Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health care setting

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Reference:

The emergence of a new virus means that understanding transmission patterns, severity, clinical features and risk factors for infection will be limited at the start of an outbreak. To address these unknowns, WHO has provided Four Early sero-epidemiological Investigation Protocols (rebranded the WHO Unity Studies). One additional study to evaluate environmental contamination of COVID-19 is also provided.

These protocols are designed to rapidly and systematically collect and share data in a format that facilitates aggregation, tabulation and analysis across different settings globally.

Data collected using these investigation protocols will be critical to refine recommendations for case definitions and surveillance, characterize key epidemiological features of COVID-19, help understand spread, severity, spectrum of disease, and impact on the community and to inform guidance for application of countermeasures such as case isolation and contact tracing.

They are available on WHO website here: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations)

COVID-19 investigations and studies protocols currently available include:

1. The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19).

2. Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)

3. Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health-care setting.

4. Population-based age-stratified seroepidemiological investigation protocol for coronavirus 2019 (COVID-19) infection

5. Surface sampling of COVID-19 virus: a practical "how to" protocol for health care and public health professionals

Please contact earlyinvestigations-2019-nCoV@who.int

All WHO protocols for COVID-19 are available on the WHO website together with the technical guidance documents.

Contents

Summary

Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health care setting	
Study population	Health workers in a health care setting in which a patient with a laboratory-confirmed COVID-19 infection is receiving care
Potential output and analysis	Transmissibility in health care settings through estimates of: • secondary infection rate (SIR) among health workers; • range of clinical presentation and risk factors for infection; • serological response following symptomatic COVID-19 infection Identification of possible routes of transmission
Study design	Prospective study of health workers involved in the care of any confirmed COVID-19 case, irrespective of symptoms
Minimum information and specimens to be obtained from participants	**Data collection** Epidemiological data including: clinical symptoms; exposures in health care facility, including contact with confirmed case(s); and use of personal protective equipment **Specimens** • Serum to inform seroepidemiological inferences • Optional – respiratory (and other) to diagnose current COVID-19 infection

The World Health Organization (WHO), in collaboration with technical partners, has developed a series of enhanced surveillance protocols that are harmonized to help provide detailed insight into the epidemiological characteristics of COVID-19.

The scope and focus of this document and the other COVID-19 investigations protocols listed above are compared in Appendix B.
All WHO protocols for COVID-19 are available on the WHO website, together with technical guidance documents, including surveillance and case definitions; patient management; laboratory guidance; infection prevention and control; risk communication and community engagement; travel advice; and more.

Comments for the user's consideration are provided in purple text throughout this document as the user may need to modify the methods described due to the local context in which this study will be carried out.

1 Background

The detection and spread of an emerging respiratory pathogen are accompanied by uncertainty concerning the key epidemiological, clinical and virological characteristics of the novel pathogen, particularly its ability to spread in the human population and its virulence (case severity). This is the case for the coronavirus disease 2019 (COVID-19 first detected in Wuhan, China in December 2019 *(1)*.

Other coronaviruses, such as severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV), have been characterized by inefficient transmission in general community settings. However, they have also been associated with amplification events in health care settings, occasionally resulting in large nosocomial outbreaks. Overcrowding in emergency rooms, non-adherence to infection prevention and control measures, and possible environmental contamination are all thought to be implicated in such amplification in the case of MERS-CoV outbreaks *(2–6)*.

Health workers play a critical role not only in the clinical management of patients but also in ensuring that adequate infection prevention and control measures are implemented in health care facilities. As initial surveillance activities focus primarily on patients with severe disease the full spectrum of disease, including the extent and fraction of mild or asymptomatic infections that do not require medical attention, will not be immediately clear, along with the role that such infections may play in secondary transmission.

Understanding COVID-19 infection among health workers and the risk factors for adverse outcomes is important not only for characterizing virus transmission patterns and risk factors for infection, but also for preventing the future infection of health workers and other patients, for informing and updating infection prevention and control measures at health care facility and national level, and for reducing secondary COVID-19 transmission within health care settings.

Currently, the extent of COVID-19 infection in health care settings is not clear – nor is it clear whether there are certain risk factors associated with infection in health workers. The following protocol has been designed to investigate the extent of infection in health care settings and to identify risk factors for infection among health workers. Follow-up and testing of respiratory specimens and serum of health workers within a facility in which a confirmed case of COVID-19 infection is receiving care can provide useful information on virus transmissibility and routes of transmission, and will be an important step in limiting amplification events in health care facilities.

Each country may need to tailor selected aspects of this protocol to align with their public health, laboratory and clinical systems, according to capacity, availability of resources and cultural appropriateness. However, by using the standardized protocol described below, data on epidemiological exposure and on biological samples can be systematically collected and shared rapidly in a format that can be easily aggregated, tabulated and analyzed across many different settings globally. This will then allow for the timely estimation of COVID-19 infection severity and attack rates, thus informing public health responses and policy decisions. Such information is particularly important in the context of a novel respiratory pathogen, such as COVID-19.

1.1 Objectives

There are four primary objectives of this prospective study among health workers in a health care facility in which a patient with a laboratory-confirmed COVID-19 infection is receiving care:

1. To better understand the extent of human-to-human transmission among health workers by estimating the secondary infection rate[1] for health worker contacts at the individual level.
2. To characterize the range of clinical presentations of infection and the risk factors for infection among health workers.
3. To evaluate the effectiveness of infection prevention and control measures among health workers.
4. To evaluate the effectiveness of infection prevention and control programmes at health facility and national level.

The study can also permit the evaluation of a number of secondary objectives, including but not limited to:

1. determining the serological response of health workers with symptomatic and possibly asymptomatic COVID-19 infection;
2. characterizing the duration and severity of COVID-19-associated disease among health workers.

COMMENT: The antibody kinetics of COVID-19 infection are currently not known, and the serological response in cases of mild or asymptomatic COVID-19 infections may be limited. The study investigators may wish to consider using molecular testing of health worker contacts to capture acute infection (regardless of symptoms) if the study is started shortly after the identification of a patient with COVID-19 infection within the health care facility.

1.2 Coordination of health workers investigation

Coordination of investigations and sharing of information in real-time will be needed at both country and global levels. Epidemiologists, modellers, virologists, statisticians, clinicians and public health experts will all assist in developing early estimates of key clinical, epidemiological and virological parameters of the COVID-19 virus. Table 1 shows the roles and responsibilities involved for Country X.

Table 1. Coordination matrix of roles and responsibilities in Country X

What?	Who?
Overall coordination of the early investigation	[Cite institution/ body/person(s)]
Case detection and investigation	[Cite institution/ body/person(s)]
Contact identification and follow-up	[Cite institution/ body/person(s)]
Analysis of data	[Cite institution/ body/person(s)]
Data management	[Cite institution/ body/person(s)]
Go.Data super-users (if Go.Data tool is used)	[Cite institution/ body/person(s)]
IT management	[Cite institution/ body/person(s)]
[add more roles, as per country context]	[Cite institution/ body/person(s)]

The FFX system will be maintained centrally by [cite institution/body/person(s)]. Centralized coordination will require development of a "command and control" plan, to allow for triage and prioritization of investigations.

[1] In this context the **secondary infection rate (SIR)** is a measure of the frequency of new infections of COVID-19 among contacts of confirmed cases in a defined period of time, as determined by a positive COVID-19 result. In other words, it is the rate of contacts being infected, assessed through polymerase chain reaction (PCR)/serological assays on paired samples.

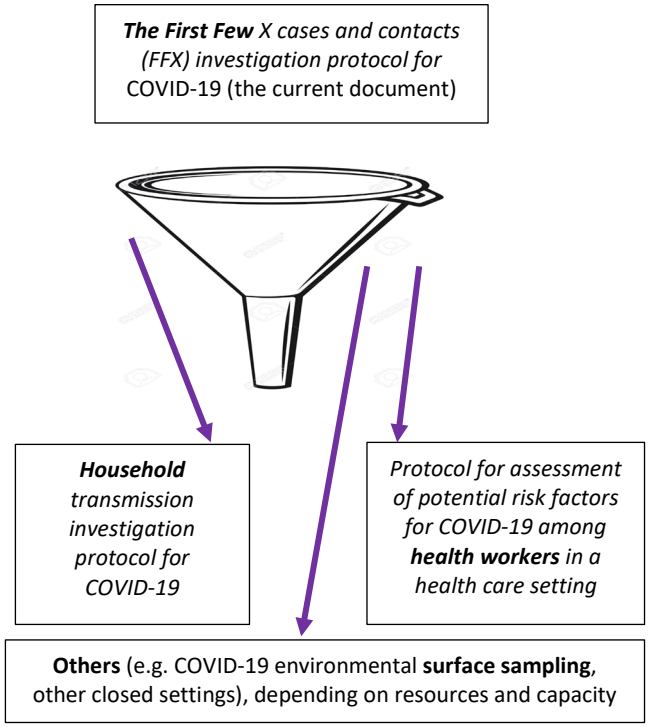
1.3 Harmonization of early COVID-19 investigations

Early COVID-19 investigations are a suite of enhanced surveillance activities that are harmonized to help provide detailed insight into the epidemiological characteristics of COVID-19.

The **FFX protocol** outlines the process for early and rapid data collection for the first few early cases of the pandemic, which will provide critical early insight into key epidemiological characteristics such as the transmissibility and severity of COVID-19 infection. This protocol may be the first investigation to be conducted. Other early investigations of COVID-19 could be simultaneously or subsequently undertaken to collect further information relating to COVID-19 infection, depending on the availability of resources and capacity. These could include prospective investigations of transmission of COVID-19 in **households** and also in closed environments, such as for **health workers**. These investigations will provide a more detailed insight on transmissibility and severity; the effect of interventions in reducing the risk of infection; and the risk of secondary infection, as well as giving an estimate the asymptomatic fraction (proportion of asymptomatic cases).

All WHO early investigation protocols for COVID-19 are available on the WHO website (Fig. 1).

Fig. 1. Complementarity of COVID-19 protocols currently available on the WHO website



2 Methods

2.1 Design

This is a prospective study of all identified health worker contacts working in a health care facility in which a patient with a laboratory-confirmed COVID-19 infection is receiving care (see section 2.2 Study population). Note that this study can be conducted in health care facilities at all three levels of a health system – not just in hospitals. It is intended to provide epidemiological and serological information which will inform the identification of risk factors for COVID-19 infection among health workers.

The timing of this study is critical. Ideally, it should be conducted as soon as possible after a patient with COVID-19 is identified at a health care facility. It must also be possible to define a discrete period of potential exposure for each area of the health care facility that the patient has visited, and to produce an exhaustive list of all health workers who have been present in the same area as the patient. It should also ideally be conducted during the early phases of an epidemic, before widespread transmission or nosocomial outbreaks occur.

2.2 Population

The study population is derived from the identification of all health personnel who have worked in a health care facility in which a patient with a laboratory-confirmed COVID-19 infection is receiving care. Every effort should be made to include all identified health workers who have worked at any point during the time that the patient has been in the health care facility.

COMMENT: It is likely that a patient will have moved around several areas of a health care facility – for example, while being admitted at the Emergency Room, transported to radiology and moved to a ward. Every effort should be made to include all health workers who have been in the same areas as the patient following their admission.

For the purpose of this study the definition of **health worker** should not be too restrictive so that a large number of potentially exposed health personnel are included in the study. For this reason, **health worker** should be defined as all staff in the health care facility involved in the provision of care for a COVID-19-infected patient, including those who have been present in the same area as the patient as well as those who may not have provided direct care to the patient but who have had contact with the patient's body fluids, potentially contaminated items or environmental surfaces. This will include health care professionals, allied health workers and auxiliary health workers such as cleaning and laundry personnel, x-ray physicians and technicians, clerks, phlebotomists, respiratory therapists, nutritionists, social workers, physical therapists, laboratory personnel, cleaners, admission/reception clerks, patient transporters, catering staff etc.).

Once a case of COVID-19 infection has been identified in a health care facility, a list of all health workers with any exposure to the affected patient will need to be drawn up (see **Guidance for identifying all health workers with possible exposure** in Appendix A). This should be done in consultation with supervisors and colleagues using duty rosters and possibly the medical file of the patient to identify all the areas of the health care facility the patient has visited and to ensure that all relevant health workers can be identified and recruited into the study.

COMMENT: This protocol is designed to assess risk factors for infection among health workers with potential exposure to COVID-19. It does not include visitors to the health care facility who may have had contact with a COVID-19-infected patient or with the patient's materials.

COMMENT: For the purpose of comparability between different studies it is important that health worker encounters are defined clearly in terms of type and duration of potential exposure in the study report.

2.3 Eligibility criteria

Inclusion criteria
All health workers with possible exposure to COVID-19 in a health care facility in which a patient with laboratory-confirmed COVID-19 infection is receiving care, including exposure to the patient's blood and body fluids, and to contaminated materials or devices and equipment linked to the patient.

Exclusion criteria
Health workers who work in another health care facility, particularly those that work in a health care facility which has recently experienced, or is experiencing, widespread nosocomial transmission of COVID-19; and health workers who have a confirmed COVID-19 case among their household/close contacts.

COMMENT: The concept of "protected exposure" will be evaluated as part of this study. As such, the wearing of personal protective equipment (PPE) should not be considered an exclusion criterion as one of the risk factors to be studied is the use of appropriate PPE.

Equally, symptomatic health workers should also not be excluded from the study. In the event that a symptomatic health worker is too ill to be interviewed, the investigators should consider whether a proxy (colleague or supervisor) may be able to be complete the questionnaire on their behalf.

2.4 Data collection

All health workers recruited into the study will need to complete a questionnaire (see Appendix A) which covers: (a) demographic information; (b) adherence to infection prevention and control measures; and (c) contact with, and possible exposure to, the COVID-19-infected patient following their admission to the health care facility. Although the forms provided in Appendix A which constitute the questionnaire are not exhaustive they outline the data collection required to provide insights into the epidemiology of COVID-19 (Table 2), and may be further updated and revised. The study protocol and questionnaire may need to be adapted depending on the local setting and on the outbreak characteristics.

Table 2. Summary of data-collection tools

Form number	Purpose of form	Collecting from whom?	When should it be collected?
HEALTH WORKERS			
Form 1	**Initial** reporting form	For health workers with possible exposure	As soon as possible after laboratory confirmation of a case in a health care facility in which the case is receiving care (**Day 1**)
Form 2	**Follow-up** reporting form	For health workers: final outcome	At least 21 days after completion of Form 1 (**Day > 21**) Updates should be sought regularly, if all the required information is not available at the time of completing this form
Form 3: Symptom diary	Record the presence or absence of various signs or symptoms	For health workers with possible exposure	For a **minimum of 21 days** after administration of the initial questionnaire (Form 1)
HEATH CARE FACILITY			
Form 4	Health care facility infection prevention and control assessment	For health care facility administrator	Needs to be filled out once for every health care facility involved in the study

Table 3. Timeline of data and specimen collection in the health worker investigation protocol

Day since recruitment	1	…	…	**21-28**
Visit to health care facility and data collection				
Serum sample				
Respiratory samples	Optional and dependent upon situation and upon resource availability			Optional and dependent upon situation and upon resource availability
Other specimens (if relevant)	Optional and dependent upon situation and upon resource availability			

Blue boxes indicate activities which are needed for the study.
Green boxes indicate when additional specimens could be collected above the minimum specimen requirements of the study to increase the information available. These could include respiratory samples for molecular testing to detect acute COVID-19 infection, regardless of symptoms.

2.5 Use of Go.Data tool

Go.Data is an electronic field data collection tool that has been designed to be used by WHO, the Global Outbreak Alert and Response Network (GOARN), Member States and partners to support and facilitate outbreak investigation including field data collection, contact tracing and visualization of chains of transmission. The tool includes functionality for case and contact data collection, contact follow-up and visualization of chains of transmission. It has two components: a web application and an optional mobile app. The tool is targeted at any outbreak responders, including WHO staff, and staff from ministries of health and partner institutions.

Key features of the Go.Data software include (for more details and screen shots, please refer to Appendix C):

- it is open source and free for use with no licensing costs;
- it offers different types of operation (server or stand-alone) on different platforms (Windows, Linux, Mac);
- it allows for data collection from cases and contacts, including laboratory data;
- it is not built for a specific disease or specific country; it is highly configurable, with configurable reference, outbreak and location data;
- one Go.Data installation can be used to collect data for many outbreaks;
- it provides multilingual support, with the possibility to add and manage additional languages though the user interface;
- it allows granular user roles and permissions, including the possibility to provide user access at outbreak level;
- outbreak templates are included for easier creation of outbreak data-collection forms;
- it generates a contact follow-up list and visualizes chains of transmission;
- users with appropriate rights can configure the case investigation form, contact follow-up form and laboratory data-collection form; and
- it has an optional mobile app (Android and iOS) focused on case and contact data collection, and contact tracing and follow-up.

Several options are available for Go.Data hosting in countries (see Appendix C).

For further information contact: godata@who.int or visit https://www.who.int/godata *(19).*

2.6 Laboratory evaluations

2.6.1 Specimen collection

COMMENT: The following is intended to guide minimum specimen collection from all health workers. Depending on how long after the identification of the COVID-19 case in the health care facility the study is conducted, the study investigators may also want to consider including respiratory samples for molecular testing to detect acute COVID-19 infection, and/or serial respiratory sampling. Please note that appropriate PPE must be worn by study investigators during the collection of any specimen (see section 2.7.5 below on Prevention of COVID-19 infection in study personnel).

A **baseline serum sample** should be collected from all health workers as soon as possible after confirmation of the admission of a COVID-19-infected patient into the health care facility.

A second serum sample will then need to be collected from the same health workers at least 21 days after collection of the first serum sample. These paired serological samples will allow for detection of seroconversion, for better understanding of the secondary infection attack rate and for determination of the proportion of infections that are asymptomatic. These paired serological samples should be taken from all identified health worker contacts, regardless of symptoms.

Respiratory specimen collection (e.g. nasopharyngeal) **and other specimens** may be collected to determine acute COVID-19 infection, as determined by the objectives of the investigation and the available resources and capacity.

2.6.2 Specimen transport

All those involved in collecting and transporting specimens should be trained in safe handling practices and spill decontamination procedures. For details regarding the transport of samples collected and infection control advice, please refer to the case management algorithm and laboratory guidance in the country, or to WHO laboratory guidance, available on the WHO website.

For each biological sample collected, the time of collection, the conditions for transportation and the time of arrival at the laboratory will be recorded. Specimens should reach the laboratory as soon as possible after collection. If the specimen is not likely to reach the laboratory within 72 hours, it should be frozen, preferably at –80 °C, and shipped on dry ice. It is, however, important to avoid repeated freezing and thawing of specimens. The storage of respiratory and serum specimens in domestic frost-free freezers should be avoided, owing to their wide temperature fluctuations. Serum should be separated from whole blood and can be stored and shipped at 4 °C or frozen to –20 °C or lower (at -80°C) and shipped on dry ice.

Transport of specimens within national borders should comply with applicable national regulations. International transport of specimens should follow applicable international regulations as described in the WHO *Guidance on regulations for the transport of infectious substances 2019–2020*.

2.6.3 Laboratory analysis

Several assays that detect the novel coronaviruses have been recently developed and the protocols or standard operating procedures can also be found on the WHO website .

Serologic assays specific to COVID-19 are currently under development / in the process of evaluation. The protocols or Standard Operating Procedures (SOPs) will be published on the WHO website once they become available. Cross reactivity to other coronaviruses may be an issue and should be considered in the interpretation of data. Multiple assays may be required to confirm a seropositive for COVID-19 virus. Serum samples could be stored at -80°C until more information on performance of available assays are available.

2.7 Ethical considerations

Ethical requirements will vary by country. In some countries, this investigation may fall under public health surveillance (emergency response) acts and may not require ethical approval from an institutional review board.

2.7.1 Informed consent

The purpose of the study must be explained to all known health worker contacts of a confirmed COVID-19-infected patient. In addition, informed consent must be obtained from all health worker contacts willing to participate in the study before any procedure is performed as part of the investigation by a trained member of the investigation team. Each participant must be informed that participation in the study is voluntary and that they are free to withdraw, without justification, at any time without consequences and without affecting their professional responsibilities.

COMMENT: The age at which informed consent to study participation can be given may vary by country. The requirements of local, regional or national authorities in this regard must therefore be ascertained in advance.

It should be explained to study subjects that informed consent will mean that blood samples and epidemiological data for the intended purpose of the study will be collected, that samples may be shipped outside of the country for additional testing and that samples may be used for future research purposes.

2.7.2 Risks and benefits for subjects

This study poses minimal risk to participants involving the collection of a small amount of blood. The direct benefit to the participant will be the potential detection of COVID-19 infection, which would then allow for appropriate monitoring and treatment. The primary benefit of the study is indirect in that the data collected will help to improve and guide efforts to understand the transmission of COVID-19 and to prevent its further spread.

2.7.3 Confidentiality

Participant confidentiality must be maintained throughout the study, especially in the case of health workers exposed to COVID-19. All study participants must be assigned a study identification number by the investigation team for the labelling of questionnaires and clinical specimens. The linking of this identification number to individuals will be managed by the investigation team and the Ministry of Health (or equivalent) and will not be disclosed elsewhere.

If data are to be shared by the implementing organization with WHO or any agency or institution providing support for data analysis then only the study identification number and not any personally identifiable information should be included.

Article 45 of the International Health Regulations (IHR, 2005) describes the “treatment of personal data”. Personally identifiable data collected under IHR (2005) should be kept confidential and processed anonymously, as required by national law. However, such data may be disclosed for the assessment and management of public health risks, provided the data are processed fairly and lawfully. The third edition of the IHR (2005) is available on the WHO website at: https://www.who.int/ihr/publications/9789241580496/en/

2.7.4 Terms of use: Go.Data

If groups implementing the investigation opt to use open-source Go.Data as a tool to run this investigation *(18)*, several options are available for Go.Data hosting in countries. Detailed information is presented in Appendix C of this document. The group implementing the investigation will need to consider the best approach for the investigation setting.

If the Go.Data server is to be based at WHO, access to the Go.Data application on this server will

be restricted to users who have valid login credentials for the Go.Data application. Please see Appendix C for the terms of use of Go.Data.

2.7.5 Prevention of COVID-19 infection in study personnel

All personnel involved in the study need to be trained in infection prevention and control procedures (standard contact, droplet and airborne precautions, as determined by national or local guidelines). These procedures should include proper hand hygiene and the correct use of medical or respiratory face masks, if necessary, not only to minimize their own risk of infection when in close contact with health workers who have had potential exposure to a COVID-19-infected patient, but also to minimize the risk of spread among health worker contacts of a COVID-19-infected patient.

WHO technical guidance on infection prevention and control specific to COVID-19 is available on the WHO website at: https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected

3 Statistical analyses

3.1 Sample size

The prospective study described in this protocol document is intended to provide information on the extent of COVID-19 infection among health workers and on possible risk factors for infection. Larger studies will undoubtedly permit a more robust analysis of potential factors affecting the risk of secondary infection and a more detailed characterization of serological responses following infection.

Sample sizes can be calculated using **statistical formulas or tools** available online (e.g. http://www.openepi.com/Menu/OE_Menu.htm) or in standard statistical packages. Note that for household surveys, the design effect is likely to increase the required sample size of the study. For the serial sampling investigations (i.e. repeated cross-sectional or longitudinal cohort investigations) or risk factor studies, investigators should perform sample size calculations to ensure that their investigations are adequately powered.

3.2 Plan of analysis

The combination of epidemiological, virological (genomic, antigenic) and serological data can provide unparalleled early situational awareness of the pandemic, which will promote a proportionate and targeted public health response.

A descriptive analysis (time, place and person) should provide preliminary insight into the clinical spectrum and course of disease due to COVID-19 infection among health workers

Advanced analytics Table 4 provides an overview of the epidemiological parameters that that can be calculated using the forms/questionnaires and specimens generated. The table includes a comments/limitations section which provides insight into the strengths and weaknesses of this protocol.

Table 4. Definition and source of epidemiological parameters that can be estimated during a health workers investigation

Parameter	**Definition** *Simplified" expression shown in italics immediately below*	**Required Form (and questions) for obtaining the data needed to calculate the parameter concerned**	**Comments, limitations**
Secondary infection rate (also called secondary infection incidence)	A measure of the frequency of new cases of COVID-19 infection among the health worker contacts of a confirmed case in a defined period of time *The rate of infection among contacts –inferred*	Form 3	The numerator will be determined as the number of health workers confirmed to have COVID-19 infection, while the denominator will be determined as the total number of health workers

	through serological assays on paired samples		enrolled as contacts of the case Represents an overall risk of infection among health worker contacts for a defined period of time
Serological response to infection	Change in serum level of specific antibodies to COVID-19 *Increase in titre*.	Form 3	This can only be calculated with the addition of laboratory data Will be supplemented by the findings of clinical studies and first few outbreak studies to confirm that seroconversion following an infection is anticipated
Type of contact associated with highest risk of infection	Determining the groups who are most vulnerable to COVID-19 infection (for example, age groups, gender, occupation)	Form 1: Q6 Form 2: Q10	May only be an early signal, and other sources of information will need to be used to inform decision-making (line listing of cases and other clinical case series) This may be biased in this study as it is based on subjects being actively detected , and health care seeking behaviour may vary between population groups

4 Reporting of findings

Any investigation of this nature should include reporting on the following information, stratified by age, sex, and relevant time and place characteristics:

1. the number of laboratory-confirmed cases of COVID-19 infection, the number of health workers identified and, of those, the number enrolled and types of role they fulfil in the health care facility;
2. the number of health workers contacts with serological evidence of COVID-19 infection.

COMMENT: If molecular testing is included as part of the study, it will be important to report the number of health workers with acute COVID-19 infection and to characterize the severity of their illness.

It is also important to fully document the study design, including the definition of the health care facility and health worker, the approach to identification of health workers potentially exposed to a COVID-19-infected patient, the duration between collection of serum samples, and the laboratory methods used to ensure that data can be pooled to increase statistical power when estimating epidemiological parameters.

Ideally, information should be collected in a standardized format according to the questionnaires and tools provided in this generic protocol in order to support data harmonization and the comparison of results (see Forms 1–4 in Appendix A).

If the data are to be shared by the implementing organization with WHO or any agency or institution providing support for data analysis then such data must only be linked to the study identification number and not any personally identifiable information.

5 References

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6 Further reading and online courses

- World Health Organization. Coronavirus disease (COVID-19) situation reports (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/, accessed 12 February 2020).
- World Health Organization. National capacities review tool for a novel coronavirus (nCoV) (https://www.who.int/publications-detail/national-capacities-review-tool-for-a-novel-coronavirus-(ncov), accessed 12 February 2020).
- Risk communication and community engagement (RCCE) readiness and response to the coronavirus disease 2019 (COVID-19) Interim guidance v2. Geneva: World Health Organization; 2020 (WHO/2019nCoV/RCCE/v2020.2; https://www.who.int/publications-detail/risk-communication-and-community-engagement-readiness-and-initial-response-for-novel-coronaviruses-(-ncov), accessed 12 February 2020).
- Disease commodity package – novel coronavirus (nCoV). Geneva: World Health Organization; 2020 (https://www.who.int/publications-detail/disease-commodity-package---novel-coronavirus-(ncov), accessed 12 February 2020).
- World Health Organization. WHO recommendations to reduce risk of transmission of emerging pathogens from animals to humans in live animal markets (https://www.who.int/health-topics/coronavirus/who-recommendations-to-reduce-risk-of-transmission-of-emerging-pathogens-from-animals-to-humans-in-live-animal-markets, accessed 12 February 2020).
- Protocol to investigate non-seasonal influenza and other emerging acute respiratory

diseases. Geneva: World Health Organization; 2018 (WHO/WHE/IHM/GIP/2018.2; https://www.who.int/influenza/resources/publications/outbreak_investigation_protocol/en/, accessed 12 February 2020).

Online courses

- There are training resources for COVID-19 available on the WHO online learning platform (https://openwho.org/, accessed 12 February 2020).
- World Health Organization. Emerging respiratory viruses, including nCoV: methods for detection, prevention, response and control (https://openwho.org/courses/introduction-to-ncov, accessed 12 February 2020).
- World Health Organization. Critical care severe acute respiratory infection training (https://openwho.org/courses/severe-acute-respiratory-infection, accessed 12 February 2020).

More courses are in development; check the https://openwho.org/ link regularly

7 Acknowledgments

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Appendix A: Questionnaires and guidance

FOR HEALTH WORKERS
• **Form 1: Initial reporting form (Day 1)** • **Form 2: Follow-up reporting form (Day > 21)** • **Form 3: Symptom diary for health workers**
FOR HEALTH CARE FACILITY
• **Form 4: Health care facility infection prevention and control assessment**

Guidance for identifying all health workers with possible exposure

Before the study begins, all health workers with possible exposure to COVID-19 in a health care facility in which a patient with a laboratory-confirmed COVID-19 infection is receiving care need to be identified. This needs to begin with a consultation of the patient's medical file and health records to establish the date of admission and the periods of time spent in each area of the health care facility based on the patient's movements within the health care facility since admission.

For every area of the health care facility that the patient has been in since admission, all staff with exposure to the patient care area irrespective of direct contact with the patient need to be identified and included in the study.

Please note: **health worker** should be defined as all staff in the health care facility involved in the provision of care for a COVID-19 infected patient, including those who have been present in the same area as the patient, as well as those who may not have provided direct care to the patient, but who have had contact with the patient's body fluids, potentially contaminated items or environmental surfaces. This will include health care professionals, allied health workers and auxiliary health workers (such as cleaning and laundry personnel, x-ray physicians and technicians, clerks, phlebotomists, respiratory therapist, nutritionists, social workers, physical therapists, laboratory personnel, cleaners, admission/reception clerks, patient transporters, catering staff etc.).

Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health care setting

Form 1: Initial reporting form for health worker (Day 1)

Unique ID/Cluster number (if applicable):

1. Current status
□ Alive □ Dead □ Unknown/lost to follow-up

2. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	___/___/___
Name of data collector	
Data collector institution	

3. Contact identifier information	
First name	
Family name	
Sex	□ Male □ Female □ Not known
Date of birth (dd/mm/yyyy)	___/___/___ □ Unknown
Telephone (mobile) number	
Email	
Address (village/town, district, province/region)	
Country of residence	
Nationality	
Ethnicity (optional)	
Smoker	□ Yes □ No
Occupation in health care facility	□ Medical doctor □ Registered nurse (or equivalent) □ Assistant nurse, nurse technician (or equivalent) □ Radiology/x-ray technician □ Phlebotomist □ Physical therapist □ Nutritionist/dietitian **Other health personnel**: □ Laboratory personnel □ Admission/reception clerks □ Patient transporters □ Catering staff □ Cleaners

4. Adherence to infection prevention and control (IPC) measures information	
What was the date of your most recent IPC training within the health care facility (dd/mm/yyyy)	___/___/___
How much cumulative IPC training (standard precautions, additional precautions) have you had at this health care facility	□ Less than 2 hours □ More than 2 hours
Do you follow recommended hand hygiene practices?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Do you use alcohol-based hand rub or soap and water before touching a patient?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Do you use alcohol-based hand rub or soap and water before cleaning/aseptic procedures?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Do you use alcohol-based hand rub or soap and water after (risk of) body fluid exposure?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Do you use alcohol-based hand rub or soap and water after touching a patient?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Do you use alcohol-based hand rub or soap and water after touching a patient's surroundings?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Do you follow IPC standard precautions when in contact with any patient?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely □ I don't know what IPC standard precautions are
Do you wear PPE when indicated? (PPE includes: medical mask, face shield, gloves, goggles/glasses, gown, coverall, head cover, respirator (for example, N95 or equivalent) and shoe covers)	□ Always, according to the risk assessment □ Most of the time, according to the risk assessment □ Occasionally □ Rarely
Is PPE available in sufficient quantity in the health care facility?	□ Yes □ No □ Unknown

5. Exposures to COVID-19-infected patient	
Date of admission of confirmed COVID-19-infected patient (dd/mm/yyyy)	___/___/___
Have you had close contact with the patient (within 1 metre) since their admission?	□ Yes □ No □ Unknown

- If yes, how many times (total)?	
- If yes, for how long each time?	□ < 5 minutes □ 5–15 minutes □ > 15 minutes
- If yes, did you have prolonged face-to-face exposure (> 15 minutes)?	□ Yes □ No □ Unknown If yes, did you wear PPE? □ Yes □ No □ Unknown If yes, what type? Tick all that apply: □ Medical/surgical mask □ Respirator (for example,FFP2 or N95 masks or equivalent) □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Shoe covers
If you were wearing a medical mask, what type:	
If you were wearing a respirator, was it test fitted?	□ Yes □ No □ Unknown
If you were wearing gloves, did you remove them after contact with the patient?	□ Yes □ No
- If yes, did you perform hand hygiene before contact with the patient?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely If yes: □ Alcohol-based hand rub □ Soap and water □ Water
- If yes, did you perform hand hygiene after contact with the patient?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely If yes: □ Alcohol-based hand rub □ Soap and water □ Water
- If yes, were you present for any aerosolizing procedures performed on the patient?	□ Yes □ No □ Unknown If yes, describe the procedure: If yes, did you wear PPE?

	□ Yes □ No □ Unknown If yes, what type? Tick all that apply: □ Medical/surgical mask □ Respirator (for example,FFP2 or N95 masks or equivalent) □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Shoe covers
- If yes, did you come into contact with the patient's body fluids?	□ Yes □ No □ Unknown If yes, which body fluids: If yes, were you wearing PPE? □ Yes □ No □ Unknown If yes, what type? Tick all that apply: □ Medical/surgical mask □ Respirator (for example,FFP2 or N95 masks or equivalent) □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Respirator (for example, N95 or equivalent) □ Shoe covers
Have you had direct contact with the patient's materials since their admission? *Patient's materials: personal belongings, linen and medical equipment that the patient may have had contact with*	□ Yes □ No □ Unknown
- If yes, which materials?	Tick all that apply: □ Clothes □ Personal items □ Linen □ Medical devices used on the patient □ Medical equipment connected to the patient (ventilator, infusion pump etc.) □ Other:
- If yes, how many times since their admission (total)?	

- If yes, did you come into contact with the patient's body fluids via the patient's materials?	□ Yes □ No □ Unknown If yes, which body fluids: If yes, were you wearing PPE? □ Yes □ No □ Unknown If yes, what type? Tick all that apply: □ Medical/surgical mask □ Respirator (for example,FFP2 or N95 masks or equivalent) □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Shoe covers
- If yes, did you perform hand hygiene before contact with the patient's materials?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely If yes: □ Alcohol-based hand rub □ Soap and water □ Water
- If yes and you were wearing gloves, did you remove them after contact with the patient's materials?	□ Yes □ No
- If yes, did you perform hand hygiene after contact with the patient's materials?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely If yes: □ Alcohol-based hand rub □ Soap and water □ Water
Have you had direct contact with the surfaces around the patient?	□ Yes □ No □ Unknown
- If yes, which surfaces?	Tick all that apply: □ Bed □ Bathroom □ Ward corridor □ Patient table □ Bedside table □ Dining table □ Medical gas panel □ Other:

- If yes, how many times since their admission (total)?	
- If yes, did you come into contact with the patient's body fluids via the surfaces around the patient?	□ Yes □ No □ Unknown If yes, which body fluids: If yes, were you wearing PPE? □ Yes □ No □ Unknown If yes, what type? Tick all that apply: □ Medical/surgical mask □ Respirator (for example,FFP2 or N95 masks or equivalent) □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Shoe covers
- If yes, did you perform hand hygiene after contact with these surfaces?	□ Yes □ No □ Unknown If yes: □ Alcohol-based hand rub □ Soap and water □ Water

6a. Health worker symptoms	
Have you experienced any respiratory symptoms (sore throat, cough, running nose, shortness of breath) in the period since the patient was admitted?	□ Yes □ No If no, please move on to section 6c
If yes, date of first symptom onset (dd/mm/yyyy)	___/___/___ □ Unknown
Fever (≥ 38 °C) or history of fever	□ Yes □ No □ Unknown If Yes, date ___/___/___ If yes, specify maximum temperature:
6b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown

6c. Other symptoms	
Chills	□ Yes □ No □ Unknown
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhoea	□ Yes □ No □ Unknown
Headache	□ Yes □ No □ Unknown
Rash	□ Yes □ No □ Unknown
Conjunctivitis	□ Yes □ No □ Unknown
Muscle aches	□ Yes □ No □ Unknown
Joint ache	□ Yes □ No □ Unknown
Loss of appetite	□ Yes □ No □ Unknown
Loss of smell (anosmia) or taste	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Other neurological signs	□ Yes □ No □ Unknown If Yes, specify:
Other symptoms	□ Yes □ No □ Unknown If yes, specify:

7. Health worker pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If Yes, specify trimester: □ First □ Second □ Third □ Unknown
Obesity	□ Yes □ No □ Unknown
Cancer	□ Yes □ No □ Unknown
Diabetes	□ Yes □ No □ Unknown
HIV/other immune deficiency	□ Yes □ No □ Unknown
Heart disease	□ Yes □ No □ Unknown
Asthma (requiring medication)	□ Yes □ No □ Unknown
Chronic lung disease (non-asthma)	□ Yes □ No □ Unknown
Chronic liver disease	□ Yes □ No □ Unknown
Chronic haematological disorder	□ Yes □ No □ Unknown

Chronic kidney disease	□ Yes □ No □ Unknown
Chronic neurological impairment/disease	□ Yes □ No □ Unknown
Organ or bone marrow recipient	□ Yes □ No □ Unknown
Other pre-existing condition(s)	□ Yes □ No □ Unknown If yes, specify:

The following part will be filled out **by study coordinator or equivalent**

8a. Laboratory: Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result (COVID-19 antibody titres)**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Other, specify:	Specify type (ELISA/IFA IgM/IgG, neutralization assay, etc.):	□ POSITIVE If positive, titre: □ NEGATIVE □ INCONCLUSIVE	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: □ No

8b. Laboratory: Virology testing methods and results (OPTIONAL)							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Other, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for COVID-19 □ NEGATIVE for COVID-19 □ POSITIVE for other pathogens Please specify which pathogens:	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: □ No

9. Status of form completion	
Form completed	□ Yes □ No or partially If No or partially, reason: □ Missed □ Not attempted □ Not performed □ Refusal □ Other, specify:

Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health care setting

Form 2: Follow-up reporting form for health worker (Day > 21)

Unique ID/Cluster number (if applicable):

1. Current status
□ Alive □ Dead □ Unknown/lost to follow-up

2. Health worker pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If Yes, specify trimester: □ First □ Second □ Third □ Unknown

3a. Health worker symptoms	
Have you experienced any respiratory symptoms (sore throat, cough, running nose, shortness of breath) in the period since the baseline visit and specimen collection?	□ Yes □ No If no, please move on to section 3c
If yes, date of first symptom onset (dd/mm/yyyy)	___/___/___ □ Unknown
Fever (≥ 38 °C) or history of fever	□ Yes □ No □ Unknown If Yes, date ___/___/___ If yes, specify maximum temperature:
3b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown
3c. Other symptoms	
Chills	□ Yes □ No □ Unknown
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhoea	□ Yes □ No □ Unknown
Headache	□ Yes □ No □ Unknown
Rash	□ Yes □ No □ Unknown

Conjunctivitis	□ Yes □ No □ Unknown
Muscle aches	□ Yes □ No □ Unknown
Joint ache	□ Yes □ No □ Unknown
Loss of appetite	□ Yes □ No □ Unknown
Loss of smell (anosmia) or taste	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Other neurological signs	□ Yes □ No □ Unknown If Yes, specify:
Other symptoms	□ Yes □ No □ Unknown If yes, specify:

The following part will be filled out **by study coordinator or equivalent**

4a. Laboratory: Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result (COVID-19 antibody titres)**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Other, specify:	Specify type (ELISA/IFA IgM/IgG, neutralization assay, etc.):	□ POSITIVE If positive, titre: □ NEGATIVE □ INCONCLUSIVE	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: □ No

4b. Laboratory: Virology testing methods and results (OPTIONNAL)							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Other, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for COVID-19 □ NEGATIVE for COVID-19 □ POSITIVE for other pathogens Please specify which pathogens:	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: □ No

5. Status of form completion	
Form completed	□ Yes □ No or partially If No or partially, reason: □ Missed □ Not attempted □ Not performed □ Refusal □ Other, specify:

6. Outcome (Day > 21)	
Outcome	□ Alive □ Died □ NA □ Unknown If dead, cause:
Outcome current as of date (dd/mm/yyyy)	___/___/___ □ Unknown □ NA
Hospitalization	□ Yes □ No □ Unknown If yes, date of first hospitalization ___/___/___ □ Unknown If yes, reason for hospitalization:

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Form 3: Symptom diary for health workers

Symptom diaries will be provided to each health worker, for them to record the presence or absence of various signs or symptoms for a minimum of 21 days after the administration of the initial questionnaire (Form 1).

The symptom diary template provided below is generic. In the context of a new virus with uncertain clinical presentation and spectrum, symptom diaries may be broadened to include vomiting, diarrhoea, abdominal pain, etc., as relevant, and may be altered to include symptom data for longer than 14 days.

In the event of the contact developing any of these symptoms, ask them to inform your local public health team.

Day	**Symptoms***						
	No symptoms (check if none experienced)	**Fever ≥38 °C**	**Runny nose**	**Cough**	**Sore throat**	**Shortness of breath**	**Other symptoms: specify**
0	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
1	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
2	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
3	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
4	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
6	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
7	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
8	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
9	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
…							
…							
21	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	

*Please select “None” for no symptoms. If no symptoms are experienced, then consider the entry complete.

Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health care setting

Form 4: Health care facility infection prevention and control assessment

The following form will need to be filled out by a health care facility administrator once for every health care facility involved in the study.

Health care facility information	
Name of the health care facility in which a patient with a laboratory-confirmed COVID-19 infection is receiving care	
Does the health care facility have appropriate WASH services and materials?	□ Yes □ No □ Unknown
Does the health care facility have an infection prevention and control (IPC) programme and team or at least a dedicated and trained focal point?	Tick all that apply: □ IPC programme □ IPC team/service □ IPC focal point □ IPC training
Does the health care facility have IPC guidelines for health workers?	□ Yes □ No □ Unknown
Does the health care facility have IPC guidelines for standard and additional (transmission-based) precautions?	□ Yes □ No □ Unknown
Does the health care facility have regular IPC training for health workers (at least once a year)?	□ Yes □ No □ Unknown
Does the health care facility have personal protective equipment (PPE)?	□ Yes □ No □ Unknown
Is PPE available in sufficient quantity in the health care facility?	□ Yes □ No □ Unknown
Is the PPE available of good quality and fit for purpose?	□ Yes □ No □ Unknown
Is alcohol-based hand rub easily available (that is, at the point of care) for hand hygiene within the health care facility?	□ Yes □ No □ Unknown
Are soap and water available for hand hygiene within the health care facility?	□ Yes □ No □ Unknown
Does the health care facility conduct regular (at least once a year) hand hygiene audits and provide feedback to health workers?	□ Yes □ No □ Unknown If yes, date of last hand hygiene audit (dd/mm/yyyy): __/___/___
Does the health care facility conduct other IPC audits?	□ Yes □ No □ Unknown If yes, date of most recent IPC audit (dd/mm/yyyy): ___/___/___
Does the health care facility have a surveillance system for nosocomial infections in patients?	□ Yes □ No □ Unknown
Does the health care facility have a surveillance system for nosocomial infections in health workers?	□ Yes □ No □ Unknown
Does the health care facility screen staff on arrival for symptoms of infection?	□ Yes □ No □ Unknown

Does the health care facility management alert all health workers if a COVID-19-infected patient is being cared for within the health care facility?	□ Always □ In most situations □ Sometimes we are not alerted on time □ Rarely alerted on time
Does the health care facility have a well-equipped triage station at the entrance, supported by trained staff?	□ Yes □ No □ Unknown
Are patients with suspected COVID-19 infection isolated upon arrival in the health care facility?	□ Always □ Most of the time □ Occasionally □ Rarely □ Unknown
Is a medical mask fitted to patients with suspected COVID-19 infection upon arrival in the health care facility?	□ Always □ Most of the time □ Occasionally □ Rarely □ Unknown
Are health worker staffing levels adequate for the patient workload?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Does bed occupancy exceed the standard capacity of the health care facility?	□ Always □ Most of the time □ Occasionally □ Rarely

Appendix B: Comparison between the features and complementarity of the main coronavirus disease 2019 (COVID-19) early investigation protocols

	The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)	**Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)**	**Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health care setting**
Population	The First Few X number of confirmed cases of COVID-19 and their close contacts in the general population.	Household close contacts of confirmed cases of COVID-19 (smaller epidemiological unit than FFX).	Health workers in a health care setting in which a confirmed COVID-19 case has received care.
Aim	Transmission dynamics, severity and clinical spectrum, in a proxy of the general population.	Transmission dynamics, severity and clinical spectrum, in household settings.	Transmission dynamics, severity and clinical spectrum, in closed settings such as hospitals and health care centres.
Potential output and analysis	Transmission dynamics, severity and clinical spectrum, through estimates of, primarily: • the clinical presentation of COVID-19 infection and course of associated disease. • the secondary infection rate (SIR) and secondary clinical attack rate of COVID-19 among close contacts. • the serial interval of COVID-19 infection. • the symptomatic proportion of COVID-19 cases (through contact tracing and laboratory testing). • identification of possible routes of transmission. and secondarily:	Key epidemiological data **to complement and reinforce the findings of FFX**, in the areas of, primarily: • the proportion of asymptomatic cases and symptomatic cases. • the incubation period and the duration of infectiousness and of detectable shedding. • the serial interval • reproduction numbers: R_0 and R of COVID-19. • clinical risk factors, and clinical course and severity of disease. • high-risk population subgroups • the secondary infection rate and secondary clinical attack rate.	Transmission dynamics in health care settings, through estimates of: • the secondary infection rate (SIR) among health workers. • the range of clinical presentation and risk factors for infection. • the serological response following symptomatic COVID-19 infection. • possible routes of transmission

	• the basic reproduction number (R_0) of COVID-19. • the incubation period of COVID-19. • the preliminary infection and disease-severity ratios (e.g. case-hospitalization and case-fatality ratios).	• patterns of health care seeking	
Duration	At a minimum, enrolled cases and close contacts will complete data and specimen collection at enrolment (Day 1) and 14–21 days later, with two home visits.	Households will complete a minimum of four home visits within 28 days of enrolment/follow-up. Enrolment could be extended as far as desired; however, the most valuable period in order to use data for targeted public health action is in the early phases of the epidemic (first 2–3 months).	Health workers and health care facilities will complete a minimum of two site visits within 21 days of enrolment/follow-up.
Start of the investigation	To be initiated in the first days after the arrival in Country X of a confirmed case of COVID-19. FFX is the primary protocol to be initiated in the case of a COVID-19 outbreak, upon identification of the initial laboratory-confirmed cases of COVID-19 virus in Country X in the early epidemic phases.	Ideally to be initiated before widespread community transmission occurs: as early as possible after the first cases of COVID-19 infection are confirmed and at least within the first 2–3 months after identification of initial cases. This should be followed by subsequent tracing of household contacts of early laboratory-confirmed cases of COVID-19 in Country X in the early epidemic phases.	To be initiated with the first identification of a laboratory-confirmed case of COVID-19 in a health care setting. This should be followed by subsequent tracing of health worker contacts of early laboratory-confirmed cases of COVID-19 in Country X in the early epidemic/pandemic phases.

Recruitment	The first few confirmed cases of COVID-19 in Country X, and their close contacts, will be first few participants to be recruited. *Note*: Previous FF100/FFX studies for pandemic influenza have recruited 300–400 cases, along with their household contacts *(17)*.	Household contacts of primary cases of laboratory-confirmed COVID-19 infection.	Health worker contacts of early laboratory-confirmed cases of COVID-19 infection in Country X in the early epidemic/pandemic phases.
Minimum data and specimens to be obtained from participants	• Data collection: epidemiological data, including clinical symptoms; exposures, including contact with confirmed case(s); and pre-existing conditions. • Specimens: respiratory (and other) to diagnose current COVID-19 infection; and serum to inform seroepidemiological inferences. *Note*: Serum samples are mandatory to inform early seroepidemiological inferences, and respiratory (and other) samples to diagnose current COVID-19 infection.	• Household visit with respiratory sample collection at Days 1, 7, 14 and 28. • Serum sample collection is needed at Days 1 and 28, and highly encouraged at Day 14. • Symptom diaries recorded by household contacts from Day 0 to Day 14 and highly encouraged until Day 28. *Note*: Serum samples are mandatory to inform early seroepidemiological inferences, and respiratory (and other) samples to diagnose current COVID-19 infection.	• Health care setting visit with serum sample collection at Day 1 and Day > 21. • Symptom diaries recorded by health worker contacts from Day 0 to day 14 and highly encouraged until Day 28. *Note*: Serum samples are mandatory to inform early seroepidemiological inferences.

Appendix C: Go.Data software

Go.Data: what is it?

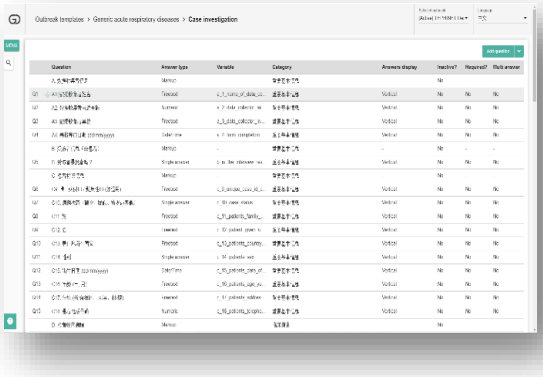
Go.Data is a field data-collection platform focusing on case data (including laboratory, hospitalization and other variables, through a case investigation form) and contact data (including contact follow-up). Main outputs from the Go.Data platform are contact follow-up lists and chains of transmission.

What are the key features of the Go.Data software?

Multiplatform
Go.Data offers different types of operation (online, offline) and different types of installation (server, stand-alone). It functions on a range of operating systems (Windows, Linux, Mac). In addition, Go.Data has an optional mobile app for Android and iOS. The mobile app is focused on case and contact data collection, and contact tracing and follow-up.

Multilingual
Go.Data is multilingual, with the possibility to add and manage additional languages through the user interface.

Configurable



It is highly configurable, with the possibility to manage:

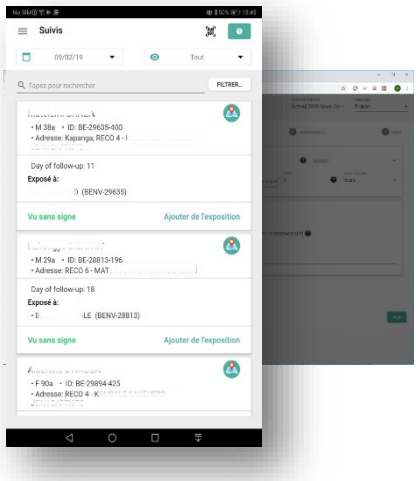
- reference data,
- location data, including coordinates,
- outbreak data, including variables on the case investigation form and the contact follow-up form.

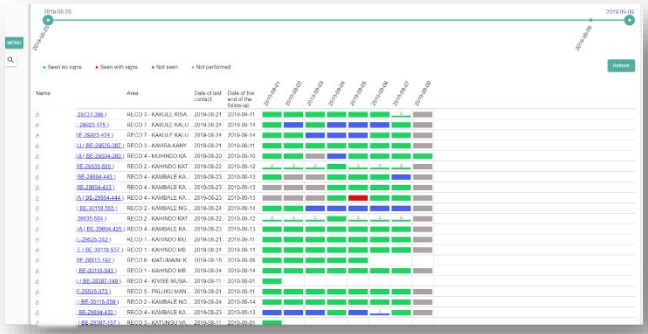
One Go.Data installation can be used to manage multiple outbreaks. Each outbreak can be configured in a different way to match the specifics of a pathogen or environment.

Case and contact data collection
The user can add cases, contacts and laboratory results. In addition, users also have an option to create events that may be relevant for outbreak investigation.

Contact follow-up lists are generated using outbreak parameters (that is, the number of days to follow up contacts, how many times per day should contacts be followed up).

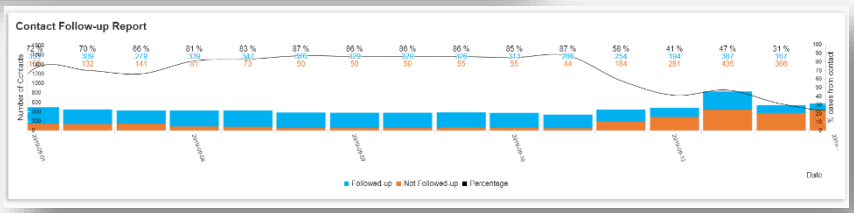
Extensive data export and import features are available to support the work of the data managers and data analysts.





Performing contact follow-up

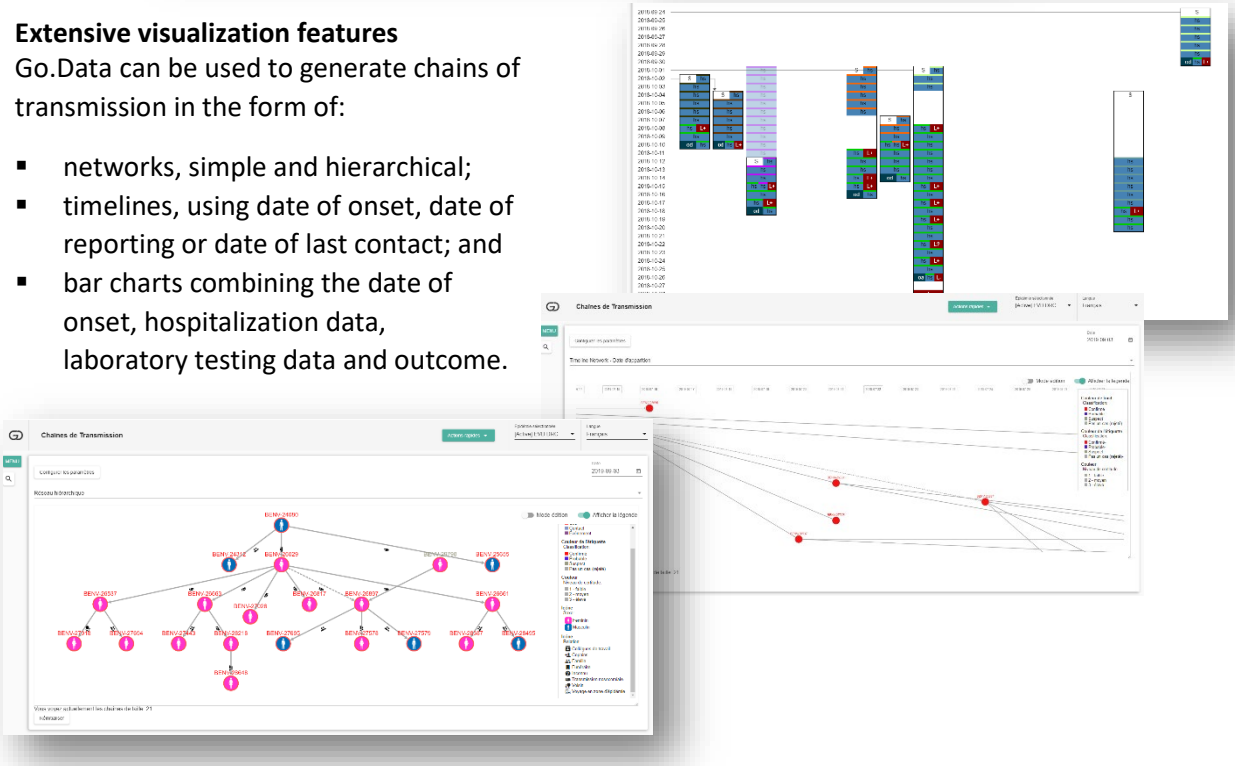
Go.Data has features to perform contact tracing using the web app or optional mobile app. Contact follow-up data are presented in the form of lists, graphs and operational dashboards. Contact tracing coordinators can review the workload of each contact tracing team.



Extensive visualization features

Go.Data can be used to generate chains of transmission in the form of:

- networks, simple and hierarchical;
- timelines, using date of onset, date of reporting or date of last contact; and
- bar charts combining the date of onset, hospitalization data, laboratory testing data and outcome.



System administration

System administrators have access to an extensive set of features to manage users, assign roles and permissions and limit access to specific outbreak(s) only. In addition, they have access to usage logs, and can create and restore backups and manage the settings of one Go.Data instance.

Please visit www.who.int/godata or contact godata@who.int for more information.

Options for Go.Data hosting in countries

Option #1
Centrally Hosted server

One Go.Data installation for the entire region or for multiple countries. Separate outbreak is created for each country on the central server instance of Go.Data, and user access is provided at outbreak level (i.e. users from one country can only access case and contact data from their own country).

+

- Maintenance is easier.
- Installation of any updates is done centrally.
- Synchronization of the mobile phones can be done from anywhere.

–

- Countries may be reluctant to host detailed information that is required for contact tracing (e.g. names, addresses) on an external server.
- May require agreements between centralized server owner and Member States for this arrangement.
- Centralized server to manage user accounts and user access.

Option #2
Country hosted server

Separate Go.Data installation for each country. Countries install Go.Data on their infrastructure.

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- Country has complete ownership and control of the server.
- Synchronization of the mobile phones can be done from anywhere.

–

- Likely to take more time to implement, as this option requires internal governmental approvals and provisioning infrastructure.
- Requires dedicated staff/team to manage the server.
- Not all countries may be in a position to host a Go.Data server.

Option #3
Standalone installation

Go.Data is installed on one or more computers in the country. These are typically personal computers or notebook/laptop computers. Data can be replicated across the computers.

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- Fast to implement.
- User has complete ownership and control of the computer and data.

–

- In order to synchronize mobile phones, users have to be physically in the same location where the computer is.
- If there are multiple instances in a country it will be required to setup consolidation point.
- Personal data stored on multiple standalone computers.
- Limited availability of Go.Data to when laptop is running.
- Increased security risks through loss or damage of the standalone computer.

Go.Data terms of use and software license agreement

Please read these Terms of Use and Software License Agreement (the "**Agreement**") carefully before installing the Go.Data Software (the "**Software**").

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