The First Few X (FFX)
Cases and contact investigation protocol
for 2019-novel coronavirus (2019-nCoV) infection

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The First Few X (FFX): Cases and contact investigation protocol for 2019-novel coronavirus (2019-nCoV) infection

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Protocol summary

The First Few X (FFX): Cases and contact investigation protocol for 2019-novel coronavirus (2019-nCoV) infection	
Study population	The first few cases of 2019-nCoV infection and their close contacts
Potential output and analysis	Transmission dynamics, severity, clinical spectrum, through estimates of, primarily • clinical presentation of 2019-nCoV infection and course of associated disease • Secondary infection rate (SIR) and clinical attack rate of 2019-nCoV infection among close contacts • Serial interval of 2019-nCoV infection • Symptomatic proportion of 2019-nCoV cases (through contact tracing and laboratory testing) • Identification of possible routes of transmission Secondarily: estimation of: • The basic reproductive number (R_0) • Incubation period • Preliminary infection and diseases-severity ratios (e.g. case-hospitalization and case-fatality ratios)
Study design	Prospective study of close contacts of confirmed 2019-nCoV case
Start of the study	To be imitated in the first days after the arrival in Country x of 2019-nCoV. FFX is the primary protocol to be initiated.
Study duration	At a minimum, enrolled cases and close contacts will complete data and specimen collection at enrolment and 14-21 days later
Minimum information and specimens to be obtained from participants	Data collection: Epidemiological data including: clinical symptoms, exposures including contact with confirmed case(s), pre-existing conditions Specimens: Respiratory (and other) to diagnose current 2019-nCoV infection, serum to inform seroepidemiological inferences

The methods to guide data collection and the public health investigation for the comprehensive assessment of confirmed 2019-nCoV cases and their close contacts are set out in this document.

WHO, in collaboration with technical partners has developed a series of enhanced surveillance protocols, that are harmonized to help provide detailed insight into the epidemiological characteristics of the 2019-nCoV. Other 2019-nCoV investigations and studies protocols currently available include:

- Households' Transmission Investigation Protocol for 2019-nCoV
- Health Care Workers Transmission Investigation Protocol for 2019-nCoV (under finalization)

All WHO protocols for 2019-nCoV are available on the WHO website together with the technical guidance documents, including case definitions, laboratory guidance, infection prevention and control, travel guidance, clinical management, risk communication and community engagement, and more

1 Background

The detection and spread of an emerging respiratory pathogen are accompanied by uncertainty over the key epidemiological, clinical and virological characteristics of the novel pathogen and particularly its ability to spread in the human population and its virulence (case-severity). This is the case for the novel coronavirus (2019-nCoV), first detected in Wuhan city, China in December 2019 (1).

As with many novel respiratory pathogens, a lot the key epidemiological, clinical and virological parameters of the virus and the outbreak dynamics are unknown at the beginning. At this stage, the extent of infection, the routine of transmission, the full range of disease presentation and the viral dynamics remain unknown for 2019-nCoV. As a result, understanding the epidemiological, clinical and virological characteristics of the First Few X cases (FFX) of 2019-nCoV and their close contacts is essential in order to inform targeted guidance and measures for the Country X Public health response.

The following protocol has been designed to investigate the First Few X cases (FFX) and their close contacts. It is an adaptation of generic protocols already in place in some countries like The First Few Hundred (FF100) Pandemic Influenza United Kingdom protocol. A harmonised global approach will facilitate rapid aggregation of data across countries.

It is envisioned that the FFX 2019-nCoV investigation will be conducted across several countries or sites with geographical and demographical diversity. Each country may need to tailor some aspects of this protocol to align with public health, laboratory and clinical systems, according to capacity, availability of resources and cultural appropriateness. However, using a standardized protocol such as the protocol described below, epidemiological exposure data and biological samples can be systematically collected and shared rapidly in a format that can be easily aggregated, tabulated and analyzed across many different settings globally for timely estimates of 2019-nCoV infection severity and transmissibility, as well as to inform public health responses and policy decisions. This is particularly important in the context of a novel respiratory pathogen, such as 2019-nCoV.

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

1.1 Objectives

The overall aim of this protocol is to gain an early understanding of some of the key clinical, epidemiological and virological characteristics of the first cases of 2019-nCoV infection detected in Country X to inform the development and updating of public health guidance to manage cases and reduce the potential spread and impact of infection in Country X. It is important to note that the first cases likely to be identified in this study are more likely to present with severe infection, and the ability to detect a greater range of cases in terms of severity will be dependent on resources.

The **primary objectives** of this FFX investigation among cases and close contacts are to provide estimates of:

- Clinical presentation of 2019-nCoV infection and course of associated disease

- Secondary infection rate (SIR)[1] and clinical attack rate[2] of 2019-nCoV infection among close contacts (overall and by key factors such as by setting, age, and gender for various end points)
- Serial interval[3] of 2019-nCoV infection
- Symptomatic proportion of 2019-nCoV cases (through contact tracing and laboratory testing)

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

- The basic reproductive number (R_0)[4] of 2019-nCoV
- Incubation period[5] of 2019-nCoV
- Preliminary 2019-nCoV infection and diseases-severity ratios (e.g. case-hospitalisation[6] and case-fatality ratios[7])

This information will be used to refine/update recommendations for surveillance (e.g. case definitions), to characterize the key epidemiological transmission features of the virus, help understand geographic spread, severity and impact on the community and inform operational models for implementation of countermeasures such non-pharmaceutical interventions[8] (eg. case isolation, contact tracing, etc) and medical interventions, if possible.

1.2 Coordination of FFX investigation

Coordination of investigations and sharing of information in real time will be needed at both country and global levels. Epidemiologists, modellers, virologists, statisticians, clinicians and public health experts will all assist in in developing early estimates of key epidemiological, clinical and virological parameters of the 2019-nCoV virus.

[1] In this context the **secondary infection rate** is a measure of the frequency of new infection of 2019-nCoV among the close contacts of confirmed cases in a defined period of time, as determined by a positive 2019-nCoV result. *Or in other words the rate of contacts being infected, assessed through PCR/serological assays on paired samples*

[2] **Secondary clinical attack** is a measure of the frequency of new cases of 2019-nCoV among the close contacts of confirmed cases in a defined period of time, as determined by a positive 2019-nCoV result rates is t*he rate of clinical manifestation of the infection in close contacts*

[3] The **serial interval** is defined as the period of time from the onset of symptoms in the primary case to the onset of symptoms in a contact case.

[4] The **reproduction number R_0**, is defined as the average number of secondary cases that result from one infected person in a fully susceptible population. Note we can assume that there will be very little to no immunity to 2019-nCoV.

[5] **Incubation period** is defined as the period of time between an exposure resulting in 2019-nCov infection and the onset of clinical symptoms of disease (*from infection to disease*)

[6] **Case hospitalisation ratio (CHR)** is defined as the proportion of those infected with 2019-nCoV who are admitted to hospital.

[7] The **case fatality ratio (CFR)** is defined as the proportion of people infected with 2019-nCoV which die as a direct or indirect consequence of their infection.

[8] WHO guidance document "Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza".https://www.who.int/influenza/publications/public_health_measures/publication/en/

Table 1: Coordination matrix of roles and responsibilities in *Country X*

What ?	**Who ?**
Overall co-ordination of the system	*[Cite Institution/ body/ person(s)]*
Case detection and investigation	*[Cite Institution/ body/ person(s)]*
Contact identification and follow-up	*[Cite Institution/ body/ person(s)]*
Analysis of data	*[Cite Institution/ body/ person(s)]*
Data management	*[Cite Institution/ body/ person(s)]*
Go.Data super-users (if Go.Data tool is used)	*[Cite Institution/ body/ person(s)]*
IT management	*[Cite Institution/ body/ person(s)]*
[add more roles, as per country context]	*[Cite Institution/ body/ person(s)]*

The FFX system will be maintained centrally by *[Cite Institution/ body/ person(s)].* Centralised coordination will require development of a "command and control" plan to allow for triage and prioritisation of investigations.

1.3 Harmonisation of 2019-nCoV early investigations

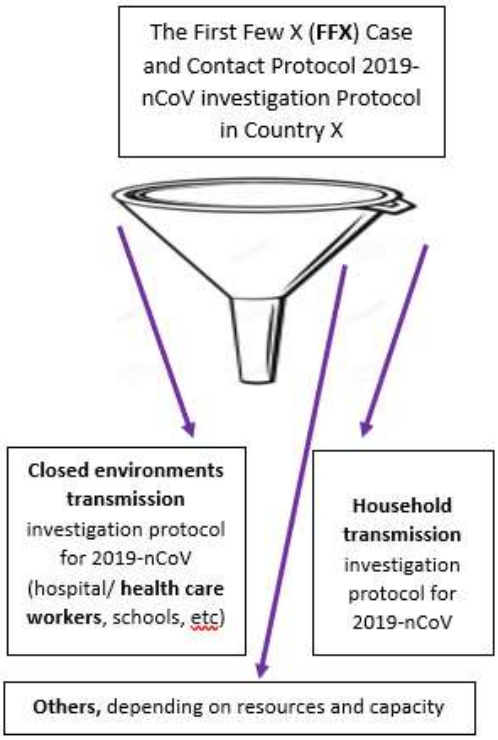
2019-nCoV early investigations are a suite of enhanced surveillance activities, that are harmonized to help provide detailed insight into the epidemiological characteristics of the 2019-nCoV.

This **FFX protocol** outlines the process for early and rapid data collection for the first few early cases of the pandemic, which will provide critical early insight into key epidemiological characteristics such as transmissibility and severity of the 2019-nCoV. This protocol will probably be the first investigation to be conducted.

Other 2019-nCoV early investigations could be simultaneously or subsequently undertaken to collect further information relating to the 2019-nCoV infection depending on availability of resources and capacity. These could include prospective investigations of transmission of 2019-nCoV **in households** and also in closed environments, such for **health care workers**. These investigations will provide a more detailed insight on transmissibility and severity, the effect of interventions in reducing risk of infection and secondary infection risk and on top give an estimate the asymptomatic fraction.

All WHO early investigation protocols for 2019-nCoV are available on the WHO website.

Figure 1 : *Complementarity of 2019-nCoV protocols currently available on WHO website*



2 Study procedures

2.1 Study design

This FFX investigation is a case-ascertained prospective study of all identified close contacts of a laboratory confirmed 2019-nCoV infection (see 2.2 Study population). It is intended to provide rapid and early information on the clinical, epidemiological and virological characteristics of 2019-nCoV.

This FFX investigation should be established following the identification of the first laboratory-confirmed 2019-nCoV cases in any country. It should also ideally be conducted before widespread community transmission occurs. That is, within the early phases of the 2019-nCoV epidemic in the country. The FFX aim to identify key clinical, virological and epidemiological characteristics infection with this novel virus in near real-time.

2.2 Study population

The study population are the first few confirmed cases of 2019-nCoV and their close contacts
For the purpose of this investigation, the primary case will be identified through the national surveillance system.

2019-nCoV **case definitions** for reporting are available on the WHO website, although they are subject to further updates as more information becomes available. The generic case definitions for 2019-nCoV are proposed in the table below.

Table 2 : Interim case definitions (check regularly WHO website for any update)

Case definitions: As of 29 January 2020, the case definitions for 2019-nCoV are as follows:
Suspected (/possible) case: Two definitions: 1. Patients with severe acute respiratory infection (fever, cough, and requiring admission to hospital), AND with no other etiology that fully explains the clinical presentation AND at least one of the following: • a history of travel to or residence in the city of Wuhan, Hubei Province, China in the 14 days prior to symptom onset, OR • patient is a health care worker who has been working in an environment where severe acute respiratory infections of unknown etiology are being cared for. 2. Patients with any acute respiratory illness AND at least one of the following: • close contact with a confirmed or probable case of 2019-nCoV in the 14 days prior to illness onset, OR • visiting or working in a live animal market in Wuhan, Hubei Province, China in the 14 days prior to symptom onset, OR • worked or attended a health care facility in the 14 days prior to onset of symptoms where patients with hospital-associated 2019-nCov infections have been reported.
Probable case: A suspect case for whom testing for 2019-nCoV is inconclusive or for whom testing was positive on a pan-coronavirus assay.
Confirmed case: A person with laboratory confirmation of 2019-nCoV infection, irrespective of clinical signs and symptoms.
Further confirmed case definitions:
A: Primary case: A primary case is an individual who tests positive for 2019-nCoV and has the earliest onset date in a particular setting e.g. household, school, hospital etc. Cases with onset dates less than 24 hours of the onset date of the primary case are considered to be "co-primary" cases. **B: Secondary case:** A secondary case is a contact who becomes a case with onset of symptoms 24 hours or more after the latest onset date of the primary and/or co-primary case. **C: Imported case:** An imported case is a case with a history of travel from an affected area in the 14 days before disease onset.

Contacts are defined as all individuals who are associated with some sphere of activity of the case and may have similar or other exposures as the case. Contacts can include household members, other family contacts, visitors, neighbours, colleagues, teachers, classmates, co-workers, social or health workers, and members of a social group.

Close contact definition, and further classification are described in the table below

Table 3: Close contacts definition and classification (check regularly WHO website for any update)

Contact definitions:
Close contact Any person who had contact (within 1 meter) with a confirmed case during their symptomatic period, including one day before symptom onset. COMMENT: contact does not have to be direct physical contact.
Further close contacts classification (For use in contact questionnaires) **:**
• **Social and health care workers contact** Any social or health care worker, who provided direct personal or clinical care, or examination of a symptomatic confirmed case of 2019-nCoV or within the same indoor space, when an aerosol generating procedure was implemented
• **Household (or closed setting) contact:** Any person who has resided in the same household (or other closed setting) as the primary 2019-nCoV case

2.3 Study duration

The investigation can continue for as long as is determined feasible by the country implementing the investigation.

Initially most laboratory-confirmed cases need to be enrolled. Attempt to follow-up all confirmed cases in the FFX database can be resource and time intensive. As case numbers began to increase rapidly, the proportion of cases to include could decreased according to Country X capacity and needs.

COMMENT: As an example, the UK 2009 Pandemic Influenza First Few Hundred (FF100) project ran from April–June 2009 with in total 392 confirmed cases followed up

For each enrolled participant (case and close contact), a follow-up data and specimen collection visit will be completed approximately 14-21 days after enrolment. The duration of follow-up may vary depending on the characteristics and transmission dynamics of the virus, antibody kinetics and specific research priorities.

COMMENT: As an example, the UK Pandemic Influenza First Few Hundred (FF100) project ran for 3 months

2.4 Data collection

Summary

Information on primary cases and their close contacts should be sought through a 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, self-reporting, interview of health care providers and/or review of medical records where required.

Investigation questionnaires can be found in Appendices of this document. These forms are not

exhaustive, but outline the data collection required for insight into the epidemiology of 2019-nCoV and may be updated further. This will still need to be adapted based on the local setting, and outbreak characteristics.

Once a case of 2019-nCoV infection has been identified and recruited into the investigation, a visit will need to be conducted to identify all eligible close contacts, to collect relevant socio-demographic and clinical information and to allow molecular confirmation of secondary infections and establish baseline antibody status, (or at a minimum to collect serum to test serologic status once serology capacity is available).

Please note regarding the **suspected cases**: Identifying and maintaining the line listing of suspected cases can be resource and time intensive. A fine balance should be found between time taken to identify the suspected cases and time spent in collecting data on probable and confirmed cases; the latter being of more importance.

It is advised that a variety of **confirmed cases** are enrolled in regard to geography, age, illness severity and setting.

Every effort should be made to include all known **close contacts**, including infants and children, of the confirmed case to generate the specimen and data sampling time frame for follow-up. Some aspects to keep in mind are:

- Ask each contact to report any signs and symptoms compatible with 2019-nCoV to the relevant Health authorities
- Any contact with clinical symptoms within 14 days of the last exposure/contact with the primary case should be considered as a symptomatic contact and so a **suspected case**, and therefore managed as such.
- Contacts found to be infected with 2019-nCoV would be re-classified as **confirmed cases** (dotted line in Figure 2) and follow-up would occur as described in the case investigation algorithm (Figure 2). The fact that a close contact becomes a confirmed cases , may not retrigger the data collection process, depending on the country resources and the type of contact (ex: if the contact is a health care worker, then it might be worth investigating further to inform public health action)

Please note that these investigations are incredibly resource intensive. It may be best to focus initially on the follow-up of **household and health care worker contacts,** and then expand to other close contacts if resources allow. More extensive follow-up of all close contacts may be better studied in closed settings such as households, health care settings(Health care workers) These protocols are available on the WHO website.

Use of Go.Data tool

Go.Data is software which has been designed to be used by WHO, GOARN, Member states and partners to support and facilitate outbreak investigation including field data collection, contact tracing and visualization of chains of transmission. The tool includes functionality for case and contact data collection, contact follow-up and visualization of chains of transmission. It has 2 components: a web application and an optional mobile app. The tool is targeted at any outbreak responders, including WHO staff, staff from MoH and partner institutions.

Go.Data can be used for running FFX investigation

Key features of the Go.Data software include:

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

Contact: godata@who.int
WHO weblink: https://www.who.int/godata

COMMENT: The standardized questionnaires available in the appendix of this document will be uploaded to and made available shortly on Go.Data.

2.5 Specimen collection

COMMENT: The following is intended to guide minimum specimen collection from confirmed cases and their close contacts. It may be more useful to collect respiratory specimens from study participants at a more frequent interval to provide more detailed insight into the duration of shedding and the serial interval.

2.5.1 Confirmed cases

All baseline respiratory and serum samples (as directed by specimen collection guidance in Country X should be collected from confirmed cases, as soon as possible after laboratory confirmation. Liaise with the relevant local public health laboratory or the nearest relevant laboratory to determine which specimens have already been collected for confirmed cases and if they are of sufficient quality and quantity for this investigation. Collect new samples if needed.

Follow-up samples may include upper and lower respiratory tract samples, clotted blood,9. and should be collected as described in Figures. . Lower respiratory tract samples can also be collected, if feasible but recommended infection prevention and control precautions should be in place prior to collection (see 2.9.5 Prevention of 2019-nCoV infection in investigation personnel).

Other specimens (oral fluid, urine, faeces, etc) may be collected according to clinical presentation, resources and observed patterns of viral shedding (described earlier) and may be collected from research staff or self-collected depending on resources, logistics and training.

[9] Adapted from WHO guidelines Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care, 2014.
https://www.who.int/csr/bioriskreduction/infection_control/publication/en/

Appropriate PPE should be worn when specimens are being collected from confirmed cases.[10]

2.5.2 Close contacts

All baseline upper respiratory specimens and serum samples should be collected at the initial home visit.
Follow-up respiratory and serum samples should be collected also
Other specimens (oral fluid, urine, faeces, etc) as described for confirmed cases, may be collected

2.5.3 Note on serology

Paired clotted blood samples should be taken for serology and handled and separated correctly by the laboratory. Paired serological samples are needed to aid the development of serological testing, to determine an accurate secondary-infection attack rate and the proportion of infections that are asymptomatic.

Serum samples should be taken on all 2019-nCoV confirmed cases, and in close contacts regardless of symptoms.

- An acute baseline clotted blood sample should be taken as soon as possible, and ideally no later than 7 days after symptom onset (for cases) and no later than 7 days after exposure with the confirmed cases (for close contacts).
- A follow up (or convalescent) clotted blood sample should be taken:
    - at least 14 days after the baseline sample,
    - or (for a case) 28 days after symptom onset if an acute sample couldn't be taken when the case was symptomatic.
    - Or (for a contact) 28 days after last exposure if an acute sample was not taken

[10] Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care - WHO Guidelines. Geneva, World Health Organization, 2014. Available at http://apps.who.int/iris/bitstream/10665/112656/1/97892 41507134_eng.pdf

2.6 Follow up of cases and contacts

For cases, data will be collected using **Forms A0 or A1** for the first visit, followed by **Forms A2**. For close contacts, data will be collected using **Form B1** for the first visit, followed by **Form B2**.

Figure 2. Case investigation algorithm, and summary of data collection tools

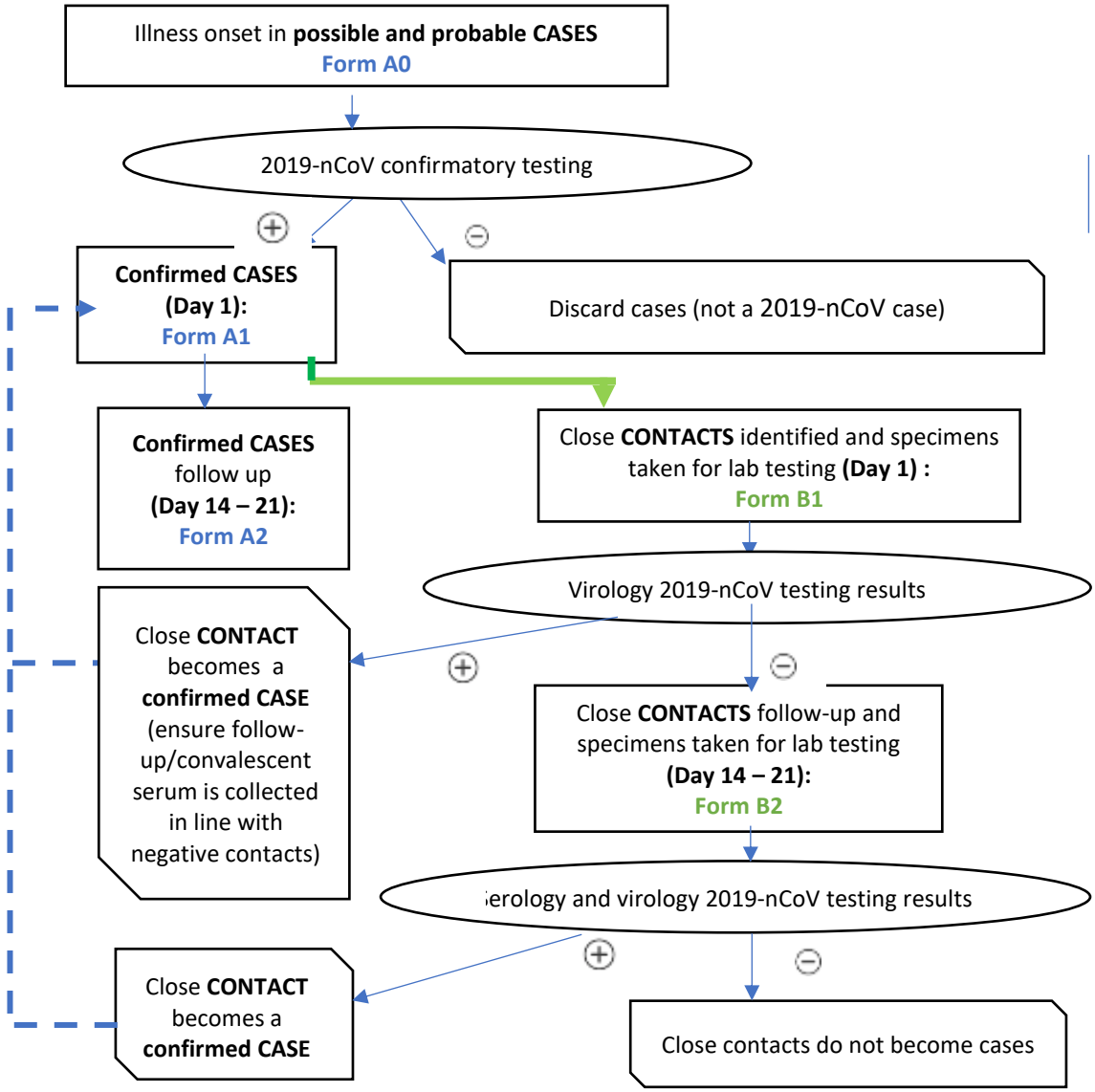


Table 4: Summary of data collection tools

Form number	Purpose of form	Collecting from whom?	When should it be collected?
CASES			
Form A0	Minimum data reporting form	For **suspected and probable** 2019-nCoV cases	As soon as possible after the suspected case is detected or notified.
Form A1	Case **initial** report form	For **confirmed** 2019-nCoV cases	As soon as possible after laboratory confirmation of a case **(Day 1)**
Form A2	Case **follow-up** form	For **confirmed** 2019-nCoV cases: final outcome	14-21 days after completion of Form A1, which is approx. 21 days after initial symptom onset of the case **(Day 14-21)**. Updates should be sought regularly, if all the required information is not available at the time of completing this form.
CONTACTS			
Form B1	Contact **initial** reporting form	For close contacts (of confirmed 2019-nCoV cases)	As soon as possible, ideally within 24 hours after laboratory confirmation of the primary case (**Day 1**)
Form B2	Contact **follow-up** form	For close contacts (of confirmed 2019-nCoV cases): final outcome	14-21 days after completion of Form B2 **(Day 14-21**)

Figure 3: Timeline of data and specimen collection in the FFX

Day since recruitment	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14 to 21**
Home visit														
Respiratory sample		(optional)												
Serum sample														
Other specimens sampling (if relevant)	(optional)	(optional)												(optional)

Legend:
Blue boxes indicate activities which are needed for the study
Green boxes indicate where additional specimens could be collected above the minimum specimen requirements of this study to increase information available.

2.7 Specimen transport

All those involved in collection and transporting specimens should be trained in safe handling practices and spill decontamination procedures. or details regarding the transport of samples collected and infection control advice, please refer to case management algorithm and laboratory guidance in the country or WHO laboratory guidance, available on the WHO website.

For each biological sample collected, the time of collection, the conditions for transportation and the time of arrival at the study laboratory will be recorded. Specimens should reach the laboratory as soon as possible after collection. If the specimen is not likely to reach the laboratory within 72 hours, specimens should be frozen, preferably at -80°C, and shipped on dry ice. It is, however, important to avoid repeated freezing and thawing of specimens. The storage of respiratory and serum specimens in domestic frost-free freezers should be avoided, owing to their wide temperature fluctuations. Serum should be separated from whole blood and can be stored and shipped at 4°C or frozen to -20°C or lower and shipped on dry ice.

Transport of specimens within national borders should comply with applicable national regulations. International transport of specimens should follow applicable international regulations as described in the WHO Guidance on Regulations for the Transport of Infectious Substances 2019- 2020.

2.8 Ethical considerations

Ethical requirements will vary by country. In some countries, this investigation may fall under public health surveillance (emergency response) acts and may not require ethical approval from an Institutional Review Board.

2.9.1 Informed consent and assent

The purpose of the investigation will be explained to all known contacts of a confirmed 2019-nCoV infected patient. Informed consent will be obtained from all cases and contacts willing to participate in the investigation before any procedure is performed as part of the investigation by a trained member of the investigation team. Consent for children under the legal age of consent will be obtained from a parent or legal guardian. Each participant must be informed that participation in the investigation is voluntary and that s/he is free to withdraw, without justification, from the investigation at any time without consequences and without affecting professional responsibilities.

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

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

2.9.2 Risks and benefits for subjects

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

2.9.3 Confidentiality

Participant confidentiality will be maintained throughout the investigation. All subjects who participate in the investigation will be assigned a study identification number by the investigation team for the labelling of questionnaires and clinical specimens. The link of this identification number

to individuals will be maintained by the investigation team and the Ministry of Health (or equivalent) and will not be disclosed elsewhere.
If the data is shared by the implementing organization to WHO or any agency or institution providing support for data analysis, data shared will include only the study identification number and not any personably identifiable information.

Article 45 of the IHR (2005) describes the "treatment of personal data".[11] Person identifiable data collected under the IHR should be kept confidential and processed anonymously, as required by national law. However, such data may be disclosed for assessments and management of public health risks, provided the data are processed fairly and lawfully.

2.9.4 Terms of use: Go.Data

If groups implementing the investigation opt to use open-source Go.Data as a tool to run this investigation, the Go.Data server can be hosted either on a server within the country or at WHO. The group implementing the study will need to consider the best approach for the investigation setting. If the Go.Data server is to be based at WHO, access to the Go.Data application on this server will be restricted to users who have valid login credentials for the Go.Data application. Please see Appendix for Go.Data term of use

2.9.5 Prevention of 2019-nCoV infection in investigation personnel

All personnel involved in the investigation need to be trained in infection prevention and control procedures (standard contact, droplet or airborne precautions, as determined by national or local guidelines). These procedures should include proper hand hygiene and the correct use of surgical or respiratory face masks, if necessary, not only to minimize their own risk of infection when in close contact with 2019-nCoV infected patients, but also to minimize the risk of spread among contacts of 2019-nCoV infected patients.

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

3 Laboratory evaluations

COMMENT: laboratory testing guidance is subject to change depending on the context of the specific evolution of the epidemic.

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

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

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

4 Statistical analyses

4.1 Statistical considerations

FFX investigation will be not be able to answer every question we have about 2019-nCoV infection, but it will contribute key data in the early stages of an outbreak which can inform public health interventions. Other protocols for investigations adapted for 2019-nCoV can assist in providing supplementary data to help with the calculation of key epidemiological parameters. All WHO protocols for 2019-nCoV are available on the WHO website.

The combination of epidemiological, virological (genomic, antigenic and serological) data can provide unparalleled early situational awareness of the pandemic, which will promote a proportionate and targeted public health response.

A descriptive analysis of the FFX should provide preliminary insight into the clinical spectrum and course of disease due to 2019-nCoV infection from individual cases; the initial population groups most affected initially with symptomatic confirmed infection, by age, and underlying risk factors for example.

Genomic analysis of the specimens generated though this study can help provide a detailed insight into the origin of the pandemic, monitor the potential spread of antiviral resistance mutation and identify transmission chains using the confirmed case as a potential origin (by comparing the relatedness of two virus isolates), which in turn helps to estimate the reproductive number. The latter can be incredibly useful to determine the extent of community transmission that is occurring in the early stages of the pandemic and if the strain was locally acquired or imported from another region.

4.2 Sample size

The sample size of Country X will be determined by the number of contacts within each social sphere of the confirmed 2019-nCoV infected individual and assumptions made relating to the transmissibility of the 2019-nCoV. Every effort should be made to include all contacts of the confirmed 2019-nCoV infected individual to maximize the statistical power of the investigation. In 2009, many countries used a sample size of 300-400 cases using different power and attack rates for their calculations.

4.3 Epidemiological parameters

The table below outlines the **epidemiological parameters** that are desirable to be calculated during a pandemic using the FFX forms/questionnaires and specimens generated. The table includes a comments/limitations section, which provides gives insight into the strengths and weaknesses of this protocol.

Parameter	**Definition** (*in bracket*: "simplified" expression of it)	**FFX's form and questions where to get the data to calculate the parameters concerned**	**Comments, limitations**
Course of disease (time, person and place)	A description of the distribution of cases by time, person and place	Demography Date of laboratory confirmation Location Form A0: Q3, Q4 Form A1: Q5, Q7, Q13 Form A2: not applicable Form B1: Q3, Q4, Q6 Form B2: Q3, Q4, Q7	-Location will need to be supplemented by notification data to recognize geospatial trends

Heath care seeking behaviors	To determine the proportion of people who sought healthcare (not necessarily just hospitalization)	Form A0: Q6 Form A1: Q7, Q8, Q11, Q12 Form A2: Q3, Q5 Form B1: Q7 Form B2:	
Symptomatic proportion of cases, and asymptomatic fraction	The proportion of cases who show symptoms or signs of 2019-nCoV infection or The proportion of cases who do not show symptoms or signs of 2019-nCoV infection	Laboratory confirmation and symptoms Form A0: Q4 Form A1: Q7, Q13 Form A2: Q4, Q9 Form B1: Q6 Form B2: Q4, Q6, Q7	-Through contact tracing and laboratory testing
Hospitalization rate or incident hospitalizations	A measure of the frequency of hospitalized cases of 2019-nCoV among the confirmed cases in a defined period of time.	Hospitalization data and complications Form A0: Q5, Q6 Form A1: Q6, Q7, Q8, Q11, Q12 Form A2: Q5 Form B1: Q7 Form B2:	
Secondary clinical attack rate	The number of cases of 2019-nCoV infection that occur amongst contacts within the incubation period (range) following exposure to a primary case in relation to the total number of exposed contacts; the denominator is restricted to susceptible contacts when these can be determined *(The rate of clinical manifestation in close contacts)* It is a good measure of person-to-person spread of disease after the disease has been introduced into a population	Symptoms and dates of contact with confirmed cases Form A0: Form A1: Form A2: Form B1: Q4, Q6 Form B2: Q4	-Note that early estimates are likely to be biased due to some cases being able to more successfully produce secondary cases -Note that these estimates will be specific to setting and contact type
Secondary infection rate (also called secondary infection incidence)	A measure of the frequency of new cases of 2019-nCoV) among the close contacts of confirmed cases in a defined period of time, as determined by a positive 2019-nCoV result. *(The rate of contacts being infected.* *Assessed through serological assays/PCR on paired samples)* It is a good measure of person-to-person spread of the infection after the infection has been introduced into a population	Laboratory confirmation (serology and/or virology testing (ex.PCR) Form A0: Form A1: Form A2: Form B1: Q9 Form B2: Q7	
Case hospitalization ratio	Case hospitalization ratio (CHR**)** is defined as the proportion of those affected (with symptoms) that are admitted to hospital compared to cases who do not require hospitalization *(Proportion of cases who require hospitalization)*	Hospitalization data and complications Form A0: Q5, Q6 Form A1: Q6, Q7, Q8, Q11, Q12 Form A2: Q5 Form B1: Q7 Form B2:	-Note that initial cases being recruited are likely to be more severe and so this may be biased due to such recruitment. Secondary cases may be more representative of "typical" infections
Clinical presentation	The range of clinical symptoms in cases and contacts. *(Clinical symptoms and severity)*	Symptoms Form A0: Q4, Q5 Form A1: Q7, Q8 Form A2: Q4, Q5 Form B1: Q6 Form B2: Q4	-In-hospital clinical studies will enhance understanding of clinical course, severity and risk determinants, as well as case fatality
Clinical risk factors, especially for critical illness	Underlying clinical conditions and comorbidities	Co-morbidities and pre-existing medical conditions Form A0: Form A1: Q9 Form A2: Q6	-For estimating risk factors for severe disease, we may need something like a hospitalization case-

		Form B1: Q8 Form B2:	control study to do so accurately
Serological response to infection	Change in serum level of specific antibodies to 2019-nCoV *(Increase in titre*)	Laboratory results Form A0: Form A1: Q13 Form A2: Q9 Form B1: Q6 Form B2: Q7	-This will only be able to be calculated with the addition of laboratory data -Will be supplemented by findings of clinical studies and first few outbreak investigations to confirm that seroconversion following an infection is anticipated
Incubation period	The time period between exposure to 2019-nCoV and the appearance of the first sign or symptom of the disease *(from infection to disease)*	Date of onset of symptoms and dates of contact with confirmed case. Form A0: Q4, Q6, Q7 (optional) Form A1: Q7 Form A2: Form B1: Q4, Q5, Q6 Form B2: Q3, Q4	
Serial interval distribution	The time between onset of symptoms in the case to onset of symptoms in the close contact (*from clinical onset to clinical onset*)	Symptoms and dates Form A0: Q4 Form A1: Q7 Form A2: Q4 Form B1: Q6 Form B2: Q4	-Will be greatly enhanced by information from first few outbreaks where transmission chains may be more identifiable and prolonged
Generation time distribution	Time between infection in the case and infection in the close contact (*from infection to infection*)	Specimens and dates Form A0: Form A1: Q13 Form A2: Q9 Form B1: Q4 Form B2: Q7	-Will be greatly enhanced by information from first few outbreaks where transmission chains may be more identifiable and prolonged
Case fatality ratio	The number of deaths causes by 2019-nCoV in cases compared to the total number of cases with 2019-nCoV (*Proportion of 2019-nCoV cases who die*)	Death/alive status and case confirmation Form A0: Q1, Form A1: Q1, Q8, Q13 Form A2: Q3. Q9 Form B1: Q7 Form B2: Q6, Q7	-Will likely need a large number of cases before we see a significant number of deaths to have reliable estimates through the FFX (also follow-up may end before we can observe deaths due to secondary infections) -More likely to be overestimate in FFX due to reporting/selection bias of the initial cases
Population groups most at risk	Determining the groups who are most vulnerable to infection with 2019-nCoV (e.g. age groups, gender, occupation)	Demographic data Form A0: Q3, Q6, Q7 (optional) Form A1: Q5, Q12 Form A2: Form B1: Q3, Q4, Q5 Form B2:	-Risk groups might not show up in FFX, for example the UK Pandemic influenza FFX in 2009 only had 4 pregnant women in the 392 cases followed up. -May only be an early signal, other sources of information will need to be used to inform decision making (line listing of cases and other clinical case series)
Genomic data, including		Laboratory data Form A0:	-An alternate means to estimate the reproduction number,

phylogenetic analysis		Form A1: Q13 Form A2: Q9 Form B1: Form B2: Q7	from comparing the relatedness of strains between cases and their close contacts and confirming transmission between individuals -May supplement other transmission data to inform transmission parameter estimates, although likely to be delayed beyond the initial public health response phase.
Basic reproduction number ($R_{0)}$	A measure of the number of infections produced, on average, by an infected individual in the early stages of the epidemic, when virtually all contacts are susceptible. Note we can assume that there will be very little to no immunity to a 2019-nCoV. (*average number of infections/disease arising from one infection*) Reminder: Basic reproductive ratio (R0) – everyone is susceptible and there is no control, maximum value that R can take is equal to the transmission potential.	Laboratory data, dates of contact, symptoms in contacts Form A0: Form A1: Q13 Form A2: Q9 Form B1: Q4, Q5, Q6 Form B2: Q3, Q4, Q7	-Can be calculated using different approaches; identifying clusters and cluster size (using epi methods and potentially genetic information to identify how many secondary cases are occurring), and using the epidemic curve and how steep it is -R can be calculated using multiple sources of information incident case notifications, incident hospitalizations by age (as a potentially more stable alternative) or genomic data, all of which will be taken together as an estimate of transmissibility.
Reproductive ratio (R)	Ever-changing quantity of the amount of secondary cases produced by a primary case across time and space (i.e. context-specific)	Laboratory data, dates of contact, symptoms in contacts Form A0: Form A1: Q13 Form A2: Q9 Form B1: Q4, Q5, Q6 Form B2: Q3, Q4, Q7	-Not the main aim of FFX in the early stage, but if the investigation is continued and transformed into a "cohort" study we may be able to calculate it.

5 Reporting of findings

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

(1) the number of cases, the number of close contacts included;
(2) the number of PCR-confirmed 2019-nCoV cases among the close contacts;
(3) the number of symptomatic and asymptomatic close contacts;
(4) the number of close contacts with serologic evidence of 2019-nCoV infection. If sample size permits, these numbers should be stratified by age.

The timely dissemination of the results of this study are critical to understanding the transmission of new pandemic virus, in order to update guidance and inform national and international public health responses and infection prevention and control policies

It is also important to fully document the study design, including the definition of close contacts, the approach to ascertainment of primary cases and secondary cases, the duration of follow-up, and the laboratory methods used to ensure that data can be pooled to increase power in estimating epidemiological parameters.

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

If the data is shared by the implementing organization to WHO or any agency or institution providing support for data analysis, data shared will include only the study identification number and not any personably identifiable information.

6 References

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

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

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

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

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

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

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Appendix A : Questionnaires and guidance

The First Few X (FFX): Cases and contact investigation protocol for 2019-novel coronavirus (2019-nCoV) infection

Form A0: Minimum data reporting form – for suspected and probable cases
Form A1: Case initial report form – for confirmed cases (Day 1)
Form A2: Case follow-up form – for confirmed cases (Day 14-21)

Form B1: Contact initial reporting form – for close contacts (Day 1)
Form B2: Contact follow-up reporting form – for close contacts (Day 14-21)

The First Few X (FFX): Cases and contact investigation protocol for 2019-nCoV

For cases

Form A0: Minimum data reporting form – for suspected and probable cases

Unique Case ID / Cluster Number (if applicable):

1. Current Status
□ Alive □ Dead

2. Data Collector Information	
Name of data collector	
Data collector Institution	
Data collector telephone number	
Email	
Form completion date (dd/mm/yyyy)	___/___/___

3a. Case Identifier Information	
Given name(s)	
Family name	
Sex	□ Male □ Female □ Not known
Date of Birth (dd/mm/yyyy)	___/___/___ □ Unknown
Telephone (mobile) number	
Age (years, months)	___ years ___ months □ Unknown
Email	
Address	
National social number/ identifier (if applicable)	
Country of residence	
Case status	□ Suspected □ Probable □ Confirmed
3b. Interview respondent information (if the persons providing the information is not the patient)	
First name	
Surname	
Sex	□ Male □ Female □ Not known
Date of Birth (dd/mm/yyyy)	___/___/___
Relationship to patient	
Respondent address	
Telephone (mobile) number	

4. Patient symptoms (from disease onset)	
Date of first symptom onset (dd/mm/yyyy)	___/___/___ □ No symptoms □ Unknown
Fever (≥38 °C) or history of fever	□ Yes □ No □ Unknown
Sore throat	□ Yes □ No □ Unknown
Runny nose	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown
Shortness of Breath	□ Yes □ No □ Unknown

5. Initial respiratory sample collection	
Date respiratory sample collected (dd/mm/yyyy)	___/___/___ □ NA
What type of respiratory sample was collected?	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Other, specify
Has baseline serum been taken?	□ Yes □ No □ Unknown If yes, date baseline serum taken (dd/mm/yyyy) ___/___/___
Were other samples collected?	□ Yes □ No □ Unknown If yes, which samples: If yes, date baseline serum taken (dd/mm/yyyy) ___/___/___

6. Clinical Course: Complications	
Hospitalization required?	□ Yes □ No □ Unknown If yes, name of hospital
ICU (Intensive Care Unit) admission required	□ Yes □ No □ Unknown
Acute Respiratory Distress Syndrome (ARDS)	□ Yes □ No □ Unknown
Pneumonia by chest X-ray	□ Yes □ No □ Not applicable (no X-ray performed) □ Date ___/___/___
Other severe or life threatening illness suggesting of an infective process	□ Yes □ No □ Unknown If yes, specify:
Mechanical ventilation required	□ Yes □ No □ Unknown
Extracorporeal membrane oxygenation (EMO)	□ Yes □ No □ Unknown

7. Human exposures in the 14 days before illness onset	
Have you travelled within the last 14 days domestically?	□ Yes □ No □ Unknown If Yes, dates of travel (DD/MM/YYYY): ___/___/___ to ___/___/___ Regions: Cities visited:
Have you travelled within the last 14 days internationally?	□ Yes □ No □ Unknown If Yes, dates of travel (DD/MM/YYYY): ___/___/___ to ___/___/___ Countries visited:

	Cities visited:
In the past 14 days, have you had contact with a anyone with suspected or confirmed 2019-nCoV infection?	□ Yes □ No □ Unknown If Yes, dates of last contact (DD/MM/YYYY): ___/___/___
Patient attended festival or mass gathering	□ Yes □ No □ Unknown If yes, specify:
Patient exposed to person with similar illness	□ Yes □ No □ Unknown
Location of exposure	□ Home □ Hospital □ Workplace □ Tour group □ Unknown □ Other, specify:
Patient visited or was admitted to inpatient health facility	□ Yes □ No □ Unknown If yes, specify:
Patient visited outpatient treatment facility	□ Yes □ No □ Unknown If yes, specify:
Patient visited traditional healer	□ Yes □ No □ Unknown If yes, specify type:
Patient occupation (specify location/facility)	□ Health care worker □ Working with animals □ Health laboratory worker □ Student □ Other, specify: For each occupation, please specify location or facility:_____

8. Status of form completion	
Form completed	□ Yes □ No or partially If no or partially, reason : □ Missed □ Not attempted □ Not performed □ Refusal □ Other, specific:

ADDITIONNAL INFORMATION TO COLLECT (only relevant for cases in China

8. Human exposures to animals in the 14 days before illness onset		
A	Patient handled animals	□ Yes □ No □ Unknown If no or unknown, skip to F
B	Types of animals handled (e.g. pigs, chicken, ducks or others)	Specify:
C	Nature of contact (e.g. feed, groom or slaughter, specify)	Specify:
D	Location of animal contact	□ Home □ Workplace □ Hospital □ Tour group □ Other, specify:

E	Within 2 weeks before or after contact, any animals sick or dead?	□ Yes □ No □ Unknown If yes specify type and number, and proportion from flock or herd:
F	Patient exposed to animals in the environment but did not handle them (e.g. in neighborhood, farm, zoo, at home, agricultural fair or work)	□ Yes □ No □ Unknown If yes specify, otherwise skip to J
G	Types of animals in that environment	Specify:
H	Location of exposure	□ Home □ Neighborhood □ Market □ Agricultural fair/ zoo group □ Farm □ Other, specify
I	Within 2 weeks before or after exposure, any animals sick or dead?	□ Yes □ No □ Unknown If yes specify type and number, and proportion from flock or herd:
J	Patient exposed to animal by-products (e.g. bird feathers) or animal excreta	□ Yes □ No □ Unknown If yes, specify:
K	Patient visited live animal market	□ Yes □ No □ Unknown If yes, specify:

The First Few X (FFX): Cases and contact investigation protocol for 2019-novel coronavirus (2019-nCoV) infection

Form A1: Case initial report form – for confirmed cases (Day 1)

COMMENT: Information in this form may already have been completed in the Case Minimum Data Reporting Form (Form A0). It is therefore not necessary to repeat any data in these sections that has already been completed.

Unique Case ID / Cluster Number (if applicable):

1. Current Status
□ Alive □ Dead
2. Further case classification
□ Primary □ Secondary □ Imported

3. Data Collector Information	
Name of data collector	
Data collector Institution	
Data collector telephone number	
Email	
Form completion date (dd/mm/yyyy)	___/___/___

4. Interview respondent information (if the persons providing the information is not the patient)	
First name	
Surname	
Sex	□ Male □ Female □ Not known
Date of Birth (dd/mm/yyyy)	___/___/___
Relationship to patient	
Respondent address	
Telephone (mobile) number	

5. Patient Identifier Information	
First name	
Surname	
Sex	□ Male □ Female □ Not known
Date of Birth (dd/mm/yyyy)	___/___/___
Telephone (mobile) number	
Age (years, months)	
Email	
Address	
National social number/ identifier (if applicable)	
Country of residence	
Nationality	
Ethnicity (optional)	

Responsible Health Centre	
Nursery/School/College if appropriate	

6. Health care center/ treating physicians details	
Name	
Practice name	
Is this case part of an institutional outbreak?	□ Yes □ No □ Unknown If yes, specify:
Telephone number	
Fax	
Address	

7a. Patient symptoms from onset of symptoms	
Date of first symptom onset (dd/mm/yyyy)	___/___/___ □ Asymptomatic □ Unknown
Fever (≥38 °C) or history of fever	□ Yes □ No □ Unknown If yes, specify maximum temperature:
Date of first health facility visit (including traditional care) (dd/mm/yyyy)	___/___/___ □ NA □ Unknown
Total health facilities visited to date	□ NA □ Unknown Specify:
7b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy): ___/___/___
Cough	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy): ___/___/___
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy): ___/___/___

7c. Other symptoms	
Chills	□ Yes □ No □ Unknown
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhea	□ Yes □ No □ Unknown
Headache	□ Yes □ No □ Unknown
Rash	□ Yes □ No □ Unknown
Conjunctivitis	□ Yes □ No □ Unknown
Muscle aches	□ Yes □ No □ Unknown
Joint ache	□ Yes □ No □ Unknown
Loss of appetite	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Neurological signs	□ Yes □ No □ Unknown

If Yes, specify	
Other symptoms	□ Yes □ No □ Unknown If yes, specify:

8. Patient symptoms: Complications	
Hospitalization	□ Yes □ No □ Unknown
Date of first hospitalization	___/___/___ □ Unknown
ICU (Intensive Care Unit) Admission	□ Yes □ No □ Unknown
Date of ICU admission (dd/mm/yyyy)	___/___/___ □ Unknown
Date of discharge from ICU (dd/mm/yyyy)	___/___/___ □ Unknown □ NA
Mechanical ventilation	□ Yes □ No □ Unknown
Dates of mechanical ventilation (dd/mm/yyyy)	Start:___/___/___ Stop: ___/___/___ □ Unknown □ NA
Length of ventilation (days)	
Acute Respiratory Distress Syndrome (ARDS)	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Acute renal failure	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Cardiac failure	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Consumptive coagulopathy	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Pneumonia by chest X-ray	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy) ___/___/___
Other symptoms	□ Yes □ No □ Unknown If yes, specify:
Extracorporeal membrane oxygenation (EMO) required	□ Yes □ No □ Unknown
Hypotension requiring vasopressors	□ Yes □ No □ Unknown
Date of discharge from hospital (if applicable) (dd/mm/yyyy)	___/___/___
Outcome	□ Alive □ Died □ NA □ Unknown
Outcome current as of date (dd/mm/yyyy)	___/___/___ □ Unknown □ NA

9. Patient pre-existing condition(s)	
Obesity	□ Yes □ No □ Unknown
Cancer	□ Yes □ No □ Unknown
Diabetes	□ Yes □ No □ Unknown
HIV/other immune deficiency	□ Yes □ No □ Unknown
Heart disease	□ Yes □ No □ Unknown
Asthma (requiring medication)	□ Yes □ No □ Unknown
Chronic lung disease (non-asthma)	□ Yes □ No □ Unknown
Chronic liver disease	□ Yes □ No □ Unknown

Chronic haematological disorder	□ Yes □ No □ Unknown
Pregnancy	□ Yes □ No □ Unknown If yes, specify trimester: □ First □ Second □ Third □ NA Estimated delivery date (dd/mm/yyyy) ___/___/___
Chronic kidney disease	□ Yes □ No □ Unknown
Chronic neurological impairment/disease	□ Yes □ No □ Unknown
Organ or bone narrow recipient	□ Yes □ No □ Unknown
Other pre-existing condition(s)	□ Yes □ No □ Unknown If yes, specify:

10. Health care interactions	
Contact with emergency number	□ Yes □ No □ Unknown
Date of emergency contact (dd/mm/yyyy)	___/___/___ □ Unknown
Visit to primary health care PHC (GP, etc) (repeat for as many visits as required)	□ Yes □ No □ Unknown
Date of first PHC contact (dd/mm/yyyy)	___/___/___ □ Unknown □ NA
Visited Emergency Department (A&E) (repeat for as many contacts as required)	□ Yes □ No □ Unknown
Date of first A&E contact (dd/mm/yyyy)	___/___/___ □ Unknown □ NA
Hospitalisation (repeat for as many admissions as required)	□ Yes □ No □ Unknown Skip rest of form 11 if no
Date of first admission to hospital (dd/mm/yyyy)	___/___/___ □ Unknown □ NA
Name and place of first hospital	

11. Human exposures in the 14 days before illness onset	
Have you travelled within the last 14 days domestically?	□ Yes □ No □ Unknown If Yes, dates of travel (DD/MM/YYYY): ___/___/___ to ___/___/___ Regions: Cities visited:
Have you travelled within the last 14 days internationally?	□ Yes □ No □ Unknown If Yes, dates of travel (DD/MM/YYYY): ___/___/___ to ___/___/___ Countries visited: Cities visited:
In the past 14 days, have you had contact with a anyone with suspected or confirmed 2019-nCoV infection?	□ Yes □ No □ Unknown If Yes, dates of last contact (DD/MM/YYYY): ___/___/___

Form A1: Case initial report form – for confirmed cases (Day 1)

Patient attended festival or mass gathering	□ Yes □ No □ Unknown If yes, specify:
Patient exposed to person with similar illness	□ Yes □ No □ Unknown
Location of exposure	□ Home □ Hospital □ Workplace □ Tour group □ School □ Unknown □ Other, specify:
Patient visited or was admitted to inpatient health facility	□ Yes □ No □ Unknown If yes, specify:
Patient visited outpatient treatment facility	□ Yes □ No □ Unknown If yes, specify:
Patient visited traditional healer	□ Yes □ No □ Unknown If yes, specify type:
Patient occupation (specify location/facility)	□ Health care worker □ Working with animals □ Health laboratory worker □ Student □ Other, specify: For each occupation, please specify location or facility:_____

12a. Molecular testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Type of test**	**Result**	**Result Date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Others, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for 2019-nCoV □ NEGATIVE for 2019-nCoV □ POSITIVE for others pathogens Please specify which pathogens: ….	___/___/___	□ Yes If yes, specify Date ___/___/___ □ No

12b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Result date (dd/mm/yyyy)**	**Type of test**	**Result (**2019-nCoV antibody titres)	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Others, specify:	___/___/___	Specify type (ELISA / IFA IgM/ IgG, Neutralization assay, etc): ___	□ POSITIVE If positive, titre : ___ □ NEGATIVE □ INCONCLUSIVE	□ Yes If yes, specify Date ___/___/___ □ No

13. Status of form completion	
Form completed	□ Yes □ No or partially If no or partially, reason : □ Missed □ Not attempted □ Not performed □ Refusal □ Other, specific:

The First Few X (FFX): Cases and contact investigation protocol for 2019-nCoV

Form A2: Case follow-up form – for confirmed cases (Day 14-21)

COMMENT: Information in this form may already have been completed in the Case Minimum Data Reporting Form (Form A1). It is therefore not necessary to repeat any data in these sections that has already been completed

Unique Case ID / Cluster Number (if applicable):

1. Data Collector Information	
Name of data collector	
Data collector Institution	
Data collector telephone number	
Email	
Form completion date (dd/mm/yyyy)	___/___/___

2. Interview respondent information (if different from initial interview)	
First name	
Surname	
Sex	□ Male □ Female □ Not known
Date of Birth (dd/mm/yyyy)	___/___/___
Relationship to patient	
Respondent address	
Telephone (mobile) number	

3. Outcome/status	
Status	□ Recovered, if yes specify date symptoms resolved ___/___/___ □ Still ill □ Dead, if yes specify date of death ___/___/___
Hospitalization ever required?	□ Yes □ No □ Not Unknown
If dead (NB. If this information is not currently available, please leave blank and send through an update as soon as results are available) Contribution of 2019-nCoV to death: Was a port-mortem performed? Cause of death on Death certificate (specify) Results of post-mortem's report where available	 □ Underlying/primary □ Contributing/secondary □ No contribution to death □ Unknown □ Yes □ No □ Unknown

Form A2: Case follow-up form – for confirmed cases (Day 14-21)

4. Patient symptoms during the entirety of illness	
Maximum Temperature (specify)	, □ NA
4b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy) ___/___/___
Cough	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy) ___/___/___
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy) ___/___/___
4c. Other symptoms	
Chills	□ Yes □ No □ Unknown
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhoea	□ Yes □ No □ Unknown
Headache	□ Yes □ No □ Unknown
Rash	□ Yes □ No □ Unknown
Conjunctivitis	□ Yes □ No □ Unknown
Muscle aches	□ Yes □ No □ Unknown
Joint ache	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Loss of appetite	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Neurological signs If Yes, specify	□ Yes □ No □ Unknown
Other symptoms	□ Yes □ No □ Unknown If yes, specify:

5. Patient symptoms: Complications	
Hospitalization	□ Yes □ No □ Unknown
Date of first hospitalization	___/___/___ □ Unknown
ICU (Intensive Care Unit) Admission	□ Yes □ No □ Unknown
ICU admission	___/___/___ □ Unknown
Date of discharge from ICU	___/___/___ □ Unknown □ NA
Mechanical ventilation	□ Yes □ No □ Unknown
Dates of mechanical ventilation (dd/mm/yyyy)	Start___/___/___ Stop___/___/___

	□ Unknown □ NA
Length of ventilation (days)	
Acute Respiratory Distress Syndrome (ADRS)	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Acute renal failure	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Cardiac failure	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Consumptive coagulopathy	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Pneumonia by chest X-ray	□ Yes □ No □ Unknown If yes, date started (dd/mm/yyyy)___/___/___
Hypotension requiring vasopressors	□ Yes □ No □ Unknown
Other symptoms	□ Yes □ No □ Unknown If yes, specify:
Extracorporeal membrane oxygenation (EMO) required	□ Yes □ No □ Unknown

6. Patient pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If yes, specify trimester: □ First □ Second □ Third □ NA

7. Secondary bacterial infection		
Date of sample	**Site:**	**Positive results**
/ /	□ Sputum □ Endotracheal aspirate □ Pleural fluid □ CSF □ Blood □Urine □ Other, please specify:	□ *Haemophilus influenza* □ MRSA □ *Staphylococcus aureus* □ *Streptococcus pneumoniae* □ E.coli □ Other organism, please specify:
/ /	□ Sputum □ Endotracheal aspirate □ Pleural fluid □ CSF □ Blood □Urine □ Other, specify:	□ *Haemophilus influenza* □ MRSA □ *Staphylococcus aureus* □ *Streptococcus pneumoniae* □ E.coli □ Other organism, please specify:

8a. Virology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Type of test**	**Result**	**Result Date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Others, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for 2019-nCoV □ NEGATIVE for 2019-nCoV □ POSITIVE for others pathogens Please specify which pathogens: ….	___/___/___	□ Yes If yes, specify Date ___/___/___ □ No

8b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Result date (dd/mm/yyyy)**	**Type of test**	**Result (**2019-nCoV antibody titres)	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Others, specify:	___/___/___	Specify type (ELISA / IFA IgM/ IgG, Neutralization assay, etc): ___	□ POSITIVE If positive, titre : ___ □ NEGATIVE □ INCONCLUSIVE	□ Yes If yes, specify Date ___/___/___ □ No

9. Status of form completion	
Form completed	□ Yes □ No or partially If no or partially, reason : □ Missed □ Not attempted □ Not performed □ Refusal □ Other, specific:

The First Few X (FFX): Cases and contact investigation protocol for 2019-nCoV

For close contacts

Form B1: Contact initial reporting form – for close contacts (Day 1)

Confirmed Case ID / Cluster Number (if applicable):

Contact ID Number (C…):
Note: Contact ID numbers should be issued at the time of completion of Form A1.

Name of confirmed case

1. Data Collector Information	
Name of data collector	
Data collector Institution	
Phone number	
Email	
Form completion date (dd/mm/yyyy)	___/___/___

2. Interview respondent information (if the persons providing the information is not the contact)	
First name	
Surname	
Sex	□ Male □ Female □ Not known
Date of Birth	___/___/___
Relationship to patient	
Respondent address	
Telephone (mobile) number	

3. Contact Details (Details of the contact)	
Given name(s)	
Family name	
Sex	□ Male □ Female □ Not known
Date of Birth	___/___/___
Relationship to case	
Address (village/town, district, province/region)	
Telephone number	
Email address	
Preferred mode of contact	□ Mobile □ Work □ Home □ Email
Nationality	
Country of residence	
National social number/ identifier (optional)	
Have you travelled within the last 14 days domestically?	□ Yes □ No □ Unknown

Form B1: : Contact initial reporting form – for close contacts (Day 1)

	If Yes, dates of travel (DD/MM/YYYY): ___/___/___ to ___/___/___ Regions: Cities visited:
Have you travelled within the last 14 days internationally?	□ Yes □ No □ Unknown If Yes, dates of travel (DD/MM/YYYY): ___/___/___ to ___/___/___ Countries visited: Cities visited:
In the past 14 days, have you had contact with a anyone with suspected or confirmed 2019-nCoV infection?	□ Yes □ No □ Unknown If Yes, dates of last contact (DD/MM/YYYY): ___/___/___
Occupation (specify location/facility)	□ Health care worker □ Working with animals □ Health laboratory worker □ Student □ Other, specify: For each occupation, please specify location or facility:_____

Complete Section 4 if the contact is NOT a Health care worker**.**

Complete Section 5 if the contact is a Health care worker**.**

4. Exposure Information (Non-Health care workers)			
Type of contact	□ Household □ Health care worker □ Other, specify:		
State dates of contact and duration of contact with the confirmed case from first contact. while the primary case was symptomatic (Add as required)	Date	(dd/mm/yyyy)	
	Duration	(mins)	
	Setting	□ Home/ household □ Hospital / health care □ Workplace □ Tour group □ Other, specify:	

5 Exposure Information (Health care workers)	
Job title (specify)	
Place of work	
Direct physical contact with the confirmed case (e.g. Hands-on physical contact)	□ Yes □ No
What type of protective equipment was used by the health care worker?	□ Gown □ Surgical/medical mask □ Gloves □ NIOSH-CERTIFIED N95, AN EU STANDARD FFP2 □ FFP3 □ Eye protection

Form B1: : Contact initial reporting form – for close contacts (Day 1)

Was the contact present while any aerosol generating procedures took place? If yes, specify procedure and date	□ Yes □ No Procedure: ___/___/___ Procedure: ___/___/___
Was the contact wearing any type of a mask at this/these procedures?	□ Surgical/medical □ NIOSH-CERTIFIED N95, AN EU STANDARD FFP2 □ FFP3 □ None

6a. Symptoms in contact	
Has the contact experienced any respiratory symptoms (sore throat, cough, running nose, shortness of breath) in the period from 10 days before onset in the confirmed case until the present?	□ Yes □ No
Has the contact experienced any respiratory symptoms (sore throat, cough, running nose, shortness of breath) in the period up to 10 days after last contact or until the present date, whichever is the earliest?	□ Yes □ No
Currently ill	□ Yes □ No
Date and time of first symptom onset	___/___/___ □ AM □ PM
Maximum temperature	
6b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If yes, date ___/___/___
Cough	□ Yes □ No □ Unknown If yes, date ___/___/___
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown If yes, date ___/___/___
6c. other symptoms	
Chills	□ Yes □ No □ Unknown
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhoea	□ Yes □ No □ Unknown
Headache	□ Yes □ No □ Unknown
Rash	□ Yes □ No □ Unknown
Conjunctivitis	□ Yes □ No □ Unknown
Muscle aches	□ Yes □ No □ Unknown
Joint ache	□ Yes □ No □ Unknown
Loss of appetite	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Neurological signs If Yes, specify	□ Yes □ No □ Unknown
Other symptoms	□ Yes □ No □ Unknown If yes, specify:

7. Outcome/status of contact (Only complete if contact has been ill or is currently ill)	
Status	□ Recovered, if yes specify date symptoms resolved ___/___/___ □ Still ill □ Never ill □ Dead, if yes specify date of death ___/___/___

Hospitalization ever required?	□ Yes □ No □ Not Unknown If yes, date of hospitalization and date of discharge (dd/mm/yyyy) ___/___/___ - ___/___/___
If dead (NB. If this information is not currently available, please leave blank and send through an update as soon as results are available) Contribution of 2019-nCoV to death: Was a port-mortem performed? Cause of death on Death certificate (specify) Results of post-mortem report where available	 □ Underlying/primary □ Contributing/secondary □ No contribution to death □ Unknown □ Yes □ No □ Unknown

8. Contact pre-existing condition(s)	
Obesity	□ Yes □ No □ Unknown
Heart disease	□ Yes □ No □ Unknown
Asthma requiring medication	□ Yes □ No □ Unknown
Chronic lung disease (non-asthma)	□ Yes □ No □ Unknown
Chronic liver disease	□ Yes □ No □ Unknown
Chronic haematological disorder	□ Yes □ No □ Unknown
Pregnancy	Yes □ No □ Unknown □ First □ Second □ Third □ NA If yes, specify trimester: Estimated delivery date (dd/mm/yyyy) ___/___/___
Chronic kidney disease	□ Yes □ No □ Unknown
Chronic neurological impairment/disease	□ Yes □ No □ Unknown
Organ or bone narrow recipient	□ Yes □ No □ Unknown
Other pre-existing condition(s)	□ Yes □ No □ Unknown If yes, specify:
Comments if appropriate	

9a. Virology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Type of test**	**Result**	**Result Date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Others, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for 2019-nCoV □ NEGATIVE for 2019-nCoV □ POSITIVE for others pathogens Please specify which pathogens: ….	___/___/___	□ Yes If yes, specify Date ___/___/___ □ No

9b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Result date (dd/mm/yyyy)**	**Type of test**	**Result (**2019-nCoV antibody titres)	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Others, specify:	___/___/___	Specify type (ELISA / IFA IgM/ IgG, Neutralization assay, etc): ___	□ POSITIVE If positive, titre : ___ □ NEGATIVE □ INCONCLUSIVE	□ Yes If yes, specify Date ___/___/___ □ No

Form B1: : Contact initial reporting form – for close contacts (Day 1)

10. Status of form completion	
Form completed	□ Yes □ No or partially If no or partially, reason : □ Missed □ Not attempted □ Not performed □ Refusal □ Other, specific:

The First Few X (FFX): Cases and contact investigation protocol for 2019-nCoV

Form B2: Contact follow-up reporting form – for close contacts (Day 14-21)

COMMENT: Information in this form may already have been completed in the Case Minimum Data Reporting Form (Form B2). It is therefore not necessary to repeat any data in these sections that has already been completed.

Confirmed Case ID / Cluster Number (if applicable):

Contact ID Number (C…):

Name of confirmed case:

1. Data Collector Information	
Name of data collector	
Data collector Institution	
Phone number	
Email	
Form completion date (dd/mm/yyyy)	___/___/___

2. Interview respondent information (if the persons providing the information is not the contact)	
First name	
Surname	
Sex	□ Male □ Female □ Not known
Date of Birth (dd/mm/yyyy)	___/___/___
Relationship to patient	
Respondent address	
Telephone (mobile) number	

3. Exposure Information			
Type of contact	□ Household □ Health care worker □ Other, specify:		
State date(s) of contact and duration of contact with the confirmed case from first contact while the primary case was symptomatic (Add as many dates required)	Date	(dd/mm/yyyy)	___/___/___
	Duration	(mins)	
	Setting	□ Home/ household □ Hospital / health care □ Workplace □ Tour group □ Other, specify:	

4a. Symptoms in contact	
Has the contact experienced any respiratory symptoms (sore throat, cough, running nose, shortness of breath) in the period from 10 days before onset in the confirmed case until the present?	□ Yes □ No
Has the contact experienced any respiratory symptoms (sore throat, cough, running nose, shortness of breath) in the period up to 10 days after last contact or until the present date, whichever is the earliest?	□ Yes □ No
Currently ill	□ Yes □ No
Please only complete following section if contact has demonstrated symptoms since last follow up:	
Date and time of first symptom onset	___/___/___ □ AM □ PM
Maximum temperature	____^{o}C
Fever (>38^{o}C) or history of fever	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy - dd/mm/yyyy) ___/___/___ - ___/___/___
4b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy - dd/mm/yyyy) ___/___/___ - ___/___/___
Cough	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy - dd/mm/yyyy) ___/___/___ - ___/___/___
Runny nose	□ Yes □ No □ Unknown
Shortness of breath	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy - dd/mm/yyyy) ___/___/___ - ___/___/___
4c. other symptoms	
Chills	□ Yes □ No □ Unknown
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhea	□ Yes □ No □ Unknown
Headache	□ Yes □ No □ Unknown
Rash	□ Yes □ No □ Unknown
Conjunctivitis	□ Yes □ No □ Unknown
Muscle aches	□ Yes □ No □ Unknown
Joint ache	□ Yes □ No □ Unknown
Loss of appetite	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Neurological signs If Yes, specify	□ Yes □ No □ Unknown
Other symptoms	□ Yes □ No □ Unknown

	If yes, specify:

5. Patient pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If yes, specify trimester: □ First □ Second □ Third □ NA Estimated delivery date (dd/mm/yyyy) ___/___/___

6a. Virology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Type of test**	**Result**	**Result Date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Others, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for 2019-nCoV □ NEGATIVE for 2019-nCoV □ POSITIVE for others pathogens Please specify which pathogens: ….	___/___/___	□ Yes If yes, specify Date ___/___/___ □ No

7b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Lab identification number	**Date Sample collected (dd/mm/yyyy)**	**Date Sample Received (dd/mm/yyyy)**	**Type of Sample**	**Result date (dd/mm/yyyy)**	**Type of test**	**Result (**2019-nCoV antibody titres)	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Others, specify:	___/___/___	Specify type (ELISA / IFA IgM/ IgG, Neutralization assay, etc): ___	□ POSITIVE If positive, titre : ___ □ NEGATIVE □ INCONCLUSIVE	□ Yes If yes, specify Date ___/___/___ □ No

8. Final contact classification (at final follow-up)	
Please mark	□ Never ill/ not a case □ Confirmed secondary case □ Lost to follow-up □ Suspected case □ Probable case

9. Status of form completion	
Form completed	□ Yes □ No or partially If no or partially, reason : □ Missed □ Not attempted □ Not performed □ Refusal □ Other, specific:

The First Few X (FFX): Cases and contact investigation protocol for 2019-nCoV

FFX reporting forms: completion guidance

These notes are to provide guidance in 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) Form A0: Minimum data reporting form – for suspected and probable cases – This form should be completed predominately by the 'Case' reporter team.

Section	Sources	Verified against
Case Classification	Case Reporter	
Reporter Details	Case Reporter	
Informant Details	Informant	
Patient Details	Informant	
Physician Details	Informant	GP Database
Presenting illness	Informant	Healthcare provider/ review of medical records
Exposures in the 10 days before onset	Informant	
Medical History	Informant	Healthcare provider/GP/review of medical records
Hospitalization	Informant/Hospital	Hospital health information system
Test results	Testing laboratory	Lab database
Contact details	Informant	

b) Form A1: Case initial report form – for confirmed cases (Day 1) +
Form A2: Case follow-up form – for confirmed cases (Day 14-21). These forms should be completed by 'Case' reporter team Lab

Section	**Sources**	**Verified against**
Final case classification	Contact Reporter /Hospital	
Reporter details	Contact Reporter	
Informant details	Informant	
Outcome/Status	Informant	Statistical data, mortality, GP / hospital
Illness	Informant	Healthcare provider / review of medical records
Clinical Course/Complications	Informant / interview with healthcare provider	Review of medical records
Interaction with National security system	Informant / Hospital	National Social Health Information system
Reference Test Results	Testing laboratory	Lab database
Bacterial Infections	Testing laboratory	Lab database

c) **Form B1: Contact Initial Reporting Form – Contacts (Day 1) –** This form should be completed by the 'Contacts' reporter team and should be completed after the Initial Case Report form 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
Outcome/Status	Informant	Statistical data, mortality, GP / hospital
Case classification	Contact reporter	
Virological Tests	Testing laboratory	Lab database
Medical History	Informant	Healthcare provider / GP / review of medical records

d) **Form B2: Contact Follow-up reporting Form – Contacts (Day 14-21)** This form should be completed by the 'Contacts' reporter team

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	Review of medical records
Virological Tests	Testing laboratory	Lab database

Appendix B:

Comparison between the features and complementarity of the main 2019-novel coronavirus (2019-nCoV) early investigation protocols

	First Few X cases (FFX) Protocol	**Households transmission Protocol**	**HCW transmission protocol**
Population	First Few X number of confirmed cases and their close contacts	Household close contacts of confirmed cases (smaller epidemiological unit)	Closed setting close contacts of confirmed cases (larger epidemiological unit)
Aim	Transmission dynamics, severity, clinical spectrum, in a proxy of the general population	Transmission dynamics, severity, clinical spectrum, in household settings	Transmission dynamics, severity, clinical spectrum, in closed settings such as hospitals and health care centers
Design	Prospective case finding, and prospective follow-up of contact	Case-ascertained[12] prospective study, ideally before widespread community transmission occurs, within first 2-3 months after identification of initial cases.	Case-ascertained prospective study, at best before widespread community transmission occurs.
Potential output and analysis	Transmission dynamics, severity, clinical spectrum, through estimates of, primarily • clinical presentation and course of associated disease • Secondary infection rate (SIR) and clinical attack rate among close contacts • Serial interval • Symptomatic proportion (through contact tracing and	Provide key epidemiological data **to complement and reinforce findings of FFX** in the areas of: • Clinical risk factors • Clinical course of disease and severity • High-risk population subgroups • Geographical mapping of outbreaks • Health-care seeking patterns Generate epidemiological modeling parameters such as: • Reproduction numbers: R0 and R	

[12] Study participants and closed settings are identified from those with laboratory confirmed influenza infection, which is distinct from a closed setting cohort study in which a group of disease-free individuals in a closed setting are recruited and then followed over time.

	laboratory testing) • Identification of possible routes of transmission Secondarily: estimation of: • The basic reproductive number (R_0) • Incubation period • Preliminary infection and diseases-severity ratios (e.g. case-hospitalization and case-fatality ratios)	• Serial intervals specific to setting • Incubation period • Proportion of asymptomatic cases and symptomatic cases • Infection and clinical attack rates	
Start of the study	To be imitated in the first days after the arrival in Country x of 2019-nCoV FFX is the primary protocol to be initiated in the case of a 2019-nCoV outbreak upon identification of the initial laboratory-confirmed cases of 2019-nCoV virus in Country x in the early epidemic/pandemic phases.	Ideally before widespread community transmission occurs: as early as possible after first cases confirmed and at least within first 2-3 months after identification of initial cases Subsequent tracing of household contacts of early laboratory-confirmed cases of 2019-nCoV in Country x in the early epidemic/pandemic phases.	At best before widespread community transmission occurs: : as early as possible after first 2019-nCoV cases confirmed and at least within first 2-3 months after identification of initial cases Identification of HCW contacts of early laboratory-confirmed cases of 2019-nCoV in Country x in the early epidemic/pandemic phases.
Design	Retrospective or prospective case finding, and prospective follow-up of contact	Case-ascertained[13] prospective study	Case-ascertained prospective study ,
Duration	Participants- min 2 home visits within 14-21 days from enrolment (day 1) to final follow up	Households will complete a minimum of 4 home visits (if no self-sampling) within 28 days of enrolment/follow-up.	(text pending finalization of the protocol)

[13] Study participants and closed settings are identified from those with laboratory confirmed infection, which is distinct from a closed setting cohort study in which a group of disease-free individuals in a closed setting are recruited and then followed over time.

		Study enrolment could be extended as far as desired, however but the most valuable period in order to use data for targeted public health action is in the early phases of the epidemic/ pandemic (first 2-3 months).	
Recruitment	The first few confirmed cases of 2019-nCoV in Country x, and their close contacts will be first few participants to be recruited. To be noted: Previous FF100/FFX studies for Pandemic Influenza have recruited 300-400 cases along with their household contact.	Household contacts of primary cases with 2019-nCoV virus (laboratory confirmed).	(text pending finalization of the protocol)
Minimum information and specimens to be obtained from participants	Clinical history and assessment with collection of respiratory sample and serum. Detailed case follow-up with home visit. To be noted**:** Serum highly recommended to inform early seroepidemiological inferences, and respiratory (and other) to diagnose current 2019-nCoV infection. .	Household visit with respiratory sample collection of day 0/1; 7; 14;28. Serum sample collection highly encouraged at initiation and day 28 Symptom diaries record by household contacts from day 0-14 and highly encouraged till day 28. To be noted: Serum mandatory to inform early seroepidemiological inferences, and respiratory (and other) to diagnose current 2019-nCoV infection.	(text pending finalization of the protocol)

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