Technical Guide Preliminary Version

COVER PAGE

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Introduction

Intended audience

This guide is intended for health professionals and technical staff working in immunization programs.

Objectives

Primary

To demonstrate how to calculate immunization coverage from immunization registries and household surveys.

Secondary

- To compare coverage estimates using different sources of data
- To use immunization registry and survey data to identify opportunities for immunization program improvements

Example Survey Data

A coverage survey was completed in about 80% of Country A regions in 2011. This survey includes 3,319 children between the ages of 12 and 35 months. Doses recorded on the individual's vaccination card or recorded at the Health Center were considered administered. Examples of calculations from the survey are used throughout this guide.

Getting Organized

Definitions and Schedules

The first step is to become familiar with the national immunization schedule you will be working with for the years the children in the survey were vaccinated. Below is the national schedule from Country A's, used for the examples in this guide. It shows the recommended ages of administration for each dose of vaccine.

Table 1. Childhood Immunization Schedule.Country A, 2011.			
Age	Vaccines Dose		
Birth	BCG	1 st Dose	
	OPV		
2 months	Pentavalent	1 st Dose	
	Rotavirus		
	OPV		
4 months	Pentavalent	2 nd Dose	
	Rotavirus		
6 months	OPV	3 rd Dose	
0 monuns	Pentavalent	3 D05e	
12 months	MMR	1 st Dose	
	Yellow Fever	I Dose	
18 months	OPV	1 st Booster	
To monuns	DTP	I DUUSIEI	
	OPV	2 nd Booster	
4 years	DTP	2 DUUSIEI	
	MMR	Booster	
6-35 months	Influenza	Annual	

The PAHO Technical Advisory Group (TAG) and WHO's Strategic Advisory Group of Experts (SAGE) on immunizations make recommendations about the number of doses in a series and timing of the doses based on evidence from the data that maximizes the effectiveness of the vaccines and minimizes the time children are unprotected from the diseases. For more information, please reference the Summary of WHO Position Papers- Recommended Routine Immunizations for Children: http://www.who.int/immunization/policy/immunization_tables/en/

Doses scheduled for the first year of life may include:

- Bacillus Calmette-Guerin (BCG)
- Hepatitis B birth dose
- Pentavalent (diphtheria, tetanus, pertussis, H. influenzae type b, hepatitis B) doses 1-3

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- Oral Polio Vaccine (OPV) doses 1-3
- Pneumococcal conjugate vaccine (PCV) doses 1 & 2 or doses 1-3
- Rotavirus vaccine doses 1 & 2 or doses 1-3

Doses scheduled for the second year of life may include:

- Measles-Mumps-Rubella or Measles-Rubella (MMR/MR) vaccine doses 1 & 2
- Yellow fever vaccine
- PCV booster
- Diphtheria-tetanus-pertussis (DTP) booster 1
- OPV booster 1

Booster doses scheduled for 4-6 years of age may include:

- DTP booster 2
- OPV booster 2
- MMR/MR 2

Influenza vaccine is also recommended annually starting at 6 months of age. For children less than 9 years of age who are receiving influenza vaccine for the first time, a second dose of the same season's vaccine should be administered at least 28 days later.

Below is a sample excerpt from one recent PAHO TAG recommendation about the infant vaccine schedule.

Example 1. PAHO Technical Advisory Group Recommendations on Pneumococcal Vaccine, 2011.

"Countries should consider three doses of the pneumococcal conjugate vaccine as the minimum for a vaccination schedule. The administration options can be 3 doses (primary series) without a booster or 2 doses (primary series) with a booster for children aged between 12 and 15 months, taking into account the epidemiological profile of the disease in each country.

"Countries should base the decision regarding the option of opting for a 3 dose schedule (primary series) without booster or a 2 dose schedule (primary series) with a booster for children aged between 12 and 15 months, mainly on the burden of the pneumococcal disease of the country and pneumonia mortality in children aged <2 years. If the country has a high burden of disease and a high mortality in children aged <7 months, the country should opt for the 3 dose schedule in the primary series; if the burden of disease and mortality is more important in children aged >7 months, the country could consider using the 2 dose schedule in the primary series with a booster."

Source: Pan American Health Organization (PAHO). "Vaccinate Your Family. Protect Your Community." Meeting of the Technical Advisory Group on Vaccine-Preventable Diseases (TAG), Buenos Aires, Argentina, July 2011. http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=14164&Itemid=&lang=en

When looking at the schedule, it is also important to know the year(s) of introduction of any new vaccines and if there have been any changes to the schedule. If new vaccine introduction or schedule changes occurred during the period the children were receiving the vaccines of interest, this will need to be accounted for in the analysis.

Data Sources

Administrative Data

Administrative data is based on the number of doses of vaccine administered and the estimated population of the target age group either for the entire country or for a particular geographic area within a country. This method is different from survey and registry data in that the doses are reported as doses administered, rather than individual children vaccinated. The age of administration and interval between doses is not available.

WHO reports that there can be problems with these estimates, for example:

"Numerator problems

• underestimated (due to incomplete reporting from reporting units or non-inclusion of other vaccinating sources (e.g. private sector, non-governmental organizations), or

• overestimated (due to over-reporting from reporting units e.g. inclusion of other target groups or inclusion of other age groups)

Denominator inaccuracies may be due to issues such as:

- population movement
- inaccurate census estimations or projections and/or
- numerous sources of denominator data"

(Source: http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index1.html)

Survey Data

"A standard WHO methodology for determining immunization coverage is based on a survey of small numbers of individuals.... Homes are visited and immunization records examined to calculated immunization coverage in children.... The surveys use a cluster sampling technique to ensure that data from a small sample of homes can be generalized to a larger population, but these data can be used only in the aggregate."

(Source: Immunization Essentials: A Practical Field Guide; http://www.mchip.net/sites/default/files/Immunization%20Essentials _English.pdf)

"Although the primary objective of an immunization coverage survey is to provide a coverage estimate for selected vaccines (for infants and/or women), other information, which is usually not available through routine monitoring systems, can be collected simultaneously" (Source: http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index2.html)

Surveys may collect immunization records through

- Vaccination cards kept with the family. The data collection teams may record which vaccines were administered and/or the dates of administration. This can also provide information about health card distribution and retention.
- Facility records. Data collection teams may record which vaccines were administered and/or the dates of administration.
- Parental recall. Data collection teams will only be able to determine which vaccines are reported as administered, but not the exact date when the dose or doses were administered.

Survey data is weighted, meaning the data from each child was given a value based the probability of that child being selected to participate. This allows us to use the information to describe the entire population, rather than just the children included in the survey.

We also present confidence intervals around the point estimate for sampled data. Confidence intervals show the uncertainty of the point estimate because we are using a small number of children to represent a larger group of children. Conventionally, we use a 95% confidence interval, but other values like 90% are also possible. We do not need weights or confidence intervals for administrative data or complete registry data because they include the entire population.

The example from Country A in this guide uses weights to calculate the point estimates and confidence intervals. For additional information see Appendix A.

Demographic and Health Surveys

The Demographic and Health Survey (DHS) is one source of survey data that is free and available to download online. Data from the DHS can be a useful source for vaccination information. The DHS is typically performed every five years in select countries and includes sample sizes of 5,000-30,000 households. The survey contains information on immunizations administered to surveyed children under 5 years old, as well as many other population, nutrition, and health indicators. There is not much 'missing' data (item non-response) in the DHS but the survey only collects dates of immunization administration for children with vaccination cards. When card retention in a DHS sample population is low, the inferences we can make about coverage or schedule adherence may be limited.

DHS data represent the population of the country when the weights provided are used for each child included in the survey. The DHS provides representative estimates of some subpopulations, called 'Survey Domains' (e.g., rural and urban areas). Data from the DHS cannot be used to calculate representative measures below the regional level, the smallest domain level included.

There are multiple data files that contain the data from each DHS. Immunization information is available in the 'children's file'. There are also two types of DHS files available: hierarchical and rectangular. For analysis in SAS, STATA, or SPSS, we will need the rectangular data file

Information regarding the coding of variables for DHS datasets and tips for analysis can be found online in the Recode Manual. The most recent Recode Manual is the 6th version, DHS6, and provides information for surveys conducted from 2008 through 2013 (available from: http://dhsprogram.com/pubs/pdf/DHSG4/Recode6_DHS_22March2013_DHSG4.pdf)

Registry Data

Ideally, registries link the individual child to their immunization record and include doses administered as well as their dates of administration. Registries may also include other medical records. Registries can improve data quality in a well performing system but are limited by data entered into the registry, both vaccines for individual children and the overall inclusion of children in the registry. When a lot of data is missing from a registry, the inferences we can make from the results of an analysis are limited.

Examples

Below are two examples comparing coverage estimates between different sources of immunization data.

Example 2. Comparing Administrative and Survey Data

Country A: administrative estimates compared with results from coverage survey.

	Administrative Data		Survey Results
	# of doses administered	% of target population	% (CI 95%)
BCG	113,048	76	93 (92, 94)
OPV 1	113,986	77	95 (95, 96)
OPV 2	113,269	76	94 (93, 95)
OPV3	112,222	75	91 (89, 92)
Pentavalent 1	114,015	77	95 (94, 96)
Pentavalent 2	113,269	76	94 (93, 95)
Pentavalent 3	112,222	76	90 (89, 91)
Rotavirus 1	109,299	74	88 (86, 91)
Rotavirus 2	106,349	72	83 (80, 85)
MMR	113,494	77	88 (87, 90)
Yellow Fever	109,781	74	86 (84, 87)

Example 3. Published Registry Data.

Luhm et al 2011 used a sample of registry data to evaluate the immunization program in one area of Brazil. A random sample was selected from the registry and was supplemented with a household survey where the registry was incomplete. The results from the registry sample were compared with the administrative data.

This article is an example of use of a registry to improve data quality in a wellperforming system. The authors point out that before using the data it is important to know if the registry is complete.

Table 3. Coverage estimates. Curitiba, Southern Brazil, 2002.			
	Administrative Data Registry Data		
	% % (Cl 95%)		
BCG	98.6	99.9 (99.9, 100.0)	
DPT-Hib (3 doses)	94.3	96.7 (96.0, 97.4)	
OPV (3 doses)	93.3	96.8 (96.1, 97.5)	
Hepatitis B (3 doses)	93.1	97.3 (96.7, 97.9)	

There have been other recent published articles that have considered the completeness of immunization registries and their agreement with other written records. One recent example from Belgium by Braeckman (2014) found the coverage estimated by the registry was lower than with cards for every vaccine dose and the dates entered often differed from physician and card-based records.

Sources: Luhm, K. R., Cardoso, M. R., & Waldman, E. A. (2011). Vaccination coverage among children under two years of age based on electronic immunization registry in Southern Brazil. Rev Saude Publica, 45(1), 90-98.

Braeckman, T., T. Lernout, G. Top, A. Paeps, M. Roelants, K. Hoppenbrouwers, P. Van Damme, and H. Theeten. "Assessing Vaccination Coverage in Infants, Survey Studies Versus the Flemish Immunisation Register: Achieving the Best of Both Worlds." Vaccine 32, no. 3 (Jan 9 2014): 345-9.

Defining a Population

For each calculation, all of the children in the denominator must have the possibility of being included in the numerator.

For example, in order to be included in the analysis, the children in the survey or registry must have reached the recommended age for the dose of interest. In the example from Country A, some of the children were not 18 months or older at the time of the survey and therefore had not reached the recommended age for the DTP and OPV booster doses. Though some younger children had received the DTP and OPV boosters, the analyses that include the booster doses are limited to only children who were 18 months or older at the time of the survey.

As another example, in order to be included in the analysis, the vaccine of interest must have been available to the children in the survey or registry. In Country A's survey, some of the children were not eligible for rotavirus vaccine because it had not been introduced before their year of birth. About half of the children were born after rotavirus vaccine was introduced and were eligible to receive the vaccine. Any analysis that includes rotavirus was limited to only children who were born after rotavirus vaccine introduction.

Additionally, all children in the numerator must also be counted in the denominator.

Bias and Random Error

There are two main types of error: random error and systematic error.

Random

Random error is error that is not specific to any particular group; there is an equal chance that anyone could have an error. Misrecorded dates of administration that are not specific to a certain survey interviewer (this would be systematic error) and are not specific to a particular clinic with poor record keeping (this would be systematic error) are an example of random error. This error is accounted for with 95% confidence intervals.

Systematic

Systematic error is error that happens differently in different groups; it is also called bias. For example, interviews are only done weekdays between 9am and 5pm. Children whose caregivers work outside the home during those hours are less likely to be included. They may have different patterns of immunization than children with a stay-at-home caregiver or children whose caregivers work night shifts.

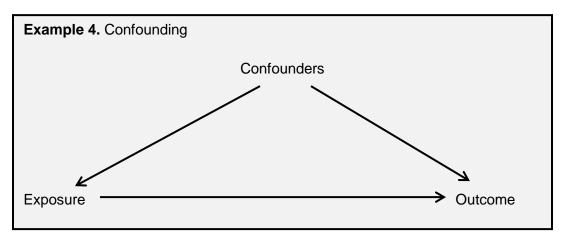
Another example of systematic error is if only doses with a date of administration on the child's vaccination card are considered in an analysis of timing of administration. Children without cards may be less likely to be vaccinated and may have more delayed vaccination. Results that only include children with cards cannot be used to make inferences about children who do not have vaccination cards.

Additional Information

2009 PAHO TAG identified development of questions for vaccinations surveys, training of survey interviewers, data collection practices and analysis of survey results as potential sources of bias in surveys. For more information, refer to the 2009 PAHO TAG report: http://www2.paho. org/hq/dmdocuments/2010/tag18_2009_Final%20Report_Eng.pdf

Confounding

Confounding is not a form of bias or error, although it can also cause estimates to be incorrect. Confounders are factors that effect both the exposure and the outcome of interest. When we do not account for confounders in the design of a study or in the data analysis phase, confounders can cause inaccurate estimates for the relationship between exposure and outcome. Confounders may be things we can measure or may be unmeasured.



Data Cleaning with Dates

Data Cleaning

Data cleaning is one way of improving the quality of the data and the reliability of the results. Data quality can also be improved during the data collection step and measurement processes.

This section focuses on quantitative data cleaning for dates of administration. There are other methods for data cleaning qualitative data and categorized responses (e.g. categorizing reasons for non-vaccination) that are not discussed here.

Potential Sources of Error

Vaccination cards and facility records can contain errors, including:

- Errors in documentation at the time of service, for example, if the date is incorrectly recorded.
- Lost or unavailable vaccination cards
- Vaccines administered at multiple facilities, which can cause record keeping problems and incomplete facility records.

Cards and facility records can be difficult to decipher because of:

- Disorganization of records
- Hard to read handwriting
- Storage conditions
- Damage to the card

Errors in transferring information, for example:

- When transferring the dates from the record onto the data collection form
- If data collection is not electronic, when entering the information from the data collection form into the electronic dataset

Minimizing Error

Some sources of errors do not apply to electronic registries because some of the data entry steps may be eliminated, communication between health facilities may be improved, and paper record keeping challenges may be minimized.

Errors in transferring information from paper records to a data entry system can be minimized, but not eliminated, by double data entry.

It may be possible to correct some obvious data entry errors (e.g. implausible dates) during data cleaning. If the original data source is available, one could check that the data was recorded correctly by referencing the registry, data collection form, a photograph of card, or health facility records.

It may also be possible to correct some obvious data entry errors by cross reference dates of vaccines scheduled for administration on the same date.

Implausible Dates

Dates of administration prior to birth

Table 4. Implausible dates: Administration prior to	o date of birth
Steps	Example
1. Find dates of administration prior to child's date of birth for each child and vaccine dose. Dates of administration can be plausible even if the dose would not be considered valid.	Plausible: DOB: February 29, 2012 Pentavalent 1: April 30, 2012 Implausible: DOB: February 29, 2012 Pentavalent 1: April 30, 2011
2. Check the original data source, if possible.	The error may be a mistake during data collection or data entry. In the example above, checking the original data source may show the year of administration was incorrectly copied.
3. If step 2 is not possible, compare dates of administration with vaccines scheduled for co-administration	Pentavalent 1: April 30, 2011 DOB: February 29, 2012 Polio 1: April 30, 2012 Pentavalent 2: June 25, 2012 Polio 2: June 25, 2012 In this example, we may be able to assume that the implausible year is due to a data entry error because of the dates of administration for the first dose of polio and the second doses of pentavalent and polio.
4. If the implausible data is not able to be corrected in steps 2 or 3, eliminate the date(s) and dose(s) where the administration date is prior to the child's date of birth	Pentavalent 1: April 30, 2011 Polio 1: April 30, 2011 DOB: February 29, 2012 Pentavalent 2: June 25, 2012 Polio 2: June 25, 2012 If we did not find evidence for a correct date of administration, such as with the information above, pentavalent 1 would be recoded as 'not administered' with a missing date of administration
5. Double check that any changes were made correctly	If it was decided that it was appropriate to change the year of administration, we would check that the date of administration for pentavalent 1 is now coded as April 30, 2012.

Dates of administration after the date of the survey

Table 5. Implausible dates: Administration after the	ne date of the survey
Steps	Example
1. Find dates of administration after the date of the survey for each child and vaccine dose. Dates of administration can be plausible even if the dose would not be considered valid.	Plausible: Polio 2: December 30, 2010 Date of the survey: December 1, 2012 Implausible: Polio 2: December 30, 2012 Date of the survey: December 1, 2012
2. Check the original data source, if possible.	The error may be a mistake during data collection or data entry. In the example above, checking the original data source may show the year of administration was incorrectly copied.
3. If step 2 is not possible, compare dates of administration with vaccines scheduled for co-administration	Polio 1: April 1, 2010 Pentavalent 2: December 30, 2010 Polio 3: February 15, 2011 Date of the survey: December 1, 2012 Polio 2: December 30, 2012 In this example, we may be able to assume that the implausible year is due to a data entry error because of the dates of administration for the first and third doses of polio and the second dose of pentavalent.
4. If the implausible data is not able to be corrected in steps 2 or 3, eliminate the date(s) and dose(s) where the administration date is prior to the child's date of birth	Polio 1: April 1, 2010 Date of the survey: December 1, 2012 Polio 2: December 30, 2012 Pentavalent 2: December 30, 2012 Polio 3: February 15, 2013 If we did not find evidence for a correct date of administration, such as with the information above, all of the vaccine doses with implausible dates would be recoded as 'not administration
5. Double check that any changes were made correctly	If it was decided that it was appropriate to change the year of administration, we would check that the date of administration for polio 2 is now recorded as December 15, 2010.

Sequential Doses

Step 1: Check that 2 or more doses of the same vaccine do not have the same recorded date of administration

Table 6. Sequential Doses, Part 1	
Steps	Example
1. Find dates of administration that are the same for 2 or more doses of the same vaccine for each child and each vaccine. Dates of administration can be plausible even if the dose	Plausible: Polio 1: July 29, 2009 Polio 2: August 22, 2009 Polio 3: October 29, 2009 Implausible:
would not be considered valid.	Polio 1: July 29, 2009 Polio 2: July 29, 2009 Polio 3: October 29, 2009
2. Check the original data source, if possible.	The error may be a mistake during data collection or data entry. In the example above, checking the original data source may show the date of administration was incorrectly copied.
3. If step 2 is not possible, compare dates of administration with vaccines scheduled for co-administration	Polio 1: July 29, 2009 Polio 2: July 29, 2009 Polio 3: October 29, 2009 Pentavalent 1: August 22, 2009 Pentavalent 2: August 22, 2009 Pentavalent 3: October 29, 2009 Rotavirus 1: July 29, 2009 Rotavirus 2: August 22, 2009 In this example, we may be able to assume that there was a data entry error and that the first doses of pentavalent and polio were administered on July 29, 2009 and the second doses of pentavalent and polio were administered on August 22, 2009.
4. If the implausible data is not able to be corrected in steps 2 or 3, eliminate the date(s) and dose(s) where the administration date is prior to the child's date of birth	Polio 1: July 29, 2009 Polio 2: July 29, 2009 Polio 3: August 22, 2009 Pentavalent 1: July 29, 2009 Pentavalent 2: August 22, 2009 Pentavalent 3: October 29, 2009 If we did not find evidence for a correct date of administration, such as with the information above, polio 2 would be recoded as 'not administered'.

5. Double check that any changes were made correctly	If it was decided that it was appropriate to change the date of administration, we would check that the date of administration for the first doses of polio and pentavalent are now recorded as July 29, 2009 and the second doses of polio and pentavalent are now recorded as August 22, 2009.
------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Step 2: Check that the dose order and dates of administration correspond for sequential doses of the same vaccine

Table 7. Sequential Doses, Part 2	
Steps	Example
1. Find dates of administration that are not in order by dose for each child and each vaccine. Dates of administration can be plausible even if the dose would not be considered valid.	Plausible: Pentavalent 1: February 10, 2012 Pentavalent 2: February 22, 2012 Pentavalent 3: May 26, 2012 Implausible: Pentavalent 1: February 10, 2012 Pentavalent 2: May 26, 2012 Pentavalent 3: February 22, 2012
2. Check the original data source, if possible.	The error may be a mistake during data collection or data entry. In the example above, checking the original data source may show the date of administration was incorrectly copied.
3. If step 2 is not possible, compare dates of administration with vaccines scheduled for co-administration	Pentavalent 1: February 10, 2012 Pentavalent 2: May 26, 2012 Pentavalent 3: February 22, 2012 Polio 1: February 10, 2012 Polio 2: February 22, 2012 Polio 3: May 26, 2012 In this example, we may be able to assume that there was a data entry error and that the dates for the second and third doses of pentavalent were entered in the wrong order.
4. Double check that any changes were made correctly	If it was decided that it was appropriate to change the date of administration, we would check that the date of administration for the second dose of pentavalent was recoded as February 22, 2012 and the third dose of pentavalent was recoded as June 10, 2012.

Table 8. Sequential Doses, Part 3	
Steps	Example
1. Find each child where the earlier doses of a vaccine are missing but the subsequent doses are recorded with dates of administration for each vaccine.	Plausible: Polio 1: July 29, 2009 Polio 2: August 22, 2009 Polio 3: October 29, 2009 Implausible: Polio 1: July 29, 2009 Polio 2: Missing Polio 3: October 29, 2009
2. Check the original data source, if possible.	The error may be a mistake during data collection or data entry. In the example above, checking the original data source may show the year of administration was incorrectly copied.
3. In this case, we cannot compare doses scheduled for co-administration.	Polio 1: July 29, 2009 Polio 2: Missing Polio 3: October 29, 2009 Pentavalent 1: July 29, 2009 Pentavalent 2: August 22, 2009 Pentavalent 3: October 29, 2009 We cannot assume that because pentavalent 2 was administered, polio 2 was also administered.
4. Recode earlier missing doses with the administration information from subsequent doses and recode the subsequent doses as not administered with missing dates of administrations	Original: Polio 1: July 29, 2009 Polio 2: Missing Polio 3: October 29, 2009 Recoded: Polio 1: July 29, 2009 Polio 2: October 29, 2009 Polio 2: October 29, 2009 Polio 3: Missing We recoded the second dose of polio with the information from the third dose of polio. Then we set the third dose of polio to 'not administered.'
5. Double check that any changes were made correctly	If it was decided that it was appropriate to make these changes, we would check that the date of administration for the second dose of polio is now October 29, 2009 and the date of administration of the third dose of polio is now missing.

Step 3: Check that when subsequent doses are administered, earlier doses are not missing

Multiple Formulations

In some countries, multiple formulations of the same antigens are available, for example pentavalent and DTP. It is best to recode as the individual components, for example pentavalent would become DTP, HiB, and Hepatitis B, all with the date of administration of the pentavalent dose. After this, follow the steps above to clean the data and ensure the doses are in the correct order.

Documentation

It is important to document the data cleaning process and keep track of any changes that are made. Additionally, information about the percent of records that had implausible dates may be informative for a publication, future survey data collection, and frontline healthcare documentation practices.

Calculating Coverage Using Administrative Data, Registries and Surveys

Coverage

Basic Formula

Below is the basic formula for calculating coverage, no matter the type of data.

Example 5. Basic Formula for Coverage

Doses administered Target Population

Numerators and Denominators

Table 9 compares the numerators and denominators used to calculate coverage for each type of data.

Table 9. Estimating coverage with all doses			
	Administrative Data	Survey	Registry
Numerator	Number of doses administered	Number of children in the survey who were vaccinated	Number of children in the registry who were vaccinated
Denominator	Target population (for example, children under 1 year)	Number of children in the survey	Number of children in the registry

Example

Here is an example from Country A, showing the coverage calculation with both administrative and survey data. Additional comparisons were shown in Example 3.

Example 6. Pentavalent 3 Administrative data: <u>112,222 pentavalent 3 doses administered among children < 1 year of age</u> 148,630 children in the target population < 1 year of age =75.5% Survey data*: <u>2,874 children received pentavalent 3 by 365 days of age</u> 3,319 children in the survey over 365 days of age = 86.6%

*The survey data should be weighted, meaning the data from each child was given a value based the probability of that child being selected to participate. This allows us to use the information to describe the entire population, rather than just the children included in the survey. For simplicity, this example shows the crude calculation of coverage, which assumes that every child had the same chance of being included.

With a survey or registry, there are some alternative ways to calculate coverage.

- One could limit the denominator to children born in a particular year and the numerator to children born in that year who received the dose of interest prior to 12 months of age. This is comparable to coverage among children aged less than one year in a birth cohort.
- If the overall analysis will be limited to children with written record of vaccine administration, limit the denominator to children with an observed written vaccination record for any vaccine dose. The results of an analysis limited to only children with observed written documentation will not be representative of the entire population.

Dropout

<u>Method 1:</u> In assessing dropout from the first dose of pentavalent vaccine to the third dose of pentavalent vaccine, we are comparing the number of children who initially accessed immunization services by receiving the first dose of pentavalent vaccine but did not complete the series.

Basic Formula

Below is the basic formula for calculating pentavalent vaccine dose 1 to pentavalent vaccine dose 3 drop out, no matter the type of data.

Example 7. Dropout Pentavalent 1 to Pentavalent 3

Pentavalent 1 doses [minus] Pentavalent 3 doses x 100 Pentavalent 1 doses

Numerators and Denominators

Table 10 compares the numerators and denominators used to calculate pentavalent vaccine dose 1 to penvalent vaccine dose 3 for each type of data.

Table 10. Estim	Table 10. Estimating pentavalent 1 to pentavalent 3 dropout.		
	Administrative Data	Survey	Registry
Numerator	Subtract the number of doses of pentavalent 3 administered from the number of doses of pentavalent 1 administered	The number of children with a dose of pentavalent 1 who had not received pentavalent 3 by 12 months of age	The number of children with a dose of pentavalent 1 who had not received pentavalent 3 by 12 months of age
Denominator	Number of doses of pentavalent 1 administered	Number of children over 1 year of age with a recorded dose of pentavalent 1	Number of children over 1 year of age with a recorded dose of pentavalent 1

There are a few things to note when comparing drop out between administrative data and survey and registry data:

- Administrative data is aggregated and it is not possible to track individual children. When
 using administrative data, we are not comparing the exact same group of children. This
 is because we are measuring doses given to children under one year during a calendar
 year. Some children will receive their pentvalent 1 dose during one calendar year and
 their pentavalent 3 dose during the next calendar year.
- When using survey and registry data, we are able to know which children did not return for subsequent immunization visits. We may also have other information about their risk factors, such as rural residence or socio-economic status.

Example

Here is an example from Country A, showing the pentavalent vaccine dose 1 to pentavalent vaccine dose 3 calculation with both administrative and survey data.

Example 8. Dropout rate Pentavalent 1 to Pentavalent 3
Administrative data:
114,015 pentavalent 1 doses in children < 1 [minus] <u>112,222 pentavalent 3 doses in children < 1</u> 114,015 pentavalent 1 doses in children < 1
=1.6%
Survey data:
<u>176 children who received pentavalent 1 but not pentavalent 3 by 12 months</u> 3,157 children who received pentavalent 1 by 12 months of age
=5.6%

Programmatic Implications

"High drop-out rates may reflect problems in demand for vaccinations, client satisfaction, and the ability of the immunization program to provide those services."

(Source: Immunization Essentials: A Practical Field Guide http://www.mchip.net/sites/default/files/Immunization%20 Essentials_English.pdf)

Dropout highlights children who accessed immunization services for the first dose of DTP but were lost to follow-up before receiving the third dose of DTP. It is important to note that most vaccines can still be given even if the child is late, though these doses may not be reflected in administrative estimates.

Drop-out may also reflect delays in completing the routine infant vaccination schedule or children who complete the schedule after their first birthday.

<u>Method 2:</u> In assessing the dropout from the third dose of pentavalent vaccine to the first dose of MMR or MR vaccine, we are comparing the number of children who accessed immunization services and received the third dose of pentavalent vaccine at 6 months of age but who did not return to finish the infant immunization schedule at 12 months of age.

Basic Formula

Below is the basic formula for calculating dropout from the third dose of pentavalent vaccine to the first dose of MMR/MR vaccine, no matter the type of data.

Example 9. Dropout Pentavalent 3 to MMR 1

Pentavalent 3 doses [minus] MMR doses Pentavalent 3 doses

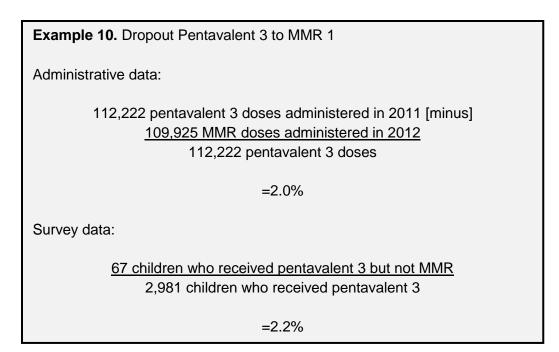
Numerators and Denominators

Table 11 compares the numerators and denominators used to calculate dropout from the third dose of pentavalent vaccine to the first dose of MMR/MR vaccine for each type of data.

Table 11. Estimating pentavalent 3 to MMR dropout rate						
	Administrative Data	Survey	Registry			
Numerator	Subtract the number of doses of MMR administered in one year from the number of doses of pentavalent 3 administered in the previous year	The number of children who had received a dose of pentavalent 3 who had not received MMR by 24 months of age	The number of children who had received a dose of pentavalent 3 who had not received MMR by 24 months of age			
Denominator	Number of doses of pentavalent 3 administered	Number of children with a recorded dose of pentavalent 3 by 24 months of age	Number of children with a recorded dose of pentavalent 3 by 24 months of age			

Example

Here is an example from Country A, showing dropout calculation for the third dose of pentavalent vaccine to the first dose of MMR/MR vaccine with both administrative and survey data.



Programmatic Implications

Drop out is the percentage of children who received the third dose of DTP accessed services but were lost to follow-up before receiving measles-containing vaccine. It is important to note that most vaccines can still be given even if the child presents well after the recommended age, though these doses may not be reflected in administrative estimates.

Other Analyses

Valid Dose Coverage

Valid doses are doses administered once the child has reached the minimum age for vaccination and/or a minimum number of days since the administration of the previous dose in the series. Invalid doses may leave children unimmunized and susceptible to infections prevented by the vaccines.

Goal: to determine the proportion of valid doses administered for each vaccine

Assessing valid dose coverage

Below is the basic formula for calculating valid dose coverage, no matter the type of data.

Example 11. Formula for Valid Dose Coverage	
Valid Doses Administered Target Population	

Definition of Validity

Below are four tables showing the PAHO TAG and WHO SAGE recommendations for valid doses. The definitions of validity are based on immunogenicity data.

Table 12. Defini	tions of Validity- Prima	ary Series		
	Recommended age	Minimum Age	Minimum Interval	Maximum age
Hepatitis B	Birth	0 days of age	N/A	If administered after 59 days of age, it is considered Hepatitis B 1
BCG	Birth	0 days of age	N/A	Not recommended after 365 days of age
Rotavirus 1	2 months	42 days of age	N/A	104 days of age
Rotavirus 2	4 months	70 days of age	28 days after the first dose of rotavirus	223 days of age
Polio1/ Penta1/PCV1	2 months	42 days of age	N/A	None
Polio2/ Penta2/PCV2	4 months	70 days of age	28 days after the first dose	None
Polio3/ Penta3/PCV3	6 months	98 days of age	28 days after the second dose	None
Yellow Fever	12 months	182 days of age	If yellow fever and MMR/MR are not administered on the same date but are	None
MMR/MR1	12 months	270 days of age	administered within 28 days of each other, the second vaccine administered is invalid.	None

Minimum intervals for validity

In addition to minimum intervals between two doses of the same vaccine, if two live injected or nasal vaccines are administered on the different dates less than 28 days apart, the second vaccine is invalid. If two live injected or nasal vaccines are administered on the same date, both vaccines are valid. Live injected vaccines include single antigen measles, measles-rubella (MR), measles-mumps-rubella (MMR), yellow fever, and varicella. Nasal influenza is a live nasal vaccine. This rule does not apply to oral live vaccines such as OPV and rotavirus vaccine. For additional information, reference Chapter 2 of 'the Pink Book' at http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf

Maximum age

There are 3 vaccines that have maximum recommended ages of administration

• BCG can be administered after 364 days of life but it is not recommended. Doses administered after 364 days of life are not included in coverage. Reference the full position paper at: http://www.who.int/wer/2004/en/wer7904.pdf?ua=1

- Hepatitis B dose administered more than 24 hours after birth would not protect the child from perinatal Hepatitis B transmission. Hepatitis B administered after 59 days is no longer considered the birth dose. Doses administered at 60 days or later are considered the first dose of Hepatitis B. Reference the full position paper at: http://www.who.int/wer/2009/wer8440.pdf?ua=1
- The upper age limits of administration for rotavirus vaccine are based on 2009 WHO recommendations (14 weeks and 6 days to start series and 32 weeks to complete the series). 2012 SAGE position paper recommends countries consider administering rotavirus concurrently with the first and second doses of DTP, regardless of age up to 24 months of age. Reference the full position paper at: http://www.who.int/wer/2013/ wer8805.pdf?ua=1

The 2012 PAHO TAG recommended the vaccine can be administered up to 1 year of age in areas with high diarrheal morbidity and mortality, but countries should try to adhere to the upper age limits. Reference the full report at: http://www.paho.org/hq/index.php?option=com_content&view=article&id=1862&Itemid=1682&Iang=en This document reflects the 2009 recommendations.

Measles-containing vaccine

The WHO SAGE recommends administering the first dose of measles-containing vaccine (MR or MMR) at 9 months of age in areas where measles transmission is high and at 12 months of age where transmission is low. They estimate that 90% of infants who are administered measles vaccine at 8-9 months of age seroconvert whereas 99% of infants who are vaccinated at 12 months of age seroconvert. For more information, please reference the WHO position paper on measles containing vaccine at: http://www.who.int/wer/2009/wer8435.pdf?ua=1

Because of variability of national recommendations for age of administration in the PAHO region, this guide reflects 9 months as an acceptable age to vaccinate with measles-containing vaccine. It may be appropriate to modify this to better reflect national recommendations.

Table 13. Definitions of Validity- Booster Series						
	Recommended age	Minimum Age	Minimum Interval	Maximum age		
PCV Booster	12 months	365 days of age	56 days after previous dose of pneumococcal	None		
Polio booster	Refer to national schedule.	126 days of age	28 days after previous dose of polio	None		
DTP booster	18 months	365 days of age	181 days after previous dose of DTP-containing vaccine	None		
MMR/MR 2	Refer to national schedule.	298 days of age	28 days after previous dose of measles- containing vaccine	None		

Table 14. Definitions of Validity- School Entry Series						
	Recommended age	Minimum Age	Minimum Interval	Maximum age		
Polio booster 2	Refer to national schedule.	At least 181 days from previous polio dose. May be 4 years in some countries.	181 days after previous dose of polio	None		
DTP booster 2	Refer to national schedule	446 days of age	181 days after previous dose of DTP-containing vaccine	None		

Table 15. Definitions of Validity- Annual Influenza						
	Recommended age	Minimum Age	Minimum Interval	Maximum age		
Influenza 1	Every year after 6 months of age	181 days of age	N/A	None		
Influenza 2	One month after the first dose during first flu vaccination season only	209 days of age	28 days from previous dose of influenza	8 years and 364 days of age		

Influenza Dose 2

A second dose of influenza vaccine is only recommended for children up to 9 years of age during the first influenza season a child is vaccinated with influenza vaccine.

4 Day Grace Period

USA Advisory Committee on Immunization Practices (ACIP) considers doses to be valid if they are administered up to 4 days before minimum age for validity or 4 days before minimum interval between doses. For additional information, reference Chapter 2 of 'the Pink Book' at http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/genrec.pdf

This 4 day grace period was not used in these examples to calculate validity. One example where this has been used in a published article is by Dayan with an analysis from Buenos Aires, Argentina.

(Source: Dayan, G. H., K. M. Shaw, A. L. Baughman, L. C. Orellana, R. Forlenza, A. Ellis, J. Chaui, S. Kaplan, and P. Strebel. "Assessment of Delay in Age-Appropriate Vaccination Using Survival Analysis." Am J Epidemiol 163, no. 6 (Mar 15 2006): 561-70.)

How to Calculate Valid Dose Coverage

Numerators and Denominators

Table 11 compares the numerators and denominators used to calculate valid dose coverage for each type of data.

With administrative data, we can't know at what ages the doses were administered because we don't have dates of birth and dates of administration for each child. We also don't know the intervals between doses for each child. It is not possible to calculate valid dose coverage with administrative data. With survey and registry data, the doses are individually linked to each child, making it possible to assess validity.

Table 16. Estimating coverage with valid doses only						
	Administrative Data	Survey	Registries			
Numerator	N/A	Number of children in the target age group with a valid dose for the vaccine of interest	Number of children in the target age group with a valid dose of the vaccine of interest recorded in the registry			
Denominator	N/A	Number of children in the target age group who participated in the survey	Number of children in the target age group in the registry			

Examples

Here is an example from Country A, showing the total dose and valid dose coverage calculations with survey data.

Example 12. MMR
In this example, 53 children received a dose of MMR that was not valid, either because it was administered before 270 days of age (9 months) or it was administered 1 to 27 days after yellow fever vaccine was administered.
Total MMR doses*:
2,914 children received a dose of MMR
3,319 age-eligible children in the survey
=87.8%
Valid MMR doses*:
2,861 children received a valid dose of MMR
3,319 age-eligible children in the survey
=86.2%

*The survey data should be weighted, meaning the data from each child was given a value based the probability of that child being selected to participate. This allows us to use the information to describe the entire population, rather than just the children included in the survey.

For simplicity, this example shows the crude calculation of coverage, which assumes that every child had the same chance of being included.

The following three tables show examples all dose coverage and valid dose coverage using survey data. You will notice that each table uses a different number of children in the denominator to account for children in the survey who were eligible for different vaccine doses.

Table 17. Vaccine coverage by total doses and valid doses among children 12-35 months old.Country A, 2011.

	Total	Total Do	Fotal Doses Administered		Valid Doses Administered	
	Children	n	% (Cl 95%)	n	% (CI 95%)	n
BCG	3,319	3,079	92.8 (91.9, 93.8)	3,079	92.8 (91.9, 93.8)	0
OPV 1	3,319	3,163	95.3 (94.5, 96.2)	3,130	94.3 (93.4, 95.2)	33
OPV 2	3,319	3,133	94.4 (93.4, 95.4)	3,076	92.7 (91.6, 93.8)	57
OPV 3	3,319	3,004	90.5 (89.2, 91.8)	2,962	89.2 (87.9, 90.6)	42
Pentavalent 1	3,319	3,157	95.1 (94.3, 96.0)	3,123	94.1 (93.2, 95.0)	34
Pentavalent 2	3,319	3,129	94.3 (93.3, 95.2)	3,053	92.0 (90.9, 93.1)	76
Pentavalent 3	3,319	2,981	89.8 (88.5, 91.1)	2,937	88.4 (87.1, 89.8)	44
MMR	3,319	2,914	88.1 (86.6, 89.6)	2,861	86.5 (85.1, 88.0)	53
Yellow Fever	3,319	2,834	85.8 (84.2, 87.4)	2,775	84.1 (82.5, 85.7)	59

Table 18. Vaccine coverage by total doses and valid doses among children born in 2010. Country A, 2011.

	Total	Total Doses Administered		V Ac	Invalid Doses	
Children		n	% (CI 95%)	n	% (CI 95%)	n
Rotavirus 1	1,194	1,058	88.4 (86.4, 90.5)	988	82.6 (80.0, 85.2)	70
Rotavirus 2	1,194	986	82.5 (79.8, 85.1)	960	80.4 (77.7, 83.1)	26

*Rotavirus vaccine was introduced in Country A in 2010 but the survey includes children born in 2008-2010. Only children born in 2010 were included in the analysis.

Table 19. Vaccine coverage by total doses and valid doses among children ages 18-35 months. Country A, 2011.

	Total	Total Doses Administered		Valid Doses Administered		Invalid Doses
	Children	n	% (Cl 95%)	n	% (CI 95%)	n
OPV Booster	2,419	1,810	74.9 (72.6, 77.2)	1,785	73.8 (71.5, 76.1)	25
DTP Booster	2,419	1,804	74.6 (72.3, 76.9)	1,743	72.0 (69.7, 74.4)	61

*The DTP and OPV boosters are recommended for children at 18 months of age. This analysis only includes children 18-35 months at the time of the survey.

Programmatic Implications

The goal of validity is to maximize effectiveness of every dose administered. It is important for vaccines to be given at an age when there is the best chance that vaccinated children develop an immune response and are protected from vaccine preventable diseases.

Valid dose coverage also provides information about how well vaccinators understand and follow the guidelines.

Timeliness Analysis and Inverse Kaplan-Meier

Goal: To assess adherence to the recommended vaccination schedule.

Assess

Tables 20-23 define the age of the child at the time of vaccine administration in to categories of timeliness or schedule adherence for valid doses only. To determine which doses are valid, please see the previous section.

This guide defines timeliness as the period from when the child reaches the recommended age for vaccination with the dose of interest until one month (30 days) after the recommended age. There are several definitions of timeliness in the literature, but most define the timely period as the month following the recommended age of vaccination. These categories of immunization timing are based on schedule adherence for valid doses only.

Table 20. Definition of	Age of Administrat	ion Adherence for V	alid Doses- Infant Se	eries
	Before the Recommended Age	Recommended Age	After the Recommended Age	Late
Hepatitis B	N/A	0-1 days	2-28 days of age	29-59 days of age (doses administered > 59 days are counted as HepB1)
BCG	N/A	0-30 days of age	31-364 days of age	>365 days (not recommended)
Rotavirus 1	42-59 days of age	60-90 days of age	91-104 days of age	>104 days of age
Rotavirus 2	70-119 days of age	120-150 days of age	151-223 days of age	>223 days of age
Polio1/Penta1/PCV1	42-59 days of age	60-90 days of age	91-364 days of age	>1 year of age (365 days)
Polio2/Penta2/PCV2	70-119 days of age	120-150 days of age	151-364 days of age	>1 year of age (365 days)
Polio3/Penta3/PCV3	98-179 days of age	180-210 days of age	211-364 days of age	>1 year of age (365 days)

Late Initiation

If a child begins the series after an age where all doses will be administered after their recommended ages, consider a secondary analysis assessing adherence to an accelerated schedule based on minimum validity intervals between doses.

Table 21. Definition of Age of Administration Adherence for Valid Doses- Booster Series							
	Before the Recommended Age	Recommended Age	After the Recommended Age	Late			
MMR/MR1	270-364 days of age	365-395 days of age	396-729 days of age	>2 years of age (730 days)			
Yellow Fever	181-364 days of age	365-395 days of age	396-729 days of age	>2 years of age (730 days)			
PCV Booster	N/A	365-395 days of age	396-729 days of age	>2 years of age (730 days)			
DTP booster	N/A	547-577 days of age	578-729 days of age	>2 years of age (730 days)			
Polio booster	N/A	547-577 days of age	578-729 days of age	>2 years of age (730 days)			

Measles-containing vaccine 1

The WHO recommends administering the first dose of measles-containing vaccine (MR or MMR) at 9 months of age in areas where measles transmission is high and at 12 months of age where transmission is low. They estimate that 90% of infants who are administered measles vaccine at 8-9 months of age seroconvert whereas 99% of infants who are vaccinated at 12 months of age seroconvert. For more information, please reference the WHO position paper on measles containing vaccine.

Because of variability of national recommendations for age of administration in the PAHO region, this guide reflects 9 months as an acceptable age to vaccinate with measles containing vaccine. It may be appropriate to modify this to better reflect national recommendations.

Table 22. Definition of Age of Administration Adherence for Valid Doses- School Entry						
	Before the Recommended Age	Recommended Age	After the Recommended Age	Late		
MMR/MR2	N/A	Up to 30 days after the recommended age on the national schedule	More than 30 days after the recommended age on the national schedule	>the next birthday		
Polio booster 2	N/A	Up to 30 days after the recommended age on the national schedule	More than 30 days after the recommended age on the national schedule	>the next birthday		
DTP booster 2	N/A	Up to 30 days after the recommended age on the national schedule	More than 30 days after the recommended age on the national schedule	>the next birthday		

Measles-containing vaccine 2

PAHO TAG recommends the second dose of MMR/MR vaccine to be schedule for administration at 18 months of age, with the first DTP vaccine booster. In this case, the dose will be late after the 2nd birthday (730 days of age).

Table 23. Definition of Age of Administration Adherence for Valid Doses- Influenza						
	Before the Recommended Age	Recommended Age	After the Recommended Age	Late		
Influenza1	6 months of age	(Dependent on age during influenza season)				
Influenza2	Less than 28 days after 1 st dose	28-58 days after previous dose	58-181 days after previous dose	9 years of age		

Influenza, dose 2

A second dose of influenza vaccine is only recommended for children under 9 years of age who have not been vaccinated against influenza in any previous flu seasons.

Assess

Table 24 shows the steps to assess dose timeliness with an example using survey data from Country A.

Table 24. Calculating Timely Immunization Coverage				
Steps	Example			
1. Choose the vaccine(s) of interest.	DTP booster			
2. Choose a group of children who were age- eligible for the vaccine of interest.	Children between 24 and 35 months of age			
3. The total number of children in the age group is the denominator.	1,621 children between 24 and 35 months of age at the time of the survey			
4. Calculate the age of administration of the vaccine.	Date of administration of the vaccine of interest [minus] the child's date of birth			
5. Count the number of children who do not have a recorded date of administration for the vaccine of interest.	318 children between 24 and 35 months did not have a date of administration of DTP booster recorded.			
6. Count the number of children who received an invalid dose because it was administered before the minimum age.	An invalid dose of the DTP booster is one that was administered before 365 days of age. 25 children between 24 and 35 months had a dose of DTP administered before 365 days of age.			
7. Count the number of children who received an invalid dose because it was administered before the minimum interval from the previous dose.	An invalid dose of the DTP booster is one that was administered within 181 days of the last dose of pentavalent vaccine. 22 children between 24 and 35 months had a dose of DTP administered less than 181 days after pentavalent 3.			

8. Add the total number of invalid doses.	The total number of children with an invalid dose is 25+22=47.
9. Count the number of children who received a timely dose.	Timely doses are administered from 365 days of age and the minimum interval until 569 days of age. 605 children between 24 and 35 months received a timely dose of DTP.
10. Count the number of children who received a dose after the timely period.	Doses that are not timely are administered from 570 to 729 days of age. 500 children between 24 and 35 months received a dose of DTP that was not timely.
11. Count the number of children who received a late dose.	Late doses are administered after 730 days of age. 151 children between 24 and 35 months received a dose of DTP after their 2 nd birthday.
12. Calculate the percent timely coverage.	605 children received <u>a timely DTP booster, weighted</u> 1,621 children were ages 24 months and older at the time of the survey, weighted =37.3% (CI 95% 34.2, 40.5) of children received a valid DTP booster within 30 days of the recommended age.

Assess

Table 25 shows the steps to assess the average age of vaccine administration with an example using survey data from Country A.

Table 25. Calculating Mean Age of Vaccination		
Steps	Example	
1. Determine the vaccine(s) of interest	The 2 nd dose of rotavirus	
2. Choose a group of children who were age- eligible for the vaccine of interest.	1,194 children were born after rotavirus vaccine was introduced in 2010	
3. Limit the number of children to those who received the vaccine of interest.	986 born in 2010 had received the second dose of rotavirus vaccine.	
4. Calculate the age of administration of the vaccine for each child.	Date of administration of the 2 nd dose of rotavirus [minus] the child's date of birth = age of vaccination for the 2 nd dose of rotavirus	
5. Add up all of the ages of administration	131,984 is the sum of all of the ages of vaccination for the 986 children born in 2010 who had received the 2 nd dose of rotavirus vaccine.	
6. Divide the sum of the ages by the number of children vaccinated. This is the mean age of vaccination	$\frac{131,984}{986 \text{ children}}$ = 133.9 days of age This is the mean age of administration for the 2 nd dose of rotavirus in this survey.	

Assess

Table 26 shows the steps to assess the median age of vaccine administration and the interquartile range with an example using survey data from Country A.

The median age is the age when 50% of the children who were administered the dose received it before and 50% received it after. It is also called the 50th percentile or the 2nd quartile. The Inter Quartile Range (IQR) is the range from the 25th percentile (1st quartile) to the 75th percentile (3rd quartile).

Table 26. Calculating Median Age of Vaccination and IQR		
Steps	Example	
1. Determine the vaccine(s) of interest	The 2 nd dose of rotavirus	
2. Choose a group of children who were age- eligible for the vaccine of interest.	1,194 children were born after rotavirus vaccine was introduced in 2010 and 986 received the second dose of rotavirus vaccine.	
3. Calculate the age of administration of the vaccine for each child.	Date of administration of the 2 nd dose of rotavirus [minus] the child's date of birth = age of vaccination for the 2 nd dose of rotavirus	
4. Divide the total number of children in half.	<u>986 children</u> 2 =493 rd child	
5. Order the ages from smallest to largest.	The range of ages among the 986 children is from 50 days to 495 days of age.*	
6. Taking the list created in step 5, the age of the child from step 4 represents the median for the vaccinated children in the survey.	The age of administration for the 493 rd is 127 days of age. This is the median for the group.	
7. Divide the total number of children by 4.	986 children 4 =246.5 th child	
8. The age of administration that falls on the child in step 7 is the lower bound of the interquartile range.	Because this is not a whole number, the mean of the age of administration for the 246 th and 247 th children is the 1 st quartile. The mean age of administration for the 246 th and 247 th children is 122.5 days of age. This is the 1 st quartile for the group.	
9. Add the number of children in step 4 and step 7.	493 + 246.5 = 739.5 th child	

10. The age of administration that falls on the child in step 9 is the upper bound of the interquartile range.	Because this is not a whole number, the mean of the age of administration for the 739 th and 740 th children is the 3 rd quartile. The mean age of administration for the 739 th and 740 th children is 137 days of age. This is the 3 rd quartile for the group.
11. Report the median age of administration and the interquartile range (IQR). This is the range of ages when the majority of children in the group received the vaccine of interest.	Median: 127 days of age IQR: 122.5- 137 days of age Range: 50- 497 days of age

*Some of these doses are not valid but are included in this analysis.

Note that the mean (133.9 days) and median (127 days) ages of administration are not the same for the 2nd dose of rotavirus vaccine in this group. This is because the mean is easily influenced by outlying observations, like the 497 days of age of vaccination seen here. It can be useful to report the mean, median, IQR and range together because of these differences.

Assess

Inverse Kaplan Meier curve is one way to present a descriptive visualization of the proportion of children vaccinated by age in months. Children who are unvaccinated are included in the group eligible for vaccination from birth until their age at the time of data collection. These graphs assume that each dose is independent from all other doses, including doses in the same series.

One example of a published time-to-event analysis using DHS data is by Clark and Sanderson. Source: Clark, A., and C. Sanderson. "Timing of Children's Vaccinations in 45 Low-Income and Middle-Income Countries: An Analysis of Survey Data." Lancet 373, no. 9674 (May 2 2009): 1543-9.

Table 27 shows the steps to set up variables to create an inverse Kaplan-Meier time-to-event curve with an example using survey data from Country A.

Table 27. Setting Up an inverse Kaplan-Meier Curve		
Steps	Example	
1. Choose the vaccine(s) of interest.	Pentavalent dose 2	
2. Choose a group of children who were age- eligible for the vaccine of interest.	All children the survey (all were over 12 months)	
3. Create an administered/not administered variable for each vaccine.	If the child received pentavalent 2=1 and if they did not receive the pentavalent 2=0.	
4. Create a 'time-to-event variable' for children who received the vaccine.	If the child received pentavalent 2, the time to event is the recorded age of administration.	

5. Create a 'time-to-event variable' for children who did not received the vaccine. Some children will have received some doses and not others.	If the child did not receive pentavalent 2, the time to event is the age at the time of the data collection. These children are 'censored,' meaning they did not receive the vaccine before the time of the survey but are eligible to receive the vaccine at some future time.
6. Use a computer software to draw 1 [minus] Kaplan-Meier (inverted) time-to-event curves and corresponding confidence intervals	The figure below was created using R.*

*See List of Resources for sample Kaplan-Meier R survey methods programming code.

Alternatives

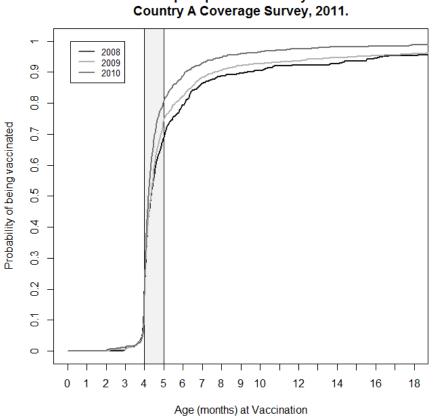
- Multiple doses of the same vaccine on one plot
- One vaccine by multiple birth cohorts, as seen in the example
- One vaccine by subnational regions

Including a band that shows the target vaccine's timely period may help visualize. In the example from Country A below, the grey bands indicate the recommended age of administration.

It is possible to include confidence intervals in the Kaplan-Meier plots, as seen in figure 2.

Notice in both figures the y-axis is labeled as the probability of vaccination, rather than coverage.

Figure 1. Inverse Kaplan-Meier Plot.



Time to receipt of pentavalent 2 by birth cohort. Country A Coverage Survey, 2011.

Figure 1 does not include confidence intervals. The grey box highlights the recommended age for administration. This type of image could be used for a large group presentation.



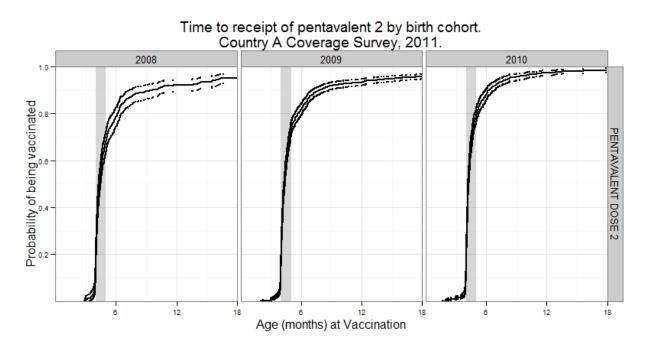


Figure 2 shows the same information as Figure one, except it also includes confidence intervals. Each panel is a different birth cohort, labeled across the top x-axis. The grey boxes highlight the recommended age for administration. This type of image could be used for a written report.

Programmatic Implications

Significant delays in vaccination can lower coverage estimates. Delays in vaccination also increase the time children are unprotected and delay when herd immunity is reached in a cohort.

Timeliness analyses can show also changes over time or differences in vaccination practice between subnational regions.

Limitations

In order to do these analyses, the data set must include complete dates of administration.

Fully Immunized Child

<u>Goal:</u> To assess the number of children who have received all recommended vaccines by a certain age.

Assess

<u>Method 1:</u> Table 20 shows the steps to assess the fully immunized child using only the basic EPI vaccines with an example using survey data from Country A.

Table 28. Calculating Fully Immunized Child- Basic EPI Vaccines		
Steps	Example	
1. Choose the vaccines of interest	OPV 1, 2, and 3, Pentavalent 1, 2, and 3, and MMR	
2. Choose a group of children who were age- eligible for all the vaccines of interest.	Children between 18 and 35 months of age	
3. The total group of children in this age group is the denominator.	There were 2,419 children between 18 and 35 months of age at the time of the survey.	
4. Determine the number of children who had received all of the vaccines of interest prior to the age of the youngest children included. This is the numerator.	1,908 children between 18 and 35 months received all 7 doses of vaccine before 18 months (547 days) of age.	
5. Calculate the percentage of children who received all the vaccines interest by the determined age.	1,908 children received all 7 vaccines before <u>18 months of age, weighted</u> 2,419 children 18 months and older, weighted =79.1% (CI 95% 77.0, 81.2)	

<u>Method 2:</u> Table 21 shows the steps to assess the fully immunized child using the full immunization schedule with an example using survey data from Country A.

Table 29. Calculating Fully Immunized Child- Complete National Schedule		
Steps	Example	
1. Choose the vaccines of interest	OPV 1, 2, and 3, Pentavalent 1, 2, and 3, MMR, Yellow Fever, OPV booster, and DTP booster	
2. Choose a group of children who were age- eligible for all the vaccines of interest.	Children between 24 and 35 months of age	
3. The total group of children in this age group is the denominator.	1,621 children between 24 and 35 months of age at the time of the survey	
4. Determine the number of children who had received all of the vaccines of interest prior to the age of the youngest children included. This is the numerator.	1,041 children between 24 and 35 months received all 10 vaccines before 24 months (730 days) of age.	
5. Calculate the percentage of children who received all the vaccines interest by the determined age.	1,041 children received all 10 vaccines before <u>24 months of age, weighted</u> 1,621 children 24 months and older, weighted =64.5% (CI 95% 61.4, 67.6)	

Alternate Numerators

It is also possible to do this analysis limiting step 4 to only valid doses or only timely doses. In the literature, these have been called 'Up-to-Date' when only valid doses are included and 'Age-Appropriately Vaccinated' when only timely doses are included.

Programmatic Implications

This analysis shows the proportion of children completing entire vaccination series by a certain age.

Limitations

In order to do this analysis, the data set must include complete dates of administration.

This analysis does not allow us to know which children had legitimate contraindications to vaccination.

Simultaneity

<u>Goal:</u> To assess how often vaccines that are recommended to be administered together are administered on the same date.

Assess

<u>Method 1:</u> Table 22 shows the basic steps to assess simultaneity of vaccines recommended for the same age and an example using survey data with an example using survey data from Country A.

Table 30. Calculating Simultaneity, Method 1		
Steps	Example	
1. Choose 2 vaccines of interest that have the same recommended age of administration	Pentavalent 3 and OPV 3	
2. Choose a group of children who were age- eligible for the vaccines of interest.	Children between 12 and 35 months of age	
3. Limit the group to children who had received both vaccines of interest. This is the denominator.	2,973 children between 12 and 35 months had received pentavalent 3 and OPV 3.	
4. Determine if the dates of administration are the same for both vaccines. This is the numerator.	2,924 children between 12 and 35 months received pentavalent 3 and OPV 3 on the same date. 49 children received pentavalent 3 and OPV 3 on different dates.	
5. Calculate the percentage of children who received the vaccines of interest simultaneously.	2,924 children received pentavalent 3 and OPV 3 on the same date, weighted 2,973 children received both doses, weighted =98.4% (CI 95% 97.9, 98.8)	

Alternative Denominators

For Method 1, you may consider including children who had either vaccine, as well as those who received both vaccines of interest, and categorize the remaining children by receiving only one of the vaccines, both vaccines on the same date, or each vaccine on a different date.

<u>Method 2:</u> Table 23 shows more advanced steps to assess simultaneity of vaccines recommended for the same age and recommended for different ages with an example using survey data from Country A.

Table 31. Calculating Simultaneity, Method 2		
Steps	Example	Calculate the percentage of children in each category.
1. Choose a vaccine of interest.	Rotavirus 1	
2. Choose a group of children who were age- eligible for the vaccines of interest.	Children born in 2010	
3. Limit the group to children who had received the vaccine of interest. This is the denominator.	1,058 children born in 2010 had received rotavirus vaccine dose 1.	
4. Count the number of children who received the vaccine interest on the same date as a vaccine scheduled for administration at the same age.	There were 1,008 children born in 2010 who received rotavirus vaccine dose 1 and pentavalent vaccine dose 1 on the same date.	1,008 children who received rota 1 and <u>penta 1 on the same date, weighted</u> 1,058 children born in 2010 who received rota 1, weighted =95.1% (CI 95% 93.6, 96.6)
5. Count the number of children who received the vaccine interest on the same date as the subsequent dose the second vaccine in step 4.	There were 15 children born in 2010 who received rotavirus vaccine dose 1 and pentavalent vaccine dose 2 on the same date.	15 children who received rota 1 and <u>penta 2 on the same date, weighted</u> 1,058 children born in 2010 who received rota 1, weighted =1.5% (CI 95% 0.6, 2.3)
6. Count the number of children who received the vaccine interest on the same date as the subsequent dose the second vaccine in step 5.	There were 0 children born in 2010 who received rotavirus vaccine dose 1 and pentavalent vaccine dose 3 on the same date.	0 children who received rota 1 and <u>penta 3 on the same date, weighted</u> 1,058 children born in 2010 who received rota 1, weighted = 0.0%

7. Count the number of children who received the vaccine interest on a different date than the other vaccine.	There were 35 children born in 2010 who received rotavirus vaccine dose 1 on a different date then pentavalent vaccine doses 1, 2, and 3	35 children who received rota 1 and <u>penta 1 on the same date, weighted</u> 1,058 children born in 2010 who received rota 1, weighted =3.4% (CI 95% 2.2, 4.7)
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Alternative Denominators

In Method 2, you may consider including all children, even those that did not receive the vaccine of interest.

Programmatic Implications

This analysis can highlight opportunities to improve vaccination services by ensuring that every child receives all of the indicated vaccines at each visit.

It may also highlight vaccinator flexibility and adaptability in giving all indicated vaccines at each visit, even if the doses are not scheduled for the same visit.

The results of this analysis may reflect shortages of vaccine, nationally or subnationally.

Limitations

In order to do this analysis, the data set must include complete dates of administration.

All Indicated Vaccines Administered at a Healthcare Visit

Goal: To assess if children receive all indicated immunizations during an immunization visit.

Assess

<u>Method 1:</u> If child is late receiving pentavalent 3 and it could be administered simultaneously with MMR, is the opportunity taken to administer the pentavalent 3 and MMR on the same date?

Table 28 shows the steps to assess if opportunities are taken to catch up late vaccines with an example using survey data from Country A.

Table 32. All Indicated Vaccines Administered, Option 1		
Steps	Example	Calculate the percentage of children in each category.
1. Choose the vaccine(s) of interest.	Pentavalent 3 and MMR	
2. Choose a group of children who were age- eligible for the vaccine of interest.	Children between 12 and 35 months of age	
3. Limit the group to children who had not received the earlier scheduled vaccine by the time they were eligible for the vaccine scheduled for an older age. This is the denominator.	There were 498 children between 12 and 35 months of age who had not received the third dose of pentavalent 3 by the time they reached the recommended age for MMR, 365 days of age.	
4. Count the number of children who did not received either vaccine.	There were 204 children between 12 and 35 months of age who did not receive either MMR or the 3rd dose of pentavalent before the time of the survey.	204 children who did not receive <u>MMR or pentavalent 3 vaccine, weighted</u> 498 children who did not receive pentavalent 3 by 365 days of age, weighted =40.7% (CI 95% 36.5, 45.0)
5. Count the number of children who received both vaccines on the same date. These children did not have a missed opportunity when they presented to the immunization clinic.	There were 60 children between 12 and 35 months of age who received MMR and the 3rd dose of pentavalent vaccine on the same date.	60 children who received both MMR and <u>pentavalent 3 on the same date, weighted</u> 498 children who did not receive pentavalent 3 by 365 days of age, weighted =12.1% (CI 95% 9.2, 15.0)
 Count the number of children who received the vaccine 1 but not vaccine 2. This is a numerator. 	There were 12 children between 12 and 35 months of age who received pentavalent 3 after 365 days of age but did not receive a dose of MMR before the time of the survey.	12 children who received <u>pentavalent 3 but not MMR, weighted</u> 498 children who did not receive pentavalent 3 by 365 days of age, weighted = 2.3% (CI 95% 1.1, 3.6)

7. Count the number of children who received vaccine 2 but not vaccine 1. This is a numerator.	There were 134 children between 12 and 35 months of age who received a dose of MMR but did not receive a third dose of pentavalent vaccine before the time of the survey.	134 children who received MMR <u>but not pentavalent 3, weighted</u> 498 children who did not receive pentavalent 3 by 365 days of age, weighted = 26.6% (CI 95% 22.6, 30.5)
8. Count the number of children who received neither both vaccines but not on the same date. This is also a numerator.	There were 88 children between 12 and 35 months of age who received both MMR and the 3rd dose of pentavalent but the two vaccines were administered on different dates.	88 children who received MMR and <u>pentavalent 3 on different dates, weighted</u> 498 children who did not receive pentavalent 3 by 365 days of age, weighted = 18.3% (CI 95% 14.9, 21.6)

<u>Method 2:</u> If a vaccine recommended for the second year of life was not administered before 24 months (730 days) of age, were other vaccines administered between 365 and 730 days of age?

Table 29 shows the steps to assess if opportunities to administer a late vaccine during timely and not timely periods with an example using survey data from Country A.

Table 33. All Indicated Vaccines Administered, Option 2		
Steps	Example	
1. Choose the vaccine(s) of interest.	MMR and yellow fever	
2. Choose a group of children who were age- eligible for the vaccine of interest.	Children 24 to 35 months	
 Limit the group to children who did not receive the vaccine by their next birthday. This is the denominator. 	There were 262 children did not received a either MMR or yellow fever by their second birthday.	
4. Count how many children received a different vaccine between the recommended age of the vaccine of interest and the birthday of interest. This is the numerator.	There were 96 children who had a date of administration for another vaccine between 12 months of age and 24 months of age.	
5. Calculate the percentage of children who had an opportunity to receive the vaccine of interest but did not.	96 children with an immunization visit <u>between 12 and 24 months, weighted</u> 262 children missing MMR or yellow fever at 24 months of age, weighted = 36.3% (CI 95% 29.7, 42.8)	

Programmatic Implications

Method 1 assesses if children with a delayed vaccination miss opportunities to be caught up at subsequent immunization visits.

Method 2 assesses if children with a late immunization had opportunities to be vaccinated before the vaccine became late.

Limitations

This analysis does not allow us to know which children had legitimate contraindications to vaccination.

The results of this analysis may be impacted by stock issues and shortages of vaccine.

In order to do this analysis, the data set must include complete dates of administration.

Visits Needed to Bring Up-to-Date

<u>Goal:</u> Assess how many additional immunization visits will be needed to catch children up for age, considering immunizations that can be administered in the same visit and minimum intervals between doses of the same vaccine.

Assess

Table 30 shows the steps to assess how many visits are needed to catch up children who are behind with an example using survey data from Country A.

Steps	Example	Calculate the percentage of children in each category.
1. Choose the vaccines of interest	OPV 1-3, pentavalent 1-3, MMR 1	
2. Choose a group of children who were age- eligible for the vaccine of interest.	Children between 18 and 35 months of age	
3. The total number of children in the target age group is the denominator.	There were 2,419 children between 18 and 35 months of age at the time of the survey.	
4. Count the number of vaccines needed for each child to be up to date for a specific age.	Count any vaccines missing that were not administered by 18 months of age. Child A received 3 OPV, 3 penta, 0 MMR. Child A is missing 1 vaccine. Child B received 3 OPV, 3 penta, 1 MMR.	
	Child B is missing 0 vaccines. Child C received 2 OPV, 1 penta, 1 MMR. Child C is missing 3 vaccines.	
5. Count the number of children who are up to date for age. This is the numerator.	1,908 children received all 7 vaccines before 18 months of age.	1,908 children received all 7 vaccines before <u>18 months of age, weighted</u> 2,419 children 18 months and older, weighted =79.1% (CI 95% 77.0, 81.2)
6. Determine the number of children missing 1 or more vaccines by subtracting the number of up-to-date children from all the children. This is the new denominator	2,419 [minus] 1,908 = 511	

7. Determine how many missing vaccines could be administered in the same visit for each child. All vaccines that can be administered in the same visit should be. Additional visits may be needed if the child is missing more than one vaccine in the same series.	Child A needs 1 visit to catch up 1 vaccine, MMR. Child B is already caught up Child C will need 2 visits to catch up: 1 visit for OPV 3 and penta 2, and a second visit for penta 3.	
9. Count how many children need 1 visit to be up-to-date. This is a numerator.	344 children need 1 visit to catch up.	344 children need 1 visit <u>to catch up, weighted</u> 511 children missing at least 1 vaccine, weighted =66.8% (CI 95% 62.7, 70.9)
10. Count how many children need 2 visits to be up-to-date. This is a numerator.	29 children need 2 visits to catch up.	29 children need 2 visits <u>to catch up, weighted</u> 511 children missing at least 1 vaccine, weighted =5.8% (CI 95% 3.9, 7.7)
11. Count how many children need 3 visits to be up-to-date. This is a numerator.	138 children need 3 visits to catch up.	138 children need 3 visit <u>to catch up, weighted</u> 511 children missing at least 1 vaccine, weighted =27.4% (Cl 95% 23.6, 31.1)

Programmatic Implications

This analysis provides information about how many visits will be needed for all children to be up to date.

Limitations

This analysis does not allow us to know which children had legitimate contraindications to vaccination.

The results of this analysis may be impacted by stock issues and shortages of vaccine.

In order to do this analysis, the data set must include complete dates of administration.

Modeling

We can use modeling techniques to better understand the risk factors associated with vaccination after the recommended age and non-vaccination.

Types of models

Three types of models have been used in the literature for vaccination timeliness

Logistic Regression

Possible outcomes in a logistic regression model include:

- Administered/not administered
- Timely/not timely
- Simultaneous/non-simultaneous
- Categorical timeliness

Cox Proportional Hazards

Possible outcomes in a time-to-event model (Cox regression) include:

- Individual dose administration
- Series completion

Poisson Regression

Poisson regression is used for rates from group level data.

Modeling Strategy

When modeling immunization data, we follow a normal modeling strategy with the following steps:

- 1. Choose covariates to model. Your choice of covariates will depend on the design of the study and the available data. Previously published models of timeliness have looked at:
 - Factors associated with the child or family (i.e. maternal education, SES)
 - Factors associated with the provider or facility (i.e. public or private facility, administered by a physician, nurse, or other vaccinator)
 - Factors associated with the community (i.e. region, urban/rural residence, community violence)
- 2. Check assumptions appropriate to the type of model
- 3. Assess interaction and confounding
- 4. Check goodness of fit of final model

Special Considerations

When modeling vaccination, it is important to remember that the timing of a dose series is not independent from the timing of previous doses in the same series. Models of timeliness should control for timing of previous dose by including it in the model. Previously published studies have also addressed this problem by considering administration of the entire series or time to series completion as the outcome, instead of individual doses.

Appendix

Sample Size

To calculate the needed number of children in the sample for the survey, we use the following formula for a simple random sample.

Example 13. Initial sample size calculation for estimating a binomial proportion

$$n_0 = \frac{t^2 pq}{d^2}$$

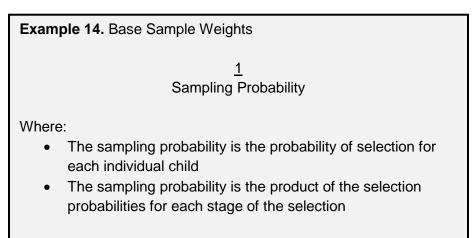
Where:

- n_{0:} is the simple size
- t: is equal to 1.96 for a 95% confidence interval.
- p: is the proportion vaccinated, in this example 0.5
- q: is the proportion unvaccinated, in this example 0.5
- d: is the desired precision for the estimate, in this example 0.02

Choosing 0.5 as the proportion of the total population that is vaccinated will lead to the largest sample size.

Additional Information about Sample Size

Weighted Samples



The base weight can be adjusted for non-response, and standardized to match external source of population totals, if they are available.

Weights are calculated based on the sampling process and the probability of being selected into the survey at each stage. This is different for every situation. The WHO 30 by 7 cluster survey is assumed to be self-weighting.

In the sample data from Country A, the processes for selecting participants in the capital region and outside of the capital region were different. Children in each area did not have the same chance of being selected to participate in the survey. The survey is weighted to reflect these differences.

In the example from Country A, all age eligible children in each household were included therefore this was not included in the calculation of the weights. Had one child from each household been randomly selected, we would account for this in the calculations for weighting.

DHS Weighting

DHS usually uses a two-stage, stratified household-based sampling design to select survey participants. There are four variables in the DHS that must be used when estimating statistics representative of the entire survey population: the primary sampling unit (PSU), cluster, stratum, and weight. These variables are included within the dataset. When weighted, DHS data represent the entire survey population. If calculating measures for population subgroups, there domain variable in the dataset.

The weights are only needed for analyses in which we want to estimate representative population statistics.

Design Effect

Example 15. Basic Design Effect Formula

Variance estimate accounting for cluster sampling Variance estimate under simple random sample

With a cluster design, to achieve the same precision as you would get under a simple random sample, the sample size needs to be increased. To calculate the needed sample size accounting for the cluster design, take the simple size calculated in Example 13 and multiply it by the design effect.

Usually, WHO recommends that design effect is 2 for a survey with 7 children enrolled per cluster, unless there is information from the data analysis phase of previous surveys that indicates the design effect should be larger or smaller for the factor we are interested in measuring. The design effect may be different for different factors.

An assumption of the design effect is used to account for survey design in determining needed sample size before the survey is collected. The observed design effect is used to calculate Intra Cluster Correlation (ICC) at the time of analysis.

Example 16. Sample size calculation, accounting for design effect

The formula for calculating sample size is:

 $n = n_0 * DE$

Where:

- n_{0:} is the simple size cacluated in Example 2
- DE is the design effect, usually 2

In the example from Country A, they used a design effect of 1.5 because of information from previous surveys. The calculation is:

2,400 * 1.5

= 3,600 children needed in the survey

Intra Cluster Correlation (ICC)

The ICC is a statistic that measures the tendency for measures of interest to be more similar for people in the same cluster. A larger ICC indicates greater similarity and therefore less information is obtained when selecting more participants from the same cluster. The result is a greater design effect. The ICC can be estimated for a given measure from survey data using observed design effect and the average number of responses in each cluster.

The ICC can inform the design and sample size needs of future surveys that measure the same factors. The ICC is a feature of the population, not the design of the study. Sometimes, ICC stands for intra class correlation but has the same meaning as intra cluster correlation.

Example 17. ICC calculation
ICC formula:
Design effect [minus] 1 Average number of responses per cluster [minus] 1 =ICC
MMR ICC example:
<u>1.7734 MMR design effect [minus] 1</u> 8.7 average children per cluster
=0.100

In a 30x7 survey design, we would expect the ICC to be about 0.167. Because the ICC is a feature of the population and is specific to the vaccine and dose we are measuring, there can be a lot of variability between countries, age groups, and vaccines.

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Sample Statistical Software Code

Additional Resources

Computer Programs

- a. R (free data analysis software)
- b. CDSi

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