



## Section 4: Developing Your Evaluation Plan

This section describes ten steps for developing an evaluation plan:

1. Defining evaluation goals and objectives
2. Identifying potential evaluation measures
3. Designing the evaluation study
4. Identifying data sources
5. Identifying candidate evaluation measures
6. Considering the impact of data collection strategy on relative cost and feasibility;
7. Developing your evaluation plan based on selected measures
8. Completing your evaluation plan
9. Reviewing your evaluation budget
10. Finalizing your evaluation plan.



Each step is described in detail in the following subsections.

### Defining Evaluation Goals and Objectives

This subsection describes the method to define proposed evaluation goals and objectives by—

- Discussing evaluation goals with your governing group
- Operationalizing the goals with evaluation objectives
- Considering the need for institutional review board (IRB) review of your evaluation

In Section 2 of this guide you determined the goals and objectives of your project. The next step is to determine how your evaluation can help demonstrate the attainment of these goals and objectives. Evaluation goals may range from mitigating risks to proving efficacy and benefits. (See Figure 4-1 for examples.) The goals will vary depending upon your stakeholders and funding sources. It is recommended that you seek guidance from your HIE project governance group when selecting the goals. Discussions with the governance group provide an opportunity to articulate the potential goals of your evaluation, and to define goals as you draft the evaluation plan.

#### Figure 4-1. Examples of HIE evaluation goals

To demonstrate improvement in care delivery for the senior population as set forth in the HIE project goals.

To continuously monitor early user reactions during the implementation process to minimize risks of poor adoption.



Once you have established your evaluation goals, operationalize what you want to accomplish by defining your objectives (measurable steps and deadlines). To begin developing a set of evaluation objectives that assess goal attainment, consider the following:

- How would you break your goals down into measurable steps (objectives)?
- How would you prioritize those steps?
- If all of these objectives were met, would you attain your goal(s)?

Figure 4-2 offers examples of objectives that could correspond to the goals in Figure 4-1.

Next, it is important to determine whether your evaluation is considered research and involves human subjects. An IRB and its representatives may be helpful in determining whether your project falls into either of these two categories.

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102[d]).<sup>23</sup> A human subject is defined as a “living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) obtains identifiable private information” (45CFR46.102[f]).<sup>23</sup>

Factors that may influence whether your project requires IRB review include project type and funding source (e.g., the study may receive support for operations activities under contract with a Federal agency); funding source requirements for IRB review (common for grants); whether the study’s purpose will involve contributing to generalizable knowledge by expanding the knowledge base of a scientific discipline (or other scholarly field of study); whether you or others plan to publish findings (many journals will not publish studies without IRB approval or exemption); and your own organization’s requirements.

Your evaluation team should not make the determination as to whether your evaluation requires IRB review. If your evaluation involves any data collection such as surveys, focus groups, and interviews, or possible access to data that include identifiers of persons, it is best to contact your organization’s IRB to see if the evaluation study description and protocols should be submitted to the IRB for determination of whether full IRB review is required. The organization funding your evaluation also may be able to advise you. If your organization does not have an IRB or a relationship with one, you should check with your organization’s legal counsel or privacy office.

**Figure 4-2. Examples of HIE evaluation objectives**

Enable providers to access glycosylated hemoglobin (HbA1c) test result history in at least 85 percent of the senior diabetic population by the end of the first year after implementation.

Conduct at least three user satisfaction surveys during the implementation period, and present summarized reports to implementers, trainers, and stakeholder representatives.



## Identifying Potential Evaluation Measures

This subsection discusses the identification of potential evaluation measures by (1) performing a literature review and (2) conducting a brainstorming session.

The next step in developing your evaluation plan is to write down evaluation measures that you could use in assessing your HIE project. You can engage in brainstorming sessions with your team and conduct literature reviews to identify useful measures.

### Literature Review

A literature review involves identifying relevant materials in peer-reviewed or gray literature (information that falls outside the mainstream of published journal and monograph literature), reading those materials, and analyzing the information provided. To conduct a literature review, the research methodologist in your team can work with a librarian to develop search parameters. If he or she has the experience and expertise, the research methodologist can also develop procedures for conducting the review, including what terms to use, which sources to search, how to select articles for inclusion, how to summarize the results, and how to use the results in your evaluation. The HIE field is relatively young and the body of research is small and growing, so it may be helpful to start with more recent articles and technical reports that include a review of HIE evaluation studies or frameworks. See Appendix B for a sample literature search strategy.

### Brainstorming

Brainstorming is a group collaboration designed to generate ideas using an open and receptive environment for group discussion. Brainstorming guidelines include encouragement of all ideas and suggestions, withholding and postponing any judgment of ideas, and building on ideas put forward by others.<sup>24</sup> It is important that key stakeholders and all members of the evaluation team participate in a focused brainstorming session, with ample time set aside for discussion.

For effective brainstorming, you should outline the purpose and goals of the session, which are to identify and prioritize evaluation measures. Depending on the stage of your HIE project, measures may include assessments of process, clinical outcomes, patient and provider attitudes and adoption, efficiencies, and workflow impact. Brainstorming discussions for identifying evaluation measures may include many aspects of the project, such as whether the “groundwork” for the project was successfully completed. This groundwork may include developing a governance structure, coming to a consensus on how to handle privacy and security issues, or developing a sustainability model. For example, was the HIE organization able to agree on a minimum data set to exchange? Was the organization able to deliver results to participating organizations at an agreed-upon rate of exchange? See Appendix C for additional information on brainstorming.

During brainstorming, consider quantitative and qualitative approaches, keeping in mind that it is premature to discuss specifics, such as how the data will be collected, statistics, sample size, and logistics around data collection. It is helpful to discuss everything that is considered





important to measure, without regard to feasibility, in order to generate as many ideas as possible. Capture all ideas, preferably by writing them down in a prominent place.<sup>24</sup>

Collate the ideas and distribute them promptly to the group. Emphasize that anyone who has any additional thoughts or ideas should share them with you or the group.<sup>24</sup> The results of the brainstorming session and literature review, by identifying potential evaluation measures, will guide the subsequent steps.

## Designing the Evaluation Study

This subsection describes evaluation design considerations, including—

- Formative and summative evaluations
- Prospective and retrospective evaluation designs
- Qualitative versus quantitative methodologies

Now that you have identified potential measures for your evaluation, the next step is to design the evaluation to be able to collect and analyze data in order to produce each measure. The considerations discussed below will serve as a foundation for your study design.

### Types of Evaluation

Evaluations are commonly conceptualized as either formative or summative, depending on the purpose of the evaluation:

1. **Formative evaluation** is an iterative assessment of a project's implementation and how well it meets defined benchmarks.<sup>25</sup> Formative evaluations strengthen or improve the program being evaluated—they help inform it by examining the delivery of the program or technology; the quality of its implementation; and the assessment of the organizational context, personnel, procedures, and inputs.<sup>15,26</sup>

Within the category of formative evaluation, there are two subtypes that are most relevant to HIE project evaluations—implementation evaluations and process evaluations:

**Implementation evaluation** monitors the fidelity of the program or technology delivery—the extent to which it was implemented or delivered as intended. An implementation evaluation enhances the likelihood of success by providing indications of what happened and why. This type of evaluation focuses on information that will help document a project's evolution, and continually assess whether modifications and changes in the evolution are connected to goals, relevant contextual factors, and the needs of the target population.<sup>27</sup> Section 6 includes several examples of HIE project implementation measures.

**Process evaluation** investigates the process of delivering the program or technology, including alternative delivery procedures. A process evaluation focuses on describing the course and activities of a program. Section 6 includes many examples of HIE project process measures.<sup>27</sup>



2. **Summative evaluation** examines the effects or outcomes of some program and technology such as implementation of an HIE project. A summative evaluation describes what happens subsequent to delivery of the program or technology, assesses whether the object can be said to have caused the outcome, determines the overall impact of the causal or contributory factors (e.g., introduction of HIE, clinician training) beyond the immediate target outcomes, and estimates the relative costs associated with the object.<sup>26</sup> Three summative evaluation types may be applied to HIE project evaluation:

**Outcome evaluation** attempts to attribute changes in high-level outcomes (intended and unintended, positive and negative) to a particular program or intervention. These outcomes include clinical changes, such as changes in receiving preventive care or chronic care management; health care utilization, such as hospitalizations and laboratory work; and workflow changes, such as time spent accessing patient information.

**Impact evaluation** is broader and assesses the overall or net effects—intended or unintended—of the program or technology as a whole.

**Cost-effectiveness and cost-benefit analysis** addresses questions of efficiency by standardizing outcomes in terms of their dollar costs and values.

Section 6 includes examples of clinical measures and other summative evaluation measures.

## Determining Research Design

Your evaluation may be a formative as well as a summative evaluation. In fact, both approaches can study the same types of outcomes, but for different purposes. Both types of evaluation can serve important roles during each phase of an HIE project. An example of an evaluation framework that was developed to formatively evaluate an HIE organization as it matured had five evaluation dimensions: implementation, technology choices, policy issues, data to be shared, and value derived from the data. The formative evaluation questions addressed matters such as how national policies affected the local HIE project, what technology choices were made, what technology and policy barriers were encountered and how they were overcome, the amount of data exchanged, and the completeness and accuracy of the data.<sup>15</sup>

HIE projects involve many organizations, stakeholders, and other individuals across implementation phases. This adds to the complexity of conducting an effective evaluation. Because of this complexity, and because many HIE organizations are still in early phases of implementation and not fully operational, experts have recommended formative evaluation of HIE projects, which allows evaluators to continually use and apply what is learned during the evaluation.<sup>28</sup> Early formative evaluation activities increase the likelihood that implementation activities are linked to the intended outcomes, and help staff and stakeholders to stay focused on the expected effects of the HIE project, such as improved health care quality and efficiency.

One formative evaluation approach is the “smallball” model that is based on established IT implementation phases, with appropriate evaluation dimensions linked to each phase so as to incrementally capture and report data relevant to the impact and value of a technology such as HIE.<sup>29</sup>



In later phases of HIE project maturity, an effective summative outcome evaluation is critical to achieve the following:

- Demonstrate the effectiveness of the HIE project and make a case for its continued funding, or for expansion/replication.
- Answer questions about what works, for whom, and in what circumstances, and how to improve program delivery and services.
- Determine which implementation activities and contextual factors support or hinder outcomes and overall program effectiveness.<sup>21</sup>

## Evaluation Design

Other types of study design may be used in your evaluation. Evaluations that use an experimental design can be conducted (1) *prospectively*—looking forward to collect and analyze new data as they are collected, or (2) *retrospectively*—looking back to collect and analyze data from the past. These designs apply primarily to summative evaluations. Many evaluations do not use experimental designs, such as the ones discussed previously in this subsection.

The following discussion is not meant to be a substitute for hands-on guidance from a trained research methodologist, but rather to provide a high-level overview of potential prospective and retrospective evaluation methods and approaches.

**Prospective studies** ask a question and look forward. The studies are designed before any information is collected. Study subjects are identified and followed forward to see if the outcome of interest occurs. This outcome is assessed relative to the intervention factor (HIE project).

Randomized controlled trials, which are considered the gold standard of study design, are prospective studies. They can provide evidence of cause-and-effect relationships and can support changes in clinical practice or workplace interventions. In a randomized controlled trial, subjects are randomly assigned to receive the intervention or control treatment, and outcomes are evaluated after the intervention period. The control group receives standard care, no intervention, or a placebo.<sup>30</sup> In an HIE project, the researchers would randomly assign the patients or health care settings into two groups: one that participates in the HIE project and the other that does not. These two groups would be followed over a period of time, and the outcomes of the groups would be compared.

**Retrospective studies** look backwards and examine factors in relation to an outcome that is established at the start of the study. These studies use information that is usually collected for reasons other than research, such as administrative data and medical records. Therefore, the outcome of interest will already have occurred (or not) by the time the study is started.<sup>30</sup>

For example, researchers might turn to hospital administrative data. They might retrieve hospital admission data for patients seen in the emergency department, for hospitals that used the HIE system and those that did not, in order to look for associations.







Case-control studies are considered to be the highest quality of retrospective studies, because they seek to approximate a control or comparison group. Depending on the study design, a retrospective study may include making inferences about outcomes in groups that have been exposed to an intervention (e.g., use of an HIE system for a given period of time) compared with similar groups that were not exposed to the intervention during the same time period. A retrospective study may also include reviews of paper or electronic health record (EHR) system data.

Section 4, “Considering the Impact of Data Collection Strategies on Relative Cost and Feasibility,” discusses data collection strategies and provides more information, considerations, and resources for using retrospective and prospective study designs, such as those that use control groups. Manual record review and data mining of administrative data are examples of data collection methods that might be used for both types of study designs. Surveys are another data collection method that can be used for both types of studies.

Table 4-1 below lists typical study designs and data collection methods for prospective and retrospective studies. More examples and resources are provided later in this section.

**TABLE 4-1. COMMONLY USED STUDY DESIGNS AND DATA COLLECTION METHODS FOR PROSPECTIVE AND RETROSPECTIVE STUDIES**

|   | Prospective studies | Retrospective studies |
|---|---------------------|-----------------------|
| <b>Study Designs</b>                                      |                     |                       |
| Prospective Cohort Study                                  | ✓                   |                       |
| Case Series   |                     | ✓                     |
| Randomized Controlled Trial                               | ✓                   |                       |
| Retrospective Case-Control Study                          |                     | ✓                     |
| Pre-Post Study  | ✓                   | ✓                     |
| Meta-Analysis   | ✓                   | ✓                     |
| Non-Experimental Designs                                  | ✓                   |                       |
| <b>Data Collection Strategies</b>                         |                     |                       |
| Manual Medical Record Review                              | ✓                   | ✓                     |
| Data Mining of EHR Data                                   | ✓                   | ✓                     |
| Instrumentation of EHR System to Capture Clickstream Data | ✓                   | ✓                     |
| Surveys (Paper/Electronic)                                | ✓                   | ✓                     |
| Expert Review   | ✓                   | ✓                     |
| Phone Interview   | ✓                   | ✓                     |
| Focus Group   | ✓                   | ✓                     |
| Direct Observation and Field Notes                        | ✓                   |                       |



## Qualitative and Quantitative Methods and Data

Evaluation methods and the data they produce are grouped into two basic categories—quantitative and qualitative. In general, quantitative methods produce “hard numbers,” while qualitative methods capture more descriptive data. The method(s) you choose are determined by the purpose(s) of your evaluation and the resources you have to design and conduct it. It is widely recommended that evaluations combine quantitative and qualitative techniques (sometimes called “mixed method” evaluations) to produce a richer and more comprehensive understanding of a project.<sup>27, 31</sup>

Examples of quantitative data collection methods include administration of tests and questionnaires, including pre- and posttests; analysis of existing data sets (e.g., administrative data, medical records); nonparticipant structured observations; structured and formal interviews; experiments; survey research; and quasi-experiments. All of these methods yield data that can undergo statistical analyses. Examples of quantitative data often used for HIE project evaluation are number of laboratory reports exchanged, number of immunizations submitted, number of patients with data in the HIE system, and the number of providers with access to the HIE system. An example of a study that would use quantitative measures is a prospective study that compares these outcomes before and after the introduction of the HIE system, for persons exposed to the HIE system and for a control group of persons not exposed. More information on some of these quantitative data collection methods—record review, data mining, and surveys—is provided in Section 4, “Considering the Impact of Data Collection Strategies on Relative Cost and Feasibility.”

Examples of qualitative data collection methods include observations, unstructured and informal interviews, focus groups, field notes (informal observations about how a study is proceeding), and document and artifact collection. Examples of qualitative data are themes from interviews or focus groups; attitudes and opinions expressed during interviews; analyses of documents such as HIE organization governance plans, legal and partner agreements, HIE organization sustainability plans, and other plans and policies; training and meeting notes; and privacy and confidentiality policies. These documents can help in the assessment of HIE project maturity or implementation stage. Section 4, “Focus Group Planning and Execution,” provides additional information and resources for focus groups.

The use of only quantitative approaches for an HIE project evaluation will provide only a partial picture and can lead to conclusions about your HIE project that miss the larger picture. Therefore, qualitative approaches are often used to help interpret a quantitative outcome. Quantitative and qualitative data can effectively complement one another.

For example, in one practice the HIE system began delivering results electronically, which were then printed for providers. A quantitative satisfaction survey revealed that providers were unhappy with the system, but did not assess why they were unhappy. During a focus group, providers reported that the system affected their workflow because it printed one result per page along with some ancillary information, making it difficult to review results. These qualitative findings were then used to refocus the design of the intervention. Without the qualitative evaluation, the HIE project team would not have known about the difficulties users were having with the HIE system. Therefore, it is important to consider using both quantitative and qualitative methods as part of your evaluation.





**Figure 4-3. Example of a “lesson learned” from qualitative techniques**

You observe early on in the project that the electronic exchange of laboratory test orders between ambulatory practices and commercial laboratories is not meeting important milestones (e.g., 60% of all laboratory test orders will be transmitted electronically by 6 months post-implementation). You want to evaluate why the milestones are not being met and identify any barriers. You conduct in-person semistructured interviews with the stakeholders involved, and learn that representatives of several of the commercial laboratories were concerned about an increase in workload if they began accepting orders generated using different EHR systems. You report this finding to the design and implementation teams, and determine that the best course of action is to ask the State medical society to convene a joint meeting with the major EHR vendors and commercial laboratories so the parties can better understand each other’s requirements.

This approach is successful in helping the laboratories see that workload demands should decline, not increase, with electronic exchange. A key lesson learned is the need to consider and communicate in advance with key stakeholders about their concerns about HIE, such as impact on workload. A small pilot study of HIE impact on workflow of a commercial laboratory would have been helpful in understanding the impact before going live with all laboratories. Another lesson is to monitor use of the HIE system, and not assume that stakeholders will use the system once implemented.

Qualitative techniques such as field notes can help to identify and understand any unanticipated consequences (both positive and negative) of the HIE system’s implementation, as well as other factors that may influence the success of an HIE project. These can result in valuable lessons learned. Qualitative methods can help to identify negative consequences of implementation, such as disruption of workflow for providers and staff, which can help explain why users may not be using the HIE system. Evaluators may use field notes, for example, when observing clinician trainings around the HIE system, noting things such as how the presentation was received, what kinds of questions were asked, and if there was any active resistance to the HIE project.

This approach is successful in helping the laboratories see that workload demands should decline, not increase, with electronic exchange. A key lesson learned is the need to consider and communicate in advance with key stakeholders about their concerns about HIE, such as impact on workload. A small pilot study of HIE impact on workflow of a commercial laboratory would have been helpful in understanding the impact before going live with all laboratories. Another lesson is to monitor use of the HIE system, and not assume that stakeholders will use the system once implemented.

Qualitative techniques also can help monitor barriers and facilitators to the HIE project or evaluation, and any steps that were taken to overcome barriers. These techniques can yield important lessons learned. (See Figure 4-3 for an example.) Barriers may include organizational barriers, technology barriers, security and privacy barriers, financial barriers, legal barriers, and others. Qualitative methods can help to document effective ways to overcome barriers, such as strong leadership, strong clinical champions, high-quality training, strong support for early stages of implementation, and buy-in from users and other stakeholders.



Lastly, qualitative results, in the form of quotations or anecdotal stories, can provide immediate evidence of benefits to stakeholders long before long-term quantitative evaluations are completed.

## Identifying Data Sources

This subsection describes how to identify data sources by considering the following:

- Currently available data that could be used for each measure.
- Technology that can be leveraged to assist in the evaluation process.
- The type of data-sharing agreement that is appropriate for your evaluation

Identify the sources from which you will obtain data. Potential sources of data include the following:

1. Primary field-based data collection
2. Paper medical records
3. Paper or electronic logs (e.g., phone, fax, mail logs)
4. Electronic data repositories and EHR system databases
  - a. Laboratory system
  - b. Pharmacy system (including pharmacy logs)
  - c. Billing system
  - d. Registration system
  - e. Radiology information system
  - f. Pathology information system
  - g. Health information exchange system
  - h. Personal health record system
  - i. EHR data
  - j. Administrative systems
  - k. Disease registries
  - l. Prescription review databases
5. Real-time capture from medical devices (e.g., barcode readers)
6. Specific programs at participating institutions (e.g., hospital quality control program)
7. HIE server log files of transactions
8. Systems that track patients opting in and opting out of the HIE system
9. HIE master patient index of patients whose information can be exchanged



Once you have identified currently available data sources for the measures you have identified thus far, you should identify and document other measures that can be readily obtained from members of your HIE organization. You should also investigate what technology would be used by these sources in order to generate these measures (e.g., HIE vendor turning on system logging and generating log reports, data mining of EHR database files) and determine how technology can support your evaluation process.

### **HIE Organization Members as Sources for Measures**

It is likely that teams within your HIE organization's participating groups are already collecting data that might be useful to you. Reach out to these groups to learn what information they are collecting, and determine whether that information can be used as an evaluation measure. (See Figure 4-4 for an example.) Stakeholders in your HIE organization that may be able to assist you with measures may include the following:

- Clinicians
- Laboratory services
- Pharmacies
- Hospitals
- Payers
- Intermediaries
- Claims processors
- Public health departments

These and other HIE partners probably collect a tremendous amount of data for multiple purposes. Your HIE project's ability to re-use and re-purpose existing data may be an important value to your stakeholders, and a useful evaluation measure.

### **Identifying Data Sources From Participating Organizations**

Contact the participating organizations in your HIE organization to learn the reporting capabilities of their current software programs. There may be opportunities to leverage those reporting capabilities for your evaluations. For example, asking the following questions can identify potential opportunities to capitalize on data available from your HIE organization partners.

- Do your participating laboratories already monitor phone calls from clinicians requesting results?
- Are the participating pharmacies already evaluating customer satisfaction?
- Could your evaluation team work with another project team or participating organization that is abstracting medical records to gather additional information needed for your evaluation?





**Figure 4-4. Example of how to identify a data source for a measure from HIE project participants**

**Measure:** E-prescribing (electronic exchange of prescription information) will reduce the number of phone calls between prescribers and pharmacies to clarify prescriptions.

**Identifying existing data sources for this measure:** Your team contacts the participating pharmacies to ask about any reports generated on a routine basis and finds that all of the participating pharmacies actively monitor and document the number and types of phone calls they make to physicians to clarify information on prescriptions. You can add this measure to the evaluation plan to determine whether the HIE project has an impact on the number of clarifying phone calls between pharmacies and physicians.

### Ensure That Data-Sharing Agreements Support the Evaluation

The types of data-sharing agreements needed for an evaluation will vary based on the types of data being shared and the evaluator’s relationship to the HIE project. First, it is important to ensure that the health care organizations have approved the use of HIE data for evaluation. Language about the use of HIE data for evaluation may be found in data-sharing agreements (e.g., the Data Use and Reciprocal Support Agreement [DURSA]) or user participation agreements). These agreements should clearly define the purposes of the agreement and the permitted uses of the data. Commonly permitted uses related to evaluation include, but are not limited to, studies to assess HIE network activity, reduction of costs, improvement of health care operations, improvement of the quality and efficiency of health care, and the appropriate and secure exchange of electronic data in compliance with applicable laws. If the existing user participation agreements do not permit the use of data for evaluation purposes, you must not start your evaluation until proper legal authorization is obtained. Failure to do so can lead to suspension of evaluation efforts or substantial delays.



If the evaluation team will have access to data sources with sensitive information (e.g., identifiable information or budget data) and is not directly affiliated with the organization providing the data, additional data-sharing agreements that define the terms and conditions for data sharing may be needed. Consult your legal counsel or privacy office to determine the type of agreement that is appropriate for your evaluation. Possible options include a business associate agreement (BAA), data use agreement (DUA), or nondisclosure agreement (NDA), depending on the type of data being shared and the purpose of the data sharing.



## Prioritizing Candidate Evaluation Measures

This subsection describes how to narrow the list of candidate measures by—

- Ranking each measure based on feasibility and potential impact
- Understanding the relative importance of each measure to different stakeholders

You should evaluate each potential measure that you identified in Section 4, “Identifying Potential Evaluation Measures” to narrow down to a set of candidate measures before you assess their feasibility and relative cost. In this section, through brainstorming and literature reviews, you were instructed to cast a wide net and identify potentially useful measures without much constraint. In selecting the candidate measures from the collection of all potential measures, the first question is whether you expect your HIE project to impact the measures, and if so, how? You may find that this exercise eliminates some measures from your list because they will not be affected by your HIE project. You should now have a list of potential measures that will be affected by your HIE project.

The next step in developing your plan is to rank each potential measure in terms of feasibility and importance to your stakeholders. To do so, you may use the methods described below.

### 1-2-3 Ranking and Quadrant Analysis Method

This type of assessment includes the use of a simple scale to assign priorities to each measure along the dimensions of importance and feasibility. You then combine the two dimensions in a quadrant analysis.

#### Importance

The first step is to review the potential measures with your stakeholders to understand the relative importance of each measure to different stakeholders. HIE projects typically have a variety of stakeholders, across many types of facilities, and may have different goals and priorities. It is best to recognize this up front and maintain your impartiality as best as you can. If necessary, you can bring all the players to the table and together determine what is most important to the HIE organization as a whole.

Another approach to determining the importance of measures is to consider any requirements that your HIE organization has to meet. For instance, if an organization is required to be exchanging a given percentage of data by a particular date, this may be prioritized as a “very important” measure to evaluate.

The importance scale is defined as follows:

- 1 = Very important.** These measures are required for your HIE project, and are considered most important by your stakeholders.
- 2 = Moderately important.** These measures are required for your HIE project, or are considered important by most of your stakeholders.
- 3 = Not important.** These measures are not required by your HIE project, and are not considered important to most of your stakeholders.



## Feasibility

The next step is to determine which measures are feasible for you to evaluate. Be realistic about the resources available to you. Teams frequently are forced to abandon evaluation projects that are labor-intensive and expensive. Focus on what is achievable and what needs to be measured to determine whether your HIE project implementation has met its goals.

### Determine Sample Size for the Measure

The feasibility of measuring a specific outcome or process measure often depends on the minimal sample size you need. In a typical evaluation project, you will be interested in examining whether your HIE project has impacted a measure of interest. In general, if the measure is capturing rare or infrequent events, perhaps because HIE usage is low for certain types of users is low (e.g., if considering a measure related to HIE usage in an emergency department), you will need to make many observations in order to observe a sufficient number of events to draw meaningful conclusions. Also, if the impact of the HIE project is small, you will need to make more observations in order to say with confidence that any measured impact is truly due to the HIE project itself and not due to random chance.

You should become familiar with how to determine sample sizes, particularly if you have chosen to include quantitative measures in your HIE project evaluation. If your team does not possess the needed statistical expertise, you may want to acquire the help of a statistician to help you estimate the number of data points you will need for each outcome or process measure. Large sample size requirements might lead you to exclude certain measures from consideration. Appendix D offers an example to illustrate the importance of sample size.

The feasibility scale is defined as follows:

- 1 = Feasible.** These measures are readily available from your data sources, without significant additional work, and any sample size requirements can be met.
- 2 = Feasible with moderate effort.** The measures can be derived from your data sources with some data manipulation or data entry/data capture efforts, and any sample size requirements can be met.
- 3 = Not feasible.** These measures cannot be captured from your existing data sources, and sample size requirements cannot be met.

For example, you might want to know whether your implementation reduces adverse drug events. Your stakeholders may consider this measure very important, but if you have neither the funds nor the resources needed (e.g., staff time) for medical record abstraction, the evaluation for this measure will likely fail. Rate these types of measures as not feasible. Remember to focus on what can be achieved.

Once you have ranked measures on the 1-2-3 scale based on importance and feasibility, you can conduct a quadrant analysis. A quadrant analysis is a measure assessment that uses a simple numeric scale to assign priorities to each measure along two different dimensions. This method uses a table to visually present the ranking of each dimension as a way to group information and guide decisionmaking. You may use this technique to group measures in terms of their feasibility and importance using a quadrant analysis table like the one shown below (Table 4-2). Colors can be added to the table, often called heat maps, to provide visual cues for your team.





TABLE 4-2. QUADRANT ANALYSIS TABLE

|                  |                         | Feasibility scale |                                  |                 |
|------------------|-------------------------|-------------------|----------------------------------|-----------------|
|                  |                         | 1: Feasible       | 2: Feasible With Moderate Effort | 3: Not Feasible |
| Importance Scale | 1: Very Important       | (1)               | (2)                              |                 |
|                  | 2: Moderately Important | (3)               | (4)                              |                 |
|                  | 3: Not Important        | (5)               |                                  |                 |

Using the importance and feasibility ratings, place your measures into the cells identified in the table, and determine their overall ranking based on the number associated with the cell in which they fall. These rankings, or quadrant analysis values, are then used to rank the measures to identify your primary measures. For example, if you rated measure A as “very important” on the importance scale and “feasible” on the feasibility scale, you would place the measure in the box created by the intersection of the first row and first column. Measures falling into this box receive an overall rank or analysis value of 1. Likewise, if you rated measure B as “not important” on the importance scale and “feasible” on the feasibility scale, you would place the measure in the box created by the intersection of the third row and first column. Measures falling into this box receive an overall rank or quadrant analysis value of 5.

Those measures that fall within the heavily shaded zone (i.e., measures with a score of 1, considered very important and most feasible) are measures that you should include in your evaluation plan. Measures in the lightly shaded zones, with scores of 2 to 5, are measures that you can undertake based on their quadrant analysis scores. Finally, measures in the white zones of the table, with no numerical score, probably should not be included in your evaluation plan.

Using the results of the quadrant analysis, create a short list of four to five primary measures to evaluate in your HIE project evaluation plan. If you want to evaluate other measures and you believe that you will have the required resources available to you, list those as secondary measures.

## Considering the Impact of Data Collection Strategies on Relative Cost and Feasibility

This subsection describes how to refine the data collection strategy by—

- Determining whether it is feasible to collect data for a given measure
- Considering whether the selected data collection method and design are feasible with regard to time and expense



Now that you have chosen your primary measures, the next step is to consider data collection methods. In deciding whether it is feasible to collect data for a given measure, it is important to consider the cost of the methods required to collect the data, as well as any challenges involved. There are two general methodological approaches for evaluation research design—retrospective and prospective. Measures collected using these methods are either qualitative or quantitative. Both the methodological approach and the measure type factor into the feasibility of a given measure.

The discussion below describes commonly used study designs for qualitative and quantitative data collection, along with relative cost considerations, to provide you with strategies to address potential challenges. Determination of method feasibility may lead you to exclude some of the measures that you identified and ranked in the previous step.

### **Survey Instrument Development Cost Implications**

Surveys can provide both quantitative and qualitative data, and can be used for prospective study designs. For example, a survey can be used to assess clinicians' satisfaction and experience with HIE. Developing your own survey can be time-consuming. If you are conducting rigorous evaluations, you also will need to validate the survey, especially if it is scored, which can add additional time and expense.

### **Focus Group Planning and Execution**

Focus groups are a qualitative data collection method. Focus groups require planning, and the logistics can become complicated when busy participants are invited to attend. The methodology for data analysis from focus groups requires the expertise of a qualitative researcher to analyze free-text data. A well-designed focus group is much more than a group of individual interviews, and facilitating such a session requires considerable skill. Focus groups can yield rich data in a short time, but it is important to carefully select the right participants, encourage everyone to be heard, carefully steer the discussion so it stays on track, and focus on just a few main questions.<sup>28</sup>

### **Manual Medical Record Review**

Manual medical record review is usually a quantitative data collection method. This method can be time-consuming and expensive, depending on how many medical records need to be reviewed or how many data elements need to be abstracted from each record. Common difficulties with the use of medical record reviews include unintentional data omission, manual data entry errors, or accessing medical records that may be incomplete. In addition, reviewers can easily become fatigued from the tediousness of the work.

### **Data Mining**

Data mining, another quantitative technique, is “an iterative process of selecting, exploring and modeling large amounts of data to identify meaningful, logical patterns and relationships among key variables. Data mining is used to uncover trends, predict future events and assess the merits of various courses of action.”<sup>33</sup> You may need to have access to experienced programmers or statisticians to extract data, model and analyze patterns within a data set, and interpret the findings. However, identifying care patterns from clinical data warehouses or utilization patterns



from billing databases could give evaluators and stakeholders rich insights into the health care system and suggest critical quality improvement initiatives or business strategies.

## Other Study Designs

### Time and Motion Studies

Some prospective studies can be conducted in a fairly efficient and quick manner. For example, non-interventional studies that make use of well-established methods such as time and motion studies can be quickly conducted using research assistants or students.

### Randomized Controlled Trials

Other types of prospective studies, such as experimental studies (e.g., randomized controlled trials) and quasi-experimental studies are more complicated and expensive. Studies that are designed to make inferences based on causality require the use of statistical inferences, statistical induction, or inferential statistics procedures that can be used to draw conclusions from datasets. Although such study designs may provide the most accurate and valid data of all, they are also very expensive to undertake.

### Case-Control Designs

Other study designs (e.g., case-control studies) require the use of a group of subjects (e.g., cohort or control group) that is similar to those participating in an HIE project, in order to evaluate the outcome in question. Identifying cohorts or control groups can pose a challenge.

## Developing Your Evaluation Plan Based on Selected Measures

This subsection describes drafting and reviewing an evaluation plan and includes a measures review template.

Once you have considered the impact of study design, data sources, and data collection strategies on your evaluation, and made any needed adjustments to the measures you selected in Section 4, “Prioritizing Candidate Evaluation Measures” or to the methods to be used, you should have a final set of evaluation measures. You are then ready to begin drafting your evaluation plan. For each measure, document important information such as what evaluation goal each measure will address, how you will collect the data, and how you will analyze each of the final measures. Have your proposed methodology reviewed by the research methodological experts. For example, if your evaluation will include a quantitative study, you may want to have a statistician review your plan, as this may save you time later in your evaluation. In addition, you may want to test your proposed methods. For example, if you will use survey methods as part of your evaluation, you may want to conduct a small pilot test to ensure that the survey instrument you have developed is easily understood and can be used in accordance with your plan.

In developing your plan, you can use the following template (Table 4-3) to help you outline the details. Although this table has columns for four measures, your evaluation design might involve a smaller or larger number of measures.



TABLE 4-3. EVALUATION PLAN DETAILS

| Document for Each Measure  | Final Evaluation Measures |           |           |           |
|--|---------------------------|-----------|-----------|-----------|
|  | Measure 1                 | Measure 2 | Measure 3 | Measure 4 |
| Briefly describe the HIE project.  |                           |           |           |           |
| Describe the HIE intervention and the intended impact.   |                           |           |           |           |
| What questions do you want to ask to evaluate this impact (either positive or negative)?   |                           |           |           |           |
| What will you measure to answer these questions?   |                           |           |           |           |
| How will you collect the needed data?  |                           |           |           |           |
| How will you design your study?<br><br>For a quantitative study, you might consider what comparison group you will use. For a qualitative study, you might consider whether you will make observations or interview users.   |                           |           |           |           |
| Analysis:<br><br>• For quantitative methods: What types of statistical analysis will you perform on your data?<br><br>• For qualitative methods: What analysis will you conduct using qualitative data?  |                           |           |           |           |
| Sample size:<br><br>• For quantitative methods: Estimate the number of observations needed to demonstrate that the measure has changed statistically.<br><br>• For qualitative methods: Estimate the appropriate sample size needed to reach conclusions regarding this measure. |                           |           |           |           |
| How would the answers to these questions inform future decisionmaking about the HIE project and/or HIE system implementations?   |                           |           |           |           |
| What is the planned timeframe for evaluating this measure?   |                           |           |           |           |
| Responsibilities:<br><br>• Who will take the lead for the evaluation for this measure?<br><br>• Who will be responsible for data collection?<br><br>• Who will lead data analysis?<br><br>• Who will present the findings?<br><br>• Who will draft a summary of the findings?    |                           |           |           |           |



TABLE 4-3. EVALUATION PLAN DETAILS (CONTINUED)

| Document for Each Measure  | Final Evaluation Measures |           |           |           |
|--|---------------------------|-----------|-----------|-----------|
|  | Measure 1                 | Measure 2 | Measure 3 | Measure 4 |
| Estimate the cost for evaluating the measures. Take into consideration planning, meetings, travel, analysis, consultation time with a methodologist (e.g., statistician, qualitative researcher, survey methods expert), and time to prepare a final report or summary on your findings, if necessary. |                           |           |           |           |

## Completing Your Draft Evaluation Plan

This subsection provides a sample evaluation plan outline.

Based on your work to this point, you have everything you need to complete a draft evaluation plan for your HIE project. You are now ready to write your evaluation plan following the suggested outline below, with a quantitative and qualitative measure example. In addition to evaluation approaches, your plan should have some discussion of budget considerations that show you have considered costs and available staffing resources.

### Outline for Evaluation Plan

1. Short Description of the HIE Project
2. Goals and Objectives of the HIE Project
3. Questions To Be Answered by the Evaluation Effort
4. First Measure To Be Evaluated – Quantitative
  - a. Overview—General Considerations
  - b. Timeframe
  - c. Study Design/Comparison Group
  - d. Data Collection Plan (Including Power/Sample Size Calculation for Quantitative Measures)
  - e. Analysis Plan
5. Second Measure To Be Evaluated—Qualitative
  - a. Overview—General Considerations
  - b. Timeframe
  - c. Study Design
  - d. Data Collection Plan
  - e. Analysis Plan
6. Subsequent Measures To Be Evaluated in Same Format
7. Budget Considerations
8. Conclusion



## Checking Your Evaluation Budget

This subsection describes budgetary considerations, including—

- Ensuring that the evaluation can be completed within budget
- Determining potential ways to reduce costs

Prior to finalizing your evaluation plan, you should review the costs associated with implementing it as currently drafted. Your evaluation team needs to ensure that your planned evaluation can be conducted within your evaluation budget. Your review should focus on measures that could put your budget at risk due to the complexity and costs associated with the study design, data collection, and/or data analysis activities. By conducting this review, you should determine if there are ways to reduce the costs of including these measures in your evaluation plan. Below are some suggestions on how to review your budget prior to finalizing your evaluation plan.

### Review or Revise Your Quadrant Analysis

If it is clear that your budget is insufficient to conduct all evaluation activities for your planned measures, have your team reassess the importance and feasibility of these measures and develop a second quadrant analysis table (see Section 4, “Prioritizing Candidate Evaluation Measures” for original discussion). Criteria that could guide your reassessment are whether the proposed study design for a given measure is too expensive, as this may impact your team’s estimation as to whether it is feasible to evaluate as planned. Alternatively, the evaluation approach for a given measure may be expensive, but the measure is critical to understanding the impact of your HIE project, which might cause you to exclude several of the less important measures from the evaluation plan.

### Approaches for Reducing Budget Requirements

One approach you can use to maintain some measures that your team considers important in your evaluation plan is to change the study design that will be used to evaluate your HIE project’s impact on that measure. For example, instead of obtaining rigorous quantitative measures to evaluate “efficiency” by comparing “time on task” before and after implementation, you could instead conduct a survey of system users to obtain their feedback regarding how the HIE system has impacted efficiency in conducting their work.

## Finalizing Your Evaluation Plan

This subsection describes how to finalize the evaluation plan and share it with all key stakeholders.

At this point, you have reviewed the evaluation budget and completed the draft evaluation plan. Depending on the costs associated with implementing your study design, data collection, and data analyses activities, you may have revised the evaluation plan to accommodate your available evaluation budget. Before you finalize your evaluation plan and budget, you should review the evaluation again to ensure that it conveys the steps, insights, recommendations,





and measures that are important to the evaluation team, the HIE project, and the stakeholders. Update your evaluation plan to balance your needs and constraints. If appropriate, you may want to have your usability expert review the plan to ensure usability for the implementation team. You may also need to satisfy any formal review processes imposed by your HIE project, member organizations, and stakeholders, such as an oversight committee. Once you have completed all of these steps and finalized your evaluation plan, distribute the plan widely to ensure that you have informed all of the stakeholders and can maximize buy-in. By following the steps outlined in this guide, balancing your needs and constraints, and connecting with your stakeholders, you will have a strong foundation for a successful evaluation.

