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**CROSS-SECTIONAL STUDY ON PREVALENCE, GEOSPATIAL DISTRIBUTION  
AND CONTRIBUTING FACTORS OF 'ZERO DOSE' VACCINATION AMONG  
CHILDREN AGED 12 TO 23 MONTHS IN KWILU PROVINCE, DRC**

**STUDY PROTOCOL**

**June 2022**

<b>Sponsor</b>	Institut of Tropicale Medicine Nationalestraat 155 B-2000 Antwerp – Belgium
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## STATEMENT OF COMPLIANCE

This protocol contains the information necessary to conduct this research study. By signing this document, the Investigator agrees to conduct the study in accordance with the protocol, applicable ethical guidelines such as the Declaration of Helsinki, the European General Data Protection Regulation (GDPR), the ESF/ALLEA Code of Conduct for Research Integrity, as well as in compliance with international scientific standards and all applicable regulatory requirements. The Investigator will also make every reasonable effort to complete the study within the designated time frame.

Once the protocol has been published and signed by the Investigator(s) and authorized signatories, it cannot be informally amended. Amendments to the protocol have the same legal status and must go through the mandatory review and approval steps before being implemented.

Principal Investigator INRB

Dr Mutwadi Malembe Armand

Date: July 26, 2022

Signed: \_\_\_\_\_

Principal Investigator ITM

Prof. Marianne van der Sande

Date: July 26, 2022

Signed: \_\_\_\_\_

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## 0. Key Information

### **What is already known?**

- In 2020, an estimated 17 million children globally had not received any routine vaccinations, about half live in sub-Saharan Africa or conflict-affected areas.
- The Democratic Republic of the Congo (DRC) fully vaccination coverage at 12 months is highly variable depending on the source used and was, based on vaccination card revision, 18.4% in 2020 among children aged 12 to 23 months at the time of survey, while it rose to 42.5%, based on information provided by the mothers. The proportion of zero-dose children (= not a single dose of Diphtheria Tetanus and Pertussis vaccine received) aged 12 to 23 months was estimated at 10% in 2020 in the DRC.
- Zero-dose children especially remain vulnerable to vaccine-preventable diseases and can sustain transmission in otherwise highly vaccinated populations.
- A lack of understanding of the prevalence, risk factors and spatial distribution of zero-dose children makes targeting vaccination activities to reach this group challenging.

### **What knowledge is expected to arise from this study?**

- Estimate the prevalence of zero-dose children in the city of Kikwit at fine scale level, DRC
- Identify risk factors (socio-demographic, health area/zone features) of zero-dose children.
- Geolocate where these children reside in order to address the problem in a locally tailored approach, taking into account the particularities of the environment.
- Explore in depth reasons of no or partial vaccination.

## I. Rationale

Zero-dose children, defined as children who have not received a single dose of Diphtheria Tetanus and Pertussis (DTP) vaccine, remain vulnerable to vaccine-preventable diseases and can sustain transmission in otherwise highly vaccinated populations. There were an estimated 17 million zero-dose children in 2020, the majority living in sub-Saharan Africa or conflict-affected areas [1][2]. The Immunization Agenda 2030 (IA2030) has identified reaching out to zero-dose children as a strategic priority, and has set a target of a 50% reduction in the number of zero-dose children by 2030 [3].

According to the World Health Organization (WHO), vaccination is one of the most successful and cost-effective health interventions because it has drastically reduced infant and child mortality and the prevalence of several diseases. Vaccination has led to the eradication of smallpox, and has reduced the incidence of polio by more than 99% and that of neonatal tetanus by 94% worldwide [3].

The contribution of immunization is particularly critical to the achievement of the third Sustainable Development Goal (SDG) on health and well-being, specifically the goal: *by 2030, eliminate preventable deaths of newborns and children under 5 years of age*, with as target *all countries seeking to reduce neonatal mortality to no more than 12 per 1000 live births and child mortality (less than 5 years old) to 25 per 1000 live births at most* [5]. It is estimated that vaccination prevents 2.5 million child deaths each year. However, despite this success, millions of children living in low resource settings – nearly 20% of the annual total births – do not receive all the planned vaccinations in their first year of life (WHO, UNICEF, World Bank, 2010).

Communities whose children are partially or not at all vaccinated are most at risk of outbreaks. According to GAVI, zero-dose children are defined as children who have not received a single dose of Diphtheria Tetanus and Pertussis vaccine (DTP1 vaccine) [3][6][7].

Zero-dose prevalence in children aged 12 to 23 months ranged from 5.2% in upper-middle income countries to 11.1% in low-income countries, with a total pooled prevalence of 7.7% in all countries studied [3].

In a study published in India in 2020, it was observed that zero-dose children were concentrated among disadvantaged groups (the bottom wealth quintile) and among mothers with no formal education [8]; in addition, non-receipt of tetanus immunization for mothers during pregnancy was significantly associated with having zero-dose children [9]. A systematic review, including 202 articles, on reasons and factors related to the under-vaccination (= DTP3 not received) and non-vaccination of children

concluded that 45% of determinants associated with under-vaccination were related to immunization systems, 26% to family characteristics, 22% to parental attitudes and knowledge, and 7% to limitations in immunization-related communication and information [10].

In the DRC, despite progress in reducing under-five mortality from 158 per 1000 living births in 2007 [11] to 104 per 1000 living births in 2013[12], the situation remains worrying in relation to the global situation and the achievement of SDG 3. This excess child mortality is largely due to vaccine-preventable diseases [13].

Estimated immunization coverage in DRC in 2020, based on information from the vaccination cards, showed that only 18.4% of children aged 12 to 23 months had been fully vaccinated before the age of 12 months. Taking into account the information provided by the mothers, this percentage rose to 42.5%, while the zero-dose children represented 10% during the vaccination coverage survey in 2020 [14]. This discrepancy between register and maternal recall data underscores the relevance of an independent validation of prevalence, distribution and associated risk factors of zero-dose children.

A lack of understanding of the burden, the risk factors, and spatial distribution of zero-dose children makes targeting vaccination activities to reach this group challenging. In this study, we aim to determine the prevalence of this problem and identify risk factors of zero-dose status among children aged 12 to 23 months in the Province of Kwilu (DRC).

## II. Research Question

- What are the prevalence, the geospatial distribution and contributing factors of zero-dose children aged 12 to 23 months in the Kwilu province, DRC in 2022?

## III. Aim:

- Determine the prevalence, geospatial distribution and contributing factors of zero-dose children aged 12 to 23 months in the DRC in 2022

## IV. Specific objectives

- Determine socio-demographic, geospatial, and health area/district characteristics of vaccination coverage
- Calculate the prevalence of zero-dose children, defined as the proportion of children aged 12 to 23 months who did not receive DTP1 at the age of 12 months among targeted children.
- Determine the spatial distribution of zero-dose children
- Identify risk factors associated to zero-dose children

- Explore reasons of no or partial vaccination and parent's perception on activities related to vaccination
- Secondary objective: calculate the prevalence of children that didn't receive the measles vaccination at 12 months of age.

## **V. Methods**

### **A. Type of study**

We will use a mixed study design, including a cross-sectional study to evaluate coverage and associated factors, and a qualitative study in the form of focus group discussions to explore and deepen the reasons for non- or partial vaccination.

### **B. Study site**

The survey will take place in Kikwit city, which has two health zones, the health zone of North Kikwit and the health zone of South Kikwit. Kikwit city is located in the province of Kwilu, neighboring Kinshasa to the west side. It is limited in the west by the city of Bandundu and by the two Kasaïs in the east. The city of Kikwit is 525 kilometers away from Kinshasa and 400 kilometers from the city of Bandundu.

The city of Kikwit spreads over an area of 92 km<sup>2</sup>, and has a total population estimated at 1,326,068 inhabitants [14]. It has a humid tropical climate. An alternation of two seasons is observed: a long rainy season from September to May (9 months), interspersed by a short dry season from mid-January to mid-February and the dry season from June to August. North Kikwit Health Zone is urbanized, while South Kikwit Health Zone has still a lot of rural characteristics.

### **C. Quantitative part**

#### **Sampling**

#### **Study population**

The survey targets children aged 12 to 23 months at the moment of survey. Respondents will be heads of household, mothers and guardians, and full or assistant nurses. In each health area, the main health center will be selected for a closed interview on the demographic characteristics of the health area and vaccination activities (see below the list of key variables).

#### **Estimated sample size**

The sample size was estimated using the following formula for estimating a proportion in each health zone:



$$n \geq \frac{Z^2 \times p \times q}{d^2} \times \text{deff}$$

where

- Z: confidence coefficient for a confidence threshold of 95%
- p: proportion of zero-dose children aged 12-23 months in the DRC = 10%;
- q: reciprocal of p (q=1- 0.10)
- d eff: cluster effect (design effect = 2);
- d: degree of precision (3%);

The minimum sample size (children 12-23 months of age) at the health zone level is calculated on the basis of an estimated 10% zero-dose children (according to the vaccine coverage survey in 2020); a confidence level at the threshold of 95%; and a precision of 3%, taking into account a cluster effect of 2, and having 24 clusters for North Kikwit health zone and 25 clusters for South Kikwit health zone. This minimum size was increased by 10% to take into account non-responses, leading to a sample size per health zone of 864 (and 900 for North HZ) children, or 36 children per health area (or cluster). For the two zones (49 health areas), the total sample size is 1764 children. aged 12 to 23 months.

This sample size also allows to detect with 95% precision a difference of 4 % between the two zones, starting from 10% baseline estimate in one of the zones (difference detected between 6 and 14% with 80% power and an alfa of 5%).

## Sampling technique

The survey will use two-stage cluster sampling. To do this, each health zone (HZ) was considered an area of study, and in each area of study, health areas (HAs) are considered as clusters. All 49 health areas (= all clusters) will be included.

In practical terms, we will proceed as follows:

- At 1st degree (primary sampling unit): in each cluster, 6 avenues (or villages for the rural places) will be randomly selected based on a map or on a list of villages
- At 2nd degree (secondary survey unit): in each selected avenue/village, 6 households will be selected based on a systematic random sampling technique. The identification will be as follows: on beforehand a starting point of the avenue, or the central place of a village will be identified. The study team will then go to that starting point of avenue (or central place of village identifying the street to enter with a bottle-spinning) and take the 3<sup>rd</sup> house to the left to see if there are children according inclusion criteria. If so, and consent is given, the child is included; and then the team is entering each following 3<sup>rd</sup> house (on the left side of the street) up to the sample size (6 children per street) is reached or the end of

the avenue/street is reached. In case the sample size is not reached at the end of the avenue/street, the team goes back to the starting point and takes the street/avenue to the right (or in a village re-spin the bottle), and enters again in the 3<sup>rd</sup> house on the left side of the street; team continues up to reaching the sample size of 6 children per avenue/village.

- In the household, all children between the age of 12 to 23 months will be included in the survey (also if there is more than 1 child in this age range)

In households with children aged 12-23 months selected, the interviewer will fill in the questionnaire with the mother/guardian of the child aged 12-23 months (or the head of household). All eligible children in a household will be investigated and a questionnaire need to be filled for each included child.

### **At the household level**

Once in a household with a target (child 12-23 months old), we will approach the head of household or his or her alternate (husband or wife), who will answer questions about the household and introduce us to the mother/guardian who will answer questions about her and those addressed for the child. So, it is possible that we will have a respondent head of household and mother/guardian of the child.

### **At the level of Health Centers**

Before reaching the health facilities, we will first go to the central office of the health zone to inform them about the study and obtain authorizations. Each health zone is administratively subdivided into health areas.

In each health area, there is a health center that centralizes all health information from the health area and sends it to the central office of the health zone. So, in each health area, we will visit at least one health center, because there are health areas with more than one health center that report to the health zone.

The respondent at the health center level will be the head nurse of the health area or his/her deputy.

### **List of key variables**

<b>Household Questionnaire</b>		
1	Socio-demographic characteristics of the household and head of household	- Type of environment (urban/rural)
		- Geolocation of the household,
		- Age of head of household,
		- Gender of head of household
		- Religion of the head of household,
		- Occupation of the head of household,
		- Number of persons in the household, number of children under 5 years of age,

		<ul style="list-style-type: none"> <li>- Number of children from 6 to 11 months,</li> <li>- Number of children from 12 to 23 months,</li> <li>- Possession of goods (electricity, radio, TV, landline telephone, refrigerator, bed, generator, etc.)</li> </ul>
2	Socio-demographic characteristics of the mother/guardian	<ul style="list-style-type: none"> <li>- Age</li> <li>- Marital status,</li> <li>- Level of education,</li> <li>- Religion</li> <li>- Profession</li> <li>- Age</li> <li>- Gender;</li> </ul>
3	Characteristics of the included child	<ul style="list-style-type: none"> <li>- Brachial perimeter</li> <li>- Possession of the vaccination card</li> <li>- Vaccination status of the child for each antigen;</li> </ul>
4	Variables related to childhood immunization	<ul style="list-style-type: none"> <li>- Date of vaccination for each antigen received (day, month, year),</li> <li>- Source of information (vaccination card, vaccination register, mother's declaration)</li> <li>- Participation in a vaccination campaign,</li> <li>- Vaccines received during vaccination campaigns,</li> <li>- Reason for non-vaccination,</li> <li>- Attitude towards the vaccination of children,</li> <li>- Use of vaccination services since the outbreak of Covid-19 in the DRC.</li> <li>- Use of vaccination services since the outbreak of Covid-19 in the DRC.</li> <li>- Area of health centre</li> </ul>
<b>Health Center Questionnaire</b>		
1	Health area characteristics	<ul style="list-style-type: none"> <li>- Number of inhabitants by age group</li> <li>- Number of vaccination sites by strategy (fixed and advanced)</li> <li>- Availability of vaccines</li> <li>- Availability of other inputs (syringes, thinners, scorecards, etc.)</li> </ul>
2	Availability of vaccines and other immunization inputs in the 12 months prior to the survey	<ul style="list-style-type: none"> <li>- Availability of completed records</li> </ul>
		<ul style="list-style-type: none"> <li>- Holding vaccination cards</li> </ul>
3	Availability of registry and vaccination card in the 12 months prior to the survey	<ul style="list-style-type: none"> <li>- Number of sessions overall</li> <li>- Number of sessions per fixed strategy</li> </ul>
4	Number of vaccination sessions held in the health area per month in the past 12 months	<ul style="list-style-type: none"> <li>- Number of sessions per advanced strategy</li> </ul>

## **Recruitment and training of field teams**

Data will be collected by a total of 50 data collectors (medical students in the last year of training) – 2 data collectors working together in 2 health areas. They will be supervised by a supervisor – in total there will be 10 supervisors (5 in each health zone); one supervisor will be responsible of 5 health areas and 10 data collectors. The field supervisor will be responsible to ensure the implementation of the study (preparing, organizing, and directing the work) in the areas assigned to him/her. As such, he/she will be responsible for ensuring that data collection is done in accordance with the procedures detailed in the research protocol and that the data collected are of good quality.

During 3 days, data collectors will be trained on the importance of data and data collection for scientific investigation and research ethics. It will also cover the objectives of the survey, the data collection procedure, the content of the questionnaire and the use of tablet for data collection/entry. On the fourth day, the entire study team will go into the field (real targets in a health area not included in the study) for the practical part of pre-testing the questionnaire and rehearsing household selection and data collection using the tablet.

The results of the pre-test will be used to revise the questionnaire in case there are inconsistencies in understanding, to assess the interviewers' mastery of the survey methodology and to correct any systematic errors.

## **Programming the tablet with the data collection instruments**

The programming of the tablet data collection tool will be done by Patrick Mutombo, INRB data management expert. A sufficient number of tablets will be made available according to the number of interviewers and supervisors in the two health zones.

The standard MICS questionnaire for children under five years of age in its contextualized immunization component for the DRC will be complemented with additional questions related to factors estimated to be associated with partial or non-vaccination and knowledge of the importance of vaccination. Questionnaire on household socio-demographic characteristics is drawn from the Demographic and Health Surveys (DHS) conducted in DRC.

## **Data Management**

All data tools will be filled in French (but questions can be translated on the spot to local language in case the respondent doesn't understand the question), checked for

completeness, consistency and other quality aspects before analysis. The data collected with the Kobo collect/ODK application will be stored on the server (max of 10 years) secured by a password to which only a restricted team leading the project will have access. Access to outsiders can be requested and allowed if request deemed relevant by the research team.

### **Data collection itself**

The data to be collected for the survey will be encoded on an android tablet through a program called “Kobo collect or Open Data Kit collection (ODK)” that is currently widely used in public health data collection programs throughout Africa. All data, including GPS coordinates, will be transmitted from the interviewer’s tablet to a secure virtual server after collection. However, in order to ensure quality control, the collected data will be saved until it is verified for accuracy by the field supervisor, as described below. Only then will the field supervisor be able to submit the completed form to the server.

### **Quality control of field data collection:**

An ongoing process to ensure quality data throughout the collection will be carried out by the field supervisor, and by the data collector, with the following methodology:

- *At the beginning of each day’s work:* The field supervisor should designate to each data collector in his or her team all the households and health facilities to be interviewed. The field supervisor should also insist that no household can be replaced unilaterally and without the permission of the supervisor;
- *During the day’s work:* During the primary visit, the field supervisor should select at random from the list of households to be interviewed for that day, a few households to be surveyed and then visit them personally to verify the effectiveness of the data collector’s visit and the administration of the questionnaire to an eligible person;
- *At the end of the day’s work:* the field supervisor checks with the data collector all the data encoded during the day and possibly correct any errors, either directly or after a second visit to the household. Only after all these checks, the field supervisor will submit the completed form to the server (while keeping a copy on the tablet up to the end of the study as back up).

### **Data security/Anonymization or pseudonymization**

### **Data sharing**

Access to outsiders can be requested and allowed if request deemed relevant by the research team. The study will make its research data available for secondary research or to support research on non- and/or partial vaccination of children by considering the following key aspects:

- The ITM data sharing policy will be followed, with the following key aspects mentioned below.
- The European FAIR data principles ("Findable"; "Accessible"; "Interoperable"; "Reusable") will also be followed ("as open as possible, as closed as necessary")
- Ensure confidentiality by anonymizing its data (e.g., replacing the study subject's identification code with a new code that can no longer be used to identify the patient; generalizing and randomizing specific variables)
- Ensuring that ethical approvals have been obtained by ethics committees and by study participants.
- Making available data, primarily medical, personal and sensitive, through a governed data access mechanism and along a transparent decision-making process, with:

(i) Completion of a data request form,

(ii) Evaluation through a data access committee,

(iii) agreement to share data by that committee,

(iv) secure transfer of anonymized data,

(v) additional metadata that clarifies the research data. The metadata will include the study protocol, questionnaire(s), data dictionary.

## **Record retention**

The principal investigator is responsible for the retention of all essential documents listed in the Good Clinical Practice guideline: Informed Consent (Form) or IC(F) or Informed Consent Form. All essential documentation for all study subjects must be retained by the principal investigator in a secure storage facility for a minimum of 20 years in accordance with NIBR policies or local country regulatory requirements (whichever is longer). The DRC requires that study records be retained for up to 2 years after publication. These records must also be retained in accordance with the ethics committee's medical record retention requirements, whichever is longer.

## **Data processing and analysis**

Data analysis will be done using R Version 4.0.5 software and will take place in two stages. First, the data will be uploaded on a regular basis by the team of investigators to check their quality using a working file. To verify data quality, frequency tables will be

produced for each variable to identify outliers and missing responses. Second, the data will be analyzed to produce the expected frequencies, including the main indicators by health zone.

Tables of frequencies for the following indicators will be produced (including 95% CI):

- Proportion of zero-dose children
- Proportion of children for whom a vaccination card is present.
- Proportion of children, overall and by age group, who received the BCG vaccine at birth.
- Proportion of children, overall and by age group, who have received all the doses of vaccines in time as per official vaccination schedule of DRC.
- Proportion of children under-vaccinated, define as not having received DTP3.
- Proportion of zero-measles children at 12 months, i.e., never received measles vaccination.
- A multilevel logistic regression model will be used to identify factors associated with zero-dose status and zero-measles children.
- Hotspot analysis (geospatial clustering) will be used to identify areas in which children are most at risk of being zero-dose

The variables relating to the characteristics of the health facility, the health area, as well as the socio-demographic variables of the head of household and the mother/guardian of the child will be the main variables that will be evaluated for association with the zero-dose children.

#### **D. Qualitative part**

This part will be done in a second step, adapting the interview guides for key-stakeholder in depth interview and questions for Focus Group Discussions to the findings of the quantitative cross-sectional survey. The detailed methodology and data collection tools will be elaborated and submitted as an amendment to this protocol in a later stage.

#### **E. Ethical Considerations**

##### **Ethical Approval and Permissions**

We will submit the study protocol to the Kinshasa School of Public Health and Institute of Tropical Medicine's IRB for approval. The data will be kept without personal identifying information and remain confidential. Any identifying data temporarily recorded during the survey will only be used for quality control by the supervisor.

For all study data: Participants will not be identified in any written or oral report, especially in relation to the data they provided. Participant's information will not be released to anybody outside the research team.

## **Consent**

Prior to conducting the interviews, the data collector shall follow the process to obtain informed consent. The data collector will explain the project, how responses will be used, and data be kept, answer any questions participants may have, and obtain written informed consent, by signing the form.

## **Compensation**

The respondents will not receive payment for participating in this study.

## **Benefice of the study**

The expected benefits of this study will be the identification of the importance of zero-dose children per health zone and its associated factors. This information can guide vaccination strategies to decrease the number of children, vulnerable to vaccine-preventable diseases, and to reduce their impact on sustained disease transmission even among highly vaccinated populations.

## **F. COVID-19 Precautions**

In case the COVID-epidemic is still ongoing and in order to minimize the risk of COVID-19 for participants and the data collector conducting the interviews, a series of COVID-19 precautionary measures will be taken.

Just prior to convening the one-to-one (face-to-face) interviews, the data collector will humbly ask interviewees if they are experiencing any symptoms of illness. Interviewees exhibiting signs of illness will not be interviewed.

If your child is exhibiting clinical signs of illness when we are visiting you, we will advise you what to do and refer you to a health center for proper care.

### **At the time of interview:**

- The Data Collector conducting the interviews will wear face masks at all times. The Data collector may offer a face mask to interviewee if does not have one.
- The Data collector will use alcohol-based hand sanitizers to sanitize hands before entering the room for conducting interview.
- Physical contact between the Data collector and Interviewee must be minimized as much as possible.
- Where digital device is being used for recording the interview, the Data collector shall be responsible for handling the digital recorders before, during and after each interview session. Digital recorders will be wiped down with 70% alcohol swabs at the start and end of each session.



- The Data collector shall not share any materials (pens, pencils, paper, and devices) with the interviewee.

## VI. Scope of Work Proposal Timeline (2022)

Key milestones	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan
Mentor meetings									
Updating protocol and study tools									
Ethical approval									
Contacting health facilities authorities at provincial level									
Data collector recruitment									
Data collector training for quantitative data collection									
Quantitative data collection									
Data Analysis									
Manuscript writing									

## VII. Budget

## VIII. References

- [1] "Vaccination and Immunization Statistics - UNICEF DATA." <https://data.unicef.org/topic/child-health/immunization/> (accessed May 09, 2022).
- [2] J. Cadena, A. Marathe, and A. Vullikanti, "Critical Spatial Clusters for Vaccine Preventable Diseases," *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*, vol. 12268 LNCS, pp. 213–223, 2020, doi: 10.1007/978-3-030-61255-9\_21.
- [3] B. O. Cata-Preta, T. M. Santos, T. Mengistu, D. R. Hogan, A. J. D. Barros, and C. G. Victora, "Zero-dose children and the immunisation cascade: Understanding immunisation pathways in low and middle-income countries," *Vaccine*, vol. 39, no. 32, pp. 4564–4570, 2021, doi: 10.1016/j.vaccine.2021.02.072.
- [4] I. Division, "Global routine vaccination coverage, 2018 – Couverture de la vaccination systématique dans le monde, 2018," *Weekly Epidemiological Record = Relevé épidémiologique hebdomadaire*, vol. 94, no. 43, pp. 498–504, 2019, doi: 10.15406/ijvv.2015.01.00004.Burton.
- [5] Y. HARUYAMA, "Building Health Impact Assessment in community health promotion," *Japanese Journal of Health Education and Promotion*, vol. 19, no. 1, pp. 77–82, 2011.

- [6] A. N. Chard, M. Gacic-dobo, M. S. Diallo, S. V Sodha, and A. S. Wallace, "Routine Vaccination Coverage — Worldwide , 2019," vol. 69, no. 45, pp. 1706–1710, 2020.
- [7] WHO, "Immunization Agenda 2030," pp. 1–24, 2021, [Online]. Available: [https://www.who.int/immunization/ia2030\\_Draft\\_One\\_English.pdf?ua=1](https://www.who.int/immunization/ia2030_Draft_One_English.pdf?ua=1)
- [8] M. Johri, S. Rajpal, and S. V. Subramanian, "Progress in reaching unvaccinated (zero-dose) children in India, 1992–2016: a multilevel, geospatial analysis of repeated cross-sectional surveys," *Lancet Glob Health*, vol. 9, no. 12, pp. e1697–e1706, 2021, doi: 10.1016/S2214-109X(21)00349-1.
- [9] D. Sissoko, H. Trottier, D. Malvy, and M. Johri, "The influence of compositional and contextual factors on non-receipt of basic vaccines among children of 12-23-month old in India: A multilevel analysis," *PLoS One*, vol. 9, no. 9, 2014, doi: 10.1371/journal.pone.0106528.
- [10] J. J. Rainey, M. Watkins, T. K. Ryman, P. Sandhu, A. Bo, and K. Banerjee, "Reasons related to non-vaccination and under-vaccination of children in low and middle income countries: Findings from a systematic review of the published literature, 1999-2009," *Vaccine*, vol. 29, no. 46, pp. 8215–8221, 2011, doi: 10.1016/j.vaccine.2011.08.096.
- [11] Ministère du Plan et Macro International, "Enquête Démographique et de Santé, République Démocratique du Congo 2007," *Calverton, Maryland, U.S.A. : Ministère du Plan et Macro International*, pp. 1–499, 2008.
- [12] M. de la S. P. (MSP) et I. I. Ministère du Plan et Suivi de la Mise en œuvre de la Révolution de la Modernité, "Enquête Démographique et de Santé en République Démocratique du Congo 2013-2014.," *Rockville, Maryland, USA : MPSMRM, MSP et ICF International*, p. 34, 2014.
- [13] C. H. Ngwa, B. C. K. Dountsop, R. Bihniwi, N. V. Ngo, and N. M. Yang, "Burden of vaccine-preventable diseases, trends in vaccine coverage and current challenges in the implementation of the expanded program on immunization: A situation analysis of Cameroon," *Hum Vaccin Immunother*, vol. 18, no. 1, 2022, doi: 10.1080/21645515.2021.1939620.
- [14] "Ville de Kikwit – CAID." <https://www.caid.cd/index.php/donnees-par-villes/ville-de-kikwit/?domaine=fiche> (accessed May 30, 2022).

## ANNEXE: STUDY QUESTIONNAIRE

### SECTION 1. ENUMERATION FORM AND IDENTIFICATION OF THE HOUSEHOLD

1. Enumeration Form and Identification of the Household		
Q100	Health Zone Name	
Q101	Cluster Name (Health Area)	
Q102	Name of Avenue /street/village	.....N°.....
Q103	Household location medium	1. Urban

		2. Rural
Q104	surveyor's name	
Q105	Field Supervisor Name	
Q106	Date of the visit	
Q107	Time of the visit	
Q108	Building ID Number	Number
Q109	Occupation: this construction houses households? [If "No", go to the next building and the next line of the form.]	1: Yes; 2: No
Q110	Household serial number (F) in the building	
Q111	Household ID Number	Building ID Number - Household Serial Number (e.g. 44-3)
Q112	Address or description	Open text
Q113	Latitude	##, ####
Q114	Longitude	##, ####
Q115	Visit N°	
Q116	Start date of the interview during visit	Date
Q117	Start time of the interview during visit	Hour
Q118	Code of Conduct for the Visit	Coming back later: absent from the household To be completed: interview started but not completed Refusal: someone is present, but refuses to participate

## SECTION 2. CHARACTERISTICS OF THE HOUSEHOLD

2. Household characteristics		
Q201	Gender of head of household	Masculine Feminine
Q202	What is the current marital status of the head of household?	Married Common-law relationship Separate Bachelor Divorced Widower (widower)
Q203	On what day, month and year was the head of household born?	
Q204	How old is the head of household now?	Age in years
Q205	What is the highest level of education attained by the head of the household?	Never been to school Primary
	The investigator will ask the preliminary question of whether the head of household attended the school?	Secondary
	Circle a single answer	Upper
		Don't know

		Non-response
Q206	What is the profession of the head of household? Circle a single answer	No occupancy
		Teacher
		Official
		Farmer/breeder
		Fisherman
		Merchant
		Blue collar
		Other (to be specified)
Q207	Currently, what is the religion of the head of household?	No religion
		Catholic
		Protestant
		Kimbanguist
		Muslim
		Revival/independent church
		Other religion (to be specified)
		Don't know
Q208	What is the ethnicity of the head of household	No answer
		1. Mbala
		2. Mbunda
		3. Pende
		4. Kongo
		5. Luba
		6. Swahili
		7. Mungala
		8. Other
Q209	Is there in this household:	9. No answer
	[A] a TV?	Yes No
	[B] a radio?	1 2
	[C] a refrigerator?	1 2
Q210	Does a member of your household have:	1 2
	[A] a wristwatch?	1 2
	[B] a bicycle?	1 2
	[C] a motorcycle?	1 2
	[D] a car, a truck or a van?	1 2
	[E] cart with animal?	1 2
	[F] Boat with motor?	1 2
	[G] canoe?	1 2
Q211	Does a member of this household have a computer?	1. Yes 2. No
Q212	Does a member of this household have a mobile phone?	1. Yes 2. No
Q213	Do you have internet access at home?	1 Yes 2. No

Q214	Does you or anyone else living in this household own this home?	
	If "No" ask: Are you renting this home from someone else who doesn't live in this household?	Owner 1
	If "Rented from someone else" record "2". For	Tenant 2
	" Other responses", record "6" and specify	Other (specify)
Q215	Does a member of this household have a bank account?	1. Yes 2. No 3. Don't know
Q216	Are you covered by health insurance?	1. Yes 2. No
Q217	What types of health insurance are you covered by?	Mutual organization of health /
		Community basic health insurance a
		Employer's health insurance b
		Social security c
		Other private commercial health insurance
		Purchased.....
		Don't know
Q218	Does your household own land?	No Answer
Q218	Does your household own land?	1.yes
		2.No
Q219	If so, how many square meters does it have?	.....
Q220	Does your household have livestock?	1. Yes
		2. No
Q221	If yes, for each of the following livestock, say how many the household has.	Cattle
		Cattle (cows,
		Oxen)
		Sheep/dear
		Pigs
		Poultry
Q222	Total number of household members?	Other to be specified
Q223	Number of children under 5 years old?	
Q224	Number of children aged 12-23 months?	
Q225	If there is more than one child aged 12 to 23 months in the household, do they all have the same guardian mother?	Yes 1
		No 2
Q226	If not, how many mothers who are caregivers aged 12 to 23 months in this household?	

### SECTION 3. SOCIO-DEMOGRAPHIC CHARACTERISTICS OF MOTHER/GUARDIAN

3. SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE MOTHER/GUARDIAN OF THE CHILD AGED 12-23 MONTHS		
Q300		1. Mother of the child

	What is the relationship between the respondent and the selected child?	2. Guardian
Q301	What is the current marital status of the child's mother/guardian?	Bride
		Common-law relationship
		Separate
		Bachelor
		Divorcee
		Widow
Q302	On what day, month (*) and year was the child's mother/guardian born?	
Q303	How old is the mother/guardian of the child?	Age in years
	Compare and correct if necessary according to QA102	Don't know
		No- answer
Q304	What is the highest level of education achieved by the mother/guardian of the child?	Never been to school
	The investigator will ask the preliminary question of whether the child's mother/guardian attended school?	Primary
	Circle a single answer	Secondary
		Upper
		Don't know
		Non-response
Q305	Currently, what is the profession of the mother/guardian of the child?	Without a profession
		Teacher
		Official
		Farmer/breeder
		Fisherwomen?
		Merchant
		Blue collar?
		Other (to be specified)
Q306	Currently, what is the religion of the mother/guardian of the child?	No religion
		Catholic
		Protestant
		Kimbanguist
		Muslim
		Revival/independent church
		Other religion (to be specified)
		Don't know
Q307	Did the mother of this child receive TETANOS vaccine during or before the pregnancy?	No answer
		Yes 1
		No 2
Q307A	If yes, how many doses (shots) of TETANOS vaccine she received?	Don't know 3
Q308	Did the mother of this child had antenatal care visit during the last pregnancy?	Yes 1
		No 2
		Don't know 3
Q308A	If yes, how many visit of antenatal care she had?	

Q309	During the last 3 months, did Community healthcare workers visit you at home?	
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#### SECTION 4. VACCINATION OF CHILDREN AGED 12 TO 23 MONTHS

4. VACCINATION OF CHILDREN AGED 12-23 MONTHS		
Q401	Child's full name	Open text
Q402	Name of the child's father	Open text
Q403	Name of the child's mother	Open text
Q404	Sex of the child	1. Male
		2. Feminine
Q405	Brachial perimeter	.....cm
<p>NOTE: BEFORE I START THE INTERVIEW, COULD YOU PLEASE BRING (name's) birth certificate, his or her vaccination card/record or any vaccination card from a private health worker? We will need to refer to these documents.</p>		
Q406	DATE OF BIRTH	
Q407	On what day,	Day
Q408	In Which Month	Month
Q409	In what year (name) was he/she born?	Year
Q410	Do you have a vaccination booklet/card or a document from a private health worker where vaccinations of (name) are recorded?	Yes, has only one notebook/card 1 yes, has only another document 2 Yes, has a notebook/card and other document.... 3 No, has no notebook/card or other document 4
Q411	Have you ever had a vaccination booklet/card or a document from a health worker for (name)?	Yes 1 No 2
Q412	Can I see the notebook/card (and/or) the other document?	Yes, notebook/card only seen 1 yes, other document only seen 2 Yes, notebook/card and other document seen ..... 3 No notebook/card or other document seen ..... 4 Date of vaccination
Q413	Take picture of the document	
Q413	<b>For each vaccine, indicate:</b>	
	Data source	Mother/Guardian Statement
		Vaccination card or other document
	Date of vaccination	
	BCG	
	OPV 0	
	DTP1-HepB1+Hib1	
	OPV 1	
	Pneumo 1	
	Rota1	

	DTP2-HepB2+Hib2	
	OPV 2	
	Pneumo 2	
	Rota2	
	DTP3-HepB3+Hib3	
	OPV 3	
	Pneumo 3	
	IPV	
	Rota3	
	Measles Vaccine	
	Amaryl vaccine	
Q414	Why is the card no longer available?	Lost Card 1
		Destroyed map 2
		Don't know 3
Q415	Why didn't the child receive a vaccination card?	Card kept in the center Out of stock in center 2
		Don't know 99 Other to specify 3
Q416	Childhood immunization status	Not vaccinated ..... 1
		Partially vaccinated..... 2 Completely vaccinated..... 3
Q417	Why didn't the child receive all the recommended vaccines?	
Q418	Have you ever brought a child to the health centre to vaccinate him or her and he or she has not been vaccinated?	1: Yes
		2: No
		99: Don't remember

**SECTION 5. LEVEL OF INFORMATION FOR MOTHERS/GUARDIANS OF 12 Q 23 MONTHS OF AGE ON VACCINATION**

5. LEVEL OF INFORMATION AMONG MOTHERS/GUARDIANS OF CHILDREN AGED 12-23 MONTHS ON VACCINATION			
			Yes No
Q501	Do you know the diseases of children that can be prevented by vaccination? if so, quote them.	Tuberculosis	1 2
		Diphtheria	1 2
		Whooping cough	1 2
		Hepatitis	1 2
		Haemophilus influenzae b	1 2
		Poliomyelitis	1 2
		Measles	1 2
		Yellow fever	1 2
		Tetanus	1 2
		Pneumonia	1 2
		Meningitis	1 2
		Diarrhoea	1 2
		Don't know	1 2
		Other (to be specified)	1 2



Q502	Who do you think are the best people to talk to you about vaccination?	Health personnel	1	2
		Parents	1	2
		Grandparents	1	2
		Other parents	1	2
		Friends/colleagues/neighbours	1	2
		Social mobilizers / community relays	1	2
		Chief quarter/village/customary	1	2
		Journalist	1	2
		Opinion leader	1	2
		Theatre actor	1	2
		Pastor/Priest/Imam	1	2
		Traditional practitioner	1	2
		Other (to be specified)	1	2
		Don't know	1	2
Q503	What are your preferred information channels to be informed about routine vaccination?	Television	1	2
		Radio	1	2
		Associations/meetings	1	2
		Social mobilizers/community relays	1	2
		Posters/banners	1	2
		Newspapers	1	2
		Church/Mosque	1	2
		Health personnel	1	2
		Neighbouring friends/colleagues	1	2
		Sound vehicles	1	2
		SMS	1	2
		Internet	1	2
		Billboards	1	2
		Other (to be specified)	1	2
Q504	At what time of day would you like information about vaccination?			
Q505	Do you receive home visits from community relays?			

## SECTION 6. HEALTH CENTRE QUESTIONNAIRE

6. SURVEY IN HEALTH CENTRES		
<b>Q601</b>	<b>DEMOGRAPHIC DATA</b>	
Q6011	Latitude	
Q6012	Longitude	

Q6013	Area of health area	
	In this health area, give:	# and their proportion in %
Q6014	1. Total population	I_____I
Q6015	2. Number of children aged 0 to 59 months	
Q6016	3. Number of children aged 0 to 5 months	I_____I
Q6017	4. Number of children aged 6 to 11 months	I_____I I_____I
Q6018	5. Number of children aged 12 to 23 months	I_____I I_____I
Q6019	6. How many villages/streets/avenues have the health area	I_____I I_____I
<b>Q602</b>	<b>AVAILABILITY OF VACCINES IN THE 12 MONTHS PRECEDING THE SURVEY</b>	
Q6021	1. In the Health Zone, in the past 12 months, has there been:	
Q6022	Vaccine out of stock?.....	
Q6022A	If yes, specify which vaccine(s) (list of antigens) (list of inputs to be added):	1. Yes 2. No
Q6023	2. Have there been any inaccessible villages/streets/avenues in your health area in the last 12 months? If so, how many are they?	1. Yes 2. No
Q6023A	If yes, specify the reason(s) for the inaccessibility	I_____I
Q6024	3. In the last 12 months, was the cold chain functional?	
Q6024A	If not, specify the cold chain problem(s):	1. Yes 2. No
Q6025	4. Are there partners who support vaccination in your health area?	
Q6025A	If yes, indicate the name(s) of this Partner(s):	1. Yes 2. No
Q6026	5. In the last two years Have vaccination officers been trained/retrained?	
Q6026A	If so, on which theme(s)?	1. Yes 2. No
Q6027	6. What does it cost families to vaccinate a child in your health area?	
Q6027A	Vaccination Card \u2012 Equipment	
Q6027B	Other cost	Amount: I_____I FC
<b>Q603</b>	<b>AVAILABILITY OF THE VACCINATION CARD IN THE LAST 12 MONTHS</b>	
Q6031	Where are vaccination cards kept?	<div>At the Health center.</div> <div>By the mothers/guardians of the children.</div> <div>By mothers/babysitters and a copy to HEALTH CENTER.</div>

Q6032	In this HEALTH CENTER, how many providers were responsible for vaccinating children in the last 12 months (November 2020 to November 2021)?	
Q6033	How many training sessions or retraining have these providers participated in in the last two years, i.e. the years 2020 and 2021?	
<b>Q604</b>	Number of training/refreshers sessions	
Q605	In this HEALTH CENTER/Health Area, how many routine vaccination sessions were held each month for children in the last 12 months	
Q6061	Number of sessions per month	
Q6062	In this HEALTH CENTER, how many routine vaccination sessions were held each week for children in the last 12 months	Number of sessions per week
Q6063	In addition to the vaccination sessions held in this HEALTH CENTER, had you regularly organized vaccination sessions at other sites over the past 12 months?	Yes 1 No 2
Q6064	If so, how many vaccination sessions were held each month at other sites in the last 12 months?	Number of vaccination sessions per month
Q6065	If so, how many vaccination sessions were held weekly at other sites in the last 12 months?	Number of vaccination sessions per week