Protocol for assessment of potential risk factors for 2019-novel coronavirus (2019-nCoV) infection among health care workers in a health care setting

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World Health Organization

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Protocol summary

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Study population	Health care workers in a health care setting in which a confirmed 2019-nCoV case has received care
Potential output and analysis	Transmissibility in healthcare settings, through estimates of: • Secondary Infection rate (SIR) among healthcare workers • Range of clinical presentation, risk factors for infection • Serologic response following symptomatic 2019-nCoV infection Identification of possible routes of transmission
Study design	Prospective study of health care workers involved in care of any confirmed 2019-nCoV 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 2019-nCoV infection

1 Background

The detection and spread of an emerging respiratory pathogen are accompanied by uncertainty over the key epidemiological, clinical and virological characteristics of the novel pathogen and particularly its ability to spread in the human population and its virulence (case-severity). This is the case for the novel coronavirus (2019-nCoV), first detected in Wuhan city, 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, but also by amplification events in health care settings occasionally resulting in large nosocomial outbreaks. Overcrowding in emergency rooms, non-adherence to infection prevention and control precautions, as well as possible environmental contamination are thought to be implicated in such amplification in MERS-CoV outbreaks (2-6).

Health care workers play a critical role, not only in the clinical management of patients, but also in ensuring adequate infection prevention and control measures are implemented in healthcare facilities. Initial surveillance focuses primarily on patients with severe disease, and as such, the full spectrum of diseases, including the extent and fraction of mild or asymptomatic infection that do not require medical attention and the role they may play in secondary transmission are not clear.

Understanding 2019-nCoV infection among healthcare workers and the risk factors for adverse outcomes is important not only for characterising virus transmission patterns and risk factors for infection, but also for preventing future infection of healthcare workers and other patients, for informing and updating infection prevention and control measures at healthcare facility and national level and for reducing secondary 2019-nCoV transmission within healthcare settings.

At this stage, the extent of 2019-nCoV infection in health care settings is not clear, nor whether there are certain risk factors associated with infection in health care workers. The following protocol has been designed to investigate the extent of infection and risk factors for infection among health care workers. Follow-up and testing of respiratory specimens and serum of health care workers within a facility in which a confirmed case of 2019-nCoV infection is receiving care can provide useful information on transmissibility and routes of transmission, and are important for limiting amplification events in health care facilities.

Each country may need to tailor some aspects of this protocol to align with public health, laboratory and clinical systems, according to capacity, availability of resources and cultural appropriateness. However, using a standardized protocol such as the protocol described below, epidemiological exposure data and 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 for timely estimates of 2019-nCoV infection severity and attack rates, as well as to inform public health responses and policy decisions. This is particularly important in the context of a novel respiratory pathogen, such as 2019-nCoV.

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

1.1 Objectives

There are three primary objectives of this investigation among health care workers in a health care setting where a 2019-nCoV infected patient is being cared for:

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

This investigation among health care workers can permit evaluation of secondary objectives such as, but not limited to:

1. To determine the serologic response for health care workers with symptomatic and possibly asymptomatic 2019-nCoV infection
2. To characterize duration and severity of 2019-nCoV-associated disease among health care workers.
3. Others (context specific/ optional)

COMMENT: Antibody kinetics of 2019-nCoV infection are currently not known, and the serologic response of mild or asymptomatic 2019-nCoV infections may be limited. The study investigators may wish to consider using molecular testing of health care worker contacts to capture acute infection (regardless of symptoms), if the study is started shortly after the identification of a patient with 2019-nCoV infection within the health care facility.

2 Study procedures

2.1 Study design

This is a case-ascertained prospective investigation of all identified health care contacts working in a health care facility in which a laboratory confirmed 2019-nCoV infected patient (see 2.2 Study population) receives care. Note that this study can be done in health care facilities at all 3 levels of a health system – not just in hospitals. It is intended to provide epidemiological and serologic information which will inform the identification of risk factors 2019-nCoV infection among health care workers.

The timing of this study is critical. Ideally, this study should be conducted as soon after a patient with 2019-nCoV is identified at a health care facility. It needs to be possible to define a discrete period of possible exposure for each are of the health care facility that the patient has visited and an exhaustive list of all health care workers who have been present in the same area as the patient. It should also ideally be conducted within the early phases of an epidemic, before widespread transmission or nosocomial outbreaks occur.

[1] In this context the **secondary infection rate (SIR)** is a measure of the frequency of new cases of 2019-nCoV infection among the health care worker contacts of a primary confirmed case within the same health care facility in a defined period of time, as determined by a confirmed 2019-nCoV positive lab result. In simple terms: the proportion of health care worker contacts of a primary case who subsequently become infected with 2019-nCoV

2.2 Study population

The study population is derived from the identification of all health care personnel who have worked in a health care facility where there is a laboratory confirmed 2019-nCoV infected patient receiving care. Every effort should be made to include all identified health care workers who have worked at any point during the time that the laboratory confirmed 2019-nCoV infected 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 – e.g. admission at Emergency Room, transported to radiology, moved to a ward. Every effort should be made to include all health care workers (see below) who have been in the same area as the patient as he/she moved through the health care facility.

For the purpose of this investigation, **health care worker** should not be too restrictive so that a large number of potentially exposed health care workers are included in the study. For this reason, **health care worker** should be defined as all staff in the health care facility involved in the provision of care for a 2019-nCoV 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 includes health care professionals, allied health workers, auxiliary health workers (e.g. cleaning and laundry personnel, x-ray physicians and technicians, clerks, phlebotomists, respiratory therapist, nutritionists, social workers, physical therapists, lab personnel, cleaners, admission/reception clerks, patient transporters, catering staff etc.).

Once a case of 2019-nCoV infection has been identified in a health care facility, a list of all health care workers with any exposure to 2019-nCoV patient will need to be drawn up (see Considerations for identifying health care workers in Appendix 1). This should be done in consultation with supervisors and colleagues, duty rosters and possibly the medical file of the patient to understand all the areas of the health care facility the patient has visited and to ensure all health care workers can be identified and recruited into the study.

COMMENT: This protocol is designed to assess risk factors for infection among health care workers with potential exposure to 2019-nCoV. It does not include visitors to the health care facility who may have had contact with a 2019-nCoV infected patient or the patient's material.

COMMENT: For the purposes of comparability between investigations, it is important that health care worker encounters are defined clearly in terms of type and duration of potential exposure in any reporting on the investigation.

2.3 Eligibility criteria

Inclusion criteria: All health care workers with any potential exposure to a 2019-nCoV infected patient within a health care facility, 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 care workers who work in another health care facility, particularly those that work in a health care facility which has recently experienced/is experiencing widespread nosocomial transmission; health care workers who have a confirmed 2019-nCoV case among his/her household/close contacts.

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

Equally, symptomatic health care workers should also not be excluded from the study. In the event that a symptomatic health care 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 his/her behalf.

2.4 Data collection

All health care workers recruited into the study will need to complete a questionnaire which covers demographic information, contact and possible exposure with the 2019-nCoV infected patient since he/she has been admitted to the health care facility and infection prevention and control measures. A questionnaire can be found in Appendix 1 of this document. These forms are not exhaustive, but outline the data collection required for insight into the epidemiology of 2019-nCoV and may be updated further. This protocol and questionnaire will still need to be adapted based on the local setting, and outbreak characteristics.

2.5 Specimen collection

COMMENT: The following is intended to guide minimum specimen collection from all health care workers. Depending on how long after the identification of the 2019-nCoV infection 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 2019-nCoV infection, and/or serial respiratory sampling. Please note that appropriate PPE needs to be worn by study investigators for the collection of any specimen (see 2.8.5 Prevention of 2019-nCoV infection in investigation personnel).

A baseline serum sample should be collected from all health care workers, as soon as possible after confirmation of a 2019-nCoV infected patient in the health care facility.

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

Table 1: Timeline of data and specimen collection in the health care worker contact study

Day since recruitment	**0** (±1)	**…**		**…**	**>21**
Visit to health care facility and data collection					
Serum sample					
Other specimens, such as serial respiratory samples	(optional: situation/resource-dependent)				

Legend:
Blue boxes indicate activities which are needed for the study
Green boxes indicate where additional specimens could be collected above the minimum specimen requirements of this study to increase information available. This could include respiratory samples for molecular testing to capture acute 2019-nCoV infection, regardless of symptoms.

2.6 Use of Go.Data tool (optional)

Go.Data is software which has been designed to be used by WHO, 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 2 components: a web application and an optional mobile app. The tool is targeted at any outbreak responders, including WHO staff, staff from Ministry of Health and partner institutions.

Key features of the Go.Data software include:

- Users with appropriate rights can configure case investigation form, contact follow-up form and lab data collection form.
- Outbreak templates are included for easier creation of outbreak data collection forms.
- Open source and free for use with no licensing costs.
- Go.Data offers different types of operation (server or stand-alone) on different platforms (Windows, Linux, Mac).
- Allows for case and contact data collection, including lab data.
- Generates contact follow-up list and visualizes chains of transmission.
- It provides multi-lingual support, with possibility to add additional languages though user interface.
- Go.Data is not build for a specific disease or specific country, it is highly configurable, with configurable reference and location data.
- One Go.Data installation can be used to collect data for many outbreaks.
- Granular user roles and permissions, including possibility to provide user access at outbreak level
- Has optional mobile app (Android and iOS) focused on contact tracing and possibility to register cases and contacts.

Contact: godata@who.int
WHO Go.Data website

2.7 Specimen transport

All those involved in collection 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 case management algorithm and laboratory guidance in the country or 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 study 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, specimens 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 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 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 2013- 2014.

2.8 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.

2.8.1 Informed consent

The purpose of the investigation will be explained to all known health care worker contacts of a confirmed 2019-nCoV infected patient. Informed consent will be obtained from all health care worker contacts willing to participate in the investigation 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 investigation is voluntary and that s/he is free to withdraw, without justification, from the investigation at any time without consequences and without affecting professional responsibilities.

COMMENT: The age of consent may vary by country. Check the requirements of local, regional or national authorities.

Informed consent will seek approval to collect blood samples and epidemiological data for the intended purpose of this investigation, that samples may be shipped outside of the country for additional testing and that samples may be used for future research purposes.

2.8.2 Risks and benefits for subjects

This investigation poses minimal risk to participants, involving the collection of a small amount of blood. The direct benefit to the participant is the ability to detect 2019-nCoV infection which would allow for appropriate monitoring and treatment. The primary benefit of the study is indirect in that data collected will help improve and guide efforts to understand transmission of 2019-nCoV and prevent further spread of 2019-nCoV.

2.8.3 Confidentiality

Participant confidentiality will be maintained throughout the investigation, especially exposure of health care workers to 2019-nCoV. All subjects who participate in the investigation will be assigned a study identification number by the investigation team for the labelling of questionnaires and clinical specimens. The link of this identification number to individuals will be maintained by the investigation team and the Ministry of Health (or equivalent) and will not be disclosed elsewhere. If the data is shared by the implementing organization to 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.

Article 45 of the IHR (2005) describes the "treatment of personal data".[2] Person identifiable data collected under the IHR should be kept confidential and processed anonymously, as required by national law. However, such data may be disclosed for assessments and management of public health risks, provided the data are processed fairly and lawfully.

2.8.4 Terms of use: Go.Data

If groups implementing the investigation opt to use open-source Go.Data as a tool to run this investigation, the Go.Data server can be hosted either on a server within the country or at WHO. The group implementing the study 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

[2] https://www.who.int/ihr/publications/9789241580496/en/

restricted to users who have valid login credentials for the Go.Data application.

2.8.5 Prevention of 2019-nCoV infection in investigation personnel

All personnel involved in the investigation need to be trained in infection prevention and control procedures (standard contact, droplet, contact 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 care workers who have had potential exposure to a 2019-nCoV infected patient, but also to minimize the risk of spread among health care worker contacts of a 2019-nCoV infected patient.

WHO technical guidance on infection prevention and control specific to 2019-nCoV can be found on the WHO website.

3 Laboratory evaluations

Laboratory guidance for 2019-nCoV can be found on the WHO website.

Several assays that detect 2019-nCoV have been recently developed and the protocols or SOPs can also be found on the WHO website.

4 Statistical analyses

4.1 Sample size

This investigation is intended to be implemented to provide information on the extent of 2019-nCoV infection among health care workers and on possible risk factors for infection. Larger studies will undoubtedly permit more robust analysis of potential factors affecting the secondary infection risk and more detailed characterization of serologic responses following infection

4.2 Epidemiological parameters

The table below provides an overview of the epidemiological parameters that can be measured as part of this investigation

Parameter	**Definition** (*in bracket*: "simplified" expression of it)	**Form and questions where to get the data to calculate the parameters concerned**	**Comments, limitations**
Secondary infection rate (also called secondary infection incidence)	A measure of the frequency of new cases of 2019-nCoV infection among the health care worker contacts of confirmed case in a defined period of time *(The rate of infection among contacts. Inferred through serological assays on paired samples)*	Form 3	*The numerator will be determined as the number of health care workers confirmed to have 2019-nCoV infection, while the denominator will be determined as the total number of health care workers enrolled as contacts of the case. *represents an overall risk of infection among health care worker

			contacts for a defined time period.
Serological response to infection	Change in serum level of specific antibodies to 2019-nCoV (*Increase in titre*)	Form 3	*This will only be able to be calculated with the addition of laboratory data *Will be supplemented by 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 2019-nCoV infection (e.g. age groups, gender, occupation)	Form 1: Q6 Form 2: Q10	*May only be an early signal, 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 from this study, as we are recruiting on the basis of being detected and confirmed to have 2019-nCoV and healthcare seeking behaviour may vary between population groups

5 Reporting of findings

5.1 Reporting

Any investigation of this nature should include reporting on the following information:

(1) the number of laboratory confirmed cases of 2019-nCoV infection, the number of health care workers identified and, of those, the number enrolled and types of roles they have in the health care facility;

(2 the number of household contacts with serologic evidence of 2019-nCoV infection. If sample size permits, these numbers should be stratified by age, role within the hospital and possible type of exposure (direct care, environmental exposure etc);

COMMENT: If molecular testing is included as part of this study, it would be important to report the number of health care workers with acute 2019-nCoV infection, and of these, the characterisation of illness.

It is also important to fully document the study design, including the definition of the health care facility and health care worker, the approach to identification of health care workers possibly exposed to 2019-nCoV infected patient, the duration between collection of serum samples, and the laboratory methods used to ensure that data can be pooled to increase power in estimating epidemiological parameters.

Ideally, information would be collected in a standardized format according to the questionnaires and tools in this generic protocol to assist with data harmonization and comparison of results (see forms in Appendix A).

If the data is shared by the implementing organization to 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 References

1. World Health Organization. Disease Outbreak News: Pneumonia of unknown cause – China https://www.who.int/csr/don/05-january-2020-pneumonia-of-unkown-cause-china/en/?fbclid=IwAR2v89e9lp70O6GTra13FIPHCLw4WJ8kL20Uylx5zZNtWAYvbR0sEATr_rg (Accessed 22 January 2020)

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6. Hijawi B, Abdallat M, Sayaydeh A, Alqasrawi S, Haddadin A, et al. (2013) Novel coronavirus infections in Jordan, April 2012: epidemiological findings from a retrospective investigation. *East Mediterr Health J* 19: S12-S18.

6.1 Further references for 2019-nCoV

WHO Disease Outbreak News
https://www.who.int/csr/don/en/

Surveillance and case definitions
https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)

Laboratory guidance
https://www.who.int/health-topics/coronavirus/laboratory-diagnostics-for-novel-coronavirus

Clinical management
https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected

Infection prevention and control
https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected

Risk communications
https://www.who.int/publications-detail/risk-communication-and-community-engagement-readiness-and-initial-response-for-novel-coronaviruses-(-ncov)

7 Acknowledgments

This generic protocol was adapted from the protocol entitled “Assessment of potential risk factors of Middle East respiratory syndrome coronavirus (MERS-CoV) infection among health care personnel in a health care setting” by WHO and “Prospective Study of household transmission of Influenza” by the Consortium for the Standardisation for Influenza Seroepidemiology (CONSISE). CONSISE is a global partnership aiming to develop influenza investigation protocols and standardise seroepidemiology to inform public health policy for pandemic, zoonotic and seasonal influenza. This international partnership was created out of a need, identified during the 2009 H1N1 pandemic, for better (standardised, validated) seroepidemiological data to estimate infection attack rates and severity of the pandemic virus and to inform policy decisions.

WHO staff: Isabel Bergeri, Kaat Vandemaele, Maria Van Kerkhove, Ann Moen, Wenqing Zhang, Aspen Hammond, Julia Fitzner, John Watson (US CDC), April Baller, Maria Clara Padoveze, Anne Perrocheau, Yuka Jinnai, Stéphane Huggonnet, Oliver Morgan, Sooyoung Kim, Rebecca Grant.

Outside WHO, a large number of extra non-WHO individuals were involved in the creation and revision of this protocol as part of the WHO expert working Group on Pandemic Influenza Special Investigation Studies (by alphabetical order). These include:
Silke Buda (RK Institute, Germany), Cheryl Cohen (MoH South Africa), Ben Cowling (Hong Kong University, Jeffery Cutter (MoH Singapore), Vernon Lee (MoH Singapore), Rodrigo Fasce (NIC Chile), Gail Carson (GOARN operational support team), Jean-Michel Heraud (Institut Pasteur de Madagascar), Peter Horby (ISARIC, United Kingdom), Sue Huang (NIC, Institute of Environmental Science and Research, New Zealand), Arunkumar Govindakarnavar (Manipal Institute of Virology Manipal, Academy of Higher Education), Bryan Kim (WHO GOARN operational support team, Switzerland), Vernon Lee (MoH Singapore), Adrian Marcato (University of Melbourne, Australia), Jodie McVernon (Peter Doherty Institute, Australia), Richard Pebody (Public Health England, United Kingdom), Melissa Rolf (US CDC), Hassan Zaraket (American University of Beirut, Lebanon), Lei Zhou (China CDC).

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Appendices

Appendix A: Sample questionnaires - Household transmission investigation protocol for 2019-novel coronavirus (2019-nCoV) infection

Considerations for identifying all health care workers with possible exposure to 2019-nCoV infected patient while the patient has received care within the health care facility

Form 1: Report Form for health care worker (Day 1)
Form 2: Report Form for health care worker (>Day 21)

Form 3: Laboratory results
Form 4: Symptom diary

Form 5: Health care facility infection prevention and control

Go.Data Terms of Use

Assessment of potential risk factors for 2019-novel coronavirus infection among health care workers in a health care setting

Considerations for identifying all health care workers with possible exposure to 2019-nCoV infected patient while the patient has received care within the health care facility

Before the study begins, all health care workers with possible exposure through working in close proximity to the 2019-nCoV infected patient 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 visited 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 care worker** should be defined as all staff in the health care facility involved in the provision of care for a 2019-nCoV 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 includes health care professionals, allied health workers, auxiliary health workers (e.g. cleaning and laundry personnel, x-ray physicians and technicians, clerks, phlebotomists, respiratory therapist, nutritionists, social workers, physical therapists, lab personnel, cleaners, admission/reception clerks, patient transporters, catering staff etc.).

Assessment of potential risk factors for 2019-novel coronavirus infection among health care workers in a health care setting

Form 1: Report Form for health care worker (Day 1)

Unique health care worker ID	
2019-nCoV patient ID	

1. Current Status	□ Alive □ Dead

2. Data Collector Information	
Name of data collector	
Data collector Institution	
Data collector telephone number	
Mobile number	
Email	
Form completion date (DD/MM/YYYY)	(DD/MM/YYYY) ___/___/___
Date of interview with informant (DD/MM/YYYY)	(DD/MM/YYYY) ___/___/___

3. Contact Identifier Information	
First name	
Surname	
Sex	□ Male □ Female □ Not known
Date of Birth (DD/MM/YYYY)	(DD/MM/YYYY) ___/___/___
Telephone (mobile) number	
Age (years, months)	
Email	
National social number/ identifier (if applicable)	
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 □ Phlebotomists □ Physical therapists □ Nutritionists/dietitians □ Other health care provider: □ Lab personnel □ Admission/reception clerks □ Patient transporters □ Catering staff □ Cleaners

4. Adherence to infection prevention and control measures information	
What date was your most recent IPC training within the health care facility? (DD/MM/YYYY)	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: Face mask, Face shield, Gloves, Goggles/glasses, Gown, Coverall, Head cover, Respirator (e.g. N95 or equivalent), 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 2019-nCoV infected patient	
Date of admission of 2019-nCoV confirmed patient (DD/MM/YYYY)	DD/MM/YYYY:
Have you had close contact (within 1 meter) with the patient since his/her 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: □ Face mask □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Respirator (e.g. N95 or equivalent) □ Shoe covers
- If yes, were you present for any aerosolising 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: □ Face mask □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Respirator (e.g. N95 or equivalent) □ 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: □ Face mask □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Respirator (e.g. N95 or equivalent) □ Shoe covers
- If you were wearing gloves, did you remove gloves after contact with the patient?	□ Yes □ No
- If you were wearing a face mask, what type:	
- If you were wearing a respirator, was it test fitted?	□ Yes □ No □ Unknown
- 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
Have you had direct contact with the patient's materials since his/her 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 (e.g. ventilator, infusion pump etc) □ Other:
- If yes, how many times since his/her 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: □ Face mask □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Respirator (e.g. N95 or equivalent) □ 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 you were wearing gloves, did you remove gloves after contact with the patient?	□ 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:
- How many times since his/her 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: □ Face mask □ Face shield □ Gloves □ Goggles/glasses □ Gown □ Coverall □ Head cover □ Respirator (e.g. N95 or equivalent) □ 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 care worker symptoms

Have you experienced any respiratory symptoms (sore throat, cough, running nose, shortness of breath) in the period since the patient has been admitted?	□ Yes □ No If no, please skip to next section 5c
Date of first symptom onset (DD/MM/YYYY)	(DD/MM/YYYY)___/___/___ □ Asymptomatic □ Unknown
Fever (≥38 °C) or history of fever	□ Yes □ No □ Unknown If yes, specify maximum temperature:
6b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, date (DD/MM/YYYY): ___/___/___
Cough	□ Yes □ No □ Unknown If Yes, date (DD/MM/YYYY): ___/___/___
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown If Yes, date (DD/MM/YYYY): ___/___/___
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
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
General malaise	□ Yes □ No □ Unknown
Other symptoms	□ Yes □ No □ Unknown If yes, specify:

7. Health care worker pre-existing condition(s)	
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
Pregnancy	□ Yes □ No □ Unknown If yes, specify trimester: □ First □ Second □ Third □ NA Estimated delivery date (DD/MM/YYYY) ___/___/___
Chronic kidney disease	□ Yes □ No □ Unknown
Chronic neurological impairment/disease	□ Yes □ No □ Unknown
Organ or bone narrow recipient	□ Yes □ No □ Unknown
Other pre-existing condition(s)	□ Yes □ No □ Unknown If yes, specify:

To be collected by study coordinator:

8. Contact specimen collection (Day 1- baseline)	
Has baseline serum been taken?	□ Yes □ No □ Unknown If yes, specify date (DD/MM/YYYY):
Which laboratory was the specimen sent to?	
Date sent to other laboratory with coronavirus expertise (if applicable) (DD/MM/YYYY)	___/___/___

Assessment of potential risk factors for 2019-novel coronavirus infection among health care workers in a health care setting

Form 2: Report Form for health care worker (Day >21)

9a. Health care 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 skip to next section 5c
Date of first symptom onset (DD/MM/YYYY)	(DD/MM/YYYY)___/___/___ □ Asymptomatic □ Unknown
Fever (≥38 °C) or history of fever	□ Yes □ No □ Unknown If yes, specify maximum temperature:
9b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, date (DD/MM/YYYY): ___/___/___
Cough	□ Yes □ No □ Unknown If Yes, date (DD/MM/YYYY): ___/___/___
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown If Yes, date (DD/MM/YYYY): ___/___/___
9c. 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
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
General malaise	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Other symptoms	□ Yes □ No □ Unknown If yes, specify:

To be completed by study coordinator or equivalent:

10. Specimen collection (>Day 21)	
Unique Primary Case ID / Household number	□ NA
Has baseline serum been taken?	□ Yes □ No □ Unknown If yes, specify date (DD/MM/YYYY):
Date of sample collection (DD/MM/YYYY)	(DD/MM/YYYY)___/___/___ □ NA
Which laboratory was the specimen sent to?	
Date sent to other laboratory with coronavirus expertise (if applicable) (DD/MM/YYYY)	___/___/___

11. 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, specify reason for hospitalisation:

Assessment of potential risk factors for 2019-novel coronavirus infection among health care workers in a health care setting

Form 3: Laboratory results

To be completed by coordinator:

12a. Baseline serology testing methods and results:	
Lab identification number	
Date baseline sample collected (DD/MM/YYYY)	(DD/MM/YYYY)___/___/___
Date baseline sample received (DD/MM/YYYY)	(DD/MM/YYYY)___/___/___
Type of sample	□ Serum □ Others, specify:
Result (2019-nCoV antibody titres)	
Date of result (DD/MM/YYYY)	___/___/___
Specimen shipped to other laboratory for confirmation - Date (DD/MM/YYYY)	□ Yes □ No (DD/MM/YYYY)___/___/___

12b. Follow-up serology testing methods and results:	
Lab identification number	
Date follow up sample collected (DD/MM/YYYY)	(DD/MM/YYYY)___/___/___
Date follow up sample received (DD/MM/YYYY)	(DD/MM/YYYY)___/___/___
Type of sample	□ Serum □ Others, specify:
Result (2019-nCoV antibody titres)	
Date of result (DD/MM/YYYY)	___/___/___
Specimen shipped to other laboratory for confirmation - Date (DD/MM/YYYY)	□ Yes □ No (DD/MM/YYYY)___/___/___

Assessment of potential risk factors for 2019-novel coronavirus infection among health care workers in a health care setting

Form 4: Symptom diary

Each health care worker contact will be asked to record the presence or absence of various signs or symptoms each day for up to 21 days after the administration of the baseline questionnaire (minimum 14 days).

With 2019-nCoV, the extent of clinical presentation and spectrum remains unclear, so symptom diaries may be broadened to include vomiting, diarrhea, abdominal pain, etc., as relevant and may need to be altered to include symptom data for longer than 14 days.

If no symptoms are experienced, ensure that *None* is selected in the second column.

Day	**Symptoms**						
	No symptoms (check if none experienced)	**Fever ≥38°C**	**Sore throat**	**Cough**	**Runny nose**	**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	
10	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
11	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
12	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
13	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
14	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
…							
21	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	

Assessment of potential risk factors for 2019-novel coronavirus infection among health care workers in a health care setting

Form 5: Health care facility infection prevention and control

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

Health care facility information	
Name of health care facility in which 2019-nCoV confirmed patient is being cared for	
Does the health care facility have an appropriate WASH services and materials?	□ Yes □ No □ Unknown
Does the health care facility have an infection prevention and control (IPC) program and team or at least a focal point dedicated and trained?	Tick all that apply: □ IPC program □ IPC team/service □ IPC focal point □ IPC training
Does the health care facility have infection prevention and control (IPC) guidelines for health care 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 care 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
Are the PPE available of good quality and fit for purposes?	□ Yes □ No □ Unknown
Is alcohol-based hand rub easily available (i.e. 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 feedback to health care 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 last 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 care 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 alert all health care workers if a 2019-nCoV 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 2019-nCoV infection isolated upon arrival in the health care facility?	□ Always □ Most of the time □ Occasionally □ Rarely □ Unknown
Is a medical mask systemically fitted to the patients with suspected 2019-nCoV infection upon arrival in the health care facility?	□ Always □ Most of the time □ Occasionally □ Rarely □ Unknown
Are health care worker staffing levels adequately assigned according to patient workload?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely
Does bed occupancy exceed standard capacity of the health care facility?	□ Always, as recommended □ Most of the time □ Occasionally □ Rarely

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