Public Health England

“The First Few Hundred (FF100)” Enhanced Case and Contact Protocol v6.2

Epidemiological Protocols for Comprehensive Assessment of Early Middle East Respiratory Syndrome Coronavirus Cases and their close contacts in the United Kingdom

Executive summary

The epidemiological and virological investigation of the first cases of acute respiratory infection associated with Middle East respiratory coronavirus (MERS-CoV) and their close contacts is essential in order to inform guidance and policy in directing the United Kingdom's (UK) public health response.

The epidemiological methods to guide data collection for the comprehensive assessment of the "first few hundred cases and their close contacts" are set out in this document. The protocol outlines the investigation of persons with laboratory confirmed MERS-CoV infection, along with their close contacts.

1.0 Overview of FF100 approach

1.1 Introduction and overview

With the confirmation of the first case of MERS-CoV in the UK on 22 September 2012, the epidemiological and virological investigation of the initial cases and their close contacts is essential to provide information to enable the development of guidance and policy in directing the United Kingdom's (UK) public health response.

A flexible and multifaceted approach is required to collect key epidemiological, clinical and virological data on cases.

1.2 Protocol objectives

The overall aim of the FF100 is to gain an early understanding of some of the key clinical, epidemiological, and virological characteristics of the first suspect and confirmed cases to inform the development and updating of national policy and guidance to manage cases and reduce the spread and impact of infection in the UK.

The primary objectives are to provide estimates of:

- Clinical presentation and course of disease
- Secondary attack rate (overall and by key factors such as by setting, age and gender for various end-points)[1]
- Serial interval[2]
- Symptomatic proportion of cases

The secondary objectives are to provide data to support the estimation of:

- The basic reproductive number (R_0)[3].
- Incubation period[4]
- Preliminary case-severity ratios (e.g. case-hospitalisation and case-fatality ratios)[5]

[1] Attack rate is defined as the proportion of a well-defined population that develops illness over a particular period of time. The secondary attack rate is a measure of the frequency of new cases of an illness among the contacts of known cases in a defined period of time.
[2] Serial interval is defined as the period of time from the onset of symptoms in the index case to the onset of symptoms in a contact case.
[3] The reproduction number, R_0, is defined as the average number of secondary cases of an infectious disease that result from one infected person in a wholly susceptible population.
[4] Incubation period is defined as the period of time between an exposure resulting in infection until the onset of clinical symptoms of disease.
[5] Case hospitalisation ratio (CHR) is defined as the proportion of those affected (with symptoms) that are admitted to hospital. The case fatality ratio (CFR) is defined as the proportion of those affected who die as a direct or indirect consequence of their infection.

This information will be used to refine/update recommendations for surveillance (e.g. case definitions), to characterise the key epidemiological transmission features of the corona virus, help understand geographic spread, severity and impact on the community and inform operational models for implementation of countermeasures such as case isolation and contact tracing.

1.5 Coordination of investigations and review of data

Coordination of investigations and sharing of information in real time will be needed at both country and UK levels. Epidemiologists, modellers, virologists, statisticians, clinicians and public health experts will assess progress in developing early estimates of key epidemiological, clinical and virological parameters.

The responsibility of the FF100 investigations will lie with local Health Protection Teams and the equivalents in the Devolved Administrations. Co-ordination of the system will be undertaken by PHE.

The FF100 system will be maintained centrally by the PHE. Centralised coordination at the UK-level will require development of a "command and control" plan to allow for triage and prioritisation of investigations.

1.6 Country-specific adaptation of the protocols

It is envisioned that all countries of the UK will use FF100 protocols to guide their investigations of laboratory confirmed case(s). A common UK approach will facilitate aggregation of data across countries of the UK. However, it is recognised that the devolved UK administrations may need to tailor some aspects of the protocols to their individual public health, laboratory and clinical care systems.

2. Methods

2.1 Case and contact definitions

The following case definitions are proposed:

PATIENT UNDER INVESTIGATION:

- Any person with severe acute respiratory infection requiring admission to hospital;
  - With symptoms of fever (≥38º) or history of fever, and cough

    AND
  - With evidence of pulmonary parenchymal disease (e.g. clinical or radiological evidence of pneumonia or Acute Respiratory Distress Syndrome (ARDS))

AND

- Not already explained by any other infection or aetiology[6]

AND AT LEAST ONE OF

- History of travel to, or residence in an area where infection with MERS-CoV could have been acquired[7] in the 14 days before symptom onset

OR

- Close contact[8] during the **fourteen days** before onset of illness with a confirmed case of MERS-CoV while the case was symptomatic

OR

- Healthcare worker based in ICU caring for patients with severe acute respiratory infection, regardless of history of travel or use of PPE

OR

- Part of a cluster of two or more epidemiologically linked cases within a two week period requiring ICU admission, regardless of history of travel

Case classification:

A. Possible case
Any person meeting the criteria for a 'Patient under investigation'

B. Presumptive positive case
Any person with PHE MERS-CoV Testing Laboratory positive confirmation of infection with MERS-CoV

B. Confirmed case

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[6] If the patient has an alternative aetiology, but this does not fully explain the presentation and/or clinical course, then the patient should be considered a possible case and tested for MERS-CoV

[7] As of 01/11/2013: Bahrain, Iraq, Israel, Jordan, Kingdom of Saudi Arabia, Kuwait, Lebanon, Occupied Palestinian territories, Oman, Qatar, Syria, UAE and Yemen – see map

[8] Close contact is defined as: - prolonged face-to-face contact (>15 minutes) with a symptomatic confirmed case in a household or other closed setting OR – healthcare or social worker who provided direct clinical or personal care or examination of a symptomatic confirmed case, or within close vicinity of an aerosol generating procedure AND who was not wearing full PPE (correctly fitted high filtration respirator (FFP3), gown, gloves and eye protection) at the time

Any person with PHE National Reference Laboratory (RVU) positive confirmation of infection with MERS-CoV

C. Discarded case
Any possible case with a negative MERS-CoV laboratory result

Contact classification:

Close contact definitions:

From date of illness onset in index case (the first laboratory confirmed case) and throughout their symptomatic period.

Health and social care workers: worker who provided direct clinical or personal care or examination of a symptomatic confirmed case of MERS-CoV, or was within close vicinity of an aerosol generating procedure AND who was not wearing full personal protective equipment (PPE) at the time. Full PPE is defined as correctly fitted high filtration mask (FFP3), gown, gloves and eye protection.

Household or close contact: any person who has had prolonged face-to-face contact (>15 minutes) with a symptomatic confirmed case of MERS-CoV in a household or other closed setting.

Other classifications:

A. Primary case: A primary case is defined as an individual who tests positive for MERS-CoV by the PHE reference laboratory and has the earliest onset date in a particular setting e.g. hospital, household, school etc. Those cases with onset dates within 24 hours of the onset date of the index case are considered to be “co-primary” cases.

B. Secondary case: After excluding the primary / co-primary cases, a secondary case is defined as the contact whose onset date is 24 hours or more after the latest onset date of the primary and/or co-primary case-contact and confirmed positive for MERS-CoV.

C. Sporadic case: A sporadic case is defined as a case confirmed positive for MERS-CoV with no recent travel (in the 14 days before disease onset) from a known affected area and no recent (in 14 days before disease onset) close contact with a confirmed case.

D: Imported case: An imported case is defined as a case confirmed positive for MERS-CoV with a history of travel from an affected area as defined below in the 14 days before disease onset.

E. Affected area: An affected area is a country/region having had recent confirmed MERS-CoV which is not import related

2.2 Possible case investigation

The investigation of possible cases is detailed in the Case Management Algorithm.

The clinician/Microbiologist should notify the local PHE Health Protection team and local PHE Laboratory and ensure that full PPE is worn by clinical staff caring for the patient. Infection control advice can be found here. Appropriate samples should be collected and sent to both the designated PHE MERS-CoV testing laboratory and local PHE Laboratory - lab guidance can be found here. Please see algorithm and other related documents for infection control advice and further instructions about collection of samples.

In the event of detection of a possible case, PHE Health Protection team staff will inform CIDSC Colindale by email (respiratory.lead@phe.gov.uk or contact the duty doctor if out of hours) and enter case details on HPZone (Infection and specific context MERS-CoV). PHE Health Protection teams will begin to collect core information on notified possible cases using the **Minimum Data Set Form 1** (Section 3). This should then be emailed to CIDSC Colindale. PHE Health Protection team staff will, if a cluster is suspected, establish if there is an epidemiological link between cases.

2.3 Recruitment and follow-up of confirmed cases and their close contacts

For instructions regarding the management and sampling of cases please refer to case algorithm and laboratory documents.

FF100 case-contact investigation would begin upon receipt of MERS-CoV presumptive confirmatory test results from the PHE MERS-CoV Testing Lab by the PHE Health Protection team. On notification that the PHE MERS-CoV Testing Lab result is positive for MERS-CoV then CIDSC Colindale should be informed.

Confirmed cases identified as part of individual-case investigations will serve as the “starting point” for contact investigations. A list of close contacts should be identified and collated using the contact line list by the PHE Health Protection team (Page 14) and emailed to CIDSC Colindale pending results of confirmatory testing by the PHE National Reference Laboratory. Efforts should be made to identify every close contact at the initial recruitment including infants and children to generate the sampling frame for follow up. This line list should be reviewed on a daily basis and sent to CIDSC Colindale daily.

Cases should be interviewed as rapidly as possible after confirmation by PHE National Reference Laboratory **(Form 1a)** and then 14-21 days **(Form 1b)** after completion of Form1a. Information on the primary case and their close contacts at the initial recruitment should be sought through combination of face-to-face or telephone interview of the case (or family members if the case is too ill to be interviewed), household members, interview of health care providers and/or review of medical records where required.

Baseline samples should be collected on confirmed cases as soon after confirmation as possible and full PPE should be worn. For details regarding the type and transport of these samples please refer to the case algorithm and PHE lab guidance and infection control advice. Follow up samples from cases should be taken after discussion with the CIDSC Colindale incident control team, and sent to PHE National Reference Laboratory– please see lab guidance here.

Active follow-up of contacts should take place ideally through face-to-face or telephone interview ideally as soon as possible after identification of a confirmed case to query about

the possible development of respiratory illness using **Form 2a.** A baseline clotted blood sample should be taken as soon as possible and ideally within 7 days of last exposure and sent to PHE National Reference Laboratory. For more detailed information please refer to the Close Contact Algorithm and laboratory guidance.

If the contact is ill with acute respiratory symptoms (fever or cough) that developed within 14 days of exposure with confirmed case they should be treated as a symptomatic contact. Please refer to Close Contact Algorithm for further details about how to deal with symptomatic contacts and the respiratory and serological samples required. NB If there is no possibility of laboratory confirmation because the patient or samples are not available and the symptoms are not explained by any other infection or aetiology, the symptomatic contact becomes a probable case (see WHO interim recommendations for further details). Infection control guidance should be followed in handling the contact.

If contact is not ill with acute respiratory symptoms that developed within 14 days of exposure with confirmed case then complete **Form 2b** 14 days since last exposure. The final follow-up should involve collection of convalescent sera at least 21 days after baseline sample collected. If more than 28 days have passed since last exposure, only a single serological sample is required. Note serological samples are not required from children under five years of age. Samples should be sent to PHE National Reference Laboratory. Please refer to Close Contact Algorithm and laboratory guidance including on transportation.

Contacts found to be infected with MERS-CoV as determined by PHE National Reference Laboratory testing would be re-classified as confirmed cases and case follow-up forms would be completed (Form 1a and 1b) and the Case Management algorithm should be followed.

2.4 Data collection on cases and household contacts

2.4.1 Data collection on cases

Further guidance on the completion of FF100 forms can be found in Appendix A, including additional sources of data to be used for verification. Questionnaires can be found in Section 3 of this document. The following questionnaires are used:

Minimum Data Set Form 1 (Section 3) should be completed for all possible cases on identification and emailed to CIDSC Colindale.

Contact line list (Section 3) should be collated and emailed to CIDSC Colindale (respiratory.lead@phe.gov.uk) when the designated PHE MERS-CoV testing laboratory test for a MERS-CoV possible case is positive. This line list should be updated daily and updates sent to CIDSC Colindale.

The Initial Confirmed Case Report Form 1a (Section 3) should be completed as soon as possible after PHE National Reference Laboratory confirmation of a case and includes the following information: identifiers, basic demographic information, presenting illness, antiviral use, hospitalisation details (including ICU admission, secondary infections, complications and outcome), pre-existing medical conditions, exposure history and details of household and other close contacts.

The **Case Follow-up Form 1b** (Section 3) should then be completed 14-21 days since Form 1a was completed. The form will gather information including identifiers; hospitalisation details; illness characteristics; death details; treatment with antivirals and antibiotics; clinical course and complications including details of secondary bacterial complications.

2.4.2 Data collection on close contacts

The key activities for the initial investigation of close contacts are:

- Verification of close contacts of the index case patient and completion of contact line-listing.

- Determination if each contact is ill, including dates of onset. If confirmed and onset is prior to the index case will require reclassifying the primary case. Any contact with acute respiratory symptoms (fever and cough) within 14 days of last exposure with the case should be treated as a symptomatic contact. Please refer to the Close Contact algorithm.

- Collection of baseline information from close contacts **(Initial Contact Report Form 2a** (Section 3)**)** of a confirmed case including information about exposures to the confirmed case, illness and treatment (if applicable), and medical history. Collection of baseline clotted blood samples should be arranged. Ideally this should occur on the day of first interview of confirmed case where possible, or as soon after as possible.

- Contacts should be informed to report any respiratory illness to their local PHE Health Protection team following completion of Form 2a. Please refer to algorithm about how to deal with symptomatic contacts.

- **The Contact Follow Up Form 2b** (Section 3) should be completed 14 days since last exposure with confirmed case. The Contact Follow-up Form includes information about exposures to the primary case, and recent respiratory illness.

- Contacts found to be infected with MERS-CoV as determined by PHE National Reference Laboratory testing would be re-classified as confirmed cases and follow-up would occur as described in the case investigation algorithm.

2.5 Role of laboratory testing

A real time PCR test is currently available in a designated PHE MERS-CoV testing laboratory and the three Devolved Administrations where UpE Assay testing takes place. Where the virus is detected by UpE screening, the PHE testing laboratory will send residual material urgently to the PHE National Reference Laboratory for confirmatory testing. Results will be reported to the source Trust/GP by telephone and hard copy report, to the local PHE Health Protection team and to CIDSC Colindale through the Respiratory Datamart system.

Blood samples (and/or other self-collected samples should tests be available) should be taken on all FF100 confirmed cases. Acute sera sample should be taken as soon as possible and ideally no later than 7 days after symptom onset. A follow up blood sample should be taken at least 21 days after the baseline sample, or 28 days after illness onset if a sample couldn't be taken when the case was symptomatic. Details on sampling and transportation are available here.

It is also necessary to obtain paired serological samples from close contacts in order to determine the secondary infection-attack rate and the proportion of infections that are asymptomatic. Acute and follow-up serology samples will be taken on close contacts regardless of symptoms. The baseline clotted blood sample should be taken as soon as possible and ideally no later than 7 days after last exposure. A follow up blood sample should be taken at least 21 days after the baseline sample, or 28 days after last exposure if a sample couldn't be taken when case was symptomatic. For more information please refer to the algorithms for how samples should be taken and transported. All blood samples (both acute and convalescent) are expected to be sent to the PHE National Reference Laboratory.

2.6 Analyses and interpretation of data

A descriptive analysis of the FF100 should provide preliminary insight into the clinical spectrum and course of disease; the population groups most affected initially, by age, and underlying risk factors for example. It may also be possible to assess the effect of antiviral treatment on severity measures such as duration of illness.

3.0 Questionnaires

Unique Case Number	

1. Current Status

Please mark: Alive ☐ Dead ☐

2. Reporter Details

Reporter		**Date Reported**	/ /
Organisation		**Phone and extension**	
Mobile		**Email**	
Date of interview with informant	/ /		

3. Patient Details

Forename		**Surname**	
Sex	Male / Female / Not Known	**Date of Birth**	/ /
Local ID Number (HPZone number)		**Age**	
Post Code			

4. Presenting Illness

Date of first symptom onset	/ / Unknown	**History of Fever**	No / Yes / Unknown	**Cough**	No / Yes / Unknown

Suspicion of pulmonary parenchymal disease (e.g. pneumonia or Acute Respiratory Distress Syndrome (ARDS)) based on clinical evidence of consolidation	No / Yes / Unknown

Respiratory viral screen:	No / Yes / Unknown

If yes, results of respiratory viral screen:

Influenza A	Positive / Negative	**Influenza B**	Positive / Negative	**Other (please specify)**	

5. Clinical Course/Complications

Hospitalisation	No / Yes / Unknown	**Mechanical ventilation**	No / Yes / Unknown	**ARDS[9]**	No / Yes / Unknown
Name of hospital					
Chest xray with radiological evidence of consolidation	No / Yes / Unknown	**ECMO[10]**	No / Yes / Unknown		

6. Exposures in the 14 days before onset of first symptoms

History of travel in the 14 days before onset of symptoms	No / Yes / Unknown	**If yes, please state country**		**Date of arrival in UK**	/ /

Contact with confirmed case in past 14 days before onset of symptoms?	No / Yes / Unknown				
Health care worker caring for patients with severe acute respiratory infections in ICU	No / Yes / Unknown				
Part of a cluster	No / Yes / Unknown	**If yes, setting of cluster**	/ /	**Number of symptomatic cases in cluster**	/ /

[9] Acute Respiratory Distress Syndrome (ARDS)
[10] Extracorporeal membrane oxygenation (ECMO)

Contact Line List

Please copy and transpose the following fields into an Excel spreadsheet and use to populate the Contact Line List

caseID (if no ID assigned by CFI, name and DOB of index case)
ContactID (C…)*
firstNames
surname
Sex (M/F)
DOB (dd/mm/yyyy)
Telephone number
typeContact (HCW/relative or friend/other)
placeContact (hospital name/household/other setting)
respiratorySymptoms - cough AND fever (Y/N)
symptomsOnset (dd/mm/yyyy)
dateFirstContact (dd/mm/yyyy)
dateLastContact (dd/mm/yyyy)
form2a completed - initial questionnaire (Y/N)
form2b completed - follow-upQuestionnaire (Y/N)
baselineSerumCollected (Y/N)
follow-upSerumCollected - day14-21 (Y/N)
baselineSwabsTaken (Y/N)
OBS (any relevant remarks)

***Please number the contacts sequentially e.g. C001, C002, C003 etc.**

Initial Confirmed Case Report Form – 1a

Information in Sections 1-13 may already have been completed in the Minimum Data Set Form. It is not necessary to repeat any data in these sections that has already been completed. Please add any missing data and then go to Section 14.

Unique Case Number	

1. Current Status

Please mark: Alive ☐ Dead ☐

2. Further Case Classification

Please mark: Imported ☐ Secondary ☐ Sporadic ☐

3. Reporter Details

Reporter		**Date Reported**	/ /
Reporter code		**Position**	
Organisation		**Phone and extension**	
Mobile		**Email**	
Fax		**Date of interview with informant**	/ /

4. Informant Details

Informant	Case / other	**Relationship with case**	
If other:		**Contact details including telephone number**	

5. Patient Details

NHS number		National ID number	
Forename		**Surname**	
Sex	Male / Female / Not Known	**Date of Birth**	/ /
Local ID number (HPZone number)		**Age**	

Street Address		**Home Telephone**	
Town		**Work Telephone**	
County		**Mobile**	
Post Code		**Email address**	
Country of Residence		**Preferred mode of contact**	
Nationality		**Responsible PHE Centre**	
Country of birth			
Primary Care Trust		**School if appropriate**	
Is the case part of an institutional outbreak?	Yes/No/Unknown		
If yes, please specify:			
Occupation	HCW: Y/N Other (please specify):	**If HCW: Direct patient contact (e.g. Hands-on clinical contact)**	N / Y
If HCW: Job title		**If HCW: Place of work**	

6. GP Details

Name of GP		**Practice Name**	
Telephone		**Fax**	
Post Code			

7. Presenting Illness

Date of first symptom onset	/ / Unknown	**Time of onset**	AM / PM Unknown	**Maximum Temperature**	

Respiratory symptoms:

History of Fever	No / Yes / Unknown	**Runny nose**	No / Yes / Unknown	**Sneezing**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
Cough	No / Yes / Unknown	**Sore Throat**	No / Yes / Unknown	**Shortness of Breath**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
If Yes, dry or productive	Dry/Productive				

Other symptoms:

Muscle ache	No / Yes / Unknown	**Joint ache**	No / Yes / Unknown		
Diarrhoea	No / Yes / Unknown	**Nausea**	No / Yes / Unknown	**Vomiting**	No / Yes / Unknown
Fatigue	No / Yes / Unknown	**Loss of appetite**	No / Yes / Unknown	**Headache**	No / Yes / Unknown
Seizures	No / Yes / Unknown	**Altered Consciousness**	No / Yes / Unknown	**Nose bleed**	No / Yes / Unknown
Rash	No / Yes / Unknown	**Other**	No / Yes, please specify		

8. Clinical Course/Complications

Mechanical ventilation	No / Yes / Unknown	**ICU Admission**	No / Yes / Unknown	**ARDS**[11]	No / Yes / Unknown

[11] Acute Respiratory Distress Syndrome (ARDS)

Date of mechanical ventilation	/ / Unknown	**Date of ICU Admission**	/ / Unknown	**Date of ARDS**	/ / Unknown
Length of ventilation (days)		**Date of discharge from ICU**	/ / Unknown		

Cardiac arrest	No / Yes / Unknown	**Hypotension requiring vasopressors**	No / Yes / Unknown	**Chest Xray with pneumonia**	No / Yes / Unknown	**ECMO**[12]	No / Yes / Unknown
Renal failure	No / Yes / Unknown	**Other**				Date ECMO started:	/ / Unknown
Pregnancy		**Pregnancy outcome**				Length of ECMO (days)	

9. Exposures in the 14 days before onset of first symptoms

In the 14 days before illness onset did the case travel WITHIN the UK	Yes / No / Unknown

Date from	Date to	Location (town)
/ /	/ /	
/ /	/ /	
/ /	/ /	
/ /	/ /	
/ /	/ /	

In the 14 days before illness onset did the case spend time OUTSIDE of the UK	Yes / No / Unknown

Departure Date	Return Date	City, Country	WHO defined affected area
/ /	/ /		No / Yes / Unknown
/ /	/ /		No / Yes / Unknown
/ /	/ /		No / Yes / Unknown
/ /	/ /		No / Yes / Unknown
/ /	/ /		No / Yes / Unknown

Date arrived in UK (include details for multiple trips within last 14 days if applicable)	/ /

[12] Extracorporeal membrane oxygenation (ECMO)

Airport of arrival & flight number (include details for multiple trips within last 14 days if applicable)	
Port or train station of arrival if mode of transport different to plane (include details for multiple trips within last 14 days if applicable)	

In the 14 days before onset did the case have close contact with a confirmed or probable case while the case was symptomatic	No / Yes / Unknown

Details of case contact (if known):

Forename		**Surname**	
Age		**Date of contact with case**	
		Setting of contact	**Household / School / Plane / HC Setting / Other**

In the 14 days before onset did the case have close contact with any of the following:

Cats	Yes / No / Unknown	**Camels**	Yes / No / Unknown
Dogs	Yes / No / Unknown	**Sheep**	Yes / No / Unknown
Bats	Yes / No / Unknown		
Civets	Yes / No / Unknown		
Other animals	Yes / No / Unknown	**If yes, what animal?**	

10. Medical History

Does the case have any underlying medical conditions? Complete where appropriate.

Condition	No / Yes / Unknown	Details	
Chronic heart disease	No / Yes / Unknown		
Diabetes	No / Yes / Unknown		
HIV/other immunodeficiency	No / Yes / Unknown		
Chronic kidney disease	No / Yes / Unknown		
Chronic liver disease	No / Yes / Unknown		
Chronic respiratory disease, excluding asthma requiring medication	No / Yes / Unknown		
Asthma requiring medication	No / Yes / Unknown		
Malignancy	No / Yes / Unknown		
Organ or bone marrow recipient	No / Yes / Unknown		
Chronic neurological disease	No / Yes / Unknown		
Approximate height (cm): Approximate weight (kg):			
Pregnant	No / Yes / Unknown	If yes, trimester: Estimated delivery date:	first /second third / /
Height in cm: Weight in kg:			
Other:			

Case vaccinated with pneumococcal vaccine	No / Yes / Unknown	**Date / /**

11. Treatment with antivirals

Did the case receive antivirals in the last 14 days?

Ribavarin	No / Yes / Unknown	**Date started:**	/ /	Unknown
Other	No / Yes / Unknown	**Date started:**	/ /	Unknown

Were antivirals prescribed for ☐ **Treatment**

12. Healthcare Interactions

Has the case had interaction with any of the following healthcare settings during current illness?

Contact with NHS Direct	No / Yes / Unknown	**Date of NHS Direct contact:**	/ /
Visit to GP	No / Yes / Unknown	**Date of first GP contact:**	/ /
		Date of second GP contact:	/ /
		Date of third GP contact:	/ /
Visited A&E	No / Yes / Unknown	**Date of first A&E contact:**	/ /
		Date of second A&E contact:	
		Date of third A&E contact:	
Admitted to hospital	No / Yes / Unknown	**Date of first hospitalisation:**	/ /
Name of first hospital		**Postcode of first hospital**	
Second admission to hospital	No / Yes / Unknown	**Date of second hospitalisation:**	/ /
Name of second hospital		**Postcode of second hospital**	
Third admission to hospital	No / Yes / Unknown	**Date of third hospitalisation:**	/ /
Name of third hospital		**Postcode of third hospital**	

13. Test Results

Virological Tests

Specimen Date	Laboratory Test Date	Specimen Type BAL / Blood-Plasma / Blood-Serum / Faeces / Nose/Throat swab / NPA / Sputum / Tissue/ Oral fluid / Finger prick	Lab Name Belfast / Birmingham / Bristol / Cambridge / Cardiff / / Glasgow / Leeds / Leicester / Liverpool / London-Barts / London-Colindale/ London-Kings / London-St Thomas's / London-UCLH / Manchester / Newcastle / Nottingham / Porton / Southampton / Other (please specify)	Local Lab Number	Virus	Type of Test Molecular (RT-PCR, sequencing, pyrosequencing)/ Culture (antigenic typing, phenotypic antiviral susceptibility testing)/Serological (HA/MN)	Result
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive

14. Serology

Has baseline serology been taken on case?	Y/N/Not sure
If yes, date serology taken?	/ /
Laboratory Name	
Date serology sent to PHE MS	/ /

CASE FOLLOW-UP FORM 1b – FINAL OUTCOME - Day 14-21

(after completion of Form 1a)

Unique Case Number	

1. Reporter Details

Reporter		**Date Reported**	/ /
Reporter code		**Position**	
Organisation		**Phone and extension**	
Mobile		**Email**	
Fax		**Date of interview with informant**	/ /

2. Informant Details (if different from initial interview)

Informant	Case / other	**If other:**	**relationship with case**	
			contact details including telephone number	

3. Outcome/Status at 21 days post symptom onset (if other specify)

Status (please mark one of the following):

Recovered		**Still ill**		**Dead**	
If yes, date symptoms resolved (able to resume normal activities)	/ /			**If yes, date of death**	/ /

Was the case ever hospitalised?	Yes/No/Don't know
If yes, is the patient still hospitalised?	Yes/No/Don't know
Date of admission to hospital and date of discharge if appropriate:	/ / / /

If Dead (NB. If this information is not currently available, please leave blank and send through an update as soon as results are known):

Contribution of MERS-CoV to death:	**Underlying/primary** | **Contributing/secondary** | **No contribution to death** | **Unknown**
Was a post mortem performed:	Yes/No/Don't know
Cause of death as MCCD (Medical Certificate of the cause of death):	
Result of coroner's report where applicable:	

4. Symptoms

Symptoms ever during the course of the illness:

Maximum Temperature	

Respiratory symptoms:

History of Fever	No / Yes / Unknown	**Runny nose**	No / Yes / Unknown	**Sneezing**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
Cough	No / Yes / Unknown	**Sore Throat**	No / Yes / Unknown	**Shortness of Breath**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
If Yes, dry or productive	Dry/Productive				

Other symptoms

Muscle ache	No / Yes / Unknown	**Joint ache**	No / Yes / Unknown		
Diarrhoea	No / Yes / Unknown	**Nausea**	No / Yes / Unknown	**Vomiting**	No / Yes / Unknown
Fatigue	No / Yes / Unknown	**Loss of appetite**	No / Yes / Unknown	**Headache**	No / Yes / Unknown
Seizures	No / Yes / Unknown	**Altered Consciousness**	No / Yes / Unknown	**Nose bleed**	No / Yes / Unknown
Rash	No / Yes / Unknown	**Other**	No / Yes, please specify		

5. Clinical Course/Complications

Mechanical ventilation	No / Yes / Unknown	**ICU Admission**	No / Yes / Unknown	**ARDS**[13]	No / Yes / Unknown
Date of	/ /	**Date of ICU**	/ /	**Date of**	/ /

[13] Acute Respiratory Distress Syndrome (ARDS)

mechanical ventilation	Unknown	**Admission**	Unknown	**ARDS**	Unknown
Length of ventilation (days)		**Date of discharge from ICU**	/ / Unknown		

Cardiac arrest	No / Yes / Unknown	**Hypotension requiring vasopressors**	No / Yes / Unknown	**Chest Xray with pneumonia**	No / Yes / Unknown	**ECMO[14]**	No / Yes / Unknown
Date of cardiac arrest	/ / Unknown	**Date of use of vasopressors**	/ / Unknown	**Date of chest xray with pneumonia**	/ / Unknown	Date ECMO started:	/ / Unknown
Renal failure	/ / Unknown	**Other**				Length of ECMO (days)	
Pregnancy	Y/N/ Not applicable	**Pregnancy outcome**					

6. Secondary Bacterial Infections

Date of sample	Site **Sputum / Endotracheal aspirate / Pleural fluid / CSF / Blood / Urine / Other**	Positive Results Haemophilus influenza / MRSA / Staphylococcus aureus / Streptococcus pneumoniae / E. coli / Other organism (please specify)
/ /		
/ /		
/ /		
/ /		
/ /		
/ /		

7. Treatment with Antivirals

Patient received antivirals for treatment, please mark as appropriate

Ribavarin	Yes / No	**Date started/ended:**	/ / Unknown	/ / Unknown
Other	Yes / No / Unknown	**Date started/ended:**	/ / Unknown	/ / Unknown

[14] Extracorporeal membrane oxygenation (ECMO)

8. Reference Test Results

Additional Virological Tests

Specimen Date	Laboratory Test Date	Specimen Type BAL / Blood-Plasma / Blood-Serum / Faeces / Nose/Throat swab / NPA / Sputum / Tissue / Finger prick / Oral fluid	Lab Name Belfast / Birmingham / Bristol / Cambridge / Cardiff / / Glasgow / Leeds / Leicester / Liverpool / London-Barts / London-Cfl / London-Kings / London-St Thomas's / London-UCLH / Manchester / Newcastle / Nottingham / Porton / Southampton / Other (please specify)	Local Lab Number	Virus	Type of Test Molecular (RT-PCR, sequencing, pyrosequencing)/ Culture (antigenic typing, phenotypic antiviral susceptibility testing)/ Serological (HA/MN)	Result
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive

9. Serology

Has convalescent serology been taken on case?	Y/N/Not sure
If yes, date serology taken?	/ /
Laboratory Name	
Date serology sent to PHE MS	/ /

INITIAL CONTACT REPORT – 2a

Confirmed Case number	NA…..	Contact ID No.[15]	C…….	Name of confirmed case	

1. Reporter Details

Reporter		**Date Reported**	/ /
Reporter code		**Position**	
Organisation		**Phone and extension**	
Mobile		**Email**	
Fax		**Date of interview with contact**	/ /

2. Informant Details

Informant	Contact / other	**If other:**	**relationship with contact**
			contact details including telephone number

3. Contact Details

Forename		**Surname**	
Sex	Male / Female / Not Known	**Date of Birth**	/ /
Street Address		**Home Telephone**	
Town		**Work Telephone**	
County		**Mobile**	
Post Code		**Email address**	
Country of Residence		**Preferred mode of contact**	

[15] Contact ID numbers should have been issued at time of completion of the Minimum Data Set Form or Form 1a.

Nationality		**NHS No**	
Occupation	HCW: Y/N Other (Please specify):	**If HCW please complete Section 4, otherwise skip to Section 5**	

4. Exposure Information for Healthcare Workers

Last unprotected contact with confirmed case without full protection (if still in contact please put today's date):

Last date / /

Job title	
Place of work	
Direct patient contact (e.g. Hands-on clinical contact)	Y / N

What type of protective equipment was used during contact with confirmed case and how often?

Surgical mask:	Y / N / Don't know	If yes, how often?	□ Always (100% of time) □ Often (>50% of time) □ Infrequent (<50% of time) □ Never
High filtration mask (FFP3):	Y / N / Don't know	If yes, how often?	□ Always (100% of time) □ Often (>50% of time) □ Infrequent (<50% of time) □ Never
Eye protection:	Y / N / Don't know	If yes, how often?	□ Always (100% of time) □ Often (>50% of time) □ Infrequent (<50% of time) □ Never
Gloves:	Y / N / Don't know	If yes, how often?	□ Always (100% of time) □ Often (>50% of time) □ Infrequent (<50% of time) □ Never
Gown:	Y / N / Don't know	If yes, how often?	□ Always (100% of time) □ Often (>50% of time) □ Infrequent (<50% of time)

			☐ Never
Was the contact present while any aerosol prone procedures took place?	☐ Yes ☐ No		
If yes, what procedure were they present at? List and date if more than one.	1)……Date: / / 2)……Date: / / 3)……....Date: / /		
Was the contact wearing any type of mask at this/these procedure(s)?	1) ☐ Surgical ☐ FFP3 ☐ None 2) ☐ Surgical ☐ FFP3 ☐ None 3) ☐ Surgical ☐ FFP3 ☐ None		

If date of onset in confirmed case is known, please tick below ALL days of contact with the confirmed case in relation to their date of illness onset e.g. +1 means contact the day after onset of illness:

Date of illness onset for the confirmed case

Day	**0**	**1**	**2**	**3**	**4**	**5**	**6**
Date							

Day	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Date								

If date of onset of the confirmed case is unknown, please give the total number of days you were in contact with the confirmed case:

Please go to Section 6.

5. Exposure Information – Non Healthcare Workers

Please mark location of contact with confirmed case:

Household		**Health care setting**		**Other (specify)**	
School					

Last unprotected contact with confirmed case (if still in contact please put today's date):

Last date / /

Please tick below ALL days of contact with the confirmed case if date of onset is known, in relation to their date of illness onset e.g. -1 means contact on the day prior to onset of illness of the confirmed case, +1 means contact the day after onset of illness, etc:

Day	-7	-6	-5	-4	-3	-2	-1
Date	dd/mm/yy						

Date of illness onset for the confirmed case

Day	0	1	2	3	4	5	6
Date							

Day	7	8	9	10	11	12	13	14
Date								

If date of illness onset of the confirmed case is unknown, please give the total number of days you were in contact with the confirmed case:

6. Symptoms in contact

Symptoms in contact in 14 days *before* the contact with the confirmed case until present date or 14 days after last contact with the case, whichever is the earliest

Has the contact been ill in the period from 14 days before onset in the confirmed case until the present? No / Yes

Currently ill No / Yes

If contact has not been ill please go to Section 7.

Date of first symptom onset / / Unknown

Time of onset AM / PM Unknown

Maximum Temperature

Symptoms:

Respiratory symptoms:

History of Fever	No / Yes / Unknown	**Runny nose**	No / Yes / Unknown	**Sneezing**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
Cough	No / Yes / Unknown	**Sore Throat**	No / Yes / Unknown	**Shortness of Breath**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
If Yes, dry or productive	Dry/Productive				

Other symptoms:

Muscle ache	No / Yes / Unknown	**Joint ache**	No / Yes / Unknown		
Diarrhoea	No / Yes / Unknown	**Nausea**	No / Yes / Unknown	**Vomiting**	No / Yes / Unknown
Fatigue	No / Yes / Unknown	**Loss of appetite**	No / Yes / Unknown	**Headache**	No / Yes / Unknown
Seizures	No / Yes / Unknown	**Altered Consciousness**	No / Yes / Unknown	**Nose bleed**	No / Yes / Unknown
Rash	No / Yes / Unknown	**Other**	No / Yes, please specify		

7. Outcome/Status of Contact

Please complete only if contact has been ill or is currently ill.

Status (please mark one of the following):

Recovered		**Still ill**		**Dead**	
If yes, date symptoms resolved(able to resume normal activities)	/ /			**If yes, date of death**	/ /

If hospitalisation:

Hospitalised	Yes/No/Don't know
If yes, date of admission to hospital and date of discharge	/ / / /
If yes, still hospitalised	Yes/No/Don't know

If Dead:

(NB. If this information is not currently available, please leave blank and send through an update as soon as results are known):

Contribution of MERS-CoV to death:	**Underlying/primary** ☐ **Contributing/secondary** ☐ **No contribution to death** ☐ **Unknown** ☐
Was a post mortem performed:	Yes/No/Don't know
Cause of death as MCCD (Medical Certificate of the cause of death):	
Result of coroner's report where applicable:	

Case classification of contact if appropriate:

Confirmed ☐ **Probable** ☐ **Possible** ☐ **Discarded** ☐ **N/A** ☐

8. Medical History

Does the contact have any underlying medical conditions? Complete where appropriate.

Condition	Y/N/Unknown	Comment
Chronic heart disease	No / Yes / Unknown	
Diabetes	No / Yes / Unknown	
HIV/other immunodeficiency	No / Yes / Unknown	
Chronic kidney disease	No / Yes / Unknown	
Chronic liver disease	No / Yes / Unknown	
Chronic respiratory disease, excluding asthma requiring medication	No / Yes / Unknown	
Malignancy	No / Yes / Unknown	
Organ or bone marrow	No / Yes / Unknown	

recipient			
Seizure disorder	No / Yes / Unknown		
Chronic neurological disease	No / Yes / Unknown		
Approximate height in cm: Approximate weight in cm:			
Pregnant	No / Yes / Unknown	If yes, trimester: Estimated delivery date:	first / second / third / /
Other:			
Contact vaccinated with pneumococcal vaccine	No / Yes / Unknown	**Date of vaccination / /**	

9. Virological Tests (if appropriate)

Specimen Date	Laboratory Test Date	Specimen Type BAL / Blood-Plasma / Blood-Serum / Faeces / Nose/Throat swab / NPA / Sputum / Tissue / Oral fluid / Finger prick	Lab Name Belfast / Birmingham / Bristol / Cambridge / Cardiff / Dublin / Glasgow / Leeds / Leicester / Liverpool / London-Barts / London-Cfl / London-Kings / London-St Thomas's / London-UCLH / Manchester / Newcastle / Nottingham / Salisbury / Southampton / Other (please specify)	Local Lab Number	Virus	Type of Test Molecular (RT-PCR, sequencing, pyrosequencing)/Culture (antigenic typing, phenotypic antiviral susceptibility testing)/ Serological (HA/MN)	Result
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive
/ /	/ /						Equivocal Negative / Positive

10. Serology

Has baseline serology been taken on case?	Y/N/Not sure
If yes, date serology taken?	/ /
Laboratory Name	
Date serology sent to PHE MS	/ /

CONTACT FOLLOW UP FORM 2b – DAY 14 (Since last exposure)

Confirmed Case number	NA….	Contact ID No.[16]	C……	Name of confirmed case	

1. Reporter Details

Reporter		**Date Reported**	/ /
Reporter code		**Position**	
Organisation		**Phone and extension**	
Mobile		**Email**	
Fax		**Date of interview with contact**	/ /

2. Informant Details

Informant	Case / other	**If other:**	**relationship with case**	
			contact details including telephone number	

3. Exposure Information

Please mark location of contact with confirmed case:

Household		**Health care setting**		**Other (specify)**	
School					

Last unprotected contact with confirmed case (if still in contact please put today's date):

Last date	/ /

Please tick below ALL days of contact with the confirmed case if date of onset is known, in relation to their date of illness onset e.g. -1 means contact on the day prior to onset of illness of the confirmed case, +1 means contact the day after onset of illness, etc:

[16] Contact ID numbers should have been issued at time of completion of the Minimum Data Set Form or Form 1a.

Date of illness onset for the primary case

Day	-1	0	1	2	3	4	5	6
Date	dd/mm/yy							

Day	7	8	9	10	11	12	13	14
Date								

If date of illness onset of the case is unknown, please give the total number of days you were in contact with the confirmed case:

4. Symptoms in contacts

Did the contact ever become ill during the 14 days after contact with the confirmed case (see symptoms) No / Yes **Currently ill** No / Yes **If contact has not been ill END.**

Did the contact have any additional symptoms not previously mentioned in form 2a and up to 14 days since last contact with confirmed case?

If yes,

Date of first symptom onset / / Unknown **Time of onset** AM / PM Unknown **Maximum Temperature**

Respiratory symptoms

History of Fever	No / Yes / Unknown	**Runny nose**	No / Yes / Unknown	**Sneezing**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
Cough	No / Yes / Unknown	**Sore Throat**	No / Yes / Unknown	**Shortness of Breath**	No / Yes / Unknown
If Yes, date	/ / Unknown	**If Yes, date**	/ / Unknown	**If Yes, date**	/ / Unknown
If Yes, dry or productive	Dry/Productive				

Other symptoms:

Muscle ache	No / Yes / Unknown	**Joint ache**	No / Yes / Unknown		
Diarrhoea	No / Yes / Unknown	**Nausea**	No / Yes / Unknown	**Vomiting**	No / Yes / Unknown
Fatigue	No / Yes / Unknown	**Loss of appetite**	No / Yes / Unknown	**Headache**	No / Yes / Unknown
Seizures	No / Yes / Unknown	**Altered Consciousness**	No / Yes / Unknown	**Nose bleed**	No / Yes / Unknown
Rash	No / Yes / Unknown	**Other**	No / Yes, please specify		

5. Serology

Has convalescent serology been taken on contact?

Has convalescent serology been taken on case?	Y/N/Not sure
If yes, date serology taken?	/ /
Laboratory Name	
Date serology sent to PHE MS	/ /

6. Final contact classification

Please mark –

Confirmed		**Probable**		**Possible**		**Discarded**		**Lost to follow-up**		**NA**	

Appendix A: FF100 Form Completion Guidance

These notes are to provide guidance to those completing the forms. It is suggested that these investigations could be divided into teams – these could include a 'case reporter' team, a 'contact reporter' team and 'go to' team who would liaise with additional data sources other than the case or contact such as hospitals, laboratories etc.

(a) FF100 Initial Case Report Form 1a – This form should be completed predominately by the 'Case' reporter team. This form should be completed when as soon as the PHE Centre are notified by the Emergency Operations team at PHE, Colindale.

Section	Sources	Verified against
Case Classification	Case Reporter / EOC Colindale	
Reporter Details	Case Reporter	
Informant Details	Informant	
Patient Details	Informant	
GP Details	Informant	PDS matching (by EOC?)
Presenting illness	Informant	Healthcare provider / review of medical records
Exposures in the 7 days before onset	Informant	
Medical history	Informant	Healthcare provider / GP / review of medical records
Treatment & prophylaxis with antivirals	Informant / interview with healthcare provider	Review of medical records
Hospitalisation	Informant / Hospital	HES
Test results	Testing laboratory	Datamart
Contact Details	Informant	

(b) FF100 Case Follow-Up Form 1b – This form should be completed by the 'Case' reporter team and should be completed 21 days after symptom onset of the case.

Section	Sources	Verified against
Final case classification	Contact Reporter / EOC Colindale	
Reporter details	Contact Reporter	
Informant details	Informant	
Outcome/Status at 21 days post symptom onset	Informant	ONS mortality, PDS, GP/Hospital
Illness	Informant	Healthcare provider / review of medical records
Clinical Course/Complications	Informant / interview with healthcare provider	Review of medical records
Treatment with antivirals	Informant / interview with healthcare provider	Review of medical records
Treatment with antibiotics	Informant / interview with	Review of medical

	healthcare provider	records
Interaction with NHS	Informant / Hospital	HES
Reference Test Results	Testing laboratory	Datamart
Bacterial Infections	Testing laboratory	Lab-base/MOLIS

(c) FF100 Initial Contact Report Form 2a – This form should be completed by the 'Contacts' reporter team and should be completed after the Initial Case Report from has been completed by the 'Case' Reporter team, ideally within 24 hours.

Section	Sources	Verified against
Reporter Details	Contact reporter	
Informant Details	Informant	
Contact Details	Informant	
Exposure Information	Informant	
Illness in contacts	Informant	Healthcare provider / review of medical records
Treatment & prophylaxis with antivirals	Informant, interview with healthcare provider	Review of medical records
Outcome/Status	Informant	ONS mortality, PDS, GP / hospital
Case classification	Contact reporter	
Virological Tests	Testing laboratory	Datamart
Medical History	Informant	Healthcare provider / GP / review of medical records

(d) FF100 Contact Follow-Up Form 2b

Section	Sources	Verified against
Reporter Details	Contact reporter	
Informant Details	Informant	
Final Contact Classification	Contact reporter	
Exposure Information	Informant	
Illness in contacts	Informant	Healthcare provider / review of medical records
Clinical Course/Complications	Informant / interview with healthcare provider	Review of medical records
Treatment & prophylaxis with antivirals	Informant, interview with healthcare provider	Review of medical records
Treatment with antibiotics	Informant, interview with healthcare provider	Review of medical records
Outcome Status	Informant	ONS, PDS, GP / Hospital
Virological Tests	Testing laboratory	Datamart
Bacterial Infections	Testing laboratory	Lab-base/MOLIS

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