

Protecting and improving the nation's health

'The First Few Hundred (FF100)' Enhanced Case and Contact Protocol v6.3

Epidemiological protocols for comprehensive assessment of Early Middle East Respiratory Syndrome coronavirus cases and their close contacts in the United Kingdom

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Published December 2015

PHE publications gateway number: 2015527



Contents

About Public Health England	2	
Executive summary	4	
1.0 Overview of FF100 approach	5	
 1.1 Introduction and overview 1.2 Protocol objectives 1.5 Coordination of investigations and review of data 1.6 Country-specific adaptation of the protocols 2. Methods 	7	5 5 6 6
 2.1 Case and contact definitions 2.2 Possible case investigation 2.3 Recruitment and follow-up of confirmed cases and their close contacts 2.4 Data collection on cases and household contacts 2.4.1 Data collection on cases 2.4.2 Data collection on close contacts 2.5 Role of laboratory testing 2.6 Analyses and interpretation of data 		7 8 9 10 10 11 11
3.0 Questionnaires	13	

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 interval²
- Symptomatic proportion of cases

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

- The basic reproductive number $(R_0)^3$.
- Incubation period⁴
- Preliminary case-severity ratios (eg case-hospitalisation and case-fatality ratios)⁵

This information will be used to refine/update recommendations for surveillance (eg case definitions), to characterise the key epidemiological transmission features of

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.

the 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. Coordination of the system will be undertaken by the Centre for Infectious Disease Control and Surveillance.

The FF100 system will be maintained centrally by the Respiratory Diseases Department, CIDSC. 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;
 - o With symptoms of fever (≥38°) or history of fever, and cough

AND

 With clinical or radiological evidence of pneumonia or acute respiratory distress syndrome (ARDS)

AND

Not already explained by any other infection or aetiology⁶

AND AT LEAST ONE OF

 History of travel to, or residence in an area where infection with MERS-CoV could have been acquired⁷ in the 14 days before symptom onset

OR

• Close contact⁸ 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

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 08/06/2015: Bahrain, Iraq, Iran, Jordan, Kingdom of Saudi Arabia, Kuwait, Oman, Qatar, United Arad Emirates, Yemen and South Korea– 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 MFRS-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 eg 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.** 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.

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 followup would occur as described in the case investigation algorithm.

Data collection will be facilitated by an online web-tool. For further information about data collection using the web-tool please contact respiratory.lead@phe.gov.uk.

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.

The Respiratory Virus Unit will also request further follow-up samples for investigation (eg BAL, EDTA blood, faeces, urine, serum) from a MERS-CoV confirmed patient. All samples submitted should be urgently transported to the Respiratory Virus Unit Colindale in

accordance with Cat B transportation regulations. PHE follows the Guidance on regulations for the transport of infectious substances 2013-2014, published by WHO (http://www.who.int/ihr/publications/who_hse_ihr_2012.12/en/). Details on sampling and transportation are available here.

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	r Details		
Reporter			Date Reported	1	I
Organisatio n			Phone and extension		
Mobile			Email		
Date of interview with informant	interview / / / with				
		3. Patient	Details		
Forenan	ne		Surname		
Se	Male / Female	e / Not Known	Date of Birth	1	1
Local ID Numbe (HPZone numbe			Age		
Post Cod	le				
		4. Preser	nting Illness		
Date of first symptom onset	/ / Unknown	History of Fever	No / Yes / Unknown	Cough	No / Yes / Unknown
Suspicion of pulmonary parenchymal disease (eg pneumonia or Acute Respiratory Distress Syndrome (ARDS)) based on clinical evidence of consolidation					

Minimum Data Set Form 1 - Possible Case

Respiratory viral screen:	No / Ye: Unknov						
If yes, results of r	espiratory v	iral screen	:				
Influenza A	Positive / Negative	Influ	uenza B	Positive Negative	i (niea	se	
		5 Clinica	l Cours	e/Complica	tions		
Hospitalisatio n	No / Yes / Unknown	Med	chanical ntilation	No / Yes Unknowi	/ ARD	No / Yes / Unknown	
Name of hospital							
Chest xray with radiological evidence of consolidation	No / Yes Unknow		ECMO ¹⁰	No / Yes Unknowi			
6. E	xposures	in the 14	days b	efore onset	of first syn	nptoms	
dave hotoro	No / Yes / Unknown	If yes, plo			Date of arrival in UK	1 1	
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	lf y€	es, setting of cluster	/ /	Number of symptoma tic 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 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 eg C001, C002, C003 etc.

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. Currer	nt Status		
Please mark:	Alive	Dead			
	2.	Further Case	Classification		
Please mark:	Imported	Secondary	Sporadic		
		3. Reporte	er Details		
Reporter			Date Reported	I	1
			Position		
Organisation			Phone and extension		
Mobile			Email		
Fax			Date of interview with informant	I	I
		4. Informa	nt Details		
Intormant	Case / other:	Relationship Contact details telepho			
		5. Patien	t Details		
NHS nu	umber				
Fore	ename		Surname		
	Sex Male / Fem	ale / Not Known	Date of Birth	1	1
Local ID nu (HPZone nu			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			
Local Authority		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 Hands	t patient contact (eg s-on clinical contact)
If HCW: Job title		If HCW: Place of work	
	6. GP De	etails	
Name of GP		Practice Name	
Telephone		Fax	
Post Code]	

		7. Preser	nting Illness		
Date of first symptom onset	/ / Unknown	Time of onset	AM / PM Unknown	Maximum Temperat ure	
Respiratory s	ymptoms:				
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 Breat	
If Yes, date	/ / Unknown	If Yes, date	/ / Unknown	If Yes, da	/ / Unknown
If Yes, dry or productive	Dry/Productive				
Other sympto	ms:				
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 Consciousne ss	No / Yes / Unknown	Nose bleed	No / Yes / Unknown
Rash	No / Yes / Unknown	Other	N	lo / Yes, please	specify
8. Clinical Course/Complications					
Mechanical ventilation	No / Yes / Unknown	ICU Admission	No / Yes / Unknown	ARIIS	No / Yes / Unknown

¹¹ Acute Respiratory Distress Syndrome (ARDS)

Date of mechanical ventilation	/ / Unknov	/n		te of ICU Imission	/ / Unknown	Date of ARDS		/ known
Length of ventilation (days)			discha	Date of rge from ICU	/ / Unknown			
Cardiac arrest	No / Yes / Unknown	re	tension quiring ressors	No / Yes Unknow	Chest Xray with pneumonia	No / Yes / Unknown	ECMO ¹²	No / Yes / Unknown
Renal failure	No / Yes / Unknown		Other				Date ECMO started:	/ / Unknown
Pregnancy			gnancy utcome				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)
1 1	1 1	
1 1	1 1	
1 1	1 1	
1 1	1 1	
1 1	1 1	

In the 14 days before	illness onset	did the cas	e spend time
OUTSIDE of the UK			

Yes / No / Unknown

Departure Return Date Date		City, Country	WHO defined affected area		
1 1	1 1		No / Yes / Unknown		
1 1	1 1		No / Yes / Unknown		
1 1	1 1		No / Yes / Unknown		
1 1	1 1		No / Yes / Unknown		
1 1	1 1		No / Yes / Unknown		

Date arrived in UK (include details		
for multiple trips within last 14 days	1	1
if applicable)		

¹² Extracorporeal membrane oxygenation (ECMO)

Airport of arrival & fli (include details for mul within last 14 days if a	Itiple trips					
Port or train station of mode of transport diffusion plane (include details trips within last 14 days applicable)	iferent to for multiple					
In the 14 days before onset did the case have close contact with a confirmed of probable case while the case was symptomate					No / Yes / Unknown	
Details of case conta	ot (if known).					
	ct (ii kilowii).		1			
Forename			Surname			
Age			Date of contact with case			
			Setting of contact	Household HC Setting	d / School / Plane / g / Other	
In the 14 days before onset did the case have close contact with any of the following:						
Cats	Yes / No / Unl	known	Camels	Yes / No / I	Unknown	
Dogs	Yes / No / Unl	known	Sheep	Yes / No / I	Unknown	
Bats	Yes / No / Unl	known				
Civets	Yes / No / Unl	known				
Other animals	Yes / No / Unl	known	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	1	1

	11. Treatn	nent with ant	ivirals			
Did the case receive anti	virals in the last 14 da	ays?				
Ribavarin	No / Yes / Unknown	Date started	. /	/		Unknown
Other	No / Yes / Unknown	Date started	/	/		Unknown
Wasan and dealer annually	. 1 (7				
Were antivirals prescribe		Treatment	ctions			
llee the ease had interes				d		::Umaaa2
Has the case had interac	tion with any of the fo		care settings	auring c	urrent	illiness?
Contact with NHS Dire	No / Yes / Unkno	own Date o	f NHS Direct contact:		/	/
Visit to	GP No / Yes / Unkno	own Da	te of first GP		/	/
		Date o	contact:		/	/
		Date	contact:		/	/
		Dota	contact:			
Visited A	&E No / Yes / Unkno	own	of first A&E contact:		/	/
			second A&E contact: of third A&E			
		Date	contact:			
Admitted to hospi	ital No / Yes / Unkno	own hos	Date of first spitalisation:		/	/
Name of first hospi	ital		code of first			
Second admission hospi		-	te of second spitalisation:		/	/
Name of seco hospi		Postcoo	de of second hospital			
Third admission hospi		hos	Date of third spitalisation:		/	/
Name of third hospi	ital	Post	code of third hospital			

13. Test Results

Virological Tests

Specimen Date	Laboratory Test Date	Specimen Type BAL / Blood-Plasma / Blood-Serum /	Lab Name Belfast / Birmingham /	Local Lab Number	Virus	Type of Test Molecular (RT-	Result
		Faeces / Nose/Throat swab / NPA / Sputum / Tissue/ Oral fluid / Finger prick	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)			PCR, sequencing, pyrosequencing)/ Culture (antigenic typing, phenotypic antiviral susceptibility testing)/Serological (HA/MN)	
1 1	1 1						Equivocal Negative / Positive
1 1	1 1						Equivocal Negative / Positive
1 1	1 1						Equivocal Negative / Positive
1 1	1 1						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	1 1

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

(after completion of Form 1a)

Unique Case Nu	ımber									
			1. Rep	oorte	er Details					
					1	ate				
Reporter					Report				1	
Reporter code					Positi	ion				
Organisation					Phone a extens					
Mobile					Em	nail				
Fax					Dat interview v inform			1	1	
	2. Infori	mant D	etails (if	diffe	erent from	init	ial interview)			
Informant Case othe	I IT OTO	ner:	contact de	etails	with case s including ne number					
3. Out	come/Sta	atus at	21 days	pos	t sympton	n on	set (if other	speci	fy)	
Status (please ma	rk one of t	he follo	wing):							
Recovered			Still ill				Dead			
If yes, date symptoms resolved (able resume norm activities)		1 1				1	If yes, date of death		1 1	
	/er	s/No/Do	n't know							
hospitalise If yes, is t patient s hospitalise	he Ye	s/No/Do	n't know							
Date admission hospital and da of discharge appropria	to ate e if		1							

CASE FOLLOW-UP FORM 1b – FINAL OUTCOME - Day 14-21 (after completion of Form 1a)

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

(after completion of Form 1a)

		4. Syn	nptoms	,	
Symptoms e	ver during the cour	se of the illness:			
Maximı Temperatı					
Respiratory	symptoms:	-			
History o Feve		Runny nose	No / Yes / Unknown	Sneezing	No / Yes / Unknown
If Yes, date	e / / Unknown	If Yes, date	/ / Unknown	If Yes, date	/ / Unknown
Coug	No / Yes / Unknown	Sore Throat	No / Yes / Unknown	Shortness (Breat	
If Yes, dat	e / / Unknown	If Yes, date	/ / Unknown	If Yes, da	te / / Unknown
If Yes, dry o				-	
Other symp	<u>toms</u>				
Muscle ach	No / Yes / Unknown	Joint ache	No / Yes / Unknown		
Diarrhoe	No / Yes / Unknown	Nausea	No / Yes / Unknown	Vomiting	No / Yes / Unknown
Fatigu	No / Yes / Unknown	Loss of appetite	No / Yes / Unknown	Headache	No / Yes / Unknown
Seizure	No / Yes / Unknown	Altered Consciousne ss	No / Yes / Unknown	Nose bleed	No / Yes / Unknown
Rasi	No / Yes / Unknown	Other	1	No / Yes, please	specify
	5	5. Clinical Cour	se/Complicat	ions	
Mechanical ventilation	No / Yes / Unknown	ICU Admission	No / Yes Unknowr		No / Yes / Unknown

/ /

Date of

27 | Page V 6 . 1

Date of ICU

/ /

Date of

/

/

¹³ Acute Respiratory Distress Syndrome (ARDS)

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

(after completion of Form 1a) mechanical Unknown Admission Unknown ARDS Unknown ventilation Length of Date of / / ventilation discharge from Unknown (days) ICU No / Yes Hypotension **Chest Xray** No / Yes / No / Yes / Cardiac No / Yes / ECMO¹⁴ requiring with arrest Unknown Unknown Unknown Unknown vasopressors pneumonia Date Date of Date of Date of use **ECMO** / chest xray Unknown cardiac started: with Unknown Unknown Unknown arrest vasopressors pneumonia Length / Renal of Other failure **ECMO** Unknown (days) Y/N/ Not **Pregnancy Pregnancy** applicable outcome

6. Secondary Bacterial Infections

Date of sample	Site Sputum / Endotracheal aspirate / Pleural fluid / CSF / Blood / Urine / Other					
1 1						
1 1						
1 1						
1 1						
1 1						
1 1						

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)

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

(after completion of Form 1a)

8. Reference Test Results

Additional Virological Tests

Additional Thological 100to								
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	Molecular (RT-PCR, sequencing, pyrosequencing)/Culture (antigenic typing, phenotypic antiviral susceptibility testing)/Serological (HA/MN)	Result	
1 1	1 1						Equivocal Negative / Positive	
1 1	1 1						Equivocal Negative / Positive	
1 1	1 1						Equivocal Negative / Positive	
1 1	1 1						Equivocal Negative / Positive	

CASE FOLLOW-UP FORM 1b – FINAL OUTCOME - Day 14-21 (after completion of Form 1a)

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	/ /

Confirmed Ca numb		Contact ID No. ¹⁵	C	со	Name of nfirmed case					
	1. Reporter Details									
Reporter		•	Da Reporte		1	I				
Reporter code			Positio	on						
Organisation			Phone a extensi							
Mobile			Em	ail						
Fax		i	Date interview w cont	/ith	1	I				
		2. Informan	t Details							
Informant Contac t / other	relationship with co If other: contact details incl telephone nu									
		3. Contact	Details							
Forename			Surname							
Sex	Male / Fen	nale / Not Known	Date of Birth /		1	1				
Street Address				Home phone						
Town			Tele	Work phone						
County]	Mobile						
Post Code			Email ad	ldress						
Country of Residence			me	ferred ode of ontact						

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
4.5		n far Haalthaara	Maukaya
	cposure Information it is confirmed case with the confirmation can be confirmed case.		(if still in contact please put
Last date /	1		
Job title			
Place of work			
Direct patient contact (eg F contact)	lands-on clinical	Y/N	
What type of protective equipment case and how of		ing contact with	
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	•		any aerosol took place?		□ Yes		No	
If yes, what procedure were they present at? List and date if more than one.				2)		Date	e: //	
Was the contact wearing any type of mask at this/these procedure(s)?				: 2) □ Sur	gical □ FFF gical □ FFF gical □ FFF	3 □ None		
If date of or confirmed ca illness:								
	Date of illne for the conf		e					
Day	0		1	2	3	4	5	6
Day Date	7	8	9	10	11	12	13	14
If date of ons contact with t Please go to	Section 6.	conf	se is unknow irmed case: nformatio				days you we	re in
Please mark l	ocation of c	ontact with	n confirmed	case:				
Household School			th care setting		Other (spec	ify)		
20.1001								
Last unproted	cted contact	with confi	rmed case (i	f still in co	ntact please	e put today's	date):	
Last date	1	1						
Please tick be	elow ALL da	ys of cont	act with the	confirmed	d case if dat	e of onset is	s known, in re	elation

to their date of illness onset eg -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 or the confirm						
Day	0	1	2	3	4	5	6
Date							
Day	7	8 9	10	11	12	13	14
Date							
Present da Has the coperiod from 1		onset No / V	ontact with	the case	whichever o / Yes lf co	is the earlie entact has not n ill please go	est
_	pre st symptom o	nset / / Unknowr	Time on	e of AM /	PM Maxii		
<u>Symptoms:</u> Respiratory s	vmntoms:						
itespiratory s	ymptoms.				_		
History of Fever	No / Yes / Unknown	ixui	No / Your Unkno		Sneezing	No / Yes / Unknown	
If Yes, date	/ / Unknown	If Yes, da	/ Unkno	/ wn	If Yes, date	/ / Unknown	,
Cough	No / Yes / Unknown	Sore Thre	No / Y Unkn		Shortness of Breath	No / Yes Unknow	I
If Yes, date	/ / Unknown	If Yes, da	ate / Unkne	/ own	If Yes, date	/ / Unknow	
If Yes, dry or productive	Dry/Productiv	re e				1	

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 Consciousne ss	No / Yes / Unknown	Nose bleed	No / Yes / Unknown
Rash	No / Yes / Unknown	Other	N	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)	/	1		If	yes, date of death	1	1	

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:

Contribution of MERS-Co\ death:	/ to		Und	derlying/prima	ıry		
			Contrib	uting/seconda	iry		
		r	lo contr	ibution to dea	ıth		
				Unknov	wn		
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 Confirmed	Probable	Possib	le	Discarded		N/A	
Door the contact have any w		edical His		alata whara an	nranri	010	
Does the contact have any u Condition	Y/N/Unknow		r Comp	Comme		ale.	
Chronic heart disease	No / Yes / Unkr	nown					
Diabetes	No / Yes / Unkr	nown					
HIV/other immunodeficiency	No / Yes / Unkr	nown					
Chronic kidney disease	No / Yes / Unkr	nown					
Chronic liver disease	No / Yes / Unkr	nown					
Chronic respiratory disease, excluding asthma requiring medication	No / Yes / Unkr	nown					
Malignancy	No / Yes / Unkr	nown					
	1	nown					

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	1 1

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
1 1	1 1						Equivocal Negative / Positive
1 1	1 1						Equivocal Negative / Positive
1 1	1 1						Equivocal Negative / Positive
1 1	1 1						Equivocal Negative / Positive
1 1	1 1						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)

Confirme r	d Case number	NA	Contact No.	ID C		Name of confirmed case					
			1. Rep	orter	Details						
Reporter					D Repor	ate		1	,	!	
Reporter code					Posit	ion					
Organisation					Phone extens						
Mobile					En	nail					
Fax				in	terview	te of with ntact		1	,	/	
			2. Info	rmant	Details	3					
Informant	Case / other	If other:	contact de	etails in	ith case cluding number						
			3. Expos	ure In	formati	on					
Please mark	location	of contact	with confirmed	d case:			ı—				
Household		_ н	ealth care setting		Othe	er (sp	ecify)				
School											
-	cted cor	ntact with co	onfirmed case	(if still i	in contac	ct plea	ase put	today's	date):		
Last date		1 1									

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 eg -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.

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

Date of illness onset for the primary case 0 5 Day -1 1 2 3 4 6 dd/mm/yy Date Day 7 8 9 10 11 12 13 14 Date

If date of illness on	set 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 s	<u>ymptoms</u>				
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:

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

CONTACT FOLLOW UP FORM 2b – DAY 14 (Since last exposure)					
Muscle ache	No / Yes / Unknown	Joint ac	he No / Yes / Unknown		
Diarrhoea	No / Yes / Unknown	Naus	ea No / Yes / Unknown	Vomiting	No / Yes / Unknown
Fatigue	No / Yes / Unknown	Loss appeti		Headache	No / Yes / Unknown
Seizures	No / Yes / Unknown	Altero Conscious		Nose bleed	No / Yes / Unknown
Rash	No / Yes / Unknown	Oth	er	No / Yes, please	specify
			5. Serology		
Has convalesc	ent serology bee				
Has convalescent serology been taken on case? Y/N/Not sure					
If yes, date serology taken?			1 1		
Laboratory Name					
Date serology sent to PHE MS / /					
6. Final contact classification					
Please mark –					. — —
Confirme d	Probable	Possib le	Discarded	Lost follow-u	NA I

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	Informant	ONS mortality, PDS,
symptom onset		GP/Hospital
Illness	Informant	Healthcare provider /
		review of medical records
Clinical Course/Complications	Informant / interview with	Review of medical
	healthcare provider	records
Treatment with antivirals	Informant / interview with	Review of medical
	healthcare provider	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	Review of medical
	healthcare provider	records
Treatment & prophylaxis with	Informant, interview with	Review of medical
antivirals	healthcare provider	records
Treatment with antibiotics	Informant, interview with	Review of medical
	healthcare provider	records
Outcome Status	Informant	ONS, PDS, GP / Hospital
Virological Tests	Testing laboratory	Datamart
Bacterial Infections	Testing laboratory	Lab-base/MOLIS

Acknowledgements

The authors would like to acknowledge all those who have contributed to this current protocol and past FF100 protocols. Contributors include Richard Pebody, Nicki Boddington, Helen Green, Lucy Thomas, Carlos Carvalho, Shelly Bolotin, John Watson, Roberta Marshall, Alison Bermingham, Joanna Ellis, Katja Hoschler, Andre Charlett, Peter White, Daniela de Angelis, Jonathan Green, Jim McMenamin, Brian Smyth, Roland Salmon, Jonathan Van-Tam, Steven Gee, Sheila Bird, James Freed, Nadar Mozakka, Neill Keppie, Praveen SebastianPillai, Tony McNiff, Mary Bussell, Mary Chamberland, Zoe Couzens, Asaf Niaz, Mike Painter, Bharat Pankania, Nick Phin, Chloe Sellwood, Ben Cooper, Colin Hawkins, Estelle McLean, Maria Zambon, Richard Myers, Anthony Underwood, Oliver Blatchford, Tim Dallman, David Goldberg, Sharon Hutchinson.

Please direct any queries regarding this protocol to respiratory.lead@phe.gov.uk