



# General Study Protocol

## COVID-19 Vaccine Delivery Costing

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BREAKING NEW GROUND



THINKWELL

## ACRONYMS

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**AMC** Advanced Market Commitment

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**cPIE** COVID-19 vaccine implementation Post-Introduction Evaluation

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**CVIC** COVID-19 Vaccine Introduction and deployment Costing tool

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**HMIS** health management information system

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**IAR** Intra-Action Review

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**LMIC** Low- and middle-income countries

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## I INTRODUCTION

COVID-19 vaccine delivery poses unprecedented challenges in terms of delivery volume, reaching new target populations, and diversity of delivery strategies. Meanwhile, what it costs to deliver these vaccines is highly uncertain. To address this knowledge gap, ThinkWell, in collaboration with its partners and with support from the Bill & Melinda Gates Foundation, will produce rapid cost evidence in 6-7 countries to support a sustainable roll-out of COVID-19 vaccines in low- and middle-income countries. This study protocol describes the generalized approach that these studies will take in each of the countries. The protocol discusses the studies' scope and methods, and expected outputs. While recognizing that the diverse range of vaccine roll-out modalities will require tailored research approaches in each of the countries, this general research protocol is aimed at ensuring comparability across countries and facilitating cross-country learnings.

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## II BACKGROUND AND RATIONALE

Low- and middle-income countries (LMIC) are standing at the beginning of an incredibly challenging vaccine roll-out. COVID-19 vaccine delivery poses unprecedented challenges in terms of delivery volume, reaching new target populations, diversity of delivery strategies, and sometimes complex product profiles—elements which must all be managed at rapid speed if effective coverage is to be achieved. As of August 2021, 133 LMIC have already introduced COVID-19 vaccines, but due to supply constraints, only a small share of the target population has been reached so far.

The COVAX Facility, a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines, is aiming to considerably ramp up supply to LMICs over the coming months. By July 2021, up to 55 million doses had been delivered to the 92 LMICs that are eligible for free vaccines through COVAX's Advanced Market Commitment (AMC); this is projected to ramp up to a cumulative total of 1.2 billion doses by December 2021 and 4.6 billion by the end of 2022.

Meanwhile, what it costs to deliver these vaccines is highly uncertain. Modelled estimates at global level indicate that the delivery cost of COVID-19 vaccines in LMIC-settings could be several times greater than for routine childhood vaccines (US\$1.66 per dose in AMC countries<sup>i</sup> compared with \$1.45-1.50 per dose for routine childhood vaccines in low- and lower middle-income countries)<sup>ii</sup>. Several countries have developed their own cost projections to help plan their national roll-out, using a global tool such as the World Health Organization's (WHO) COVID-19 vaccine introduction and deployment costing tool (CVIC)<sup>iii</sup> or their own models, but these are still largely based on crude assumptions and global level parameters. Real cost evidence from countries is non-existent.

For the vaccine roll out, countries are considering many different delivery strategies designed to reach different priority target populations, which they have had to adapt to the uncertain influx of supply. These range from delivery at hospitals to reaching certain populations at their workplace, to mass delivery through large ad-hoc campaign sites to small, fixed sites in the community. In order to plan and budget for the roll-out in the most efficient manner possible, a better understanding of the costs and operational considerations associated with each of these delivery strategies is urgently needed.

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### III OBJECTIVE

#### Primary objective and sub-objectives

The primary objective of the studies is to estimate the actual cost of delivering COVID-19 vaccines through various delivery strategies.

The studies will focus on the following sub-objectives, to analyze and better understand:

- The cost of delivering COVID-19 vaccines through various strategies (e.g. hospital-based, outreach, mass vaccination sites) at different levels of delivery volume
- The cost of reaching different target populations (e.g. health workers, elderly, vulnerable populations)
- The cost of delivery of products with different cold chain requirements (e.g. regular 2-8 °C, -20 °C, ultra-cold chain of -60-80 °C)
- The different resource requirements for certain delivery strategies (in terms of numbers of health workers, cold chain equipment, etc.)

#### COVID-19 vaccine delivery costs

Delivery costs are the costs associated with delivering immunizations to target populations, exclusive of vaccine costs. They are also often referred to as operational costs. For COVID-19 vaccines, key delivery costs will, for example, include those for training, human resources, per diems and allowances, injection safety supplies, waste management, transport, cold chain maintenance, surveillance and reporting systems.

In addition to the quantitative analysis focused on costs and resource requirements, the analyses will also capture selected qualitative data from the implementation level to describe lessons learned on the roll-out to date. These will focus on:

- Identifying financial bottlenecks and lessons learned at the service delivery level, and document program managers' experiences in terms of the timeliness of funds and resource gaps.
- Mapping out the service delivery process and funding flows and for the delivery of COVID-19 vaccines.
- Mapping key funding sources for different vaccine delivery activities to help inform resource allocation decisions.
- Capturing the source and use of different types of paid and volunteer human resources for health (HRH) to deliver COVID-19 vaccines, including the mobilization of students, new recruits, retired staff, etc. to fill gaps.

#### Use case for the study outputs

The studies are aimed at helping countries make better, data-informed choices to facilitate an equitable roll-out of COVID-19 vaccines. The outcomes of the studies can be used for budgeting and planning, and can help answer questions such as:

- How much should be budgeted for outreach delivery?
- What are the key cost drivers of each of the potential delivery strategies?
- How do the cold chain and delivery costs differ depending on the product and the delivery strategy used?

The cost evidence can also be used for further analysis and to model out potential options:

- Using a mix of delivery strategies, how much will it cost to reach a certain target population?
- How will the cost of a certain delivery strategy change if delivery volume ramps up?

- How many health workers (and volunteers and other support staff) should be mobilized for efficient delivery at mass vaccination sites?

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## IV METHODOLOGY

### DESIGN

#### Overview

The C19 vaccine delivery costing studies will evaluate a range of delivery strategies across the 4-5 countries. In partnership with ThinkWell staff, in-country partner institutions will collect and analyze primary data (retrospectively and/or concurrently) from a small sample of sites using standardized questionnaires. Within each country, we will use a mixed-methods approach, including the following four methods:

- 1) light touch, bottom-up micro-costing (or ingredients-based costing) mainly at the service delivery and intermediate administrative level;
- 2) a complementary top-down analysis of financial expenditure reports and budgets;
- 3) a mapping of the service delivery process, key funding flows and funding sources relevant to the different COVID-19 vaccine delivery activities;
- 4) capturing the source and use of human resources for health (HRH) to deliver COVID-19 vaccines, including the mobilization of students, new recruits, retired staff, etc. to fill gaps.
- 5) a small-scale qualitative assessment of operational and financial challenges based on qualitative semi-structured interviews with stakeholders involved in the rollout of the COVID-19 vaccination strategy;
- 6) where possible, direct financial expenditures incurred by beneficiaries to reach the different types of vaccination sites will be captured from a small sample of client exit interviews.

In each of the countries, the study design will be tailored to the country-specific context in collaboration with the government. Ideally, study teams will include a government focal person to ensure ownership and alignment of the study with government priorities.

This section outlines the general principles of the methods that will be proposed and further adapted in each of the countries. Country studies will not all be implemented at the same time, such that methods and learnings from earlier implementers will feed into the design of subsequent studies. If necessary, this general study protocol will be updated to reflect valuable lessons learned.

#### COVID-19 vaccine programs versus routine immunization programs

COVID-19 vaccine programs represent a unique set of challenges that will require adaptation of the methods that are traditionally used to conduct routine and campaign immunization costing studies in LMIC. Routine programs and campaigns for traditional vaccines are well-established, with predictable delivery volumes and strategies, while COVID-19 vaccination programs are novel in many ways, and have been evolving and adapting since the programs were launched and as supply becomes more readily available.

The primary data gathered through the costing studies will represent a snapshot in time of the selected delivery strategies, and results must be viewed in the context of the evolving programs. The granular cost data can then feed into modeling to offer further insights into the effect of future changes to

delivery volume levels and changing resource inputs. Table 1 summarizes the key differences between the traditional routine immunization programs and the COVID-19 vaccine program, illustrating how this will affect the design and methods of the costing studies.

Table 1 – Differences between traditional routine programs and COVID-19 vaccination programs

	<b>Traditional routine programs</b>	<b>COVID-19 vaccination programs</b>	<b>Implications for the costing studies</b>
<b>Target population</b>	Usually a clear target age group that is similar in most countries.	Mix of different target population groups, many of which are not targeted by other immunization programs, and age and target groups may vary by country.	When comparing outcomes for different delivery strategies within countries, or similar delivery strategies across countries, differences in target populations need to be considered before interpreting results.
<b>Phased introductions</b>	Phasing is usually done by geography, vaccinating the entire target population group in a given area before moving onto the next.	Phasing is mostly structured to prioritize high-risk groups, rather than by geography.	Costing studies should analyze data and generate results by different target groups where sufficiently disaggregated data on this is available.
<b>Delivery strategy mix</b>	Often a mix of facility-based and outreach sessions are implemented on a routine basis, potentially complemented with periodic or outbreak response campaigns.	Delivery sites may be similar to routine (facilities, community outreach) or new (offices, elderly homes), and the strategy mix may change over time and based on coverage among various target groups.	The studies will focus on comparing the cost of various delivery strategies, some of which may no longer be utilized in the country by the time of data collection, while others have yet to be introduced, which means that a combination of retrospective, simultaneous and prospective costing may be used.
<b>Consistency of approaches over time</b>	Usually delivery approaches are well-established and consistent over time .	Delivery approaches are adjusted frequently based on vaccine supply, target populations and continuing lessons learned.	Through qualitative information gathering around potential changes to delivery strategies that are being considered, sensitivity analyses around changes in resource inputs that have occurred since data collection or are likely to change in the future (such as the size of teams, the intensity of social mobilization efforts, etc.) can be modeled to ensure the relevancy and interpretability of the findings within an evolving context.

<b>Delivery volume</b>	Delivery volume is usually relatively consistent over time.	Vaccine shipments have fluctuated, and delivery sites have been active for interrupted periods of time. Delivery volume is expected to ramp up considerably in most LMIC over the period Q3-4 2021 which will change the cost structure of certain delivery modalities.	The cost and efficiency of delivery strategies will need to be evaluated not only at the supply levels at the time of data collection, but also considering a possible ramp up or ramp down of the volume delivered per site per day. Similarly, the cost of once off system/program level investments should be considered a fixed cost when evaluating variable delivery costs to adequately compare costs across strategies.
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### Perspective

The studies will include costs incurred by both the ministry responsible for the COVID-19 vaccine roll-out as well as costs incurred by development partners (payer perspective). Where the private sector plays a large role in the roll-out of COVID-19 vaccines, private providers will be included in addition to public sector providers. Costs related to delivery of C19 vaccines incurred by other ministries will generally be excluded unless these are significant (for example, expected to make up more than 10% of the delivery cost). Although resource tracking will not be included in the scope of the studies, a 'light' mapping of funding flows from development partners and other sources will be included at the national level.

Costs will be collected at each administrative level, from national level to provinces/districts, down to hospitals and facilities and any campaign-style or other outreach vaccination sites. As costs incurred by beneficiaries to reach vaccination sites will vary across delivery modalities, out of pocket expenditures occurred by beneficiaries to reach the different types of vaccination sites may be captured from a small sample of client exit interviews, in countries where this is feasible.

### Timing of data collection

Depending on what delivery strategies will be costed, data may be collected both after and during implementation. For example, certain delivery strategies may have only been deployed during an already completed Phase 1 of the roll-out, and thus can only be costed retrospectively. On the other hand, the largest and most significant part of the roll-out may utilize delivery strategies that have not been implemented thus far, which means that data can only be collected concurrently and costs can only be estimated prospectively. As all studies should be implemented as rapidly as possible, concurrent costing methods will always be preferred to retrospective data collection. If a planned delivery strategy is still highly uncertain, data collection from implementation sites may not be possible, and projections based on data collected for other strategies and assumptions for various scenarios may be the preferred method.

## SCOPE OF THE COSTING ANALYSIS

### Delivery strategies

The focus of the costing studies will be on estimating the delivery cost of different delivery strategies. Certain delivery strategies are used in most countries (hospital-/facility-based, outreach), while others have not yet been widely utilized or can take very different forms in different countries. An initial list of

potential delivery strategies that may be included in the studies are listed in Table 2. It includes the likely key cost drivers and how volume is expected to impact the unit cost of delivery. However, the specifics will vary by country and perhaps also by region within each country. Not every country will utilize each of these strategies, and some will be used more intensively in some countries than others.

### Cost types

The studies will capture both costs specific to the COVID-19 program and costs that are shared across the wider immunization program and health system. All studies will estimate the financial cost of delivery strategies for all critical activities such as service delivery, social mobilization, supervision, waste management, monitoring, training and surveillance. Financial cost include resources such as per diems, recruiting additional HRH, fuel costs, PPE/IPC supplies, etc.

For comparability across countries and to better understand opportunity costs, namely the costs of using existing resources, economic costs may also be included. Economic cost data collection may take place on a more reduced scale than financial cost data collection, and be limited only to intermediate and service delivery levels, in order to speed up data collection. In addition, for major economic cost items such as labor, cold chain equipment and vehicles, there will be a greater focus on capturing and understanding resource use than on the cost associated with it, as this will be of more practical use for planning.

### Cross-cutting activities

In addition to the cost incurred at service delivery sites, the studies will capture recurrent costs for activities that cut across all delivery strategies, such as program management and supervision. At service delivery level the full economic cost of delivery will be captured, including the value of the use of existing resources. For higher administrative levels, labor costs will be excluded, though the cost of both new and existing capital (cold chain equipment, vehicles, etc.) will be recorded. Table 3 specifies the costs that will be captured at each level, and these may need to be adapted in line with the local context and government preferences. Table 5 in Annex I provides further detail on the relevant activities for the COVID-19 vaccination program.

In addition, one-off investments that have been incurred for the roll-out will be captured, such as investments in online training platforms or monitoring and surveillance systems. As these investments would benefit the entire COVID-19 and possibly immunization program and broader health system, these investments may be annualized where relevant to account for this.

Table 2 – Common COVID-19 vaccine delivery strategies

Delivery strategies	Main characteristics	Delivery volume, financial cost drivers	Costing approach
<b>Fixed sites: hospitals, facilities</b>	Initially utilized to reach health workers as part of the first phase, and currently also used to reach (certain groups within the) general public	Generally low-cost strategy relying mainly on the use of existing resources, with incremental financial costs limited to supplies, waste management, and cold chain expenses	Considering a typical week or month, record resource use for service delivery, social mobilization, vaccine storage, etc. in a (similar method to routine immunization costing)
<b>Work- or residence-based</b>	Utilized to reach certain priority populations including government officials, fire fighters, religious leaders, teachers, elderly populations	Per diems, social mobilization and transport costs	Considering a few ‘typical’ sites, record costs for the time period during which these were visited (could be a single day or several days, consecutively or not), including per diems, transport costs and if relevant, large investments incurred by the groups/employers themselves
<b>Outreach</b>	Utilized to reach remote and vulnerable populations	Low-volume/high-cost strategy with per diems, transport and social mobilization as the main cost drivers	Considering a typical week or month, record number of visits and duration, and resource use for key activities e.g. service delivery, social mobilization, supervision, transport, etc. (similar method to routine outreach costing)
<b>Temporary fixed sites</b>	Utilized to offer services at existing mass gathering sites such as churches, markets, community centers, etc.	High-volume sites with lower unit costs than outreach, and lower initial and recurrent costs for infrastructure compared with mass vaccination sites	For the time period during which the site was active, record resource use at, around, and to reach and supply the site (similar method to temporary fixed sites used in regular vaccination campaigns)
<b>Mass vaccination sites</b>	Usually based in urban settings (though also in rural areas in some countries such as Bangladesh) to reach large daily volumes of those in the general	High-volume sites that may have high initial and recurrent costs for the venue, additional HR needs, and on-site cold chain equipment requirements	For each site included the sample (see Sampling), record resource use at the site (in terms of the venue, staff, equipment and supplies) for a typical day (or several days if there a broader range of circumstances is

population that are eligible to receive the vaccine

expected), differentiated by whether these were incremental financial investments or reallocated from within the health system

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**Mobile clinics**

Either similar to outreach or deployed on a small scale instead of 'regular' outreach to reach specific pockets/target groups, such as refugees

Low-volume/high-cost strategy requiring in addition to costs similar to outreach, expenses for the mobile clinic itself

For the duration during which these were deployed, record resource use for the mobile clinic (expenses for the mobile clinic itself, transport costs, staffing, cold chain etc.) and related activities (social mobilization, supervision, etc.)

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**Private sector delivery**

Relevant to certain countries only. Can take various forms in countries:

- Private hospitals and facilities may be included in the general fixed site strategy
- May be contracted to run a mass vaccination site
- Private sector actors may be contracted to reach certain specific populations, including through the deployment of mobile clinics

Cost drivers and volume per site will depend on the specific arrangement

Costing approach will depend highly on the specific arrangement in place

Table 3 – Costs gathered by level of the health system

Health system level	Financial/incremental cost	Opportunity/shared cost
All service delivery sites	<ul style="list-style-type: none"> <li>- Service delivery costs</li> <li>- Cold chain maintenance</li> <li>- Social mobilization and advocacy</li> <li>- Supervision</li> <li>- Waste management</li> <li>- Record-keeping, HMIS, monitoring and evaluation</li> </ul>	Quantity and value of use of existing resources (labor, cold chain equipment, vehicles) for vaccine delivery as well as the vaccines themselves
National/regional level	<ul style="list-style-type: none"> <li>- Program management</li> <li>- Training</li> <li>- Surveillance</li> <li>- Record-keeping, HMIS, monitoring and evaluation</li> <li>- Vaccine collection, distribution and storage</li> <li>- Cold chain maintenance</li> <li>- Supervision</li> <li>- Record-keeping, HMIS, monitoring and evaluation</li> </ul>	Quantity and value of use of existing resources (labor, cold chain equipment, vehicles, etc.) as well as for new investments.

### Resource types / line items

In each of the countries, costs will be captured such that they align to local budget categories and classifications needed for donor proposals and global level plans to improve the usefulness of study outcomes to the countries. At the same time, to improve comparability of results, a crosswalk to global resource types and activities (Table 6 and Table 5 in Annex I) will be included in each of the research protocols. Where global resource types and activities are not granular enough, more categories may be included to facilitate this crosswalk.

Table 5 in Annex I indicates methods for estimating the different global line items, which may need to be adapted to local contexts. The proposed methods place greater emphasis on resource use that is likely to differentiate across delivery strategies and regions (such as transport costs, health worker time), while more general assumptions may be used to estimate cost components that are less likely to vary, such as building and capital costs.

### Time period covered

The costing studies will be focused on comparing the cost of delivering COVID-19 vaccines through various strategies. These strategies may not have been implemented at the same time. Therefore, data collection at service delivery sites may cover varying periods, with the aim to obtain an average for a day, week or month of delivery using that particular strategy. Data collection may also take place at

different points in time depending on what makes sense for each delivery strategy, while keeping in mind that all data collection must be completed by April 2022 latest, in order to have final results ready by July). At national level, the cost of planning activities will also aim at getting a representative average over the period since COVID-19 vaccination planning has started (covering several months to a year), recognizing that there may be more or less intensive periods throughout the roll-out period of the vaccine.

### Allocating shared costs

To allocate costs between COVID-19 vaccine delivery and the immunization program and the broader health system, standard allocation rules will be used or adapted in line with specificities of the COVID-19 vaccination program. For example, while cold chain costs are usually allocated according to the space they take up in the cold chain compared to other vaccines, in the case of ultra-cold chain (UCC) vaccines, these will be fully specific to the COVID-19 vaccination program. In addition, some staff may be fully dedicated to COVID-19 vaccination, such that labor allocation rules do not apply. The baseline allocation rules are captured in Table 6 in Annex I, and these may need to be adapted further depending on how a country's program is run and the degree of integration with other health services.

### Modeling and scenario building

The varying time periods around the introduction and roll-out of the vaccine, and uncertainties around supply availability and the final target to be reached in each country, pose challenges to the allocation of certain kinds of shared costs, such as training and planning activities. The unit cost of such activities significantly reduces with volume, but as countries will most likely still be rolling out under some degree of uncertainty while the studies will be completed, allocating such cost across a fixed denominator may not be the correct approach. Similarly, certain service delivery strategies may be set up for greater volumes than initially observed. For example, early on in the utilization of mass vaccination sites in South Africa, low attendance at certain points of time in the day had been observed, which affects the efficiency and unit cost of delivering through such strategies, even if future throughput may lead to greater efficiency and lower unit costs.

An opportunistic approach to sampling and timing of data collection (see Sampling) will reduce the risks of some of these challenges, and that the collected data is as relevant as possible. In addition, such challenges will be addressed by not only reporting unit costs at delivery levels observed during data collection, but by also modeling the cost of a given delivery strategy at higher (or lower) supply levels or session sizes. Certain fixed costs or one-off investments can be presented separately from variable delivery costs to better illustrate how costs are expected to scale with changes in delivery volume. For example, in the case of training, costs may be reported on a per facility or per health worker basis, as opposed to merely per dose delivered, to account for the fact that delivery volume is highly variable. Modeling and scenario building will help translate the estimated costs to future changes to the delivery strategies and to assess the effect of an expected ramp-up in supply over the coming months. It will also facilitate translation of study results to other geographies, settings and countries.

## SCOPE OF THE QUALITATIVE ANALYSIS

Most countries in which the costing studies will be conducted have already conducted a country COVID-19 Intra-Action Review (IAR), which includes a pillar on vaccination that is focused on conducting a mini COVID-19 vaccine implementation Post-Introduction Evaluation (cPIE). As these are focused mainly on the national level, our qualitative assessments will focus on issues encountered at implementation level. That means interviewing those active at vaccination sites and, depending on the level of decentralization, potentially including program managers at the level just above. This can likely be done in conjunction with the cost data collection, and initial (possibly less structured) insights can also be

obtained during a scoping or piloting visit to implementation sites ahead of the development of cost data collection tools.

As part of the scoping exercise for the costing study, and to help determine the selection of most appropriate delivery strategies and sites to cost, national level stakeholders will be consulted on the COVID-19 vaccine roll-out. This will provide initial insights into the current successes and challenges of the new vaccination program, and will help to adapt and shape the example questions that will be asked at implementation level. Areas of focus will include the sourcing and deployment of HRH and financing and funding flow issues. A visual mapping of the service delivery process using the various delivery strategies will be developed as a starting point, as well as visualization of funding flows linked to this. A mapping of funding sources against key COVID-19 vaccine delivery activities will also be conducted. The scope of this qualitative analysis will be kept as narrow as possible, and so the priority areas identified at national level should be further field tested as part of the pilot phase to ensure that the questions indeed focus on key bottlenecks only.

## SAMPLING

The studies will be conducted while countries are still rolling out the vaccines, and delivery strategies and volumes are continuously changing. In addition, countries may be rolling out different types of vaccines, potentially with varying delivery requirements. Therefore, obtaining a sampling frame that completely captures all sites and site characteristics in the country will be challenging, and sampling will be done in a purposive manner.

To facilitate rapid costing, the sample size will balance the need for speed while still allowing for a robust analysis. While immunization costing studies usually aim to include a large sample of 50 delivery sites, the rapid COVID-19 vaccine delivery costing studies will include around 30 sites. This number will be spread across the different delivery strategies included in the study (about 3-4 strategies) according to their importance in the overall roll-out (in terms of overall volume as well as throughput) and the expected variance in the unit cost of delivery of a given delivery strategy.

While not nationally representative, the sites will be chosen such that estimates will be representative for the delivery method at the sampled sites, and will be indicative of the delivery costs for a range of the similar delivery modalities at other sites. If, however, the government wishes to have a more nationally representative estimate, the study team will work with the MOH focal person to select a sample, and potentially include more sites with a reduced level of detail per site to meet this demand. Table 4 outlines the general sampling approach, which will be refined and adjusted in collaboration with the MOH in each of the study countries.

Supply at certain sites may ramp up while data collection is already in progress, delivery strategies may be adapted mid-way and different products may be introduced during the study period. Therefore, to adapt to such changes, sampled sites may not all be selected at the same time, or data collection may take place at various moments in time (while still aiming to complete all data collection by April 2022, see V Indicative timeline below). Allowing for a more opportunistic approach will ensure a greater variety of data collected and greater relevance of the study outcomes.

## DATA COLLECTION

In each country, ThinkWell and its partners will partner with a local research institute, consultancy or individual data collectors to complete the study. Different collaboration models may be deployed depending on the country. In order to facilitate rapid results, existing capacity and speed at which this can be mobilized will be the key determinants when selecting a local research partner.

Data collection will be conducted using standardized questionnaires that will focus on capturing financial cost, but will include an economic cost component in a subset of the sample. The questionnaires will be tailored to align to county-specific cost components, terminology and activities, but cost calculations following from these will align to the resource types and activities defined in this research protocol to ensure cross-strategy and cross-country comparisons.

The timing of actual data collection will depend on government and ethical approval processes, as well as on the timing of certain components of the country's specific COVID-19 vaccine roll-out strategy. Data collection may therefore not take place at the same time at all sample sites, and the order at which certain data will be collected will be adapted to the country's timelines. However, as overall guidance, all data collection activities should be completed no later than February 2022 (see Timeline).

## OUTCOMES AND REPORTING

Each country study will present unit costs per delivered dose and per targeted person by delivery strategy and at high and low delivery volume levels. Larger health systems investments (e.g. IT or training) will be presented using other denominators as well, such as cost per site or for the (national) roll-out as a whole. All results will be presented and discussed with relevant stakeholders, and a report and a policy brief will be developed. Cross-country learnings will be summarized in a product for regional and global level learning as well.

Table 4 – Sample size

Selecting delivery strategies	Sample size by delivery strategy	Costs to collect
<p>If the country uses/has used 3 delivery strategies or less, include all</p> <p>Otherwise, selection criteria to determine which 3-4 delivery strategies to include:</p> <ol style="list-style-type: none"> <li>1. MOH interest</li> <li>2. Most utilized in terms of number of sites or delivery volume</li> <li>3. Most relevant, i.e. likely to be utilized/scaled up in the future</li> </ol>	<p>General guidance, to be refined and adjusted on a country-by-country basis in collaboration with MOH:</p> <ol style="list-style-type: none"> <li>1. Fixed sites (hospital, facilities) and outreach sites: 20-25 sites               <ol style="list-style-type: none"> <li>a. Include both high and low volume sites</li> <li>b. Urban and rural settings</li> <li>c. Sites using different types of vaccines (or a mix) with varying cold chain requirements</li> <li>d. Other selection criteria, if possible: high/low capacity or coverage</li> </ol> </li> <li>2. Work- or residence-based: depending on frequency of use, potentially include 1 or 2</li> <li>3. Mass vaccination sites: 1 or 2</li> <li>4. Mobile clinics: include 1 or 2</li> <li>5. If relevant: include 1 private sector contractor (could overlap with other delivery strategies such as mass vaccination sites)</li> </ol> <p>Total sample size: 20-30 sites per country covering all strategies.</p> <p>The precise number of sampled sites per strategy will be country-specific, and linked to the volume delivered through each strategy, as well as how wide of a range in delivery costs is expected for a given delivery strategy.</p>	<p>Collect from providers at all sites:</p> <ul style="list-style-type: none"> <li>- All financial costs</li> <li>- Light touch economic cost (cold chain equipment and vehicles use, labor types, use and costs)</li> </ul> <p>Collect from beneficiaries:</p> <ul style="list-style-type: none"> <li>- Conduct 20-30 exit interviews at 1 site per delivery modality (only in countries where including this does not slow down the ethical approval process)</li> </ul>

## V INDICATIVE TIMELINE OF A STUDY

Activity	2021-2022									
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10
Government demand identified	■									
Scoping in collaboration with government and identifying local research partner(s)	■	■								
Develop country-specific research protocol and data collection tools for ethical approval		■	■							
Qualitative data collection				■	■	■				
Data collection at campaign sites				■	■	■				
Data analysis and synthesis of findings							■	■	■	
Dissemination of results at country, regional and global level										■

## ANNEX I. RESOURCE TYPES & ACTIVITIES

Table 5 – COVID-19 vaccine program activities

Program activity	Definition
<b>Program management</b>	Planning, budgeting, managing the COVID-19 vaccination program.
<b>Vaccine collection, distribution and storage</b>	Collecting vaccines at the airport or other distribution points, storing vaccines in national or subnational cold stores, distributing vaccines down to the facility, and to outreach or campaign sites where relevant.
<b>Cold chain maintenance</b>	Maintaining and repairing the cold chain for the purpose of the COVID-19 vaccine roll-out.
<b>Training</b>	Attending and/or providing COVID-19 vaccination-related training, including topics such as administering vaccines, storage and logistics, record keeping, pharmacovigilance, social mobilization, planning, supervision, etc.
<b>Social mobilization and advocacy</b>	Mobilizing and sensitizing the community and households, conducting events, and advocating for COVID-19 vaccination.
<b>Supervision</b>	Supervising subordinate or peer health or community workers.
<b>Service delivery: facility-based delivery</b>	Administering the vaccine to people within the hospital/facility/compound.
<b>Service delivery: temporary fixed sites</b> (may break down further into mass vaccination sites versus more traditional temporary fixed sites)	Traveling to and from temporary fixed sites outside of the facility, the act of administering the vaccine and supporting vaccine administration (crowd control, screening). Could include mass vaccination sites, sites at markets, churches, community centers or using mobile clinics.
<b>Service delivery: outreach/mobile teams</b>	Traveling to and from a non-facility non-fixed location and the act of administering the vaccine there. Includes support such as crowd control and screening. May need to be broken down further to distinguish teams in the communities from teams visiting offices, etc.
<b>Waste management</b>	Time and resources spent on disposing sharps and infectious non-sharp wastes.
<b>AEFI management</b>	Following up on post-vaccination events following COVID-19 vaccine administration.
<b>Record-keeping, HMIS, monitoring and evaluation</b>	Data entry and analysis, reporting, monitoring.

For each of the activities listed above, one or more of the resource types/line items presented in Table 6 will be relevant.

Table 6 – Resource types/line items

Description		
Recurrent costs	Included	Estimation method and allocation to the COVID-19 vaccination program
Paid labor	Allocation of salaried labor to COVID-19 vaccination activities. Salaries are fully loaded thus including any regular allowances.	Time spent on COVID-19 vaccine program activities as a share out of the regular month * monthly salary. If activities were integrated with other services: allocate the value of labor to each of the interventions delivered based on time spent on the delivery of each intervention (e.g. as a share of the working day/week). If no data on the time spent on the delivery of each of the interventions, the value of labor can be allocated based on the volume delivered of each of the interventions.
Volunteer labor	Estimation of the market value of volunteer labor used for activities related to COVID-19 vaccine delivery. For volunteers with medical qualifications: average salary for their cadre is used.	Hours spent on COVID-19 vaccination program activities * estimated hourly rate based on volunteer qualifications or daily laborer's rate or minimum wage
Per diem and travel allowances	Any allowances paid to health workers and volunteers for COVID-19 vaccination program activities.	Most likely 100% specific to the COVID-19 vaccination program or if not, allocate based on volume of services delivered (e.g. as a share of the total delivered during the day for which the per diem was meant)
Vaccines	Cost of COVID-19 vaccines, including wastage.	Vaccine doses (differentiated by type) administered or wasted at the vaccination sites * price at which they were procured (or in case of donated vaccines, estimation of an equivalent price). If possible, the cost of international shipment of the vaccines, and any insurance, customs or handling fees will also be included here.
Vaccine injection and safety supplies	Cost of auto-disabled syringes, diluent, reconstituting syringes, safety boxes and other supplies used for administration of COVID-19 vaccines.	See Vaccine method
Stationery and other supplies	Cost of stationery and other supplies used for COVID-19 vaccine delivery.	Quantity used/purchased for COVID-19 vaccination activities * price

Transport and fuel	Cost of bus fare, plane travel, boat travel/hire, vehicle hire, and the cost of fuel for transport.	Expenditures on COVID-19 vaccine program related activities. When shared, allocate a share based on delivery volume.
Vehicle maintenance	Cost of maintaining vehicles (of all types) used for activities related to the COVID-19 vaccine program.	Captured only if any were undertaken specifically to support the roll-out of COVID-19 vaccines
Cold chain repairs and energy costs	The cost of repairing existing cold chain equipment and running the cold chain (butane, gas, electricity, etc.), and the cost of ice. Rental of cold chain equipment and related equipment (such as generators) will also be included here.	Allocation based on cold chain space usage in terms of volume. For ultra cold chain (UCC) vaccines, this will be 100% specific to the COVID-19 vaccination program.
IEC and other printing costs	The cost of printing immunization cards, training materials, radio and tv appearances and other IEC materials that are related to the COVID-19 vaccination program.	Likely 100% COVID-19 vaccine specific
Utilities	Costs related to building overheads, including maintenance, and utilities with some portion of these costs allocated to the campaign.	Exclude unless significant incremental costs are expected, such as in the case of mass vaccination sites
Workshops and meetings	Costs related to workshops, trainings and meetings, including the venue and refreshments provided on the day, but not including related transport costs.	These will likely have been 100% specific, although when shared across other health activities, allocate based on time allocated to COVID-19 vaccination during the meetings.
Communication	Costs related to purchasing airtime and mobile data for the purpose of the COVID-19 vaccination program.	Excluded: a portion of regular phone and internet connection charges.
Other recurrent	Other notable recurrent costs for COVID-19 vaccination activities that are not included in the above line items. Normally, this category should be very small.	Could include rental of incinerators, tents, building space for mass vaccination sites, if applicable
<b>Capital cost</b>	<b>Included</b>	<b>Estimation method and allocation to the COVID-19 vaccination program</b>
Cold chain equipment	Value of all cold chain equipment used to store and transport COVID-19 vaccines.	Capture any newly procured and already present cold chain equipment, annualized and discounted over its useful life, allocate a share based on number of days of use and volume of

		COVID-19 vaccines out of the total cold chain space
Vehicles	Value of all vehicles and modes of transport (could include boats).	Capture any newly procured and already owned vehicles, annualized and discounted over their useful life, allocate a share based on days of use or km usage for different COVID-19 vaccine delivery activities
Incinerators	Equipment used for waste disposal at all levels.	Capture any newly procured and already owned incinerators, annualized and discounted over their useful life, allocate a share based on days or instances of use for disposal of COVID-19 vaccine related waste
Other equipment	Value of other equipment, such as generators, computers, printers, peripherals, phones, furniture, other medical equipment used for the COVID-19 vaccination program.	Exclude
Buildings	Value of building space used to deliver and store COVID-19 vaccines.	Exclude (except in the case of a significant incremental investment as may be the case for mass vaccination sites)

## REFERENCES

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<sup>ii</sup> Portnoy, A., Vaughan, K., Clarke-Deelder, E. et al. Producing Standardized Country-Level Immunization Delivery Unit Cost Estimates. *PharmacoEconomics* 38, 995–1005 (2020). <https://doi.org/10.1007/s40273-020-00930-6>

<sup>iii</sup> COVID-19 Vaccine Introduction and deployment Costing tool (CVIC tool), Version 2.2, 10 June 2021: [https://www.who.int/publications/i/item/who-2019-ncov-vaccine\\_deployment\\_tool-2021.1](https://www.who.int/publications/i/item/who-2019-ncov-vaccine_deployment_tool-2021.1)