Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)

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Reference:

The emergence of a new virus means that understanding transmission patterns, severity, clinical features and risk factors for infection will be limited at the start of an outbreak. To address these unknowns, WHO has provided Four Early sero-epidemiological Investigation Protocols (rebranded the WHO Unity Studies). One additional study to evaluate environmental contamination of COVID-19 is also provided.

These protocols are designed to rapidly and systematically collect and share data in a format that facilitates aggregation, tabulation and analysis across different settings globally.

Data collected using these investigation protocols will be critical to refine recommendations for case definitions and surveillance, characterize key epidemiological features of COVID-19, help understand spread, severity, spectrum of disease, and impact on the community and to inform guidance for application of countermeasures such as case isolation and contact tracing.

They are available on WHO website here: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations)

COVID-19 investigations and studies protocols currently available include:

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

2. Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)

3. Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) among health workers in a health-care setting.

4. Population-based age-stratified seroepidemiological investigation protocol for coronavirus 2019 (COVID-19) infection

5. Surface sampling of COVID-19 virus: a practical "how to" protocol for health care and public health professionals

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All WHO protocols for COVID-19 are available on the WHO website together with the technical guidance documents.

Version Control

Main updates for version 2.2:

- Technically edited version including consistency check and alignement with the three other early investigation protocols.
- Capture **exposure also during the asymptomatic period of the confirmed case**.
- Update of the **Go.Data** section, as now household 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).
- Addition of an appendix on "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 (Appendix B).
- Updated references, to align with the latest WHO guidance.

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Summary

Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)	
Population	All household contacts of confirmed cases of COVID-19
Potential output and analysis	Key epidemiological data **to complement and reinforce the findings of *The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19)*** *(1)*, 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 the serial interval of COVID-19 infection • the reproduction numbers: R_0 and R of COVID-19 • clinical risk factors for COVID-19, and the clinical course and severity of disease • high-risk population subgroups • the secondary infection rate and secondary clinical attack rate of COVID-19 infection among household contacts • patterns of health-care seeking.
Design	Prospective study of household contacts of laboratory-confirmed cases of COVID-19, ideally before widespread community transmission occurs.
Duration	At a minimum, enrolled household cases and contacts will complete data and specimen collection at enrolment (Day 1) and for 28 days of follow-up, with four home visits.
Minimum information and specimens to be obtained from participants	• 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.

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

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 and study protocols currently available include:

- *The First Few X cases and contacts (FFX) investigation protocol for coronavirus disease 2019 (COVID-19) (1)*;
- *Protocol for assessment of potential risk factors for coronavirus disease 2019 (COVID-19) infection 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).*

- *Population-based age-stratified seroepidemiological investigation protocol for coronavirus 2019 (COVID-19) infection*

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 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 study will be carried out.

1. Background

1.1 Introduction

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)*.

Closed settings, such as households, have a defined population that may not mix readily with the larger surrounding community, and therefore such settings can provide a strategic way to track emerging respiratory infections and characterize virus transmission patterns because the denominator can be well defined. Also, exposure is within the setting, and follow-up of household contacts is generally more feasible in this well-defined setting as compared to an undefined one. Studies in household settings allow determination of the transmission dynamics (reproduction number and serial interval) of the virus, as well as aiding understanding of the clinical spectrum of illness in secondary cases *(15)*. Closed settings are also useful to observe chains of transmission in an epidemic, as the pool of susceptible, exposed individuals is larger. Therefore, in the case of multiple waves of infection through the closed setting, unique insight into transmission dynamics can be derived in the early epidemic stages.

To date, initial surveillance has focused primarily on patients with severe disease, and, as such, the full spectrum of the disease, including the extent and fraction of mild or asymptomatic infection that does not require medical attention, is not clear. Infections identified in close contacts are potentially generalizable to naturally acquired infections (in contrast to cases presenting for emergency care, among which there would be fewer mild cases). Following close contacts with similar levels of exposure to infection from primary cases can also permit identification of the asymptomatic fraction. Principally, follow-up and testing of respiratory specimens and serum of close contacts can provide useful information about newly identified cases, as well as the spectrum of illness and frequency (by, for example, age) of asymptomatic and symptomatic infection.

With the emergence of a novel coronavirus, the initial seroprevalence in the population will be low, due to the virus being new in origin. Therefore, surveillance of antibody seroprevalence in a population can allow inferences to be made about the cumulative incidence of infection in the population. Household transmission studies also can provide the opportunity to follow up confirmed cases, to understand antibody kinetics.

The following protocol has been designed to investigate household transmission of the virus responsible for COVID-19 in any country in which COVID-19 infection has been reported and households are exposed. 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 standardized 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.

1.2 Objectives

The overall aim of this protocol is to gain an understanding of the transmission dynamics of COVID-19 to household contacts of laboratory-confirmed cases of COVID-19, as well as rapid and early information on key clinical, epidemiological and virological characteristics of COVID-19 infection.

The primary objectives of this household transmission study are to provide key epidemiological data **to complement and reinforce the findings of FFX** *(1)*, in the areas of:

- the proportion of asymptomatic cases and symptomatic cases;
- the incubation period of COVID-19 and the duration of infectiousness and of detectable shedding;
- the serial interval of COVID-19 infection;
- the reproduction numbers: R_0 and R of COVID-19;
- clinical risk factors for COVID-19, and the clinical course and severity of disease;
- high-risk population subgroups;
- the secondary infection rate and secondary clinical attack rate of COVID-19 infection among household contacts; and
- patterns of health-care seeking.

A reminder of some definitions of epidemiological terms:

- 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 **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.
- 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 **duration of infectiousness** is the time for which virus is shed and able to be transmitted, regardless of clinical symptoms.
- It is currently not known how long detectable COVID-19 virus shedding lasts; information from this study would help to clarify the **duration of detectable shedding** among individuals with confirmed infection.

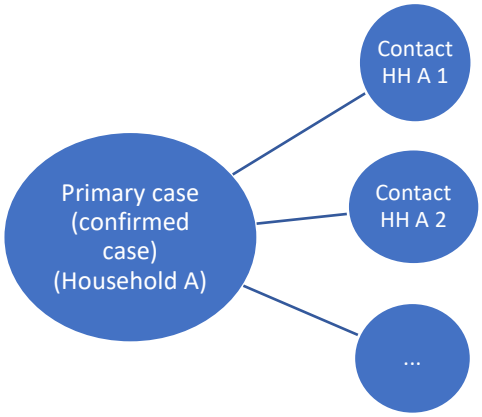
2. Methods

2.1 Design

This household transmission investigation is a prospective case-ascertained study of all identified household contacts of a laboratory-confirmed COVID-19 infection (see Section 2.2). Participants are identified from those with laboratory-confirmed infection, which is distinct from a cohort study in which a group of disease-free households are recruited and then followed over time (see Fig. 1). 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 household transmission 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 household transmission protocol aims to identify key clinical, epidemiological and virological characteristics of infection with this novel virus and its transmission in near real-time.

Fig. 1. The chain of transmission in a household transmission study



2.2 Population

The population under investigation consists of the confirmed cases of COVID-19 and their close contacts in their households. **Households** will be enrolled in the study once a confirmed COVID-19 case is identified in at least one member of the household. Households are subsequently followed up to observe secondary infections. If there is a large number of eligible primary cases it may not be feasible to follow up all households, because of limitations in resources and capacity. Therefore, it may be necessary in Country X to predetermine and agree upon a sampling strategy for the inclusion of households to remove possible sources of bias.

Every effort should be made to include all identified household contacts of cases of laboratory-confirmed COVID-19.

Other relevant inclusion/exclusion criteria for consideration by countries:

- Households could be excluded (or not, if it is possible to tease out the transmission dynamics) if:
    - the date of symptom onset of COVID-19 is the same for more than one family member

(**co-primary cases**); or
    - **a household contact is symptomatic at the initial home visit on Day 1** (so identified as a possible case), as it will increase the complexity of analyses of transmission dynamics.
- **Hospitalized cases and their contacts** may be excluded from this study, as they have been removed from the household and therefore the level of exposure of household contacts is unclear. Hospitalized individuals may only represent a small subset of individuals in the community and are likely to be picked up in other clinical studies.
- Every effort should be made to include all identified household contacts of cases of laboratory-confirmed COVID-19.

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 **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.

2.2.2 Household contact definitions

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

Box 2. Household contacts definition and classification
Household definition For the purpose of this investigation, a household is defined as a **group of people (two or more) living in the same residence**. In practice, the technical definition may vary, due to social, political and cultural practices. Definitions of a household that may be used include, but are not limited to: • two or more people living together in a domestic residence (residential institutions, such as boarding schools, dormitories, hostels or prisons will be excluded); and • a dwelling or group of dwellings with a shared kitchen or common opening onto a shared household space.
Household contact definition For the purpose of this investigation, **a household contact** is defined as any person who has resided in the same household (or other closed setting) as a confirmed COVID-19 case.

COMMENT: For the purposes of comparability between investigations, it is important that whichever definition of a household contact is used is well detailed in any reporting on the investigation.

2.3 Duration

The investigation can continue for as long as is determined feasible by the country implementing the investigation. However, ideally, enrolled household contacts will complete four home visits, to include the enrolment visit (Day 1) and three follow-up visits within 28 days of enrolment. Specimens and information on risk factors and symptoms will be collected from primary cases and from each of his/her household contacts. The duration of follow-up may vary depending on further secondary objectives.

Study enrolment could be extended as far as desired; however, the most valuable period for using data for targeted public health action is in the early phases of the epidemic (first 2–3 months).

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 household 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 seroprevalence once serology capacity is available). Follow-up would occur as described in the case investigation algorithm (see Fig. 2).

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) *(16)*, Member States and partners, to support and facilitate outbreak investigation including field data collection, contact tracing and visualization of chains of transmission *(17)*. 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 a household contact 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 household contact 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 the purposes of this investigation, data and specimens will be collected through home visits from cases and household contacts on the day of recruitment (Day 1), followed by home visits on Day 7, Day 14 and Day 28 if possible.

COMMENT: For surveillance, follow-up needs to be more frequent. The specimen collection schedule for the household transmission investigation described here, is added on top of normal follow-up of contacts.

For cases, data will be collected using **Form 1A** for the first visit, followed by **Forms 2, 3 and 4**. For contacts, data will be collected using **Form 1B** for the first visit, followed by **Forms 2, 3 and 4** (see Table 1 and Fig. 3).

Symptom diaries (template available in Appendix A of this protocol) will be provided for all household contacts to complete for a minimum of 14 days, and up to 28 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 household 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

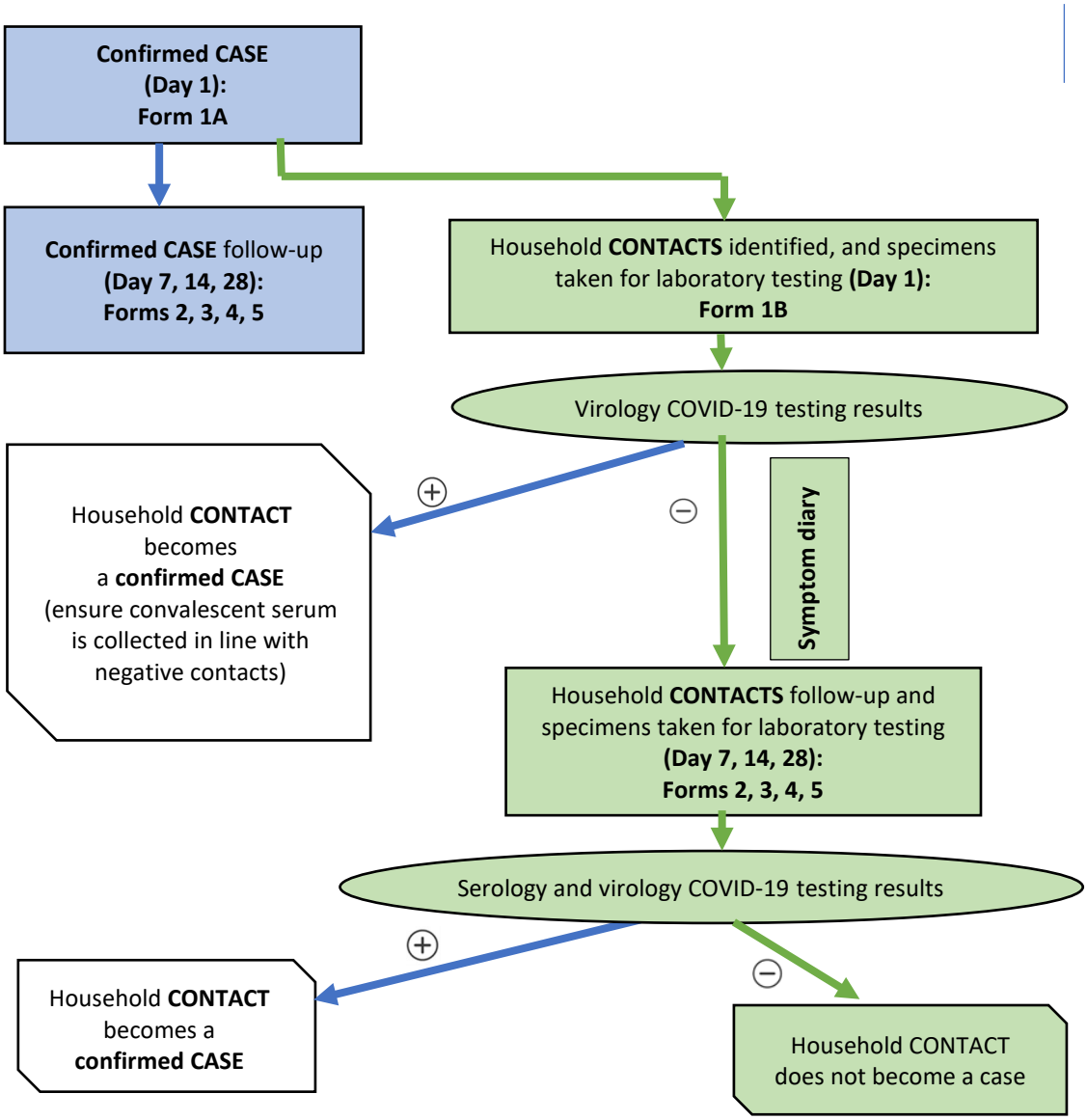


Table 1. Summary of data-collection tools

Form number	Purpose of form	Collecting from whom?	When should it be collected?
CONFIRMED CASES			
Form 1A	Case **initial** report form	For **confirmed** COVID-19 **c**ases	As soon as possible after laboratory confirmation of a case **(Day 1)**
Forms 2, 3 and 4	Case **follow-up** forms	For **confirmed** COVID-19 cases: outcomes	At home visits (**Days 7, 14 and 28**) respectively after initial symptom onset of the case
HOUSEHOLD CONTACTS			
Form 1A	Contact **initial** reporting form	For household contacts of confirmed COVID-19 cases	As soon as possible, ideally within 24 hours after laboratory confirmation of the primary case (**Day 1**)
Forms 2, 3 and 4	Contact **follow-up** forms	For household contacts of confirmed COVID-19 cases: outcomes	At home visits (**Days 7, 14 and 28**) respectively
Symptom diary	Record the presence or absence of various signs or symptoms	For confirmed COVID-19 cases (if possible) and household contacts of confirmed COVID-19 cases	For a **minimum of 14 days** and up to 28 days after administration of the initial questionnaire (Form 1a/1b)
CONFIRMED CASES AND HOUSEHOLD CONTACTS			
Form 5	**Laboratory results report:** track and summarize all laboratory results (and methods used)	For confirmed COVID-19 cases and household contacts of confirmed COVID-19 cases	This table will need to be filled in/updated at each specimen-collection time point above

Fig. 3. Timeline of data and specimen collection in the household transmission study

Day since recruitment	**1**	**…**	**7**	**…**	**14**	**…**	**28**
Home visit and data collection							
Respiratory sample		(optional)		(optional)		(optional)	(optional)
Serum sample (dependent on country)			(optional)		Highly encouraged		
Other specimens (if relevant)	(optional – situation dependent)						
Symptom diaries						Highly encouraged	

Orange boxes indicate activities that are needed for the study.
Light orange boxes indicate when serum collection (or symptom diary) is highly encouraged, but not essential, according to resources and capacity.
Green boxes indicate where additional specimens could be collected above the minimum specimen requirements of this study to increase information available. Please note that this could also include collecting specimens from household contacts when they first become symptomatic.

2.5 Laboratory evaluations

2.5.1 Laboratory analysis

Laboratory guidance for COVID-19 can be found on the WHO website *(8).* 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 *(18).*

Serologic assays specific to COVID-19 are currently under development / in the process of evaluation. The protocols or Standard Operating Procedures (SOPs) will be published on the WHO website once they become available. Cross reactivity to other coronaviruses may be an issue and should be considered in the interpretation of data. Multiple assays may be required to confirm a seropositive for COVID-19 virus. Serum samples could be stored at -80°C until more information on performance of available assays are available.

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

2.5.2 Specimen collection

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

2.5.2.1 Confirmed cases

All baseline respiratory and serum samples (as directed by specimen collection guidance in Country X) should be collected from confirmed cases and their household contacts, 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 (and other samples) may include upper respiratory tract samples and clotted blood[1], but also oral fluid, urine and faeces, and should be collected as described in Fig. 1. Lower respiratory tract samples can also be collected, if feasible, but recommended infection prevention and control precautions should be in place prior to collection (see Section 2.9.3), as these are higher-risk interventions *(19)*.

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 by research staff, depending on resources, logistics and training.

Appropriate personal protective equipment (PPE) should be worn when specimens are being collected from confirmed cases *(19)*.

[1] Adapted from reference *(19).*

2.5.2.2 Household contacts

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

Respiratory specimens should be collected for molecular testing, as well as serum samples for serology, from all members of the household, regardless of symptoms, together with the administration of the baseline questionnaire. At the Day 7 and Day 14 visits, respiratory samples (and other relevant specimens) should be collected from all members of the household, for virological testing, regardless of symptoms, and at the Day 28 visit, a serum sample (and other potentially relevant specimens) could be collected from all household contacts – see Fig. 1.

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

2.5.2.3 Note on serology

Paired clotted blood samples should be taken for serology and handled and separated correctly by the laboratory. Paired serological samples cases 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 household 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 household contacts).
- A follow-up (or convalescent) clotted blood sample should be taken:
    - at least 14 days after the baseline sample; or
    - (for a case) 28 days after symptom onset if an acute sample couldn't be taken when the case was symptomatic; or
    - (for a household contact) 28 days after the last exposure if an acute sample wasn't taken.

2.5.3 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 WHO laboratory guidance, available on the WHO website *(8)*.

For each biological sample collected, the time of collection, the conditions for transportation and the time of arrival at the study laboratory will be recorded. Specimens should reach the laboratory as soon as possible after collection. If the specimen is not likely to reach the laboratory within 72 hours, 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 (20).*

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 household contacts of a confirmed COVID-19-infected patient. Informed consent will be obtained from all cases and household 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 household contacts. The primary benefit of the study is indirect, in that data collected will help improve and guide efforts to understand transmission of 2019-nCoV and prevent further spread of 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” *(21)*. 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 *(17)*, 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 need to be trained in infection prevention and control procedures (standard contact, droplet or airborne precautions, as determined by national or local guidelines) *(19)*. 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 *(22).*

3. Statistical analyses

3.1 Sample size

The sample size of Country X will be determined by the number of household contacts of the confirmed COVID-19-infected individual. Every effort should be made to include all household contacts of the confirmed COVID-19-infected individual, to maximize the statistical power of the investigation. Larger studies will undoubtedly permit more robust analysis of potential factors affecting the secondary infection risk, more precise estimation of the asymptomatic fraction, and more detailed characterization of serological responses following infection.

3.2 Plan of analyses

Household transmission investigation will be not be able to answer every question we have about COVID-19 infection, but it will contribute to respond to the key questions in the early stages of the epidemic, which can inform public health interventions. Other protocols for investigations for COVID-19 can assist in providing supplementary data to improve estimates 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 household transmission investigation should

provide an insight into the clinical spectrum and course of disease due to COVID-19 infection from individual cases – for example, the number of households contact with symptomatic or asymptomatic 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.

More advanced analysis, using the investigation forms/questionnaires and specimens generated, should allow robust estimation of key epidemiological parameters as described in Table 2. The table includes a comments/limitations section, which provides insight into the strengths and weaknesses of this protocol.

Table 2. Definition and sources of epidemiological parameters that can be estimated during a household transmission investigation

Parameter	Definition (*"simplified" expression of the definition*)	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 1A: Q3, Q4, Q5 Form 1B: Q4, Q5 Form 2, 3, 4, 5	• 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 1A: Q6	
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 1A: Q6 Form 1B: Q6 Form 2, 3, 4, 5 Symptom diary	• The numerators of interest are the numbers of those household contacts reporting various signs and symptoms of infection (e.g. fever, cough) and the number/proportion of those contacts reporting no signs or symptoms (i.e. the asymptomatic fraction); the denominator is the total number of cases
Hospitalization rate or incident hospitalizations	A measure of the frequency of hospitalized cases of COVID-19 among the	Hospitalization data. Form 1A: Q6	

	confirmed cases in the householdin a defined period of time.	Form 1B: Q7 Form 2,3,4	
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 1A: Q6 Form 1B: Q6 Form 2, 3, 4, 5 Symptom diary	• 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 2, 3, 4, 5	• The numerator will be determined as the number of household contacts with confirmed COVID-19 infection, while the denominator will be determined as the total number of household contacts • Represents an overall risk of infection among household contacts for a defined time period.
Clinical presentation	The range of clinical symptoms in cases and contacts. (*Clinical symptoms and severity*)	Symptoms Form 1A: Q6 Form 1B: Q6	• In-hospital clinical studies will enhance understanding of the clinical course, severity and risk determinants, as well as case fatality.
Serological response to infection	Change in serum level of specific antibodies to	Laboratory results Form 2, 3, 4, 5	• It will only be possible to calculate this with the

	COVID-19 virus. (*Increase in titre*)		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. 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 1A: Q6 Form 1B: Q6 Form 2, 3, 4, 5 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 householdcontact. (*From infection to infection*)	Specimens and dates Form 1 Q5 Form 2, 3, 4, 5	• Will be greatly enhanced by information from the first few outbreaks, where transmission chains may be more identifiable and prolonged
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 1A: Q4, Q5 Form 1B Q4, Q5	• 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) • This may be biased from this study, as recruitment is on the basis of being detected and confirmed to have COVID-19 and health-care-seeking behaviour may vary between population groups
Case-fatality ratio	The number of deaths in housholds caused by COVID-19 in cases, compared to the total number of cases with COVID-19 in the household. (*Proportion of COVID-19 cases who die*)	Dead/alive status and case confirmation Form 2, 3, 4, 5	• A large number of cases will probably be needed before a significant number of deaths are seen, in order to allow reliable estimates through ousehold investogations (also

			follow-up may end before deaths due to secondary infections can be observed). • More likely to be an overestimate in this investigation, owing to reporting/selection bias of the initial cases.

Genomic data, including phylogenetic analysis		Laboratory data Form 2, 3, 4, 5	• 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 1A: Q5 Form 2, 3, 4, 5 Symptom diary	• 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 1B: Q6 Form 2, 3, 4, 5 Symptom diary	• Not the main aim of household transmission studies, but if the study is continued and transformed into a long-term "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 households and number of household contacts included;

- the number of laboratory-confirmed COVID-19 cases among the household contacts;
- the number of symptomatic and asymptomatic household contacts; and
- the number of household 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 households and household 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

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3. Surface sampling of COVID-19 virus: a practical "how to" protocol for health-care and public health professionals. Geneva: World Health Organization; 2020 (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations, accessed 29 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).
- World Health Organization. National capacities review tool for a novel coronavirus (nCoV) (https://www.who.int/publications-detail/national-capacities-review-tool-for-a-novel-coronavirus-(ncov), accessed 12 February 2020).
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- Protocol to investigate non-seasonal influenza and other emerging acute respiratory diseases. Geneva: World Health Organization; 2018 (WHO/WHE/IHM/GIP/2018.2; https://www.who.int/influenza/resources/publications/outbreak_investigation_protocol/en/, accessed 12 February 2020).

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

Household transmission investigation protocol for coronavirus disease 2019 (COVID-19)

FOR CASES
• **Form 1A : Case initial reporting from for confirmed COVID-19 cases (Day 1)** • **Form 2: Follow-up reporting from – for confirmed COVID-19 cases and household contacts (Day 7)** • **Form 3: Follow-up reporting form – for confirmed COVID-19 cases and household contacts (Day 14)** • **Form 4: Follow-up reporting form – for confirmed COVID-19 cases and household contacts (Day 28)** • **Form 5: Laboratory results reporting form**
FOR HOUSEHOLD CONTACTS
• **Form 1B : Contact initial reporting form – for household contacts of confirmed COVID-19 cases (Day 1)** • **Form 2: Follow-up reporting from – for confirmed COVID-19 cases and household contacts (Day 7)** • **Form 3: Follow-up reporting form – for confirmed COVID-19 cases and household contacts (Day 14)** • **Form 4: Follow-up reporting form – for confirmed COVID-19 cases and household contacts (Day 28)** • **Form 5: Laboratory results reporting form** • **Symptom diary for household contacts of confirmed COVID-19 cases**

Form 1A : Case initial reporting from – for confirmed cases (Day 1)

Unique Primary Case ID/Household number

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)	___/___/___

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

4. Primary 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	
Nationality	
Ethnicity (optional)	
Responsible health centre	
Occupation	□ Health worker □ Work/stay home □ Nursery/primary school/secondary school □ Student □ Other, specify:

	For each occupation, specify location or facility:

5. Household information	
Location of household/Address of primary case	
Household size (number of people who usually live in the house, this will be varied depending on culture)	
Number of rooms in house	
Number of bedrooms	
Age of each household member	_____ _____ _____ _____

6a. Primary case 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:
6b. 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): ___/___/___
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
Loss of smell (anosmia) or taste	□ 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. Primary case 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:

8. Report of laboratory results
Please impute laboratory results once they become available in the "Laboratory results report"

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

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

Unique Primary Case ID/Household number

Household Contact ID Number (C…):

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)	___/___/___

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

4. Contact identifier information	
First name	
Family name	
Sex	□ Male □ Female □ Not known
Date of birth (dd/mm/yyyy)	___/___/___ □ Unknown
Relationship to confirmd case	
Telephone (mobile) number	
Age (years, months)	___ years ___ months □ Unknown
Email	
Address	
National social number/identifier (if applicable)	
Country of residence	
Nationality	
Ethnicity (optional)	
Responsible health centre	

Occupation (specify location/facility)	□ Health worker □ Work/stay home □ Nursery/primary school/secondary school □ Student □ Other, specify: For each occupation, specify location or facility:

5. Household information	
Location of household/Address of contact if different from address of primary case	
Date of last contact with the confirmed case (dd/mm/yyyy)	___/___/___
Does the contact share a room (or usually share a room) with the primary case?	□ Yes □ No □ Unknown
Number of days during the time the case was ill at home that were spent in contact with case (refer to household contact definition)	
Did the contact take care of the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact hug the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact kiss the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact shake hands with the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact share a meal with the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact eat with hands from the same plate as the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact share a drinking cup/glass with the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact share utensils with the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact sleep in the same room as the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown
Did the contact share a toilet with the case during the time he/she was ill at home before hospitalization?	□ Yes □ No □ Unknown

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 If No, skip to Section 5c
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
Date (dd/mm/yyyy) and time of first symptom onset	___/___/___ □ am □ pm □ Asymptomatic □ Unknown
Fever (≥38 °C) or history of fever	□ Yes □ No □ Unknown If Yes, date ___/___/___

	If Yes, specify maximum temperature: °C
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
Loss of smell (anosmia) or taste	□ 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 (Day 1)	
Outcome	□ Alive □ Dead □ na □ Unknown
Outcome current as of date (dd/mm/yyyy)	___/___/___ □ Unknown □ na
Hospitalization	□ Yes □ No □ Unknown If Yes, date of first hospitalization (dd/mm/yyyy) ___/___/___ □ Unknown If Yes, specify reason for hospitalization:

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:

9. Report of laboratory results
Please impute laboratory results once they become available in the "Laboratory results report"

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

Form 2: Follow-up reporting from – for confirmed cases and household contacts (Day 7)

Unique Primary Case ID/Household number

Household Contact ID Number (C…):

1. Report of laboratory results (Day 7)
Please impute laboratory results once they become available in the "Laboratory results report"

2. Outcome (Day 7)	
Outcome	□ Alive □ Dead □ na □ Unknown
Outcome current as of date (dd/mm/yyyy)	___/___/___ □ Unknown □ na
Hospitalization	□ Yes □ No □ Unknown If Yes, date of first hospitalization (dd/mm/yyyy) ___/___/___ □ Unknown If Yes, specify reason for hospitalization:

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

Form 3: Follow-up reporting form – for confirmed cases and household contacts (Day 14)

Unique Primary Case ID/Household number

Household Contact ID Number (C…):

1. Report of laboratory results (Day 14)
Please impute laboratory results once they become available in the "Laboratory results report"

2. Outcome (Day 14)	
Outcome	□ Alive □ Dead □ na □ Unknown
Outcome current as of date (dd/mm/yyyy)	___/___/___ □ Unknown □ na
Hospitalization	□ Yes □ No □ Unknown If Yes, date of first hospitalization (dd/mm/yyyy) ___/___/___ □ Unknown If Yes, specify reason for hospitalization:

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

Form 4: Follow-up reporting form – for confirmed cases and household contacts (Day 28)

Unique Primary Case ID/Household number

Household Contact ID Number (C…):

1. Report of laboratory results (Day 28)
Please impute laboratory results once they become available in the "Laboratory results report"

2. Outcome (Day 28)	
Outcome	□ Alive □ Dead □ na □ Unknown
Outcome current as of date (dd/mm/yyyy)	___/___/___ □ Unknown □ na
Hospitalization	□ Yes □ No □ Unknown If Yes, date of first hospitalization (dd/mm/yyyy) ___/___/___ □ Unknown If Yes, specify reason for hospitalization:

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

Form 5: Lab results reporting form– for confirmed cases and household contacts (Day 1, 7, 14, 28)

This table will need to be completed for every specimen collection at each point at the basilne and in the follow-up for case and households contact, depending on the chosen specimen-collection schedule.

1a. 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

1b. 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

Symptom diary for household contacts of confirmed cases (Day 1–28)

Symptom diaries will be provided to each household contact, for them to record the presence or absence of various signs or symptoms for up to 28 days (minimum 14 days) after the administration of the initial contact questionnaire (Form 1B).

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 28 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	
…							
28	□ 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.

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-19 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	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 of COVID-19 and the duration of infectiousness and of detectable shedding • the serial interval of COVID-19 infection • the reproduction numbers: R_0 and R of COVID-19	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.

	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).	• clinical risk factors for COVID-19, and the clinical course and severity of disease • high-risk population subgroups • the secondary infection rate and secondary clinical attack rate of COVID-19 infection among household contacts • 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	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.

		COVID-19 in Country X in the early epidemic 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.	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?

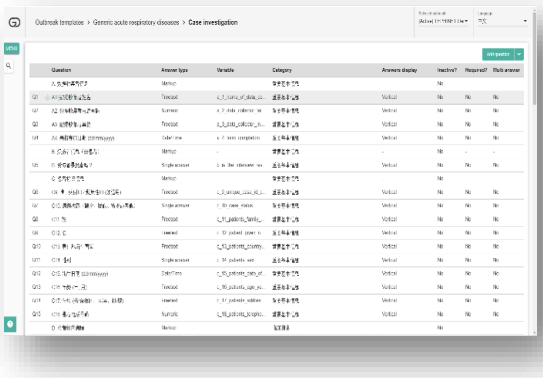
Multiplatform

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.

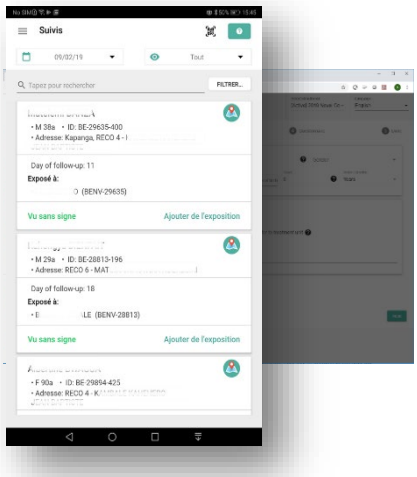
One Go.Data installation can be used to manage multiple outbreaks. Each outbreak can be configured in a different way to match the specifics of a pathogen or environment.

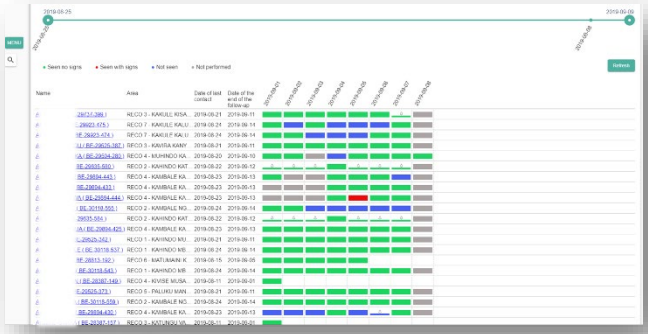
Case and contact data collection

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).

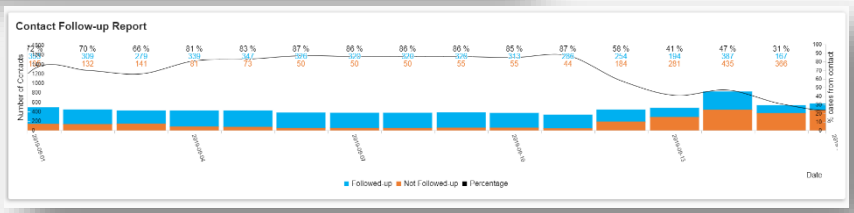
Extensive data export and import features are available to support the work of the data managers and data analysts.





Performing contact follow-up

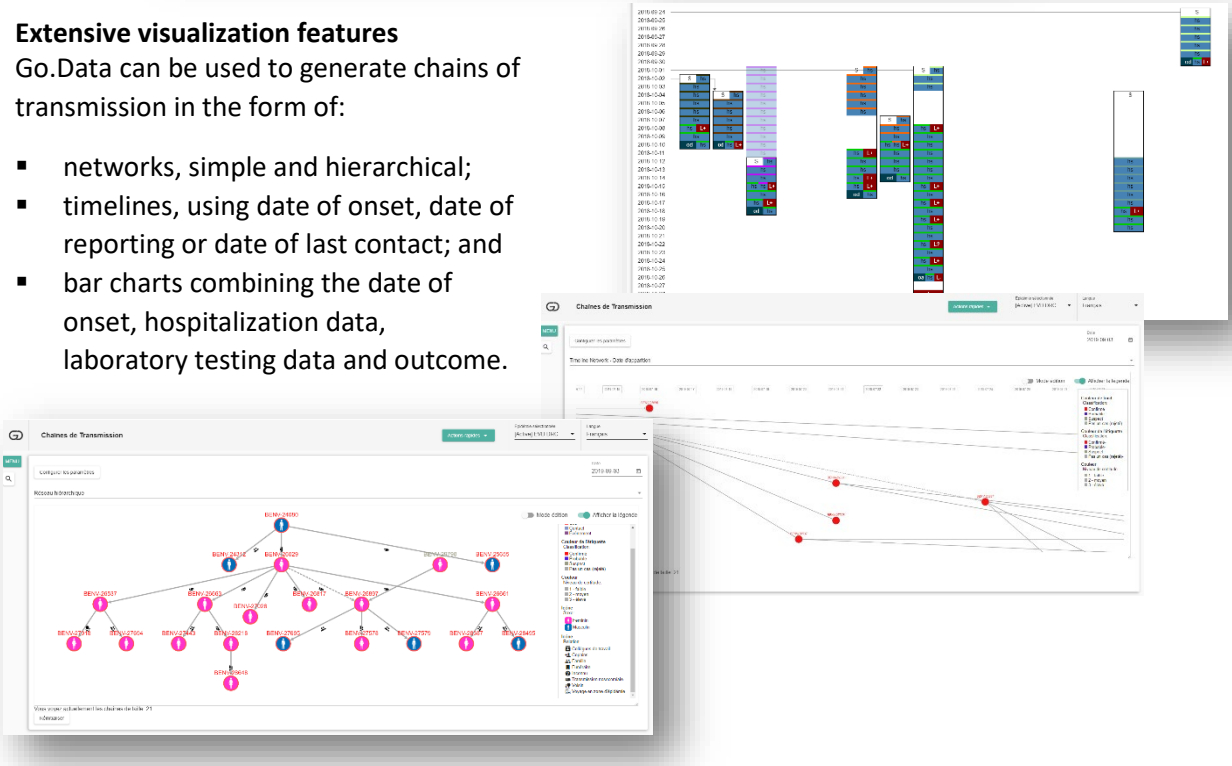
Go.Data has features to perform contact tracing using the web app or optional mobile app. Contact follow-up data are presented in the form of lists, graphs and operational dashboards. Contact tracing coordinators can review the workload of each contact tracing team.



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	OPTION #2 COUNTRY HOSTED SERVER	OPTION #3 STANDALONE INSTALLATION
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).	Separate Go.Data installation for each country. Countries install Go.Data on their infrastructure.	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.
+ ▪ Maintenance is easier. ▪ Installation of any updates is done centrally. ▪ Synchronization of the mobile phones can be done from anywhere.	+ ▪ Country has complete ownership and control of the server. ▪ Synchronization of the mobile phones can be done from anywhere.	+ ▪ Fast to implement. ▪ User has complete ownership and control of the computer and data.
– ▪ 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.	– ▪ 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.	– ▪ 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**").

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

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WHO reference number: WHO/2019-nCoV/HHtransmission/2020.4