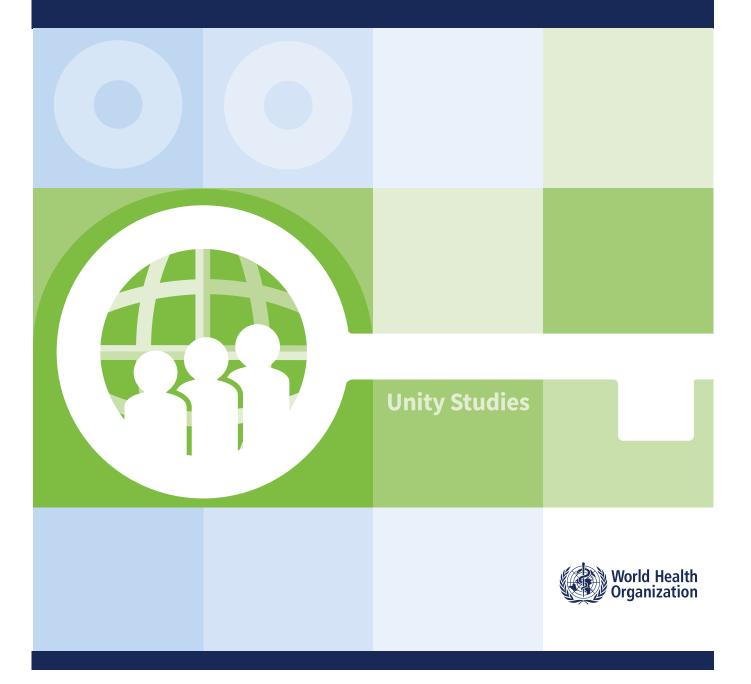
How to conduct a cohort study to assess the potential risk factors of Middle East respiratory syndrome coronavirus infection among health and care workers in a health-care setting

Protocol, tools and implementation guidance



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## Contents

List of tables	V
List of figures	v
Acknowledgements	vi
Background	vi
Protocol summary	ix
1. Scientific background and rationale	1
1.1 Study objectives	
1.1.1 Primary objectives	
1.1.2 Secondary objectives	
2. Methods	4
2.1 Study design, timing and duration	5
2.2 Study population and recruitment	
2.2.1 Study population	5
2.2.2 Eligibility criteria	
2.2.3 Recruitment, follow-up and data collection	
2.3 Specimen collection and laboratory evaluations	
2.3.1 Specimen collection	
2.3.2 Specimen transportation	
2.3.3 Laboratory evaluations	
2.3.4 Sample storage	
2.4 Data management	
2.5 Ethical considerations	
2.5.1 Informed consent	
2.5.2 Risks and benefits for participants	
2.5.3 Reporting of serious adverse events, including death of a participan	t16
2.5.4 Confidentiality	
2.5.5 Prevention of infection	
2.5.6 Mitigation of stigmatization of participants	

### iv 💳

3. Statistical analysis
3.1 Sample size considerations
3.2 Epidemiological indicators (study outcome measures)
3.3 Interpretation of results
4. Dissemination of results25
5. Composition of study team27
6. References
7. Annexes
Annex 1: Additional information and references
Annex 2: Questionnaires
Questionnaire 1: Identification of possible exposures to MERS-CoV in a health-care facility 37
Questionnaire 2: Identification of potentially exposed health and care workers (HCW)
Questionnaire 3: Frequency and pattern of exposure of health and care workers (HCW) to a MERS-CoV infected patient42
Questionnaire 4: Symptom diary for health and care worker (HCW) contacts of confirmed or probable MERS cases (Day 1 – 21)
Questionnaire 5: HCW exposures to the confirmed and probable MERS case since the time of enrolment61



## List of tables

Table 1: Type of specimen to be collected and timing of collection	
Table 2: Epidemiological characteristics to be calculated from this case-ascertained investigation21	
Table 3. Coordination matrix of roles and responsibilities in Country X	

## **List of figures**

Figure 1: Prospective cohort investigation timeline with timing of data
(questionnaires, see Annex 2) and specimen collection

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## Background

Middle East respiratory syndrome coronavirus (MERS-CoV), which was first identified in 2012, is considered an emerging virus. The emergence of a new virus means that understanding transmission patterns, severity, clinical features and risk factors for infection are limited. To address these unknowns, WHO has provided a number of protocols for MERS-CoV investigations. Data collected using these investigation protocols will be critical to refine recommendations for case definitions and surveillance, characterize key epidemiological features of MERS-CoV, help understand the geographical extent of MERS-CoV, its severity, the spectrum of the disease, and its impact on the community; and to inform guidance for application of countermeasures such as case isolation and contact tracing. These protocols are designed to rapidly and systematically collect and share data in a format that facilitates comparison across different settings globally.

They are available on the WHO website here: https://www.who.int/initiatives/mers-covinvestigations-and-studies

MERS-CoV investigation and study protocols, tools and implementation guidance <u>currently available</u> include:

How to conduct surveillance and investigations of human infection with Middle East respiratory syndrome coronavirus using WHO's Investigations and Studies (Unity Studies 2.0) protocols;

How to investigate the first few X cases and contacts of human infection with Middle East respiratory syndrome coronavirus;

How to conduct a case-control study to assess the potential risk factors related to human illness caused by Middle East respiratory syndrome coronavirus;

How to conduct a cohort study to assess the potential risk factors of Middle East respiratory syndrome coronavirus infection among health and care workers in a health-care setting;

How to sample surfaces in health-care settings for Middle East respiratory syndrome coronavirus; and

How to conduct a cross-sectional study of Middle East respiratory syndrome coronavirus infection in populations occupationally exposed to dromedary camels.

Please contact MERSHQ@who.int for further information.

All WHO protocols for MERS-CoV are available on the **WHO website** together with technical guidance documents.

This protocol incorporates elements of previously published interim guidance entitled, Assessment of potential risk factors of Middle East respiratory syndrome coronavirus (MERS-CoV) infection among health care personnel in a health care setting – Version January 2019, providing additional aspects of investigation implementation and detailed questionnaires. It reflects updated scientific knowledge about MERS-CoV, the results and experiences of similar studies conducted in several countries. The document was also adapted from and supplemented by using protocols developed and used during the COVID-19 pandemic through WHO's Investigations and Studies (Unity Studies): a standardized preparedness framework for an effective and proportionate response, as well as experiences and lessons learned during the COVID-19 pandemic.

## **Protocol summary**

## Cohort study to assess potential risk factors of MERS-CoV infection among health and care workers (HCW) in a health-care setting

Study population	Health and care workers (HCW) in a health-care setting in which a patient with a laboratory- confirmed MERS-CoV infection is receiving care, who have any possible contact to the MERS-CoV positive case, regardless of symptoms
Potential output and analysis	<ul> <li>Understand transmissibility in health-care settings through estimating:</li> <li>secondary infection rate (SIR) among HCW;</li> <li>range of clinical presentation and risk factors for infection;</li> <li>serological response following MERS-CoV infection</li> <li>identification of possible routes of transmission</li> </ul>
Study design	Cohort study (protocol is written as a prospective cohort, but this study is likely to be conducted as both a prospective and/or retrospective cohort)
Study duration	From the day that the investigation (data collection) begins, data and specimen collection is complete 21-28 days after the last MERS-CoV-positive contact (this could be the original HCW case, or a secondary HCW case).
Information and specimens to be obtained from	<b>Data:</b> Multiple questionnaires at baseline collect information such as: clinical symptoms; exposures in the health-care facility, including contact with confirmed case(s); use of personal protective equipment, other epidemiological data. HCW also complete daily symptom diaries throughout follow-up. <b>Specimens:</b>
participants	<ul> <li>Multiple serum samples per participant</li> <li>Respiratory specimen(s) to diagnose current MERS-CoV infection if a participant is symptomatic</li> </ul>

Implementation tips are provided in boxes throughout the document.

This is a *protocol template* – the user should read through the template and guidance and then modify (and make choices about) the methods according to the local context in which this study will be carried out. If being adapted for use as the investigation protocol, the user should remove any non-relevant sections and modify the language appropriately (e.g. Change the phrase "Investigators should create a detailed map(s) of the facility; within this map(s) and its legend(s), the following details should be included:..." to "We have created a detailed map of facility X, where the MERS-CoV positive patient was identified on [date], this map includes the following details:..."). Background information referenced in this document should be checked for updates by investigators at the time of protocol implementation.

## Scientific background and rationale



1

2

As of April 2024, over 2600 laboratory confirmed human cases of Middle East respiratory syndrome coronavirus (MERS-CoV), have been reported (1). MERS-CoV is a zoonotic virus and dromedary camels are the single known maintenance host and primary reservoir of MERS-CoV (2–7), but the route of transmission to humans is unknown (7). The virus appears to be circulating widely in dromedary camel populations throughout the Middle East and Africa, and has also been detected in a few countries in South and Central Asia (2). The majority of human cases have been reported from Saudi Arabia (1).

The relative novelty and sparsity of MERS-CoV infections, as well as the fact that surveillance of this infection has typically focused on patients with severe disease, has limited our understanding of the full spectrum of the disease, including the extent of mild or asymptomatic forms of infection. Severe MERS-CoV infection is often characterized by severe pneumonia with acute respiratory distress syndrome (ARDS) and other life-threatening complications (8). Since 2015, WHO has updated its guidance for contact tracing, and, as a result, more asymptomatic or mild forms of the disease have been reported. To date, approximately 20% of MERS cases that have been reported to the WHO are asymptomatic or mild (1); though the true number of infections characterized by this presentation is expected to be much greater. Mild symptoms are non-specific and can include headache, tiredness, fever, mild cough, sore throat and runny nose. Some patients may present with gastrointestinal symptoms such as mild diarrhoea (9–11).

To date, there is no evidence of sustained human-to-human transmission of MERS-CoV. Although MERS-CoV appears to be inefficient at transmitting between humans in the general population, limited human-to-human transmission has occurred and been documented in several clusters in health-care facilities in Jordan, Saudi Arabia, the Republic of Korea and the United Arab Emirates (*12*); occasionally, this has resulted in significantly large outbreaks (*13–16*). Additionally, one instance of nosocomial transmission was documented in France in 2013 (*17*). Since 2020, instances of nosocomial transmission have only been documented in Saudi Arabia (*1*). Historically, the majority of all reported human MERS-CoV infections have occurred through human-to-human transmission in healthcare settings, and as of November 2022, 17% of human MERS cases were in health-care workers (*1*). However, in recent years most cases reported have been sporadic or primary (with a reported link to camel exposure or their products). Person-to-person transmission has also been identified through investigations of clusters of cases in households and other settings (*1*, *18–27*).

Factors associated with amplified human-to-human transmission in health-care facilities have included poor infection prevention and control (IPC) compliance by health and care workers (HCW) *(12, 28).* Inversely, adherence to IPC procedures, and rapid identification and isolation of individuals positive for MERS-CoV has limited transmission in some health-care settings *(7, 12).* During past MERS-CoV nosocomial outbreaks, a number of environmental contamination studies evaluating MERS-CoV virus persistence on surfaces and other mediums in health-care settings were carried out in affected hospitals. Through these MERS-CoV ribonucleic acid (RNA) has been detected on various medical devices, ventilation equipment, facility surfaces, as well as in hospital air samples *(28–31).* 

Recurrent secondary transmission of MERS-CoV to humans, particularly in health-care facilities, call for further investigations to understand secondary transmission to and among HCW. Further studies are needed to investigate MERS-CoV superspreading events as well as to reinforce existing, and develop novel, IPC methods. (7) The investigation outlined below aims to evaluate the extent of MERS-CoV infection among HCW and identify factors that facilitate transmission in health-care facilities. This will inform the strengthening of IPC practices and help to prevent large nosocomial outbreaks.

### **1.1 Study objectives**

#### 1.1.1 Primary objectives

The primary objectives of this study are to:

- Better understand the extent of human-to-human transmission among health and care workers (HCW) by estimating the secondary infection rate (SIR)\* for HCW contacts of MERS cases at the individual level
- 2. Determine the risk factors for MERS-CoV infection in HCW
- \* In this context the *secondary infection rate (SIR)* is a measure of the frequency of new infections of MERS-CoV among contacts of confirmed cases in a defined period of time, as determined by a positive MERS-CoV result. In other words, it is the rate of contacts being infected, assessed through polymerase chain reaction (PCR) and/or serological assays on paired samples.

#### 1.1.2 Secondary objectives

This investigation can provide rich data to assess secondary objectives, including, but not limited to:

- 3. Characterize the range of clinical presentations of MERS-CoV infection among HCW, including: frequency of symptoms, severity of illness, duration of illness, proportion of asymptomatic and sub-clinical infections
- 4. Determine the serological response to MERS-CoV of HCW with symptomatic and asymptomatic infection, including quantification of the proportion of individuals in whom seroconversion occurs. See Annex 1 for more background information on antibody kinetics
- 5. Evaluate the effectiveness of infection prevention and control (IPC) measures among HCW



## 2.1 Study design, timing and duration

This is a cohort study of all identified HCW contacts working in a health-care facility in which a patient with a laboratory-confirmed MERS-CoV infection is receiving care; this protocol is written as for a prospective cohort study, however, it is likely that parts of the investigation will need to be conducted retrospectively as well (see the tip box on page 10). Note that this study can be conducted for potential HCW contacts in health-care facilities at varying levels of a health system (e.g. primary, secondary and tertiary care facilities) – not just in hospitals. It is intended to provide epidemiological, virological and serological information which will inform the extent of, and identify risk factors for, MERS-CoV human-to-human transmission and infection among HCW.

The duration of the study follow-up is a minimum of 1 month in the instance that no HCW contacts become infected with MERS-CoV (i.e. no secondary transmission). In the instance that there are secondary cases amongst HCW contacts, the study would end approximately 1 month (21 to 28 days) after the final MERS-CoV positive HCW contact is identified; therefore, this could be multiple months after the start of the study. For the full length of time it will take to conduct this study, the mentioned duration would then be added to the time it takes to set-up the study (approvals, training), process specimens, perform data analysis and generate reports.

## 2.2 Study population and recruitment

### 2.2.1 Study population

The study population is derived from the identification of all health and care workers (referred to in this protocol template as HCW) who have worked in a health-care facility in which a patient with a laboratory-confirmed MERS-CoV infection is receiving care AND who may have had any exposure to the affected patient (i.e. contacts); note that this includes 'protected exposure' with PPE, and further details are provided on this in further sections. Once a case of MERS-CoV infection has been identified in a health-care facility, a list of all HCW with any exposure to the affected patient will need to be drawn up (see **Annex 2**, **Questionnaire 2**). This should be conducted 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 HCW can be identified and recruited into the study.

Health and care workers (HCW) definition: For the purpose of this study the definition of HCW should not be too restrictive so that a large number of potentially exposed persons are included in the study. For this reason, HCW should be defined as all staff in the health-care facility involved in the provision of care for a MERS-CoV-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,

admission or reception clerks, patient transporters, catering staff etc.).

This protocol is designed to assess risk factors for infection among HCW with potential exposure to MERS-CoV. It does not include visitors to the health-care facility, or other patients who may have had contact with a MERS-CoV-infected patient or with the patient's materials. See the Reference on page 3 for a link to other MERS-CoV investigation protocols that can be used for other study populations.

If the patient with MERS-CoV infection consulted or received treatment at any other health-care facility for this illness, these health-care facilities need to be contacted and the HCW from these facilities recruited into the study with similar considerations to those mentioned above.

### 2.2.2 Eligibility criteria

**Inclusion criteria:** 1) Health and care workers (of any type) working at a facility with a MERS-CoV infected patient, AND 2) Has any potential exposure to a MERS-CoV infected patient hospitalized or previously hospitalized in the health-care facility or to the patient's materials.

Exclusion criteria: Unable to give informed consent.

*Note:* The concept of "protected exposure" should be avoided when selecting the study participants. In particular, wearing personal protective equipment (PPE) should not be considered an exclusion criterion, as one of the risk factors to be studied is the effectiveness of PPE.

### 2.2.3 Recruitment, follow-up and data collection

*Figure 1* and the details below provide an overview of the study timeline and all data and specimen collection time points in the instance that this investigation can be carried out as a prospective cohort (i.e that it can be started within 14 days of identification of the MERS-CoV positive patient at a health-care facility).

**Prior to the start of the investigation** (within 14 days of identifying the MERS-CoV positive patient): Investigators should visit the health-care facility to understand the management, infrastructure, personnel and IPC policies and the possible exposures HCW may have had to MERS-CoV. A data collection tool, **Questionnaire 1** (Annex 2), will help in formulating hypotheses about exposures; this should be filled out through a general interview of HCW, including supervisors and colleagues. During the same visit, and in conjunction with the



interview(s) described above, all potential participants (HCW with any possible exposure to the MERS-CoV positive patient) should be identified and recorded using **Questionnaire 2** (Annex 2).

**Day 1:** After all potential HCW participants have been identified and listed in **Questionnaire 2** (Annex 2), informed consent from all participants will be obtained (see Section 2.5.1 for more details). For consenting HCW, biological sampling (baseline serum) will be conducted immediately (see Figure 1 and Section 2.3 for more details). All HCW recruited into the study will need to complete **Questionnaire 3** (Annex 2) which covers: demographics, professional duties in the health-care facility, symptoms of respiratory disease, use of PPE, compliance to IPC measures (triage processes, hand hygiene, environmental cleaning etc.) and specific exposures to the MERS-CoV infected patient or patient's materials. Additional exposure (including exposures to confirmed or suspected human cases in the community and to other potential sources such as animals) questions will be included for all study subjects in the questionnaire.

**Day 1 – Day 21:** Each day, each participating HCW will fill out **Questionnaire 4** (symptom diary, **Annex 2**). If an HCW reports symptoms during this time period, the study investigators should be notified directly or via the appropriate health-care facility supervisors. The symptomatic HCW will then have biological specimens (nasopharyngeal or oropharyngeal swab, lower respiratory tract specimen) taken which will have molecular testing conducted immediately (see **Section 2.3**) to confirm whether or not the HCW is MERS-CoV positive. The isolation and clinical management of any HCW who reports symptoms will be guided by the standards of care at the site at which the investigation is being conducted (and should include restriction from work while tests are pending).

For any HCW testing positive<sup>1</sup> for MERS-CoV by molecular methods during the course of the study, all HCW contacts should be identified with Questionnaire 2 (Annex 2). For newly identified (not yet participating) HCW, all follow-up procedures, starting from consent and baseline sample and data collection on Day 1, should be carried out. For HCW already included in the study, their length of follow-up (symptom diary) should now be extended to 21 days past their most recent MERS-CoV positive contact, and they should be asked to fill out section B of Questionnaire 3 again (details of exposure to this individual positive for MERS-CoV, see Annex 2). Figure 1 shows an example of these new study 'branches' which would result from a HCW testing MERS-CoV positive.

**Day 21:** At 21 days following the HCW's exposure to a MERS-CoV positive patient (or HCW) they will have a second serum sample taken (paired serum). In order to more precisely document seroconversion, multiple subsequent paired serum samples should be taken from HCW participants with more than one MERS-CoV exposure – the first paired serum sample taken at 21 days past the first exposure, then 21 days past the next MERS-CoV exposure, and so on (see Section 2.3 for more details).

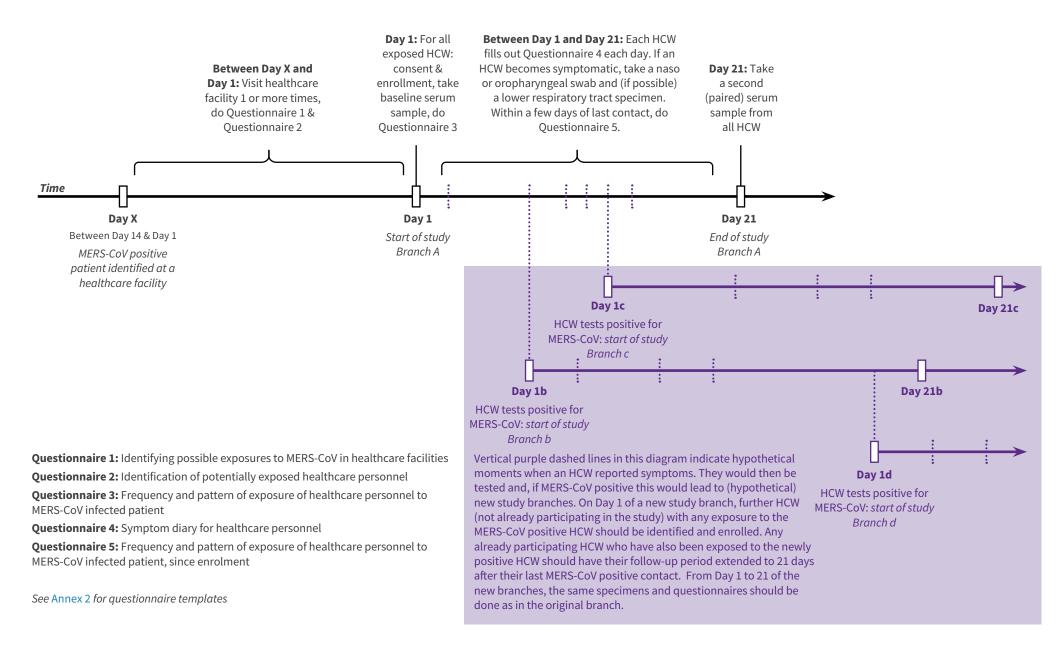
If any participants return a positive polymerase chain reaction (PCR) test for MERS-CoV, they should be reported to the national health authorities under the requirements of the International Health Regulations

8

*Note:* Annex 2 contains templates of all questionnaires; these are not exhaustive but outline data collection required to provide key epidemiological insights, they should be reviewed by study investigators and adapted depending on the local setting and outbreak characteristics. **Questionnaires 1 and 2** can be used to further adapt and specify **Questionnaire 3** (individual-level questionnaire for all participating HCW); after adaptation and before finalization, it is ideal if **Questionnaire 3** can be pilot tested in a small group of participants (e.g. 5-10 HCW), and then revised if needed before being administered to all participants.

2. Methods 9

### Figure 1: Prospective cohort investigation timeline with timing of data (questionnaires, see Annex 2) and specimen collection



### 2.3 Specimen collection and laboratory evaluations

All those involved in collection and transporting specimens should be trained in safe handling practices and spill decontamination procedures. Appropriate hand hygiene and PPE must be carried out and worn by study personnel during the collection of any specimen (see Section 2.5.5 for more details). Full details for laboratory testing, specimen collection, biosafety, sample shipment and reporting of test results for MERS-CoV can be found here: https://www.who.int/publications/i/item/10665-259952

10

If any participants return a positive polymerase chain reaction (PCR) test for MERS-CoV, they should be reported to the national health authorities under the requirements of the International Health Regulations, and all contacts (regardless of whether or not they are participants in this study) followed up for 14 days. Each newly confirmed case of MERS-CoV infection will initiate a new contact investigation as outlined above. See: https://www.who.int/publications/i/item/10665-178252

### 2.3.1 Specimen collection

Table 1 below outlines required and optional specimen collection from all HCW included in the study, in order to answer the study objectives.

As per section 2.2.3, all participants will be monitored daily for symptoms (**Questionnaire 4**, Annex 2) for 21 consecutive days after their last contact with a MERS patient (or HCW who is now a MERS case) or with the patient's (or HCW's) materials. If symptoms are reported by the HCW contact during the follow up period, a respiratory specimen (for molecular testing) will ideally be taken immediately: this includes combined nasopharyngeal and oropharyngeal swabs for case confirmation, and, ideally, specimens from the lower respiratory tract (e.g., induced sputum, aspirate, lavage, as appropriate).

*Note:* While lower respiratory tract specimen are more difficult to collect, evidence of shedding can be seen over a longer time period in this sample type, therefore, collection is highly recommended where possible. However, upper respiratory tract specimens are a valid alternative sample type, particularly in early stages of infection.

Specimen collection	Timing of collection
Serum sample (required)	<b>Baseline (Day 1):</b> at the time of recruitment - as soon as possible after exposure. <b>Day 21 to 28 (once):</b> collection of a second ('paired') serum sample from the same individuals who had baseline samples taken. If one HCW has multiple MERS-CoV positive contacts, this should be conducted repeatedly, once during the 21 to 28 days following each contact.
Combined nasopharyngeal and oropharyngeal swabs (if HCW symptomatic)	Day X (≤21 days since exposure): if HCW contact experiences any symptoms during follow-up (within 21 days of exposure to a MERS-CoV positive case) a respiratory specimen should be collected and tested as soon as possible
<b>Lower respiratory specimen</b> (optional)	<b>Day X (≤21 days since exposure):</b> if HCW contact experiences any symptoms during follow-up (within 21 days of exposure to a MERS-CoV positive case) a lower respiratory sample can also be collected as soon as possible

#### Table 1: Type of specimen to be collected and timing of collection

When collecting nasopharyngeal and oropharyngeal specimens, swabs specifically designed for collecting specimens for virology must be used. These swab kits should contain virus transport medium. The nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load.

All specimens will be collected according to standard procedures and labeled with a coded identification number that will also be recorded on the interview questionnaire (Annex 2). Date and time of collection, location and name of person collecting the specimen will also be recorded. Specimen tubes will be stored temporarily on cool packs carried by the study teams until they can be transported to the laboratory. All those involved in the collection and transportation of specimens should be trained in appropriate personal protection, safe handling practices and spill decontamination procedures.

### **Implementation tip**

For serum samples, the specific volume of blood is to be determined by study personnel, bearing in mind that the minimum required volume is 5 mL.

Some serologic assays or full genome sequencing may not be possible to perform in country, therefore specimens should be aliquotted so that specimens remain in country and only aliquots are sent to a reference laboratory.

### 2.3.2 Specimen transportation

For each biological sample collected, the date and time of collection, the conditions for transportation and the date and 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 cool packs. It is, however, important to avoid repeated

freezing and thawing of specimens. 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. It is recommended to aliquot samples prior to freezing, to minimize freeze thaw cycles.

12

Transport of specimens within national borders should comply with applicable national regulations. International transport of MERS-CoV specimens should follow applicable international regulations as described in the WHO Guidance on Regulations for the Transport of Infectious Substances 2021-2022. Appropriate Material Transfer Agreements will need to be signed if samples are to be transported between laboratories within or outside the country.

## Implementation tipFor labeling and shipping of specimens – it is key to use a basic triple packaging system,<br/>correct marking and labeling of specimens and use of appropriate shipping documents.<br/>The receiving laboratory should always be contacted before specimens are shipped.

#### 2.3.3 Laboratory evaluations

A MERS case may be laboratory confirmed by detection of viral nucleic acid or by serology. WHO case definitions for MERS-CoV can be found here: https://www.who.int/emergencies/outbreak-toolkit/disease-outbreak-toolboxes/mers-outbreak-toolbox

The following laboratory testing recommendations are subject to further updates as diagnostic tests and approaches become available. Please check the Middle East respiratory syndrome coronavirus (MERS-CoV) (who.int) for updates.

**Molecular testing:** Three real-time reverse transcription (rRT)-PCR assays for routine detection of MERS-CoV have been developed and their details published; assays targeting upstream of the E protein gene (upE) and assays targeting the open reading frame 1a (ORF 1a) are considered equally sensitive and are recommended for screening. To date, these rRT-PCR assays have shown no cross-reactivity with other respiratory viruses including human coronaviruses and are all suitable to detect all known MERS-CoV strains in humans and dromedary camels. See **Annex 1** for more background information about MERS-CoV molecular testing methods, other assays and complimentary confirmation methods.

### Implementation tip – genome sequencing

Where possible, MERS-CoV full genome sequencing from PCR-positive biological samples may provide further details on the genetic relationship of the viruses detected with other viral isolates. A RT-PCR assay for MERS-CoV targeting a 615 bp spike fragment may already provide a phylogenetic clustering of MERS-CoV variants comparable to that of full-length genomes, but this may often be insufficient for detailed molecular epidemiological investigations. Full genomes obtained by Next Generation Sequencing (NGS) using sets of specific primers to amplify the full genome for instance delivers a more detailed picture of genetic differences between viruses. Virus grown in culture may be used as an alternative source of the viral RNA.

Acquired sequence information should be shared and reported via publicly available databases; doing so will contribute valuable information to the global effort to understand MERS-CoV epidemiology and perform risk assessment.

Material and more detailed methods for MERS-CoV sequencing are described in the following bibliography of further reading:

Corman VM, Muller MA, Costabel U, et al. Assays for laboratory confirmation of novel human coronavirus (hCoV-EMC) infections. Euro Surveill 2012;17(49):20334.

Cotten M, Watson SJ, Kellam P, et al. Transmission and evolution of the Middle East respiratory syndrome coronavirus in Saudi Arabia: a descriptive genomic study. Lancet 2013;382:1993–2002.

Cotten M, Watson SJ, Zumla AI, et al. Spread, circulation, and evolution of the Middle East respiratory syndrome coronavirus. mBio 2014;5.

Smits SL, Raj VS, Pas SD, et al. Reliable typing of MERS-CoV variants with a small genome fragment. J Clin Virol 2015;64:83-7.

Serologic testing: Serological testing can be carried out in collaboration with an external laboratory partner as needed. Multiple serological assays will be needed to confirm seropositivity, and may include fluorescent antibody testing, enzyme linked immunosorbent assay (ELISA), luciferase assay, or other. In addition, all samples should be tested using a neutralization assay. These four types of assays each have advantages and disadvantages but appear to have similar utility. Until their interoperability and comparability are better understood, more than one assay should be performed for each serum sample. Testing will be conducted for antibodies against MERS-CoV specific proteins of the spike and nucleocapsid. At least two aliquots of sample should be made and at least one kept for future analysis. See Annex 1 for more background information about MERS-CoV serological testing methods as well as antibody kinetics. An algorithm has been developed to indicate which combinations of serological test results can be considered "positive" for the purpose of comparative analysis, see: https://www.who.int/emergencies/outbreak-toolkit/disease-outbreak-toolboxes/mers-outbreak-toolbox

Implementation tip Only a limited number of laboratories have the facilities for MERS-CoV serologic testing and therefore collaboration between countries without current capacity and designated reference laboratories is possible. Collaboration is at the discretion of Member States carrying out the investigation, but WHO strongly supports such collaboration and would willingly facilitate collaboration and possible shipment elsewhere for testing. For serologic testing, if capacity for performing ELISA and/or neutralization does not exist in country, WHO is able to facilitate coordination and collaboration with an external laboratory. Please contact MERSHQ@who.int

#### 2.3.4 Sample storage

In the case that serum samples cannot be processed immediately they can be stored for up to 5 days at 2-8 °C after which they should be stored at -80 °C (see section on specimen collection and transport above for more details). If -80 °C storage is not available the samples can be stored at -20 °C. It is recommended to aliquot samples prior to freezing, to minimize freeze thaw cycles. The storage of serum specimens in domestic frost-free freezers should be avoided, owing to their wide temperature fluctuations.

### 2.4 Data management

Demographic and occupational exposure data will be stored in a secure, passwordprotected database in the country where it is collected. Patient and participant identity will be protected and only aggregate summary data released publicly. Original data collection forms will be kept in locked storage.

### **2.5 Ethical considerations**

Ethical requirements will vary by country. In all cases, national and local regulations need to be followed. Investigators should confirm the requirements before implementation which may cover national ethics review only, or national and institutional review.

### **Implementation tip**

Ethical approval may be obtained from relevant ethical or institutional review boards in advance using a generic protocol such as this one before an outbreak occurs. If an outbreak occurs, the study design, questionnaires, sampling and consent forms can be modified rapidly to reflect the current outbreak situation. This will likely have to be resubmitted for ethical approval, but if the generic protocol has already been approved, the process is possible that second review may be more rapid, minimizing delays to the start of investigations. WHO guidelines on ethical issues in public health surveillance can be found here: https://www.who.int/publications/i/item/9789241512657

### 2.5.1 Informed consent

The purpose of the investigation needs to be explained to all individuals identified for recruitment into the investigation. Informed consent will be obtained from all individuals willing to participate in the investigation before any procedure is performed as part of the investigation, by a trained member of the investigation team.

Consent, or assent for children under the legal age of consent, will be obtained according to the country's national ethical requirements and thus need to comply with local regulations:

- Consent for:
  - o adults; and
  - o children under the legal age of consent (usually this is 18 years but it will vary from country to country) from a parent or legal guardian.

**Implementation tip** The age of consent may vary by country. Check the requirements of local, regional or national authorities.

### • Assent from:

o children and adolescents under the legal age of consent, but who can understand the implications of informed consent and go through the necessary procedures. This is usually children over the age of 12 to 13 years, but this will vary from country to country. A consent form from a parent or legal guardian will also be collected.

All eligible HCW should be considered for participation in the investigation, regardless of whether or not they are well or unwell, or receiving medical care for confirmed or suspected MERS-CoV. For individuals who lack the decisional capacity to consent at the time of the investigation, consent or assent by proxy (parent or guardian or spouse or family member) may be considered so as to not unduly exclude individuals from participating in the investigation. However, some sites may decide to exclude those with severe disease who are unable to complete the questionnaires if it is not possible to find a proxy. In either case, the exclusion criteria need to be clearly stated in the adapted protocol, and in the reporting of the results.

An appropriately trained member of the investigation team will need to explain to each participant that participation in the investigation is voluntary and that they are free to withdraw, without justification, from the investigation at any time without consequences and without affecting professional responsibilities. A member of the investigation must also be able to answer any questions individuals may have related to the procedures of the investigation. The processes related to withdrawal of a participant need to be described both in the protocol and in the information for the participant. In this description it must be made clear that a participant can withdraw from the investigation, without justification, at any time by informing one of the members of the investigation team. The contact details of one of the members of the investigation need to be provided in the information for the participant. If any participant decides to withdraw during the investigation, the samples collected and data should be discarded, except if the participant indicates that these can be kept for the purpose of conducting the investigation, or for future studies of other infectious pathogens.

Informed consent will seek approval to collect: blood, a nasopharyngeal and oropharyngeal sample, (possibly) lower respiratory tract specimens, demographic data and other epidemiological data (e.g. behaviors such as adherence to IPC) intended for the purpose of this investigation. It will also seek approval that samples may be shipped outside of the country for additional testing and, in accordance with national regulations, that samples may be used for future research purposes. The investigators will need to describe in the consent or assent forms how data and specimens will be securely stored. Informed consent will also indicate that any suspected or confirmed MERS-CoV infection may be notified to the national health authorities under the requirements of the International Health Regulations.

### 2.5.2 Risks and benefits for participants

This investigation poses minimal risk to participants, involving collection of a small amount of blood and upper (and possibly lower) respiratory tract specimens. The direct benefit to the participant is the possibility for identifying evidence of MERS-CoV infection, which, if the infection were acute, would allow for early monitoring and treatment. The primary benefit of the study is indirect, in that data collected will help improve and guide efforts to understand human-to-human transmission of MERS-CoV and prevent further spread of MERS-CoV in health-care facilities, particularly among HCW, and inform best IPC practices.

### **Implementation tip**

If local Institutional Review Board (IRB) regulations permit, participants may be offered reimbursement for reasonable out of pocket expenses related to the investigation; however, the level of compensation should not be such that participants are unduly influenced into consenting to participate.

#### 2.5.3 Reporting of serious adverse events, including death of a participant

Any serious adverse event, including death, of a participant during the investigation period, needs to be immediately (within 24h) reported to the Principal Investigator and the institution responsible for the investigation. The contact details for reporting serious adverse events needs to be provided to each member of the investigation team.

In accordance with national regulations, any serious adverse event, may also have to be reported to the local ethical review committee, if the adapted protocol was not deemed exempt from local ethical review committee.

### 2.5.4 Confidentiality

### National laws and regulations for data protection requirements must be followed.

Participant confidentiality needs to be maintained throughout the investigation. All subjects who participate in the investigation should be assigned a study identification number by the investigation team for the labelling of questionnaires and specimens. The link of this identification number to individuals will be maintained by the investigation team and the Ministry of Health (or equivalent), separately from the investigation files, and will not be disclosed elsewhere.

Data and specimens will be securely stored nationally. If the data are shared by the implementing organization with WHO or any agency or institution providing support for data analysis, data shared will include only the investigation identification number and not any identifiable information. Data sharing outside the country will be managed according to national laws and regulations, as appropriate.

Article 45 of the IHR (2005) describes the "treatment of personal data". 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.

### 2.5.5 Prevention of infection

**Participants.** As part of the recruitment process, all eligible participants should be provided information as to how MERS-CoV spreads and what measures can be taken to avoid infection. This should include information as to where to seek medical advice related to the investigation, the symptoms associated with MERS-CoV infection and what to do if symptoms develop during the investigation.

**Investigation personnel.** All personnel involved in the investigation need to be trained in IPC procedures (standard, contact, droplet and airborne precautions, as determined by national or local guidelines). These procedures should include proper hand hygiene and the appropriate use of personal protective equipment (such as surgical masks, gloves, long sleeve gowns, eye protection etc.), as per national or local guidelines, provided to members of the investigation team, not only to minimize their own risk of infection when in close contact with individuals with high-risk for MERS-CoV, but also to minimize the risk of spread to other participants in the investigation. Any investigation personnel who develop symptoms consistent with MERS-CoV should be immediately isolated, tested with a nasopharyngeal and oropharyngeal swab and managed as a suspect case of MERS-CoV according to the national or local guidelines.

18

# Implementation tipWhere possible, to mitigate infection risk, investigation personnel may consider<br/>administering questionnaires for participants over telecommunications (e.g. phone,<br/>videoconferencing, etc.). The feasibility of this strategy would depend on logistical<br/>factors (e.g. study personnel available and/or investigation partners) as well as local<br/>context (likelihood that all participants have phones or computers).

For example, an initial in-person visit by a study team member may include informed consent and biological sampling, with a phone-interview for the other questionnaires later on the same day, or the following day. This will work particularly well if, in any case, the study personnel doing biological sampling is not the same as the one doing the questionnaires.

WHO technical guidance on IPC specific to MERS-CoV can be found here: https://www.who.int/publications/i/item/10665-174652

### 2.5.6 Mitigation of stigmatization of participants

Stigma during MERS-CoV outbreaks involves negative social effects on a person or group due to the (real or perceived) presence of infection and/or risks of infection to others. Stigma can be particularly significant for pathogens such as MERS-CoV that are associated with large potential risks to individuals and communities and therefore significant negative social effects during outbreaks.

Individuals enrolled in MERS-CoV investigations or studies may face risks of stigma. Investigators, along with the relevant national or regional public health authorities, should therefore consider the stigma-related risks faced by individuals and weigh these against the benefits of the investigation. Enrolment of individuals in investigations and studies requires an ethical judgement that the likely public health benefits of enrolment outweigh additional risks specifically associated with the investigation, including those related to stigma. Measures to reduce stigma may include anonymity of enrolment to protect participants. However, full anonymity may not be possible due to the presence of staff involved in the investigations and public health measures (e.g., isolation). Public engagement regarding the disease and/or the investigation taking place, if carefully conducted, may also help to reduce stigma (e.g., by clarifying that infected individuals do not pose risks to others after the resolution of acute infection). For more reading on this subject, please consult the following resources:



- Collective Service (International Federation of Red Cross and Red Crescent Societies (IFRC), United Nations Children's Fund (UNICEF), World Health Organization (WHO) and Global Outbreak Alert and Response Network (GOARN) project): https://www. rcce-collective.net/
- Guidance for managing ethical issues in infectious disease outbreaks. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/250580)
- WHO community engagement framework for quality, people-centred and resilient health services. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/259280)

The investigators will need to provide specific information on how the risks of stigmatization will be mitigated as part of the implementation of the investigation and the communication of the findings.



The following section discusses sample size considerations, the epidemiological indicators that can be calculated with the data collected through this study (sometimes called 'study endpoints') and the statistical analyses that should be performed to do so.

### 3.1 Sample size considerations

The study-specific sample size will be determined by the number of HCW with any possible exposure to the confirmed MERS patient(s). Every effort should be made to include all HCW who have been or are in contact with confirmed MERS patients to maximize the statistical power of the investigation and to minimize bias in the determination of study outcome estimates.

### 3.2 Epidemiological indicators (study outcome measures)

Table 2 below provides an overview of the epidemiological characteristics that can be measured as part of this investigation. Not all of these will be a resulting outcome of each specific study implemented using this protocol – as that will depend on which aspects of this protocol are implemented.

Study Objective	Epidemiological characteristics	Definition	Comments, limitations
1. Better understand the extent of human- to-human transmission	Secondary infection rate (SIR; also called secondary infection incidence)	A measure of the frequency of new cases of MERS-CoV infection among the HCW contacts of a confirmed case in a defined period of time.	The numerator is the number of HCW confirmed to have MERS-CoV infection, while the denominator will be determined as the total number of HCW enrolled as contacts of each case under investigation.
of MERS-CoV among health and care worker (HCW)			This estimate represents an overall risk of infection among HCW contacts for a defined period of time.

#### Table 2: Epidemiological characteristics to be calculated from this case-ascertained investigation

Study Objective	Epidemiological characteristics	Definition	Comments, limitations
<ul> <li>2. Determine the risk factors for MERS-CoV infection in HCW</li> <li>AND</li> <li>3. Evaluate the effectiveness of infection prevention and control (IPC) measures among HCW</li> </ul>	Unadjusted association of the risk factor (or protective factor, e.g. IPC for objective #5) with an HCW contact becoming infected with MERS-CoV <i>OR</i> adjusted or unadjusted odds ratios or risk ratios <i>OR</i> unadjusted risk differences	Unadjusted (bivariable) associations: an assessment of whether MERS-CoV infection is more frequent (i.e. a higher proportion) among those with specific exposures (e.g. characteristics, risk factors, IPC level) vs in those without. Odds or risk ratio: odds or risk of a positive test in those with the risk or protective (IPC) factor vs odds or risk of a positive test in those without the risk or protective (IPC) factor. Regression models including other factors of interest or key baseline characteristics will give an adjusted (preferable) risk or odds ratio. Risk difference: Risk of past or present infection in those with the risk or protective (IPC) factor subtracted by risk of past or present infection in those without the risk factor or protective (IPC) factor.	The significance of bivariable (unadjusted) associations between risk or protective (IPC) factors for infection can be estimated using the chi-square statistics or 2-sided Fisher's exact test. However, expression of the associations as a risk or odds ratio with 95% confidence intervals is preferred over only reporting p-values of significance tests. Unadjusted risk and odds ratios can be generated using univariable logistic regression. Multivariable logistic regression can be used to identify independent risk or protective (IPC) factors. These models adjust for known or potential confounders (e.g. baseline characteristics like age of HCW, or other infection risk factors and/or IPC behaviors of the HCW); however, the use of multivariable logistic regression is limited by your sample size. Adjusted models are preferable. A note on evaluating the effectiveness of IPC measures are likely to be enforced across all HCW (i.e. no 'control' group), it may be of interest to compare varying levels of IPC measures among HCW. For example, there may be differences in IPC measures by HCW type, and there may be different levels of IPC used in different compartments of the facility (i.e. emergency room, ward, intensive care unit, etc.).
4. Characterize the range of clinical presentations of MERS-CoV infection among HCW	Frequency of each symptom type, severity of illness, duration of illness, proportion of asymptomatic and sub-clinical infections	Frequency of each symptom type – proportion of infected HCW with the specific symptom over total # of infected HCW. Severity of illness – proportion of infected HCW with indicators of severe illness (see comments) over total # infected HCW. Duration of illness – mean (average) or median number of days that symptoms are experienced across all HCW. Proportion of asymptomatic and sub-clinical infections – proportion of infected HCW with no symptoms (or very mild symptoms) over total # infected HCW.	For severity of illness, this may involve summarizing a variety of dichotomous (yes or no) standard severity outcomes such as hospitalized vs not hospitalized, or 'needed ventilation' vs 'did not need ventilation', or survival. Established respiratory illness scales (either already used for MERS-CoV or published for other respiratory illnesses) could also be used – e.g. mild vs moderate vs severe acute respiratory distress syndrome, and others.

Study Objective	Epidemiological characteristics	Definition	Comments, limitations
5. Determine the serological response of HCW with symptomatic	response to MERS- CoV infection	<i>Serological response</i> - change in serum level (increase or decrease in titre) of specific antibodies to MERS-CoV over a period of time	Serological response as defined here can only be calculated with the addition of further specimens (serial <sup>a</sup> serum sampling over the first 21 days, and extending past 21 days)
a a una mta martia	infected HCW who seroconvert	Seroconversion proportion – the number of HCW with MERS-CoV antibodies (serum sample) detected at 21+ days via serum sample, over total number who were positive via molecular testing	See Annex 1 for more background information on antibody kinetics.

<sup>a</sup> Serial serum sampling may be used to better understand seroconversion. It is ideal to collect at least one sample within 5-7 days of the suspected infection (symptom onset in most cases) as well as one serum sample between days 14 and 21.

### **3.3 Interpretation of results**

The following considerations are needed when interpreting the results of this investigation:

- The region of study globally was the study performed in the Middle-East region, African region, or Central Asia, where different strains of MERS-CoV may be present?
- The types of HCW included and the biases inherent with the selection of the study population were all types of HCW included, and how did findings differ by type of HCW? Were any further exclusion criteria implied in the specific study (e.g. an age requirement)?
- Characteristics, including IPC measures at the health facility where the investigation is taking place what level of facility is this (primary, secondary, tertiary) and what are the resources available at the facility? What is the physical organization of the facility (and in relation to where the MERS-CoV positive patient was admitted) and how might the layout and systems (e.g. airflow, waste management) contribute to transmission? What are the IPC measures in place, how long have they been in place and for which staff are they mandated?
- The timeline of case identification and recruitment of HCW participants were cases and HCW participants identified and interviewed in a timely manner (within a few days of the confirmed or probable MERS case)? If not, what are the potential limitations to recall (for exposure data, etc.)? Were cases identified at late or early stages in their illness and how might this bias estimates of clinical severity and case fatality?

24

- The molecular test method used - what are the specificity and sensitivity characteristics of the molecular test used to detect active infection?

### Increasing our understanding of MERS-CoV epidemiology, risk factors and severity.

The findings of this investigation will increase our global understanding of MERS-CoV transmission risks, risk factors for MERS-CoV transmission among HCW and the spectrum of MERS-CoV disease. These findings will aid in creating local and international policies for preventing MERS-CoV transmission and will inform IPC in the case of eventual outbreaks.



Recruitment method allowing, all participants should be informed of their individual results using the contact information collected as part of the investigation. The facility or facilities in which the investigation is implemented also need to receive a report on the overall findings of the investigation. This should include reporting on the following information:

26

- (1) The study design and specific procedures used (e.g. sampling method, eligibility criteria, laboratory techniques, etc.);
- (2) The number of study sites and the number of individuals approached and included, the age and sex of all individuals included is also ideally reported if this has been collected;
- (3) The types of HCW included (e.g. clinicians, laboratory staff, cleaners, etc.);
- (4) The IPC measures in place at the health-care facility, and other characteristics of the health-care facility;
- (5) Secondary infection rate –number of HCW persons with any eventual evidence (serological or molecular) of MERS-CoV over total number of contacts. This can be summarized both overall and individually by MERS-CoV positive patient or HCW.
  A breakdown of the proportion of HCW contacts with either serological or molecular (separately) MERS-CoV test positivity, as well as the raw numbers of individuals with serological or molecular testing evidence of MERS-CoV infection. If sample size permits, these estimates should be reported by your strata of interest (such as type of HCW, age category, etc.;
- (6) Any other key findings, as per the specific study objectives chosen (e.g. risk factors for HCW contact infection, protective factors for infection, serological response details, etc.).

An integrated approach which engages both researchers and stakeholders should be used for conducting dissemination activities in joint efforts by the researchers involved and advisory committee members.

Dissemination activities could include:

- Submitting progress and final research reports to the national Ministry of Health and to WHO.
- Publishing the research findings as preprints and subsequently in peer-reviewed journals and making them available in open access format. The STROBE guidelines for cross-sectional studies should be used for reporting of this study https://www.equator-network.org/reporting-guidelines/strobe/
- Organizing meetings/seminars/workshops involving a panel of the research team beside other research experts (from human and animal health) to discuss the research findings and how they may influence public health interventions and policies.
- Developing policy briefs for national human and veterinary health authorities.
- Submitting genome sequence information into international databases.

# Implementation tip

The *timely* dissemination of the results of this study are critical in understanding transmission of the MERS-CoV virus to inform guidance for policy to direct national and international public health responses.

# Composition 5. Competender of study team

27

This investigation calls for a multi-disciplinary research study team to undertake this study. The composition of the study team will be determined by each country. It is recommended that members from the Ministry of Health, national laboratories and other partners are included in the implementation and interpretation of this investigation. Coordination of investigations and sharing of information in real-time will be needed at both country and global levels. Epidemiologists, modelers, virologists, statisticians, clinicians and public health experts will all be necessary to include in this study that will help define key clinical, epidemiological and virological characteristics of MERS-CoV. Importantly, these specialists should all be included from an early stage to ensure that the study protocol and procedures adhere to best practices; e.g. making sure to include statisticians early on in the design of the study and not only after all data collection has been conducted as this may lead to having data which is not amenable to analysis.

**Implementation tip** A table such as the one below may be useful for designating roles and responsibilities and identifying study partners during the planning stage of this investigation.

What?	Who?
Overall coordination of the investigation	[Cite institution/ body/person(s)]
Identification of study population	[Cite institution/ body/person(s)]
Input on dromedary camel sampling strategy	[Cite institution/ body/person(s)]
Recruitment, informed consent, enrolment	[Cite institution/ body/person(s)]
Data and sample collection from enrolled participants	[Cite institution/ body/person(s)]
Laboratory testing and storage of samples	[Cite institution/ body/person(s)]
Data and sample collection from dromedary camels enrolled	[Cite institution/ body/person(s)]
Laboratory testing and storage of camel samples	[Cite institution/ body/person(s)]
Analysis of data and reporting	[Cite institution/ body/person(s)]
Data management	[Cite institution/ body/person(s)]
IT management	[Cite institution/ body/person(s)]
Informing participants of their individual results and the results of their camels (if tested) and communication of overall findings of investigation	[Cite institution/ body/person(s)]
[add more roles, as per country context]	[Cite institution/ body/person(s)]

### Table 3. Coordination matrix of roles and responsibilities in Country X

Once a study team is identified, a workshop and training should be conducted to familiarize the team with the objectives and organize the implementation of the study.



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30

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32

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# **Annex 1: Additional information and references**

The following information is up-to-date as of September 2023. It is recommended that investigators inquire on the **WHO website** or in recent literature online, including any recent systematic reviews on these topics for even further up-to-date information at the time of this protocol's use.

### **MERS-CoV** antibody kinetics

There is currently a lack of generalizable information on antibody kinetics of MERS-CoV in human patients. One study conducted on 42 MERS-CoV infected patients from the outbreak in the Republic of Korea in 2015 found that although all surviving patients seroconverted, none had antibodies 10 months after infection (1). The study employed the use of molecular testing of high-risk health and care worker contacts and serology, in an attempt to capture acute sub-clinical or asymptomatic infection as well as seroconversion. Another study conducted in the Republic of Korea found that although antibody responses may wane, they remain detectable beyond 12 months in patients with severe illness (2). In a study conducted in Jordan, antibody levels were found to persist and remain detectable for over 34 months in individuals following MERS-CoV infection (3). However, RT-PCR confirmed cases with mild disease failed to seroconvert or developed short-lasted antibody responses. Extensive contact tracing policies recommended by WHO and implemented in Saudi Arabia have identified a substantial number of asymptomatic secondary healthcare worker infections (4), however very few of these individuals seroconvert (personal *communication*). These considerations should be accounted for when assessing the ability of the study to capture evidence of seroconversion as a secondary objective of this study.

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### **MERS-CoV** serological testing

A number of different technical approaches for confirming MERS-CoV infection using serology have been developed. Details of two immunofluorescence assays to detect antibodies to MERS-CoV have been published *(1)*, and these assays, along with a serum neutralization test, were used in a 2 to 3 stage procedure to screen contacts of a case in Germany and determine population seroprevalences in Saudi Arabia *(2-5)*. An assay for detection of MERS-CoV antibodies using protein microarray technology has also been developed and its details published *(6,7)*. Another two-stage approach with a screening test using a recombinant nucleocapsid (N) and spike (S) protein-based indirect enzyme-linked immunosorbent (ELISA), followed by a confirmatory microneutralization has also been described *(8)*. Details of a neutralization test based on retroviral pseudoparticles which also demonstrates high levels of specificity to MERS-CoV have also been published *(9)*. A commercial ELISA assay based on the spike S1 region is available for screening. Positive ELISA results should be confirmed by neutralization assays.

### **References:**

- 1. Corman VM, Muller MA, Costabel U, et al. Assays for laboratory confirmation of novel human coronavirus (hCoV-EMC) infections. Euro Surveill 2012;17(49):20334
- 2. Corman VM, Eckerle I, Bleicker T, et al. Detection of a novel human coronavirus by realtime reverse-transcription polymerase chain reaction. Euro Surveill 2012;17(39):20285
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9. Perera RA, Wang P, Gomaa MR, et al. Seroepidemiology for MERS coronavirus using microneutralisation and pseudoparticle virus neutralisation assays reveal a high prevalence of antibody in dromedary camels in Egypt, June 2013. Euro Surveill 2013;18:pii=20574.

36

### **MERS-CoV molecular testing**

Currently described tests are an assay targeting upstream of the E protein gene (upE) and assays targeting the open reading frame 1b (ORF 1b) (1), and the open reading frame 1a (ORF 1a) (2). The assay for the upE target is considered highly sensitive and is recommended for screening, with the ORF 1a assay considered of equal sensitivity. The ORF 1b assay is considered less sensitive than the ORF 1a assay. An alternative approach involving two rRT-PCR assays targeting the MERS-CoV nucleocapsid (N) protein gene, which can complement upE and ORF 1a assays for screening and confirmation has also been published (3).

### **References:**

- 1. Corman VM, Eckerle I, Bleicker T, et al. Detection of a novel human coronavirus by realtime reverse-transcription polymerase chain reaction. Euro Surveill 2012; 17(39):20285
- 2. Corman VM, Muller MA, Costabel U, et al. Assays for laboratory confirmation of novel human coronavirus (hCoV-EMC) infections. Euro Surveill 2012;17(49): 20334
- 3. Lu X, Whitaker B, Sakthivel SK, et al. Real-time reverse transcription-PCR assay panel for Middle East respiratory syndrome coronavirus. J Clin Microbiol 2014;52:67-75.

# **Annex 2: Questionnaires**



Questionnaire 1: Identification of possible exposures to MERS-CoV in a health-care facility

This questionnaire has been designed to give a better understanding of the potential exposures to MERS-CoV and existing infection prevention and control (IPC) practices in a health-care facility as soon as a patient with MERS-CoV is identified there.

The questions below will help to formulate hypotheses about exposures which will inform the questionnaire administered to all HCW eligible for participation in the study, and they will also provide an evaluation of the health-care facility's general preparedness for managing cases of MERS-CoV.

This questionnaire should be completed by members of the health-care facility's administration and IPC team <u>before</u> the full study is implemented.

# Implementation tipAs part of study implementation, it is important to allocate time and study funds for<br/>translation and field-testing of the questionnaires and other data collection tools.<br/>Investigators are encouraged to adapt the questionnaires to local contexts to maximize<br/>the relevance of the study's results.

### Unique Case ID and Cluster number (if applicable):

1. Participant classification and outbreak context	
Role in the health-care facility of the personnel completing the questionnaire	
Date of MERS-CoV infection <u>symptom onset</u> in patient receiving treatment in the health-care facility (dd/mm/yyyy)	//
Date of MERS-CoV infection <u>confirmation</u> in patient receiving treatment in health-care facility (dd/mm/yyyy)	//

2. Data collector and interview information	
Name of data collector	
Data collector institution	
Data collector profession	
Data collector telephone number	
Data collector email	
Place of interview (region, city, further details if applicable)	
Interview start date (dd/mm/yyyy)	/
Form completion date (dd/mm/yyyy)	/
Language used for interview	

37



# Questionnaire 1: Identification of possible exposures to MERS-CoV in a health-care facility (continued)

3. Infection prevention and control (IPC) at the hea	lth-care facility
General structural IPC considerations at the health-care	acility
Does the health-care facility have appropriate water, sanitation and hygiene (WASH) services and materials?	☐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
Are health worker staffing levels adequate for the patient workload?	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
Does bed occupancy exceed the standard capacity of the health-care facility?	<ul> <li>Always</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
Does the health-care facility have a well-equipped triage station at the entrance, supported by trained staff?	☐Yes ☐No ☐Unknown
If Yes, is there a triage system in place to detect cases of respiratory pathogen illness early and isolate them?	☐Yes ☐No ☐Unknown
Are there negative-pressure airborne infection isolation rooms or well-ventilated isolation rooms that are functioning correctly and appropriately monitored for airflow and exhaust handling?	☐Yes ☐No ☐Unknown
Does the health-care facility have personal protective equipment (PPE)?	☐Yes ☐No ☐Unknown
If Yes, is the PPE available in sufficient quantities? If Yes, is the PPE available of good quality and fit for purpose?	☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown
IPC program at the heath care facility	
Does the health-care facility have dedicated IPC program, or team, or focal point?	Tick all that apply: IPC program IPC team and/or service IPC focal point IPC training None of the above
Does the health-care facility have IPC guidelines for health workers ?	☐Yes ☐No ☐Unknown
Does the health-care facility require personnel to be vaccinated?	☐ Yes ☐ No ☐ Unknown If Yes, which vaccines? Please specify:
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 <u>patients</u> ?	□Yes □No □Unknown



# Questionnaire 1: Identification of possible exposures to MERS-CoV in a health-care facility (continued)

Does the health-care facility have a surveillance system for nosocomial infections in <u>health workers</u> ?	☐Yes ☐No ☐Unknown
Does the health-care facility screen <u>health workers</u> on daily arrival for symptoms of infection?	☐Yes ☐No ☐Unknown
Are there policies and procedures (i.e. screening and work restrictions) for HCW with respiratory symptoms (regardless of MERS-CoV exposure)?	☐Yes ☐No ☐Unknown
Is IPC education and training provided to HCW? If Yes, for whom is training provided?	<ul> <li>Yes No Unknown</li> <li>All HCW at facility</li> <li>HCW doing clinical care only</li> <li>HCW with direct (e.g. clinical care) and indirect (e.g specimens and/or waste) exposure</li> <li>Other, specify:</li> </ul>
If Yes, does training include respiratory pathogen exposure scenarios? If Yes, how often does training occur?* *If frequency differs by HCW type, provide details separately	☐ Yes (all HCW) ☐ Yes (some HCW) ☐ No ☐ Unknown ☐ On employment ☐ Every year ☐ As needed
MERS-CoV-specific IPC procedures	
Are patients with suspected MERS-CoV infection isolated upon arrival at the health-care facility?	<ul> <li>Always</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> <li>Unknown</li> </ul>
Is a medical mask fitted to patients with suspected MERS- CoV infection upon arrival in the health-care facility?	<ul> <li>Always</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> <li>Unknown</li> </ul>
Does the health-care facility management alert all health workers if a MERS-CoV infected patient is being cared for within the health-care facility?	<ul> <li>Always</li> <li>In most situations</li> <li>Sometimes we are not alerted on time</li> <li>Rarely alerted on time</li> </ul>
Are there specific IPC procedures for laboratory submission of specimens for MERS-CoV testing?	□Yes □No □Unknown
Are there procedures for cleaning the room of a patient with MERS-CoV infection?	<ul> <li>Yes (if confirmed)</li> <li>Yes (since the time infection is suspected)</li> <li>No Unknown</li> </ul>
Are there policies and procedures (i.e. screening, work restrictions) for health and care worker (HCW) exposed to MERS-CoV?	☐Yes ☐No ☐Unknown
Historically (since 2012) are any HCW known to have been infected with MERS-CoV while working at the health-care facility?	☐Yes ☐No ☐Unknown
Since the time that the current MERS-CoV patient was identified, are any HCW known to have been infected while working at the health-care facility?	☐Yes ☐No ☐Unknown
What further and/or increased IPC actions were taken since the time that the current MERS-CoV patient was identified? (tick all that apply)	<ul> <li>None</li> <li>IPC information provided to HCW</li> <li>Further IPC training provided</li> <li>Other, specify:</li> </ul>



40

# Questionnaire 1: Identification of possible exposures to MERS-CoV in a health-care facility (continued)

4. End of questionnaire and status of form comple	tion
Is participant ok with being contacted again with further questions or clarifications	☐Yes ☐No
Form completed	☐ Yes ☐ No or partially
	If No or partially, reason: Missed Not attempted Not performed Refusal Other, specify:



### Questionnaire 2: Identification of potentially exposed health and care workers (HCW)

The following table should be completed to identify and trace participation of all personnel working in the health-care facility who have potentially been exposed to a MERS-CoV infected patient during all or part of the visit and/or hospitalization of the patient, or to the patient's materials (e.g. biological samples, soiled garments or potentially contaminated areas of the health-care facility). The time period of interest for this contact is from the time of the patient's illness onset and until 14 days after the end of illness onset. Identification of HCW should involve discussion with health facility authorities, consultation of duty rosters and interviewing personnel.

All personnel identified to have had any contact with the patient or their materials within that window of time should be included in the table below and invited to participate in the study. This form contains personally identifying information and should be kept securely and separately from study questionnaires. Lines should be added and modified as needed as per each specific studies scope and local context.

**Implementation tip** As part of study implementation, it is important to allocate time and study funds for translation and field-testing of the questionnaires and other data collection tools. Investigators are encouraged to adapt the questionnaires to local contexts to maximize the relevance of the study's results.

Contact ID	Initials	Age	Sex M or F	Role in health-care facility	Type of contact with MERS patient and/or materials		Date of first questionnaire administration	of first			Date of final specimen collection	
---------------	----------	-----	---------------	------------------------------------	--	--	--	----------	--	--	--	--

Doctors, nurses, dietitians, physical therapists, social workers, nursing assistants, medical orderly, hospital attendants

•	•	••	-		•	•	•••••			
echnicia	ns, laborat	ory perso	nnel, resear	ch staff, adminis	strative clerks (in e	mergency room, in	itensive care unit e	tc.)		
ospital o	cleaning sta	aff, laundr	y staff, cate	ring staff, securi	ty staff					
			ĺ							

\* as nasopharyngeal and oropharyngeal swabs need to be taken the same day as symptom onset, these dates should also be considered as dates of subsequent sampling



This questionnaire has been designed to gather information about the frequency and patterns of contact of HCW participating in this study, to the MERS-CoV infected patient and/or the patient's materials (e.g. biological samples, soiled garments or potentially contaminated areas of the health-care facility). The purpose of this is not to point out fault with HCW or procedures, but rather will allow health authorities and public health researchers to better understand potential exposures that may lead to infection of HCW and to develop hypotheses to test in subsequent studies.

Note: the questionnaire's first page should be kept securely and separately from the rest of the questionnaire

Implementation tipAs part of study implementation, it is important to allocate time and study funds for<br/>translation and field-testing of the questionnaires and other data collection tools.<br/>Investigators are encouraged to adapt the questionnaires to local contexts to maximize<br/>the relevance of the study's results.

### Unique Participant ID and Cluster number (if applicable):

Date of admission or first visit to facility of MERS patient

(as a reminder for exposure time period of interest for interviewer or interviewee), dd/mm/yyyy

1. Data collector and interview information	
Name of data collector	
Data collector institution	
Data collector profession	
Data collector telephone number	
Data collector email	
Place of interview (region, city, further details if applicable)	
Interview start date (dd/mm/yyyy)	/
Form completion date (dd/mm/yyyy)	/
Language used for interview	

## 2. Participant personally identifying information

(Note: personally identifying data should be stored securely and separately from other parts of this form)

First name	
Family name	
Date of birth (dd/mm/yyyy)	/ 🗌 Unknown
Address (if multiple residences, give addresses for all)	
Telephone (mobile) number	
Email	
National identifier or social number [optional]	
Responsible health centre, if applicable (name, address, contact information):	



3. Participant demographic information and role w	ithin health-care facility
Sex	☐ Male ☐ Female ☐ Not known ☐ Prefer not to answer
Age (years, months)	years months 🛛 Unknown
Nationality	
Ethnicity [optional, at discretion of study investigators. If using, please input checkbox style options with relevant ethnicities in the right-hand column]	
Country of residence	
Highest level of education <i>finished</i>	<ul> <li>None or not finished primary school</li> <li>Primary school (approximately 6 years)</li> <li>Secondary school (total of approximately 12 years)</li> <li>College or university undergraduate degree or postsecondary diploma</li> <li>Graduate studies (e.g. Masters, PhD)</li> </ul>
Does the participant live in a shared living facility (e.g. dormitory) with other HCW?	<ul> <li>Yes □ No □ Unknown</li> <li>If Yes, provide general address information for living facility (e.g. building block number, etc)</li> <li>If Yes, are there camels present in or close to the living facility? □ Yes □ No</li> </ul>

4. Participant current symptoms (today) and	d recent history of symptoms	(last 14 days)
Are you sick today with fever or respiratory symptoms?	☐Yes ☐No ☐Unknown	
Did you experience any fever or respiratory signs or symptoms during the last 14 days	☐Yes ☐No ☐Unknown	
If Yes, did you seek medical care?	Yes No Unknown	
	If Yes, specify location (address):	
If Yes, were you hospitalized during	□Yes □No □Unknown	
your illness?	If Yes, when? (DD/MM/YYYY):	//
	If Yes, which hospital (address):	
If you answered yes to either of the first two questions, please indicate which symptoms.	Today	Last 14 days
Fever	□Yes □No □Unknown	☐Yes ☐No ☐Unknown
Fever Dry cough	☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown ☐ Yes ☐ No ☐ Unknown
Dry cough	Yes No Unknown	 □Yes □No □Unknown
Dry cough Productive cough	Yes   No   Unknown     Yes   No   Unknown	Yes   No   Unknown     Yes   No   Unknown
Dry cough Productive cough Phlegm	Yes     No     Unknown       Yes     No     Unknown       Yes     No     Unknown	Yes     No     Unknown       Yes     No     Unknown       Yes     No     Unknown
Dry cough Productive cough Phlegm Sore throat	Yes       No       Unknown	Yes       No       Unknown
Dry cough Productive cough Phlegm Sore throat Runny nose	Yes       No       Unknown	Yes       No       Unknown
Dry cough Productive cough Phlegm Sore throat Runny nose Shortness of breath	Yes       No       Unknown	Yes       No       Unknown         Yes       No       Unknown
Dry cough Productive cough Phlegm Sore throat Runny nose Shortness of breath Chest pain	Yes       No       Unknown         Yes       No       Unknown	Yes       No       Unknown         Yes       No       Unknown



44

# Questionnaire 3: Frequency and pattern of exposure of health and care workers (HCW) to a MERS-CoV infected patient (continued)

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

### 5. Participant medical history 5a. Pre-existing conditions, chronic illnesses, recent pregnancy Obesity □Yes □No □Unknown Cancer □Yes □No □Unknown If Yes, specify (timing and specific cancer): If cancer treatment in the last year: □ Chemotherapy Radiation Other, specify: Diabetes □Yes □No □Unknown □Yes □No □Unknown If Yes, do you use insulin? HIV/other immune deficiency ☐ Yes ☐ No ☐ Unknown If Yes, specify: Heart disease □Yes □No □Unknown If Yes, specify: Asthma (requiring medication) ☐ Yes ☐ No ☐ Unknown Which medication has been used for treatment of asthma in the past month? Handheld inhalers Oral medications to open airways Oral steroids Home nebulizer treatment to open airways □ None in the past month Other, specify:



Chronic lung disease (non-asthma) If Yes, specify:	Yes No Unknown
Specify any medication used for treatment:	
Chronic liver disease If Yes, specify:	☐Yes ☐No ☐Unknown
Chronic hematological disorder If Yes, specify:	Yes No Unknown
Chronic kidney disease If Yes, are you currently receiving dialysis:	☐Yes ☐No ☐Unknown
Chronic neurological impairment or disease If Yes, specify:	☐Yes ☐No ☐Unknown
Organ or bone marrow recipient	□Yes □No □Unknown
Pregnancy	☐ Yes ☐ No ☐ Unknown If Yes, specify number of weeks:
Recent pregnancy – if female and not currently pregnant, was the participant pregnant in the last 6 months?	☐Yes ☐No ☐Unknown
Familial hereditary illness If Yes, specify:	☐Yes ☐No ☐Unknown
Other pre-existing condition(s) If Yes, specify:	☐Yes ☐No ☐Unknown
5b. Other medical history	
Participant currently smokes tobacco (e.g. cigarettes, cigars, shisha)	□ Daily □ A few days a week □ Not at all □ Unknown
If participant currently smokes tobacco, do they share their tobacco (e.g. shisha)	☐ Yes ☐ No ☐ Unknown ☐ Not applicable (does not smoke)
If participant does not currently smoke tobacco daily, have they smoked tobacco daily in the past?	☐ Yes ☐ No ☐ Unknown ☐ Not applicable (currently smokes daily)
If participant smoked tobacco in the past (but not currently), at what frequency was it?	□Daily □A few days a week □Unknown
Participant takes medications regularly	☐Yes ☐No ☐Unknown
(within the last 6 months) If Yes, taking corticosteroids: If Yes, list medications:	☐Yes ☐No ☐Unknown
Participant has seen a traditional healer in the last 6 months	Yes No Unknown
Participant has taken traditional medications within the last 6 months	☐ Yes ☐ No ☐ Unknown ☐ If Yes, list traditional medications:



6.Participant role within health-care facility and infection prevention and control (IPC)			
6.Participant role within health-care facility and in Role within health-care facility (listed alphabetically)	<ul> <li>Administrative</li> <li>Catering</li> <li>Dietician or Nutritionist</li> <li>Doctor</li> <li>Hospital cleaning (note: laundry is a separate option)</li> <li>Laboratory personnel</li> <li>Laundry</li> <li>Medical orderly or hospital assistant</li> <li>Nurse</li> <li>Nurse assistant</li> <li>Research staff</li> <li>Security</li> </ul>		
	<ul> <li>Social worker</li> <li>Technician, specify type:</li> <li>Therapist, specify type:</li> <li>Other, specify:</li> </ul>		

Infection prevention and control (IPC) training	
For how long have you been working at this health-care facility?	years months
Have you ever undertaken infection prevention and control (IPC) training as part of your job at this health-care facility?	□Yes □No □Unknown
If Yes, how frequently have you participated in this training?	<ul> <li>Once (prior to beginning job)</li> <li>Once (after beginning job)</li> <li>Multiple times, at regular intervals (e.g. yearly), if selecting, specify frequency:</li></ul>
When was the last time (i.e. how many years and months ago) you completed an IPC training at this facility?	years months
Cumulatively you have received how much IPC training?	□ ≤2 hours □>2 hours
If you've ever participated in an IPC training at this facility, please indicate components you remember being included	□ [Input topic 1] □ [Input topic 2] □ [Input topic 3]
Comment: here, topics of relevance should be input as per updated IPC standards, local context and initial interview with health-care fa- cility (i.e. info from Questionnaire 1 and other interviews with health- care facility management)	<ul> <li>[Input topic 4]</li> <li>[Input topic 5]</li> <li>[Input other topics as relevant]</li> </ul>



# Questionnaire 3: Frequency and pattern of exposure of health and care workers (HCW) to a MERS-CoV

# **infected patient** (continued)

If you've ever participated in an IPC training at this facility, has it included aspects and/or a module of respiratory pathogen infection prevention?	☐Yes ☐No ☐Unknown ☐Not applicable		
If Yes, how frequently have you participated in this respiratory pathogen specific training?	<ul> <li>Once (prior to beginning job)</li> <li>Once (after beginning job)</li> <li>Multiple times, at regular intervals (e.g. yearly), if selecting, specify frequency:</li></ul>		
When was the last time (i.e. how many years and months ago) you completed a module of respiratory pathogen IPC training at this facility?	years months		
If you've ever participated in a respiratory pathogen-specific IPC training at this facility, please indicate components:	<ul> <li>[Input topic 1]</li> <li>[Input topic 2]</li> <li>[Input topic 3]</li> </ul>		
Comment: here, topics of relevance should be input as per updated respiratory pathogen IPC standards, local context and initial interview with health-care facility (i.e. info from Questionnaire 1 and interviews with facility management)	<ul> <li>[Input topic 3]</li> <li>[Input topic 4]</li> <li>[Input topic 5]</li> <li>[Input other topics as relevant]</li> </ul>		
Comment: Add in other relevant IPC training questions here as per local context and interviews with health-care facility management	Input answer options		
Comment: Add in other relevant IPC training questions here as per local context and interviews with health-care facility management	Input answer options		
Comment: Add in other relevant IPC training questions here as per local context and interviews with health-care facility management	Input answer options		
IPC adherence general			
Do you follow recommended hand hygiene practices?	☐ Always, as recommended ☐ Occasionally	☐ Most of the time ☐ Rarely	
Do you use alcohol-based hand rub or soap and water:			
before touching a patient?	☐ Always, as recommended ☐ Occasionally	☐ Most of the time ☐ Rarely	
before cleaning and/or aseptic procedures?	☐ Always, as recommended ☐ Occasionally	☐ Most of the time ☐ Rarely	
after (risk of) body fluid exposure?	☐ Always, as recommended ☐ Occasionally	☐ Most of the time ☐ Rarely	
after touching a patient?	☐ Always, as recommended ☐ Occasionally	☐ Most of the time ☐ Rarely	
after touching a patient's surroundings?	☐ Always, as recommended ☐ Occasionally	☐ Most of the time ☐ Rarely	
Do you wear personal protective equipment (PPE) when indicated?	Always, according to the ris		
(PPE includes: medical mask, face shield, gloves, goggles or glasses, gown, coverall, head cover, respirator (for example, N95 or equivalent) and shoe covers)	☐ Occasionally ☐ Rarely		



Do you follow IPC standard precautions when in contact with any patient?	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> <li>I don't know what IPC standard precautions are</li> </ul>
Is PPE available typically available in sufficient quantity in the health-care facility?	☐Yes ☐No ☐Unknown

7. Travel and other possible MERS-CoV exposures in the last 6 months			
Participant travelled domestically within the last 6 months If Yes, dates of travel and locations (list all, add extra entries as needed)	Yes □ No □ Unknown     D1. Dates of travel (dd/mm/yyyy):    /to/     Region(s) and cities visited:		
	D1. Dates of travel (dd/mm/yyyy): /to/ Region(s) and cities visited:		
	D1. Dates of travel (dd/mm/yyyy): /to/ Region(s) and cities visited:		
Attended mass gathering (wedding, festival, religious pilgrimage) at this location?)	☐ Yes ☐ No ☐ Unknown If Yes, specify event(s) type & location(s):		
Participant travelled <i>internationally</i> within the last 6 months	☐ Yes       ☐ No       ☐ Unknown         Int1.       Dates of travel (dd/mm/yyyy):		
Attended mass gathering (wedding, festival, religious pilgrimage) at any of these locations?	☐ Yes ☐ No ☐ Unknown If Yes, specify event(s) type & location(s):		



While traveling (eit	While traveling (either domestically or internationally), did you visit any of the following venues?					
Tick all venues visited that apply:	Location of venue (detail town and country)	Animals present type	at venue and contact	Did you have direct contact with any animal carcasses, body fluids, secretions, urine, or excrement at this venue?		
☐ Farm with animals		Camel, if Yes:	Direct contact Indirect contact	☐Yes ☐No ☐Unknown		
		☐ Goat, if Yes:	Direct contact Indirect contact			
		☐ Sheep, if Yes:	Direct contact Indirect contact			
		☐ Pig, if Yes:	Direct contact Indirect contact			
		Cattle, if Yes:	Direct contact Indirect contact			
		Horse, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>			
Animal market		Camel, if Yes:	Direct contact Indirect contact	☐Yes ☐No ☐Unknown		
		☐ Goat, if Yes:	 □ Direct contact □ Indirect contact			
		☐ Sheep, if Yes:	 □ Direct contact □ Indirect contact			
		☐ Pig, if Yes:	Direct contact			
		□ Cattle, if Yes:	Direct contact Indirect contact			
		Horse, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>			
Slaughterhouse		□Camel, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>	☐Yes ☐No ☐Unknown		
		☐ Goat, if Yes:	Direct contact Indirect contact			
		☐ Sheep, if Yes:	Direct contact Indirect contact			
		☐ Pig, if Yes:	Direct contact Indirect contact			
		□ Cattle, if Yes:	Direct contact Indirect contact			
		☐ Horse, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>			
Camel quarantine site		Camel, if Yes:	Direct contact Indirect contact	☐Yes ☐No ☐Unknown		
		☐ Goat, if Yes:	Direct contact Indirect contact			
		☐ Sheep, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>			
		☐ Pig, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>			
		□ Cattle, if Yes:	Direct contact Indirect contact			
		Horse, if Yes:	Direct contact Indirect contact			



50

Tick all venues visited that apply:	Location of venue (detail town and country)	Animals present type	at venue and contact	Did you have direct contact with any animal carcasses, body fluids, secretions, urine, or excrement at this venue?
Camel racetrack		□ Camel, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>	☐Yes ☐No ☐Unknown
		☐ Goat, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>	
		☐ Sheep, if Yes:	Direct contact Indirect contact	
		☐ Pig, if Yes:	Direct contact Indirect contact	
		□ Cattle, if Yes:	Direct contact Indirect contact	
		Horse, if Yes:	Direct contact Indirect contact	
Camel beauty pageant		□ Camel, if Yes:	Direct contact Indirect contact	☐Yes ☐No ☐Unknown
		☐ Goat, if Yes:	☐ Direct contact ☐ Indirect contact	
		☐ Sheep, if Yes:	☐ Direct contact ☐ Indirect contact	
		☐ Pig, if Yes:	☐ Direct contact ☐ Indirect contact	
		□ Cattle, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>	
		Horse, if Yes:	Direct contact Indirect contact	
Other event involving		□ Camel, if Yes:	<ul> <li>Direct contact</li> <li>Indirect contact</li> </ul>	Yes No Unknown
camels		☐ Goat, if Yes:	☐ Direct contact ☐ Indirect contact	
		☐ Sheep, if Yes:	Direct contact Indirect contact	
		☐ Pig, if Yes:	Direct contact Indirect contact	
		□ Cattle, if Yes:	Direct contact Indirect contact	
		Horse, if Yes:	Direct contact Indirect contact	
Participant visited a	nyone in the hospital	in the last 6 mont	hs ☐Yes ☐No ☐Un	known
	e person sick with re	spiratory		
-	thing problems)?	·	□Yes □No □Un	known
	t hospital (regions, ci	-		
hospital?	vas your relationship	to the person in tr	e ☐Close family ☐E ☐Friend ☐Other,	-



# Questionnaire 3: Frequency and pattern of exposure of health and care workers (HCW) to a MERS-CoV

**infected patient** (continued)

8. Dromedary camel exposures in or around the home			
Participant has had any dromedary camels in or around their home in the last 6 months?	□Yes □No □Unknown		
If Yes, number of camels	□None □<10 animals □≥10 animals		
If Yes, what are the camels used for	<ul> <li>Income</li> <li>Food</li> <li>Work</li> <li>Racing</li> <li>Pets</li> <li>Other: specify</li> </ul>		
If Yes, do you have direct contact (i.e. touch) with these camels?	□Yes □No □Unknown		
If Yes, has there been any illness affected these camels in the last 6 months?	□Yes □No □Unknown		
In the last 6 months, did you have any contact with any carcasses, body fluids, secretions, urine or excrement of dromedary camels in or around your home?	☐Yes ☐No ☐Unknown		
In the last 6 months, did you have any contact with any dromedary camel bedding, stray of feed in or around your home?	☐Yes ☐No ☐Unknown		
At your home, in the last 6 months did you do any of the following activities with <b>dromedary camels:</b>	Feed them – Yes No Unknown Clean their housing – Yes No Unknown Clean camel-farm equipment – Yes No Unknown Slaughter them – Yes No Unknown Assist with their birth – Yes No Unknown Milk them – Yes No Unknown Kiss and/or hug them – Yes No Unknown Other tasks – Yes (specify below) No Unknown		
Other members of the participant's household (e.g. relatives or domestic help) frequently have had direct contact with dromedary camels	<ul> <li>☐ Yes, in the last 6 months</li> <li>☐ Yes, in the last 14 days</li> <li>☐ No</li> <li>☐ Unknown</li> </ul>		
Other members of the participant's household (e.g. relatives or domestic help) frequently visit or work on a camel farm, market, or other venue where dromedary camels are kept or sold?	<ul> <li>Yes, in the last 6 months</li> <li>Yes, in the last 14 days</li> <li>No</li> <li>Unknown</li> </ul>		



9. Food or medicinal exposures to dromedary camels			
Participant uses camel products for medicinal purposes	<ul> <li>Yes No Unknown</li> <li>If Yes, which products:</li> <li>Camel milk (to drink)</li> <li>Camel urine (to drink)</li> <li>Medication (e.g. pills, poultice) containing camel products</li> <li>Other, specify:</li></ul>		

### In the last 6 months, select the frequency at which you consumed the following:

	Daily	At least once per week	Less than once a week but more than once a month	Less than once per month but several times in the last 6 months	Never	Unknown
Unpasteurized (raw) camel milk						
Boiled camel milk						
Camel urine						
Raw camel meat						
Cooked camel meat						
Other camel products (specify)						
Loss of smell (anosmia) or taste						

**10. Exposures to the MERS-CoV infected patient** <u>since their admission</u> Note to interviewer: remind the HCW on which day the patient was admitted (see first page of questionnaire)

10a. Participant had close contact with the patient (within 1 metre)	<ul> <li>Yes □ No □ Unknown</li> <li>If NO close contact with the patient themselves, proceed directly to section 10b.</li> </ul>			
How many times (total) have you had close contact?	times □ < 5 minutes			
For approximately (on average) how long did you	5–15 minutes			
have close contact on each occasion?	 □>15 minutes			
Did you have prolonged <u>face-to-face exposure</u> (> 15 minutes)?	☐Yes ☐No ☐Unknown			
If Yes, did you wear PPE?	□Yes □No □Unknown			
If Yes to PPE during face-to-face exposure, what type?	Tick all that apply:			
	☐ Medical or surgical mask, specify type:			
	Respirator (for example, FFP2 or N95 masks or equivalent), specify type:			
	☐ Face shield			
	Gloves			
	☐ Goggles or glasses			
	Gown			
	□ Coverall			
	Head cover			
	☐ Shoe covers			



# Questionnaire 3: Frequency and pattern of exposure of health and care workers (HCW) to a MERS-CoV

# infected patient (continued)

Did you perform hand hygiene <u>before</u> contact with the patient?	☐ Always, as recommended ☐ Most of the time
	Rarely
If Yes, using what:	Alcohol-based hand rub
	Soap and water
	Water
Did you perform hand hygiene <u>after</u> contact with	Always, as recommended
the patient?	☐ Most of the time
	□ Occasionally
	Rarely
If Yes, using what:	Alcohol-based hand rub
	Soap and water
	Water
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 to PPE during aerosolizing procedure,	Tick all that apply:
what type?	Medical or surgical mask, specify type:
	Respirator (for example, FFP2 or N95 masks or
	equivalent), specify type:
	Face shield
	Gloves
	Goggles or glasses
	Gown
	Head cover
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 at the time	Yes No Unknown
in res, were you wearing it is at the time	
If Yes to PPE during contact with body fluids,	Tick all that apply:
what type?	Medical or surgical mask, specify type:
	Respirator (for example, FFP2 or N95 masks or
	equivalent), specify type:
	☐ Face shield
	Gloves
	Goggles or glasses
	Gown
	Coverall
	Head cover
	□ Shoe covers
If you were wearing gloves during close contact, did you remove them after contact with the patient?	☐Yes ☐No ☐Don't remember



10b. Participant had direct contact with the patient's materials	<ul> <li>☐ Yes</li> <li>☐ No</li> <li>☐ Unknown</li> <li>↓ If <u>NO</u> contact with the patient materials, proceed</li> </ul>
Patient's materials: personal belongings, linen and medical equipment that the patient may have had contact with	directly to section 10c.
Which materials did you have direct contact with?	<ul> <li>Tick all that apply:</li> <li>Clothes</li> <li>Personal items</li> <li>Linen</li> <li>Medical devices used on the patient</li> <li>Medical equipment connected to the patient (ventilator, infusion pump etc.)</li> <li>Other:</li> </ul>
How many times have you had contact with patient materials since their admission (total)?	times
Did you come into contact with the patient's body fluids via the patient's materials? If Yes, which body fluids:	☐Yes ☐No ☐Unknown
If Yes, were you wearing PPE at the time	□Yes □No □Unknown
If Yes to PPE during contact with body fluids, what type?	<ul> <li>Tick all that apply:</li> <li>Medical or surgical mask, specify type:</li></ul>
Did you perform hand hygiene <u>before</u> contact with the patient materials	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
If Yes, using what:	<ul> <li>Alcohol-based hand rub</li> <li>Soap and water</li> <li>Water</li> </ul>
Did you perform hand hygiene <u>after</u> contact with the patient materials	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
If Yes, using what:	<ul> <li>☐ Alcohol-based hand rub</li> <li>☐ Soap and water</li> <li>☐ Water</li> </ul>
If you were wearing gloves during contact with patient materials, did you remove them after contact with the patient's materials?	☐Yes ☐No ☐Don't remember



10c. Participant had direct contact with the surfaces	🗌 Yes 🔲 No 📋 Unknown
around the patient	↓ If <u>NO</u> contact with the surfaces around the patient,
	proceed directly to section 11.
Which surfaces have you had contact with?	Tick all that apply:
	Bed
	Bathroom
	☐ Ward corridor
	Patient table
	🗌 Bedside table
	☐ Dining table
	Medical gas panel
	Other:
How many times since the patient's admission have	
you had contact with their surfaces (total)?	times
Did you come into contact with the patient's body fluids	
via the patient surfaces you had contact with?	
If Yes, which body fluids:	
il les, which body hulds.	
If Vec, were you wearing DDE at the time	
If Yes, were you wearing PPE at the time	□Yes □No □Unknown
If Yes to PPE during contact with body fluids,	Tick all that apply:
what type?	Medical or surgical mask, specify type:
	Respirator (for example, FFP2 or N95 masks or
	equivalent), specify type:
	Face shield
	☐ Goggles or glasses
	Gown
	Coverall
	Head cover
	Shoe covers
Did you perform hand hygiene <u>before</u> contact with the	□ Always, as recommended
patient surfaces?	☐ Most of the time
	□ Occasionally
	Rarely
If Yes, using what:	Alcohol-based hand rub
	Soap and water
	│ □ Water
Did you perform hand hygiene <u>after</u> contact with the	Always, as recommended
patient surfaces?	Most of the time
If Yes, using what:	
	Alcohol-based hand rub
	Soap and water
	Water
If you were wearing gloves during contact with patient	☐ Yes ☐ No ☐ Don't remember
surfaces, did you remove them after contact with the	
patient's surfaces?	

### **11a.** Molecular testing methods and results:

Complete a new line for each specimen collected and each type of test conducted:

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
			<ul> <li>□ Nasal swab</li> <li>□ Throat swab</li> <li>□ Nasopharyngeal swab</li> <li>□ Other, specify:</li> </ul>	<ul> <li>Polymerase chain reaction (PCR)</li> <li>Whole genome sequencing</li> <li>Partial genome sequencing</li> <li>Other, specify</li> </ul>	<ul> <li>positive for MERS-CoV</li> <li>negative for MERS-CoV</li> <li>inconclusive</li> <li>positive for other pathogens</li> <li>Please specify which pathogens:</li> <li>Results of phylogenetic analysis:</li> </ul>		<ul> <li>No</li> <li>Yes</li> <li>If Yes, specify date</li> <li>/</li></ul>

# **11b. Serology testing methods and results:**

Complete a new line for each specimen collected and each type of test conducted:

Laboratory identification number	Date sample collected (dd/mm/yyyy)	Date sample received (dd/mm/yyyy)	Type of sample	Type of test	Result (MERS-CoV antibody titres)	Result date (dd/mm/yyyy)	Specimens shipped to other laboratory for confirmation
	/	/	☐ Serum ☐ Other, specify:	Specify type (enzyme linked immunosorbent assay – ELISA, indirect fluorescent antibody assay – IFA, neutralization assay, etc.):	<ul> <li>positive</li> <li>If positive, titre:</li> <li>negative</li> <li>inconclusive</li> </ul>	//	☐ Yes If Yes, specify date / If Yes, name of the laboratory: ☐ No



12. End of questionnaire and status of form completion				
Is participant ok with being contacted again with further questions or clarifications	☐Yes ☐No			
Form completed	Yes No or partially			
	If No or partially, reason: Missed Not attempted Not performed Refusal Other, specify:			



Questionnaire 4: Symptom diary for health and care worker (HCW) contacts of confirmed or probable MERS cases (Day 1 – 21)

Symptom diaries will be provided to each participating HCW, for them to record the presence or absence of various signs or symptoms for 21 days after the date of their <u>last contact</u> with the MERS-CoV infected patient or their materials. Note that this does not necessarily mean 21 days from the time of administration of the initial questionnaire (i.e. questionnaire 3) which may have been conducted a few days after the time of first contact with the MERS-CoV infected patient; in this case, fill out the symptom diary retrospectively going back to time of first contact and then prospectively from the date of start of study participation. Also note that in the case that the HCW has a prolonged contact with the MERS-CoV infected patient for a period of 5 days) then this symptom diary should be filled out for each day of contact as well as for 21 days after last contact (add lines as needed).

In the event the HCW participant develops any of these symptoms, ask them to inform the investigation team and any other relevant public health personnel.

# Implementation tipAs part of study implementation, it is important to allocate time and study funds for<br/>translation and field-testing of the questionnaires and other data collection tools.<br/>Investigators are encouraged to adapt the questionnaires to local contexts to maximize<br/>the relevance of the study's results.

Day			Symptoms*					
	No symptoms (check if none experienced)	Fever ≥38 °C	Cough (dry or productive)	Sore throat	Runny Nose	Shortness of breath	Chest pain	Other symptoms: specify
0	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
1	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
2	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
3	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
4	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
5	□ None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
6	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
7	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
8	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	



# Questionnaire 4: Symptom diary for health and care worker (HCW) contacts of confirmed or probable MERS cases (Day 1 – 21) (continued)

9	No symptoms (check if none experienced)	Fever ≥38 °C	Cough	Sore				
9	None		(dry or productive)	throat	Runny Nose	Shortness of breath	Chest pain	Other symptoms: specify
		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
10	□None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
11	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
12	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
13	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
14	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
15	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
16	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
17	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
18	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
19	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
20	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	
21	None	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	

\* Please select None for No symptoms. If no symptoms are experienced on that day, then consider the entry for that day complete.



This questionnaire is meant to capture types of exposures with the MERS case in the health-care facility as well as PPE use during the time-period from enrolment until the participants last direct or indirect contact with probable or confirmed MERS case.

Implementation tipAs part of study implementation, it is important to allocate time and study funds for<br/>translation and field-testing of the questionnaires and other data collection tools.<br/>Investigators are encouraged to adapt the questionnaires to local contexts to maximize<br/>the relevance of the study's results.

### Unique Participant ID and Cluster number (if applicable):

1. Data collector and interview information				
Name of data collector				
Data collector institution				
Data collector profession				
Data collector telephone number				
Data collector email				
Place of interview (region, city, further details if applicable)				
Interview start date (dd/mm/yyyy)	/			
Form completion date (dd/mm/yyyy)	/			
Language used for interview				

# **2. Exposures to the MERS-CoV infected patient** <u>since HCW enrolment or baseline questionnaire</u> Note to interviewer: remind the HCW on which day they did the first questionnaire

A. Participant had close contact with the patient (within 1 meter)	<ul> <li>Yes □ No □ Unknown</li> <li>↓ If <u>NO</u> close contact with the patient themselves, proceed directly to section B</li> </ul>
How many times (total) have you had close	times
contact?	$\Box$ < 5 minutes
For approximately (on average) how long did you	5–15 minutes
have close contact on each occasion?	□ > 15 minutes
Did you have prolonged <u>face-to-face exposure</u> (> 15 minutes)?	☐Yes ☐No ☐Unknown
If Yes, did you wear PPE?	☐Yes ☐No ☐Unknown
If Yes to PPE during face-to-face exposure, what type?	Tick all that apply:
	🗌 Medical or surgical mask, specify type:
	Respirator (for example, FFP2 or N95 masks or equivalent), specify type:
	☐ Face shield
	 □ Gloves
	☐ Goggles or glasses
	Gown
	Coverall
	Head cover
	Shoe covers

Did you perform hand hygiene <u>before</u> contact with the patient?	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
If Yes, using what:	<ul> <li>Alcohol-based hand rub</li> <li>Soap and water</li> <li>Water</li> </ul>
Did you perform hand hygiene <u>after</u> contact with the patient?	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
If Yes, using what:	<ul> <li>Alcohol-based hand rub</li> <li>Soap and water</li> <li>Water</li> </ul>
Were you present for any aerosolizing procedures performed on the patient? If Yes, describe the procedure:	☐Yes ☐No ☐Unknown
If Yes, did you wear PPE	□Yes □No □Unknown
If Yes to PPE during aerosolizing procedure, what type?	Tick all that apply: Medical or surgical mask, specify type: Respirator (for example, FFP2 or N95 masks or equivalent), specify type: Face shield Gloves Goggles or glasses Gown Coverall Head cover Shoe covers
Did you come into contact with the patient's body fluids? If Yes, which body fluids:	☐Yes ☐No ☐Unknown
If Yes, were you wearing PPE at the time	□Yes □No □Unknown
If Yes to PPE during contact with body fluids, what type?	Tick all that apply: Medical or surgical mask, specify type: Respirator (for example, FFP2 or N95 masks or equivalent), specify type: Face shield Gloves Goggles or glasses Gown Coverall Head cover Shoe covers
If you were wearing gloves during close contact, did you remove them after contact with the patient?	☐Yes ☐No ☐Don't remember

B. Have you had direct contact with the patient's materials?	<ul> <li>☐ Yes</li> <li>☐ No</li> <li>☐ Unknown</li> <li>↓ If <u>NO</u> contact with the patient materials, proceed</li> </ul>
Patient's materials: personal belongings, linen and medical equipment that the patient may have had contact with	directly to section C.
Which materials did you have direct contact with?	<ul> <li>Tick all that apply:</li> <li>Clothes</li> <li>Personal items</li> <li>Linen</li> <li>Medical devices used on the patient</li> <li>Medical equipment connected to the patient (ventilator, infusion pump etc.)</li> <li>Other:</li> </ul>
How many times have you had contact with patient materials since their admission (total)?	times
Did you come into contact with the patient's body fluids via the patient's materials? If Yes, which body fluids:	☐Yes ☐No ☐Unknown
If Yes, were you wearing PPE at the time	□Yes □No □Unknown
If Yes to PPE during contact with body fluids, what type?	Tick all that apply: Medical or surgical mask, specify type: Respirator (for example, FFP2 or N95 masks or equivalent), specify type: Face shield Gloves Goggles or glasses Gown Coverall Head cover Shoe covers
Did you perform hand hygiene <u>before</u> contact with the patient materials	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
If Yes, using what:	<ul> <li>Alcohol-based hand rub</li> <li>Soap and water</li> <li>Water</li> </ul>
Did you perform hand hygiene <u>after</u> contact with the patient materials	<ul> <li>Always, as recommended</li> <li>Most of the time</li> <li>Occasionally</li> <li>Rarely</li> </ul>
If Yes, using what:	<ul> <li>☐ Alcohol-based hand rub</li> <li>☐ Soap and water</li> <li>☐ Water</li> </ul>
If you were wearing gloves during contact with patient materials, did you remove them after contact with the patient's materials?	☐Yes ☐No ☐Don't remember



C. Have you had direct contact with the surfaces around the patient?	<ul> <li>Yes □ No □ Unknown</li> <li>If <u>NO</u> contact with the surfaces around the patient, end of questionnaire.</li> </ul>
Which surfaces have you had contact with?	Tick all that apply:
when surfaces have you had contact with.	Bed
	Bathroom
	Ward corridor
	Patient table
	Bedside table
	Dining table
	Medical gas panel
	☐ Other:
How many times since the patient's admission have you had contact with their surfaces (total)?	times
Did you come into contact with the patient's body fluids via the patient surfaces you had contact with?	☐Yes ☐No ☐Unknown
If Yes, which body fluids:	
If Yes, were you wearing PPE at the time	□Yes □No □Unknown
If Yes to PPE during contact with body fluids,	Tick all that apply:
what type?	Medical or surgical mask, specify type:
	Respirator (for example, FFP2 or N95 masks or equivalent), specify type:
	☐ Face shield
	Gloves
	Goggles or glasses
	Gown
	Head cover
	Shoe covers
Did you perform hand hygiene <u>before</u> contact with the	
patient surfaces?	Always, as recommended Most of the time
patient surfaces:	
	-
	Rarely
If Voc using what	
If Yes, using what:	Alcohol-based hand rub
	Soap and water
	Water
Did you perform hand hygiene <u>after</u> contact with the	Always, as recommended
patient surfaces?	☐ Most of the time
	□ Occasionally
	Rarely
If Yes, using what:	Alcohol-based hand rub
·	Soap and water
	Water
If you were wearing gloves during contact with nations	
If you were wearing gloves during contact with patient surfaces, did you remove them after contact with the patient's surfaces?	Yes No Don't remember

3. End of questionnaire and status of form completion	
Is participant ok with being contacted again with further questions or clarifications	☐Yes ☐No
Form completed	Yes No or partially
	If No or partially, reason:
	Missed
	□ Not attempted
	□ Not performed
	Refusal
	☐ Other, specify:

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