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: <u>https://www.who.int/emergencies/diseases/novel-</u> 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

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

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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			
Determined events and events in	Turnersiesikility is bookk sous actives through activestos of			
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. 			
	infection;			
	 serological response following symptomatic COVID- to informatic 			
	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	mum information and Data collection			
specimens to be obtained from	Epidemiological data including: clinical symptoms;			
participants	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 <u>WHO website</u>, 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 rate¹ 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

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