## Collecting Evidence to Inform COVID-19 Vaccine Procurement Decisions

A Toolkit for African Countries

**NOVEMBER 2021** 





### Collecting Evidence to Inform COVID-19 Vaccine Procurement Decisions

### A Toolkit for African Countries

Y-Ling Chi<sup>1</sup>, Justice Nonvignon<sup>2</sup>, Elias Asfaw<sup>2</sup>, Carleigh Krubiner<sup>1</sup>, Cassandra Nemzoff<sup>1</sup>, Anthony McDonnell<sup>1</sup>, Francis Ruiz<sup>1</sup>, Tom Drake<sup>1\*</sup>

- <sup>1</sup> Centre for Global Development, International Decision Support Initiative, Global Health Programme, Great Peter House, Abbey Gardens, Great College St, London SW1P 3SE, UK
- 2 Africa Centres for Disease Control and Prevention, Health Economics Unit, Roosevelt Street W21 K19, Addis Ababa, Ethiopia
- \* Corresponding author

#### Acknowledgments

This report was produced by the Center for Global Development (CGD), with contributions from the Africa Centers for Disease Control and Priorities (Health Economics Unit). The authors are grateful to Pete Baker (CGD), Javier Guzman (CGD), Katharina Hauck (Imperial College London), Raymond Hutubessy (WHO) and Edith Patouillard (WHO) for their review, technical guidance and comments.

Financial support for this work came from the Bill and Melinda Gates Foundation.

Grant number: OPP1202541

#### Keywords

Vaccine procurement, COVID-19, Health Technology Assessment, Priority setting, Africa, Tookit, Economic



For the last 18 months, the COVID-19 pandemic has taken a deadly toll on the African continent. As the number of cases and deaths continues to climb, and in the face of economic devastation, social unrest, and increased fragility; many countries and institutions in the region are securing deals with vaccine manufacturers to help bring the pandemic to an end. However, unlike many countries outside of the region (especially high-income countries), African countries are often in the back of the queue when it comes to vaccine procurement, incurring high costs or long delays. In addition to the procurement issues, complex challenges associated with deployment on the ground means vaccination rates in the region are still comparatively low.

This present resource will be very helpful for anyone working on the ground to generate context-specific evidence to support decision-makers when making procurement decisions. The approach of the toolkit, one that acknowledges the very specific contexts, challenges and pressures of countries (in terms of health system capacity, budget, disease burden), will make it a valuable resource and fills an important gap in the guidance that has been produced to date. The toolkit content is user friendly and its focus on the continent will help promote evidence-based approaches to procurement, and foster cross-country learning.

COVID-19 vaccine procurement can also be an opportunity to strengthen priority setting, or the application of Health Technology Assessment in Africa, which could benefit the development of strong health systems to support the recovery after the pandemic.



Prof Benjamin S.C. Uzochukwu (FAS, FAMedS)

Consultant Public Health Physician, University of Nigeria Teaching Hospital (UNTH) Enugu, Nigeria Professor of Public Health, Health Systems & Policy University of Nigeria Nsukka, (UNN) Chairman, Faculty of Community Health West African College of Physicians (WACP)

Director, Grants and Research West African College of Physicians (WACP)

# List of Abbreviations

AMC: Advance Market Commitment **ACDC:** Africa Centres for Disease Control and Prevention **CCA:** Cost-Consequence Analysis **CVIC:** COVID-19 Vaccine Introduction and deployment Costing **DALYs**: Disability-adjusted Life Year **DHIS:** District Health Information Software GHCC: Global Health Cost Consortium HMIS: Health Information and Monitoring Systems HTA: Health Technology Assessment **iDSI:** The International Decision Support Initiative **IPSOR:** Professional Society for Health Economics and Outcomes Research LMICs: Low-or Middle-Income Countries MCDA: Multi Criteria Decision Analysis NITAG: National Immunization Technical Advisory Group NDVP: National Vaccine Delivery Plan **PPE:** Personal Protective Equipment WHO SAGE: World Health Organization Strategic Advisory Group of Experts on Immunization

## Table of Contents

Summary	5	
Introduction		
1. Health Technology Assessment	9	
2. Health Technology Assessment for COVID-19 vaccine procurement		
3. Collecting the evidence		
Supply and logistical contraints	15	
Ethics and equity considerations	17	
Value for Money	20	
Budget impact analysis	33	
Conclusion	35	

## Summary

Vaccines are key to controlling COVID-19 in Africa, but available supplies across the continent remain extremely low—in most countries, doses are not even enough to vaccinate 1 in 10 people. Global, regional, and national institutions have created mechanisms to procure vaccines and deploy them to their populations. Those organizations face important decisions, with the potential to protect societies and economies from further COVID-19 shocks, but also present a risk to essential services if the cost of COVID-19 vaccines depletes scarce health budgets.

This toolkit aims to support technical staff and decision-makers in countries that are interested in using Health Technology Assessment (HTA) to inform the procurement of COVID-19 vaccines. After introducing the HTA process, it focuses on evidence collection, outlining the types of information useful to make informed decisions, and options for frameworks to harness data. The toolkit also points to relevant existing evidence, resources and key considerations from experiences garnered since the beginning of the pandemic.

# Introduction

Vaccines are key to bringing COVID-19 under control and to mitigating the health, social and economic impacts of the disease in African countries. The Africa Centers for Disease Control and Prevention (ACDC) has set a goal to work with member states towards vaccinating 60 percent of their populations, but available vaccine supplies across the continent remain extremely low: as of October 2021, only 5.6 percent of the population has been inoculated. More recently, the World Health Organisation (WHO) has set a target of vaccinating 70% of the population by June 2022.

For many African countries, getting sufficient vaccine supply is a challenge. COVAX—a global partnership to provide innovative and equitable access to COVID-19 diagnostics, treatment, and vaccines—aims to purchase and deploy vaccines for at least 20 percent of each participating low- or middleincome country in 2021. In addition to COVAX, many African governments and regional authorities are working in parallel to purchase vaccines. Such decisions prompt difficult questions: should limited health budgets be spent on COVID-19 vaccines? If so, which vaccine products will be appropriate and produce the greatest health impact? How much should be purchased, and at what price? What are the economic risks and benefits of vaccinating populations?

Getting COVID-19 vaccine procurement right matters because money spent on vaccines is not available for other essential health services. COVID-19 is an unprecedented and unusual public health challenge. Advisory panels working on COVID-19 at the country and regional levels may need to adapt to consider trade-offs beyond the health system. For those reasons, strategic procurement departments may wish to draw on additional kinds of information compared with normal practice.

Health Technology Assessment (HTA) is an approach that has supported public payers for decades in the procurement of medical products and technologies, including vaccines. It is a framework to systematically evaluate the properties of a technology, typically centred on an assessment of valuefor-money.

Given the complexity of the COVID-19 vaccine market, HTA can support decision-makers in making informed decisions and reviewing options using best available evidence.

This resource aims to aid decision-makers, their technical advisors, and researchers in collecting and assessing evidence to support the application of Health Technology Assessment to inform procurement decisions. It is likely that procurement of COVID-19 vaccines will remain a high priority for governments and regional authorities for several years. This toolkit can support technical advisors to structure evidence collections as new vaccine products come to the market, new knowledge is gained, epidemic evolves and fiscal space changes.

# What is this Toolkit for?

This toolkit aims to support technical staff and decision-makers in African countries that are considering buying COVID-19 vaccine using domestic funds—or a mix of funding—to obtain doses in international markets, rather than receiving donations from COVAX or other initiatives.

There are two components at the core of any vaccine procurement decision:

- Which vaccine products are most appropriate?
- What quantities of vaccine to purchase (and at which price)?

A range of important considerations follow from these questions: What price represents good value for different products? Are there particular constraints due to cold chain requirements? Are available products nearing expiry? And so on.

The intention of this toolkit is to support decision-makers and technical analysts to identify, organise and bring evidence to bear on COVID-19 vaccine procurement decisions using a HTA framework. It focuses on identifying potentially relevant topics for consideration and points to relevant existing evidence, resources and key considerations from experiences garnered since the beginning of the pandemic.

Ultimately, given the complexity of such decisions, COVID-19 vaccine procurement may remain a judgement call by senior decision makers. However, the establishment of a process that facilitates the use of evidence can support them in making this judgment call. Moreover, transparency about the ways of working and the evidence base underpinning decisions, even in times of pandemic, is also essential to ensuring public trust and buy-in of COVID-19 vaccination programs. In this pandemic, procurement decisions have, in many cases, been made behind closed doors and in some countries this may have been contributing to vaccine hesitancy, hindering early progress.

#### This toolkit is organised as follows:

- The first section provides a short introduction of HTA and adaptative HTA (a form a rapid and pragmatic HTA) and the benefits of applying this approach to inform procurement decisions.
- 2 The second section discusses how HTA can be applied to procurement of COVID-19 vaccines following the CAPACITI framework, which has been developed to inform vaccine procurement more broadly. Here, we emphasize the importance of HTA as a process, rather than a single analytic, which should also go beyond simple value for money considerations.
- Finally, in the third section, we focus on one aspect of the overall HTA process: information collection and assessment of evidence. Because the intention is to support technical advisors and researchers

undertaking HTA, we discuss potential sources of information, methods for analysis and point to gaps and sources of uncertainty.

For ease of use, this section is further broken down into the different criteria that can used to structure the appraisal process: from supply and logistical constraints, to purchase price and global health security.

#### Disclaimer

There are several important limitations to this document. First, while the focus of this guidance is procurement, there are related policy decisions on which groups to prioritise in vaccine roll out and methods of delivery—we only discuss superficially. Both decisions affect expected costs, benefits, and risks of COVID-19 vaccination, and therefore impact procurement. Second, HTA is a useful approach to procurement decisions, but not the only one—and a relatively nascent approach in many African countries. Finally, as the evidence on COVID-19 and vaccine products evolves, some of the content of the toolkit will inevitably become outdated. Where possible, we provide links to key sources of up-to-date relevant information.

# Health Technology Assessment

Health Technology Assessment (HTA) is a "multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle". Cost-effectiveness analysis and budget impact analysis are important components of HTA and can inform governments on the affordability of the intervention, or service under consideration. HTA is one approach, among others, that has supported public payers for decades in the procurement of medical products and technologies, including vaccines. It has become particularly attractive to decision-makers seeking to evaluate using a set framework, the costs and benefits of an intervention (including non-health benefits such as equity or societal preference). Cost-consequence analysis or a multi-criteria decision analysis (MCDA) may be used to frame an HTA. HTA is contextualised in a country to fully reflect characteristics in health systems organisation, pathways, costs, local epidemiology and demographic factors. Those last two elements will be especially important in the context of COVID-19, considering the variations in how the virus impacts health outcomes by age and co-morbidities.

HTA also helps ensuring that the analysis is high-quality, accurate, comprehensive, contextually relevant, and reflects local clinical practice. The International Decision Support Initiative's <u>HTA toolkit</u> provides an overview of HTA methods, including the process of evidence-informed decision-making. The <u>iDSI Reference Case</u> for healthcare economic evaluations also provides a principle based approach to guide the planning, conduct and reporting of economic evaluations.

Full and thorough HTAs can be time consuming, data-hungry, and very demanding in terms of statistical and health economics expertise and data. Given the exceptional circumstances of the pandemic, an exhaustive HTA analysis and process will be challenging. It will be important to take a pragmatic and flexible approach in any analysis undertaken, ensuring that it is fit for the purpose of making quick decisions.

> Some countries have established <u>rapid HTA approaches</u> aimed at addressing policy urgency, and accounting for existing resource constraints available for analysis. These include conducting literature searches, adapting existing cost-effectiveness models, benchmarking against publicly available prices in other countries, or making use of international data sets. These approaches review the costs and benefits of different health interventions, but may not <u>combine</u> of costs and benefits into a single number, as a cost-effectiveness analysis would. This may make rapid HTA approaches relevant to COVID-19 vaccines, because it will also point to different types of health benefits without having to combine. For instance, vaccines will offer protection to those vaccinated and non-vaccinated.

Examples that may be relevant to COVID-19 vaccine rapid HTAs include the <u>Canadian Rapid Response Service</u> which has various levels of literature review it undertakes, or the <u>Philippines HTA Process for Public Health</u> <u>Emergencies</u> which was designed specifically for public health emergencies. The <u>Irish Health Information and Quality Authority</u> have undertaken rapid HTAs in relation to COVID-19, including one on testing.

While <u>rapid</u>, <u>adaptive HTA approaches</u> for COVID-19 vaccines can produce evidence quickly, there are trade-offs compared to a fully-fledged HTA. Rapid HTA analyses can be less accurate, less contextually relevant, and there may be significant sources of uncertainty and data gaps. For instance, rapid HTAs will rely significantly on international data, and the transferability of such information across settings may be a limitation. Nevertheless, those limitations may be acceptable to ensure relevant information is available to support COVID-19 decisions in a timely way and can be considered and addressed through a rigorous process of assessment and appraisal, as we discuss in the following section).

# 2 Health Technology Assessment for COVID-19 vaccine procurement

# Applying the process

To maximise the relevance and timeliness of COVID-19 vaccine HTAs, it firstly is important to clearly identify the stakeholders and processes for decision making on vaccine procurement. This is likely to include the routine vaccine governance structures, such as a National Immunization Technical Advisory Group (NITAG) and leadership in the Ministry of Health and Ministry of Finance. Given the political profile of COVID-19 vaccine procurement, senior political figures and even heads of state may also require oversight of decisions. In addition, international organisations who are not directly part of decision making may influence government process or have the capability to influence vaccine donation or subsidy.

Drawing on the work from <u>CAPACITI</u>, we outline below five steps to conducting a rapid HTA to support COVID-19 vaccine procurement. Being clear from the outset, both about the decision problem and the evidence-to-policy process is particularly important in emergency or highstakes situations to ensure a range of evidence is considered and avoid miscommunication or delays.



#### Define the decision problem

The core decision problem when thinking about procurement is broadly captured in the following two questions:

- Which vaccine product?
- What quantities of vaccines to purchase (and at which price)?

Those two questions can be expanded to include further issues (e.g., price negotiation), and could also be tackled using a non-HTA type approach. For instance, on the second question, decision makers could focus on forecasting vaccine needs according to the vaccine plan. We discuss those additional approaches further in the section about collecting the evidence (see ethics and equity considerations). It is important that the process outlined in this document connects to such existing activities, if relevant.

The answers to the above questions will be constrained by contextual factors such as market availability, feasibility of cold chain requirements in a local context, variants present in the country, product licensing, budgets available (locally and externally), feasibility of some vaccine delivery strategies, existing purchase commitments and donations or political and social acceptability (e.g., vaccine hesitancy or misinformation).

Contextual factors are likely to change frequently, so the framing of the decision-problems may need to adapt to any new circumstances.

As a result, as part of defining the decision question (or set of questions), it will be critical to clearly define the options under consideration. To make choices between vaccine alternatives, analysts will be comparing alternative commodity options based on several considerations (e.g., vaccine efficacy, purchase costs etc.). For volume questions, the picture is more complicated. Analysts will need to compare different realistic options and those will need to be compared to an appropriate baseline or "do nothing" comparator. Using a "zero vaccination" baseline comparator is unlikely to be correct in most countries—a better-defined decision problem will specify the current level of coverage from previous procurement or donation agreements, and the potential additional vaccine volume under consideration.



#### Define appraisal criteria and process

Once the decision problem and corresponding options are defined, decision makers need to define the framework for considering relevant evidence. In the context of COVID-19 vaccine procurement decisions, the following appraisal criteria for COVID-19 vaccines can be considered:



This list is not exhaustive and other considerations, such as safety and relevance of the evidence may be considered (see this <u>recent exercise in</u> <u>Latin America on vaccine selection</u>). It can also be reduced or expanded depending on the country's priorities and constraints. There may be local guidance on appropriate criteria and the <u>CAPACITI</u> tool provides further information on setting or adapting appraisal criteria.

Considering value for money in further detail, a Cost Consequence Analysis (CCA) can be used to identify the broad categories of cost and impacts of vaccine procurement decisions, presented across a wide range of measures:

Cost	- -	Purchase costs Delivery costs
Consequences	-	COVID-19 health effects (includes direct effects-to those inoculated-, and indirect effects through reduced transmission) Collateral health impacts (through the wider health system)

- Micro- and macro-economic impacts
- Global health security concerns

Those measures could also be used within a dedicated rigorous HTA with a bespoke economic evaluation.

#### Cost-Consequence Analysis (CCA)

It is not always preferable to condense costs and effects into a single quantitative finding. Instead, CCA produces a tabular summary of costs and consequences, including non-quantified effects. This richer presentation of disaggregated factors can be suitable when considering COVID-19 vaccines, given the range of considerations that appear relevant to decision-makers.

This list includes considerations other than value for money, such as supply and logistical constraints and ethics and equity. For instance, when considering the number of vaccines to be purchased, the quantification exercise can be approached from an ethics perspective by looking at the vaccine campaign goals and the corresponding priority populations to cover. This will need to then be combined to different factors (e.g., purchase price, logistical constraints, budget impact).

Not all elements of the economic evaluation will be relevant to both procurement questions noted above (Table 1). For instance, when deciding which type of vaccine product to buy, one may not need to consider the collateral health impacts or the indirect health impacts because the evidence on the impacts of different vaccines products on transmission is not yet well established (although there is evidence emerging quickly on this topic).

Factors to consider	Which vaccine?	How much vaccine?
Supply and logistical constraints	>	~
Ethics and equity	>	~
Value for Money	>	~
Purchase cost	>	~
Delivery cost	>	~
COVID-19 health effects	>	~
Collateral health impacts		<b>~</b>
Micro- and macro-economic impacts		~
Global health security		✓
Budget impact	$\checkmark$	~

#### Table 1. Essential assessment factors by decision domain

Once criteria are established, decision makers need to define the appraisal process. Appraisal is the formal consideration of the evidence, following pre-defined rules. It will guide how evidence around the listed criteria are brought together by an appraisal team or committee. One useful approach put forward in the recent years is <u>Multi Criteria Decision Analysis (MCDA)</u>. MCDA is a "an umbrella term to describe a collection of formal approaches which seek to take explicit account of multiple criteria in helping individuals or groups exploring decisions that matter". Its benefits and shortfalls have been widely discussed. Indeed, <u>its use can be controversial</u>, especially more guantitative approaches to MCDA where a single number is produced.



#### **Evidence collection**

Once the decision problem and range of options have been defined, collecting evidence and synthesising data will be key. This is typically achieved through well-defined protocols, including using systematic reviews and meta-analyses, as well as ensuring that the data is of reliable quality.

The following section will provide further details on how to carry out assessment using a pragmatic yet rigorous approach to accommodate constraints relating to COVID-19 vaccine procurement.



#### Evidence appraisal and recommendation

Rapid HTA are not a narrow technical exercise and should also include an appraisal and deliberation stage to facilitate the discussion of the credibility and legitimacy of the evidence and data collected. This part of the process will need to be designed in a practical manner, given the time and policy pressures, but benefits from at a minimum engaging multidisciplinary local stakeholders and institutions across the procurement and budgeting functions. Key stakeholders will need to be involved to review, appraise and provide feedback (share both scientific and social value judgements) on the assessment component. This deliberation and judgement will be especially important in the context of COVID-19 vaccines because of the uncertainties, paucity of local data, rapid approach adopted and fast changing circumstances.

<u>Deliberation</u> over the evidence presented can help mitigate some of the limitations of rapid HTAs. Tools for supporting such deliberative processes are available, including the <u>CAPACITI</u> which incorporates multiple criteria decision analytical techniques in support of <u>vaccine development</u> and selection.

# 3 Collecting the evidence

This section will describe how to assess appraisal criteria listed above, and relevant to the two procurement question.



When discussing each item, the following information will be provided:

- 1. What to consider when applying to COVID-19 vaccines
- 2. Methods for analysis-including likely data sources and information on how to interpret the evidence and data from global or local sources
- 3. List relevant resources and evidence to support in-country use.

Considerations are not ordered according to their importance in the process—the user should ideally consider all factors but can also only select those relevant to their decision question.



# Supply and logistical constraints

#### What to consider

One of the most widely discussed logistical problem has been the cold chain requirements for the vaccine supply chain. Some vaccines are far less thermostable than others. Pfizer's in particular requires -70C storage (though <u>subsequent evidence</u> suggests it can be stored normal refrigerator temperature). As a comparison, all other vaccines—including AstraZeneca's and J&J's—can be stored in a regular fridge, with temperatures between 2-8C.

Even in high-income countries, Pfizer's requirements create enormous logistical challenges and require the <u>purchase of specialist ultracold fridges</u>. This has led to shortages or months-long waiting times for the units to be delivered.

Vaccine	Storage	Source *
CanoSino Biological	Refrigeration (2°C to 8°C)	<u>Vanaparthy et al (2021)</u>
Gamaleya	Being produced in lyophilised formula- tion1 requiring refrigeration (2°C to 8°C) or frozen formulation (maximum -18°C), but can spend a month at refrigeration	<u>Russian News Agency</u>
J&J	Refrigeration (2°C to 8°C)	Centers for Disease Control
Moderna	Refrigeration (2°C to 8°C) for up to 30 days or frozen (-15°C to -25°C) for long- term storage	Moderna website
Novavax	Refrigeration (2°C to 8°C)	Fierce Pharma
AstraZeneca	Refrigeration (2°C to 8°C)	NHS' special pharmacy service
Pfizer	Refrigeration (2°C to 8°C), for 31 days otherwise -60c and -70c	Centers for Disease Control
Sinovac	Refrigeration (2°C to 8°C)	<u>Halim et al (2021)</u>

Table 2. Vaccine storage requirement

\* all websites were accessed on the 10th of November 2021

Predicting supply chains has also been a huge issue with COVID-19 vaccines. The unprecedented pressure on manufacturing infrastructure and components has created delays. Some countries manufacturing vaccines have banned exports, and others have made it difficult for companies to export vital components.

Another related problem is the overall production capacity for some vaccine manufacturing facilities: advance purchase deals secured with high-income countries have meant that <u>80 percent of doses administered worldwide</u> went to high-income countries. As noted by others, this situation often leaves African nations <u>at the back of the queue</u> when negotiating directly with manufacturers, in part because of the relative difference in purchasing power compared to high-income countries. Many countries, even when funds are being secured, may not be able to buy vaccines on the timelines they have set. For those reasons, purchasers should build flexibility into their planning, and reduce reliance on a single product or dose numbers arriving at a specific time.

A further important consideration is the shelf life of vaccines. Expiry time has created important logistical constraints in many low- or middle-income countries, including African countries, leading to destruction of doses. In the Democratic Republic of Congo, <u>1.3 million doses (of 1.7 million doses received in total) were returned to COVAX</u> days before their expiry date due to difficulties experienced during the launch of the vaccination campaign. Finally, vaccine quantities, products and delivery strategies will need to be assessed against available human resource constraints. Hiring and training vaccinators quickly can help filling those gaps in the short term, but will require planning and resources.

#### Method for analysis

Countries will need to establish their own vaccine priorities and assess local capacity and infrastructure to make decisions on the quantities of vaccines and the product selection. The vaccine introduction readiness assessment tool can support countries on those questions (see below).

In some African countries, the availability of ultra-cold fridges may be a particularly important issue. Strategies to deliver vaccines with such requirements will require adaptation; Director John Nkengasong (of Africa Centres for Disease Control and Prevention) outlined that countries will have to rely on an urban-centred approach, equipping capital cities hospitals with such equipment.

These logistical constraints will need to be reflected in the vaccine delivery cost calculations.

#### **RELEVANT EVIDENCE AND RESOURCES**

WHO, the World Bank and UNICEF run the <u>Vaccine Introduction</u> <u>Readiness Assessment Tool</u>, which provides advice on the logistical steps needed to roll out vaccines and helps assess where specific countries are at. This is an excel sheet that outlines the steps necessary to complete a successful COVID-19 vaccination programme, and allows officials to see where they are and the steps that can be taken to improve. .



## Ethics and equity considerations

#### What to consider

Ethics and equity considerations are an important part of decision-making around COVID-19 vaccine procurement, and they will be reflected in vaccination roll-out strategies. Even countries planning to vaccinate their entire populations will need to make tough decisions about who should be prioritized for earlier access, or specific products, as supply remains constrained. Such considerations will have important implications for which products to purchase, how many doses to secure, and how limited doses should be prioritized and distributed among the population. Decision makers must have clearly defined policy objectives for their vaccination strategies that align with social values, and a transparent, legitimate process for assessing options.

Once key objectives and corresponding priority groups are defined, this information can serve as a basis to quantify vaccine needs, forecast different procurement scenarios—which may be inflated to account for

other factors such as waste—, estimate how many fall into the different priority groups and the corresponding budget impact scenarios. For instance, if a primary goal is to protect the healthcare system, then priority groups for vaccination would include front line workers at the highest risk of infection. If another goal is to protect those most likely to experience severe disease, then the elderly and those with underlying conditions will also need to be prioritised.

Defining priority groups may also influence the choice of vaccines, as some vaccines may more suitable for those groups. For example, given that the rare adverse events associated with certain adenovirus-vectored vaccines are more common among younger populations, a country prioritizing frontline workers' groups with younger members (e.g., health workers or teachers) may consider purchasing different vaccines with better risk-benefit profiles in younger populations instead of or as a complement to what they are purchasing for their elderly populations.

#### Methods for analysis

Two prominent tools are available to countries to support country decisionmaking. The first one is the World Health Organization Strategic Advisory Group of Experts on Immunization (WHO SAGE) values framework for the allocation and prioritization of COVID-19 vaccination. The SAGE Framework below lays out five principles relevant to country-level decision-making, with additional guidance to help translate these principles into specific groups that would be prioritized based on one or more principles.



#### Human Well-Being

Protect and promote human well-being inlcluding health, social and economic security, human rights and civil liberties, and child development.

#### Equal Respect

Recognize and treat all human beings as having equal moral status and their interests as desering of equal moral consideration.

#### National Equity

Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from COVID-19 pandemic.

#### Reciprocity

Honor obligations of reciprocity to those individuals and groups within countries who bear significant additional risks and burndens of OVID-19 response for the benefit of society.

#### Legitimacy

Make national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties. The WHO, through SAGE, also developed a <u>Roadmap for Prioritizing the uses</u> of COVID-19 Vaccines in the Context of Limited Supply.

The second is the <u>Interim Framework for COVID-19 Vaccine Allocation and</u> <u>Distribution in the United States</u>, developed by the Johns Hopkins Center for Health Security. This publication is designed to help policymakers move from broader ethical principles to public health goals in the pandemic response, and then define specific objectives of the vaccination programme to assess how well prioritizing certain groups achieves one or more objective. It relies on three broad ethical values:

- promoting the common good;
- treating people fairly and promote equity;
- and promoting legitimacy and trust.

The document provides a menu of options that policymakers, stakeholders, and the public can reference and choose from when they are deliberating about vaccine allocation strategies. The resource shows how different principles and objectives can translate into priority groups. For instance, if the public health objective is to protect those at greatest risk of poor outcome from infection, then the guidance recommends prioritising the following three groups: those aged > 65, those with high risk underlying conditions and those in close contact with people at very high risk of poor outcomes. Another common public health objective is to protect the healthcare system, and this would lead to prioritising healthcare workers (including support staff in health facilities) and workers needed for the vaccination effort (e.g., vaccinators, vaccine and supply chain workers).

Almost all countries publish their vaccination roll out strategy on accessible public information sources. In many high-income countries, health workers and those at the highest risk of mortality or severe illness (for example, starting with over 80 the <u>United Kingdom</u>) have been prioritised. In South Africa, healthcare workers were first prioritised, then those over 60 years of age and in congregate settings—and finally all adults. A similar approach was taken by <u>Kenya</u>. Those strategies will also need to be assessed against feasibility: more complex strategies relying on social interactions or occupation may not be feasible in many African countries. Assessment of which groups will be eligible and prioritized for vaccination should consider plans for distribution and administration, with enough flexibility to ensure minimal waste. And these will need to be explicitly accounted for at the delivery of vaccines costing stage.

#### **RELEVANT EVIDENCE AND RESOURCES**

-- The WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination provides guidance on the goals of vaccine deployment, with principles and objectives to guide prioritization and distribution.

- The Johns Hopkins Center for Global Health Security Interim for COVID-19 Vaccine Allocation and Distribution provides an additional framework to help narrow priority populations and resources to help promote legitimacy and acceptance.
- -- <u>COVID-19 Vaccine Equity Project</u> (an initiative of Sabin Vaccine Institute, Dalberg, and JSI Research & Training Institute, Inc.) has been working to support countries as they prepare for the introduction of the COVID-19 vaccine.



# Value for Money

With a complex public health intervention such as COVID-19 vaccination, it may be difficult to condense all information into a single cost-effectiveness or cost-benefit analysis. Even if some attempt is made to do this, it will be useful to lay out the details of the information collected, as well as any assumptions or uncertainties, for the appraisal committee to consider. As noted above, Cost-Consequence Analysis (CCA) provides such a framework.

#### Purchase Costs

#### What to consider

The first cost consideration is the cost of the vaccine and the accompanying supplies. Vaccine prices differ greatly, and the number of doses required to achieve protection will affect the price of the cost per vaccination course. Purchase costs typically also include some element of transportation and storage—it is important clarify exactly what is included and what isn't to make sure estimates of purchase and delivery cost do not double count or miss an important cost ingredient.

Unlike many of the other estimates involved in the HTA, the purchase price will be negotiated as part of the policy process. HTA findings themselves can help to influence price negotiations if, for example, concrete value to the purchaser can only be clearly demonstrated up to a certain price point. Procurement transparency is critical to ensuring purchasers achieve a fair deal.

#### Methods for analysis

Complex costing analysis will typically not be required to estimate purchase costs. However, it will be important to include scenario analysis for a range of purchase price points, given the likely uncertainty in the final agreed price and to support negotiations.

#### **RELEVANT EVIDENCE AND RESOURCES**

Many purchasers signed non-disclosure agreements, preventing them from sharing negotiated vaccine prices and other purchasers from making informed judgements. UNICEF collated information on negotiated prices that is publicly available –it can be found <u>here</u>. Crude estimates of vaccine price are also summarised in Table 3.

#### What to consider

Delivery

Costs

The delivery costs will include all costs from the receipt of the COVID-19 vaccine shipment to the distribution of the vaccines to the intended target population. Costs will be strongly associated with: (i) product attributes of vaccines procured (e.g., requirements for ultra-cold chain, expiry time), (ii) vaccination strategy adopted by the country (e.g., target population covered) and (iii) characteristics of the local health infrastructure system (e.g., availability of trained staff).

For this reason, to complete this section, countries will need to familiarise themselves with their local national deployment and vaccination plan first. A National Vaccine Delivery Plan (NDVP) is a "plan to deploy vaccines and deliver vaccination to identified target populations" that is unique to a given country (see <u>guidance produced and supported by the WHO</u>).

These main categories of input delivery cost; typology is drawn from the <u>COVID-19 Vaccine Introduction and deployment Costing tool</u>.

#### Main cost categories of input delivery costs

Human Resources for Health (for vaccinators: training, recruitment, wages, accommodation, food rations)

Vaccine related supplies (syringe, extra needles, alcohol swap)

PPEs (medical mask, hand sanitizer, gloves)

Logistics (airfreight price, custom clearance, outreach teams)

Cold storage and cold chain (cold box, ice packs, power, domestic transport)

Local Data Management and Monitoring (IT infrastructure, data charges for telecommunications)

Local demand generation and communications (banners, sign posting, posters)

Security (transportation, central stores)

Vaccine safety monitoring

Central planning, coordination, and M&E

#### i. Conducting a local costing study

Countries may conduct their own costing study to evaluate the delivery costs. This will require extensive data collection, although rapid approaches could be used. In the 'relevant evidence and resources' section below, we list two resources to support analysts in developing and conducting costing studies from <u>Global Health Cost Consortium (GHCC)</u> and immunizationeconomics.org. It may also be helpful to consider the balance between micro-costing and gross costing methods: micro-costing can be more precise but it also is very time consuming and may not be necessary given the urgency of those decisions.

Decision makers can use two useful source of secondary data inputs to complement any local studies. First, the <u>Immunization Delivery Cost</u> <u>Catalogue</u>—a comprehensive repository of global evidence on the cost of delivering vaccines that can be used for data inputs. <u>Rueda and colleagues</u> (2021) also produced estimates of health sector costs of different policy responses to COVID-19 for low- or middle-income countries. The aim of the study was to estimate real world costs that reflect local prices and resource use. The paper contains detailed supplementary material that provides unit costs by country.

These main categories of input delivery cost; typology is drawn from the COVID-19 Vaccine Introduction and deployment Costing tool.

#### ii. Using global tools to support rapid COVID-19 vaccination plan costing

The <u>CVIC tool</u> is an excel spreadsheet which supports countries in estimating and planning for incremental operational and selected capital costs of introducing and deploying COVID-19 vaccines. It is aligned with the national deployment and vaccination plans and is pre-populated with country-specific data from global databases, but local data input can be used to override the pre-entered values. The tool helps countries estimate the cost of their vaccination program over 2021-2023.

#### iii. Using a rough estimate from international modelling work

Existing literature put forward several country estimates, which can be used as a rapid source of information in the short term.

The COVAX Working Group on delivery costs produced estimates for delivering COVID-19 vaccines to 20 percent of the population of 92 Advance Market Commitment (AMC) countries. Those estimates "assumed that the existing health system will be leveraged, and only additional resources are included – defined as financial costs". The costs of health worker salaries are excluded from the estimates, which means analysts must factor such costs in if using those estimates to calculate delivery costs. According to this study, country-level delivery costs amount to US\$ 1.722 billion or US\$3.15 per person vaccinated with two doses. However, the costs are not disaggregated by country and they are averaged across countries, and as a result may not adequately reflect local costs. Diab and colleagues (2020) estimated the cost of procuring and delivering COVID-19 vaccines in 123 low- or middle-income countries, under different coverage scenarios. They estimate in-country delivery costs using a separate study on the delivery cost per dose of routine immunizations (Portnoy and colleagues), then inflated those by 18 percent increase for LICs and lower MICs and a 38 percent increase for upper MICs—to account for additional costs of PPE and other infection prevention control measures. Estimates of country vaccine delivery cost per dose can be viewed on their COVID-19 Vaccination Cost Map.

#### **RELEVANT EVIDENCE AND RESOURCES**

- -- The <u>GHCC Reference Case for Estimating the Costs of Global</u> <u>Health Services and Interventions</u> is a guide that "helps ensure that the process of cost estimation is clearly conveyed and reflects best practices, so that those using cost data can interpret the findings properly and assess their quality (accuracy, precision, generalizability, and consistency). The Reference Case provides a practical framework for analysts to ensure that they consider how methods may influence estimates and thereby improve the interpretation and use of cost data." It also provides a very accessible and practical introduction to costing and concept definition.
- How to cost immunization programs: a practical guide on primary data collection and analysis provides methodological guidance to carry out exercises that involve primary data collection focused on assessing the costs of routine immunization services. It uses retrospective costing and discusses topics that arise in such exercises, covering the definition of the costing question all the way to the data analysis and reporting. It also covers challenges and provides approaches to addressing them.
- -- <u>COVID-19 Vaccine Introduction and deployment Costing tool</u> (<u>CVIC tool)</u> is a global tool (excel) developed by the WHO and partners to support costing of operational and capital costs of introducing and delivering vaccines.

#### COVID-19 What to consider health effects Vaccines have three

Vaccines have three main functions. Not all vaccines will achieve all three, but most aim to reduce:

- 1. The probability that an exposed person becomes sick.
- 2. The severity of illness for those who are infected.
- 3. The transmissibility of the disease from people who are infected to those who are susceptible.

The first two benefit directly the individual who is vaccinated, whilst the first and last benefit society at large, by reducing the chance that viruses will spread through the population. Table 3 below summarises information on vaccine efficacy, looking at the reduction in chance of becoming sick that a person receives from getting vaccinated (note that the definition of 'sick' slightly differs between trials). There is a range of efficacy for the eight vaccines—with Moderna and Pfizer achieving 95 percent efficacy whilst CanSino 66 percent. For reference, WHO set a 50 percent threshold for COVID vaccines in 2020, so all considered options are above the threshold.

Vaccines' efficacy varies against different variants of COVID-19, and <u>while</u> <u>most function well</u> against current variants of concern, not all do-and there is no guarantee they will function against future variants. For example, there is evidence that <u>Novavax</u> does not function well against the Beta variant. <u>Evidence form Israel</u> released in July also suggests that the Pfizer vaccine is less effective against the Delta variant of COVID-19 compared with the original strain, reducing symptomatic COVID infections by 64 percent and hospitalisation by 93 percent-this is down from May 2021 estimates of a 95 percent reduction in symptoms from those vaccinated in Israel. It is likely that there will continue to be new variants of COVID and it's important that we continue to track how well vaccines operate against them.

Vaccine	<u>Mean</u> average price per course	Efficacy (%) symptomatic illness (primary outcome)* Efficacy secondary outcome	<u>Status</u> ( <u>Nov 2021)</u>	Doses manufactured by 31st of October (mil- lions) **
CanoSino Biological	\$27.15	The efficacy of Ad5-nCoV in preventing virologically confirmed (PCR positive) symptomatic COVID-19 disease: <u>66%</u> Severe Disease: 91%	Full or emergency use in China, Mexico, and Pakistan. Four countries report- ing use.	9.7
Gamaleya	\$19.01 (\$10.00 - \$27.15)	The proportion of partici- pants with PCR-confirmed COVID-19 from day 21 after receiving the first dose: <u>91.6%</u> Severe Disease: 100%	50 countries reporting use.	214.9
J&J	\$9.50 (\$8.50 - \$10.00)	Moderate to severe/crit- ical centrally confirmed COVID-19 with onset at least 14 days after vacci- nation among seronegative and SARS-CoV-2 negative participants in the per-pro- tocol population: <u>66.9%</u> Severe Disease: 76.7%	Granted emergency use approval by the WHO on <u>12 Mar 2021</u> 45 Countries report- ing use.	109.5
Moderna	\$25.50 (\$15.00- 37.00)	Prevention of Covid-19 illness with onset at least 14 days after the second injection: <u>94.1%</u> Severe Disease: 100%	67 countries reporting use.	456.6

#### Table 3. Summary of vaccine characteristics

Novavax	\$3.00	Virologically confirmed mild, moderate, or severe SARS-CoV-2 infection with an onset at least 7 days after the second injection in participants who were serologically negative at baseline: <u>89.7%</u> Severe Disease: 100%	Phase 3 of trials. Not currently in use	0
AstraZeneca	\$3.74 (\$2.19 - \$5.00)	COVID-19 with at least one qualifying symptom (fever, cough, shortness of breath, anosmia, or ageusia) in seronegative participants confirmed via nucleic acid test-positive swab >14 days after second dose: <u>66.7%</u> Severe Disease: <u>100%</u>	183 countries report- ing use.	1905.4
Pfizer	\$13.37 (\$6.75 - \$19.50)	Efficacy of the vaccine 7 days after second dose against laboratory-con- firmed Covid-19: <u>95%</u> Severe Disease: 100%	Approved in several countries. 114 countries report- ing use.	1882.6
Sinovac	\$17.18 (\$5.00 - \$32.52)	Efficacy against infection 14 days after the vaccina- tion : <u>50.65%</u>	39 countries reporting use.	2077.9

\* Efficacy measure wording as reported in phase III clinical trial results \*\* Data is based from <u>Affinity estimates</u>

NB: except for vaccine manufacturing info this table was updated in August 2021 and reflects the evidence up to this point. A further update will be issued at a later date.

In addition to the direct health benefits to those inoculated, there are indirect impacts of vaccination on transmission that can reduce cases and the size of the epidemic. This is for two reasons. First, because vaccinated people may be less likely to transmit SARS-CoV-2. A large scale study in England found though that the <u>likelihood of household transmission was</u> reduced by 40-50 percent from individuals diagnosed with COVID-19 after vaccination, for both AstraZeneca's and Pfizer's vaccines. Second, because vaccinated people are <u>less likely to become infected in the first place</u>. The indirect protection from vaccines also underpins the concept of <u>herd</u> immunity, which had gained popularity in the first phase of the pandemic.

In addition to the health benefits associated with different vaccine products, it is also important to assess safety profiles and any adverse health effects potentially associated with a given vaccine. There are still important gaps in this area because the size of vaccine trials (20,000-30,000 participants) means only common adverse events can be tracked prior to widespread rollout. However, pharmacovigilance systems in countries that have already

immunized large numbers of the population can provide important insights about rare but serious adverse events following immunization, including who might be at highest risk of side effects. To document rare events, realworld data is used alongside roll-out. From the <u>first 25 million AstraZeneca</u> vaccines given out in the European Economic Area and United Kingdom, there were 62 cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis (a type of blood clot), 18 of which were fatal. This came from spontaneous reporting systems, and will thus not be comprehensive, nor does it mean all cases are linked to the vaccination. The incidence of this condition seems highest in <u>younger adult age groups</u>. A similar issue occurred with J&J's vaccine, which has been linked to six blood clots (of which one fatality) from the first 6.8 million doses in the US (there is not enough case here to compare risk by age).

Most health agencies (JCI, European Medical Agency) believe the benefits of adults taking the AstraZeneca vaccine greatly outweigh the risks, although a different vaccine may be recommended for younger populations. This vaccine has been <u>approved for 172 countries</u> including 46 African countries. The <u>US CDC</u> issued a similar recommendation on the use of J&J's vaccine, which has been licenced by 78 countries.

#### Methods for analysis

Ideally, information about the effectiveness of vaccines should be translated into generic health metrics such as years of life saved, deaths averted or Disability Adjusted Life Years (DALYs). This would require building models to contextualise the effectiveness metrics to a particular population.

Models can estimate the combined health gains of vaccination, including both direct and indirect protection. All models of vaccination will include some assumptions around vaccination effectiveness against many outcomes, including transmission. In countries where such models are not available, the MRC Centre for Global Infectious Disease Analysis at Imperial College London developed an online COVID-19 scenario analysis tool called <u>CovidSim</u>. CovidSim builds on a COVID-19 transmission model to allow users to evaluate the impact of vaccines by looking at deaths averted and in combination with ongoing non-pharmaceutical interventions. The aim is to support short and medium-term planning while acknowledging uncertainties (see <u>manual</u>).

In addition to the health gains, countries need to consider adverse events too. For example, they should evaluate if the problems picked up by the on-going monitoring from health authorities across the world are likely to undermine the benefits. This may affect selection of vaccine products: for instance, alternatives to AstraZeneca are preferrable to vaccinate <u>under 40s</u> in the United Kingdom (although, if only AstraZeneca is available, the United Kingdom still recommends it compared with not providing a vaccine). Local variants are also important to consider when selecting vaccines, as some vaccines have been shown to be less effective to specific variants—an issue that was not covered by clinical trials.

#### **RELEVANT EVIDENCE AND RESOURCES**

The number of COVID-19 vaccines approved is increasing, and the information known about each one is growing quickly. This means it is an essential task to track this literature regularly to fill the information gap.

- -- Information on the direct health impacts of vaccines is likely to be documented in clinical trials, observational studies, international and local health authority literatures.
- -- The London School of Hygiene and Tropical Medicine, Milken Institute, New York Times, all have vaccine trackers that provide an easy way to get up to date information on clinical trials around COVID-19.
- -- Governments across the world are carefully monitoring vaccine rollouts to understand the benefits, risks and questions like the duration of immunity for different vaccines. They are then documenting this on their websites as an easier way of tracking progress than reading all publications. Agencies such as European Medical Agency, US CDC and FDA, the UK's JCVI, and Public Health England are good at updating advice on their websites.

#### Collateral What to consider

### health effects

Since the beginning of the outbreak, substantial evidence has emerged on the collateral health impacts of COVID-19 on broad range of health conditions. To understand the full potential impact of widespread vaccination it may be also important to consider measures that may be required in absence of widespread vaccination and their effects health.

Collateral health impact includes all effects of the pandemic on the health of populations beyond those suffering the direct effects of COVID-19. What causes those collateral health effects is often multifactorial and includes supply (e.g., unavailability of healthcare workers) and demand (e.g., avoidance of care by patients due to fear of contracting COVID-19) driven factors, as well as micro, meso and macro factors. Collateral health impacts do not need to originate from health systems disruptions, nor do they need to be negative: one positive example is the fall in road traffic accidents recorded such as in <u>Spain</u> or the <u>United Kingdom</u>. Collateral health effects are separate from excess mortality, which by definition only considers mortality and not morbidity impacts. Morbidity impacts and future impacts on mortality and morbidity should also be considered when discussing collateral health impacts.

A <u>survey administered by WHO</u> shows that 94 percent of responding countries experienced some level of disruption in the provision of essential services. 9 percent of responding countries experienced extremely serious disruptions ranging around 75-100 percent. Vaccines could be an instrument to bring an end to the pandemic and, as a result, they could also lead to improvements in health by minimising collateral health impacts.

#### Methods for analysis

A <u>framework</u> adapted from a previous work on the Ebola outbreak by <u>Elston</u> and <u>colleagues (2017)</u> was developed to list and identify impacts at country level in a comprehensive manner. This framework is organised around four types of interrelated effects: economic, environmental, health systems and social/behavioural. Some of those impacts will materialise in the short, medium and possibly long term (e.g., health losses from interrupted routine vaccination are likely to only be felt in years).

Given the scope of the possible collateral health impacts, their monitoring and measurement is challenging—especially in African countries where health surveillance or health information and monitoring systems (HMIS) are often underfunded. There are many notable exceptions which could be used:

- Electronic medical records
- Claims data
- <u>District Health Information Software 2</u> (DHIS, available in 73 countries)
- Any data on utilisation (e.g., from surveys or other primary sources)

Those data sources can be analysed for a set of tracer interventions and, on selected sites, used to understand the direction and magnitude of collateral health impacts. It is important to build this type of analysis within a broader conversation with health providers who can provide validation. Health providers can also be an important source of data and engaging them, in addition to more quantitative information, is likely to provide a clearer picture about those effects.

Published literature may also contain country estimates, and can be queried through Google or other research engines such as <u>C19economics' repository</u> of evidence. Other possible benchmarks can be used from published literature from modelling studies (which is different from studies using observational data). For instance, <u>Roberton and colleagues (2020)</u> published early estimates of the pandemic on maternal and child mortalities in low-or middle-income countries. This literature can be used in the calculator developed by Walker and colleagues (see description below).

#### **RELEVANT EVIDENCE AND RESOURCES**

-- <u>C19economics.org</u> repository of literature identifies and indexes literature on COVID-19 from different databases (including NiH iSearch COVID-19 portfolio) along different areas of interest, including 'collateral health impacts'. Analysts can use the search function to look for resources in their own countries. -- Walker and colleague's calculator was design to allow users to estimate the net health impact of COVID-19 in their country, and as part of this, the collateral health impacts. It builds on the most recent year of the Global Burden of Disease estimates. The calculator allows users to calculate the number of DALYs lost to COVID-19, based on a country's disease burden (along 22 categories) and some assumptions about the intensity and the duration of the disruption. The aim of the tool is to offer some informed back of the envelope estimate.

#### What to consider

Micro and macro economic impacts

Microeconomic consequences might include reduced health systems costs through prevented cases and shorter hospitalisations. Decision makers may also want to factor in reduced patient costs, through reduced healthcare fees and transport costs, as well as indirect costs such as lost earnings or productivity due to illness. Patient costs are particularly important to consider when the costs exceed a certain level of capacity to pay, resulting in a catastrophic health expenditure, which can itself threaten livelihoods even if a full recovery from illness is made.

The severity and transmissibility of SARS-CoV-2 has required countries around the world to implement unprecedented restrictions (e.g., lockdowns or closure of borders) to societies and economies, resulting in heavy macroeconomic impacts. In some cases, these may surpass the microeconomic costs. High-coverage vaccination can reduce likelihood of similar restrictions being required in the future. Macroeconomic benefits of vaccination should be factored in the decision-making process, particularly to assess trade-offs between different level of vaccine coverage.

#### Methods for analysis

Cost of illness analysis can be used to estimate the direct and indirect costs of COVID-19 cases to both health systems and to patients and their families. Methods for cost of illness analysis are well established (see below) and bespoke analysis should be achievable in relatively short time frame for experienced economists. If drawing on existing evidence rather than bespoke analysis, a few COVID-19 specific studies have been done — although findings in one country cannot be assumed to apply in another.

#### In African countries

**Impact of the coronavirus (COVID 18) on the African Economy:** A study modelling different scenarios to evaluate the potential impact of

the pandemic on selected dimensions of African economies, including tourism, government revenues and expenditure, sovereign debt and growth. On GDP, the models presented in the paper forecast negative economic growth ranging from -0.8 percent to -1.1 percent (or a loss of 4.18 to 4.55 percentage point compared to pre-pandemic forecasts).

The cost of clinical management of SARS-COV-2 (COVID-19) infection in Ghana: A cost of illness analysis: The cost of treating COVID-19 patients in Ghana from the perspective of the health system ranged from US\$282 (GH ¢1,629) to US\$23,382 (GH ¢135,149). The cost of treatment increased by at least 20 folds once a patient moved from home management to the treatment centre.

**Examining unit costs for COVID-19 case management in Kenya**: Per-day, per-patient unit costs for asymptomatic patients and patients with mild-to-moderate COVID-19 disease under home-based care are 1993.01 Kenyan shilling (KES) (US\$18.89) and 1995.17 KES (US\$18.991), respectively. When these patients are managed in hospital, the unit costs for asymptomatic patients and patients with mild-to-moderate disease are 6717.74 KES (US\$63.68) and 6719.90 KES (US\$63.70), respectively. Per-day unit costs for patients with severe COVID-19 disease managed in general hospital wards and those with critical COVID-19 disease admitted in intensive care units are 13 137.07 KES (US\$124.53) and 63 243.11 KES (US\$599.51).

#### In other low- or middle-income countries

**Economic burden of COVID-19, China, January–March, 2020**: a costof-illness study The control measures to prevent the spread of disease resulted in substantial costs from productivity losses amounting to 2.7 percent (US\$ 382.29 billion/US\$ 14.14 trillion) of China's annual gross domestic product.

**Estimating the cost-of-illness associated with the COVID-19 outbreak in China from January to March 2020**: The total estimated healthcare and societal cost associated with the outbreak is 4.26 billion RMB (0.62 billion USD) and 2,647 billion RMB (383 billion USD), respectively.

The economic burden of coronavirus disease 2019 (COVID-19): evidence from Iran: The direct medical costs were estimated to be 28,240,025,968 Rials (\$ 1,791,172) in total with mean cost of 59,203,409 Rials (\$ 3755) per person (SD = 4684 \$/ 73,855,161 Rials) in which significant part (41 percent) was that of intensive and general care beds.

Alternatively, WHO CHOICE provides <u>country-specific estimates of</u> <u>healthcare unit costs</u>. Estimates have been collated since 2000 and are based on modelling using local primary and secondary data, although the cost data is not always available for each country from a representative sample. For compiling healthcare costs, the <u>GHCC</u> produced a guidance (see <u>reference case</u> discussed above). Estimating the macroeconomic value of vaccination is much more complex and more uncertain. Experts can be engaged to conduct regression or advanced models such as <u>computable general equilibrium</u> models or <u>linked</u> <u>economic-epidemiological models</u>, that respond to a specific decision question and can help formulating different policy scenarios to inform policy dialogues. However, this could be expensive and time-consuming. Because such modelling efforts are complex, to be of good quality, they require significant local data inputs and specialised analytical skills which may not always be available in Ministries or government agencies.

In absence of bespoke analysis, crude analysis such as reviews of the historical macroeconomic impact of country policies or expert opinion could be used to define reasonable worst-case, as well as expected and reasonable best-case scenarios. If the decision question has a likely macroeconomic impact, it is essential that this impact is considered in some way.

It is worth reiterating here the importance of clarity about the options considered. If the decision under consideration is whether to invest in increasing supply coverage from 60 percent to 70 percent of the population, it is crucial not to attribute the total macroeconomic impact of a full lockdown, for example, to a decision representing only part of the protection against such an event.

#### **RELEVANT EVIDENCE AND RESOURCES**

#### Cost of illness

- Cost-of-Illness Studies: A Review of Current Methods
- What Are the Challenges in Conducting Cost-of-Illness Studies?
- WHO CHOICE
- <u>Measuring catastrophic medical expenditures: Reflections on</u> <u>three issues</u>
- Out-of-Pocket Expenditures on Health: A Global Stocktake
- Extended Cost-Effectiveness Analysis for Health Policy Assessment: A Tutorial

#### Macroeconomic impact

- The Economics of the COVID-19 Pandemic in Poor Countries
- <u>The impact of COVID-19, associated behaviours and policies on</u> the UK economy: A computable general equilibrium model
- DAEDALUS: An economic-epidemiological model to optimize economic activity while containing the SARS-CoV-2 pandemic
- Sustaining lives and livelihoods: a decision framework for calibrating social and movement measures during the COVID-19 pandemic

#### What to consider

Global health security

All the above categories consider the value of vaccination from a national perspective, that is, a public sector official tasked with deciding about buying COVID-19 vaccine. However, the benefits of controlling widespread SARS-CoV-2 in a particular country are also felt by the rest of the world. Moderate or high levels of transmission are a breeding ground for new virus variants, which do not restrict themselves to national boundaries. The great consequences of emergent variants of concern are becoming ever clearer. At the time of writing, the Delta variant—which first emerged in India during a period of increased transmission—is causing increases in COVID-19 cases in many other countries, including those with high vaccine coverage <u>such as the United Kingdom</u>.

While more research is needed, in many African countries the direct burden of COVID-19 does not appear to be as high as elsewhere, possibly due to younger populations and greater tendency towards interactions outdoors or in more ventilated spaces. In addition, the burden of other diseases can be higher in low- or middle-income countries and there may be wide ranging opportunities to spend on non-COVID interventions that will yield substantial gains for the resources required. In other words, competing pressures on health care financing means COVID-19 vaccines may not be a priority for domestic funding, given other disease burdens.

#### Methods for analysis

There are no rigorous quantitative methods for estimating the global health security value of COVID-19 vaccination in a particular country. However, through a process of economic evaluation from a national perspective, it may be possible to show international organisational and high-income countries that vaccine donation or co-financing is required to achieve certain levels of vaccine coverage and avoid increased transmissions, as well as the emergence of a threatening variant. It may also be possible to review agreements made in other countries to highlight donor donations or co-financing precedents.

Again, even if global health security gains are difficult to estimate, those benefits are important to account for because it creates a clear rationale for external payers to support vaccination in African countries that <u>cannot</u> afford to achieve high-coverage with domestic financing. If COVID-19 vaccines financing were only considered from a national perspective, there may be countries where available domestic resources would be deemed better spent on other national healthcare priorities. Put simply, African decision makers may not want to top up COVID-19 vaccination coverage if spending on other technologies or services would be more cost-effective for the local population.

In terms of process, it may be appropriate to consider including international representatives and potential donors in a national COVID-19 HTA process to explore alternative financing arrangements.



# **Budget Impact Analysis**

#### What to consider

A budget impact analysis assesses the direct resource consequences of implementing an intervention over a given time horizon, across the population affected. While an analysis of value for money points to the preferred strategy (most 'cost-effective'), budget impact analysis will give an insight of the overall effect of the intervention on health system resources. For this reason, it often takes a health system perspective, although the information can be disaggregated across different funding sources. Budget impact analysis should be aligned with information in the previous sections: supply and logistical constraints (which will impact costs), ethics and equity (which will inform the population affected), and purchase and delivery costs.

- Purchase unit costs
- Delivery unit costs
- Levels of anticipated coverage and uptake across the population affected
- Changes in service associated with implementing the vaccine
- Potential savings associated with the use of the COVID-19 vaccines, for example reduced hospital admissions for patients with severe illness.

Additional assessments, even if qualitative in nature, should be provided on potential feasibility constraints such workforce, training needs, and facilities.

#### Methods for analysis

The budget impact is typically expressed in terms of cost (or other currency) per programme over a 3-to-5-year time horizon, from the perspective of a specific payer to be discussed from the outset. Analysts interested in producing local estimates can access a number of methodological documents and guidance (see the IPSOR guidance under 'Relevant evidence and resources').

Once the budget impact has been calculated, it will serve as a basis to assess the vaccine programme's affordability. An important issue in this context is whether costs associated with the 'new' technology displace more health than is generated by the technology itself, in other words, opportunity costs. Decision makers can also use budget impact analysis to discuss with manufacturers reductions of procurement costs and improve relative affordability prior to implementation.

The inclusion of health interventions do not normally change the total budget (which is often set exogenously). But in the case of COVID-19 vaccines, the consequences of a particular course of action could affect macroeconomic performance and therefore impact the fiscal space for health and other public spending.

#### **RELEVANT EVIDENCE AND RESOURCES**

- Proxy figures of budget have been produced in the literature. The World Bank estimated the vaccination cost per capita as a share of the total government health expenditure for a number of low- or middle-income countries, which is shown on Figure 3 of <u>this blogpost</u>. The total cost of vaccines includes vaccine package, supply chain, climate friendly cold chain, service delivery and vaccine wastage. It is worth noting that those rough estimates were produced from global data to advocate for greater health financing for vaccines, and as a result may not be appropriate for budgeting and resource mobilisation in countries. <u>Diab and colleagues (2020)</u> also provide estimates of the total vaccination cost per country, including both purchase and delivery costs (available on this <u>cost map</u>). Note that the aim of the study is to present estimate of the likely resource needs to achieve herd immunity, again this means they may not be the best source for country budgeting.
- -- An IPSOR taskforce brought together developers and users of budget impact models from different sectors. The taskforce produced the resource Principles of Good Practice for Budget Impact Analysis on good research practice published a <u>set of</u> <u>principles applied to BIAs</u>.

# Conclusion

Rapid, adaptative Health Technology Assessments can be of great value for African countries that are facing two important COVID-19 procurement questions: what vaccine products and how much vaccine should my country/organisation procure?

The answers to these questions matters: COVID-19 vaccines have tremendous health and socio-economic benefits, but health budgets are already scarce and vaccine deals can divert resources otherwise spent on different essential services.

The intention of this toolkit has been to provide decision makers with a framework for collecting and assessing rapidly changing information and knowledge about the pandemic and vaccines. We aimed to be as practical as possible in the guidance, while retaining a strong emphasis on building a transparent and inclusive deliberative process.