# Protocol for the monitoring and evaluation of shielding against COVID-19 among high-risk persons in low-income settings

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| Design | Monitoring and Evaluation Plan including:<br>■ Prospective cohort study<br>■ Process evaluation including qualitative methods |
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## Summary

**Background**: Shielding aims to prevent infections among groups at high risk of COVID-19 mortality (e.g., persons ≥60 years and/or with non-communicable or chronic communicable disease) by temporarily housing them in 'green zones' where physical contact with the rest of the community is minimized.

**Purpose**: This protocol outlines a methodology for (1) monitoring the implementation of shielding to inform programmatic improvements and for (2) evaluating its impact on reducing infection and mortality among shielded persons and its implementation feasibility from the perspective of stakeholders, communities and beneficiaries.

**Methods**: Communities and households with high-risk persons must first decide on the modality of shielding (e.g. individuals isolate in their household or relocate in small groups at the street/block or neighbourhood/sector level). The monitoring and evaluation system aims to collect data over time on morbidity and mortality in shielding and non-shielding persons. See Figure 1 below.

The outcome measures of effectiveness are the attack rate of symptomatic suspected COVID-19 and overall death rate in the shielding group (compared with rates in the non-shielding group using relative risk estimates). Other outcomes include the proportion of green zones with potential virus introduction and shielding adherence over time.

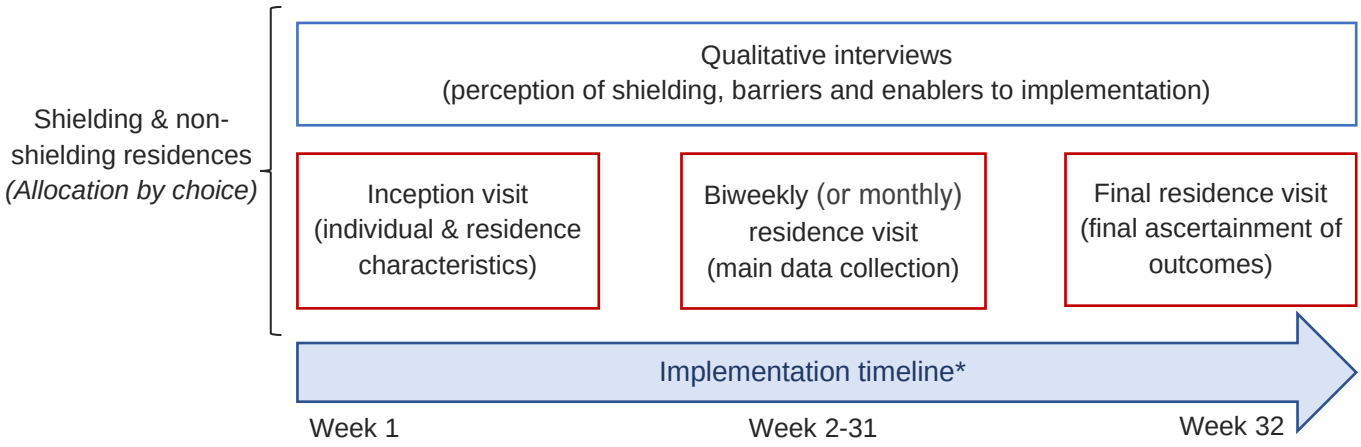


**Figure 1: Data collection strategy**

Red boxes represent routine questionnaires for the cohort study; blue box represents qualitative study

* Indicative timeline: may be different depending on the duration of the shielding intervention

# 1. Background

## 1.1. Shielding: general principles

In low-income settings, population-wide preventative measures (e.g. distancing, hygiene improvements) would have to achieve very high levels of compliance in order to decrease COVID-19 transmission to an appreciable extent; this is because the baseline transmissibility of the virus in overcrowded communities with poor sanitation and large household sizes is likely to be considerably higher than hitherto observed in high-resource settings. Moreover, stringent population-wide distancing measures ("lockdowns") are considered to be unsustainable given their deleterious effects on economies and livelihoods.

A more targeted community-led approach of specifically preventing infections among groups at high risk of COVID-19 mortality may thus be a useful strategy to reduce mortality and decrease pressure on health services: we refer to this approach as 'shielding' to denote it from more generic distancing measures.[1-3] Its core feature is to temporarily house high-risk individuals within 'green zones'– dedicated areas within the existing residence (a room or a house in a compound), other residences in the block or street, or at the level of a sector or larger neighbourhood area (options 1-3 in Figure 2).[1,2] In these green zones, high-risk individuals have minimal contact with family members and other community members, and they are supported through provision of food and other commodities. Shielding should also include essential infection prevention and control measures within and at the entrance to the green zones (e.g., hand-washing and in-home isolation of symptomatic individuals). The modality of shielding may differ according to the setting and preferences of the community and may include several options.

Findings from a recent mathematical model applied to different African countries suggest that shielding could reduce health service demand and mortality by substantially reducing contact between persons at high risk of severe outcomes and the general population, when shielding coverage is high and contact between shielding persons and the community is kept consistently low.[4] Nonetheless, its effectiveness in practice requires real-time monitoring and evaluation of its impact on preventing infections and mortality among high-risk persons, and avoiding surges in health service demand.

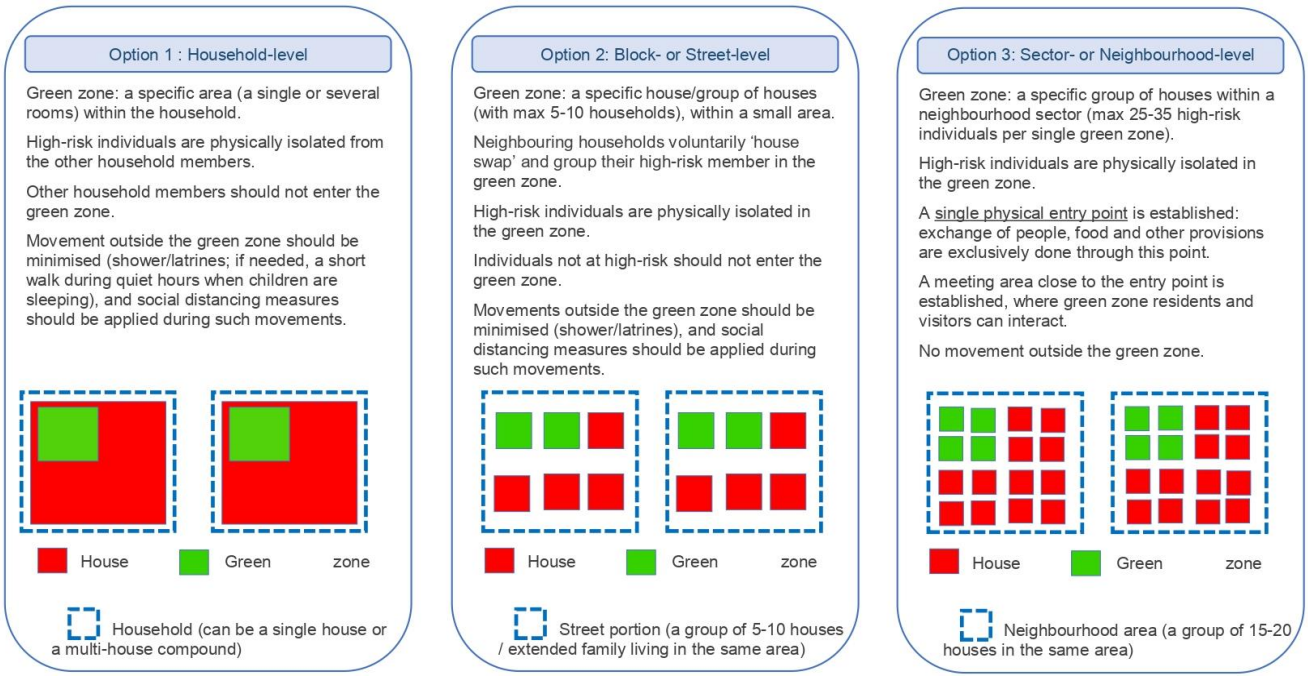


**Figure 2: Representation of housing arrangements in a shielding intervention**

## 1.2. Purpose of this document

This protocol outlines a set of methods, procedures, and tools for the monitoring and evaluation (M&E) of a shielding intervention in terms of its impact on reducing infection and mortality among shielded persons, how these effects are achieved, and the feasibility of its implementation from the perspective of stakeholders, communities and beneficiaries. The aim of the suggested M&E mechanism is to assist decision making, inform real-time programmatic improvements, and therefore ensure transparency and accountability.

Emphasis is placed on providing a light monitoring and evaluation protocol based on a mixed-methods approach. Additional monitoring mechanisms may be developed to track inputs, outputs and outcomes related to specific interventions provided to support shielding households (e.g., food support, mental health and psychosocial support, and protection). Though important, the package of support services provided, and modalities of its implementation will vary depending on the specific context. Therefore, they are not included in this generic protocol.

## 1.3. Definitions

**Box 1: Key terms definitions**

**Alert**: notification of a suspected COVID-19 case(s) for rapid investigation and response.

**High-risk group:** individuals at increased risk of severe disease and death from SARS-CoV-2 infection, mainly defined by their age and/or presence of co-morbidities.

**Green zones**: dedicated area in the household OR dedicated residential structure OR dedicated neighbourhood/camp sector, in which high-risk individuals relocate temporarily, in order to have minimal contact with family members and other community members at lower risk of severe COVID-19 disease. It is easiest to think of as an area, however large or small, that low-risk individuals should not enter.

**Shielding residence**: either a residential structure (house/compound) in which all people are shielding, or one in which the high-risk individual(s) are isolating within (a) dedicated room(s). Accordingly, a green zone could be composed of several shielding residences; could be the entire shielding residence; or could be one or more rooms within the shielding residence.

**Non-shielding residence**: residential structure (house/compound) where high-risk individuals living in the household are not shielded, and contact with family and the community members is maintained.

**Suspect case of COVID-19[2]:** (definition may evolve or may be adapted depending on local definitions.)
Patient with acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath), AND

- History of travel to/residence in a location reporting community transmission of COVID-19 disease during the 14 days prior to symptom onset; OR,
- Contact with a confirmed or probable COVID-19 case in the last 14 days prior to symptom onset;

OR,
Patient with severe acute respiratory illness (fever and at least one sign/symptom of respiratory disease, e.g., cough, shortness of breath; AND

- Requires hospitalization; AND
- Absence of an alternative diagnosis that fully explains the clinical presentation.

## 2. Objectives, and outcomes

The M&E system described in this document is grounded in a results-based management approach and focuses on the assessment of progress against and achievement of defined results of the shielding intervention, in terms of outputs, outcomes and impacts. The **primary objectives** focus on measuring the impact of shielding on reducing COVID-19 morbidity and mortality among high-risk persons and the **secondary objectives** aim to document and assess the implementation process and the feasibility and the perception of shielding from the perspectives of beneficiaries and stakeholders (Table 1).

The **primary outcome measures of effectiveness** are attack rate and death rate, defined as the number of new suspect symptomatic cases (or deaths) among the shielding group divided by the number of persons shielded, per 1,000 persons. To assess the impact, this will be compared with the attack rates/death rates in the non-shielding group using estimates of relative risk.

**Table 1: Summary of the M&E mechanism's objectives**

| Objectives | M&E mechanism | Intervention results |
|---|---|---|
| **Primary objectives** | | |
| Estimating and comparing the attack rates of symptomatic suspect COVID-19 infection among shielded and non-shielded persons | Monitoring and impact evaluation | Impacts |
| Estimating and comparing the death rates among shielded and non-shielded persons | | |
| **Secondary objectives** | | |
| Measuring the proportion of green zones that experience potential virus introduction | Monitoring | Outcome |
| Estimating population coverage of shielding among the targeted risk group | Monitoring and Process evaluation | Output |
| Estimating the proportion of shielding persons remaining shielded over time (adherence) | | |
| Assessing the fidelity of implementation in terms of key infection control measures (e.g., handwashing in the green zone) | | Process outputs |
| Assessing the fidelity of implementation in terms of availability of essential chronic disease medication for shielding persons | | |
| Documenting the barriers and enablers for adoption and implementation of shielding by the high-risk individuals | | |
| Documenting the timing from community engagement to full implementation of the intervention | Process evaluation | |

# 3. M&E system: design

## 3.1. Description of the shielding intervention

See Favas et al, 2020 for a full description of potential shielding strategies.[1,2] Decisions on the choice of shielding arrangements (at household, street or neighbourhood level, or a combination) depend on the preferences of the communities and the local socio-cultural context (e.g., whether it is acceptable for at-risk persons to be grouped and relocated into a green zone in the neighbourhood).

Similarly, the exact composition of the high-risk group will be defined locally, by the community. This protocol applies to whichever population groups are targeted for shielding in a given setting. High-risk persons may include:

- Persons ≥60 years;
- Persons with non-communicable diseases (NCDs including hypertension, diabetes, cardiovascular disease, chronic respiratory diseases, chronic kidney disease, cancer);
- Persons with chronic infectious diseases (HIV/AIDS, tuberculosis, hepatitis B or C, and other immune-deficiency conditions);
- Pregnant women, if malnourished or affected by other high-risk conditions.

At a minimum, the evaluation assumes that a shielding intervention will comprise:

- A community-based governance mechanism (e.g. social care committee), which would facilitate and support risk communication and community engagement; the development of community-level shielding plans; the identification of shielded residences; and the provision of support for the shielding persons and their families/caregivers on an ongoing basis;
- Facilitation of hygiene practices through access to sufficient water and sanitation, and other infection prevention and control measures;
- Direct support for provision of food and other commodities, as well as for delivery of essential medications to assure patient well-being (this may involve another agency);
- An alert and response mechanism for the early identification and management of suspected COVID-19 cases for shielded individuals;
- A system for collecting feedback from the community.

## 3.2. Overview of the M&E design and methods

The M&E system is based on a combination of two components, using a mixed-methods approach (Figure 3):

i) A prospective cohort study;
ii) A qualitative study

The **prospective cohort study** aims to monitor shielding residences and non-shielding residences over the entire period of shielding for incidence of symptomatic high-risk persons, deaths, and potential virus introduction into the green zones. Demographic information on shielding and non-shielding high-risk persons, and their baseline characteristics, will be collected to improve comparability between the two groups. Additionally, shielding persons will be monitored for their adherence to shielding, ability to support hygienic behaviours and other infection control measures, and continued access to medication for chronic illness.

Data will be collected via questionnaires administered every two weeks, if possible, and otherwise, monthly.

The study will be implemented in an exhaustive or representative sample of the study population. In a large population centre (e.g. a large camp or urban settlement), collecting data for the entire study population may not be feasible. Hence, systematic random sampling of shielding and non-shielding residences will be used to improve the feasibility and quality of data collection (see Section 4.4).

The **study population** consists of the high-risk individuals eligible for shielding, including those who choose to shield, and those who choose not to shield. Thus, allocation to the intervention is by choice, and not randomized: the study is therefore **observational**, not interventional; and because there is a comparison group, the study is **analytical**.

If it is not possible to identify and monitor non-shielding residences (e.g., all identified high-risk individuals in the intervention area choose to shield) or if this is considered logistically unfeasible, a direct comparison of outcomes with non-shielded individuals cannot be made. However, the impact of shielding can still be assessed through the use of a mathematical model in place of a control group (see Section 4.3).

To complement findings from the prospective cohort study, a **qualitative study** will be undertaken throughout the implementation of the shielding intervention to identify the main barriers and enablers affecting the implementation of the intervention and adoption of the shielding by the targeted high-risk individuals. Qualitative information will be collected regularly through semi-structured interviews of key informants with stakeholders, community members and beneficiaries.

A monitoring and evaluation framework is available in Annex I.

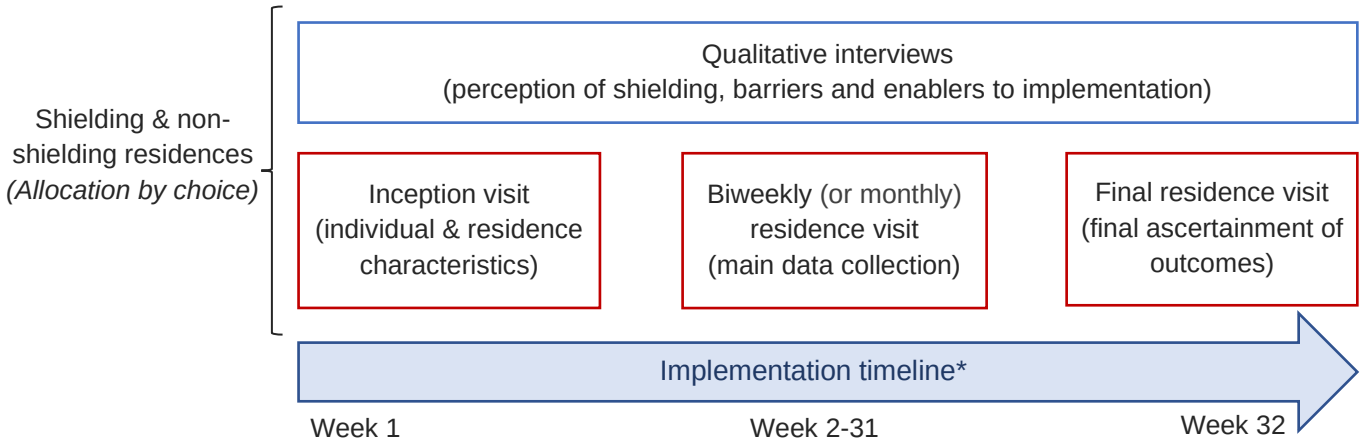


**Figure 3: Schematic of the M&E system's design**

Red boxes represent routine questionnaires for the cohort study; blue box represents qualitative study

* Indicative timeline, this may be different depending on the duration of the shielding intervention

# 4. Prospective cohort study

## 4.1. Study site and population

### Study site

The study site corresponds to the area where the shielding intervention is implemented. Based on secondary data available, baseline information will be collected on i) the general population of the intervention area (age and sex structure, mean residence size, risk factors for the spread of an epidemic including population density, indicators of access to health care and water and sanitation); and ii) on the intervention area (map of entire area, estimated population size and demarcation of the health facilities' catchment areas).

### Inclusion and exclusion criteria

Inclusion criteria:

- Residence with ≥1 eligible high-risk individual (as per the definition of the high-risk group agreed for the shielding intervention);

Exclusion criteria:

- High-risk individual or their caregiver does not consent to data collection;
- High-risk individual or their caregiver are unable to understand risks in order to offer informed consent.

## 4.2. Duration and timing of the study

The study period should cover the duration of the shielding intervention, which in turn depends on the duration of the epidemic wave. We anticipate that at maximum, the study period will be 6 to 8 months, from July 2020 onwards. Given trends in incidence in Sub-Saharan Africa and the Eastern Mediterranean regions, this period is anticipated to cover peak incidence of COVID-19 cases. However, if shielding is stopped before the end of the epidemic or if the epidemic ends sooner, the data will be collected and analysed up to that time point.

## 4.3. Defining a comparison group

The cohort study will be used to monitor and evaluate the rates of COVID-19 disease and death among shielded persons, compared to non-shielded persons. As shown in Figure 2, data collection is based on routine monitoring visits to shielding and non-shielding residences.

Depending on the context where shielding is implemented, there are two options for identifying and recruiting a control group of non-shielding residences. This choice will also depend on whether uptake of shielding is so high as to leave no residences with unshielded individuals available to construct a control group (if so, option 1, which relies on actual data, would not hold – see Box 2).

**Box 2. Options for constructing actual or modelled non-shielding control groups**

**1.Community controls**

This option assumes that not all high-risk individuals within eligible residences will choose to shield.

Some agencies routinely visit residences in their intervention areas as part of regular programming. If during such visits it is feasible to visit the residences of unshielded people, all or a sample of these (see Section 4.4) will be recruited into a control group and baseline information on the number, age and morbidity status of high-risk individuals, as well as possible confounders (educational attainment, disability status, household income) will be recorded for both shielded and unshielded people during an inception visit. Non-shielding residences will then receive a brief biweekly (or monthly) visit or phone call to monitor for new symptoms or deaths among non-shielded high-risk persons. Shielding residences will receive a more in-depth biweekly (or monthly) questionnaire and observations during biweekly (or monthly) visits (detailed under Section 4.5 on data collection).

**2. Modelling a control group**

This option assumes that either (a) nearly all high-risk individuals within eligible residences will choose to shield or (b) identifying and/or monitoring non-shielding control residences is not feasible.

To predict transmission among the high-risk group in a counterfactual scenario in which shielding is not used, a stochastic transmission model, parameterised to the evaluation locality's demographic characteristics (age distribution, residence size etc.) will be used to estimate expected infection numbers among the high-risk persons over the study period. An average rate of contact between high-risk persons and the general population will be assumed, based on the available literature.[5]

## 4.4. Sample size and sampling procedures

### 4.4.1. Sample size

The sample size is calculated to detect a relative risk (RR) of developing symptomatic COVID-19 disease in the shielding group, compared to the non-shielding group, in a time frame of 3 months. A RR of 0.5 (equivalent to shielded individuals having half the risk of developing symptomatic disease compared to unshielded individuals) is anticipated. However, sample sizes to detect a RR as pessimistic as 0.75 to as optimistic as 0.25 are provided below. The sample sizes are intended to be adequate for a study of at least 3 months (or more) of shielding, namely the approximate time before reaching the peak in infections in a low-income or camp setting.[4,6,7] The following parameters are used:

- Proportion of population ≥65 years infected over 3 months (0.2). The infection attack rate among non-shielded individuals in 3 months (240 infections/1,000 persons) is based on a projection of 250,000 infections among 1,045,038 persons ≥65 years in 3 months in Sudan (from a mathematical model of an epidemic with a reproduction number of 2.7).[7]
- Proportion of symptomatic infections among persons 70+ years of age (70%)[4,8]
- Range of relative risks of infection among shielded individuals (0.75, 0.5, 0.25)
- Proportion of visits with data loss (20%)
- Z-alpha (1.96, level of significance, e.g., 5% probability observed effect is due to chance alone)
- Z-beta (0.84, power, 80% probability to detect effect of specified minimum size if there is one)

The minimum number of high-risk persons in the shielding group and non-shielding group is at least **136 per group (total sample size of 272 individuals)**, representing a RR of 0.5. This sample size is sufficient for detecting a higher RR of infection in the shielding group of 0.75 (Table 1). If possible, a sample size of 166 individuals per group should be used to detect the range of RRs from 0.25 to 0.75.

**Table 2: Sample size (N), varied by relative risk (RR) of infection in shielding group**

| RR detectable | Individuals required per group | Total N |
|---|---|---|
| 0.25 | 166 | 331 |
| 0.5 | 136 | 272 |
| 0.75 | 114 | 228 |

### 4.4.2. Sampling procedure

If the intervention area is small (e.g., ≤100 households in a camp), data can be collected exhaustively for the entire study population. If >100 households, a two-stage sampling method will be applied (Figure 3):

i) **Selection of shielding and non-shielding residences**: systematic random sampling will be used to sample eligible residences in each study group. This requires two lists of shielding and non-shielding residences (sampling frame). A random start point will be determined for each list and a sampling interval will be calculated. From the random start point residence, the sampling interval will be applied until the required sample size is achieved. *Sampling interval = (total size of list) / (required sample size per arm)* e.g., If the list of shielding residences contains 504 eligible residences and we require 111 residences to meet the sample size, then the sampling interval = 504/111 = 4.5 (rounded down to 4). Therefore, every 4th residence on the shielding list, starting at a randomly selected residence between 1 and 504, will be enrolled;

ii) **Selection of high-risk individuals**: once residences are selected, a list of high-risk individuals will be established for each residence during the inception visit (shielding residences: high-risk individuals living in the green zones; non-shielding residences: high-risk individuals living in the household among other household members). One high-risk individual will be selected within each residence, using a simple random sampling method. This can be accomplished by writing down numbers representing each individual on different pieces of paper and randomly selecting one piece of paper, or by using a random number table, or by using an automated function in ODK or KoboCollect.

The primary outcomes (attack rate and death rate) will be measured at individual level, i.e. solely for the randomly selected high-risk individuals in both shielded and non-shielded residences; secondary outcomes (e.g. assessment of the implementation of key infection control measures) will be measured for the shielding residences only, and at the level of the entire green zone, i.e. among all shielded residents.

If study participants relocate outside of the study area, they will not be replaced.

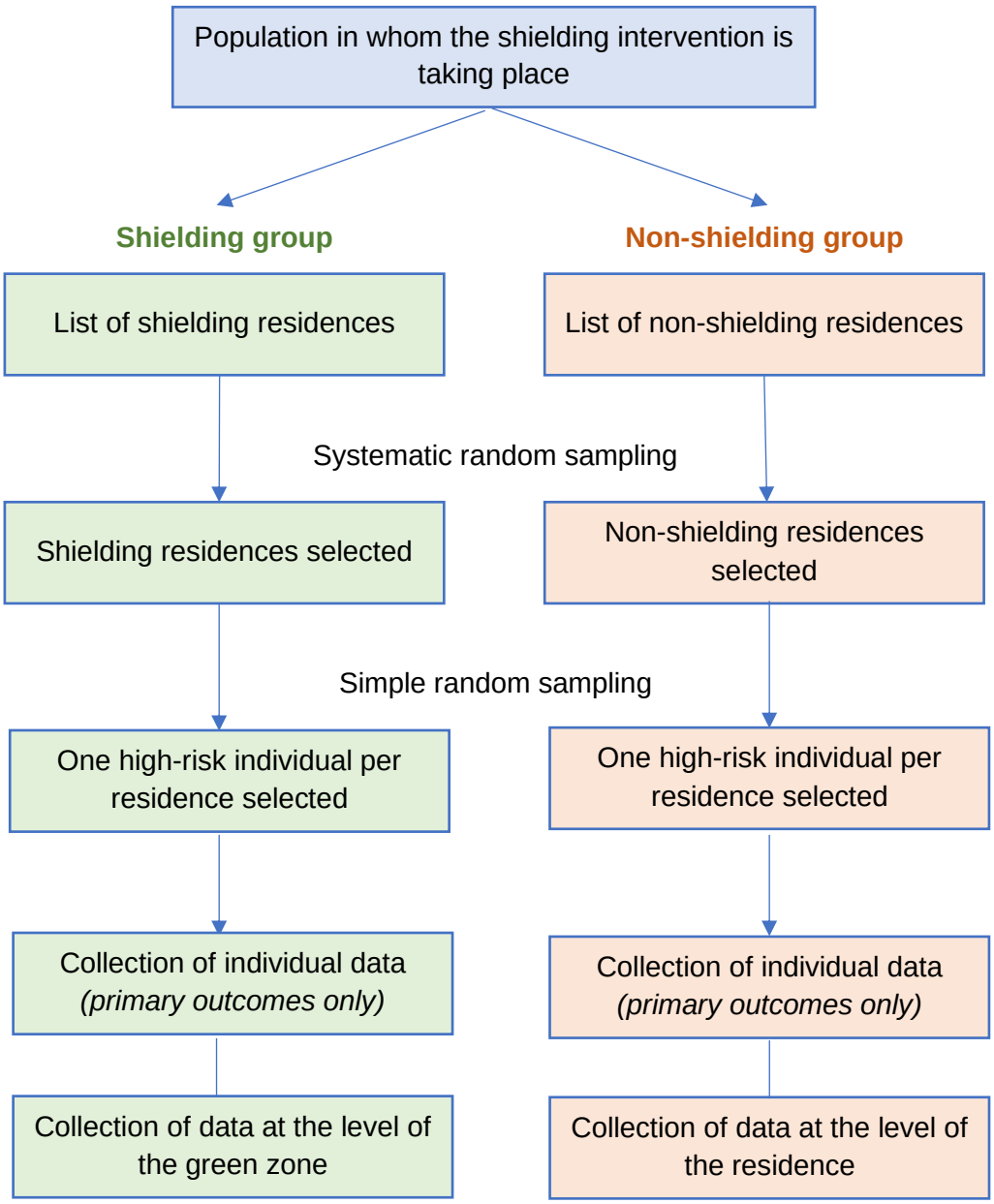


**Figure 4: Schematic of sampling approach**

## 4.5. Data collection and visit frequency

### 4.5.1. Data collection methods and frequency

Data will be collected biweekly for each selected residence. However, data collection frequency may be adapted according to specific local contexts (biweekly or monthly). Data collectors will conduct visits to the selected shielding and non-shielding residences. Alternatively, e.g. if visits are not possible due to movement restrictions, data can be collected by phone (if available).

A questionnaire will be used to collect general baseline information about the residence and its high-risk members as well as specific data related to the selected high-risk individual. The primary respondent is the randomly selected high-risk individual. However, if for any reason they are not able to answer the questions (e.g., the individual is disabled, or became sick or died), questions will be asked to the head of the residence or another individual identified by the residents. In addition, if it is difficult to ask

questions of the high-risk individual without them exiting the green zone, then a proxy (e.g. family member) should be used.

If the high-risk individual has died, it is still important to respectfully interview a proxy to collect individual data at a visit following the death as well as to continue data collection during follow-up visits to collect information on the residence.

### 4.5.2. Inception visit

*See Annex II Form 1 and 2.* At the inception visit, all high-risk persons, according to the local definition of eligibility for shielding, will be identified. After selection of one high-risk individual, informed consent will be sought (see Chapter 6), and if given, the questionnaire will be filled. Data collectors will have distinct questionnaires for shielding and non-shielding residences; the main information collected is summarised in Table 3 below.

**Table 3: Information captured during the inception visit**

| Information | Shielding residences | Non-shielding residences |
|---|---|---|
| **Residence level** | | |
| - Composition of the residence (total number of members, members at high-risk) | X | X |
| - Income source for the residence | X | X |
| - Composition of the green zone: number of high-risk individuals shielded and shielding arrangement | X | |
| - Movements into the green zone (shielded area) | X | |
| - Minimum requirements for hygiene practices (water, soap)[9-11] | X | X |
| **Individual level** | | |
| - Individual characteristics (age, sex, education, disability status, medication needs for chronic disease) | X | X |
| - COVID-like symptoms in the past week | X | X |
| - Availability of medication for chronic diseases[12] | X | X |
| - Movements outside the green zone (shielded area), frequency, and reasons | X | |

### 4.5.3. Follow-up visits

*See Annex III Form 3 and 4.* Shielding and non-shielding residences will be visited on a biweekly (or monthly) basis in order to administer the follow-up visit questionnaire to the selected high-risk individual. The information collected is summarised in Table 4 below.

If the selected high-risk individual/caregiver is not available to answer the questions, the following procedure should be followed, depending on the specific reason for non-availability:

- The individual is absent from the residence: ask when they will come back and plan a visit. If the individual is still absent after two attempts, fill in the related question, and ask if a representative of the residence can answer the questions at residence level and if the selected individual developed COVID-like symptoms since the last visit, and then stop the interview;
- The individual has moved out from the residence: fill in the related question, ask if a representative of the residence can answer the questions at residence level, and stop the

interview. The individual will be classified as lost to follow-up. However, follow-up visits to the selected residence should continue to collect information at residence level;

- The individual has died: fill in the related question, ask if a representative of the residence can answer the questions at residence level, and stop the interview. However, follow-up visits to the selected residence should continue to collect information at residence level;
- The individual is sick, or any other reasons: fill in the related questions, and ask if a representative of the residence can answer the questions at residence level and if the selected individual developed COVID-like symptoms since the last visit; then stop the interview.

In the shielding residence, if a residence member or visitor is reported as being newly symptomatic since the last visit, questions will be asked about the actions taken, and appropriate investigation and control measures will be triggered.

**Table 4: Information captured during follow-up visits**

| Information | Shielding residences | Non-shielding residences |
|---|---|---|
| **Residence level** | | |
| - Changes in the composition of the residence (total number of members, members at high-risk) | X | X |
| - Changes in the composition of the shielding residence: number of high-risk individuals shielded and shielding arrangement | X | |
| - Movements into the green zone (shielded area) since the last visit | X | |
| - Availability of minimum requirements for hygienic practices (water, soap) | X | X |
| **Individual level** | | |
| - If the selected individual is unable/unavailable to answer, reason (including death) | X | X |
| - COVID-like symptoms since the last visit | X | X |
| - Shielded individual remaining shielded | X | |
| - Availability of medication for chronic diseases | X | X |
| - Movements outside the green zone (shielded area) in the past week, frequency, and reasons | X | |

## 4.6. Data entry and management, and analysis

### 4.6.1. Data entry and data management

If possible, data entry using tablets running Open Data Kit (ODK), Kobo, or equivalent software will be used. Alternatively, data entry will be carried out in EpiData using paper questionnaires. If paper questionnaires are used, a random sample of 20% of questionnaires will be double-entered to verify accuracy of data entry; if > 20% of re-entered questionnaires have at least one discrepancy with the original entry, all data will be double-entered, with any discrepancies resolved manually. Access to the database will be restricted to data entry staff, designated programme officers from the implementing agency, and the investigators. From the inception questionnaires, an individual database of shielding and non-shielding individuals will be developed listing a minimum set of variables (*See Annex IV: database variables*).

### 4.6.2. Analysis

#### 4.6.2.1.Monitoring indicators

After each round of data collection, key monitoring indicators will be calculated. The following indicators will be calculated at a minimum on a monthly basis (unless stated otherwise).

**Table 5: Main indicators derived from the prospective cohort study**

| Indicator | Interpretation |
|---|---|
| **Primary indicators (disaggregated by shielding status)** | |
| • Symptomatic attack rate | *Cumulative (since the start of the study) and new (since last visit)*<br>Number of suspect cases[1] among high-risk persons / all high-risk persons per 1,000 persons |
| • Death risk due to COVID-19 and overall | *Cumulative (since the start of the study) and new (since last visit)*<br>Number of COVID-19 suspect and all-cause deaths among high-risk persons / all high-risk persons per 1,000 persons |
| **Secondary indicators** | |
| *(for shielding residences only)* | |
| • Proportion of shielding residences with suspected virus introduction | Cumulative (since study start) and new (since last visit) number of shielding residences in which at least one suspect case is reported in the green zone / all shielding residences |
| • Proportion of originally shielding persons who continue to shield (adherence) | Number of shielding persons who remain shielded / all shielding persons in selected residences at the start of the study |
| *(for both shielding residences and non-shielding residences*)* | |
| • Proportion of visits during which soap and water are available | Number of visits during which soap and water are observed in the first minute / all visits to shielding residences |
| • Proportion of visits during which stock-outs of medication since the last visit are reported | Number of visits during which stock-out of medications since the last visit is reported by any high-risk residents / all visits to shielding residences |

* These are indicators to monitor the minimum supportive services that should be provided as part of the shielding intervention

#### 4.6.2.2.Analysis of shielding effectiveness

Descriptive analysis of the baseline characteristics of high-risk persons and residences in the shielding and non-shielding groups will be carried out.

At the end of the study period, the two primary indicators of effectiveness will be calculated: symptomatic attack rate and overall death rate. The attack rate of symptomatic suspected COVID-19 infection in the shielding group and the non-shielding group will be calculated as incidence per 1,000 person-years. The death rate among monitored high-risk persons in the shielding group and the non-shielding group will be calculated as incidence per 1,000 person-years. Cumulative population among the shielded and unshielded groups will be used as the denominator.

To evaluate the **impact of the intervention**, the relative risks of the attack rates and death rates will be calculated *(Annex I: indicators 1 & 2)*. To derive a relative risk (RR), the incidence among the shielding group will be compared with the actual or modelled incidence among the control group of non-shielding

[1] For indicator 1, the suspect case definitions for cases and deaths set by WHO are used (see Definitions section):[2]

persons. Multivariate generalised linear models will be used to adjust for potential confounders (sex, source of funds, educational attainment level, residence size of current residence).

Crude (unadjusted) RRs can be calculated on a monthly basis to detect indications of potentially higher risk presented by shielding. This would lead to investigations to understand the reason for higher risk (e.g., poor implementation and risky behaviour), and potentially, stopping the intervention early.

To monitor the implementation of shielding, an estimation of the proportion of shielding residences with suspected introduction of the virus into the green zone will be calculated *(Annex I: indicator 3)*;

#### 4.6.2.3.Risk factors for symptomatic infection in shielding group

Risk factors for infection among shielded persons will be analysed using appropriate multiple logistic regression models, adjusting for clustering at the residence level using a random effect. Potential risk factors include exposure level (e.g. symptomatic persons in the residence preceding infection), residence size, lapses in availability of hygiene material or medication, gender, source of income, and education.

# 5. Process evaluation including qualitative data collection

A brief process evaluation will be undertaken to evaluate the acceptability of shielding, facilitators and barriers to implementation, pathways of action, and the implementation process. These data will be used to explain how, why, and for whom shielding had its effects (e.g., was beneficial or not). This process evaluation will adopt a mixed-method approach, including i) quantitative analysis using data collected from the cohort study and from administrative sources; and ii) qualitative analysis using data collected throughout the implementation of the shielding intervention via key informant interviews.

## 5.1. Quantitative component

An estimation of population coverage of shielding will be calculated using administrative data (through a tally of shielding and non-shielding individuals done by community health workers, if available); note that age is likely to be the only criterion to determine shielding eligibility, since co-morbidities may not be recorded in registration or health facility datasets, and individuals should not be asked to disclose personal medical data as part of this evaluation *(Annex I: indicator 4)*.

The biweekly (or monthly) visits and monthly reports will also be used to identify key programmatic gaps (e.g., soap and water availability; medication availability; changes in adherence over time, movements in/out of shielding residence) *(Annex I: indicators 5, 6 & 7)*. Complementary information will be collected as part of the qualitative component of the process evaluation (see below), to capture potential commonalities among shielding residences where there was / was not introduction of the virus, and assess actions taken following introduction.

The time from the start of community engagement to launch of shielding in communities and full-scale implementation will be calculated *(Annex I: indicator 9)*. This will require i) the definition of the set of activities which constitutes community consultation ahead of implementation, as well as the set of activities that needs to be conducted for full implementation of shielding and a programmatic target (e.g.,

50% of high-risk persons who wish to shield are shielded); and ii) a GANTT chart of the activities that will be updated regularly.

### 5.2. Qualitative component

The qualitative component of the process evaluation aims at complementing the quantitative findings and getting a better understanding of the perception of the shielding intervention and its implementation from the perspective of the implementers as well as the beneficiaries. Key informant semi-structured interviews will be conducted at different points in time during the shielding intervention implementation:

- 10-15 interviews with a mix of stakeholders with different roles in implementing and monitoring the response (e.g., camp coordination staff, health managers, WASH managers, members of social care committees and other community governance bodies);
- 10-15 interviews with the target group for shielding – i.e. the high-risk individuals, which will include persons who are shielded as well as those who opt not to shield or who dropped out with a key objective of understanding different experiences among the sub-groups (e.g., persons 60+ years, younger persons with NCDs, pregnant women).

Example of interview guide for implementers and beneficiaries are available in *Annex V (Forms 5 & 6)*. They may be adapted depending on the specific context and the design of the shielding intervention. Moreover, an additional interview guide may be developed according to the key informant chosen for this qualitative study (e.g. non-shielded persons, or persons who was shielded but decided to stop, other community members etc.)

Timely qualitative analysis (e.g. soon after collection) will be undertaken to identify the main challenges and enablers to implementing shielding, key contextual factors that may have influenced the perception and acceptability of shielding, challenges with assuring access to water, hygienic measures, care-giving, use of communal latrines, etc., and ability to maintain shielding over time (*Annex I: indicator 8*). This information will be cross-checked with the quantitative analyses above and integrated into the monthly and final analyses.

## 6. Ethical issues

The monitoring and evaluation protocol will be submitted to the national IRB of the intervention site and the implementing organization's IRB, seeking expedited approvals. The study will be discussed with local health authorities and communities, and their endorsement will be sought.

### 6.1. Consent and data protection

An information sheet will be read out to each participant to inform them about the purpose of the study, risks and benefits, and its voluntary nature of participation, in the local language. Oral informed consent will be sought from each participant, before the inception questionnaire is administered / the interview begins. No financial or material compensation will be given to participants; under the intervention program, shielding residences will receive supplies to enable hygiene in the green zone.

Data will remain anonymous throughout the study, with location data on residences being collected to identify the location for repeat visits for the single data collector only. Confidentiality will be ensured by

training data collectors to treat data collection as confidential. Only the data entry clerk and the investigators will have access to the password-protected database and data collection software (if used). Databases will be anonymised and all paper questionnaires (if used) will be kept under lock and key for a period of five years; these will be destroyed after.

## 6.2. Risks related to the shielding intervention

A major issue is assuring that risks associated to shielding do not outweigh benefits for beneficiaries. Shielded persons may benefit from a potentially effective intervention and the pressure on health services may be kept low due to a reduction of consultations from the high-risk group. The risks include that shielding is a novel and untested intervention, the potential for non-adherence to key hygiene tasks or challenges to carrying them out for older persons when shielded in the green zone, and the effects on mental well-being of reduced proximity to family members. In order to address whether there is an indication of high risk posed by shielding as compared to non-shielding, the RRs can be calculated on a monthly basis, followed by periodic investigations to understand the reason for higher risk (e.g., poor implementation and risky behaviour), and potentially, stopping the intervention early, following the “do no harm” principle.

## 6.3. Risks related to the monitoring and evaluation activities

Potential risks to data collectors as well as to persons interviewed include infection when interacting during residence visits, qualitative interviews or focus group discussions. Data collectors will take the following measures to minimize the risk of virus transmission (those measures can be adapted depending on the context):

- Supervisors should ask data collectors screening questions for potential symptoms before each day of data collection;
- Personal protective equipment will be given to interviewers, who will be trained on appropriate use and disposal. For example, data collectors may wear a face mask to prevent the risk of virus spread within residences;
- Data collector will administer screener questions to see if there are any household members who have COVID-like symptoms and determine whether data collection can be done safely (from outside the household);
- Stand 2 metres from the interviewee, regardless of shielding status. For shielding residences specifically, the data collector should stand outside the green zone of the residence, and high-risk persons stay inside the green zone;
- Data collector should avoid any physical contact with persons, touching surfaces inside the residence, and touching their own nose, eyes, and mouth;
- Informed consent should be verbal, to minimise interaction and for the interviewee to touch data collection material;
- Spend the minimum time possible in the residence (outside green-zones) while ensuring ethical and complete data collection practices (10-15 minutes);
- Provided with soap or hand-gels for appropriate handwashing and cleaning of data collection materials (at a minimum between visits of each residence).

# 7. Study resources

## 7.1. Team composition

The ideal composition should include the following, bearing in mind that LSHTM can provide remote support for data management, setup of data systems, training, and quantitative and qualitative analyses.

**Table 6: Suggested M&E team composition**

| Staff and number | Role |
|---|---|
| Epidemiologist (1) | Responsible for the M&E system design and the cohort study protocol, developing tools, interim and final analysis, and report writing. |
| M&E coordinator (1) | Ensure overall organization and implementation of the M&E activities, timely data collection, data quality in the field, and supervision of data collectors and the data manager. |
| Qualitative specialist (1) | Responsible for qualitative study design, interviewing, and coordination of activities. |
| Data manager (1) | Ensure data entry and cleaning of databases |
| Data collectors (4 total: 2 per group) | Responsible for routine visits to shielding and non-shielding residences for the cohort study. It is anticipated that 10 residences per day can be visited by a single interviewer. |
| Data collectors (qualitative) (2 total: 1 per group) | Responsible for qualitative interviews. |
| Logistic support | Logistic support to facilitate residence visits, hiring of staff, payments of interviewers and general administration will be required. |

## 7.2. Training

A 3-day training will be administered to data collectors on the background of the intervention and M&E design, ethical conduct, data collection, infection prevention and control during data collection, and informed consent. The duration of the training may be adapted depending on needs. Special emphasis will be given to conducting data collection safely, just outside the residence, at a safe distance from respondents, and with appropriate use of PPE. The training can be given remotely, supported by the M&E coordinator and other relevant persons (e.g., epidemiologist), in the local language. Pilot testing of the questionnaire in an area not targeted by the intervention will be included in order to practice and refine the questionnaires.

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## Annex I: Monitoring and evaluation framework

| Shielding intervention | Indicators | Definition | Method and data source | Frequency |
|---|---|---|---|---|
| **Intervention Impact**<br>Reduced COVID-19 morbidity and mortality among high-risk population | **1.** Attack rate ratio of symptomatic suspect COVID-19 infection | Attack rate among shielded / attack rate among non-shielded (control group) | Prospective cohort study: Questionnaire | At inception, and biweekly *(may be adapted)*<br>Indicator calculated monthly |
| | **2.** Death rate ratio (overall and due to COVID-19) | Death rate (all-cause and suspect COVID-19) among shielded / death rate among non-shielded (control group) | Prospective cohort study: Questionnaire | At inception, and biweekly *(may be adapted)*<br>Indicator calculated monthly |
| **Intervention Outcome**<br>Shielded high-risk community members are protected against COVID-19 | **3.** Proportion of shielding residences with suspected virus introduction in the green zone | Number of shielding residences in which at least one suspect COVID-19 case is reported in the green zone / all shielding residences | Prospective cohort study: Questionnaire | At inception, and biweekly *(may be adapted)*<br>Indicator calculated monthly |
| **Intervention Output 1**<br>High-risk community members are shielded within green zones | **4.** Population coverage of shielding among high-risk community members | Number of eligible persons shielding / all eligible persons | Administrative registers | At the end of the project |
| | **5.** Proportion of shielding persons remaining shielded (adherence) | Number of shielding persons who remain shielded / all shielding persons | Prospective cohort study: Questionnaire | At inception, and once every two weeks *(may be adapted)* |
| **Intervention Output 2**<br>Shielded high-risk community members apply key infection prevention and control measures | **6.** Proportion of visits during which soap and water is available | Proportion of visits during which soap and water are available / all visits to shielding residences | Prospective cohort study: Questionnaire | At inception, and once every two weeks *(may be adapted)* |
| **Intervention Output 3**<br>Shielded high-risk community members have access to medications for chronic diseases | **7.** Proportion of visits during which stock-out of medication since the last visit reported | Proportion of visits during which stock-out of medications since the last visit has been reported / all visits to shielding residences | Prospective cohort study: Questionnaire | At inception, and once every two weeks *(may be adapted)* |
| **Implementation Process** | **8.** Barriers and enablers for implementation of shielding | Qualitative indicator | Qualitative study:<br>Key informant interview records | Quarterly *(may be adapted)* |
| | **9.** Time from community consultation to full shielding implementation | Days between the start of community engagement in the intervention area and implementation at scale | Project records and GANTT chart | At the end of the project |

## Annex II: Inception questionnaires

### Form 1: inception visit shielding residence

| QUESTIONNAIRE FOR INCEPTION VISIT TO A SHIELDING RESIDENCE | | |
|---|---|---|
| Notes: the first section (A) is filled for the residence, and the second section (B) is filled for the selected high-risk person who lives in the residence.<br>If there is more than one shielded high-risk individual living in the residence, randomly select one shielded high-risk individual.<br>Identify yourself, explain the purpose of the study, and seek informed consent. | | |
| 1.Residence ID | [SHIELD]<br>__\|__\|__ [0-100] | Enter number by visit order. |
| 2.Interviewer number | __\|__ [1-4] | Fill number |
| 3.Date | __\|__//__\|__//__\|__ | DD/MM/YY |
| 4.Consent to conduct interview | 1-Yes, consented to be interviewed<br>2-No, refused consent **(STOP)** | Select one |
| **A. Residence information** | | |
| 5. What was the primary source of your household income during the past month? | 1-Cash-transfer<br>2-Vouchers<br>3-Loans<br>4-Paid work<br>5-Savings<br>6-Other (describe)<br>0-None currently | Select one<br>Do not prompt<br>For street/neighbourhood shielding, can clarify that this is your household of origin |
| 6. How many people live in this residence (total number)? | __\|__ [1-20] | Fill in |
| 7. How many shielding persons live in this residence? | __\|__ [1-20] | Prompt: give the definition of a high-risk person<br>Note: if shielding at block or neighbourhood level, the answer should be the same as 6. |
| 8. Shielding type | 1-In house (separate room)<br>2-In household compound (separate house)<br>3-Shielding residence at block/street level<br>4- Shielding residence at sector/neighbourhood level<br>5-Other (describe) | Select one |
| 9. Has anyone entered the green zone in the past week? | 1-Yes<br>2-No<br>88-Unclear | Select one<br>Explain the meaning of green zone. Anyone means anyone except those |

| | | |
|---|---|---|
| | 99-Refused | shielded |
| 10. Do you have soap for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| 11. Do you have water available for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| **B. Individual characteristics: only for the randomly selected high-risk individual** | | |
| 12.Age (years) | ___\|___ [0-99] | Fill |
| 13.Sex | 1-M<br>2-F | Select one |
| 14.What is your highest level of education? | 1-Primary<br>2-Secondary<br>3-Higher<br>0-None<br>88-Unclear<br>99-Refused | Select one |
| 15. Which of the following are reasons why you are shielding? | 1-Old age<br>2-Chronic disease<br>3-Pregnant<br>4-Other (specify)<br>88-Unclear<br>99-Refused | Select as many as apply |
| 16. Do you have a disability that restricts your mobility? | 1-Yes, limited mobility<br>2-No, full mobility<br>88-Unclear<br>99-Refused | Select one |
| 17. Do you require medication for a chronic disease? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select all that apply |
| 18. Have you experienced stock-out of the medication you need for your chronic disease in the past week? | 1-Yes, stock out<br>2-No, no stock out<br>0-Medication not needed<br>88-Unclear<br>99-Refused | Select one |
| 19. Have you had any COVID-like symptoms in the past week? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select one<br>Prompt: give symptoms consistent with COVID-19 |
| 20. Have you gone outside the green zone in the past week? | 1-Yes<br>2-No | Select one |

| | | |
|---|---|---|
| | 88-Unclear<br>99-Refused | |
| 21.If Yes to 22, what were the reasons? | 1-Latrines/shower<br>2-Health facility<br>3-Visit family/friends<br>4-Other (specify)<br>88-Unclear<br>99-Refused | Select all that apply |
| 22. If Yes to 22, how many times did you leave in the past week? | ___\|___ [1-99] | Fill |

## Form 2: inception visit non-shielding residence

| QUESTIONNAIRE FOR INCEPTION VISIT TO A NON-SHIELDING RESIDENCE | | |
|---|---|---|
| Notes: the first section (A) is filled for the residence, and the second section (B) is filled for the selected high-risk person who lives in the residence.<br>If there is more than one high-risk individual living in the residence, randomly select one high-risk individual.<br>Identify yourself, explain the purpose of the study, and seek informed consent. | | |
| 1.Residence ID | [NOSHIELD]<br>___\|___\|___ [0-100] | Enter number by visit order. |
| 2.Interviewer number | ___\|___ [1-4] | Fill number |
| 3.Date | __\|__//__\|__//__\|__ | DD/MM/YY |
| 4.Consent to conduct interview | 1-Yes, consented to be interviewed<br>2-No, refused consent **(STOP)** | Select one |
| **A. Residence information** | | |
| 5. What was the primary source of your residence income during the past month? | 1-Cash-transfer<br>2-Vouchers<br>3-Loans<br>4-Paid work<br>5- Savings<br>6- Other (describe:)<br>0-None currently | Select one<br>Do not prompt |
| 6. How many people live in this residence (total number)? | ___\|___ [1-20] | Fill in |
| 7. How many high-risk persons live in this residence? | ___\|___ [1-20] | Prompt: give the definition of a high-risk person |
| 8. Do you have soap for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| 9. Do you have water available for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| **B. Individual characteristics: only for the randomly selected high-risk individual** | | |
| 10.Age (years) | ___\|___ [18-99] | Fill |
| 11.Sex | 1-M<br>2-F | Select one |
| 12.What is your highest level of education? | 1-Primary<br>2-Secondary<br>3-Higher<br>0-None<br>88-Unclear | Select one |

| | | |
|---|---|---|
| | 99-Refused | |
| 13. What is the reason for your high-risk status? | 1-60+ years<br>2-Chronic disease<br>3-Pregnant and malnutrition<br>4-Other (specify)<br>99-Refused | Select one<br>(primary reason) |
| 14. Do you have a disability that restricts your mobility? | 1-Yes, limited mobility<br>2-No, full mobility<br>88-Unclear<br>99-Refused | Select one |
| 15. Do you require medication for a chronic disease? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select all that apply |
| 16. Have you experienced stock-out of the medication you need for your chronic disease in the past week? | 1-Yes, stock out<br>2-No, no stock out<br>0-Medication not needed<br>88-Unclear<br>99-Refused | Select one |
| 17. Have you had any COVID-like symptoms in the past week? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select one<br>Prompt: give symptoms consistent with COVID-19 |

# Annex III: Follow-up visit questionnaires

## Form 3: Follow-up visit to shielding residences

| QUESTIONNAIRE FOR FOLLOW-UP VISITS TO A SHIELDING RESIDENCE | | |
|---|---|---|
| Notes: the first section (A) is filled for the residence, and the second section (B) is filled for the selected high-risk person who lives in the residence.<br>Identify yourself, explain the purpose of the study, and seek informed consent. | | |
| 1. Residence ID | [SHIELD]<br>___\|___\|___ [0-100] | Enter the specific ID of the individual before the visit. |
| 2. Interviewer number | ___\|___ [1-4] | Fill number |
| 3. Consent to conduct interview | 1-Yes, consented to be interviewed<br>2-No, refused consent **(STOP)** | Select one |
| **A. Residence information** | | |
| 4. How many people live in this residence as of today (total number)? | ___\|___ [1-20] | Fill in |
| 5. How many high-risk persons live in this residence? | ___\|___ [1-20] | Prompt: give the definition of a high-risk person<br>Note: if shielding at block or neighbourhood level, the answer should be the same as Q4. |
| 6. How many shielded persons live in the residence? | ___\|___ [1-20] | Fill in<br>Note: if shielding at block or neighbourhood level, the answer should be the same as Q4. |
| 7. Since the last visit, has anyone entered the green zone (shielding area)? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select one<br>Explain the meaning of green zone. Anyone means anyone except those shielded |
| 8. Do you have soap for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| 9. Do you have water available for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| **B. Individual information: only for the randomly selected high-risk individual** | | |
| 10. Is the selected high-risk individual the respondent? | 1-Yes (➔ **Q12**)<br>2-No | Select one |

| | | |
|---|---|---|
| 11. If “No” to Q11, why? | 1-Moved out from the residence **(STOP)**<br>2-Died **(➔ ask Q13 and STOP)**<br>3-Absent (➔ **ask Q14, Q15 and STOP)**<br>4-Sick (➔ **ask Q14 , Q15 and STOP**)<br>5-Other (specify) (➔ **ask Q14, Q15 and STOP**)<br>99-Refused (➔ **ask Q14, Q15 and STOP**) | Note:<br>If the selected individual is absent, come back later to complete the questionnaire. If still absent, select 3-Absent, ask Q14, Q15 and STOP. |
| 12. If “died” to Q12, what is the cause of death? | 1-Suspected COVID-19<br>2-Other disease (specify if known)<br>3-Other cause (specify if known)<br>4-Unknown | Select one |
| 13. Is the selected individual still shielding? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select one |
| 14. Has the selected individual developed COVID-like symptoms since the last visit? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select one<br>Prompt: give symptoms consistent with COVID-19. |
| 15. Has the selected individual experienced stock-out of the medication they need for chronic disease since the last visit? | 1-Yes, stock out<br>2-No, no stock out<br>0-Medication not needed<br>88-Unclear<br>99-Refused | Select one |
| 16. Has the selected individual gone outside the green zone in the past week? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select one |
| 17. If Yes to 22, what were the reasons? | 1-Latrines/shower<br>2-Health facility<br>3-Visit family/friends<br>4-Other (specify)<br>88-Unclear<br>99-Refused | Select all that apply |
| 18. If Yes to 22, how many times? | ___\|___ [1-99] | Fill |

## Form 4: Follow-up visit to non-shielding residences

| QUESTIONNAIRE FOR FOLLOW-UP VISITS TO A NON-SHIELDING RESIDENCE | | |
|---|---|---|
| Notes: the first section (A) is filled for the residence, and the second section (B) is filled for the selected high-risk person who lives in the residence.<br>Identify yourself, explain the purpose of the study, and seek informed consent. | | |
| 1. Residence ID | [SHIELD]<br>___\|___\|___ [0-100] | Enter number of the individual before the visit. |
| 2. Interviewer number | ___\|___ [1-4] | Fill number |
| 3. Consent to conduct interview | 1-Yes, consented to be interviewed<br>2-No, refused consent **(STOP)** | Select one |
| **A. Residence information** | | |
| 4. How many people live in this residence as of today (total number)? | ___\|___ [1-20] | Fill in |
| 5. How many high-risk persons live in this residence as of today? | ___\|___ [1-20] | Prompt: give the definition of a high-risk person |
| 6. Do you have soap for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| 7. Do you have water available for handwashing? | 1-Yes, available within 1 minute<br>2-No, not available within 1 minute | Select one. Produced within 1 minute. |
| **B. Individual information: only for the randomly selected high-risk individual** | | |
| 8. Is the selected high-risk individual the respondent? | 1-Yes (➔ Q12)<br>2-No | Select one |
| 9. If "No" to Q9, why? | 1-Moved out from the residence **(STOP)**<br>2-Died **(➔ ask Q11 and STOP)**<br>3-Absent (**➔ ask Q12 and STOP)**<br>4-Sick (**➔ ask Q12 and STOP**)<br>5-Other (specify) (**➔ ask Q12 and STOP**)<br>99-Refused (**➔ ask Q14 and STOP**) | Note:<br>If the selected individual is absent, come back later to complete the questionnaire. If still absent, select 3-Absent, ask Q14 and STOP. |
| 10. If "died" to Q10, what is the cause of death? | 1-Suspected COVID-19<br>2-Other disease (specify if known)<br>3-Other cause (specify if known)<br>4-Unknown | Select one |

| | | |
|---|---|---|
| 11. Has the selected individual developed COVID-like symptoms since the last visit? | 1-Yes<br>2-No<br>88-Unclear<br>99-Refused | Select one<br>Prompt: give symptoms consistent with COVID-19. |
| 12. Has the selected individual experienced stock-out of the medication they need for chronic disease since the last visit? | 1-Yes, stock out<br>2-No, no stock out<br>0-Medication not needed<br>88-Unclear<br>99-Refused | Select one |

## Annex IV: Database variables

| **Residence-level** | **Individual-level** |
|---|---|
| Residence ID | Individual ID |
| Location | Consent |
| Source of income | Age |
| Residence size | Sex |
| Number high-risk residents | Education |
| *(If shielding)* Shielding status of household | Reason for high-risk status |
| *(If shielding)* Shielding type | Disability status |
| *(If shielding)* Number shielded persons | Medication requirement |
| Symptomatic persons among high-risk since last visit | Follow-up status (absent, sick, died, etc.) |
| Deaths among high-risk persons since last visit | Cause of death |
| *(If shielding)* Anyone entered the green zone since last visit | COVID-like symptoms since last visit |
| *(If shielding):* soap for handwashing observable | *(If shielding)* Shielding status of individual |
| *(If shielding)*: water for handwashing observable | *(If shielding)* Stock out medication since last visit |
| | *(If shielding)* Left the green zone in the past week |
| | *(If shielding)* Reason for going outside the green zone |
| | *(If shielding)* Number of times outside green zone |

# Annex V: Topic guides for interviews

## Form 5: Topic guide for implementers

| | |
|---|---|
| **Introduction** | Study aim and partners involved<br>Why you were invited to participate<br>Consent and any questions? |
| **Content** | - What are the challenges, to date, in carrying out shielding?<br>- How can the shielding approach be improved? What are the major gaps in preventing infection among the risk group?<br>- Describe how you provide hygienic materials for shielding persons? What are the major gaps in ensuring supplies? In assuring hygiene behaviours?<br>- What was your experience with ensuring shielded persons adherence to the practice?<br>- What, if anything could be done to make it easier for shielding patients to access care? Has anything hindered regular health care? Obtaining medications?<br>- Anything else to add on the topic that we haven't discussed today?<br>- Any questions for me? |

## Form 6: Topic guide for beneficiaries (shielded high-risk group)

| | |
|---|---|
| **Introduction** | Study aim and partners involved<br>Why you were invited to participate<br>Consent & any questions? |
| **Content** | What are the challenges to shielding yourself?<br>How can the shielding approach be improved? What are the major gaps for you?<br>Describe how you manage hygienic behaviours while you are shielding? What are the major gaps in assuring supplies and behaviours?<br>What was your experience with adhering to the need to stay inside your shielded residence?<br>Please describe your experience with community health volunteers who monitor your care?<br>What, if anything could be done to make it easier for shielding patients to access care? Has anything hindered your regular health care? Your access to medication?<br>Anything else to add on the topic that we haven't discussed today?<br>Any questions for me? |