between vaccines and antigens: Recommended presentation and timing of vaccinations are defined the national immunization schedule. WHO and UNICEF estimates, with the exception of DTP[5], are presented by antigen. Because combination vaccine may 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 are not the same, the WHO and UNICEF working group refers to relevant contextual data – either with reference to data reported by the national authorities through the JRF or by direct correspondence – to reconcile or explain the difference. Likewise, it is expected that

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[5] 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".

vaccinations recommended at the same age should be similar. Should there be significant differences between vaccination coverage for vaccines given at the same age the work group attempts to reconcile or explain the differences. Finally, for multi-dose vaccines it is expected that the coverage subsequent doses 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. Again, the working group refers to contextual data or corresponds with local experts to determine the most appropriate estimate.

c. If national 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 data are available for the most recent estimation period, the estimate remains the same as the previous year's. If new data or information subsequently become available, the relevant portion of the time series is updated.

d. Establish coverage at anchor points: Anchor points constitute years where vaccine/year coverage values are available from multiple sources (e.g., officially reported coverage and survey results). If estimates from both sources are similar – for example the survey data supports the nationally reported data – there is evidence the nationally reported data are correct. If the survey data challenges the nationally reported estimate the presumption is that the survey estimates are more likely to be correct. (One of the principle justifications for this assumption is that one of the common bias in administrative coverage estimates is that the denominator or estimate of the number of children in the target population is frequently based on old censuses or inappropriate projection methods. The denominator for a survey estimate is the number of children in the survey and is not affected by population estimates).

    i.   If survey results are <= 10% points different from the officially reported coverage, the anchor point value for that vaccine/year is the value of the reported data.

    ii. If survey results are > plus/minus 10% points different from the officially reported coverage, the anchor point value for that vaccine/year is the value of the survey results. 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 caretaker.

e. WHO and UNICEF estimates between anchor points. Once coverage estimates at all anchor points have been established, estimates between anchor points are made.

    i.   For years between two anchor points if both anchor point vales are based on nationally reported coverage, WHO and UNICEF estimates between the two anchor point years are based on the nationally reported data for each year.

    ii. If at least one anchor point is not based on nationally reported data, the WHO and UNICEF estimate becomes the nationally reported data calibrated to the anchor point values.

f. WHO and UNICEF estimates prior to the earliest anchor point or following the latest anchor point. For these two cases, if the anchor point value was based on the nationally reported estimate, years beyond the anchor points are based on nationally reported data. If not based on the nationally reported data, the WHO and UNICEF estimate is the same as the most

recent anchor point value. In the annex there are figures illustrating the steps used in making the estimates.

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

   a. No two approaches have ever been evaluated face-to-face
   b. As described in the papers about WUENIC [6, 7, 9], the WUENIC methodology has been refined over the years and reviewed by independent expert committees.
   c. Currently, the Institute for Health Metrics and Evaluation (IHME)(http://www.healthdata.org/) has an alternative method used in the context of the Global Burden of Disease Project. It included an estimation of uncertainty that has resulted in very wide confidence intervals for some countries. The manuscript describing this methodology is under development (as of Feb 2019).

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

- It has been externally reviewed. Sensitivity analysis may not be applicable
- QUIVER 2009 report: http://www.who.int/immunization/research/committees/QUIVER_meeting_report_oct2011_WHO_IVB_12.03_eng.pdf
- QUIVER 2011 report: http://apps.who.int/iris/bitstream/10665/70821/1/WHO_IVB_12.03_eng.pdf
- SAGE 2011 report: http://www.who.int/wer/2012/wer8701.pdf?ua=1

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

The WHO and UNICEF estimates of national immunization coverage are based on data and information — including reports by national immunization programmes regarding immunization coverage for select antigens as well as survey data from the published and grey literature [8] — that are of varying, and, in some instances, unknown quality.

In order to improve the contribution of the estimates to decision making by communicating the uncertainties associated with the estimates, WHO and UNICEF introduced a Grade of Confidence (GoC) beginning with the 2011 revision (completed July 2012). Because there is no underlying probability distribution for the WHO and UNICEF estimates, classic measures of uncertainty, such as confidence intervals are not used. A full description of the GoC is provided elsewhere [10].

Briefly, the GoC reflects the accumulation of endorsements or sources of supporting information that may influence one's certainty about an estimated value. At this writing, three endorsements are possible in the GoC. The WHO and UNICEF coverage estimate may be: 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). Using these endorsements, the GoC may take a value of three (3), reflecting high confidence in an estimate, if an estimate is supported by all three endorsements; may take a value of two (2) if an estimate is supported by at least one endorsement and there is no

challenge to the estimate by a data source; may take a value of one (1), reflecting low confidence in an estimate, if there is at least one challenge to the estimate by a data source.

The GoC does not reflect an assessment of the quality of the underlying input data to the estimates. All estimates carry a risk of being incorrect, even those for which there are multiple supporting endorsements. As noted above, reported data from national authorities may be inaccurate and/or incomplete. Survey-based estimates of coverage are subject to both sampling and non-sampling errors, the latter often being of unknown magnitude and direction.

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

- Could use a visual to show the flow of the code with a description of each part
- Available upon request at vpdata@who.int (R and prolog code)

Results and discussion

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 data are published online at Available in Excel and pdf. See:
http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index4.html

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

Refer to Section 13.

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

For all antigens, WHO and UNICEF produce county-specific, regional and global estimates of vaccination coverage. Vaccination coverage levels are presented as the percentage of a target population that has been vaccinated with a specific vaccine/dose combination. Global and regional averages are obtained by multiplying the country-specific estimated coverage and a target population weight for each country where the weight is equal to the country-specific number of children in the target population (number of births for BCG and hepatitis B birth dose (HepBB); number of births surviving to their first birthday for all other vaccines) divided by the sum of the children in the target population across all countries either globally or regionally. The estimated number of births and surviving infants for each country is obtained from the United Nations Population Division [United Nations, Department of Economic and Social Affairs, Population Division. Available at: http://www.un.org/en/development/desa/population/].

Estimated coverage levels for the current revision are not comparable to those from previous revisions. The estimated coverage time-series is updated with each annual revision to reflect newly reported data (as well as updated data for prior years) from national authorities; new estimates from surveys; new contextual information; methodological updates; and updated population estimates every two years.

18. Discuss limitations of the estimates. Include a discussion of any modelling assumptions or data limitations that affect interpretation of the estimates

An aim of the WHO and UNICEF estimates is to identify the most likely coverage level reflective of a country's immunization delivery system. The approach used also aims to ensure the consistency and comparability of estimates and projections within countries over time and across countries.

- Model related limitations: [though not really a model] due to time lags in release of survey results following completion of field work, the availability of survey results to help inform the production of WHO and UNICEF estimates are often lacking for the most recent year of the time-series, thus most recent estimates may be less stable than older ones;
  For countries with reported coverage data who may go many years between survey coverage estimates, the availability of new survey coverage data can lead to substantial changes in the historical time-series of coverage estimates.
- Input (data) related limitations: unknown and varying quality; missing reported data for one or more vaccines and/or years (e.g., administrative and/or official coverage, number of doses of vaccine administered, number of children in target population); non-reflective/inaccurate target population estimates due to poor census quality or out-dated census results and/or poor projection estimates from a poor/out-dated census; estimated vaccination coverage from surveys are 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 and/or facility-based records; Indicator definition, analysis and/or presentation of survey estimated coverage levels may be non-standard impacting on the use and interpretation of the survey results;

Each year, WHO and UNICEF conduct a review of newly reported immunization system performance data as well as any reported updates to previously reported information. These data are reviewed alongside estimated coverage levels derived from nationally representative, population-based vaccination coverage surveys or other multi-indicator surveys that include vaccination coverage indicator data as well as with recalculated coverage levels using reported data on the number of doses of vaccine administered and data on target population size from an independent source (e.g., UN Pop Div).

In some instances, information is subjected to review against certain criteria. Although not sufficient to disqualify reported data from national authorities, unexplained changes in the reported numerator and/or denominator data may heighten concerns about the reported data that impact on the interpretation of nationally reported coverage levels vis-a-vis coverage levels obtained from other sources.

In some cases, exceptions to rules are made and documented. The process of revising coverage estimates often entails not only an evaluation of the quality of the data underlying different coverage levels available for a given country/vaccine combination but also an exploration of consistency among the results.

Areas that are being considered to revise the rules include:

- Reviewing the 10%-point threshold for survey supporting reported coverage, particularly when coverage is "high"
- Reviewing the use of survey results going over n years after a survey
- Identifying an of approach for explicitly and systematically incorporating dropout between DTP1 and DTP3 coverage estimates

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11. 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 Vaccine. 2017;7(1):1–10. dx.doi.org/10.4236/wjv.2017.71001

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Annex – Step by step process for WUENIC

Figures 1-8 illustrate estimates based solely on the application of the rule set. Figures 9-21 illustrate how local contextual knowledge inform the working groups decisions regarding the selection of the sources of data upon which to base the estimate.

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.
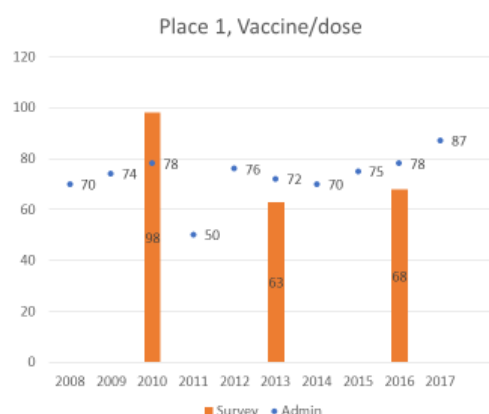
Move survey results back to reflect the child's birth year

- 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.
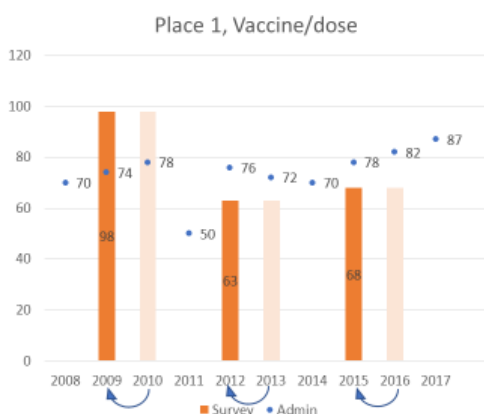
Survey data may be excluded

- 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
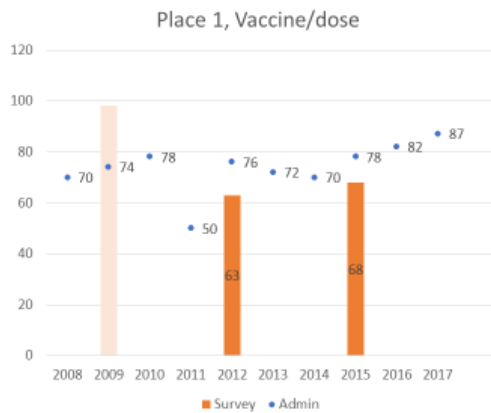
Admin data may be excluded

- 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
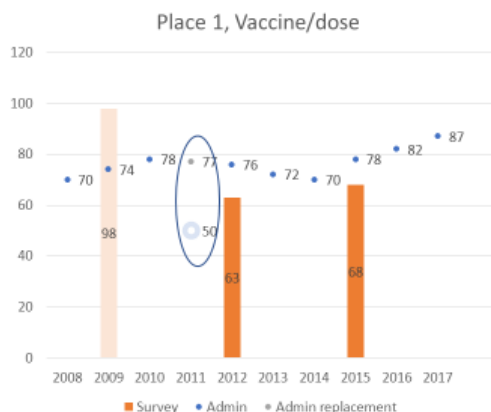
Identify anchor points

- 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
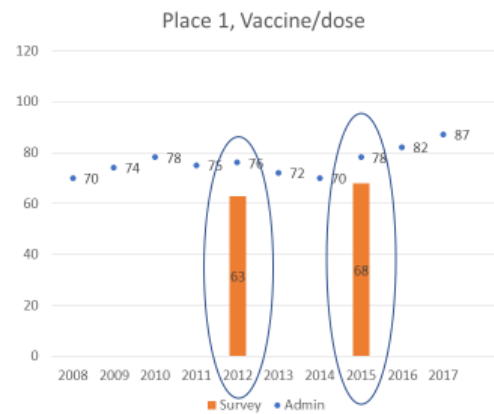
Decide estimate value at the anchor points: scenario 1a.

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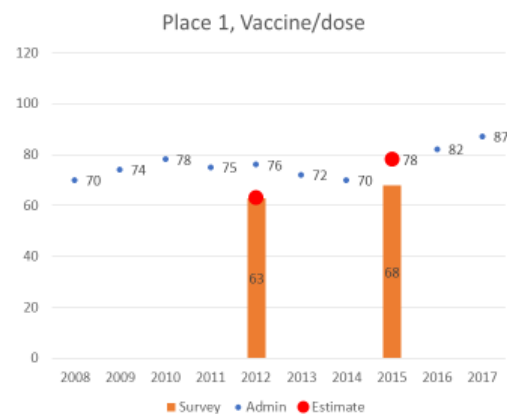
Decide estimate values <u>between</u> the anchor points - interpolate: scenario 1b.

- 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

9
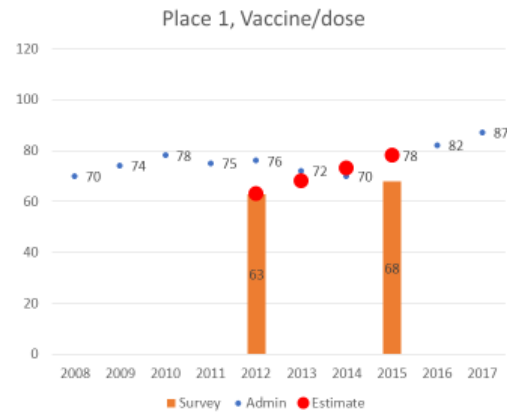
Decide estimate values <u>before</u> the earliest anchor point – nearest neighbor (NN): scenario 1c.

- *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
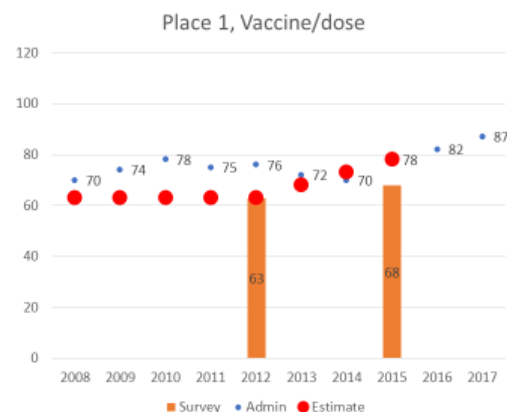
10

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)
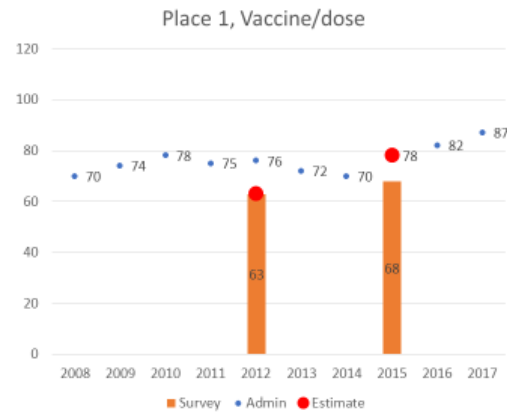 - 2017; estimate = 87% (admin)

Place 1, Vaccine/dose
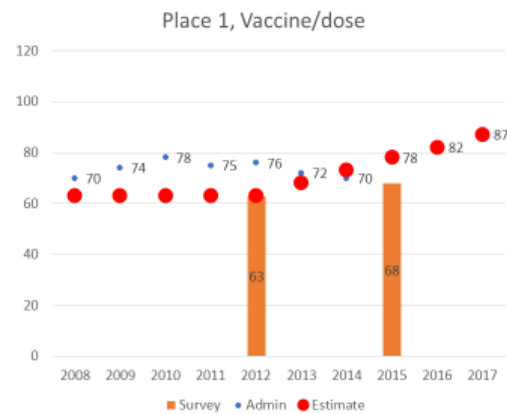
11

But wait, let's look at the results

Estimated coverage: scenario 1.

Place 1, Vaccine/dose

14

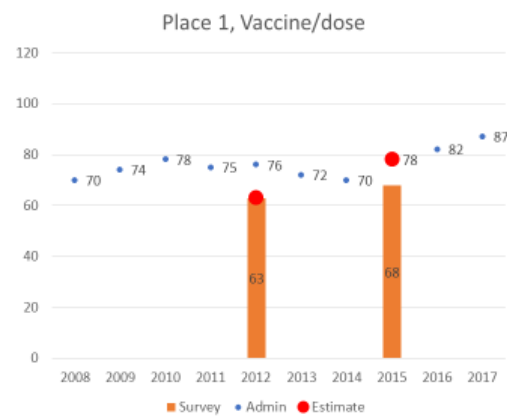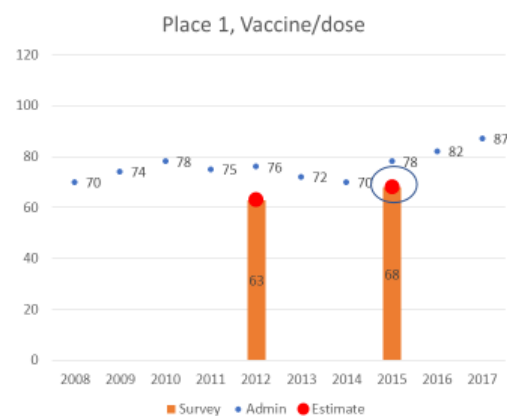# Decide estimate value at the anchor points: scenario 2a.

- 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.

Place 1, Vaccine/dose

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?

Place 1, Vaccine/dose

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.

Place 1, Vaccine/dose

17

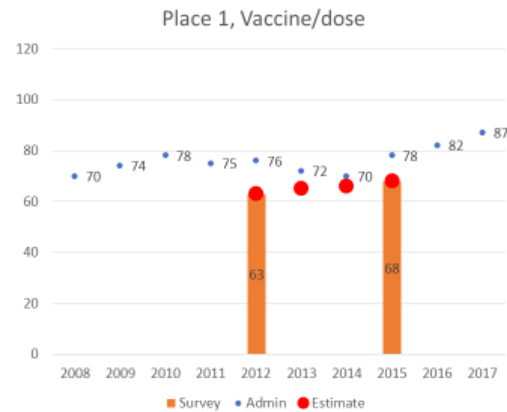# Decide estimate value at the anchor points: scenario 2a.

- 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.

Place 1, Vaccine/dose

18

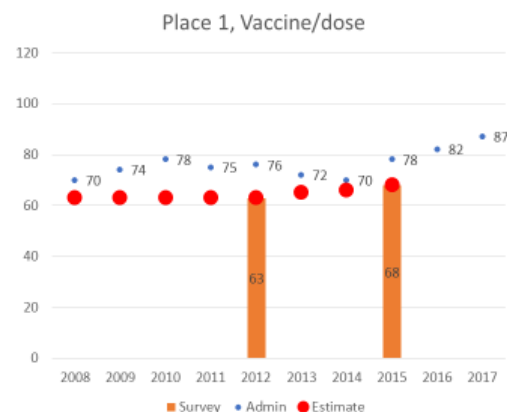## Decide estimate values <u>between</u> the anchor points - interpolate: scenario 2b.

- 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)

Place 1, Vaccine/dose

19

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

20

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
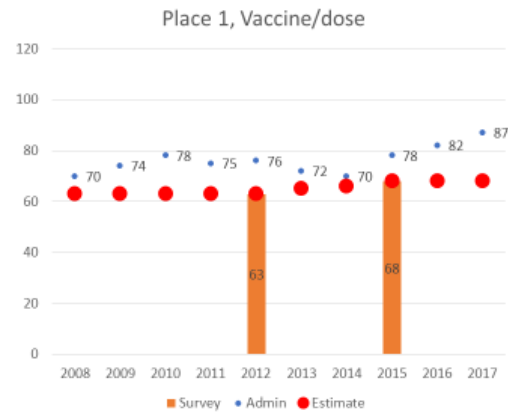
Estimated coverage: scenario 2.

Place 1, Vaccine/dose
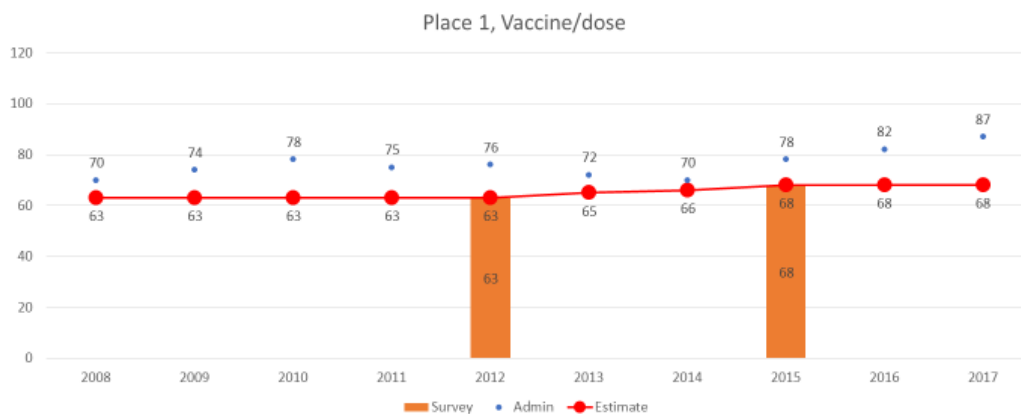
But wait, let's look at the results again

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
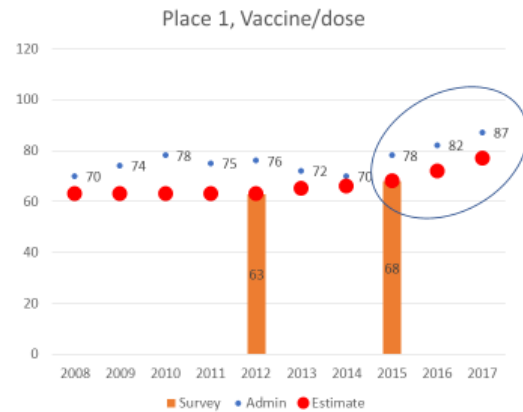
25

Estimated coverage: scenario 3.

Place 1, Vaccine/dose
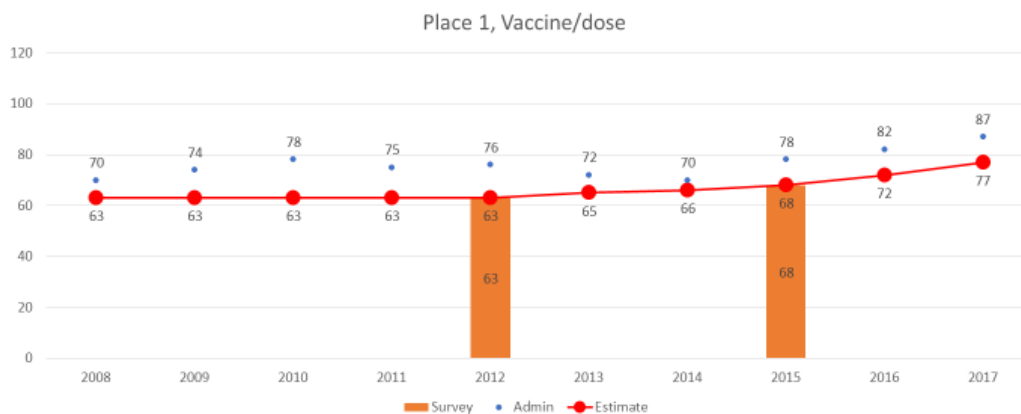
26

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.