Date	20/04/2023		
Study details Please note that if	approved by the OCA Research	Committee this concept note will be published on	the MSF-OCA Research
Management and	Impact Tool (ReMIT). Any requi	ests to opt out go to the OCA Research Committee	· · · · · · · · · · · · · · · · · · ·
Questions about F	ReMIT? Email <u>remit@oca.msf.or</u>	eg S	
Proposed study title		after mass vaccination campaign (MVC) agains province, Chad, April-May 2023	st measles in Béré, Daffra and
Purpose of study		stimate the status of vaccination in the target popu entation of prospective vaccination campaigns.	lation to provide lessons learned
Research question		ion coverage in children aged 6 -119 months in cination campaign against measles implemented b	
Objectives	districts following the mass	tion coverage in children aged 6 – 119 months in vaccination campaign against measles implemen	ted by MSF and MOH
		non-vaccination during the vaccination campaign	
	To provide recommendatio	ns for vaccination strategies and surveillance in th	is context and similar ones
Background/significance	Is the study part of an OCA top	pical research agenda / strategy document?	
1-2 paragraphs	⊠ No	☐ Yes, namely:	
	general, the measles season sta	Chad in May 2018 and the transmission chain hauts in March (halfway the dry season) and ends une measles outbreak, cases occur across the year.	
	provinces have at least one dist As of week 12, 2023, Tandjile on vaccination and where OCC 40 cases (11% of all reported c An investigation conducted by	the CERU reported 398 cases of suspected mea	the Ministry of Health (MoH) . mena (where OCG has a project on campaigns for measles) with sles, including 22 deaths (case-
	Dafra (global attack rate: 1 (123/100,000) and Béré (46/10 (76%) of all cases reported and following actions have been de Improve case management distributing of free measle Conduct a vaccination can in the districts in Bére from June 2023. Reinforce the surveillance reinforcing case definition	week 1-13 2023. As of week 13, 2023, the most 183/100,000, source: implemented line-list in 00,000). Overall, the age group 6-119 months had an attack rate of 184/100,000 children. Conside excided: In the second	health centers), Donomanga as been most affected with 302 ring this worrying situation, the ding of healthcare staff, and by nths old (37% of the population) Donomange from 23 May to 03 through implementing line-lists, ity
Study topic	□ AMR	☐ Maternal & women's health	☐ Upper/lower respiratory tract disease
Check all that apply	□ Cholera	Measles	
	□ Ebola	☐ Meningitis	☐ Sexual violence
	☐ Environmental Health	☐ Mental health	☐ Surgery
	☐ Emergency	☐ Mortality	☐ Tuberculosis
	□HIV	☐ NTDs (excluding leishmaniasis)	☐ Vaccination
	☐ Leishmaniasis	□ Neonatal & child health	□ VHF (excluding Ebola)
	☐ Malaria	□ Non-communicable diseases	☐ Violence
	☐ Nutrition	☐ Other	☐ Water & Sanitation
		L Other	
	☐ Other disease outbreak		
	If Other or Other disease outbreak, please state:		

			1
Methods - design Check one study design	Please consult the relevant study report	ing guidelines* listed a	t the end of this concept note.
check one study design	☑ Observational study	□м	lixed methods study
	☐ Randomised trial		ualitative research
	☐ Systematic review	·	uality improvement study
	☐ Case report		rediction model
	•		
	☐ Diagnostic study If Other, please state:	□0	tner
Methods - setting	Study location/setting:		
	without any borders to neighbouring continuous into health zones. In total, 116,115 child Table 1.	ountries. 75% of the pop dren aged 6 months to 9	uth of the Chari River, southeast of Ndjamena oulation live in rural areas. Each district is divided 9 years live in the three districts, for details see
	Table 1 : Health zones and population District	agea 6-119 months per Zones	Population according to projection
	Béré	18	47,788
	Dafra	7	25,666
	Donomanga	19	42,660
	Total	44	116,115
Methods – participants,	provinces have at least one district in a As of week 12, 2023, Tandjile is the s cases reported by IDS) in 2023. An investinctuding 22 deaths (case-fatality rational districts in Tandjile are Dafra (global Donomanga (123/100,000) and Béré (with 302 (76%) of all cases reported at MoH plans a periodic intensification of districts (Dafra and Donomanga) from months. The MSF team, coordination a with the planned vaccination campaign the MoH campaign between 01-07 Magnature.	we been reported for several lert for measles, according to the condition of the condition	veral provinces of the country: 19/23 (83%) of the ing to definition of the Ministry of Health (MoH). Devince after N'Djamena with 40 cases (11% of all the CERU reported 398 cases of suspected measles, 1-13 2023. As of week 13, 2023, the most affected 0, source: implemented line-list in health centres), he age group 6-119 months has been most affected 100,000 children. (PIRI) targeting children aged 0-23 months in two ding the measles vaccine for children aged 9-23 y considered this situation and agreed to proceed onths will be asked if they were vaccinated during
procedures, analysis For retrospective analyses of routine data, if this section is sufficiently complete, this concept note will serve as the study protocol and be shared on the MSF Field Research site. This enables compliance with journal requirements for observational studies. For opt-out requests see Opting out	 Average household size of 5 36.9% of children aged 6-11 Estimated coverage of 80% Confidence intervals of 95% Desired precision of 5% Design effect of 3 Non-response rate of 10% This returns a sample size of 803 children aged 6-11	9 months dren in 537 households buseholds. There is the 1	(SMART, 2019) based on the following inputs: 5. We will sample 42 clusters, containing each 13 risk that a cluster might not exist, is not identifiable usters in reserve.

or not accessible, which will be addressed by adding up to 5 clusters in reserve.

Sampling

The vaccination coverage survey will use a two-stage cluster sampling methodology.

- 1st stage: Clusters will be selected based on probability proportional to the population size (PPS), using population data provided by the chef of each health zone. The cluster and reserve clusters are identified by the ENA SMART 2020 software.
- 2nd stage: Spatial Sampling or systematic sampling will be used to select 13 households in each of 42 clusters.

All children in the eligible age range in the identified households are included in the survey, including in the final household of a cluster, even if this exceeds the total target of children for the cluster.

If multiple households live in the same compound, a household will be randomly selected by numbering them and generating a random number on the tablet.

The household head (\geq 18 years) will be asked about the age and vaccination status of all children in the household aged 6 months to 119 months.

If a selected household will not be available after two visit attempts (morning and afternoon), or is not willing to respond, that household will not be replaced.

Anticipated dates for data collection are for Béré 15-21 May, for Dafra 24-30 May and for Donomange 05-11 June 2023.

The household head will be asked to provide consent for the survey questionnaire, which will collect the information on the data variables for all children aged 6-119 months.

Data variables (quant):

- Demographics: Total number of household members, number of children aged 6-119 months, age & sex
- Measles vaccination status for all persons from 6 months to 9 years of age in the household (using vaccination card history, marked finger during vaccination campaign or oral history when vaccination cards are not available).
- · Reasons for non-vaccination
- History of measles disease

Data sources and collection: A standardized pre-piloted questionnaire will be used to collect the following data for each child of the cohort at recruitment. Data collectors will use KoboCollect software on tablets during face-to-face interviews with household heads. Paper questionnaires will be available as backups. To ensure data quality, intense training and close supervision of data collectors will be assured. For data security and integrity, smartphones and paper questionnaires will be kept in a locked box in the field and later in MSF offices (locked), databases will be password protected, and only study research team will have access.

Data analysis: Data cleaning will be done to check for inconsistencies in data entry and responses. Data analysis will be conducted using R. All indicators (e.g. sex and age of the survey population) will be calculated as proportions with 95% confidence intervals. The indicators will be presented as a total and stratified by other factors (e.g. age group, district and sex).

Resources/costs:

- 12 data collectors (6 teams of 2 data collectors) for each district (total: 18 teams of 2 data collectors; 36 data collectors).
 - o Each team completes 1-2 clusters (13-26 households) per day, depending on travel time.
 - o 7 days for the data collection for each district
 - \circ (2 days training, including pilot study + 7 days survey) x 3 = 27 days
- 8 cars: 6 cars for 6 teams of data collectors + 2 cars for 2 supervisors per district
- 8 smartphones (1 smartphone / team + 2 in reserve)
- Training materials (office space, projector, flipboard, small notebooks)
- Recording materials (pens, paper questionnaires, clipboards, backpacks)
- Food & drink for training days
- Security materials (visibility, radios)
- Phone credit for communication with the teams?

Planned dates

List proposed start/end date [mm/yyyy] of each stage and any time restrictions

- Start date: 24 April 2023
- **Protocol development:** 5 working days from 24-28 April 2023
- Ethics review: Not needed
- Study preparation: 9 working day from 02-10 May 2023
 - o questionnaire programming, logistical planning (cars/security), photocopies, recruitment of interviewers, training materials for survey teams
- Data training and pilot in Béré: 2 days from 11-12 May 2023
- Data collection in Béré: 7 days from 15-21 May 2023
- Data training and pilot in Dafra: 2 days from 22-23 May 2023
- **Data collection in Dafra :** 7 days from 24-30 May 2023
- Data training and pilot in Donomanga: 2 days from 01-02 June 2023
- **Data collection in Donomanga**: 7 days from 05-11 June 2023
- Data analysis: 5 working days from 14-20 June 2023
- Write up (report): 5 working days from 21-27 June 2023

Ethics - exemption from review by the MSF ERB (Ethics Review Board)	Is your study a retrospective review of routinely collected data and thus a candidate for exemption from MSF ERB review? ———————————————————————————————————
	⊠ No □ Yes
	Complete the OCA Ethics Review Exemption Template (see Annex) and submit with this Concept paper.
	2. Will your study use an MSF Intersectional Standardised Survey Protocol?
	\square No, continue with question 4 \square Yes, continue with question 3
	3. If you used an MSF Intersectional Standardized Survey Protocol, does it meet the MSF ERB Exemption criteria for surveys?
	□ No ⊠ Yes
	4. Do you believe that your study is exempt from ERB review for another reason?
	☑ No ☐ Yes, because:
	Complete the OCA Ethics Review Exemption Template (see Annex) and submit with this concept paper.
Ethics non-exempt studies	Benefits: Measuring vaccination coverage will inform MSF whether the campaign achieved herd immunity or whether additional vaccination activities are needed.
Do not complete this	Better understanding of reasons why children are not vaccinated can help inform and improve subsequent vaccination campaigns.
section if you have applied for exemption from MSF ERB review.	Risks: There is no risk to the survey participants as no identifying data are collected and the GPS coordinates are not retained with the survey data. However, there is some intrusion on the privacy of the household, which some households may find uncomfortable. Our interviewers will be trained to ensure privacy and help people feel comfortable.
	Consent : After a brief description of the study objectives to the head of household, data collectors will ask if the head of household consents to take part in the survey. Consent will therefore be verbal.
	Confidentiality: Privacy and confidentiality of the data collected from the participants will be ensured both during and after the conduct of the survey. Participant names will not be recorded on questionnaires, and individual person records will be linked only to a household number throughout the data entry and analysis process. Any data that could be combined with other data sources to make individual records potentially identifiable will not be distributed outside the survey location or appear in any report or publication.
	National/local review:
	1. Has a protocol been submitted to or approved by National/ Local Ethics Review Committee(s)?
	⊠ No/Not yet □ Yes
	 If not yet submitted, please indicate when and to which committee the protocol will be submitted: Protocol will be shared with national and district (Health Delegate) authorities.
D. I. H.	3. If not planned to be submitted to local committees, please note why not
	are split differently between the roles outlined below or held by other members of the research team, please a the sections below. ReMIT responsibility must be held by an MSF staff member.
Primary Investigator	Name: Emily D. Meyer
(PI)	Email address: chad-epidem@oca.msf.org
Responsible for carrying out the study with support	
and consultation from	
research team. Will usually lead on all	
journal correspondence. TOR is <u>here</u>	
Study Coordinator (SC)	Name: Grégoire Falq

Overall responsible for study, must be MSF HQ staff, usually topic specialist or epi advisor. Responsible for: updating ReMIT, translating findings into impact, appropriately disseminating materials (see later section). TOR is

Email address: Gregoire.Falq@london.msf.org

Is the topic specialist / topic holder informed/involved? Yes

MSF research team

Epidemiologist: Emily D. MEYER

Email address: chad-epidem@oca.msf.org

Responsibilities: Concept paper, Research protocol conception and submission to MSF-OCA Research Director for approval. Selection and training of data collectors and data encoders. Supervision of data collection in the

field. Data analysis, interpretation, and survey report writing.

CERU Project Coordinator Chad: Brunel Camille Margaux Louise MAI

Email address: chad-eru-pc@oca.msf.org

Responsibilities: Support of teams during intervention for successful implementation of VCS..

CERU MTL Chad: Jean-Luc MASHEKA Email address: chad-eru-mtl@oca.msf.org

Responsibilities: Support of teams during intervention for successful implementation of VCS.

CERU data manager Chad: Allafi Bow GAMAOU

Email address: chad-eru-data@oca.msf.org

Responsibilities: Training of data collectors and data encoders. Supervision of data collection in the field.

Head of Mission Chad: Khatab MUHY
Email address: Chad-hom@oca.msf.org

Responsibilities: Overall Support teams during intervention for successful implementation of VCS.

Medical Coordinator Chad: MAIKERE Jacob

Email address: chad-medco@oca.msf.org

Responsibilities: Overall Support teams during intervention for successful implementation of VCS. Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.

Deputy medical coordinator Chad: Justin M NYARWANGU

Email address: Chad-medco-dep@oca.msf.org

Responsibilities: Overall Support teams during intervention for successful implementation of VCS. Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.

Epi Advisor: Gregoire FALQ

Email address: Gregoire.Falq@london.msf.org

Responsibilities: Remote support to Epi for survey implementation, data analysis and report writing.

Vaccine Advisor: Kartini GADROEN

Email address: kartini.gadroen@amsterdam.msf.org

Responsibilities: Review of survey report and formulation of recommendations for incoming vaccination activities based on survey results.

Health Advisor: Prince ALFANI

Email address: prince.alfani@berlin.msf.org

Responsibilities: Review of survey report and formulation of recommendations for incoming vaccination

activities based on survey results.

Field involvement

Are national/other field staff informed/included as co-investigators?

	□ No ⊠ Yes	
	Will protocol development include field team input?	
	□ No ⊠ Yes	
	Please describe any planned capacity building activities for national staff:	
	Training for data collectors and data encoders	
Health Advisor (HA)	Name of relevant HA(s): Prince ALFANI	
Responsible for	Is/are the HA(s) supporting the study on behalf of the countries they manage?	
facilitating study operationally, ensuring	□ No ⊠ Yes	
desk/field have agreed to		
study and feeding back to PI/SC.		
External partners/MoH	International: None	
Name, position, role of	Local: Chad MoH via Béré, Daffra and Donomanga Districts	
external collaborators.	Community: None	
	Have resource agreements , e.g. Open Access publication costs been reached?	
	□ No □ Yes, namely:	
Constitution in the second	, , ,	
Competing interests	Members of the research team declare no competing interests	
Data management and sharing	Name: Emily D. MEYER	
Contact details of those	Email address: chad-epidem@oca.msf.org	
responsible for ensuring data are managed and shared in accordance	Data management plan : Data will be entered into smart phones using KoBo questionnaires. CSV files will be password protected and exported for analysis into R software. After the survey is completed, the questionnaires (paper versions) and the electronic database will be stored at the MSF Headquarters or country management level for 5 years after the survey.	
with MSF's Health Data Protection Policy and	Will data be shared with an external partner such as an academic institution?	
GDPR	No	
	Complete the OCA Data Sharing Agreement and submit for	
	Medical Director signature.	
Opting out	This concept paper and/or accompanying protocol cannot be made available on:	
All concept papers and/or (ERB approved) protocols	☐ ReMIT; because: ☐ MSF Field research website; because:	
are made available on		
ReMIT and the MSF Field Research website.		
Implementation/ impact a		
Responsibility of	'the Study Coordinator (unless otherwise noted in roles/responsibilities section)	
Implementation/impact	Finding from this survey will help MSF Chad mission and well as other MSF projects in similar settings to better plan and implement vaccination campaigns. In addition, these survey results could be used for advocacy in favour of vaccination campaigns.	
Dissemination	Dissemination of findings: Dissemination survey finding will be mainly through the survey report.	
Note on journal	MSF – project, mission, headquarters: Survey report	
publication -MSF has an Open Access (OA)	Participants: Not applicable	
journal publication	Community: Not applicable	
policy. Fee reduction must be requested at	In country partners (including MoH):	
article submission. See guidance on publication –	International dissemination (including WHO and other agencies, scientific publication):	
authorship, how to apply	Agreements	
for fee reduction, funding, conflict of interest, and	Authorship: list possible authors (at least 1st and last):	
response to journal data deposition requests.	Has the dissemination plan the support of the Health Advisor (HA)?	
	□ No ⊠ Yes	

Internal reports remain on Sharepoint, not ReMIT.	Research outputs must be sent in parallel, before wider distribution, to the OCA Research Committee for quality review and to the HA, who will have 1 week to raise any context concerns with the Committee. Context concerns arising since Concept paper approval or quality of output likely the main reasons to postpone outputs.

*Study Reporting Guidelines	
To assist authors in writing up their studies to meet scientific jou	rnal criteria
Observational studies – <u>STROBE</u> (<u>& extensions</u>)	Qualitative research – <u>SRQR</u> (<u>& extensions</u>)
Randomised trials – <u>CONSORT</u> (<u>& extensions</u>)	Diagnostic studies – <u>STARD</u>
Systematic reviews – <u>PRISMA</u> (<u>& extensions</u>)	Quality improvement studies – <u>SQUIRE</u>
Case reports – <u>CARE</u>	Prediction model studies - <u>BMJ</u>

Annex 1. OCA Ethics Review Exemption Template

	from ERB review. See MSF ER document to answer the question	
	me as for Concept paper): Vaccii omanga districts, Tandjile provin	ation coverage survey after mass vaccination campaign (MVC) against measles in Béré, Daffra e, Chad, April-May 2023
Name of	f Primary Investigator (PI): Emil	D. MEYER (Epidemiologist)
Has a pi	rotocol been submitted to or appr	ved by National/ Local Ethics Review Committee(s)?
	⊠ No	□ Yes
	et submitted, please indicate when will not be submitted to any ethic	and to which committee the protocol will be submitted: al review board.
The auth	anned to be submitted to local control or in an entry and the intervention in B vaccination coverage survey to be	nmittees, please note why: oré, Daffra and Donomanga districts provided by MoH to MSF-OCA includes mention of a carried out by MSF-OCA after the mass vaccination campaign.
1. Exem	ption Criteria	
1. Exem (1.1)	ption Criteria	ollected clinical data from pre-existing, established programmes?
	ption Criteria	
	ption Criteria Is the study based on routinely-c	ollected clinical data from pre-existing, established programmes? ☐ Yes
(1.1)	Is the study based on routinely-c No Is the study descriptive/evaluative No	ollected clinical data from pre-existing, established programmes? ☐ Yes e or a targeted evaluation? ☒ Yes
(1.1)	Is the study based on routinely-c No Is the study descriptive/evaluative No	ollected clinical data from pre-existing, established programmes? □ Yes e or a targeted evaluation?
(1.1)	Is the study based on routinely-c In the study descriptive/evaluative In No Explain here how confidentiality Privacy and confidentiality in the names will not be recorded, and	ollected clinical data from pre-existing, established programmes? ☐ Yes e or a targeted evaluation? ☒ Yes
(1.1)	Is the study based on routinely-c No Is the study descriptive/evaluative No Explain here how confidentiality Privacy and confidentiality in the names will not be recorded, and analysis process. We will not be potentially identifiable.	ollected clinical data from pre-existing, established programmes? ☐ Yes e or a targeted evaluation? ☐ Yes is respected – how you will ensure that no individual patient identifiers are revealed or used? e data collected from the participants will be ensured both during and after the survey. Participant individual records will be linked only to a household number throughout the data entry and
(1.1)	Is the study based on routinely-co Is the study descriptive/evaluative □ No Explain here how confidentiality Privacy and confidentiality in the names will not be recorded, and analysis process. We will not be potentially identifiable. What are anticipated harms? Entiminimal?	ollected clinical data from pre-existing, established programmes? ☐ Yes e or a targeted evaluation? ☐ Yes is respected – how you will ensure that no individual patient identifiers are revealed or used? e data collected from the participants will be ensured both during and after the survey. Participant individual records will be linked only to a household number throughout the data entry and recording any data that could be combined with other data sources to make individual records

A better understanding of the vaccination coverage ratios and causes of non-vaccination in the area will allow more tailored programming and more efficient resource use. Accurate data on vaccination status are of tremendous importance for advocacy on a national and international level.

(1.6) Describe any collaborative involvement and, if applicable, authorship from a local authority or partner (Ministry of Health, DHO, other NGO); if relevant and applicable, describe consultation with a body representing the community:

None

2. Ethics Statement

Once exemption has been granted by the OCA Research Committee, the authors can insert into their article the following statement that has been approved by the MSF ERB:

"This research fulfilled the exemption criteria set by the Médecins Sans Frontières Ethics Review Board for a posteriori analyses of routinely collected clinical data and thus did not require MSF ERB review. It was conducted with permission from (Medical Director, Operational Centre) Médecins Sans Frontières."