The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)

Version: 2
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World Health Organization

Summary: Several early epidemiological investigation protocols are available for countries (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations)

1. *The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19).* This is about dentification and tracing of cases and their close contacts in the general population, or restricted to close settings (like households, health-care settings, schools). FFX is the primary investigation protocol to be initiated upon identification of the initial laboratory-confirmed cases of COVID-19 in a country.

For a more targeted approach on specific groups and more precise estimation of epidemiological parameters, three other investigation protocols are available:
2. Household transmission investigation protocol for coronavirus disease 2019 (COVID-19) *(1)*
3. *Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health-care setting* *(2)*.
4. *Surface sampling of COVID-19 virus: a practical "how to" protocol for health-care and public health professionals* *(3)*.

Please contact earlyinvestigations-2019-nCoV@who.int for any questions.

Main updates for version 2:

- Update of the **"close contact" definition**: from 1 day before symptom onset to 4 days before symptom onset. The new definition for the purpose of this investigation protocol is: "Any person who had contact (within 1 metre) with a confirmed case during their symptomatic period, including 4 days before symptom onset".
- Capture **exposure also during the asymptomatic period of the confirmed case**.
- Expansion of symptoms questions **for suspected or probable cases to gastrointestinal symptoms** (same as for confirmed cases).
- For close contacts who health workers are, addition of risk-categorization questions to better estimate the level of the risk (high or low risk).
- Addition of a **symptom diary template** for close contacts to self-record and notify the presence or absence of various symptoms.
- Update of the **Go.Data** section, as now all FFX questionnaires are available as templates in Go.Data for country use.
- Addition of an appendix describing the key features of Go.Data and several hosting options for Go.Data (Appendix C).
- Updated references, to align with the latest WHO guidance.
- Technically edited version. Update of Appendix B, "Comparison between the features and complementarity of the main coronavirus disease 2019 (COVID-19) early investigation protocols", now that the risk assessment for health workers has been published.
- Update of the numbering of the FFX form and questions on where to get the data to calculate the epi parameters concerned (Table 3 of Section 3.3).
- Addition of the new generic WHO email address as a point of contact, to streamline all queries relating to protocols for early investigations.
- Change wording from "health-care workers" to "health workers" to account for non-medical health workers (ex. cleaners, etc.).

Contents

Summary

The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19).	
Population	The First Few X number of confirmed cases of COVID-19 infection and their close contacts.
Potential output and analysis	Transmission dynamics, severity and clinical spectrum, through estimates of, primarily: • the clinical presentation of COVID-19 infection and course of associated disease. • the secondary infection rate (SIR) and secondary clinical attack rate of COVID-19 infection among close contacts • the serial interval of COVID-19 infection. • the symptomatic proportion of COVID-19 cases (through contact tracing and laboratory testing). • identification of possible routes of transmission and secondarily: • the basic reproduction number (R_0) of COVID-19 • the incubation period of COVID-19 • the preliminary COVID-19 infection and disease-severity ratios (e.g. case-hospitalization and case-fatality ratios).
Design	Prospective case-ascertained study of all identified close contacts of laboratory-confirmed COVID-19 infections.
Start of the investigation	To be initiated in the first days after the arrival in Country X of a confirmed case of COVID-19 FFX is the primary protocol to be initiated in the case of a COVID-19 outbreak, upon identification of the initial laboratory-confirmed cases of COVID-19 virus in Country X in the early epidemic/pandemic phases.
Duration	At a minimum, enrolled cases and close contacts will complete data and specimen collection at enrolment (Day 1) and 14–21 days later, with two home visits.
Minimum data and specimens to be obtained from participants	• Data collection: epidemiological data, including clinical symptoms; exposures, including contact with confirmed case(s); and pre-existing conditions. • Specimens: respiratory (and other) to diagnose current COVID-19 infection; and serum to inform seroepidemiological inferences

This document sets out the methods to guide data collection and the public health investigation for the comprehensive assessment of confirmed COVID-19 cases and their close contacts.

The World Health Organization (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 COVID-19. Other COVID-19 investigations protocols currently available include:

- *Household transmission investigation protocol for coronavirus disease 2019 (COVID-19) (1);*
- *Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health-care setting (2)*; and
- *Surface sampling of COVID-19 virus: a practical "how to" protocol for health-care and public health professionals (3).*

The scope and focus of this document and the first two listed above are compared in Appendix B.

All WHO protocols for COVID-19 are available on the WHO website *(4)*, together with the technical guidance documents *(5)*, including surveillance and case definitions *(6)*; patient management *(7)*; laboratory guidance *(8)*; infection prevention and control *(9)*; risk communication and community engagement *(10)*; travel advice *(11)*, and more *(12, 13)*.

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 investigation will be carried out.

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 situation for coronavirus disease 2019 (COVID-19), first detected in Wuhan city, China in December 2019 *(14)*.

As with many novel respiratory pathogens, 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 route of transmission, the full range of disease presentation and the viral dynamics remain unknown for COVID-19. As a result, it is essential to understand the epidemiological, clinical and virological characteristics of the First Few X cases (FFX) of COVID-19 and their close contacts, in order to inform targeted guidance and measures for the Country X public health response.

The following protocol has been designed to investigate the FFX and their close contacts. It is an adaptation of generic protocols already in place in some countries, such as *"The First Few Hundred (FF100)" enhanced case and contact protocol* for pandemic influenza in the United Kingdom of Great Britain and Northern Ireland (United Kingdom) *(15)*. A harmonized global approach will facilitate rapid aggregation of data across countries.

It is envisioned that the FFX COVID-19 investigation will be conducted across several countries or sites with geographic and demographic diversity. Each country may need to tailor some aspects of this protocol to align with public health, laboratory and clinical systems, according to their country capacity and availability of resources, as well as the cultural appropriateness of the protocol. However, by using a standard protocol such as the one described here, epidemiological exposure data and biological samples can be systematically collected and shared rapidly in a format that can be easily aggregated, tabulated and analysed across many different settings globally. This will facilitate timely estimates of the severity and transmissibility of COVID-19 infection, as well as informing public health responses and policy decisions. This is particularly important in the context of a novel respiratory pathogen, such as the virus responsible for COVID-19.

1.1 Objectives

The overall aim of this protocol is to gain an early understanding of key clinical, epidemiological and virological characteristics of the first cases of COVID-19 infection detected in Country X, to inform the development and updating of public health guidance and 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 investigation may present with more 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 descriptions or estimates of:

- the clinical presentation of COVID-19 infection and course of associated disease;
- the secondary infection rate (SIR) and secondary clinical attack rate of COVID-19 infection among close contacts (overall, and by key factors such as setting, age and sex, for various end-points);
- the serial interval of COVID-19 infection;
- the symptomatic proportion of COVID-19 cases (through contact tracing and laboratory testing); and
- identification of possible routes of transmission.

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

- the basic reproduction number (R_0) of COVID-19 virus;
- the incubation period of COVID-19; and
- the preliminary COVID-19 infection and disease-severity ratios (for example, case-hospitalization ratio [CHR] and case-fatality ratio [CFR]).

A reminder of some definitions of epidemiological terms:

- In this context, the **secondary infection rate** is a measure of the frequency of new **infections** of COVID-19 among contacts of confirmed cases in a defined period of time, as determined by a positive COVID-19 result. *In other words, it is the rate of contacts being infected, assessed through polymerase chain reaction (PCR)/serological assays on paired samples*.
- The **secondary clinical attack rate** is a measure of the frequency of new symptomatic **cases** of COVID-19 infection among the contacts of confirmed cases in a defined period of time, as determined by a positive COVID-19 result. *In other words, it* is *the rate of clinical manifestation of the infection in contacts.*
- 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.
- The **basic reproduction number R_0** is defined as 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 that it can be assumed that there will be very little to no immunity to COVID-19.
- The **incubation period** is defined as the period of time between an exposure resulting in COVID-19 infection and the onset of the first clinical symptoms of the disease (*from infection or exposure to disease*).
- The **case-hospitalization ratio** is defined as the proportion of those infected with COVID-19 (that is, with a positive test result) who are admitted to hospital.
- The **case-fatality ratio** is defined as the proportion of people with COVID-19 (that is, with a positive test result) who die as a direct or indirect consequence of their infection.

This information will be used to refine/update recommendations for surveillance (for example, case definitions); to characterize the key epidemiological transmission features of the virus; to help understand the geographic spread, severity and impact on the community; and to inform operational models for implementation of countermeasures such non-pharmaceutical interventions *(16)* (for example, 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 developing early estimates of key clinical, epidemiological and virological parameters of the COVID-19 virus. Table 1 shows the roles and responsibilities involved for Country X.

Table 1. Coordination matrix of roles and responsibilities in Country X

What?	Who?
Overall coordination of the early investigation	[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)]. Centralized coordination will require development of a "command and control" plan, to allow for triage and prioritization of investigations.

1.3 Harmonization of early COVID-19 investigations

Early COVID-19 investigations are a suite of enhanced surveillance activities that are harmonized to help provide detailed insight into the epidemiological characteristics of COVID-19.

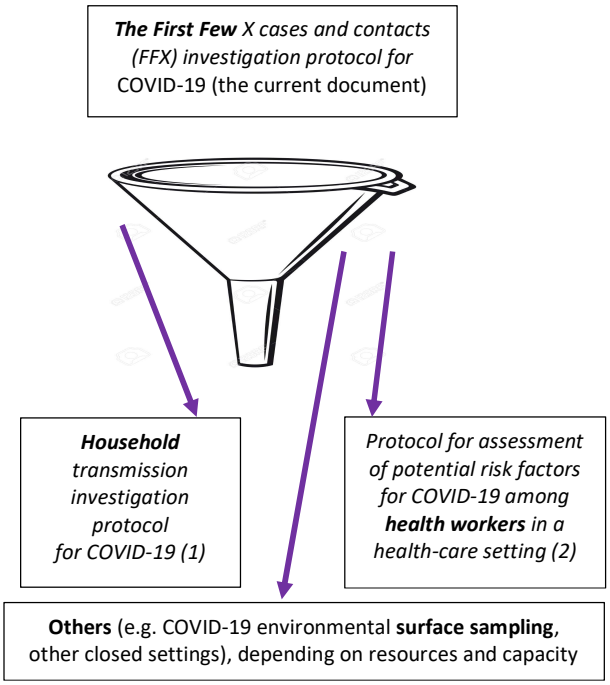
This **FFX protocol** outlines the process for early and rapid data collection for the first few early cases of the pandemic, which will provide critical early insight into key epidemiological characteristics such as the transmissibility and severity of COVID-19 infection. This protocol may be the first investigation to be conducted.

Other early investigations of COVID-19 could be simultaneously or subsequently undertaken to collect further information relating to COVID-19 infection, depending on the availability of resources and capacity. These could include prospective investigations of transmission of COVID-19 in **households** and also in closed environments, such as for **health workers**[1]. These investigations will provide a more detailed insight on transmissibility and severity; the effect of interventions in reducing the risk of infection; and the risk of secondary infection, as well as giving an estimate the asymptomatic fraction (proportion of asymptomatic cases).

All WHO early investigation protocols for COVID-19 are available on the WHO website *(4)* (see Fig. 1).

[1] Health workers at risk of infection with coronavirus include: ambulance staff, reception staff, health assistants, nurses, doctors, laboratory workers and cleaners.

Fig. 1. Complementarity of COVID-19 protocols currently available on the WHO website



2. Methods

2.1 Design

This FFX investigation is a prospective case-ascertained study of all identified close contacts of a laboratory-confirmed COVID-19 infection (see Section 2.2). Participants are identified from those with laboratory-confirmed influenza infection, which is distinct from a cohort study in which a group of disease-free households are recruited and then followed over time. Case-ascertained transmission studies are more efficient than cohort studies when interest is in early ascertainment of the clinical, epidemiological and virological characteristics of an emerging virus. This is because the risk of primary or secondary infection in a "sleeping" cohort would be expected to be low during the early stage of the pandemic before widespread community transmission is established.

This FFX investigation should be established following identification of the first laboratory-confirmed cases of COVID-19 infection in any country. It should also ideally be conducted before widespread community transmission occurs, that is, within the early phases of the COVID-19 epidemic in the country. The FFX protocol aims to identify key clinical, epidemiological and virological characteristics of infection with this novel virus in near real-time.

2.2 Population

The population under investigation consists of the first few confirmed cases of COVID-19 and their close contacts.

For the purpose of this investigation, the primary case will be identified through the national or other relevant international surveillance system.

2.2.1 Case definitions

Case definitions for COVID-19 reporting are available on the WHO website *(12)*, although they are subject to further updates as more information becomes available. For the purpose of this protocol, the generic case definitions for COVID-19 are proposed in Box 1.

Box 1. Interim case definitions for the purpose of the FFX protocol
Suspected case A. A patient with severe acute respiratory infection (fever, cough and requiring admission to hospital), **AND** with no other etiology that fully explains the clinical presentation, **AND** a history of travel to or residence in China during the 14 days prior to symptom onset, **OR** B. A patient with any acute respiratory illness **AND** at least one of the following during the 14 days prior to symptom onset: • contact with a confirmed or probable case of COVID-19 infection, **OR** • worked in or attended a health-care facility where patients with confirmed or probable COVID-19 were being treated.
Probable case A suspected case for whom testing for COVID-19 is inconclusive or who tested positive using a pan-coronavirus assay, and without laboratory evidence of other respiratory pathogens.
Confirmed case A person with laboratory confirmation of COVID-19 infection, irrespective of clinical signs and symptoms. **Further classification of confirmed case** **A. Primary case (or index case):** an individual who tests positive for COVID-19 and has the earliest onset date in a particular setting, for example, household, school, hospital, etc. Cases with onset dates less than 24 hours from the onset date of the primary case are considered to be "co-primary" cases. **B. Secondary case:** a contact who becomes a case with positive test result 24 hours or more after the latest positive test date of the primary and/or co-primary case; or with onset of symptoms 24 hours or more after the latest onset date of the primary and/or co-primary case. **C. Imported case:** a case with a history of travel from an affected area in the 14 days before disease onset.

2.2.2 Close contact definitions

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.

The definition and further classification of **close contacts** are described in Box 2.

Box 2. Close contacts definition and classification (check the WHO website *(12)* regularly for any updates).
Close contact Any person who had contact (within 1 metre) with a confirmed case during their symptomatic period, including 4 days before symptom onset. Note that contact does not have to be direct physical contact. **Further classification of close contact** (for use in contact questionnaires)- • **Health worker contact:** any social or health worker who provided direct or indirect personal or clinical care, or examination of a symptomatic or asymptomatic confirmed case of COVID-19, or who was within the same indoor space when an aerosol-generating procedure was implemented. • **Household contact:** any person who has resided in the same household (or other closed setting) as the primary COVID-19 case.

2.3 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. If case numbers begin to rise rapidly, the proportion of cases to include could be reduced according to the needs and capacity of Country X. Attempts to follow up all confirmed cases in the FFX database can be resource and time intensive.
COMMENT: As an example, the United Kingdom's FF100 project for pandemic influenza ran from April to June 2009, with a total of 392 confirmed cases followed up *(17)*.

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 United Kingdom's FF100 project for pandemic influenza ran for 3 months *(17)*.

2.4 Data collection

2.4.1 Summary

Information on primary cases and their close contacts should be sought through a combination of face-to-face or telephone interviews of the case (or family members if the case is too ill to be interviewed) and household members, self-reporting, interview of health workers and/or review of medical records where required.

Investigation questionnaires can be found in Appendix A of this document. These forms are not exhaustive but outline the data collection required for insight into the epidemiology of COVID-19 and may be updated further. They will still need to be adapted based on the local setting and outbreak characteristics.

Once a case of COVID-19 infection has been identified and recruited into the investigation, a home visit will need to be conducted to identify all eligible close contacts; to collect relevant sociodemographic 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 serological status once serology capacity is available).

*Note for **suspected cases***: identifying and maintaining the line listing of suspected cases can be resource and time intensive. A fine balance should be found between the time taken to identify suspected cases and the 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 to the relevant health authorities any signs and symptoms that are compatible with COVID-19 infection;
- 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; and
- contacts found to be infected with COVID-19 would be reclassified as **confirmed cases** (dotted line in Fig. 2) and follow-up would occur as described in the case investigation algorithm (see Fig. 2). The fact that a close contact becomes a confirmed case *may not retrigger the data-collection process*, depending on the country resources and the type of contact (for example, if the contact is a health worker, then it might be worth investigating further to inform public health action).

Please note that these investigations are resource intensive. It may be best to focus initially on the follow-up of **household and health-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 or health-care settings (health workers). These protocols are available on the WHO website *(12).*

2.4.2 Use of the Go.Data tool

Go.Data is an electronic field data-collection tool that has been designed to be used by WHO, the Global Outbreak Alert and Response Network (GOARN) *(18)*, Member States and partners, to support and facilitate outbreak investigation including field data collection, contact tracing and visualization of chains of transmission *(19)*. The tool includes functionality for case and contact data collection, contact follow-up and visualization of chains of transmission. It has two components: a web application and an optional mobile app. The tool is targeted at any outbreak responders, including WHO staff, and staff from ministries of health and partner institutions.

Go.Data can be used to run an FFX investigation.

Key features of the Go.Data software include (for more details and screen shots, please refer to Appendix C):

- it is open source and free for use with no licensing costs;
- it offers different types of operation (server or stand-alone) on different platforms (Windows, Linux, Mac);
- it allows for data collection from cases and contacts, including laboratory data;
- it is not built for a specific disease or specific country; it is highly configurable, with configurable reference, outbreak and location data;
- one Go.Data installation can be used to collect data for many outbreaks;
- it provides multilingual support, with the possibility to add and manage additional languages though the user interface;
- it allows granular user roles and permissions, including the possibility to provide user access at outbreak level;
- outbreak templates are included for easier creation of outbreak data-collection forms;
- it generates a contact follow-up list and visualizes chains of transmission;
- users with appropriate rights can configure the case investigation form, contact follow-up form and laboratory data-collection form; and
- it has an optional mobile app (Android and iOS) focused on case and contact data collection, and contact tracing and follow-up.

The standardized FFX questionnaires are available in Go.Data for country use, adaptation, and, if needed, translation into local language.

Several options are available for Go.Data hosting in countries (see Appendix C).

For further information contact: godata@who.int or visit https://www.who.int/godata *(19)*.

2.4.3 Follow-up of cases and contacts

For cases, data will be collected using **Forms A0 or A1** for the first visit, followed by **Form A2**.
For close contacts, data will be collected using **Form B1** for the first visit, followed by **Form B2** (see Table 2 and Fig. 3).

Symptom diaries (template available in Appendix A of this protocol) will be provided for all close contacts to complete for a minimum of 14 days after the administration of the baseline questionnaire, to record the presence or absence of various signs or symptoms. A proxy may fill out the symptom diaries on behalf of those unable to complete the form themselves.

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 possible/suspected case, and therefore managed as such.

Fig. 2. Case investigation algorithm and summary of data-collection tools

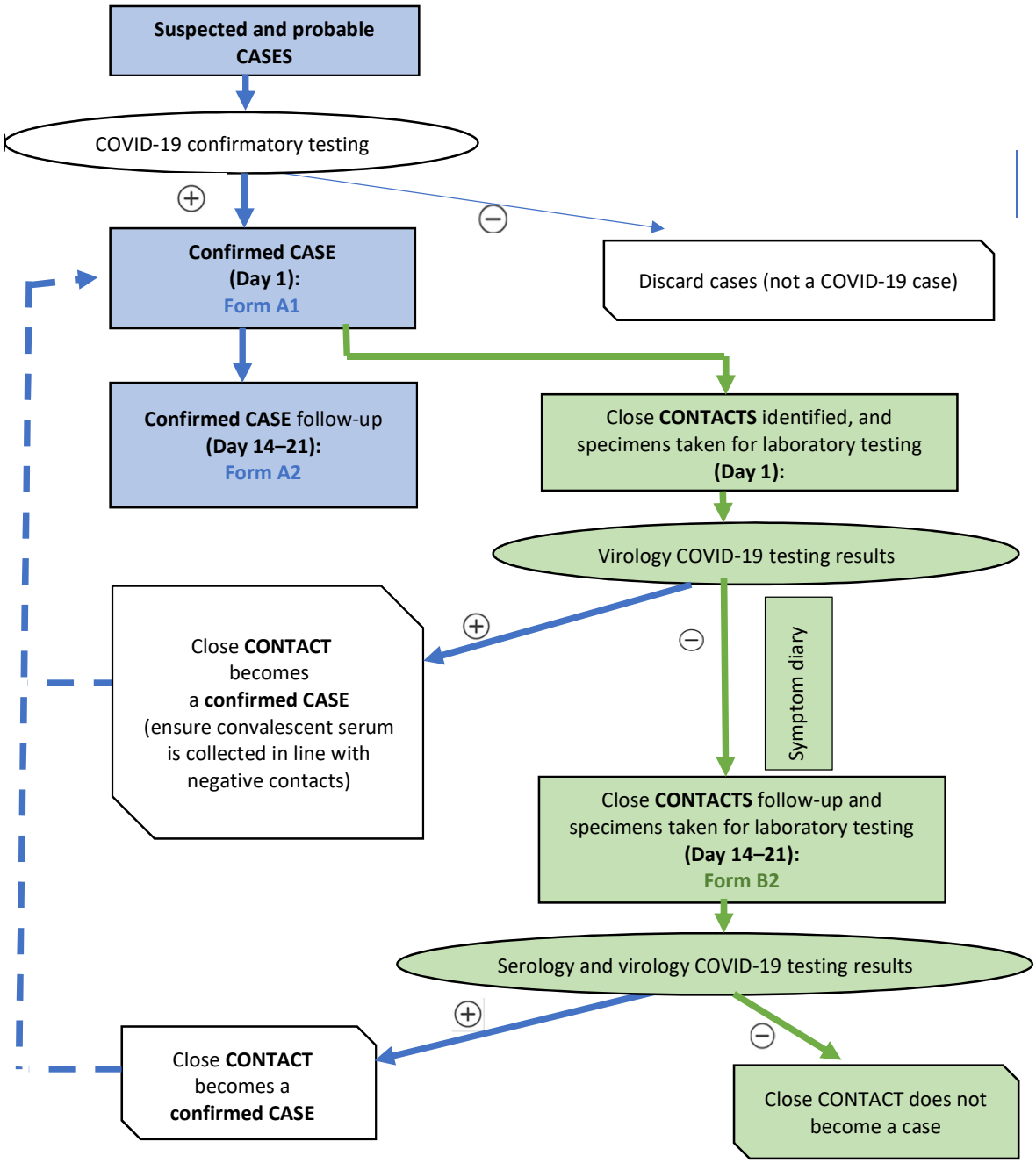
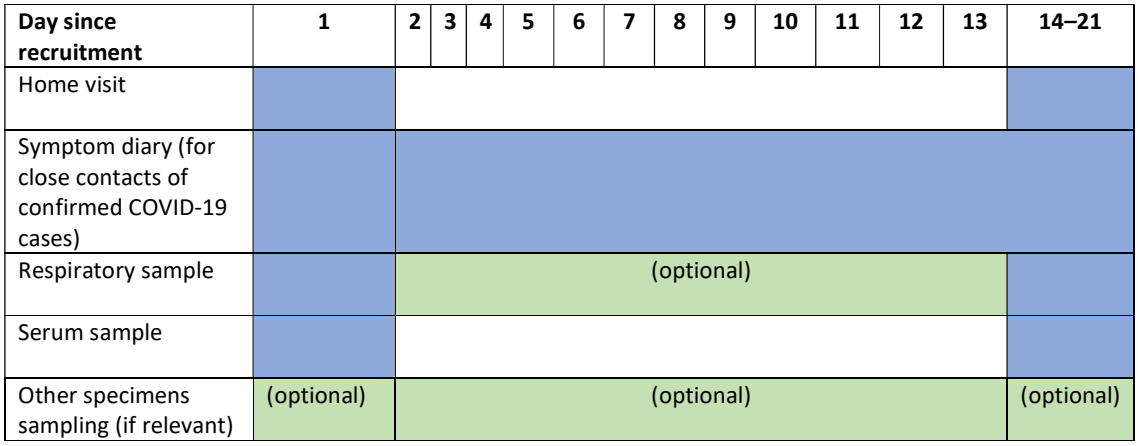


Table 2. Summary of data-collection tools

Form number	Purpose of form	Collecting from whom?	When should it be collected?
CASES			
Form A0	Minimum data reporting form	For **suspected and probable** COVID-19 cases	As soon as possible after the suspected case is detected or notified.
Form A1	Case **initial** report form	For **confirmed** COVID-19 cases	As soon as possible after laboratory confirmation of a case **(Day 1).**
Form A2	Case **follow-up** form	For **confirmed** COVID-19 cases: final outcome	14–21 days after completion of Form A1, which is approximately 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 COVID-19 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 COVID-19 cases: final outcome	14–21 days after completion of Form B1 **(Day 14–21)**
Symptom diary	Record the presence or absence of various signs or symptoms	For close contacts of confirmed COVID-19 cases	For a **minimum of 14 days** after administration of the initial questionnaire (Form B1.)

Fig. 3. Timeline of data and specimen collection in the FFX



Blue boxes indicate activities that are needed for the investigation.
Green boxes indicate where additional specimens could be collected above the minimum specimen requirements of this investigation, to increase the information available.

2.5 Laboratory evaluations

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

Laboratory guidance for COVID-19 can be found on the WHO website *(20).* Several assays that detect the novel coronaviruses have been recently developed and the protocols or standard operating procedures can also be found on the WHO website *(8)*.

2.5.1 Specimen collection

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

2.5.1.1 Confirmed cases

All baseline respiratory and serum samples (as directed by specimen collection guidance in Country X) should be collected from confirmed cases, including any persons without symptoms who have been screened and found to be positive for COVID-19, as soon as possible after laboratory confirmation. It is important to 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 whether they are of sufficient quality and quantity for this investigation. New samples should be collected if needed.

Follow-up samples may include upper respiratory tract samples or clotted blood,[1] and should be collected as described in Fig. 2. Lower respiratory tract samples can also be collected, if feasible, but recommended infection prevention and control precautions must be in place prior to collection (see Section 2.6.5), as these are higher-risk interventions *(21)*.

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.

Appropriate personal protective equipment (PPE) should be worn when specimens are being collected from confirmed cases *(21)*.

2.5.1.2 Close contacts

All baseline upper respiratory tract specimens (nasopharyngeal/oropharyngeal swab) and serum samples should be collected at the initial home visit.

Follow-up respiratory and serum samples should also be collected.

Other specimens (oral fluid, urine, faeces, etc.), as described for confirmed cases, may be collected.

[1] Adapted from reference *(21).*

2.5.1.3 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, in order to determine an accurate SIR and the proportion of infections that are asymptomatic.

Serum samples should be taken from all confirmed COVID-19 cases, and from 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 could not be taken when the case was symptomatic; or
    - (for a contact) 28 days after the last exposure if an acute sample was not taken.

2.5.2 Specimen transport

All those involved in collecting and transporting specimens should be trained in safe handling practices and spill decontamination procedures. For details regarding the transport of samples collected and infection control advice, please refer to the case management algorithm and laboratory guidance in the country, or to WHO laboratory guidance, available on the WHO website *(20).*

For each biological sample collected, the time of collection, the conditions for transportation and the time of arrival at the 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, it 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 (22).*

2.6 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.

2.6.1 Informed consent and assent

The purpose of the investigation will be explained to all known contacts of a confirmed COVID-19-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 he or she 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.

2.6.2 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 COVID-19 infection, which would allow for appropriate monitoring and treatment for themselves and their close contacts. The primary benefit of the investigation is indirect, in that data collected will help improve and guide efforts to understand transmission of COVID-19 and prevent further spread of the virus.

2.6.3 Confidentiality

Participant confidentiality will be maintained throughout the investigation. All subjects who participate in the investigation will be assigned an 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 are shared by the implementing organization with WHO or any agency or institution providing support for data analysis, data shared will include only the investigation identification number and not any personally identifiable information.

Article 45 of the *International Health Regulations (2005)* (IHR) describes the "treatment of personal data" *(23)*. Personally, 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.

2.6.4 Terms of use: Go.Data

If groups implementing the investigation opt to use open-source Go.Data as a tool to run this investigation *(18)*, several options are available for Go.Data hosting in countries. Detailed information is presented in Appendix C of this document. The group implementing the investigation 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 C for the terms of use of Go.Data.

2.6.5 Prevention of COVID-19 infection in investigation personnel

All personnel involved in the investigation must be trained in procedures for infection prevention and control (standard contact, droplet or airborne precautions, as determined by national or local guidelines) *(21)*. 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 COVID-19-infected patients, but also to minimize the risk of spread among contacts of COVID-19-infected patients.

WHO technical guidance on infection prevention and control specific to COVID-19 can be found on the WHO website *(24).*

3. Statistical analyses

3.1 Sample size

The sample size of Country X will be determined by the number of contacts within each social sphere of the confirmed COVID-19-infected individual and assumptions made relating to the transmissibility of COVID-19. Every effort should be made to include all contacts of the confirmed COVID-19-infected individual, to maximize the statistical power of the investigation. In the influenza pandemic in 2009, many countries used a sample size of 300–400 cases, using different power and attack rates for their calculations.

3.2 Plan of analyses

FFX investigation will be not be able to answer every question we have about COVID-19 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 COVID-19 can assist in providing supplementary data to help with the calculation of key epidemiological parameters. All WHO protocols for COVID-19 are available on the WHO website *(12)*.

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 (time, place, person) of the FFX should provide preliminary insight into the clinical spectrum and course of disease due to COVID-19 infection from individual cases – for example, the initial population groups most affected initially with symptomatic confirmed infection, by age and underlying risk factors.

Genomic analysis of the specimens generated though this investigation 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 will help with estimation of the basic reproduction number. The latter can be incredibly useful for determination of the extent of community transmission that is occurring in the early stages of the pandemic and whether the strain was locally acquired or imported from another region.

Advanced analytics (epidemiological parameters estimation) that can be calculated using the FFX forms/questionnaires and specimens generated are described in Table 3. The table includes a comments/limitations section, which provides insight into the strengths and weaknesses of this protocol.

Table 3. Definition and source of **epidemiological parameters that can be estimated during an FFX early investigation.**

Parameter	Definition (*"simplified" expression of the definition*)	FFX's form and questions where data can be obtained 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: Q6, Q8, Q13 Form A2: not applicable (na) Form B1: Q3, Q5, Q6 Form B2: Q3, Q4, Q5, Q7	• Location will need to be supplemented by notification data to indicate geospatial trends.
Health-care-seeking behaviours	Determination of the proportion of people who sought health care (not necessarily just hospitalization).	Form A0: Q7 Form A1: Q8, Q9, Q11, Q12 Form A2: Q3, Q5 Form B1: Q7 Form B2: na	
Symptomatic proportion of cases or asymptomatic fraction	The proportion of cases who show symptoms or signs of COVID-19 infection or The proportion of cases who do not show symptoms or signs of COVID-19 infection.	Laboratory confirmation and symptoms Form A0: Q4 Form A1: Q8, Q13 Form A2: Q4, Q8 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 COVID-19 among the confirmed cases in a defined period of time.	Hospitalization data and complications. Form A0: Q6, Q7 Form A1: Q7, Q8, Q9, Q11, Q12 Form A2: Q5 Form B1: Q7 Form B2: Q7	

Secondary clinical attack rate	A measure of the frequency of new symptomatic cases of COVID-19 infection that occur among contacts within the incubation period (range) following exposure to a primary confirmed 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 of COVID-19 infection in 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 of COVID-19 infection. Form A0: na Form A1: na Form A2: na Form B1: Q5, 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 infections of COVID-19 among contacts within the incubation period (range) following exposure to a primary confirmed 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 contacts being infected, assessed through serological assays/polymerase chain reaction 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). Form A0: na Form A1: na Form A2: na Form B1: Q9 Form B2: Q6, Q7	

Case-hospitalization ratio	The proportion of those infected with COVID-19 (i.e. with a positive test result) who are admitted to hospital, compared to cases who do not require hospitalization *(Proportion of cases who require hospitalization).*	Hospitalization data and complications Form A0: Q6, Q7 Form A1: Q7, Q8, Q9, Q11, Q12 Form A2: Q5 Form B1: Q7 Form B2: na	• 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, Q6 Form A1: Q8, Q9 Form A2: Q4, Q5 Form B1: Q6 Form B2: Q4	• In-hospital clinical studies will enhance understanding of the clinical course, severity and risk determinants, as well as case fatality.
Clinical risk factors, especially for critical illness	Underlying clinical conditions and comorbidities	Comorbidities and pre-existing medical conditions Form A0: na Form A1: Q10 Form A2: Q6 Form B1: Q8 Form B2: Q5	• For estimating risk factors for severe disease accurately, something like a hospitalization case-control study may be needed.
Serological response to infection	Change in serum level of specific antibodies to COVID-19 virus *(Increase in titre*)	Laboratory results Form A0: na Form A1: Q13 Form A2: Q8 Form B1: Q9 Form B2: Q6, Q7	• It will only be possible to calculate this with the addition of laboratory data. • Will be supplemented by the findings of clinical studies and investigations of the first few outbreaks, to confirm that seroconversion following an infection is anticipated.
Incubation period	The period of time between an exposure resulting in COVID-19 infection 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 or event of concern (e.g. animal exposure). Form A0: Q4, Q7, Q9 (optional) Form A1: Q8 Form A2: Q4 Form B1: Q4, Q5, Q6 Form B2: Q3, Q4 Symptom diary	

Serial interval	The period of time from the onset of symptoms in the primary case to the onset of symptoms in a contact (*From clinical onset to clinical onset*)	Symptoms and dates Form A0: Q4 Form A1: Q8 Form A2: Q4 Form B1: Q6 Form B2: Q4 Symptom diary	• Will be greatly enhanced by information from the first few outbreaks, where transmission chains may be more identifiable and prolonged.
Generation time distribution	The time between infection in the case and infection in the close contact (*From infection to infection*)	Specimens and dates Form A0: Q5 Form A1: Q13 Form A2: Q8 Form B1: Q5 Form B2: Q7	• Will be greatly enhanced by information from the first few outbreaks, where transmission chains may be more identifiable and prolonged.
Case-fatality ratio	The number of deaths caused by COVID-19 in cases, compared to the total number of cases with COVID-19 (*Proportion of COVID-19 cases who die*).	Dead/alive status and case confirmation Form A0: Q1 Form A1: Q1, Q9, Q13 Form A2: Q3, Q8 Form B1: Q7 Form B2: Q6, Q7	• A large number of cases will probably be needed before a significant number of deaths are seen, in order to allow reliable estimates through the FFX (also follow-up may end before deaths due to secondary infections can be observed). • More likely to be an overestimate in FFX, owing to reporting/selection bias of the initial cases.

Population groups most at risk	Determination of the groups that are most vulnerable to infection with COVID-19 (e.g. age groups, sex, occupation)	Demographic data Form A0: Q3, Q7, Q9 (optional) Form A1: Q6, Q12 Form A2: Q3, Q6 Form B1: Q3, Q4, Q5 Form B2: Q3, Q5	• Risk groups might not show up in FFX, for example the United Kingdom 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 phylogenetic analysis		Laboratory data Form A0: Q5 Form A1: Q13 Form A2: Q8 Form B1: Q9 Form B2: Q6	• An alternate means to estimate the basic reproduction number, from comparing the relatedness of strains between cases and their close contacts and confirming transmission between individuals. • The data may supplement other transmission data to inform transmission parameter estimates, although these data are 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 that it can be assumed that there will be very little to no immunity to COVID-19 (*Average number of infections/disease arising from one infection*) Reminder: R_0 – everyone is susceptible and there is no control; the maximum value that *R* can take is equal to the transmission potential.	Laboratory data, dates of contact, symptoms in contacts Form A0: na Form A1: Q13 Form A2: Q8 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_0 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.
Reproduction ratio (*R*)	Ever-changing quantity of the number 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: na Form A1: Q13 Form A2: Q8 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, it may be possible to calculate this.

4. Reporting of findings

Any investigation of this nature should include reporting on the following information, stratified by age, sex, and relevant time and place characteristics:

- the number of cases and number of close contacts included;
- the number of laboratory-confirmed COVID-19 cases among the close contacts;
- the number of symptomatic and asymptomatic close contacts; and
- the number of close contacts with serological evidence of COVID-19 infection.

Timely dissemination of the results of this investigation is critical to understanding the transmission of the new pandemic virus, in order to update guidance and inform national and international public health responses and policies for infection prevention and control.

It is also important to fully document the investigation 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 are shared by the implementing organization, with WHO or with any agency or institution providing support for data analysis, data shared will include only the investigation identification number and not any personally identifiable information.

5. References

1. Household transmission investigation protocol for coronavirus disease 2019 (COVID-19). Geneva: World Health Organization; 2020 (https://www.who.int/publications-detail/household-transmission-investigation-protocol-for-2019-novel-coronavirus-(2019-ncov)-infection, accessed 11 February 2020).
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4. World Health Organization. Coronavirus disease (COVID-19) technical guidance: early investigations (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations, accessed 11 February 2020).
5. World Health Organization. Coronavirus disease (COVID 19) technical guidance (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance, accessed 11 February 2020).
6. World Health Organization. Novel coronavirus (2019-nCoV) technical guidance: surveillance and case definitions (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/surveillance-and-case-definitions, accessed 11 February 2020).
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6. Further reading and online courses

- World Health Organization. Coronavirus disease (COVID-19) situation reports (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/, accessed 12 February 2020).
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- Risk communication and community engagement (RCCE) readiness and response to the 2019 novel coronavirus (2019-nCoV). Interim guidance v2. Geneva: World Health Organization; 2020 (WHO/2019nCoV/RCCE/v2020.2; https://www.who.int/publications-detail/risk-communication-and-community-engagement-readiness-and-initial-response-for-novel-coronaviruses-(-ncov), accessed 12 February 2020).

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Online courses

- There are training resources for COVID-19 available on the WHO online learning platform (https://openwho.org/, accessed 12 February 2020).
- World Health Organization. Emerging respiratory viruses, including nCoV: methods for detection, prevention, response and control (https://openwho.org/courses/introduction-to-ncov, accessed 12 February 2020).
- World Health Organization. Critical care severe acute respiratory infection training (https://openwho.org/courses/severe-acute-respiratory-infection, accessed 12 February 2020).

More courses are in development; check the https://openwho.org/ link regularly

7. Acknowledgments

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Appendix A: Questionnaires and guidance

The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)

FOR CASES
• **Form A0: Minimum data-reporting form – for suspected and probable COVID-19 cases** • **Form A1: Case initial report form – for confirmed COVID-19 cases (Day 1)** • **Form A2: Case follow-up form – for confirmed COVID-19 cases (Day 14–21)**
FOR CONTACTS
• **Form B1: Contact initial reporting form – for close contacts of confirmed COVID-19 cases (Day 1).** • **Form B2: Contact follow-up reporting form – for close contacts of confirmed COVID-19 cases (Day 14–21).** • **Symptom diary for close contacts of confirmed COVID-19 cases**

The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)

1. For cases

Form A0: Minimum data reporting form – for suspected and probable COVID-19 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	
Data collector email	
Form completion date (dd/mm/yyyy)	___/___/___

3a. Case identifier information	
First name	
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 person providing the information is not the patient)	
First name	
Family name	
Sex	□ Male □ Female □ Not known
Date of birth (dd/mm/yyyy)	___/___/___ □ Unknown
Relationship to patient	
Respondent address	
Telephone (mobile) number	

4. Patient symptoms (from onset of symptoms)	
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
Vomiting	□ Yes □ No □ Unknown
Nausea	□ Yes □ No □ Unknown
Diarrhoea	□ Yes □ No □ Unknown

5. Initial sample collection	
Date respiratory sample collected (dd/mm/yyyy)	___/___/___
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 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 suggestive of an infection	□ Yes □ No □ Unknown If Yes, specify:
Mechanical ventilation required	□ Yes □ No □ Unknown
Extracorporeal membrane oxygenation (EMO) required	□ Yes □ No □ Unknown

7. Human exposures in the days before symptom onset (as of February 2020, in the past 14 days)	
Have you travelled within the last 14 days domestically?	□ Yes □ No □ Unknown If Yes, dates of travel (dd/mm/yyyy): ___/___/___ to ___/___/___ Regions visited: 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 anyone with suspected or confirmed COVID-19 infection?	□ Yes □ No □ Unknown If Yes, dates of last contact (dd/mm/yyyy): ___/___/___
Patient attended festival or mass gathering in the past 14 days	□ Yes □ No □ Unknown If Yes, specify:
Patient exposed to person with similar illness in the past 14 days	□ Yes □ No □ Unknown
Location of exposure in the past 14 days	□ Home □ Hospital □ Workplace □ Tour group □ School □ Unknown □ Other, specify:
Patient visited or was admitted to inpatient health facility in the past 14 days	□ Yes □ No □ Unknown If Yes, specify:
Patient visited outpatient treatment facility in the past 14 days	□ Yes □ No □ Unknown If Yes, specify:
Patient visited traditional healer in the past 14 days	□ Yes □ No □ Unknown If Yes, specify type:
Patient occupation (specify location/facility)	□ Health 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, specify:

ADDITIONAL INFORMATION TO COLLECT (relevant for cases in China)

9. Human exposures to animals in the days before illness onset (as of February 2020, in the past 14 days)		
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:
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 No or Unknown, skip to J If Yes, specify:
G	Types of animals in that environment	Specify:
H	Location of exposure	□ Home □ Neighbourhood □ 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:

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Form A1: Case initial reporting form – for confirmed COVID-19 cases (Day 1)

COMMENT: Information in this form may already have been completed in the *Minimum data-reporting form – for suspected and probable COVID-19 cases* (Form A0). It is therefore not necessary to repeat any data in these sections that have already been completed.

However, if Form A0 has never been completed, then all questions/variables in Form A1 should be collected.

Unique Case ID/Cluster number (if applicable):

1. Current status
□ Alive □ Dead □ Unknown/lost to follow-up
2. Further case classification
□ Primary □ Secondary □ Imported

3. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	___/___/___

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

5. Patient identifier information	
First name	
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	
Nationality	
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:_____
Ethnicity (optional)	
Responsible health centre	
Nursery/school/college if appropriate	

6. Health-care centre/treating physician's details	
Name of health-care centre	
Name of treating physician	
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)	___/___/___ □ No symptoms □ Unknown
Fever (≥38 °C) or history of fever	□ Yes □ No □ Unknown If Yes, specify maximum temperature: °C
Date of first health facility visit (including traditional care) (dd/mm/yyyy)	___/___/___ □ Not applicable (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): ___/___/___
Runny nose	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy): ___/___/___
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
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
Other 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 (dd/mm/yyyy)	___/___/___ □ 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 complications	□ Yes □ No □ Unknown If Yes, specify:
Hypotension requiring vasopressors	□ Yes □ No □ Unknown
Extracorporeal membrane oxygenation (EMO) required	□ Yes □ No □ Unknown

Date of discharge from hospital (if applicable) (dd/mm/yyyy)	___/___/___
Outcome	□ Alive □ Dead □ na □ Unknown
Outcome current as of date (dd/mm/yyyy)	___/___/___ □ Unknown □ na

9. Patient pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If Yes, specify trimester: □ First □ Second □ Third □ Unknown
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
Chronic kidney disease	□ Yes □ No □ Unknown
Chronic neurological impairment/disease	□ Yes □ No □ Unknown
Organ or bone marrow recipient	□ Yes □ No □ Unknown
Other pre-existing condition(s)	□ Yes □ No □ Unknown If Yes, specify:

10. Health-care interactions	
Contact with emergency number/ hotline	□ Yes □ No □ Unknown
Date of emergency contact (dd/mm/yyyy)	___/___/___ □ Unknown
Visit to primary healthcare (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
Hospitalization (repeat for as many admissions as required)	□ Yes □ No □ Unknown
Date of admission to hospital (dd/mm/yyyy)	___/___/___ □ Unknown □ na
Name and place of hospital	

11. Human exposures in the days before symptom onset (as of February 2020, in the past 14 days)	
Have you travelled within the last 14 days domestically?	□ Yes □ No □ Unknown If Yes, dates of travel (dd/mm/yyyy): ___/___/___ to ___/___/___ Regions visited: 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 anyone with suspected or confirmed COVID-19 infection?	□ Yes □ No □ Unknown If Yes, dates of last contact (dd/mm/yyyy): ___/___/___
Patient attended festival or mass gathering in the past 14 days	□ Yes □ No □ Unknown If Yes, specify:
Patient exposed to person with similar illness in the past 14 days	□ Yes □ No □ Unknown
Location of exposure in the past 14 days	□ Home □ Hospital □ Workplace □ Tour group □ School □ Unknown □ Other, specify:
Patient visited or was admitted to inpatient health facility in the past 14 days	□ Yes □ No □ Unknown If Yes, specify:
Patient visited outpatient treatment facility in the past 14 days	□ Yes □ No □ Unknown If Yes, specify:
Patient visited traditional healer in the past 14 days	□ Yes □ No □ Unknown If Yes, specify type:
Patient occupation (specify location/facility)	□ Health 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:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Other, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for COVID-19 □ NEGATIVE for COVID-19 □ POSITIVE for other pathogens Please specify which pathogens:	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: ____ □ No

12b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result (COVID-19 antibody titres)**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Other, specify:	Specify type (ELISA/IFA IgM/IgG, neutralization assay, etc.):	□ POSITIVE If positive, titre: □ NEGATIVE □ INCONCLUSIVE	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: ____ □ No

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

The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)

Form A2: Case follow-up reporting form – for confirmed COVID-19 cases (Day 14–21)

COMMENT: Information in this form may already have been completed in the *Minimum data-reporting form – for suspected and probable COVID-19 cases* (Form A0) or the *Case initial report form – for confirmed COVID-19 cases (Day 1)* (Form A1). It is therefore not necessary to repeat any data in these sections that have 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	
Data collector email	
Form completion date (dd/mm/yyyy)	___/___/___

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

3. Outcome/status	
Status	□ Recovered, if Yes specify date symptoms resolved (dd/mm/yyyy) ___/___/___ □ Still ill □ Dead, if Yes, specify date of death (dd/mm/yyyy): ___/___/___ □ Unknown/lost to follow-up
Hospitalization ever required?	□ Yes □ No □ Unknown
(NB. If the information below is not currently available, please leave blank and send through an update as soon as results are available)	
If dead, contribution of COVID-19 to death:	□ Underlying/primary □ Contributing/secondary □ No contribution to death □ Unknown
If dead, was a postmortem performed?	□ Yes □ No □ Unknown

If dead, results of postmortem's report where available:	
If dead, cause of death on Death certificate (specify)	

4a. Patient symptoms during the entirety of illness	
Maximum temperature (specify)	°C □ Not applicable (na)
4b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy) ___/___/___
Runny nose	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown If Yes, date (dd/mm/yyyy) ___/___/___
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
Loss of appetite	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Other neurological signs	□ Yes □ No □ Unknown If Yes, specify
Other symptoms	□ Yes □ No □ Unknown If Yes, specify:

5. Patient symptoms: complications	
Hospitalization	□ Yes □ No □ Unknown
Date of first hospitalization (dd/mm/yyyy)	___/___/___ □ Unknown
ICU (intensive care unit) admission	□ Yes □ No □ Unknown
ICU admission	___/___/___ □ 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 complications	□ Yes □ No □ Unknown If Yes, specify:
Hypotension requiring vasopressors	□ Yes □ No □ Unknown
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 □ Unknown

7. Secondary bacterial infection

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

Date of sample (dd/mm/yyyy)	**Type of sample**	**Positive results**
/ /	□ Sputum □ Endotracheal aspirate □ Pleural fluid □ CSF □ Blood □ Urine □ Faeces □ Other, please specify:	□ *Haemophilus influenza* □ MRSA □ *Staphylococcus aureus* □ *Streptococcus pneumoniae* □ *E. coli* □ Other organism, please specify:

Form A2: Case follow-up reporting form – for confirmed COVID-19 cases (Day 14–21)

8a. Virology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Other, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for COVID-19 □ NEGATIVE for COVID-19 □ POSITIVE for other pathogens Please specify which pathogens:	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: ____ □ No

8b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result (COVID-19 antibody titres)**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Other, specify:	Specify type (ELISA / IFA IgM/ IgG, neutralization assay, etc.): ___	□ POSITIVE If positive, titre: □ NEGATIVE □ INCONCLUSIVE	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: ____ □ No

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

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2. For close contacts

Form B1: Contact initial reporting form – for close contacts of confirmed COVID-19 cases (Day 1)

Name of confirmed case

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.

1. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	___/___/___

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

3. Contact details (details of the contact)	
First name	
Family name	
Sex	□ Male □ Female □ Not known
Date of birth (dd/mm/yyyy)	___/___/___ □ Unknown
Relationship to case	
Address (village/town, district, province/region)	
Telephone (mobile) number	
Email	
Preferred mode of contact	□ Mobile □ Work □ Home □ Email
Nationality	
Country of residence	

National social number/identifier (optional)	
Ethnicity (optional)	

4. General exposure information	
Have you travelled within the last 14 days domestically?	□ Yes □ No □ Unknown If Yes, dates of travel (dd/mm/yyyy): ___/___/___ to ___/___/___ Regions visited: 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 anyone with suspected or confirmed COVID-19 infection?	□ Yes □ No □ Unknown If Yes, dates of last contact (dd/mm/yyyy): ___/___/___
Occupation (specify location/facility)	□ Health worker □ Working with animals □ Health laboratory worker □ Student □ Other, specify: For each occupation, please specify location or facility:

Note for next 2 sections:

- **Complete Section 5** if the contact is a health worker (HW).
- **Complete Section 6** if the contact is NOT a health worker.

5. Exposure information (if the close contact is a Health Worker (HW))	
Job title (specify)	
Place of work	
Direct physical contact with the confirmed case (e.g. hands-on physical contact)	□ Yes □ No

Has the HW had prolonged face-to-face contact (>15 minutes) with a **symptomatic** confirmed case in a health facility? (Add as many procedures and their dates as required)	□ Yes □ No If Yes, what type of protective equipment was used by the HW? □ Gown □ Gloves □ Eye protection □ Surgical/medical mask □ NIOSH-certified N95 or an EU standard FFP2 mask □ FFP3 mask
Has the HW had prolonged face-to-face contact (>15 minutes) with an **asymptomatic** confirmed case in a health facility? (Add as many procedures and their dates as required)	□ Yes □ No If Yes, what type of personal protective equipment (PPE) was used by the HW? □ Gown □ Gloves □ Eye protection □ Surgical/medical mask □ NIOSH-certified N95, an EU standard FFP2 mask □ FFP3 mask
Was the contact present while any aerosol-generating procedures took place?	□ Yes □ No If Yes, specify procedure and date (dd/mm/yyyy) Procedure: ___/___/___ Procedure: ___/___/___ Was the contact wearing any type of a mask at this/these procedures? □ Surgical/medical mask □ NIOSH-certified N95, an EU standard FFP2 mask □ FFP3 mask □ None

6. Exposure information (if the close contact is NOT a Health W)		
Type of contact	□ Household □ Other, specify:	
Specify characteristics of contact with the confirmed case from first contact, while the primary case was **symptomatic** (Add as many dates as required)	Date (dd/mm/yyyy)	__/__/__
	Duration	_____(minutes)
	Setting	□ Home/household □ Hospital/health care □ Workplace □ Tour group □ Other, specify:

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

Specify characteristics of contact with the confirmed case from first contact, while the primary case was **asymptomatic** (Add as many dates as required)	Date (dd/mm/yyyy)	__/__/__
	Duration	_____(minutes)
	Setting	□ Home/household □ Hospital/health care □ Workplace □ Tour group □ Other, specify:

6a. Symptoms in contact	
Has the contact experienced any respiratory symptoms (sore throat, runny nose, cough, shortness of breath) in the period from 14 days **before** symptom onset in the confirmed case until the present?	□ Yes □ No
Has the contact experienced any respiratory symptoms (sore throat, runny nose, cough, shortness of breath) in the period up to 14 days **after** the last contact or until the present date, whichever is the earlier?	□ Yes □ No
Currently ill	□ Yes □ No
Date (dd/mm/yyyy) and time of first symptom onset	___/___/___ □ am □ pm
Fever (>38 °C) or history of fever	□ Yes □ No □ Unknown If Yes, date ___/___/___
Maximum temperature	°C □ Not applicable (na)
6b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, date ___/___/___
Runny nose	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown If Yes, date ___/___/___
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

Other neurological signs	□ Yes □ No □ Unknown If Yes, specify:
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 (dd/mm/yyyy) ___/___/___ □ Still ill □ Dead, if Yes, specify date of death (dd/mm/yyyy) ___/___/___ □ Unknown/lost to follow-up
Hospitalization ever required?	□ Yes □ No □ Unknown If yes, date of hospitalization and date of discharge (dd/mm/yyyy) ___/___/___ to ___/___/___
(NB. If the information below is not currently available, please leave blank and send through an update as soon as results are available)	
If dead, contribution of COVID-19 to death:	□ Underlying/primary □ Contributing/secondary □ No contribution to death □ Unknown
If dead, was a postmortem performed?	□ Yes □ No □ Unknown
If dead, results of postmortem's report where available:	
If dead, cause of death on Death certificate (specify)	

8. Contact pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If Yes, specify trimester: □ First □ Second □ Third □ Unknown
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
Chronic kidney disease	□ Yes □ No □ Unknown
Chronic neurological impairment/disease	□ Yes □ No □ Unknown
Organ or bone marrow 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:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Other, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for COVID-19 □ NEGATIVE for COVID-19 □ POSITIVE for other pathogens Please specify which pathogens:	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: □ No

9b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result (COVID-19 antibody titres)**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Other, specify:	Specify type (ELISA/IFA IgM/IgG, neutralization assay, etc.):	□ POSITIVE If positive, titre: □ NEGATIVE □ INCONCLUSIVE	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: ____ □ No

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

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Form B2: Contact follow-up reporting form – for close contacts of confirmed COVID-19 cases (Day 14–21)

COMMENT: Information in this form may already have been completed in the *Contact initial reporting form* (Form B1). It is therefore not necessary to repeat any data in these sections that have already been completed.

Name of confirmed case:

Unique Case ID/Cluster number (if applicable):

Contact ID number (C…):

1. Data collector information	
Name of data collector	
Data collector institution	
Data collector telephone number	
Data collector email	
Form completion date (dd/mm/yyyy)	___/___/___

2. Interview respondent information (if the person providing the information is not the contact)	
First name	
Family name	
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 worker □ Other, specify:	
Specify characteristics of contact with the confirmed case from first contact, while the primary case was **symptomatic** (Add as many dates as required)	Date (dd/mm/yyyy)	__/__/___
	Duration	_____(minutes)
	Setting	□ Home/household □ Hospital/health care □ Workplace □ Tour group □ Other, specify:

Specify characteristics of contact with the confirmed case from first contact, while the primary case was **asymptomatic** (Add as many dates as required)	Date (dd/mm/yyyy)	__/__/__
	Duration	_____(minutes)
	Setting	□ Home/household □ Hospital/health care □ Workplace □ Tour group □ Other, specify:

4a. Symptoms in contact	
Has the contact experienced any respiratory symptoms (sore throat, runny nose, cough, shortness of breath) in the period from 14 days **before** symptom onset in the confirmed case until the present?	□ Yes □ No
Has the contact experienced any respiratory symptoms (sore throat, runny nose, cough, shortness of breath) in the period up to 14 days **after** the last contact or until the present date, whichever is the earlier?	□ Yes □ No
Currently ill	□ Yes □ No
Please only complete following section if contact has demonstrated symptoms since last follow-up:	
Date (dd/mm/yyyy) and time of first symptom onset	___/___/___ □ am □ pm
Fever (>38 °C) or history of fever	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy to dd/mm/yyyy) ___/___/___ to ___/___/___
Maximum temperature	____°C □ na
4b. Respiratory symptoms	
Sore throat	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy to dd/mm/yyyy) ___/___/___ to ___/___/___
Runny nose	□ Yes □ No □ Unknown
Cough	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy to dd/mm/yyyy) ___/___/___ to ___/___/___
Shortness of breath	□ Yes □ No □ Unknown If Yes, dates (dd/mm/yyyy to dd/mm/yyyy) ___/___/___ to ___/___/___
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
Loss of appetite	□ Yes □ No □ Unknown
Nose bleed	□ Yes □ No □ Unknown
Fatigue	□ Yes □ No □ Unknown
Seizures	□ Yes □ No □ Unknown
Altered consciousness	□ Yes □ No □ Unknown
Other neurological signs	□ Yes □ No □ Unknown If Yes, specify:
Other symptoms	□ Yes □ No □ Unknown If Yes, specify:

5. Contact pre-existing condition(s)	
Pregnancy	□ Yes □ No □ Unknown If Yes, specify trimester: □ First □ Second □ Third □ Unknown

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

6a. Virology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Nasal swab □ Throat swab □ Nasopharyngeal swab □ Other, specify:	□ PCR □ Whole genome sequencing □ Partial genome sequencing □ Other, specify	□ POSITIVE for COVID-19 □ NEGATIVE for COVID-19 □ POSITIVE for other pathogens Please specify which pathogens:	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: □ No

6b. Serology testing methods and results:							
Complete a new line for each specimen collected and each type of test done:							
Laboratory identification number	**Date sample collected (dd/mm/yyyy)**	**Date sample received (dd/mm/yyyy)**	**Type of sample**	**Type of test**	**Result (COVID-19 antibody titres)**	**Result date (dd/mm/yyyy)**	**Specimens shipped to other laboratory for confirmation**
	___/___/___	___/___/___	□ Serum □ Other, specify:	Specify type (ELISA/IFA IgM/IgG, neutralization assay, etc.):	□ POSITIVE If positive, titre: □ NEGATIVE □ INCONCLUSIVE	___/___/___	□ Yes If Yes, specify date ___/___/___ If Yes, name of the laboratory: □ No

7. 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

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

Symptom diary for close contacts of confirmed COV-19 cases (Day 1–14)

Symptom diaries will be provided to each close contact, for them to record the presence or absence of various signs or symptoms for a minimum of 14 days after the administration of the initial contact questionnaire (Form B1).

The symptom diary template provided below is generic. In the context of a new virus with uncertain clinical presentation and spectrum, symptom diaries may be broadened to include vomiting, diarrhoea, abdominal pain, etc., as relevant, and may be altered to include symptom data for longer than 14 days.

In the event the contact develops any of these symptoms, ask him/her to inform your local public health team.

Day	**Symptoms***						
	No symptoms (check if none experienced)	**Fever ≥38 °C**	**Runny nose**	**Cough**	**Sore throat**	**Shortness of breath**	**Other symptoms: specify**
0	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
1	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
2	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
3	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
4	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
6	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
7	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
8	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
9	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
10	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
11	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
12	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
13	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	
14	□ None	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	□ Yes □ No	

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

3. FFX reporting forms: completion guidance

These notes are to provide guidance in completing the forms. It is suggested that the investigations could be divided into teams – these could include:

- a **"case reporter" team;**
- a **"contact reporter" team**; and
- **A "go to" team** who would liaise with additional data sources other than the case or contact, such as hospitals, laboratories, etc.

Form A0: Minimum data reporting form – for suspected and probable COVID-19 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	Health-care provider/review of medical records
Exposures in the 10 days before onset	Informant	
Medical history	Informant	Health-care provider/GP/review of medical records
Hospitalization	Informant/hospital	Hospital health information system
Test results	Testing laboratory	Laboratory database
Contact details	Informant	

Form A1: Case initial report form – for confirmed COVID cases (Day 1) and Form A2: Case follow-up form – for confirmed COVID cases (Day 14–21)

These forms should be completed by the "Case reporter" team.

Section	Sources	Verified against
Final case classification	Case reporter/hospital	
Reporter details	Case reporter	
Informant details	Informant	
Outcome/status	Informant	Statistical data, mortality, GP/hospital
Illness	Informant	Health-care provider/review of medical records
Clinical course/complications	Informant/interview with health-care provider	Review of medical records
Interaction with national security system	Informant/hospital	National social health information system
Reference test results	Testing laboratory	Laboratory database
Bacterial infections	Testing laboratory	Laboratory database

Form B1: Contact initial reporting form – for close contacts of confirmed COVID-19 cases (Day 1)

This form should be completed by the "Contacts reporter" team and should be completed after the initial case report form (B1) 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	Health-care provider/review of medical records
Outcome/status	Informant	Statistical data, mortality, GP/hospital
Case classification	Contact reporter	
Virological tests	Testing laboratory	Laboratory database
Medical history	Informant	Health-care provider/GP/review of medical records

Form B2: Contact follow-up reporting form – for close contacts of confirmed COVID-19 cases (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	Health-care provider/review of medical records
Clinical course/complications	Informant/interview with health-care provider	Review of medical records
Virological tests	Testing laboratory	Laboratory database

Symptom diary for close contacts of confirmed COV-19 cases (Day 1–14)

This form should be completed by the contacts themselves.

Symptom diaries will be provided to each close contact for them to record the presence or absence of various signs or symptoms for a minimum of 14 days after the administration of the baseline questionnaire (Form B1).

The symptom diary template provided is generic. In the context of a new virus with uncertain clinical presentation and spectrum, symptom diaries may be broadened to include vomiting, diarrhoea, abdominal pain, etc., as relevant, and may be altered to include symptom data for longer than 14 days.

In the event a contact develops any of these symptoms, he or she needs to inform your local public health team.

Appendix B: Comparison between the features and complementarity of the main coronavirus disease 2019 (COVID-19) early investigation protocols

	The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)	**Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)**	**Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health-care setting**
Population	The First Few X number of confirmed cases of COVID-19 and their close contacts in the general population.	Household close contacts of confirmed cases of COVID-19 (smaller epidemiological unit than FFX).	Health workers in a health-care setting in which a confirmed COVID-19 case has received care.
Aim	Transmission dynamics, severity and clinical spectrum, in a proxy of the general population.	Transmission dynamics, severity and clinical spectrum, in household settings.	Transmission dynamics, severity and clinical spectrum, in closed settings such as hospitals and health-care centres.
Potential output and analysis	Transmission dynamics, severity and clinical spectrum, through estimates of, primarily: • the clinical presentation of COVID infection and course of associated disease. • the secondary infection rate (SIR) and secondary clinical attack rate of COVID-19 among close contacts. • the serial interval of COVID-19 infection. • the symptomatic proportion of COVID cases (through contact tracing and laboratory testing). • identification of possible routes of transmission.	Key epidemiological data **to complement and reinforce the findings of FFX**, in the areas of, primarily: • the proportion of asymptomatic cases and symptomatic cases. • the incubation period and the duration of infectiousness and of detectable shedding. • the serial interval • reproduction numbers: R_0 and R of COVID-19. • clinical risk factors, and clinical course and severity of disease. • high-risk population subgroups	Transmission dynamics in health-care settings, through estimates of: • she secondary Infection rate (SIR) among health workers. • the range of clinical presentation and risk factors for infection. • the serological response following symptomatic COVID-19 infection. • possible routes of transmission

	and secondarily: • the basic reproduction number (R_0) of COVID-19. • the incubation period of COVID-19. • the preliminary infection and disease-severity ratios (e.g. case-hospitalization and case-fatality ratios).	• the secondary infection rate and secondary clinical attack rate. • patterns of health-care seeking	
Duration	At a minimum, enrolled cases and close contacts will complete data and specimen collection at enrolment (Day 1) and 14–21 days later, with two home visits.	Households will complete a minimum of four home visits within 28 days of enrolment/follow-up. Enrolment could be extended as far as desired; however, the most valuable period in order to use data for targeted public health action is in the early phases of the epidemic (first 2–3 months).	Health workers and health-care facilities will complete a minimum of two site visits within 21 days of enrolment/follow-up.
Start of the investigation	To be initiated in the first days after the arrival in Country X of a confirmed case of COVID-19. FFX is the primary protocol to be initiated in the case of a COVID-19 outbreak, upon identification of the initial laboratory-confirmed cases of COVID-19 virus in Country X in the early epidemic phases.	Ideally to be initiated before widespread community transmission occurs: as early as possible after the first cases of COVID-19 infection are confirmed and at least within the first 2–3 months after identification of initial cases. This should be followed by subsequent tracing of household contacts of early laboratory-confirmed cases of COVID-19 in Country X in the early epidemic phases.	To be initiated with the first identification of a laboratory-confirmed case of COVID-19 in a health-care setting. This should be followed by subsequent tracing of health worker contacts of early laboratory-confirmed cases of COVID-19 in Country X in the early epidemic/pandemic phases.

Recruitment	The first few confirmed cases of COVID-19 in Country X, and their close contacts, will be first few participants to be recruited. *Note*: Previous FF100/FFX studies for pandemic influenza have recruited 300–400 cases, along with their household contacts *(17)*.	Household contacts of primary cases of laboratory-confirmed COVID-19 infection.	Health worker contacts of early laboratory-confirmed cases of COVID-19 infection in Country X in the early epidemic/pandemic phases.
Minimum data and specimens to be obtained from participants	• Data collection: epidemiological data, including clinical symptoms; exposures, including contact with confirmed case(s); and pre-existing conditions. • Specimens: respiratory (and other) to diagnose current COVID-19 infection; and serum to inform seroepidemiological inferences. *Note*: Serum samples are mandatory to inform early seroepidemiological inferences, and respiratory (and other) samples to diagnose current COVID-19 infection.	• Household visit with respiratory sample collection at Days 1, 7, 14 and 28. • Serum sample collection is needed at Days 1 and 28, and highly encouraged at Day 14. • Symptom diaries recorded by household contacts from Day 0 to Day 14 and highly encouraged until Day 28. *Note*: Serum samples are mandatory to inform early seroepidemiological inferences, and respiratory (and other) samples to diagnose current COVID-19 infection.	• Health-care setting visit with serum sample collection at Day 1 and Day >21. • Symptom diaries recorded by health worker contacts from Day 0 to day 14 and highly encouraged until Day 28. *Note*: Serum samples are mandatory to inform early seroepidemiological inferences.

Appendix C: Go.Data software

Go.Data: what is it?

Go.Data is a field data-collection platform focusing on case data (including laboratory, hospitalization and other variables, through a case investigation form) and contact data (including contact follow-up). Main outputs from the Go.Data platform are contact follow-up lists and chains of transmission.

What are the key features of the Go.Data software?

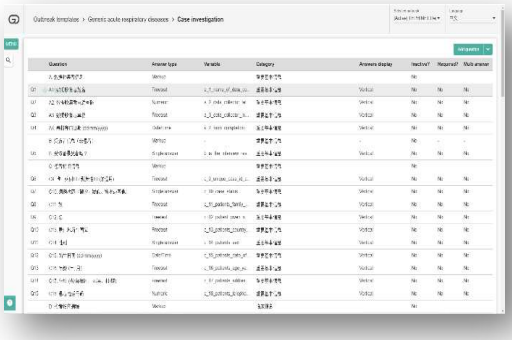
Multiplatform

Go.Data offers different types of operation (online, offline) and different types of installation (server, stand-alone). It functions on a range of operating systems (Windows, Linux, Mac). In addition, Go.Data has an optional mobile app for Android and iOS. The mobile app is focused on case and contact data collection, and contact tracing and follow-up.

Multilingual

Go.Data is multilingual, with the possibility to add and manage additional languages through the user interface.

Configurable



It is highly configurable, with the possibility to manage:

- reference data,
- location data, including coordinates,
- outbreak data, including variables on the case investigation form and the contact follow-up form.

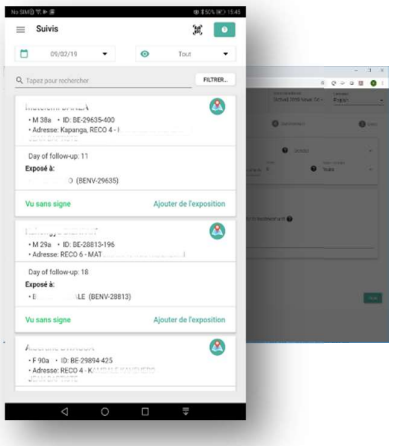
One Go.Data installation can be used to manage multiple outbreaks. Each outbreak can be configured in a different way to match the specifics of a pathogen or environment.

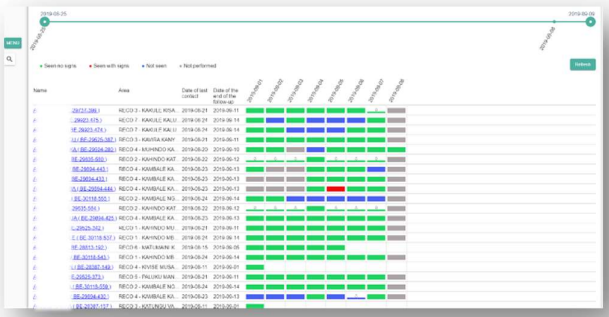
Case and contact data collection

The user can add cases, contacts and laboratory results. In addition, users also have an option to create events that may be relevant for outbreak investigation.

Contact follow-up lists are generated using outbreak parameters (that is, the number of days to follow up contacts, how many times per day should contacts be followed up).

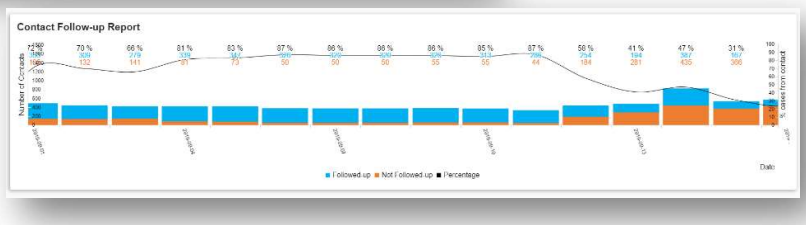
Extensive data export and import features are available to support the work of the data managers and data analysts.





Performing contact follow-up

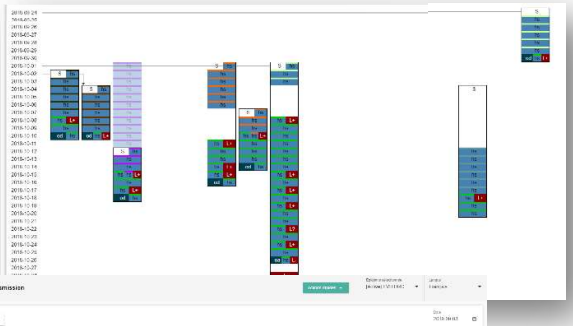
Go.Data has features to perform contact tracing using the web app or optional mobile app. Contact follow-up data are presented in the form of lists, graphs and operational dashboards. Contact tracing coordinators can review the workload of each contact tracing team.

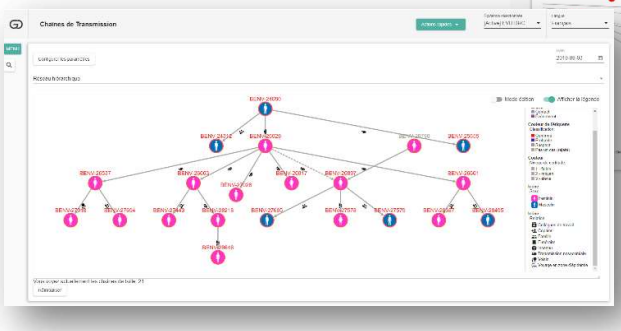


Extensive visualization features

Go.Data can be used to generate chains of transmission in the form of:

- networks, simple and hierarchical;
- timelines, using date of onset, date of reporting or date of last contact; and
- bar charts combining the date of onset, hospitalization data, laboratory testing data and outcome.





System administration

System administrators have access to an extensive set of features to manage users, assign roles and permissions and limit access to specific outbreak(s) only. In addition, they have access to usage logs, and can create and restore backups and manage the settings of one Go.Data instance.

Please visit www.who.int/godata or contact godata@who.int for more information.

Options for Go.Data hosting in countries

Option #1
Centrally Hosted server

One Go.Data installation for the entire region or for multiple countries. Separate outbreak is created for each country on the central server instance of Go.Data, and user access is provided at outbreak level (i.e. users from one country can only access case and contact data from their own country).

+

- Maintenance is easier.
- Installation of any updates is done centrally.
- Synchronization of the mobile phones can be done from anywhere.

–

- Countries may be reluctant to host detailed information that is required for contact tracing (e.g. names, addresses) on an external server.
- May require agreements between centralized server owner and Member States for this arrangement.
- Centralized server to manage user accounts and user access.

Option #2
Country hosted server

Separate Go.Data installation for each country. Countries install Go.Data on their infrastructure.

+

- Country has complete ownership and control of the server.
- Synchronization of the mobile phones can be done from anywhere.

–

- Likely to take more time to implement, as this option requires internal governmental approvals and provisioning infrastructure.
- Requires dedicated staff/team to manage the server.
- Not all countries may be in a position to host a Go.Data server.

Option #3
Standalone installation

Go.Data is installed on one or more computers in the country. These are typically personal computers or notebook/laptop computers. Data can be replicated across the computers.

+

- Fast to implement.
- User has complete ownership and control of the computer and data.

–

- In order to synchronize mobile phones, users have to be physically in the same location where the computer is.
- If there are multiple instances in a country it will be required to setup consolidation point.
- Personal data stored on multiple standalone computers.
- Limited availability of Go.Data to when laptop is running.
- Increased security risks through loss or damage of the standalone computer.

Go.Data terms of use and software license agreement

Please read these Terms of Use and Software License Agreement (the "**Agreement**") carefully before installing the Go.Data Software (the "**Software**").

By installing and/or using the Software, you (the "**Licensee**") enter into an agreement with the World Health Organization ("**WHO**") and you accept all terms, conditions, and requirements of the Agreement.

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11. General provisions

11.1. You may not assign this Agreement without the prior written agreement of WHO (such agreement not to be unreasonably withheld).

11.2. This Agreement may not be supplemented, modified, amended, released or discharged, unless approved in writing by WHO. WHO reserves the right to make changes and updates to this Agreement without prior notification. Such changes and updates shall be applied as of the date of their issuance. Any waiver by WHO of any default or breach hereunder shall not constitute a waiver of any provision of this Agreement or of any subsequent default or breach of the same or a different kind.

11.3. If any provision of this Agreement is invalid or unenforceable, it is to that extent to be deemed omitted. The remainder of the Agreement shall be valid and enforceable to the maximum extent possible.

11.4. Paragraph headings in this Agreement are for reference only.

11.5. Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, in accordance with the UNCITRAL Arbitration Rules. The parties shall accept the arbitral award as final.

12. Privileges and Immunities of WHO

12.1. Nothing contained herein or in any license or terms of use related to the subject matter herein (including, without limitation, the GNU General Public License discussed in paragraph 3.1 above) shall be construed as a waiver of any of the privileges and immunities enjoyed by the World Health Organization under national or international law, and/or as submitting the World Health Organization to any national jurisdiction.

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