Seroprevalence of SARS-CoV-2 antibodies among people experiencing homelessness

Ile de France, France

ID-RCB N° 2020-A01554-35

Protocol

Version 1.2 (May 2020)

Operational summary

1st version	**April 2020**
Type	Cross-sectional serosurvey with systematic (or simple, if feasible) random sampling in population attending MSF activities
Time Period	May-June 2020
Site	Departments 75 and 93, Ile-De-France Region, France
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Partners	Institut Pasteur, France Regional Health Agency (Agence Regionale de Santé), France

List of acronyms

ARS	Regional Health Agency (Agence régionale de santé)
COVID-19	Coronavirus Disease 2019
ELISA	Enzyme linked immunosorbent assay
IgG	Immunoglobulin G
IgM	Immunoglobulin M
LuLISA	Luciferase immunosorbent assay
MoH	Ministry of Health
MSF-OCP	Médecins Sans Frontières – Centre Opérationnel Paris
Rt-PCR	Reverse transcription polymerase chain reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
WHO	World Health Organization

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1 Introduction – Context

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is associated with coronavirus disease (COVID-19) and was first detected in December 2019 in Wuhan, China. As of May 15th, more than 4.4 million confirmed cases and 300,000 deaths have been reported globally [1]. Many key epidemiological and serologic characteristics of COVID-19 are still unknown, including the ability to spread and severity of the illness. The scale of mild and asymptomatic infections and the extent to which people who are reported as asymptomatic can transmit the virus is not yet clear.

The first confirmed case of COVID-19 in France was reported at the end of January 2020, with more than 180,000 confirmed cases and 26,000 deaths to date [1]. People experiencing homelessness are particularly vulnerable to COVID-19. In France, an estimated 900,000 people, mostly migrants, lack permanent personal housing, with an estimated 250,000 people experiencing recurrent homelessness. At least 3,500 people are homeless on the streets of Paris [2, 3]. Shared housing, including shelters and encampments, and poor sanitary conditions are factors that can expedite virus transmission. Many of the recommended COVID-19 prevention measures, such as hand-washing, social-distancing and self-isolation if symptomatic, are ~~generally~~ often not feasible for this population under these circumstances. Many people who are homeless are older adults or have underlying medical conditions; each put individuals at higher risk for severe COVID-related illness [4, 5]. The rapidity with which COVID-19 can be transmitted in a homeless shelter setting has been documented, including in a recent survey in Marseille, France [6 - 8]. Furthermore, reduction in outreach services for homeless to reduce exposure often reduces access to care for other medical conditions [6,7].

In late 2016, MSF-OCP opened a project called Mission France in Paris following the closure of Calais, a migrant refugee camp where MSF had provided medical care. Many of the migrants who were living in Calais when French authorities closed the camp settled in informal camps all around northern parts of Paris and nearby suburbs. Project activities included support for legal recourses, healthcare (vaccination, treatment, referrals and mental health), and access to water, food and shelter. While setting up mobile clinic activities and managing a shelter for unaccompanied minors in Pantin, a Parisian suburb, MSF-OCP worked within a network of actors, including NGOs, French local associations and citizen initiatives. This model was subsequently replicated in other French cities.

Once the COVID-19 pandemic reached the Ile-De-France region, the Mission France team adapted their activities, particularly after a nationwide lockdown was effectuated on March 17th as a response to the epidemic. French authorities moved vulnerable people, including homeless, migrants, unaccompanied minors, sex workers and Roma communities, into emergency shelters, hotels and large venues. NGOs and associations filled several resulting gaps, including access to medical care. The Mission France mobile

clinic activities include clinical management of non-COVID cases, COVID screening and hospital referrals for suspected COVID cases. The mobile clinic provides similar medical care at migrant worker hostels, among people squatting and at informal camps/settlements of people who refused to go to or fled from shelters. Additionally, the mobile clinic responds to requests from other actors, including local associations, other structures with vulnerable people and nursing homes, for support in management of suspected COVID+ cases, COVID-19 screening and testing, referrals of positive cases, setting up isolation rooms, training and counselling staff. This activity relied on a phone hotline which could help assess the needs for the mobile clinics, provided guidance and orientation for people calling. Finally, MSF was responsible for the management and follow-up of COVID+ patients in 2 treatment centres opened for people experiencing homelessness.

The particular vulnerability of people experiencing homelessness during the COVID-19 epidemic has led MSF-OCP to ask Epicentre to conduct a study to estimate the burden of disease among this population. The rate of COVID-19 infection among the homeless populations in France is unknown. Given that COVID-19 is a novel coronavirus and thus populations are assumed to have been completely susceptible before the emergence of the virus, surveillance of antibody seropositivity can allow inferences to be made about the extent of infection and about the cumulative incidence of infection. Several serological/seroprevalence studies are or will be done at the population level in France, but few include vulnerable populations such as those served by Mission France activities [9,10]. Recent recommendations from the National Health Authority (Haute Autorité de santé) underscore the need for more serology surveys in specific populations, including among vulnerable people, to evaluate the overall exposition to the virus, raise awareness and improve preparation for a potential rebound in COVID-19 cases [11].

To better understand the risk of infection in this population and specific risk factors, the prevalence of COVID antibodies and associated risk factors in this population at shelters after the confinement period will be measured

Objectives

1.1 PRIMARY OBJECTIVE

To determine the extent of COVID-19 infection, as determined by seropositivity, among the homeless population temporarily housed in MSF-supported structures (shelters, COVID+ centres, hotels) or attending mobile clinics in Ile de France since the start of the epidemic (March 1st)

1.2 SECONDARY OBJECTIVES

- To compare the level of seropositivity between the populations living in the 4 following types of accommodation: official shelters/hotels, migrant worker hostels, squatting and streets/settlements
- To determine risk factors for infection by comparing the exposures of (ever) COVID-infected and non-infected individuals
- To determine the fraction of asymptomatic or subclinical infections

2 Methods

2.1 STUDY TYPE

This study will be a cross-sectional survey using systematic (or simple, if feasible) random sampling in the targeted population.

2.2 STUDY POPULATION

The target population will be persons 18 years and older housed in the sites supported by MSF in the department 75 (Paris) and 93 (Seine-Saint-Denis) of Ile de France region.

2.3 ELIGIBILITY CRITERIA

Inclusion criteria:

- All individuals 18 years and older identified for recruitment into the survey.

Exclusion criteria:

- Refusal to give informed consent
- Refusal to give blood
- Contraindication to venepuncture

2.4 COMMUNITY MOBILIZATION

During the implementation of a preceding survey carried out by MSF (socio-anthropological assessment) in the previous weeks, the target population at each site will be informed of this survey and the acceptance will be measured. If necessary, additional sensitization activities will be added to increase acceptance among the population.

Social workers and staff at each selected site will play an important role in enhancing recruitment and minimizing attrition.

2.5 DATA COLLECTION

The purpose of the survey will be explained by study interviewers to eligible participants and consent obtained to conduct the interviews and blood collection. Each participant recruited into the survey will be asked to complete a questionnaire during a face-to-face interview (see Appendix 2). The data will be collected using electronic data forms (Kobo collect) on mobile devices (Samsung pad©). If a participant declines to participate in the study, this will be accepted and noted. Interviews will be done in the participant's preferred language (French, English, Arabic, Pashtun, Albanian, Roma, or Farsi).

The questionnaire consists of the following sections:

- Demographic information (age, sex, nationality, education, country of residence)
- Medical History/Comorbidities (focusing on diseases known to be aggravating COVID severity or alter immune response)
- Ongoing Treatments
- Exposure to suspected or confirmed COVID-19 case
- Symptoms since March

Laboratory registers will be used to capture laboratory data, depending on the standard procedures of each laboratory. Study forms will be linked through a unique study identification number assigned to each study participant.

2.6 SPECIMEN COLLECTION

A qualified nurse will collect serum samples from all participants who agree to participate in the study. A total of 3-4 ml of venous blood will be collected in one serum separator with clot activator tube (VACUETTE™). A laboratory form will accompany each serum sample (see Appendix 3). Lab forms and tubes will be identified using only the study number, the participant's initials and the date of collection.
The collection of serum samples will follow specimen collection guidance used in France.

2.7 SPECIMEN TRANSPORT

All individuals involved in the collection and transportation of specimens will be trained in safe handling practices, transport and spill decontamination procedures. MSF and Epicentre will be responsible for collection of all blood specimens, transport and storage until specimens reach the laboratory (Institut Pasteur) where tests will be performed.

Institut Pasteur will then be responsible of the storage of the samples for 6 months after the end of the survey, and will be responsible as well for their destruction after 6 months (or immediately after the communication of the results to the participant, if s/he requests so).

For each biological sample collected, the date and time of collection, the conditions for transportation and the date and time of arrival at Institut Pasteur will be recorded. Specimens will be sent to the laboratory at the end of each working day.
For each blood sample, serum will be separated from whole blood by centrifugation within 12 hours of collection, and should be stored and transported to the Institut Pasteur at 4 ° C at the end of the working day.

Storage of serum samples should not, as far as possible, be done in domestic refrigerators, in regard to their thermal instability. Upon reception at Institut Pasteur, serum samples will be aliquoted and stored at -80 ° C in the case that the serology testing is delayed.

Transport of specimens within national borders will comply with applicable French regulations.

2.8 TRAINING

The data will be collected by at least 5 nurses and 5 surveyors/translators to ensure interviews can be done in the participant's preferred language (French, English, Arabic, Pashtun, Albanian, Roma, or Farsi).
If the live translation by the interviewer is not easy / possible, the possibility of reaching translators by telephone to carry out the interview will be considered.
Before the start of the survey, the team involved in the study will undergo 2 days of training on study procedures, entry using tablets, the informed consent process and ethics in medical research involving humans. The training will focus on:

- Study protocol and procedures
- Methodology for selecting participants
- Filling of the questionnaires using tablets
- Blood collection
- Informed consent
- Ethics and confidentiality

The training will include a detailed review of the questionnaires. Standard procedures for collection, handling, transport and storage of blood samples will also be covered.

A pilot will be done involving 20 individuals at a site managed by MSF but not included in the survey. Modifications to the questionnaires and consent forms will be made based on lessons learned from the exercise. Information collected during the pilot will

not be included in the analysis nor stored. However, COVID-19 serology test results will be given to pilot participants following the same procedures as for other survey participants.

2.9 REDUCING OCCUPATIONAL EXPOSURES AMONG SURVEY PERSONNEL

All personnel involved in the survey will be trained in infection prevention and control procedures (standard contact and droplet precautions, as determined by national guidelines). These procedures include proper hand hygiene, proper disinfection of study tools (including tablet) and the correct use of surgical masks to minimize the risk for survey team and participants.

Staff handling biological specimens will be trained to avoid needle-stick and other injuries. Protection equipment (aprons, gloves and masks) and plastic sharps containers will be provided. Staff will be trained to report all needle-stick injuries to their supervisor immediately. Hazardous waste will be destroyed by Institut Pasteur.

3 Laboratory evaluations

3.1 SEROLOGICAL TESTING

Institut Pasteur developed a novel luciferase immunosorbent assay (LuLISA) based on SARS-COV2 fragments of nucleoprotein (N protein). The relation between the antibodies and the N protein can be detected through bioluminescence (measure of luciferase activity, here the Nanoluc luciferase or NLuc). [12,13].
Similar to the enzyme linked immunosorbent assay (ELISA) technique (standard), this test uses plates coated with the protein N of the virus originating from a cell with a purified His-tagged SARS-CoV. It also allows the assay of all the antibodies involved in the response to the virus (IgA, IgM and IgG) [12 - 14].

The Pasteur assay has a high-throughput with the ability to run hundreds of tests at once and is ultrasensitive; IgG antibodies have been detected in 100% of patient's blood collected more than 15 days after PCR confirmation of COVID-19 [15]. An additional advantage of this new technique is that it does not need to be performed in a biosafety level 3 laboratory (BSL-3), unlike other neutralization or immunoprecipitation techniques.

Laboratory and biosafety guidance provided by the World Health Organization (WHO) as well as protocols and SOPS for serological assays specific to COVID-19 will be followed. Laboratory procedures involving sample manipulation will be carried out in a biosafety cabinet.

3.2 SAMPLE STORAGE

The samples will be shipped to the Institut Pasteur at the end of the working day and immediately stored at 4 ° C. In the event that serological analyzes cannot be carried out within 72 hours after collection, the samples will be frozen and stored at -80 ° C. It is recommended to aliquot (divide into different tubes) the samples before freezing in order to decrease the freeze-thaw cycles.
After communication of the serology results to the participants, and upon participants' permission, blood samples will be stored by Institut Pasteur for 6 months in the event of new related studies, such as improvement of this novel serological technique, or neutralization tests to verify that antibodies are involved in immune protection.

4 Statistical analyses

4.1 SAMPLE SIZE

Various serological surveys carried out in different cities of France have found seroprevalence results varying between 2% and 15%, including a seroprevalence estimation of 12% in the general population of Paris and suburbs [16, 17]. More recently, several surveys have been carried out in populations very similar to the target population of this survey (people experiencing homelessness in Marseille and Geneva); the prevalence of COVID+ patients (confirmed by reverse transcription polymerase chain reaction (Rt-PCR) test) or people who presented symptoms and were hospitalized appeared to be 2 to 3 times greater than those in the general population [6,7]. Thus, we would like to compare the seroprevalence in the following subgroups to 12%:

	Centers	Migrant Houses	Squats	Street/ Camps
Null Hypothesis H_0 (%)	12	12	12	12
Power (β, in %)	90	90	90	90
Type I Error risk (α, in %)	2	2	2	2
Estimated Population	500	1000	300	600
Odds-Ratio (Alternative hypothesis H_1 vs H_0)	2	3	3	2
Number of samples necessary	293	191	138	132
Indeterminate results/sample loss (%)	5	5	5	5
Final number of samples necessary	**307**	**201**	**145**	**138**
Non-response/Refusals(%)	20	20	20	20
Final number of people to interview	**368**	**241**	**174**	**165**

This sample size of 791 blood samples will allow the estimation of an odds ratio≥2 compared to the null hypothesis, in each subgroup and overall.

With an expected non-response rate of 20% during the interviews (following results of the same surveys [5,6]), 948 people will be invited to participate.

4.2 SAMPLING METHOD

At facilities where registers are in place, participants will be selected by simple random sampling with probability proportional to population size (e.g. number of beds). Where registers do not exist or are not up to date, a list of current residents will be assembled or updated and potential participants will be chosen using the same methodology. Where assembly of a list is not possible, systematic sampling by sleeping location (or similar) will be carried out after mapping out the location. The sampling interval would be proportional to the sites current population size..

4.3 DATA ANALYSIS AND STATISTICAL METHODS

The data will be analysed using Stata V.15 (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LP). Descriptive analysis, including age, sex and type of accommodation of the study population, will be calculated as proportions. Two-sample t-test and Pearson chi-square statistics will be used to compare continuous and categorical descriptive outcomes, respectively. Logistic regression including risk-factors will be performed and odds-ratio (overall and by subpopulations) will be calculated. Outcomes will be calculated with corresponding 95% Confidence Intervals and stratified by age group, sex and type of accommodation.

5 Ethical considerations

5.1 COLLABORATION

This study will be carried out as a collaboration between MSF-OCP, Epicentre and local partners, including Institut Pasteur and the Regional Health Agency for Ile de France (MoH). MSF-OCP is the study sponsor and is responsible for the funding. MSF-OCP and Epicentre are in charge of the implementation, the analysis and report writing. The report will also be shared with other actors working in the area. Permission for publication must be obtained from MSF-OCP and Epicentre.

5.2 INSTITUTIONAL REVIEW BOARD APPROVAL

This protocol will be concurrently submitted to the MSF Ethical Review, Pasteur Institute's Institutional Review Board and France's Committee of Protection of Person's (CPP) of Ile de France Region. Study documents will be reviewed and validated by the CNIL (National Information Commissioner's Office), according to French regulations.

5.3 INFORMED CONSENT

The purpose of the survey will be explained to all individuals identified for recruitment into the survey. Informed consent will be obtained from all individuals willing to participate in the survey before any procedure is performed as part of the survey, by a trained member of the survey team. Each participant must be informed that participation in the survey is voluntary and that s/he is free to withdraw, without providing justification, from the survey at any time without consequences and without affecting any access to care support. The participant will have the opportunity to ask questions and receive clarification on anything that s/he does not understand. When ready, each participant will be asked to sign the consent documentation, giving her/his consent to voluntarily participate in the study with the knowledge that s/he may terminate study participation at any time. The participant, if functionally illiterate, will requirethe presence of a witness who will also have to sign the document. The witness will be a person who does not belong to the study team and who will be identified by the participant.

The informed consent process will be carried out with a written consent document in a language understandable to the participant (including French, English, Arabic, Pashtun, Albanian, Roma and Farsi) and an interpreter fluent in both French and the participant's spoken language to aid in the consent process. Written informed consent documents will be available in French, English, Arabic, Pashtun, Albanian, Roma and Farsi. In the case that the potential participant does not speak any of noted languages, he/she will not be included in the study.

If COVID-19 is suspected (presence of several symptoms) at the time of the interview, the participant will be offered a Rt-PCR screening test.

Due to the recent nature of the epidemic, participants' permission will be asked for their blood sample to be stored by Institut Pasteur for 6 months after the end of the survey, in the event of new studies, such as improvement of this novel serological technique, or neutralization tests to verify that antibodies are involved in immune protection.

5.4 RISKS AND BENEFITS FOR SUBJECTS

This survey poses minimal risk to participants, involving the collection of a small amount of blood. If it is too difficult to get blood, or if the participant is too uncomfortable, we will not include the participant in this study. The primary benefit of the study is the opportunity for the participant to have a test done to determine if s/he was previously exposed to COVID-19; an indirect benefit is that data collected will help improve and guide efforts to understand the extent of COVID-19 virus infection and help plan for better ways to protect vulnerable populations experiencing homelessness.

Participants suspected of active COVID-19 infection during the interview will have the option to get screened by Rt-PCR test by sample collection with a nasopharyngeal swab and receive healthcare counselling (according to routine MSF mobile clinic protocol). Study nurses will also be trained on this sampling technique.

In case of any medical conditions requiring care (COVID or non-COVID), the study team will follow the system currently in place and will call the MSF hotline in order to organize referral and management.
All study participants and study staff will be covered by insurance against any event affecting their health related to study procedures.

5.5 CONFIDENTIALITY

Participant confidentiality will be maintained throughout the survey. All subjects who participate in the survey will be assigned a unique study identification number by the survey team for the labelling of questionnaires and specimens. All laboratory specimens, reports, data collection tools, process logs and administrative forms will be solely identified with the participant study ID number to maintain participant confidentiality. The link of this identification number to individuals will be maintained by the survey team and will not be disclosed elsewhere. All data on tablets will be erased once it is uploaded to the secured server. Forms, logbooks and any other listings that link participant ID numbers to other identifying information will be stored in separate locked filling cabinets accessible only to the principal investigator or appropriate designee. All study-related information will be stored securely at Epicentre/ MSF facilities. All participant information will be stored in locked filing cabinets in areas with study staff access only. All databases will be password-protected and stored on secured server at Epicentre.

If the data is shared with the WHO or any agency or institution providing support for data analysis, data shared will include only the study identification number and not any personably identifiable information.

6 Dissemination of results

6.1 NOTIFYING PARTICIPANTS OF INDIVIDUAL RESULTS

The survey team will clearly explain at enrolment the process for collecting the individual result and note the preferred location for delivering the result to each participant. Lab results will be available within 2 weeks of blood collection. If a contact telephone number is available, the study team will contact participants by telephone in order to notify participants that lab results are available.

The team will go to the different sites after contacting the participants by phone (if feasible) to inform them of the availability of serological results and to agree on a date of appointment to provide individual participant's result. The team will keep this personal information separately from other study data, and will destroy it once the results are communicated to participants.

6.2 DISSEMINATING STUDY RESULTS

The research team will develop a range of activities to disseminate the study findings. These dissemination activities will be coordinated by MSF and Epicentre. The results will be presented in an internal report and an external report for the Ministry of Health (MoH), the French National Public Health Agency and Institut Pasteur. The main findings of this survey could potentially be compared with findings from similar ongoing studies, once they are completed. An abstract of the findings will be submitted for presentation at a scientific conference, and at least one manuscript will be submitted for publication in a peer-reviewed scientific journal. Investigators from all participating institutions will be given the opportunity to share authorship on presentations and publications arising from the study, subject to the standard rules of scientific authorship. The findings of the survey will also be used for advocacy purposes, in coordination with community leaders of participating communities.

The results of the survey, and their possible use for advocacy / communication, will be shared with the staff and residents of the MSF activity sites, whether or not they actually participated in the survey.

7 Premature study termination or suspension

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated, the investigators will promptly inform the ERB and will provide the reason(s) for the termination or suspension. Any resulting analysis would depend on the status of the data collection and the reason for premature termination. If the situation allows, partial results would be shared. In any case, results of all serological analyses already performed by Institut Pasteur will be communicated to the participants.

8 Archiving

Coded participant data (identified by study number only) will be stored until the results of the research are published, then archived by MSF for 15 years, with all documents relating to the study, according to the regulations in force. The key linking study ID to participants' name will be destroyed once results are provided to participants.

9 Potential interests of the parties involved in the research

The different parties involved in this research declare that they have no potential or competing interests.

10 Timeline and resources for the study

The timeline of activities is shown in Appendix 4. Activities are expected to start immediately after ethical approvals are obtained.

11 Acknowledgements

This protocol was informed by a WHO protocol for population-level COVID-19 antibody testing [17].

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13 Appendices

13.1 APPENDIX 1: CONSENT FORMS/INFO SHEETS

INFORMATION SHEET TO PARTICIPATE IN RESEARCH – ADULTS ≥18 years

Seroprevalence of SARS-CoV-2 antibodies among people experiencing homelessness, Ile de France, France

Epicentre
14-34 avenue Jean Jaurès
75019 Paris – France

Médecins sans Frontières- Centre opérationnel Paris (MSF-OCP)
14-34 avenue Jean Jaurès
75019 Paris – France

Institut Pasteur
25-28 Rue du Dr Roux
75015 Paris – France

Agence Régionale de Santé (ARS)
Millénaire 2, 35 Rue de la Gare
75019 Paris – France

We are inviting you to take part in a study organized by Doctors without Borders (MSF), a humanitarian medical organisation. In collaboration with Epicentre (French research institution) and the Regional Health Agency (ARS), MSF is carrying out a survey about COVID-19 among people experiencing homelessness. The survey involves a questionnaire and a collection of a blood sample.

MSF is working with the ARS to support activities related to response to COVID-19, including screening and referrals for suspected cases of COVID-19.

The purpose of this information note and its subsequent form is to give you the information you need to make a decision. Thank you for taking the time to listen to us and please read carefully if you can.

The investigator is available to describe the research and how you can participate, to answer all your questions and to explain what you did not understand. You can take the time to reflect on your participation in this research, and to discuss it with anyone you deem necessary.

At the end of the document, if you agree to participate to this research, the investigator will ask you to put your signature and the date of your consent, and we will give you a copy.

Why is the survey being done?

The survey is a research study and is not part of the health services normally provided to you as part of the COVID19 response. We are carrying out the survey to better understand COVID-19 infection among people experiencing homelessness. Besides this, we would like to determine risk factors for becoming infected and see if there are any differences depending on where people have been staying.

The results of the survey will be used to improve the response for vulnerable people who are experiencing homelessness.

How are people chosen to take part?

We hope that about 800 people in total will take part in the survey across several sites. We have randomly selected individuals to participate based on registers of everyone who stays in this facility. Each person had an equal chance of being chosen, whether or not anyone has been infected with COVID-19. We are asking all those aged 18 years and older to take part in the survey.

What happens to those who take part?

There are two parts to taking part in the survey today: Answering a questionnaire; and providing samples of blood for tests for research purposes.

Questionnaire: An interviewer will ask you a set of questions. The interview will be done in a private area. The questionnaire will take about 20 minutes to complete. The questions will cover:

Questions about you, such as age, sex, occupation, main nationality

Questions about symptoms you have experienced since March and potential COVID exposures

Questions about any previously diagnosed illnesses you may have had and any medicines you take.

Blood samples: You will be asked to provide 1 tube of blood taken from a vein in your arm. The blood will be sent to the lab at Institut Pasteur to conduct tests. All the tests done will be related to COVID-19 infection. The tests will be done for research purposes, but you will be able to get the results of tests that can tell you if you have been or are infected with COVID-19.

The serology test will be performed by Institute Pasteur (Paris) and the results should be available within 2 weeks of the survey. If you want to know your test results, we will need to record some personal information in order to contact you within 2 weeks with the results. You have the right to refuse to get the results and to refuse to give us any personal information.

MSF will be responsible for collection of all blood specimens, transport and storage until they reach the laboratory where the different tests will be performed. Institut Pasteur will be responsible for the samples until the serology analysis is performed.

You will be asked permission to store your blood sample at Institut Pasteur for the 6 months following the end of the survey, for potential new research on Covid-19 (to improve the current serology technique, for example). You are free to accept or refuse without any impact on participation in the current survey. If you accept, you will have the possibility, at any moment, to ask for the destruction of your sample, without giving any reason or explanation.

Why test for antibodies?

Antibodies are part of your immune system's response to infection. They are proteins your body makes which stay in your blood once infected with a bacterium or virus. COVID-19 antibodies appear in your blood around 7-10 days after an infection.

The serology test we are using to test for antibodies in the study is called LuLISA. The LuLISA blood test will tell you (and us) if you were exposed to COVID-19 in the past or not, as it detects the antibodies your body produces in response to the virus, not the virus itself.

The LuLISA blood test is different from lab tests to detect the active COVID-19 virus (which use samples from the back of your throat or nose). If you have any COVID-19 symptoms when we talk with you, you can have an oral or nasal swab test as well, to confirm whether or not you have acute COVID-19 illness.

• If your test shows you have zero antibodies it does not mean you could not have COVID-19 now, but it does mean you have not been exposed in the past.

Can I choose not to take part?

It is up to you whether you take part in the survey or not.

How will I be affected if I choose not to take part?

If you decide not to take part, there will be no consequence, and you will still be able to use all the health services that are normally available.

If you decide to take part, please be aware that you can withdraw your consent to this survey at any time, without having to give any reason and without any consequence on the health services that MSF could offer you now or in the future.

What are the risks of taking part?

There are some risks that go with taking part in the survey. The researchers and survey teams will do everything possible to keep the risks as small as possible.

Having blood taken from the arm may hurt and cause bleeding or bruising. A few people may feel faint at the sight of blood. The sampling will be carried out by trained nurses and special care will be taken to avoid any discomfort. If it is not possible to get enough blood, or if you are too uncomfortable, we will not include you in this study. You can decide if you are too uncomfortable to continue. This will have no impact on your access to health services.

The study documents and samples collected will not mention your name but there is still a small risk of loss of confidentiality.. To minimize this risk, study staff will be trained to keep everything secure and secret, study areas will be carefully selected, blood test results will only be given to you in private, and study documents will be kept in a locked cabinet only accessible by the study team

All study participants will be covered by insurance against any event affecting their health related to study procedures.

What are the advantages of taking part?

Taking part in the survey means that you will be given an opportunity to have COVID testing and be given your COVID test result to determine if you have been previously exposed to COVID-19.

Furthermore, you are taking part in a research that will help improve and guide efforts to understand the extent of COVID-19 virus infection among people experiencing homelessness, sowe can help improve the response to this and other epidemics in future.

How will my privacy be protected?

Your participation in this survey involves collecting personal data about you. To this end, your medical data, data related to your lifestyle and, as far as it is necessary for research, data related to your ethnic origins and your education level will be transmitted to Thomas Roederer (study coordinator) or to persons acting on behalf of MSF, in France. These data will be recorded electronically and confidentiality will be ensured through a study number.

All information that you provide when answering the questionnaire, and all test results will be kept confidential (private) and will not be given to anyone other than the researchers.

You will not have your names written on the questionnaire, and your names will not be given to people in the laboratories doing the research tests. No participants' names will be given when the results of the survey are reported.

Your name and contact information will be kept separately from all other study documents and this information will be used to contact you for the follow-up appointment and to notify you of the availability of test results.

For each question that we ask you, your responses will be recorded on a tablet, with the identifier being your study number. The information will then be saved on a computer, and the analyses will be performed once all of the information from all of the participants has been collected, later in the month.

The paper survey documents will be stored in a secure room at the MSF office in Paris for the duration of the survey, then archived for 15 years and then destroyed. But the file which matches your study number to your name will be destroyed after we give you your blood test results. The computers and tablets will be password-protected. You have the right to access your personal data at any time, to request a copy, to provide corrections or to request that the data be permanently deleted by contacting MSF. These decisions will not have any negative effect on any care that you may need in the future.

Your rights

In accordance with Law No. 78-17 regarding data processing, files and freedoms and to the General Data Protection Regulation (Regulation (EU) 2016/679), you have the following rights:

• the right to request access, modification, deletion or limitation of the data collected as part of the research. You can also obtain access directly (or through a doctor of your choice) to all of your medical data in accordance with article L. 1111-7 of the Public Health Code

• the right to refuse the collection and transmission of the data covered by medical confidentiality

• the right to claim all your data back, if you chose to transfer them to another data controller (right to portability)

• the right to withdraw your consent to collection of your data at any time. If during the research you no longer wish to participate, the collected data before the withdrawal will be used by the investigator, unless you object. In this case, your data be will destroyed.

These rights are exercised with the investigator or his or her designated representative who follows you in the research and who knows your identity. You may also contact the Data Protection Officer appointed by Commission Nationale de l'Informatique et des Libertés - CNIL.

You also have the right to file a complaint with the Commission Nationale de l'Informatique et des Libertés - CNIL (French data protection authority).

Will I be entitled to compensation if I agree to participate?

No compensation is provided for participation in this research.

Who can I contact if I have questions or concerns about the survey?

If you have questions that you would like to ask before deciding whether to take part, you can ask them now. If you have questions later about the survey, you can call MSF hotline free numberat **07 85 05 37 64**.

If you would like to report concerns about the survey or think that you have been harmed by taking part, you can call [full name], [job title and ethics committee], the committee giving ethical approval for this study, at [telephone number].

Authorizations

This survey received final approval from the MSF Ethics Review Board and from the Committee for the Protection of Persons on [date].

The survey is conducted in accordance with the reference methodology MR 001 approved by the Commission Nationale de l'Informatique et des Libertés (CNIL) and to which MSF has obligation to comply (receipt no. XXXXX of XXXXXX).

You are making a decision whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered, and have decided to participate.

You will be given a copy of this form to keep.

CONSENT FORM TO PARTICIPATE IN RESEARCH – ADULTS ≥18 years

Seroprevalence of SARS-CoV-2 antibodies among people experiencing homelessness, Ile de France, France

If you are willing to participate in the study, please confirm by signing your name below.

1. I confirm that I have understood all of the information that the interviewer has given to me, and the expected risks and benefits

2. I confirm that I was encouraged to ask questions and given time for that, and a member of study staff has answered clearly all my questions about the study, before giving my consent to participate

3. I understand that if I don't want to participate, it will not affect my standard care in all the health services that are normally available

4. I understand that my participation is voluntary, and that I'm free to withdraw from the study at any time, without giving any reason, and without affecting my standard care now or in the future.

5. I agree to answer to an individual questionnaire today

6. I agree to a for COVID-19 test today by giving a blood sample. My sample will be labelled with my sample number only. That number will be linked to your name on a list kept separately than all other documents and to which on the study investigator has access. This list will be destroyed after results are given to you.

7. PERMISSION FOR SAMPLE STORAGE

□ I want my blood sample to be destroyed immediately after the exam.

□ I give my permission for my blood sample to be stored for a maximum of 6 months and during this period, to be used in future research about Covid-19 along with the data from me collected in this study.

8. I understand that my sample will be sent directly and with only my study number to the Institut Pasteur lab for processing Under no circumstance will any of my personal information be made available or disclosed for the purposes of these studies.

9. I understand that I will be informed about approximately when and where test results will be available.

10. I understand that my data will be kept for 15 years and that during this period, I may at any time request that they be modified or deleted from the investigator who knows my identity;

11. I understand that there will be no charge to me

13. I have received and read the information sheet, and someone has read it to me.
14. I confirm that it is totally free to participate

_____	_____	_____
Name of participant	Signature	Date

_____	_____	_____
Name of fieldworker	Signature	Date

WITNESS (If the person providing consent is unable to read.)

_____	_____	_____
Name of witness	Signature	Date

13.2 APPENDIX 2: REPORT FORM FOR ALL PARTICIPANTS

Variable	Categories
Surveyor Info	
Surveyour's initials	
Surveyour's phone number	
Date of interview (DD/MM/YYYY)	___/___/___
Inclusion site	List of codes
Participant Info	
Unique Identifier (study number)	
Translator present?	☐ No need for translator ☐ Translator (present) ☐ translator (by phone)
Language of the interview	☐ French ☐ English ☐ Other:_____
Gender	☐ Male ☐ Female ☐ Intersex ☐ Prefer not to answer
Country of Origin	
Date of Birth (DD/MM/YYYY)	___/___/___
Age (in years)	
Highest level of education reached	☐ Primary School ☐ Middle School ☐ High School ☐ University or equivalent ☐ Never attended school
COVID-19 Signs	
Since March 1st, have you had any of the following:	
Fever ≥38°C	☐ Yes ☐ No
Chills	☐ Yes ☐ No
Fatigue	☐ Yes ☐ No
Muscle ache (myalgia)	☐ Yes ☐ No
Sore throat	☐ Yes ☐ No
Cough	☐ Yes ☐ No
Runny nose (rhinorrea)	☐ Yes ☐ No
Shortness of breath	☐ Yes ☐ No
Wheezing	☐ Yes ☐ No
Chest pain	☐ Yes ☐ No
Other respiratory symptoms	☐ Yes ☐ No
Headache	☐ Yes ☐ No
Nausea/vomiting	☐ Yes ☐ No

Abdominal pain	□ Yes □ No
Diarrhoea	□ Yes □ No
Loss of taste	□ Yes □ No
Loss of smell	□ Yes □ No
If 1 or more signs, when did you experienced them (approx.)?	□ Before confinement (1-16 march) □ First month of confinement (17march-15 april)h □ 2d month (16 april-11 may) □ After deconfinement (>11 may) □ DNK
How long did they last (approx.)?	□ < 2 days □ 2 days to 1 week □ 1 to 2 weeks □ 2 to 3 weeks □ > 3 weeks □ DNK
Did you see a doctor for any of these signs?	□ Yes □ No □ DNK
Did you receive a nasal or throat swab (PCR test) for these signs?	□ Yes □ No □ DNK
If yes, when (approx.)?	□ 01-15 March □ 16-31 March □ 01-15 April □ 16-31 April □ 01-15 May □ 16-31 May □ 01-15 June □ DNK
What was the final result?	□ Positive □ Negative □ Undetermined □ Never received the results □ DNK
Did you go the hospital for any of these signs?	□ Yes □ No □ DNK
COVID among your live-in relatives and other people you live	
Did any of your live-in relatives or other people you share a room or kitchen with show signs of COVID?	□ Yes □ No □ DNK
Have any of them been confirmed COVID+ (PCR test)?	□ Yes □ No □ DNK
Have any of them been hospitalized for COVID+?	□ Yes □ No □ DNK
Who was/were this/those person(s)? (multiple choices)	□ Your spouse □ Your family (living with you) □ Roommates (same room) □ Flatmates (same flat, shared kitchen and sanitary) □ Neighbours (same building, different flat) □ Work colleagues □ Others, specify:
Residency	
BEFORE the lockdown, where did you sleep most of the time ?	□ My own flat □ Hotel room □ Sport facility □ Migrant Workers House □ Friend or relative □ Emergency shelter □ Camp □ Squat □ Street □ Do No Know
DURING the lockdown, where did you sleep most of the time ?	□ My own flat □ Hotel room □ Sport facility □ Migrant Workers House □ Friend or relative □ Emergency shelter □ Camp □ Squat □ Street □ DNK
DURING the lockdown, how many people did you share your place with (flat, house…) ?	

How many people did you share your room with (place to sleep) ?	
How many people did you share your toilet or shower with?	
How many people did you share your cooking space with ?	
What medical cover do you have (for healthcare) ?	□ Social Security only □ Social Security + Insurance or any additional cover □ Universal Medical Coverage (CMU) □ Aide Médicale d'Etat (AME) □ None □ No rights or under process □ DNK
Life during lockdown	
Did you work just before the lockdown (March 17th)?	□Yes □No □ not specified/not answered
-> If yes, during lockdown : did you go to work?	□ Almost every day □ Sometimes □ Rarely □ Never
During the lockdown, did you attend a food/items distribution ?	□ Almost every day □ Sometimes □ Rarely □ Never
During the lockdown, did you have children under your care ?	□Yes □No
During the lockdown, did you take any public transportation system?	□ Almost every day □ Sometimes □ Rarely □ Never
Approximately, how long did you stay outside of your place? (work, shopping, distribution, healthcare…) ?	□ Never □ <1h per day □ 1 to 3h per day □ 3 to 6h per day □ >6h per day
Approximately, how far from your place did you use to go? (maximum)	□ I never went out □ < 300m □ 300m to 1km □ 1 to 5km □ > 5 km
On average, every day : how many people were you in contact with (distance <1m for >15min) **inside** your home ?	□ Nobody □ 1 person □ 2 to 4 □ 5 to 10 □ 10 to 20 □ > 20
On average, every day : how many people were you in contact with (distance <1m for >15min) **outside of** your home ?	□ Nobody □ 1 person □ 2 to 4 □ 5 to 10 □ 10 to 20 □ > 20

During the lockdown, and considering your life conditions, which measure(s) could you actually follow :

	Every day	Often	Quite Often	Rarely	Very Rarely	Never	Impossible to apply (in my situation)	DNK
Regular handwashing (soap, gel…)	☐	☐	☐	☐	☐	☐	☐	☐
Avoiding direct physical contact (handshake, greetings…)	☐	☐	☐	☐	☐	☐	☐	☐
Wearing a face mask (any type)	☐	☐	☐	☐	☐	☐	☐	☐
Sneezing/coughing into my elbow	☐	☐	☐	☐	☐	☐	☐	☐
Disinfecting my everyday tools (cellphone, keys…)	☐	☐	☐	☐	☐	☐	☐	☐
Disinfecting my place of living	☐	☐	☐	☐	☐	☐	☐	☐

Medical History/Comorbidities	
Hypertension	☐ Yes ☐ No ☐ Unknown
Coronary Heart Disease	☐ Yes ☐ No ☐ Unknown
Congestive Heart Failure	☐ Yes ☐ No ☐ Unknown
Asthma	☐ Yes ☐ No ☐ Unknown
Chronic lung disease	☐ Yes ☐ No ☐ Unknown
HIV	☐ Yes ☐ No ☐ Unknown
Kidney Disease	☐ Yes ☐ No ☐ Unknown
Cirrhosis	☐ Yes ☐ No ☐ Unknown
Hep B	☐ Yes ☐ No ☐ Unknown
Hep C	☐ Yes ☐ No ☐ Unknown
Obesity (BMI >35)	☐ Yes ☐ No ☐ Unknown
Diabetes	☐ Yes ☐ No ☐ Unknown
Cancer	☐ Yes ☐ No ☐ Unknown
Past transplant (any organ)	☐ Yes ☐ No ☐ DNK
Autoimmune disease (Polyarthritis, Crohn, Lupus, Multiple Sclerosis…)	If yes, specify:
Smoking habits	☐ Current Smoker ☐ Former Smoker ☐ Never smoked
Ongoing Treatments	
Corticosteroids	☐ Yes ☐ No ☐ DNK

Cyclophosphamide/cyclosporines	□ Yes □ No □ DNK
Monoclonal antibodies	□ Yes □ No □ DNK
Anti Cancer treatment	□ Yes □ No □ DNK
Post-Transplant treament	□ Yes □ No □ DNK

13.3 APPENDIX 3: LABORATORY RESULTS (ONE PER SERUM SAMPLE COLLECTED)

Variable	**Coding**
Unique Identifier (study number)	
Date sample collected (DD/MM/YYYY)	___/___/___
Hour of collection	Hh : mm
Date sample received (DD/MM/YYYY)	___/___/___
Hour of reception	Hh : mm
Type of sample	□ Serum □ Other, specify:
Type of serological assay	
Serology result	□ Positive □ Negative □ Unknown
COVID-19 virus titres	
Date of result (DD/MM/YYYY)	___/___/___

13.4 APPENDIX 4: TIMELINE FOR THE STUDY

Week	W1	W2	W3	W4	W5	W6	W7	W8	W9	W10
Protocol										
Protocol submission	X									
Human Resources										
Recruitment of investigators		X								
Training		X								
Implementation										
Data collection			X							
Laboratory										
Send blood samples to lab			X							
Laboratory analysis			X	X						
Data analysis										
Data analysis				X	X	X				
Results and Communication										
Preliminary results							X	X		
Final report									X	X

13.5 APPENDIX 5: RESOURCES FOR THE STUDY

Estimated budget

Item	Quantity	Unit Price(€)	Duration (month)	Workload	Cost (€)
Surveyor / Translator	5	2409	0,40	100%	4 818
Translator (results)	1	2409	0,15	100%	361
Nurse	5	2703	0,40	100%	5 406
Nurse (hotline, results)	1	2703	0,15	100%	405
Survey Coordinator (nurse) : field	1	2703	0,50	100%	1 352
Survey Coordinator : later stage	1	2703	0,75	50%	1 014
Survey Coordinator (med) : field	1	3049	0,50	20%	305
Survey Coordinator (med) : later stage	1	3049	0,75	50%	1 143
Principal Investigator (statistician/epi)	1	3049	1,00	80%	2 439
Translation of study docs	70	60	1	100%	4 200
Protection Material : gloves	500	0.4	-	-	200
Protection Material : masks	1000				750
Blood collection kit	1000	3	1,00	100%	3 000
Vehicle	2	800	0,50	100%	800
			Total		**26 193**

Costs of serology assays, reagents, materials as well as lab technician salary will be covered by Institut Pasteur.
Costs of management and destruction of hazardous medical waste will be covered by Institut Pasteur.