HOW TO COST IMMUNIZATION PROGRAMS

A practical guide on primary data collection and analysis

Recommendations from
IMMUNIZATIONECONOMICS.ORG
the community of practice

Guide Development
HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

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Authors

Stephen Resch, Harvard T.H. Chan School of Public Health

Nicolas Menzies, Harvard T.H. Chan School of Public Health

Allison Portnoy, Harvard T.H. Chan School of Public Health

Emma Clarke-Deelder, Harvard T.H. Chan School of Public Health

Lucy O'Keeffe, Harvard T.H. Chan School of Public Health

Christian Suharlim, MSH

Logan Brenzel, The Bill & Melinda Gates Foundation

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CONTENTS

Acronyms

BCG bacille Calmette-Guérin

CESAMO *Centro de Salud con Médico y Odontólogo* [Health Centers with Physicians and Dentistry in Honduras]

CESAR *Centro de Salud Rural* [Rural Health Centers in Honduras]

CIF cost, insurance, and freight

cMYP comprehensive multi-year plan

DHS Demographic and Health Surveys

DTP diphtheria-tetanus-pertussis

EPI Expanded Programme on Immunization

EPIC Expanded Program on Immunization Costing and Financing

eVIN Electronic Vaccine Intelligence Network

FOB free on board

HPV human papillomavirus

ICAN Immunization Costing Action Network

MOH ministry of health

NGO nongovernmental organization

PAHO Pan American Health Organization

PIRI Periodic Intensification of Routine Immunization

PV present value

PPS probability proportional to size

SMS short message service

WHO World Health Organization

1 ABOUT THIS GUIDE

This guide offers practical methodological guidance for country immunization program staff and consultants who are planning exercises that involve primary data collection focused on using retrospective costing information to assess the costs of routine immunization services. It provides up-to-date information on approaches and methods consolidated from similar studies in recent years.

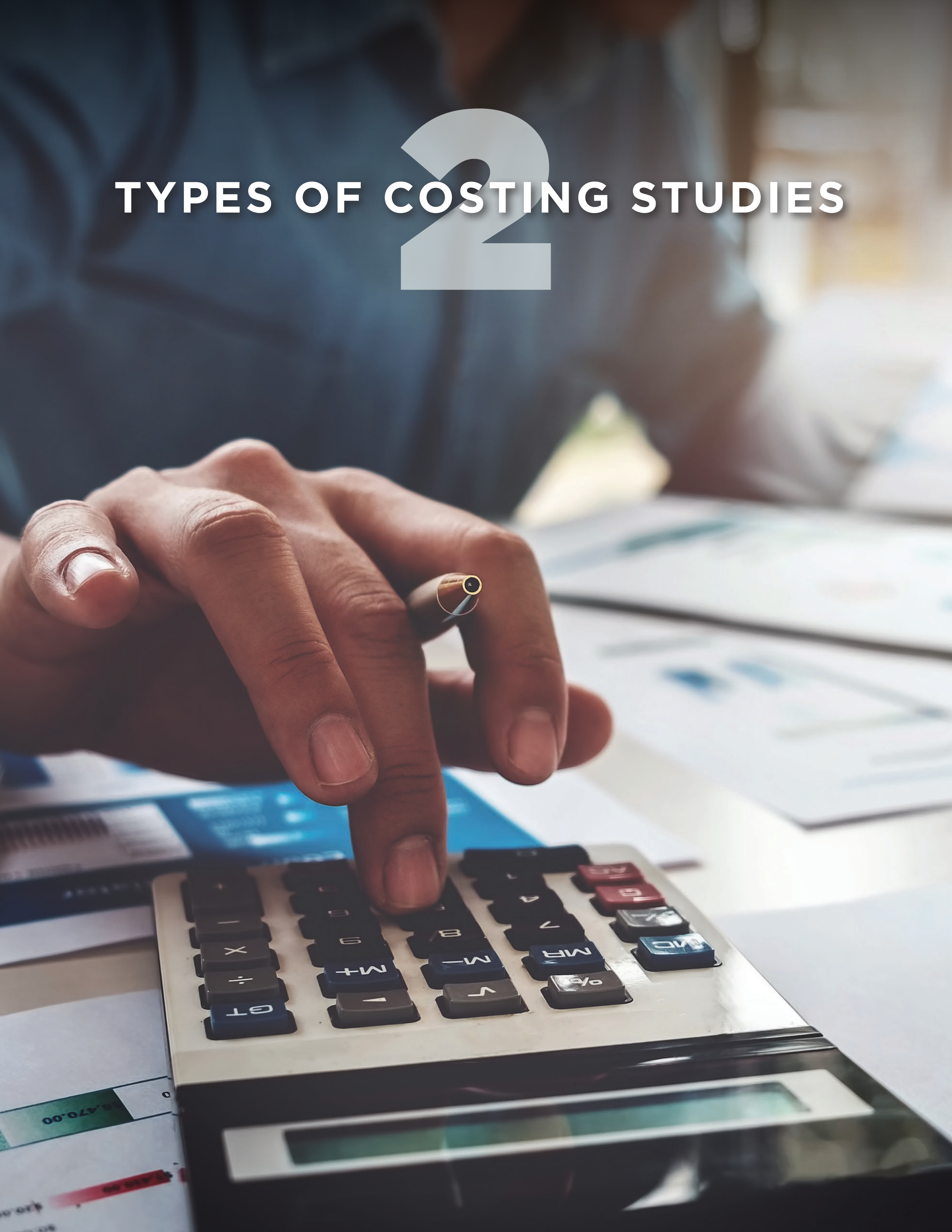
We draw heavily on first-hand experience in the Expanded Program on Immunization Costing and Financing (EPIC) Project [1-6], the ProVac Initiative of the Pan American Health Organization (PAHO) [7-10], and the Immunization Costing Action Network (ICAN) [11, 12]. These projects included costing exercises in 10 countries that collected primary data retrospectively from a representative sample of immunization sites. Their goal was to describe the total and delivery costs of childhood immunization programs since the emergence of Gavi, the Vaccine Alliance and the introduction of a new generation of vaccines including pentavalent, pneumococcal conjugate, rotavirus, inactivated polio, and human papillomavirus (HPV) vaccines. Most studies estimated the cost of a full childhood immunization program, but some focused on specific components, such as measles-rubella campaigns or periodic intensification of routine immunization (PIRI) campaigns. Usually, these studies also sought to describe the factors that were associated with variation in cost per dose between service delivery sites. Their major strength is their emphasis on sample design and generalizability.

The added value of this guide is that it focuses on methods related to collecting and analyzing primary data from a sample of health facilities. This guide is distinct from other resources in that its emphasis is on methodological issues related to data collection and analysis, including resource measurement methods, aggregation of costs from sample estimates, determinants/contextual factors for explaining/predicting cost variation, and efficient sample design.

The guide complements a sizable set of related methodological resources, and readers will likely benefit from referring to a mix of them. Some provide excellent general guidance on costing health services. Others are immunization specific but tied to particular purposes, such as strategic planning or cost-effectiveness analysis or are oriented to the use of specific costing tools. A list of selected complementary resources is found in Annex 1.

We proceed through topics in the order in which they typically arise in retrospective costing exercises, such as identifying the questions to be addressed, scoping what should be measured, identifying data needs and relevant sources, deciding on data collection methods, analyzing data, and reporting. We cover many of the common “pain points” that present challenges at each stage and discuss alternative approaches to address them, using illustrative examples from recent studies. Where we believe in a clearly superior approach to pursue, we say so. But we recognize practical constraints may often force use of second-best options. Ultimately, we hope this guide helps readers develop better methods, protocols, and tools for their own studies.

2 TYPES OF COSTING STUDIES



Immunization costing exercises may be used to answer two main types of questions: 1) descriptive ("what is") questions, which focus on either estimating the costs of the immunization program as it currently operates or estimating the incremental cost of some implemented innovation (introducing a new vaccine or different delivery strategy), and 2) projection ("what if") questions, which focus on what future costs will be under different assumptions (e.g., projections of how a change to a vaccine schedule or efforts to increase coverage). Table 1 includes examples of both types of questions.

We describe methods to address descriptive questions using retrospective, cross-sectional data collection without comparison groups (i.e., Objectives 1 and 2 in Table 1). In addition to answering questions about current immunization program costs, the methods can measure variation in cost across vaccine delivery sites and identify factors associated with that variation. Although they can sometimes be used to estimate the cost of an incremental change in the immunization program, estimating the cost of specific innovations that have been implemented (i.e., Objectives 5 and 6 in Table 1) usually requires methods not covered in this guide. For example, rigorously answering these causal questions calls for a comparison group and preferably prospective data collection. This guide also does not describe methods to make future cost projections. These types of exercises may use information from descriptive costing (e.g., basing future cost projections on costs estimated from a recent past period) but typically depend on additional assumptions and require additional methodological considerations.

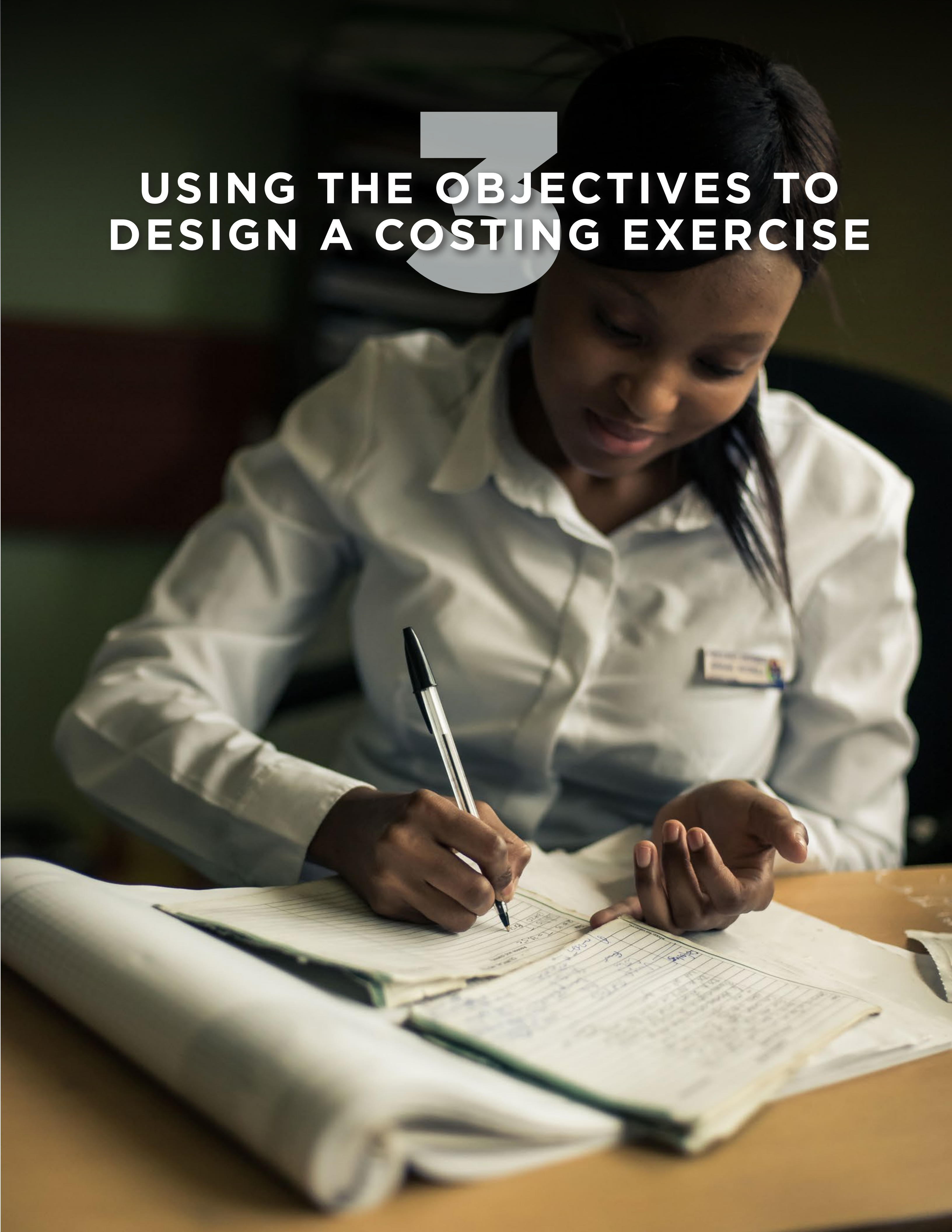
Section 3 provides an overview of the broader set of costing questions to help ensure researchers use methods that are appropriate.

Table 1. Relationship of Study Objectives and Research Questions to Design Choices

Study Objective and Question	Cost components to be measured	Output data to be measured	Other data to be measured	Comments
1. Estimating total resource use and costs and disaggregated resource use and unit costs of the overall immunization program: What are the total cost and unit costs of a national childhood immunization program at various levels of the health system by line item and by program activity category?	Prices and quantities of resources used, whether immunization-specific, or shared, and whether consumed at immunization delivery sites or above the level of service delivery	Target population Doses delivered Children (or persons) immunized Children fully immunized	Perhaps none	Using an ingredients approach in which prices and quantities of resources are measured will improve the adaptability/comparability of the study results to other settings or time periods
2. Estimating total resource use and costs and disaggregated resource use and unit costs, of a new vaccine introduction: What are the total cost and unit costs of new vaccine introduction (the one-time cost of rolling out a new vaccine)?	Prices and quantities of resources used for one-time start-up activities (e.g., social mobilization, cold chain capacity expansion) in a defined time period around the introduction	A measure of the scale of the introduction, such as the size of the target population, or number of immunization delivery sites at which new vaccine is introduced	Perhaps none	
3. Estimating total and unit costs of delivering a specific vaccine: What is the total and/or unit cost of ongoing delivery for a new vaccine added to the routine schedule?	Same as #1 for the program without the new vaccine and for the program with the new vaccine Alternatively, one may make an assumption about which cost categories are affected and measure costs only in those categories	Doses of new vaccines delivered Number of children (or persons) reached with new vaccine	Perhaps none	A pre-post design or some other design allowing comparison of two versions of program is needed
4. Describing variation in unit costs across delivery sites or strategies: How does the cost per dose delivered vary across immunization sites or immunization strategies (fixed sites, outreach, campaigns) within an immunization program?	Same as #1, but allocating resource use to each delivery strategy employed and/or each study site	Same as #1, but separately for each delivery strategy and/or each study site	Measures of the factors hypothesized to be associated with variation (such as facility type, staff experience, population density of catchment area, etc.)	
5. Estimating cost-effectiveness of an intervention to improve performance: What is the cost-effectiveness of an intervention to improve immunization program performance (e.g., coverage or efficiency)?	Same as #1 for the program without the intervention, and for the program with the intervention	Same as #1, but separately for program without intervention and for program with intervention	Variables that might confound the relationship between the intervention and the outcome In addition, if the causal effect of the intervention is expected to vary (e.g., the effect might be larger in urban vs. rural areas), it also can be useful to collect data on the relevant variables (in this case, level of urbanization) to allow for a stratified analysis	A randomized trial, pre-post design, difference-in-difference, or some other design allowing comparison of two versions of program is needed
6. Estimating the cost of an intervention to improve coverage: What is the cost of improving coverage from X% to Y% using a particular strategy?	Same as #1 for the program without the intervention and for the program with the intervention • For quasi-experimental difference-in-difference analysis, measures in #1 also for the program before and the program after the intervention	Same as #1, but separately for program without intervention and for program with intervention • For quasi-experimental difference-in-difference analysis, outputs in #1 also separately for the program before and the program after the intervention	Same as #5 Capacity utilization in secondary analysis	To answer this question, it is important to define the intervention(s) of interest that will be used to increase coverage
7. Identifying drivers of costs: What factors lead to higher delivery cost at some sites?	Same as #1	Same as #1	Variables representing demand-side and supply-side factors that might impact cost per dose such as wastage rates, coverage level, population density, frequency/length of immunization sessions, number of clients per session, experience/skill level of staff, amount of supervision/management oversight, stock-outs, or failures of required equipment	If one is trying to explain variation in cost across sites, substantial additional information is needed. Most important, the quality of service may impact its cost • Some drivers of cost variation may be fixed characteristics of the sites (such as population density) and others may be changeable (such as session frequency)
8. Identifying drivers of inefficiency: What factors contribute to inefficient use of resources?	Same as #1	Same as #1	Same as #7	Same as #7
9. Estimating the cost of reaching hard-to-reach populations: What is the cost to vaccinate target populations facing demand-side and/or supply-side barriers to vaccination?	Same as #1 for the program without targeting hard-to-reach population and for the program with targeting hard-to-reach population	Same as #1, but separately for program without targeting hard-to-reach population and for program with targeting hard-to-reach population	Same as #5	To answer this question, it is important to define additional demographic information of the individuals that are targeted, including mechanisms that make populations hard to reach (both demand and supply side)

3

USING THE OBJECTIVES TO DESIGN A COSTING EXERCISE



To plan a costing exercise, consider the objectives and rationale.

3.1 Define and write down the objectives

Why is the cost information being collected? Following are some potential uses for cost data:

- Periodic activities such as preparing annual budgets for the immunization programs, multi-year strategic plans, or monitoring operational efficiency
- Economic evaluation of interventions to improve immunization programs such as increasing coverage through an outreach campaign or changing the schedule to include a new vaccine
- An investment case to mobilize resources to introduce new vaccines or scale up current coverage
- Describe how costs differ between different types of service providers or the variation in costs across the immunization program

Another goal may be to generate cost data for secondary purposes, including those not known at the time of data collection. Study design choices and reporting results can greatly improve the value of the costing study for other research that relies on secondary data. Indeed, this aspect of costing research motivates the Global Health Cost Consortium effort to improve consistency of methods and reporting around unit costs of service delivery (Vassall et al., 2017, see Annex 1).

At this early stage, it is also a good idea to identify and involve relevant stakeholders. Indeed, stakeholder input may contribute to determining the study objectives.

3.2 Use the objectives to shape the data collection plan and analytical methods

Being precise about the objectives will help determine data requirements and methods. For example, when gathering baseline data on current immunization program costs to inform a strategic planning process—such as the development of comprehensive multi-year plans (cMYPs) required by applicants for vaccine program support from Gavi, the Vaccine Alliance—descriptive study designs may be sufficient. The scope of analysis will likely be the entire immunization program and concern resources at all organizational levels, perhaps with an emphasis on resources that appear in immunization program or health sector budgets, rather than all economic costs. The costing exercise's objectives will also affect the amount of ancillary data regarding the quantity and quality of program outcomes, as well as other important contextual factors that may drive resource use. If the goal is simply to measure the "average cost per dose delivered" or "average cost per child fully immunized," one may only need information about "total doses delivered" or "total number of children (fully) immunized." But to analyze variation in those indicators across geography or types of vaccination sites, additional information will be important.

Examples from the EPIC studies

The original EPIC studies had multiple goals.

- To generate a series of cost benchmarks that could be useful for future costing exercises. These could be derived as unit costs based on line item costs per dose and/or per child.
- To describe variation in total facility costs and unit costs.
- To compare results to country-reported data collected from cMYPs.

3.3 Different uses for cost data

3.3.1 Causal questions

A costing exercise may be part of a larger economic evaluation that aims to answer a causal question. These exercises may be focused on estimating the costs of interventions to improve efficiency, coverage, or quality. For example, costing exercises may help evaluate an information technology solution for cold chain monitoring to ensure the quality of vaccine products, a periodic campaign to improve coverage, or an SMS-based (i.e., short message service or text messages) reminder system to bolster patient demand for immunization services. In these cases, costing will focus on the resources required to deliver the intervention as well as any downstream cost implications of the intervention (e.g., less wastage). For this type of research question, more attention must be paid to incremental costs and intervention effects. This may narrow the scope of the cost data collection, but the methods must be capable of attributing costs and effects to the intervention, which can add considerable complexity.

To answer a causal question about how much additional program output can be achieved with additional resources, it is important to explicitly define the intervention(s) used to increase coverage (e.g., social mobilization, outreach programs). Different interventions will have different costs and different effects on coverage, so it is not possible to credibly estimate the costs of increasing coverage without defining the intervention(s) of interest. Ideally, some experimental or quasi-experimental approach can be applied in the costing exercise to isolate the cost and effect of interest.

3.3.2 Cross-sectional studies

Cross-sectional studies are unlikely to be sufficient when the study objective is to understand the effect of a change in the program on costs or efficiency. Cross-sectional designs measure the costs of a particular service delivery arrangement (which may be inefficient) or achieving a particular level of coverage and quality at a particular time. Such designs will therefore be of limited use to project the resources required to improve efficiency, coverage, or quality. It may be possible to explore causal questions with cross-sectional data using econometric methods (e.g., regression with propensity scores or instrumental variables, data envelope analysis, stochastic frontier analysis). However, to rigorously answer causal questions, studies should use experimental or quasi-experimental designs that allow a comparison between the costs (or efficiency) *with* the change and the costs (or efficiency) *without* the change.

The demand for costing exercises is often to estimate the resources needed to increase coverage from the current level to some targeted level. Using cross-sectional costing to establish the average cost per dose (or per child) of the current program at its current coverage level may be an excellent starting point; however, this average cost for a unit of output is not a good proxy for the cost of the additional units of output needed to increase coverage. Making a cross-sectional comparison of cost differences between high- and low-coverage providers (or regions) and using that information to inform an estimate of the extra cost to achieve a higher coverage will likely produce biased results. There are many reasons why cost and coverage will differ between providers. Some factors associated with variation in cost may be within the control of the provider (e.g., session hours or frequency, staffing patterns) and others may not (e.g., catchment area population density, attitudes toward vaccines among those in target population).

3.3.3 Identifying inefficiency

If a costing exercise's objective is to identify sources of inefficiency in vaccine delivery, it will need to measure "capacity" and "utilized capacity" of resource inputs, as described in Table 1. Throughput (the quantity of vaccines delivered) at a delivery site is a function of demand, supply (of resource inputs), and technical efficiency (how the resource inputs are used). Understanding whether current throughput is constrained by the supply of inputs (e.g., health worker labor, vaccines, cold chain space, building space, and hours of operation) or demand for services (e.g., size of target population, share of target population seeking vaccination) may be important in understanding variation in cost per dose delivered across sites.

Likewise, measuring the use of specific resources to identify "slack capacity" might help estimate the marginal cost associated with certain program changes, such as adding a new vaccine to the schedule or increasing coverage though some form of demand stimulation. A site with underused labor and cold chain capacity may have lower marginal costs associated with an incremental increase in coverage than a facility with no slack in resource inputs.

3.3.4 Secondary data

Finally, one might consider whether costing exercise data is likely to become a public good or be used as secondary data in future studies. In general, more granular costing data and more contextual information describing the scale, quality, service delivery processes, staffing patterns, decentralization of management, physical infrastructure, population/demand-side factors, and so forth, will likely be more useful as secondary data. The richness of the data enables more sophisticated approaches to adapting the cost data to other settings and situations.

BOX 1 COSTING VS. BUDGETING

Costing for routine immunization activities can be directly linked to budget line items; however, budget structures can vary substantially between countries and do not always have a line item for vaccines or immunization [1]. For example, a 2020 analysis of budget line items in 33 African countries found that the number of immunization line items ranged from 0 to 42 with a median of 8 [1]. Immunization line items may not be labeled as such or may be shared across the health sector (i.e., line items might not be immunization specific). In addition, large differences remain between budgets and expenditures [2], and estimates of actual expenditures may more reliably inform a costing analysis. Budgets also have a narrow perspective that includes the fiscal costs or financial outlays of purchases, payments, and supplies (i.e., costs are not annualized). They do not always include labor costs or other costs that do not include budget line items. Economic costs may be drawn from several different budgets, and some economic costs never appear in any budget. Many immunization costs might fall in donor budgets rather than government budgets. When relying on budget line items for a costing analysis, economic and financial costs need to be well delineated and attributed to the relevant budget.

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4 WHAT SHOULD BE MEASURED?

The scope, or boundaries, of a costing exercise defines what things are being measured, such as which costs to count and which (if any) to ignore. Scope can be defined around:

- Immunization activities (e.g., routine childhood vaccination, campaigns, outbreak response, surveillance)
- Organizational levels (e.g., facility level, district level, state/national level, public sector, private sector)
- Geographical boundaries
- Time (e.g., one specific calendar year of an immunization program)

Study designers should make decisions about scope when planning the costing exercise and align it with the study objectives. Following are descriptions of different dimensions used to specify a study's scope.

4.1 Perspective

Perspective is a concept somewhat unique to economic studies compared to other types of health service research [13]. Perspective has to do with which costs we care about. The commonly used "health sector" or "health system" perspective should include all direct health care costs, no matter who pays for them. This perspective includes the costs required to provide health care services, which are often financed by a combination of payers. The "societal" perspective is broader and includes costs outside of the health sector, both direct nonmedical costs and indirect costs, for example, patient transportation costs to reach a vaccination site, lost wages for caregivers, or productivity loss due to premature death or disability. A narrow "payer" perspective is used when cost data is needed for strategic planning for a particular payer. This might be called a "government" perspective when the government is the relevant payer. This perspective concentrates on government expenditure and ignores costs paid by others, such as out-of-pocket payments by patients.

For costing exercises that are a component of an economic evaluation or that will be used as secondary data, we recommend a broader, ideally societal, perspective [14, 15]. However, for strategic planning exercises, narrower perspectives are likely to be adequate.

The perspective will set some natural boundaries on which costs are included in the costing exercise scope, but scope can also be influenced by other dimensions of the immunization program.

> ***Examples from the EPIC studies***
>
> The EPIC costing studies took a health sector perspective, and thus ignored costs that accrued to patients outside the health sector, such as patient expenditure on transportation to reach a vaccination site. This simplified data collection and patient costs were not expected to be large.

4.2 Financial vs. economic cost

Closely related to perspective is the distinction between financial and economic costing. Financial costing is concerned with accounting transactions (i.e., monetary outlays or expenditures), while economic costing assigns values to resources based on their opportunity cost, regardless of whether a financial transaction occurred. For example, a financial analysis from a government perspective would not count community outreach workers' volunteer labor. Although the volunteers' time has a real opportunity cost for them, the government has no financial transaction associated with this resource. From a societal perspective, however, the value of volunteer labor should be counted.

Even after deciding the perspective, figuring out what is in scope can be tricky. For example, economic costs from a health sector perspective should include donated resources, including volunteer time. In-kind donations, such as cold chain equipment donated by UNICEF, should usually be counted based on their monetary value. Likewise, the Gavi subsidy for vaccine purchases is a type of donation, and these resources may be important to include when estimating the full program cost to the health system.

The research question should also contribute to scope decisions. If the costing study will inform an intervention's cost-effectiveness, including donated resources allows for fair comparisons with other interventions. If the goal is to inform government budgeting and planning, estimates of actual expenditures may be more important. But if the analysis focuses on long-term sustainability, it needs to explicitly consider the extent to which donated resources are expected to be available in the future. In general, it is safer to include data on the monetary value of donated resources, which allows for the option to compute costs with and without these costs in the analytical phase.

Examples from the EPIC studies

EPIC studies focused on the economic costs of the routine immunization program.

Costs were included whether or not they were part of the immunization budget, and resources were valued even if they were donated.

4.3 Full vs. incremental cost

In exercises that cost a specific activity or intervention, the researcher could either do a full costing or measure particular resources that the intervention affected. The results of this incremental approach will tell how much additional cost was required for the intervention, but the baseline for that additional cost will be unknown. Often, the baseline context can affect the amount of incremental cost required; therefore, incremental costings are not as easy to use in secondary analysis or to adapt to other contexts.

4.4 Immunization activities

The scope of activities, resources, and outputs to measure will also depend on the study objectives. For example, if the research question focuses on the cost-effectiveness of an SMS reminder system, many aspects of the immunization program, such as cold chain cost, may be minimally affected and, therefore, excluded. Instead, the study should look at the capital and labor required to implement and operate the SMS system.

National immunization programs often distinguish routine immunization from supplementary immunization activities. Routine immunization services may be delivered in facilities but can also include outreach services provided at a separate location. Supplementary immunization activities include epidemic and outbreak response and periodic campaigns. PIRI campaigns may occur with regularity and be designed to bolster the routine immunization program. Other campaigns may have a special purpose, such as polio eradication. Costing studies may address one or several of these service delivery approaches.

Depending on the study objectives, the costing exercise scope may exclude some immunization program activities; for example, a study to measure the average cost of delivering routine immunization may not include disease surveillance or outbreak response activities.

Examples from the EPIC studies

In the original EPIC studies, scope was limited to routine immunization of children up to 1 year of age during the calendar year 2011.

In most countries, this included regularly scheduled local outreach from fixed sites. In some countries, campaign style activities designed to bolster routine immunization were also included.

The scope included all routine immunization activities at all organizational levels (e.g., facility level, district level, regional/provincial health level, and national level).

4.5 Low-cost components

Another way to limit the scope is to omit resource types that do not contribute much toward the total cost or which are relatively fixed. For instance, vaccine programs require physical infrastructure, but with the exception of central storage facilities, the economic cost of the building space for service delivery sites may be a small proportion of the total program cost. Likewise, office equipment might be considered a small and relatively fixed cost. Omitting such resources can reduce data collection burden.

Typically, the vaccine program components that contribute the most to total cost and which are most available for policy action are the vaccines themselves, cold chain equipment, labor, and non-labor expenses for outreach activities such as travel and per diems. Still, the best practice is to identify all categories of resource inputs during the study design phase and carefully consider the study impact prior to omitting certain resource input categories from measurement.

4.6 Target population

National immunization programs have several target populations. A costing study may limit its scope to childhood vaccination or more specifically to a subset defined by age (e.g., all vaccines scheduled to be administered before 12 months of age). It is important to define and report the target population in addition to reporting doses delivered and outcomes such as fully immunized children for use in economic evaluations and as secondary data.

4.7 Sector

Researchers may also limit the scope of a costing study according to the sector, or provider, involved in service provision. For example, the study may consider only including public sector delivery and excluding private or nongovernmental organization (NGO) services.

4.8 Organizational factors

Some costing exercises may set boundaries based on an immunization program's organizational processes such as including only supply chain costs or costs grouped by level (e.g., national or district). Some costing exercises may be concerned only with the resources that are part of an immunization program budget and not those that appear in other budgets such as the salaries of nurses who administer vaccines.

4.9 Time horizon

Retrospective data collection must have time boundaries. If the costing exercise is using financial transaction records as a data source, transaction dates should fall into the time horizon with some exceptions to consider. For example, if the time horizon is January 1, 2017, through December 31, 2017, and a large expense for a vaccine purchase is made in late December 2017, it might not be appropriate to count that as part of the cost of the delivering the immunization program in 2017. Likewise, if a large vaccine purchase was made in December 2016, it could be important to include it in the cost of delivering services in 2017.

Immunization costing exercises commonly combine information from different time periods. In most EPIC studies, the time horizon was the 2011 calendar year; however, much of the data was collected in 2012. For many key items, such as number of vaccine doses used, staff salaries, and outreach events, 2011 data was available in physical or computer records, but some information had to be obtained from interviews. Because of the challenge of respondents accurately recalling events from the previous year, questionnaires often asked about current practice (in 2012) and assumed that practices were similar in 2011. It is much easier to get answers about what is happening now and supplementing them with questions to confirm that no radical changes have occurred that would dispute the use of "now" as a proxy for the time period of interest.

5 DATA NEEDS

When the results of a costing study are going to be used for strategic planning, it is useful to take an "ingredients" approach by measuring both resource prices and quantities rather than aggregating them. By reporting prices and quantities separately, researchers and decision-makers can decide whether either component should be adjusted (e.g., have prices changed or is the number of units required expected to rise?). In addition, separating expenditures by activity categories within the immunization program can be useful if the relative levels of those activities are expected to change in the future. Some information on the volume of services delivered is also needed so that the cost information can be adapted to a future budget with a different target population size (see Box 2).

If the costing study objective is to describe cost variations across sites, identify factors associated with higher immunization delivery costs, or identify sites producing less than expected, other information will need to be collected in addition to the data on resource use and costs. In particular, measuring the "quality" of program output will be important. Some program cost drivers may contribute to program quality in ways that basic output measures like "doses delivered" do not capture well. Moreover, some factors affecting cost variation may be fixed, whereas, others may be changeable through policy and management choices. The biggest challenge in immunization costing studies is not usually measuring resource use itself, but rather measuring what that resource use produced and measuring the contextual factors that would help explain whether the resource use was efficient or not.

BOX 2 ESTIMATING THE COST OF PROGRAM CHANGES

To estimate the costs of program changes, it is important to determine whether the research objective requires an experimental or quasi-experimental study design to answer a causal question regarding program changes, or if a projection exercise to support strategic planning is sufficient. For example, to estimate the costs of increased service volume (or change to some other program aspect), the first step is to identify and quantify the activities needed to achieve the changes desired, such as greater community outreach or new service delivery outlets, and then use available cost data and programmatic experience to budget for these proposed activities. While a common assumption is that total costs will increase proportional to service volume, this assumption is frequently incorrect and can lead to under-budgeting. The costs of some commodities (e.g., fuel, syringes/injection equipment) may scale proportional to volume, but clinical service and program support costs will not, because the actions required to achieve higher service volume will differ from those required to maintain the status quo. Efforts to improve the quality or coverage of reasonably well-functioning immunization programs will likely increase costs more than proportionally. At the same time, there may be opportunities to improve efficiency of resource use in some programs.

5.1 Categorizing cost data

For most costing studies, parsing total cost into categories defined by programmatic activities or resource types is useful; at a minimum, costing studies should separate labor from other inputs. Usually resource-type categories also distinguish *capital* items (durable goods such as buildings, equipment, and vehicles) from *recurrent* items (labor and consumable items such as vaccine doses, supplies, fuel, and travel costs). Sometimes, when the study is on new vaccine introduction or a quality improvement intervention, it is useful to separate one-time start-up costs from ongoing intervention costs.

In immunization costing, it is good practice to separate vaccine cost from service delivery cost. This is because vaccine cost may be known with a high level of precision, and there may be little variability in vaccine cost across sites within countries that purchase through a common procurement mechanism such as a revolving fund or Gavi grant. For countries without a common procurement mechanism, separating vaccine cost is also important to identify and address variability in vaccine prices. Service delivery cost may be much more uncertain and variable than the vaccine cost across sites both within a country and across countries.

5.1.1 Activity categories

Adopting activity categories used locally can also be helpful, as local data sources are more likely to organize resource use and expenditure information this way. One of the goals of the EPIC studies was cross-country comparison, so researchers adopted a common set of activities derived from the Expanded Programme on Immunization (EPI) annual plan of action (Box 3) [1, 10]. These categories work well for a comprehensive costing; however, research questions on specific quality-improvement interventions or new vaccine introduction may involve only a subset of these activities or require a wholly different categorization such as supplementary immunization activities.

BOX 3 COST ACTIVITY DEFINITIONS

- **Routine facility-based service delivery:** Time and resources spent on the act of administering the vaccine to children within the facility/compound.
- **Record-keeping, health management information systems, monitoring and evaluation:** Time and resources spent on data entry and analysis, including maintaining stock registers, maintaining records of children vaccinated, completing reports and analysis, and monitoring and evaluating immunization program data.
- **Supervision:** Time and resources spent by facility (or district-level) staff to supervise subordinate or peer health or community workers.
- **Outreach service delivery:** Time and resources spent traveling to and from a place with the express purpose of vaccinating children outside of the facility. [Note: feel free to add additional activities if the country differentiates between mobile service delivery, outreach service delivery, school-based service delivery, etc.]
- **Training:** Time and resources spent attending and/or providing immunization-related training. Initial training should be thought of as a capital cost, while ongoing, routine training is a recurrent cost. Training costs include the cost of venue, per diem for participants, cost of trainers, and reproduction of training materials.
- **Social mobilization and advocacy:** Social mobilization includes holding community meetings, printing flyers and educational materials, conducting events, and other sensitization of the community. Include any time and resources spent mobilizing the community and households and advocating for vaccination (value of time, per diem, cost of materials, etc.). This could include the cost of television and radio time, as well as the cost of hiring actors, etc. Some of these costs may be one-time costs and should be thought of as capital investments to be depreciated over an estimated useful life.
- **Surveillance:** Time and resources spent following up on post-vaccination events and active cases of diseases that are prevented by vaccination.

Continued

Box 3 continued

- **Vaccine collection, distribution, and storage:** Time and resources spent collecting vaccines at the airport or other distribution points, storing vaccines in national or subnational cold stores, maintaining stock records of vaccines, and distributing vaccines down to the facility.
- **Program management:** Time and resources spent on planning, budgeting, and managing the immunization program at various levels. This would include the cost of time and resources spent on forecasting vaccine needs and procuring vaccines. Costs may include time spent preparing Gavi applications and other applications for funding and technical support. Costs may include attendance at immunization-related meetings. General management of the health system would not be allocated here.
- **Cold chain maintenance:** Time and resources spent maintaining the cold chain at the respective level of analysis.
- **Other:** Time and other resources spent on any other immunization-related activity not covered in the above categories. This category should be very small or not represented at all in the analysis.

5.1.2 Resource categories

Box 4 includes a list of categories for resource types used in the EPIC studies. These categories match how costs might be subdivided in an annual plan for the immunization program so it can facilitate data collection. Different resource types generally require different data collection methods, formats, and key informants.

BOX 4 RESOURCE TYPE DEFINITIONS

Recurrent

- **Paid labor:** Labor for immunization-related activities.
- **Volunteer labor:** Estimation of the market value of volunteer labor used for immunization-related activities.
- **Per diem and travel allowances:** Any allowances paid or paid to volunteer workers for immunization-related activities.
- **Vaccines:** Cost of traditional and new vaccines, including insurance, freight, and wastage. There may be other services, fees, and transport costs. However, local customs duties/levies/taxes should usually be excluded since these are transfer payments without true opportunity cost.
- **Vaccine injection and safety supplies:** Cost of auto-disabled syringes, reconstituting syringes, safety boxes, and other supplies used for administration of vaccines.
- **Other supplies:** Cost of stationery and other supplies for the immunization program.
- **Transport and fuel:** Cost of bus fare, plane travel, and fuel for immunization-related transport.
- **Vehicle maintenance:** Cost of maintaining vehicles (of all types) used for immunization-related activities.
- **Cold chain energy costs:** Cost of running the cold chain (fuel, electricity, etc.) and the cost of ice.

Continued

Box 4 continued

- **Printing costs:** Cost of printing immunization cards and training, information, education, and communication materials and other immunization-related materials.
- **Utilities and communication:** Costs related to building overheads, including maintenance, utilities, telephone, and internet connections, with some portion of these costs allocated to immunization.
- **Other recurrent:** Other recurrent costs for immunization-related activities that are not included in the above line items. Normally, this category should be very small. For the financial cost analysis, this could include customs duties and taxes, which are transfers.

Capital

- **Cold chain equipment:** Value of all cold chain equipment used to store and transport vaccines.
- **Vehicles:** Value of all vehicles and modes of transport (could include boats).
- **Lab equipment:** Value of any specific equipment used for laboratory testing and diagnosis related to surveillance. Note that most of these costs will be health system costs and are not specific to immunization.
- **Other equipment:** Value of other equipment, such as computers, printers, peripherals, furniture, and other medical equipment used for immunization-related activities.
- **Buildings:** Value of building space used to deliver and store vaccines.
- **Other capital:** Any other capital investments (this category should be very small).
- **Other:** Time and other resources spent on any other immunization-related activity not covered in the above categories. This category should be very small or not represented at all in the analysis.

5.2 Other data: Immunization program output and contextual factors

For any costing study, collecting descriptive information in addition to the cost data is useful. Even the simplest costing study with modest descriptive goals still needs to include some measure of program output to be meaningful. In most cases, knowing that a district spent $41,000 on immunization without also knowing something about what this spending achieved is not useful. In addition to measures of program output (e.g., doses delivered), contextual factors may also be important, such as number of children immunized, proportion of the target population immunized, mix of facility-based and outreach methods, population density in the district, number of vaccination sites are in the district, frequency and duration of vaccination sessions, etc.

5.2.1 Output of immunization programs

The primary direct output of an immunization program is vaccinations administered or doses delivered or fully immunized individuals for a given age or vaccine series. In most programs, the number of doses of each vaccine is recorded on paper or electronic tally sheets that serve as the basis of reporting.

While doses delivered is a useful measure of program performance, it does not capture several important aspects of program quality. For example, for a program to be most effective, all scheduled doses must be undamaged and delivered on time; for maximum efficacy, vaccines should be administered when a patient is a specific age; some vaccines must be given as multiple doses with set time intervals between doses; and many vaccines have a shelf life and need to be stored within a specific temperature range.

Some immunization programs may have stock-tracking and temperature-logging systems that report routine data on the cold chain system performance. An example is the Electronic Vaccine Intelligence Network (eVIN) system implemented in some Indian states. Detailed information about the vaccine product integrity may not be available when it is administered, but there may be related information available such as the quantity of doses discarded due to expiration or damage. Usually a costing exercise would not involve a detailed audit of vaccine integrity, stock-outs, expirations, and other indicators of supply chain performance, but existing routine indicators of supply chain performance can be incorporated as contextual variables.

The difference between the number of doses consumed by the program and the number of doses delivered to patients can be substantial and vary significantly by antigen and presentation (e.g., single-dose or multidose vials). Some wastage may result from poor stock management (expiration, lack of temperature control), but can also occur when multidose vials are opened then not all needed during a session.

Strong clinical immunization record-keeping systems—particularly where electronic registries are used consistently—allow for the direct measurement of the number of children fully immunized or even the number of children fully immunized on schedule. Still, in many studies, the researcher may have to rely on a proxy measure for full immunization, such as the number of children who received the third dose of diphtheria-tetanus-pertussis (DTP) vaccine. In the ICAN costing exercises in Tanzania and Indonesia, the measles second dose is being used as a proxy of full immunization.

The difference between a "doses delivered" measure and "fully immunized child" measure is that the latter ignores the benefits of partially immunized children. Conceptually, a crude measure of program efficiency with respect to completing schedules would be the ratio of doses delivered to fully immunized children. For example, if 14 doses are required to fully immunize a one-year-old child, then a "perfect" program would have a ratio between "doses delivered" and "fully immunized child" of 14:1. If, instead, we observe an average of 17.5 doses delivered per fully immunized child, this would indicate a certain number of incomplete schedules or unnecessarily repeated doses. Of course, contributions from the specific vaccine antigens and the extent to which under-administration or over-administration of doses is causing the inefficiency would be important to discover.

When child-wise record-keeping exists only in paper logbooks or vaccination cards, it may be possible to take a sample of records from these sources to get a better picture of the timeliness of vaccine delivery and the patterns of incomplete schedules in partially vaccinated children. However, this additional data collection will be time consuming and may be of limited value if record-keeping systems are incomplete or inconsistently used across sample sites.

In general, costing exercises should include some testing of the validity of proxy measures for "fully immunized child" to determine the need for adjustments. Similarly, when collecting data on doses delivered, the quality of available data sources and reporting systems should be noted, including any incentives that might contribute to bias. Where possible, comparing data sources for a sample of records may clarify their quality and possibly inform adjustment factors in the analysis phase.

5.2.1.1 COVERAGE AS A MEASURE OF OUTPUT

A primary goal of immunization programs is to reach all people in the target population. Therefore, in addition to "doses delivered" or "children fully vaccinated," a key indicator related to program output is coverage. However, collecting accurate measures of coverage at the same time as the cost data is usually challenging. The most common source for coverage estimates is administrative data, but these estimates are likely to be biased (upward) and uncertain.

One problem is the denominator—knowing the precise size of the target population at a specific time and location. If vital registration is incomplete or not easily linked to immunization records, the number of children in the immunization records will probably be less than the number of children in the target population. Census figures may be old, and even if estimates of the under-one year population size based on the last census are reasonably accurate at a national level, they can be highly uncertain at the district or sub-district level.

When measuring coverage for small local geographical areas (e.g., sub-districts), a second problem is population mobility and the overlap of catchment areas for vaccination sites. Members of the target population may have more than one vaccination site available to them, and they may not consistently use the same site. More than one immunization site may contribute to the overall immunization coverage in a partially shared area. This can make it difficult to link coverage to a specific immunization site.

A third problem occurs when measuring coverage over short periods (e.g., monthly) in very rural locations with small target populations. If the target population is 20 children for one month, 1 child represents 5% coverage. An inaccurate target population size or children vaccinated late can result in months with coverage over 100%.

Household surveys such as Demographic and Health Surveys (DHS) or rapid coverage evaluation surveys may be less biased sources of coverage information [16, 17]. However, they still face some measurement challenges related to self-report, recall, and parental record-keeping. Moreover, these surveys are not done frequently and usually have cluster sampling designs to generate estimates for relatively large geographical areas (e.g., districts). As a result, they may not be able to provide coverage estimates matching the time period or geographical locations of the costing study.

If coverage is a critical contextual factor for the costing exercise, and recent coverage estimates are not available, we recommend including a household-based rapid coverage assessment in the fieldwork protocol.

5.2.1.2 DETERMINANTS OF COST VARIATION

Vaccination sites with large target populations and thus more doses delivered may exploit economies of scale and thus have lower cost per dose delivered. Indeed, one of the most consistent findings across studies of immunization cost is the inverse relationship between doses delivered at vaccination sites and cost per dose [18]. High-volume sites may be able to spread the fixed cost of vaccine session set-up and breakdown across more doses delivered in a session. They may also be able to divide labor tasks among multi-person teams and better manage a labor disruption (such as when an employee is absent). They will also have more flexibility to modulate supply to match demand. In low-volume sites, requirements to have immunization services available on a certain number of days/hours per week may result in underutilized labor. Remote sites, which are also likely to have smaller catchment populations, may have higher cost per dose due to the time required for outreach to individual clients.

Besides volume, other factors may affect the cost per dose including:

- Service delivery approach (e.g., the mix of periodic campaigns, routine outreach, and fixed-site sessions)
- Staff mix
- Price levels (e.g., higher cost of labor in cities)
- Type of health facility that serves as the vaccination site (e.g., more infrastructure at hospitals compared to health clinics or health posts)
- Distance of the vaccination site from the “hubs” of the supply chain
- Intensity of supervision and accountability
- Timely monitoring and maintenance of equipment
- Use of information systems for record-keeping

In a site that has achieved moderate coverage of 50-80%, economic theory predicts that the marginal cost of achieving higher coverage will be increasing [19, 20]. Assuming the members of the target population differ in their willingness or ability to access immunization services, those not yet covered are likely to be a harder-to-reach group, who will cost more to identify and reach. Thus, coverage may be an important variable for explaining variation in immunization program cost across sites and even imprecise coverage estimates may be worth including.

When collecting data to help explain cost variation, including both controllable and uncontrollable factors is important. The density of a population around a health facility is not something an immunization manager can control, and vaccination sites in sparsely populated areas may have higher cost per dose delivered due to the fixed costs of providing services in that area. In contrast, the frequency of outreach, supervision visits, and staffing patterns are controllable to varying degrees.

A similar consideration is whether the collected data represents an input or an output. For example, consider a variable “frequency of supervision visits” that is (hypothetically) associated with higher cost per child immunized. Supervision visits have a cost but may also improve program quality. A manager can directly control the frequency of supervision visits and may increase supervision as a response to poor performance. But the effect of supervision on performance will be difficult to ascertain from cross-sectional data, and conclusions about the efficiency of allocating resources to supervision will be tentative. Determining the impact of supervision on performance will require repeated data collection to detect trends and suggest causality. An example of an output-type factor is the variable “vaccine stock-out frequency,” an indicator of quality. Program managers cannot *directly* adjust the frequency of stock-outs the way they can adjust supervision visits or training to improve performance. To reduce stock-outs, they have to take some action to strengthen supply chain management (e.g., investing in a barcode-based inventory management system).

In the case of stock-outs, the problem could be at the site experiencing stock-out or it could be upstream in the supply chain. The direction of association with cost is still not easy to predict. Sites with frequent stock-outs may have relatively higher costs per fully immunized child, since they incur the cost of running immunization sessions but miss opportunities to complete a child's vaccination schedule due to lack of product. However, if sites need to spend a lot of money to keep stock-outs low, then sites with low stock-out frequency might actually have a higher cost. Only experimental or quasi-experimental study designs can confidently disentangle these sorts of causal relationships.

6 DATA COLLECTION METHODS

6.1 Sampling

There is extensive literature on survey sampling, and guidance for sampling health facilities that was developed for DHS can be applied to immunization costing studies [16, 21]. In this section, we provide some general advice about sample design. When possible, and especially for more complex sample design situations, a statistician should be consulted.

6.1.1 Types of sampling for immunization costing studies

Common sample design questions that research teams have when planning an immunization costing study include:

- How many sites do we need to collect data from?
- How should we select those sites?
- Will my design lead to a representative sample?
- Should we use a form of cluster sampling in which we first select clusters (e.g., districts) and then a sample of sites within clusters (e.g., facilities)?
- Should we stratify districts or health facilities, and if so, on what basis?
- How will different sample designs impact the cost of data collection and the precision of the results?
- Can information from prior studies be used to improve sample design?

For most costing exercises that involve collecting data at sites involved in immunization delivery, visiting all sites will be impractical. The sites chosen for data collection should be representative of those not selected. One of the best ways to ensure the validity of generalizing from the sample to the larger group of sites is to use **random sampling** procedures, particularly when the goal is to estimate total cost or mean cost per dose or to compare costs between different locations, types of sites, or services delivery approaches.

There are some cases where it may be necessary or even desirable to select sites purposefully rather than randomly. In a very small study, or in a study that specifically wants to measure cost differences between sites that are different in some way, such as urban vs. rural and public vs. private, a **purposeful selection** is appropriate. However, most of these considerations can be incorporated into a randomized sampling procedure. For example, if comparing low-volume and high-volume sites is important, a stratified random sample can be drawn with strata defined based on volume of doses delivered. In that way, the researcher is assured that the sample will include variation along the dimension of interest (dose volume), but still include sites that are likely to be representative of their respective stratum.

The benefit of random sampling is that standard statistical approaches can be used to calculate an unbiased measure of the mean and the uncertainty in this mean estimate. When facilities are selected purposively, these choices may bias study results (either by mistake or by design), and it will be difficult to estimate uncertainty in the final results.

> ***Sample Design Optimizer Tool***
>
> The EPIC Project developed an Excel-based tool that can help construct efficient hierarchical sample designs for costing studies.
>
> When sampling frame data is available, the tool can be used to compare a large set of alternative sample designs and identify designs that efficiently maximize precision for a fixed data collection budget.
>
> The tool requires a "prior" estimate of the outcome that the study is trying to estimate (e.g., immunization program cost), which can be supplied by the user or be generated based on a predictive model derived from previous studies.
>
> (For more information on the Sample Design Optimizer Tool, please see http://immunizationeconomics.org/sample-design-optimizer.)

In general, increasing the number of sites included in the sample will improve the precision (reduce sampling uncertainty) of the results. At the same time, budget will determine the number of sites included. Thus, sample size can be approached in one of two ways:

- Given a fixed data collection budget, what sample design will result in the most precise estimates of the quantities of interest in this study?
- Given that a certain level of precision is required at the end of this study (e.g., estimate cost per dose delivered with a 10% margin of error), what is the most efficient sample design for achieving this, and how much will the data collection cost?

Ultimately, the sample design for an immunization costing study will depend on the information available prior to data collection—the most critical being a list of all relevant sites. For example, if the study is going to collect information at the central/national level and from a sample of districts and from a sample of facilities within the sampled districts, the researcher will need to know the total number of districts and the total number of facilities within each district. This list of sites is the **sampling frame**. The researcher will make inferences about this list based on what is learned from the sample sites.

Additional prior information about the sites can be used for stratification, assigning selection probability, and predicting precision. This information can include stratification characteristics such as whether a district is urban or rural; whether facilities are public or private; whether facilities are hospitals, health centers, clinics, or health posts; or whether they are high-volume or low-volume immunization sites. A design with **probability-proportional-to-size** (PPS) sampling (vs. a simple random sample in which all units have equal probability) requires a "size" variable, such as number of facilities per district, under-one-year-old population of districts, or doses delivered in the facility. This design element can affect precision as can the structure of a cluster design. Having a prior estimate of the outcome of interest is advantageous; for example, if the study goal is to estimate cost per dose, knowing a prior estimate of the cost per dose at each facility is helpful. This could be available from a prior study in that setting, or it could be predicted based on data from other studies (e.g., EPIC studies).

6.1.2 Typical sampling procedure

To sample a large number of sites at different organizational levels, we recommend using a cluster design to reduce data collection cost. Below is an outline of a possible cluster sampling procedure for a cost study of routine facility-based immunization delivery.

1. **Select geographical areas that will be the focus of the study.** If the country is small, the geographical area may be the entire country. If it is large, provinces or regions may be selected at random or purposively. If selected purposively, we suggest selecting provinces or regions that reflect the range of immunization activities in the country (e.g., high, medium, and low performance). However, as noted previously, purposive selection may introduce bias and complicate the uncertainty estimation.

2. **Select districts within these regions or provinces.** The number of districts to select will depend on the data collection budget. Often districts are selected with PPS random sampling based on the number of health facilities or population size. Where available, we recommend using the under-one-year-old population size, as immunization programs tend to focus on this population segment. If costing a vaccination approach for a different or broader target population, it may be appropriate to use that target population size (if available) as the basis of PPS random sampling.

3. **Develop a complete list of health facilities that are relevant to the study scope.** This list of facilities is needed at least for the districts that were selected in the previous step. Moreover, if the scope of the study is restricted to the public sector, the list of facilities should include only public facilities; if the scope considers only certain facilities that have immunization services available, then the list would be restricted to these immunization-relevant sites, etc. However, if the researcher is going to use the Sample Design Optimizer Tool (see box on the previous page) to evaluate sample design options, a facility list will be needed for all districts. This is because the tool runs simulations that repeatedly draw samples using a given sample design, so all districts and all facilities can potentially be selected during these simulations. (Note: if regions or provinces were selected purposively, then a list of facilities for all the districts in the selected regions/provinces would suffice.)

   Information should be obtained on the number of doses of vaccine administered in the past year at both the district and facility level. If doses delivered is not available, alternative "size" variables for facilities—in order of preference—would be "number of outpatient visits," "number of nursing full-time equivalent," or "number of nurses." Each of these are indicators that are likely to be correlated with the number of vaccine doses delivered per year. For each district, information on population density should be obtained. When possible, facility classifications such as urbanity (e.g., urban, peri-urban, rural, remote) and ownership (e.g., government, NGO, private) should be obtained.

4. **Randomly select facilities from the list within each district**. It often makes sense to over-sample rural/remote facilities compared to urban/peri-urban facilities, because health care costs are generally right-skewed rather than normally distributed [22]. In particular, variation in technical efficiency between sites can affect the cost per dose delivered, resulting in right-skewness of the distribution of immunization delivery costs [18]. In this case, having a sample that includes more facilities associated with the right tail would result in a greater probability of those facilities appearing in the sample. We recommend simple random sampling, because PPS sampling based on the number of doses would tend to favor facilities that administer a large number of doses, which is the opposite of what the sample needs. To oversample rural/remote or low-volume facilities, stratify them on this basis and select a relatively larger sample from the stratum to over-sample. When taking this approach, the analysis will have to include sampling weights when making population-level inferences.

The sampling procedure will determine sample weights used in the analysis. Sample weight is equal to the inverse of the probability of a unit being selected for the sample. These sampling weights are important because each sampled unit may have a different probability of being selected. As a result, each unit in the sample may represent a different size portion of the sampling frame, and this should be accounted for when making inferences from the sample to the larger population.

Should a facility be dysfunctional or logistically impossible to survey or if the respondents are unavailable, that facility should be replaced in the sample through random sampling. In one EPIC study, we randomly pre-selected replacement facilities to use as substitutes if needed. Only the study's principal investigator had access to this list to prevent local stakeholders or data collectors from influencing sample site selection.

Example Sampling Procedure: Honduras EPIC Study

Honduras has 20 health regions, 2 of which are metropolitan regions. Within non-metropolitan regions, there are 298 municipalities. In metropolitan regions and in non-metropolitan municipalities there are 1,554 health facilities. There are three types of health facilities: hospitals, *CESAMOs* (health centers with physicians and dentistry), and *CESARs* (rural health facilities). In each municipality and metropolitan region, there is one health facility that is the lead facility for immunization that serves as a coordinating hub.

The sampling procedure was as follows:

1. Eight health regions were purposively selected (nonrandom). In addition to the two metropolitan regions, the other six regions were selected to achieve a mix of contexts for immunization delivery as well as geographic spread.
2. In each of the non-metropolitan regions, three municipalities were selected at random (total of 18) with the probability of being selected proportional to the population size of under-one-year-olds (a major target population of vaccination activities).
3. In each of the 18 municipalities selected, three health facilities were selected, always including the lead facility. One *CESAR* was selected at random from all *CESARs* in the municipality, and one *CESAMO* was selected at random from all *CESAMOs* in the municipality. Hospitals were only included when they were the lead facility. When there was not a *CESAR* or *CESAMO* to select, an extra facility of the other type was included.
4. In the two metropolitan regions, since there were no municipalities, nine facilities were selected at random. The lead was selected with probability of 100%, and for the remaining eight facilities, five *CESAMOs* were selected at random from all the *CESAMOs* in the region, and three *CESARs* were selected at random from all the *CESARs* in the region.

6.2 Information gathering and data sources

Retrospective costing studies often rely heavily on administrative records, such as expenditure data in the cost accounting system, purchase orders, payroll or personnel records, activity logs, routine reports, inventory lists, and clinical records. This data is typically supplemented with data gathered via interview or questionnaire from program managers and other key staff. Another type of data collection is direct observation. Although there are limitations in combining direct observation (which is prospective) with other data collected retrospectively, it can be a useful approach to measuring certain aspects of resource use—especially the allocation of shared labor resources.

6.2.1 Administrative records

Accounting systems are a frequent source of information on expenditures such as utilities, fuel, per diems, and expenses for training activities such as venue rental, catering, and travel. Using information from a cost accounting system requires knowing which financial transactions can be mapped specifically to immunization inputs or activities. Other records and their use as data sources include:

- **Purchase orders:** price paid for commodities, vehicles, and equipment
- **Payroll records:** estimating average salaries for workers with different job positions and levels of experience
- **Activity log/vehicle trip log:** allocating an appropriate portion of a health facility's shared vehicle pool to immunization activities
- **Other logbooks:** number of training, management, or supervision events and details regarding the duration and number of participants at such events
- **Routine reports:** number of immunization sessions held, number of outreach activities and campaigns, number of doses used and discarded, and vaccine inventory stock levels
- **Inventory lists for cold chain equipment and vehicles:** make and model, location, condition, and age of capital items
- **Clinical records:** number of doses delivered

6.2.2 Retrospective self-report of program manager and staff

Interviews or questionnaires can be used for gathering complementary information about the frequency or duration of outreach sessions, training events, supervision visits, or use of vehicles. An important example is labor quantity, which represents a substantial share of total immunization program cost. The share of nursing labor that is dedicated to immunization is usually not routinely tracked; however, questionnaires administered to a sample of nurses (or program managers) can reveal the overall time spent on immunization and the share of time spent on different immunization activities.

Designing questionnaires relies on choosing who will be interviewed. In some EPIC studies, the senior nurse in charge of immunization at the health facility was asked to estimate

> ***Example from EPIC Studies***
>
> A generic questionnaire format for health facilities was shared with the country teams as a starting point for customizing the form within each country. Additional formats for data collection at the district, regional, and national levels were developed to capture all relevant data on costs and outputs.
>
> Questionnaires were pre-tested and revised in an iterative process. Each country team was required to train data collectors and field supervisors in how to use the questionnaire.

the number of hours (or percent of total hours) of each staff member that was spent on immunization-related activities. The hours were further divided among activity categories such as vaccine administration (i.e., vaccinating children during immunization sessions), record-keeping, and cold chain. The EPIC studies focused on the cost of immunization programs in 2011 but data was collected in 2012. The nurse manager reporting labor allocation information often referred to current staff schedule sheets and other records to aid recall. Therefore, responses probably represented labor allocations in the recent past, rather than a quantitatively precise overview of the full 2011 year. Interviewing workers themselves about their own time would be far more time consuming and maybe not much more accurate.

One common issue with allocating labor time is deciding how to handle “downtime” when staff is not busy due to demand-side factors (i.e., a lack of patients). Especially in very low-volume sites, such as in sparsely populated rural areas, nurses may have no patients for substantial periods during the workday. Interviews about time use should also cover downtime. When questionnaires do not explicitly capture downtime, estimates will have to rely on guesses about how the respondents did or did not factor downtime into their responses. If downtime is explicitly collected, it can be allocated to immunization proportionally based on immunization’s share of non-downtime. In this case, the resulting average labor cost per dose will include downtime. If downtime is explicitly collected and then excluded from immunization, the average labor cost per dose will more closely represent the productive labor time required for immunization. Both approaches to handling downtime in immunization costing have merit, and the choice between them depends on what is needed to answer the study research question.

6.2.3 Direct observation

Direct observation methods such as time motion or work sampling (prospective data collection) are alternatives or supplements to questionnaires. The major advantage of direct observation is the lack of recall bias. However, because direct observation is prospective, it will not match the time period of the retrospective data collected in the study; therefore, the researcher must assume that the share of labor allocated to immunization activities has not changed between the study period and the current period. Another disadvantage of direct observation methods is that they are time-consuming to carry out, especially when there is a lot of day-to-day variability in time use by the facility workers. Sometimes, vaccination is only delivered in sessions on certain days of the week or activities such as community outreach may only happen one day per month. A direct observation design will need to accommodate these patterns. Workers may also behave differently when they know they are being observed.

Annex 3 provides an excerpted section of the ICAN methods guide pertaining to gathering data on labor cost.

6.3 Data collection instruments

Data on costs, outputs, and facility characteristics should be collected using pre-tested, standardized questionnaire formats. Several tools exist to construct data collection instruments. The ProVac Initiative designed tools specifically for immunization costing studies—UNIVAC and COSTVAC [10]. In the Excel-based COSTVAC tool, custom data collection forms can be tailored to specific studies. Other convenient features are the ability to include instructions and scripts for data collectors to use and built-in data validations and data consistency checks. It also has a feature to create one unique workbook per sampled site and a macro to aggregate data from all of these workbooks once data has been collected. Other generic tools include EpiInfo7, KoboToolbox, and RedCap.

7 DATA ANALYSIS

The data analysis plan serves as a rough guide to the sort of information that will need to be collected to support the required analysis and how that information will be used to estimate costs; consequently, the plan needs to be developed before data collection starts. It may need to be modified based on the data available and the study's research questions. Below are some examples of how to estimate immunization program costs, in particular, cost categories, assuming economic costs (see 4.2) from the health system perspective (see 4.1).

7.1 Shared costs

Shared costs and resources apply not only for immunization, but also for other activities; for example, nursing labor, which is shared between immunization and other primary care services or a vehicle used to deliver vaccines and transport patients. Determining what portion of a shared resource to allocate to immunization to estimate immunization-specific costs can be tricky. Allocation is based on an "allocation key" or "tracing factor." These tracing factors can also be used to allocate input costs within immunization to different program activities. Annex 4 gives examples of the use of tracing factors.

If shared resources have not been fully allocated across all of their uses as part of a previous internally consistent cost-accounting process, and the immunization costing exercise's data collection focuses only on estimating the portion of the resource used for immunization, the risk is that the resource may be over- or under-allocated to immunization. For example, if the focus of the questions is on the use of the resource for immunization, the respondent who does not have to reconcile the allocation across all uses might over-estimate the portion going to immunization. Likewise, if the resource is often idle, the respondent may or may not allocate a portion of idle time to immunization.

7.2 Replacement prices

Replacement price is the price to buy an equivalent piece of equipment today, and it should generally be used to represent a unit cost in a cost exercise. For equipment that is less than about five years old, it is reasonable to use the actual price paid, adjusted for inflation. For some, especially older equipment, the inflation-adjusted actual price paid may vary substantially from the replacement price. This can happen due to technology or market changes. One example is desktop computer equipment. The inflation-adjusted price paid for a desktop computer 10 years ago might be $3,000, but today, that computer might be replaced for only $1,500 (and it would have far superior computing power). In contrast, the replacement cost for old vehicles may be higher than the inflation-adjusted purchase price, because new vehicles contain additional technology (more reliable and efficient engines, safety features such as airbags) that has raised prices. In these situations, using the current price of a similar replacement unit will usually be better. This is especially true if the costing study could be used to estimate the future cost of continuing the immunization program.

Sources of information to determine replacement prices include the following:

- Vaccine unit prices: country records including free on board/cost, insurance, freight (FOB/CIF) prices (estimate on a per dose basis)
- Procurement records at national and/or regional levels: this information tends to be at higher levels of the health system

- UNICEF and World Health Organization (WHO) product information sheets
- Donor procurement records
- Interviews with key personnel at facility, district, regional, or national level

7.3 Analysis of recurrent costs

7.3.1 Labor

Wage rate Hours allocated to immunization*

OR

Annual salary Portion of paid work hours allocated to immunization*

The wage rate should include base salary plus any benefits and bonuses. In many cases, obtaining actual wages paid to individual employees may be difficult due to privacy concerns; in this case, we recommend getting information on the average wages paid to a cadre of full-time equivalent employees (e.g., nurses, technical officers, midwives, clinical officers, managers). Using "job position" codes and the number of years of experience to look up salary level (or salary range) in official tables is another option.

As discussed in section 6.2, to determine the immunization-specific share of labor, a questionnaire can be used to determine a worker's hours allocated to immunization. Such a questionnaire might ask, "In a typical week, how many total hours do you work? How many of those hours do you spend working on immunization-related tasks?" Alternatively, a questionnaire might ask, "In a typical month, what portion of your work hours is spent on immunization-related tasks?" The reported proportion will be applied to an estimate of total hours worked. To estimate an hourly wage for the person, the researcher needs to know if he or she is a full-time or part-time worker.

7.3.2 Vaccine

Doses used Average price per dose*

If good vaccine stock records are available, the total vaccine doses used can be measured directly. Otherwise, an alternative is to use the number of doses delivered from immunization session reports and adjust it for wastage. Doses can be wasted if stock expires or is damaged or when unused doses in opened multidose vials are discarded. Wastage rates will likely vary substantially across vaccines. For example, the bacille Calmette-Guérin (BCG) vaccine comes in multidose vials, and doses are often wasted since they can only be used for six hours after the vial is opened. Single-dose vials such as those for rotavirus and products with longer shelf life or that do not require refrigeration are less likely to be wasted. Even when the quantity of doses used cannot be obtained from vaccine stock data, the cold chain manager may have records or an expert opinion regarding wastage rates. The WHO also provides a vaccine wastage rates calculator to support these estimates in specific country contexts [23].

The prices of vaccines should include freight and insurance cost (CIF) and can be obtained from the UNICEF Supply Division, UNICEF local office procurement records, or the ministry of health (MOH)/EPI.

7.3.3 Injection supplies and reconstitution syringes

Quantity of supply item used Item price*

OR

Doses delivered Expected quantity of supplies consumed per dose* Item price*

In general, the average quantity of consumable supplies used should be estimated per dose delivered and adjusted for wastage. Different vaccines use different types of syringes, and some also require a reconstitution syringe. Vaccines such as oral polio do not require injection supplies. Other injection supplies may include gloves, alcohol swabs, and bandages. While guidance from agencies such as WHO, UNICEF, or Gavi may not recommend the use of certain supplies, we recommend costing all supplies used in a specific country setting.

Alternatively, the number of syringes and other supplies used can be estimated based on stock position (e.g., number of syringes at the beginning of the period + number of syringes received during the period – number of syringes at the end of the period). Be careful to use purchases made in a particular year, as previously purchased stock can spill over to subsequent years.

The prices of syringes and supplies should also reflect CIF and can be obtained from the UNICEF Supply Division, UNICEF local office procurement records, or the MOH/EPI.

7.3.4 Waste disposal

Medical waste disposal methods can vary widely, from the use of incinerators to simple open burn pits and burial. Costs may include safety boxes to collect used sharps, the capital and energy costs for operating incinerators, transportation of waste to the incinerator site, and associated labor. Since immunization waste is likely a small fraction of the waste handled by a centrally located incinerator, a cost per unit of waste product may be an appropriate proxy, especially if the incinerator facility is privately run. Other methods of waste disposal, such as burning and burying on the health facility site, may only have labor costs.

7.3.5 Training

Training event cost = venue rental + catering + training materials + travel + (number of participants number of days)* (per diem + daily wage rate)*

Training costs include the cost of the venue, per diem for participants, cost of trainers' and participants' time (valued at wage rate), and reproduction of training materials.

Initial training, such as when a new vaccine is introduced, should be treated as a capital cost and allocated over a multi-year time horizon. For example, if staff turnover is 20% per year, training would be a capital cost with a useful life of five years. In other words, every year, 20% of the training has to be replaced. See section 7.4 on allocation of capital costs over multiple years. In contrast, routine refresher training or trainings before annual campaigns can be treated as a recurrent cost.

Note: In some costing studies, if the trainees are health sector employees, their labor time (valued based on wages) might not be counted or may be separated from the other costs, because it may fall under a separate budget. While there is a clear opportunity cost to employees attending trainings (e.g., as opposed to providing clinical services), the labor cost associated with the training may not represent additional spending, from the government employer perspective.

7.3.6 Social mobilization

These are costs associated with holding community meetings, printing flyers and educational materials, conducting events, and other community sensitization (per diem, value of time, cost of materials). Social mobilization might also include media buys such as billboards and radio and TV spots.

If these are one-time activities (such as when a new vaccine is being introduced), they could be categorized as one-time (start-up) costs. Alternatively, these start-up costs could be treated as capital investments and allocated over a multi-year period. In this way, the up-front start-up costs are allocated over a large number of doses delivered and more fairly rolled into the delivery "cost per dose" of a new vaccine. See section 7.4 on allocation of capital costs over multiple years.

7.3.7 Vehicle maintenance

We suggest estimating total vehicle maintenance costs per facility (per district) and multiplying that by the share of mileage (kms) made for routine immunization-related activities. When this information is not available, other standard benchmarks can be used. For example, in the United States, many businesses reimburse employee for miles traveled for work trips in their personal vehicle. The American Auto Association estimates that the cost of passenger car maintenance is about 50% of fuel cost and that maintenance is about 25% of the total operating cost, which includes fuel, maintenance, tires, and insurance.

7.3.8 Cold chain energy cost and maintenance

These costs include both the fuel and energy costs required to run the cold chain as well as the cost of repairs and spare parts. The cMYP Guidelines suggested a rule of thumb to estimating cold chain operation and maintenance as 5% of the capital cost of equipment [24]. Alternatively, researchers can conduct a more detailed analysis based on type of energy, frequency of energy replacement, unit prices, and estimates of frequency of repairs.

7.4 Annualization of capital costs

For capital inputs that last more than one year, economic costs will include some portion of their value as well as reflect the cost of tying up capital rather than using it in another way. Such capital inputs include cold chain equipment, buildings, computers, furniture, initial investments in social mobilization, and initial training.

For economic cost evaluation, all capital costs need to be annualized based on a discount rate and estimates of the useful life of the item. A "useful life" is defined as the period during which an asset or property is expected to be usable for the purpose it was acquired. A general rule of thumb is that useful life is equivalent to the number of years until the cost of maintaining and repairing a piece of equipment outweighs the cost of buying a new piece of equipment. Often, items that have exceeded their useful life are still in use; however, the definition of useful life should not be based on these examples, nor on the current age of the item. Useful life is an average. Items that fell short of their expected useful life will not be observed in a cross-sectional review of current inventory, while items that exceeded their useful life will be observed. Many countries have standard benchmark values for useful life of capital items. An alternative is benchmarks generated by WHO CHOICE [25].

In costing studies focused on fiscal outlays, actual expenditures by calendar period may be important (e.g., for cash-flow planning), but in most costing studies, it is more useful to spread the cost of large purchases over a reasonable time that the item is expected to be a productive resource within the immunization program. In economic studies, the actual dates when capital items are expected to be replaced is not a factor for consideration. Instead, annualization of capital cost "smooths out" the actual stream of financial investments in capital items to give a better picture of the long-run average cost of an immunization program.

In economic evaluation, resources that are utilized in the future must be discounted to their present value to adjust for opportunity cost. *Present value of cost* = Future cost * present value (PV) factor, where the PV factor = $1/(1+r)^n$ and where r = discount rate and n = number of years of useful life. When annualizing the cost of a capital item, the researcher converts it to a constant cost to be paid each year of its useful life, while simultaneously adjusting the year of life for opportunity cost. From the standpoint of the time of purchase, the present value of those annual payments is equivalent to the purchase price. For economic evaluation, the annualized cost of a capital item is the cost estimate divided by annualization factor (see box below and Annex 5). This approach is different than financial cost evaluation, where capital costs are divided by the number of years of useful life without discounting (straight line depreciation).

Annualization Factor

$$\frac{(1 + \mathrm{r})^n - 1}{r \times (1 + \mathrm{r})^n}$$

r = discount rate (use 3% unless you have justification for using a higher rate)

n = number of years of useful life (period during which an asset or property is expected to be usable for the purpose it was acquired; may or may not correspond with the item's actual physical or economic life)

A table of these factors is included in Annex 5

The easiest and least error-prone approach to calculating equivalent annual cost is to use the *PMT* formula in Microsoft Excel. Note that to use *PMT* you have to include a minus sign, because Excel assumes you are using *PMT* to get the value of an annual payment that will be equivalent to the present value of some lump sum (such as a loan amount).

Example:

Cost estimate: $10,000
Discount rate: 5%

Years of useful life: 10
Annualization factor = ((1+0.05)^(10)-1)/(0.05*(1+0.05)^10) = 7.7217

Also in Annex 5, column 5, row 10 = 7.7217
Annualized cost = cost estimate divided by annualization factor
$10,000 / 7.7217 = $1,295.05
Excel: = - PMT (0.05;10;$10000) = $1,295.05.

In some cases, a residual or scrap value at the end of useful life is considered and needs to be adjusted for. Textbooks on costing methods explain how to handle this more complicated case [13].

7.5 Analysis of capital costs

7.5.1 Cold chain equipment

Number of cold chain equipment pieces (by type) x average replacement price; annualized over useful life of item

The number of cold chain equipment pieces by type can be obtained via questionnaire, direct observation, or inventory records. Types of equipment include cold rooms or walk-ins, refrigerators, freezers, vaccine carriers, thermometers, temperature logging equipment, and generators. Information about the make and model of each item, as well as the size (capacity of storage devices, horsepower, or energy output of generator) can help determine the replacement price. The cost required to replace the cold chain equipment (which may be different from the price originally paid for it) can be obtained from local donor offices procurement records, MOH/EPI financial records, UNICEF Supply Division, or WHO Product Information Sheets [26]. These prices should include freight and insurance costs.

For economic costing studies (i.e., those that seek to estimate opportunity cost of immunization programs), the price of equipment should be counted even if the item was donated.

7.5.2 Vehicles

Number of vehicles (by type) x replacement price (by type) x % use by the routine immunization program; annualized over useful life of vehicles

In addition to the operating cost of vehicles used for routine immunization, a portion of their purchase value should be allocated to the program as it represents an opportunity cost of using the vehicle for immunization rather than for other services.

Several sources of information are available to allocate vehicles to the immunization program:

- Vehicle use records (e.g., driver's logbook) is the first choice. They may include number of trips, kilometers traveled, or hours used. Identifying the immunization-specific trips may be straightforward or may rely on using some proxy variable from the vehicle use records, such as the person using the vehicle or the destination. If records are kept in paper form, a sampling strategy may be necessary (e.g., choosing a random subset of pages of a logbook from the time period that is the focus of the study).
- When records are not available or do not have sufficient detail, they can be supplemented by interviews with the responsible officer at the facility or the relevant office, whether national, regional, district, or otherwise.
- As a last resort, the vehicles might be allocated based on the share of facility hours for immunization or the ratio (e.g., [*Immunization-specific allocation factor * Doses delivered / Outpatient visits*]), or other allocation keys. For example, in Honduras, the immunization-specific allocation factor assumed that an immunization dose was about one-third as vehicle-resource intensive as an outpatient visit.

Replacement prices could come from MOH/EPI financial records or donor procurement records.

7.5.3 Office equipment

The methods for analyzing the costs for office equipment are the same as for cold chain equipment and vehicles.

For simplicity, and because office equipment is usually not a major driver of immunization program cost, rules to limit the scope of data collection are sometimes used:

- Omit equipment items costing less than some threshold price (e.g., $250)
- Omit general infrastructure associated with the building such as furniture and air conditioning units
- Focus only on office equipment dedicated to the immunization program

7.5.4 Buildings

*Area (square meters) of building space devoted to immunization program / Total building area * Building rental price per square meter*

Vaccinations provided in facilities will entail use of the primary health care facility and so carry a resource cost. The value of buildings will be related to the space that is used to administer vaccines and store vaccines and supplies. If the building is rented, the value is equal to the facility's rent and the proportion of the facility used for immunization services. If the building is owned, then the value could be estimated through equivalent rental cost, annual mortgage payment, or the building's annualized purchase price or construction price.

7.6 Estimating unit costs and total program costs with data from a sample of sites

One goal of collecting cost data from a sample of health facilities is to make inferences about unit and total costs in the program. In this type of analysis, it is important to use methods that correctly account for the underlying relationship between cost and volume and that are appropriate for the approach used to choose the sample. There are several ways to minimize bias and maximize precision in unit and total cost estimates. The simplest approach is to take a volume-weighted mean of unit costs across the sites in the sample. To get more precision, more complex techniques including a calibration estimator or a regression estimator may be preferred if auxiliary data are available. These different techniques are described briefly below.

7.6.1 Methods for point estimates of unit and total costs

In the descriptions below, N represents the number of health care delivery sites in the overall program being studied, n represents the number of health care delivery sites in the sample, C_i represents the total service delivery costs at site i, and Q_i represents the total service delivery volume at site i. Error term is denoted in ϵ.

The **volume-weighted mean unit cost** is calculated as the sum of the total costs across all sites in the sample divided by the sum of the delivery volumes across all sites in the sample:

$$unitcost_{vw} = \frac{\sum_{i=1}^{n} C_i}{\sum_{i=1}^{n} Q_i}$$

In this calculation, C_i is the total cost for site i, and $\sum_{i=1}^{n} C_i$ is the total cost for all sampled sites. Similarly, Q_i is the delivery volume for site i, and $\sum_{i=1}^{n} Q_i$ is the total delivery volume for all sampled sites. This approach is simple to implement using spreadsheet or statistical software, requires only the data collected as part of the sample, and (assuming a sufficiently large sample) generates unbiased estimates of the unit cost. However, it has lower precision than the calibration and regression estimators described below.

A similar approach to estimate the total cost in the overall program is the **volume-weighted total cost**. It is calculated as the volume-weighted mean *unit cost*, multiplied by total delivery volume for the program:

$$totalcost_{vw} = unitcost_{vw} * \sum_{i=1}^{N} Q_i$$

This approach requires additional information (i.e., total program delivery volume), but has significantly improved precision over an estimator that multiplies the mean of total costs across all sites by the number of sites (N) in the program.

More sophisticated options may be possible depending on the auxiliary information available.

The **calibration estimator**, described in detail in Rivera et al. [27], uses auxiliary information to re-weight the data in the sample to more closely match the true distribution of costs in the population. At a minimum, auxiliary information must include the total volume of services delivered in the overall program ($\sum_{i=1}^{N} Q_i$) and the total number of sites in the overall program of interest (N). Information about other variables that drive costs can be incorporated to further improve precision. This approach can be implemented in the *survey* package in R (a software) to estimate either unit or total costs.

The calibration estimator has improved precision relative to the volume-weighted mean (and has a similar upward bias in small samples). However, estimation is more complex and requires the use of more advanced software than the volume-weighted mean.

A **regression estimator** may also be used to improve precision through the use of auxiliary information. This estimator can take many forms. One simple example is a log-log regression of costs on delivery volumes as shown below. Using a model of this form, unit costs may be estimated as the sum of the predicted costs divided by the (known) total delivery volume in the population.

$$\log(\mathrm{C_i}) = \alpha + \beta \log(Q_i) + \epsilon_i$$

As with the calibration estimator, additional variables may be included in the model to improve precision. The regression estimator requires more auxiliary information than the calibration estimator; while the calibration estimator only requires information on the *total* population value of any auxiliary variable, the regression estimator requires information on the full population distribution of a given auxiliary variable. As with both the volume-weighted mean and the calibration estimator, the regression estimator exhibits bias in small samples.

A note of caution: In the existing literature on health care costs in low- and middle-income countries, researchers commonly use a simple mean to estimate unit costs based on data from a sample of health care facilities. This approach, calculated as the mean of the ratio of costs to volumes across sites in the sample, has a large upward bias in simulations based on empirical cost data from low- and middle-income countries. It should not be used.

$$Mean_s = \frac{1}{n} \sum_{i=1}^{n} \frac{C_i}{Q_i}$$

Inverse probability of **sampling weights** should be incorporated into whichever approach is used to calculate point estimates. The weights should follow from the study's health facility sampling scheme. The sampling procedure will determine the weights used in the aggregation of costs, in the statistical analysis of costs, and in reporting average weighted total and unit costs for the facility sample. Weights are the inverse of the probability of being selected. With stratification, multiple probabilities are selected, which should be multiplied by each other, with weights being the inverse of these joint probabilities. For example, if one district is selected out of four (1/4), and two facilities are selected out of ten (2/10), then the probability of facilities being selected in the sample is (1/4 * 1/5 = 1/20). The sample weight for that facility would be the inverse, or 20.

Note that the calibration estimator is compatible with sampling weights. The *survey* package in R augments sampling weights with additional information for calibration.

The sampling weights and survey design (e.g., clustering and stratification approaches) should also be incorporated into the estimation of standard errors for unit and total costs, using techniques described elsewhere [28]. Many software packages are designed to routinize estimation with clustering and stratification.

7.6.2 Aggregating cost data collected from multiple levels of the health care system

The methods described above focus on estimating unit costs and total costs for data collected from health care delivery sites. Researchers may be interested in calculating unit and total cost estimates that aggregate data from multiple levels of the health care system—the facility, district, and national level—and these methods can be used to calculate summary estimates of unit and total costs at each level before aggregation. Appropriate sample weights and methods to estimate standard errors should be used at each level of the analysis. For example, to estimate total costs across three levels of the health system, the following procedure could be used:

1. **Use one of the estimation methods described above to calculate the total or unit cost** (whichever is of interest) at the first level (e.g., the facility level) using the inverse probability of sampling weights for that level.
2. **Use one of the estimation methods described above to calculate the total or unit cost** (whichever is of interest) at the second level (e.g., the district level) using the inverse probability of sampling weights for that level.
3. **Calculate the total or unit costs at the third level** (e.g., the national level). This may not require use of one of the estimation methods above because the data collected represent all costs at the national level (rather than a sample).
4. **Add estimates from the three levels together to generate estimates of unit or total costs** of routine immunization in the overall program.

When choosing more complicated sampling and/or analysis methods, we recommended having them reviewed by a survey statistician or other expert in applying them.

A demonstration example and tutorial summarizing cost data using data from the Honduras EPIC Study is available at immunizationeconomics.org.

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Annex 1: List of other methodological resources for immunization costing exercises

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Annex 2: Input – Activity matrix

Input/ Line Item	Routine Facility-based Service Delivery	Outreach Service Delivery	Record-Keeping & Health Information System	Super-vision	Training	Social Mobiliz-ation & Advocacy	Surveill-ance	Vaccine Collection, Distribu-tion, and Storage	Program Manage-ment	Other
Salaried Labor	X	X	X	X	X	X	X	X	X	X
Volunteer Labor	X	X				X	X			?
Per Diem & Travel Allowances		X		X	X	X	X	X		
Vaccines	X	X								
Vaccine Injection & Safety Supplies	X	X								
Transport /Fuel		X		X	?	X	X	X	X	
Vehicle Maintenance	X	X		X			X	X		
Cold Chain Energy Costs								X		
Printing	X		X		X	X				
Building Overhead, Utilities, Communi-cation	X						X			
Cold Chain Equipment								X		
Vehicles		X		X		X	X	X	X	
Lab Equipment							X			
Other Recurrent	X	X	X	X	X	X	X	X	X	X
Other Capital	X	X	X	X	X	X	X	X	X	X

Annex 3: Present value of annuity factors: $1/(1+i)^t$

(adapted from ICAN Methods Guide)

Labor is an estimate of salary, benefits, and allowances x % of time allocated to the strategy or service delivery or specific delivery activity. You can estimate the monthly and daily salaries by dividing yearly salaries by (52 weeks/year minus holiday/vacation time, public holidays, and average sick days), multiplied by 5 days/week to get the daily salary. The hourly rate is the daily rate divided by the standard number of working hours per day (usually 8).

- **Example:**
  - Annual salary including benefits and allowances = $21,000
  - Average 3 weeks holiday, 10 public holidays, and 5 sick days
  - 52 weeks – 3 – 2 – 1 = 46 weeks = 230 days
  - Daily rate = $21,000/230 = $91.30
  - Hourly rate = $91.30/8 = $11.41

Focus on staff time of persons involved with vaccine-related tasks, which may include administering vaccines, record-keeping, collecting vaccines, outreach, supervision, management of vaccination services, or others.

There are a number of ways to measure staff time, each with strengths and drawbacks/challenges.

Method	Strengths	Drawbacks and challenges
Interviews with staff to determine how much time they spend on activities	• Relatively easy to collect using appropriate questions	• Subject to recall error • Responses are often based on the most recent period, which may not reflect average time spent • No “push-back” from time allocated to other health programs • Responses may/may not include time allocation for campaigns, immunization days/weeks, or other special events
Interviewing supervisors and managers about staff time	• Relatively easy to collect using appropriate questions • Supervisors may have a good idea of immunization staff time allocation	• Supervisors may NOT have a good idea of immunization staff time allocation • All the same drawbacks and challenges of interviews with staff
Observation and time and motion studies	• Higher level of accuracy	• A reasonable number of observations is required to arrive at a representative time and a typical day with no disruptions, thus may require more effort
Timesheets (kept by staff for a limited amount of time)	• Can produce valuable data if staff are willing to participate (not just timing data) when introduced early in the process	• May require some incentive to participate and validation of self-reported time • No point if the timesheets cannot be relied upon • Staff are often stretched as it is and may not want to participate
Campaign reports (for immunization weeks/days or campaigns funded by donors)	• Easy to access	• May only provide approximations

The recommended approach for pilot given time and budget constraints is to interview staff and supervisors and compare with timesheets and time and motion studies for a subsample of facilities to validate interview responses.

For actual data collection, given time and budget constraints, please decide based on the pilot results:

- If results from interviews, timesheets, and time and motion studies were similar, go with the easiest/cheapest (likely to be interviews).
- If results were widely different, try to assess which might be most accurate (likely time and motion, if you are confident in your execution) but still feasible.

Make sure to allocate 100% of staff time to activities. For example, if staff are on an outreach visit that takes the total day, even though there is a lot of downtime during the visit when no children are present, the entire day should be allocated to outreach service delivery. As another example, when staff wait for transport to fetch vaccines, you should allocate all time (including waiting) to vaccine collection. You should assume that inefficiency is built in (i.e., that most people will only spend 90% of the day actually working)—no adjustments are needed to account for this.

We will not be evaluating overtime of facility staff, except in rare cases when overtime is paid routinely in addition to regular salaries.

Support staff: Include all support staff (monitoring and evaluation personnel, data capturers, clinic supervisors, bookkeepers and administrators, drivers, and cleaners). The recommended tracing factor is immunization visits as a proportion of all clinic visits, except for data capture staff/monitoring and evaluation staff; the number of reported indicators could be used.

Volunteers: Include volunteers using the estimated market value of their time for immunization-related activities.

For all types of staff, only include human resources who were present during the period of analysis (i.e., vacant posts should be excluded).

Shared labor costs – best practices

1. Group discussions to review results

- May be useful to have immunization staff and supervisors to review results together at end of facility visit
- Find optimal time for a review meeting when the facility is less busy to maximize participation

2. Triangulation

- Compare time estimates per dose or visit with actual reported service volumes in facility immunization records to serve as a gut check
- Review results across facilities to check whether differences can be explained or suggest inaccuracy

Annex 4: Tracing factors

The purpose of this table is to outline preferred approaches for allocating shared costs to routine immunization in the first instance, and then allocating routine immunization cost to relevant functions/activities as outlined in the matrix for the Common Approach.

Line item	Expenditure item	Type of shared costs	Tracing factors: Total to immunization portion	Tracing factors: Immunization portion to activities
Staff time	Salaries of health and other staff	Allocation to routine immunization and then to activities	% of time	% of time
Other staff	Cost of community health workers (CHWs) and volunteers	Allocation to routine immunization and then to activities	% of time spent on immunization services as recorded during data collection	Allocate to the activities most relevant such as outreach or social mobilization or facility-based delivery based on interview results (% of time) supplemented with probing questions.
Vaccines	Cost of vaccines	Allocation between routine, facility-based vaccines and those given during outreach sessions	100% to immunization (make sure that doses given during campaigns or supplementary immunization activities are not included)	Facility statistics should help to allocate between doses given in the facility and during outreach sessions. If these are unavailable, then ask probing questions about approximately how many doses are given per outreach session to try to estimate the ratio.
Equipment	Annualized capital cost of equipment	Cold chain equipment: • Fridges could be allocated between routine and outreach • Small cold boxes/ carriers to outreach • Incinerator • Office equipment to wide range of possible activities	• % used for immunization (proportion of space use for routine) • In large facilities, vaccines may take up only a small proportion of total waste • Focus on equipment that is used for routine immunization, such as a computer used by the EPI manager	• % of doses for outreach/ facility-based • Allocation of small cold boxes/carriers to outreach based on the % of time in the week spent on outreach • Allocate between routine/ outreach on the basis of the ratio of doses or similar ratio • Allocate office equipment/ furniture to program management activity
Vehicles	Annualized capital cost of vehicles	• Vehicles at facility to mainly outreach and vaccine collection • At higher levels to management/ surveillance	% used for immunization based on vehicle logbook data= share of kms travelled for routine immunization compared to other health activities. In the absence of this information, then use the ratio of routine doses/ (total outpatient visits and inpatient admissions) using the factors estimated in the attached Excel file.	If the vehicle logbook contains details on the purpose of the trip, then use these details to allocate. Otherwise, estimate ratios from the number of trips and kms per trips over total kms traveled for activities related to supervision, management, and vaccine collection.
Building	Building or rental value	• Health facility • Health posts/other fixed sites	Number of square meters for the area relevant for routine immunization (where vaccines are administered, stored), or % of facility footprint allocated to immunization	• Allocate to facility-based service delivery at the facility level; but allocate to program management at the management level • Allocate 100% of health posts to outreach (Zambia case)

Annex 4: Tracing Factors, continued

Line item	Expenditure item	Type of shared costs	Tracing factors: Total to immunization portion	Tracing factors: Immunization portion to activities
Transport	Specific questions for transport for: • Outreach • Vaccine collection • Supervision • Meetings (social mobilization) • Other	• All allocated directly to correct activity • If something crops up under Other, we will have to choose the most likely fit (e.g., surveillance)	• 100% to immunization, unless trips are multi-purpose. Ask about share for routine • If unable to allocate directly, use the same ratios as generated for vehicles	• 100% to best fit activity • Problems may arise where one trip is used to do a number of activities (e.g., outreach and supervision) • For a trip that involved more than one purpose, allocate evenly across purposes
Training	All training-related costs including per diems, printing, and travel allowances		100% to immunization	100% to training
Social mobilization		Mainly per diems. Any transport costs to be recorded under transport tab	• 100% to immunization • If the activity covers a number of different health topics (i.e., including non-immunization health topics), allocate evenly across the various topics and absorb only the immunization portion.	100% to social mobilization
Cold chain operating and maintenance	Various fuels and maintenance	Energy consumption for the facility needs to be allocated to routine immunization	• Maintenance share for immunization asked directly in the questionnaire • Cold chain energy costs best based on kw/hour and the unit cost/kw hour	• 100% to cold chain maintenance • Estimated cold chain energy cost should not be double-counted in Overhead cost below
Overhead costs	Expenditures for heating, phone, internet, electricity, and stationery	Need to allocate first to routine immunization and then to activities	Total routine doses/number of outpatient visits	Allocate all to program management (costs should be net of cold chain energy)
Waste disposal	Running costs of incinerator	Important to estimate additional cost for new vaccines; however, it might be challenging to get at all of these inputs	• Apportion to the routine immunization program based on a share of the vaccine load to total load in the incinerator • Energy costs also must be taken into account	Allocate to facility-based and outreach based on share of doses • (This assumes that waste from outreach is returned for incineration. If not, then allocate 100% to facility-based immunization)
Health committee meetings and stakeholder groups	Mainly qualitative questions	The value of community participant time should be costed	Number of routine doses/ total outpatient visits	100% to social mobilization

Annex 5: Annualization factors $\frac{(1+r)^n-1}{r \times (1+r)^n}$

r (discount rate)

n (useful life)	1%	2%	3%	4%	5%	6%	7%	8%	9%	10%
1	0.9901	0.9804	0.9709	0.9615	0.9524	0.9434	0.9346	0.9259	0.9174	0.9091
2	1.9704	1.9416	1.9135	1.8861	1.8594	1.8334	1.8080	1.7833	1.7591	1.7355
3	2.9410	2.8839	2.8286	2.7751	2.7232	2.6730	2.6243	2.5771	2.5313	2.4869
4	3.9020	3.8077	3.7171	3.6299	3.5460	3.4651	3.3872	3.3121	3.2397	3.1699
5	4.8534	4.7135	4.5797	4.4518	4.3295	4.2124	4.1002	3.9927	3.8897	3.7908
6	5.7955	5.6014	5.4172	5.2421	5.0757	4.9173	4.7665	4.6229	4.4859	4.3553
7	6.7282	6.4720	6.2303	6.0021	5.7864	5.5824	5.3893	5.2064	5.0330	4.8684
8	7.6517	7.3255	7.0197	6.7327	6.4632	6.2098	5.9713	5.7466	5.5348	5.3349
9	8.5660	8.1622	7.7861	7.4353	7.1078	6.8017	6.5152	6.2469	5.9952	5.7590
10	9.4713	8.9826	8.5302	8.1109	7.7217	7.3601	7.0236	6.7101	6.4177	6.1446
11	10.3676	9.7868	9.2526	8.7605	8.3064	7.8869	7.4987	7.1390	6.8052	6.4951
12	11.2551	10.5753	9.9540	9.3851	8.8633	8.3838	7.9427	7.5361	7.1607	6.8137
13	12.1337	11.3484	10.6350	9.9856	9.3936	8.8527	8.3577	7.9038	7.4869	7.1034
14	13.0037	12.1062	11.2961	10.5631	9.8986	9.2950	8.7455	8.2442	7.7862	7.3667
15	13.8651	12.8493	11.9379	11.1184	10.3797	9.7122	9.1079	8.5595	8.0607	7.6061
16	14.7179	13.5777	12.5611	11.6523	10.8378	10.1059	9.4466	8.8514	8.3126	7.8237
17	15.5623	14.2919	13.1661	12.1657	11.2741	10.4773	9.7632	9.1216	8.5436	8.0216
18	16.3983	14.9920	13.7535	12.6593	11.6896	10.8276	10.0591	9.3719	8.7556	8.2014
19	17.2260	15.6785	14.3238	13.1339	12.0853	11.1581	10.3356	9.6036	8.9501	8.3649
20	18.0456	16.3514	14.8775	13.5903	12.4622	11.4699	10.5940	9.8181	9.1285	8.5136
21	18.8570	17.0112	15.4150	14.0292	12.8212	11.7641	10.8355	10.0168	9.2922	8.6487
22	19.6604	17.6580	15.9369	14.4511	13.1630	12.0416	11.0612	10.2007	9.4424	8.7715
23	20.4558	18.2922	16.4436	14.8568	13.4886	12.3034	11.2722	10.3711	9.5802	8.8832
24	21.2434	18.9139	16.9355	15.2470	13.7986	12.5504	11.4693	10.5288	9.7066	8.9847
25	22.0232	19.5235	17.4131	15.6221	14.0939	12.7834	11.6536	10.6748	9.8226	9.0770
30	25.8077	22.3965	19.6004	17.2920	15.3725	13.7648	12.4090	11.2578	10.2737	9.4269
40	32.8347	27.3555	23.1148	19.7928	17.1591	15.0463	13.3317	11.9246	10.7574	9.7791
50	39.1961	31.4236	25.7298	21.4822	18.2559	15.7619	13.8007	12.2335	10.9617	9.9148

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