4. Formative Evaluation

A. The Role of Evaluation in QUERI

In general, there is a lack of agreement about the differentiation or association between research and evaluation. While some define this relationship as evaluation research, others see the two terms as separate concepts with different purposes and techniques. The argument arises from the fundamentally different paradigms that guide these seemingly disparate activities: the research paradigm is one of hypothesis testing, while evaluation is geared toward improving rather than proving.

Paradigmatic differences notwithstanding, a combination of the terms is an accurate reflection of an important type of investigation that is conducted in QUERI. Within this context, traditional research methods provide the means to obtain credible summative information, while standard evaluation modes are used to elicit a better understanding of why interventions succeed or fail. The importance of this understanding becomes more self-evident the closer the research objective is to enabling system-wide change, especially in regard to evidence-based healthcare delivery.

More specifically, within QUERI, formative evaluation (FE), at times also referred to as process evaluation, is an important segment of quality improvement research and has been characterized by Stetler (Stetler, Legro et al., 2006) as "**a rigorous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts**." FE is oriented towards understanding the process rather than the outcomes of implementation, as is more typical in research-related efforts. However, FE is seldom an end in itself; on the contrary, its greatest value lies in the information it yields to understand study outcomes or summative evaluation.

B. The Need for FE in Implementation Research

FE allows you to understand the context in which implementation of a program or intervention may occur, as well as to assess program/implementation process as it is happening. This permits the capture of information on factors that shape (e.g., facilitate or impede) successful implementation in "real-time," and also can offer insight into strategies that could be used to amplify (in the case of facilitating factors) or mitigate (in the case of impeding factors) the implementation effort.

FE findings can be used to modify an intervention and/or the process by which the intervention is implemented. They allow for the identification and assessment of local factors that may not be generalizable to all facilities, but that nonetheless exert an important influence on the success of a given implementation effort. FEs also can help: avoid "implementation assessment failure" (erroneous study results because an intervention was not implemented as planned); avoid "explanation and outcome attribution failure" (failure to establish what was accomplished/not accomplished in implementation plan and factors that influenced implementation); and enhance understanding of study outcomes, which provides further support for study replication and further dissemination.

For more information on the benefits of utilizing formative evaluation please see Stetler, Legro et al., 2006) and Smith, Williams et al., 2008).

C. Purposes

FE is unique in that it occurs *during* the research project, not after. Consequently, results can be used to describe and inform the process. One use of FE is to identify parts of the process that need refinement to maximize the effect of the project. While FE can be used during the research project, the data may be analyzed in relation to summative findings (outcomes) to better interpret findings. What influenced the degree of success or failure? What was required to "make the change happen?" How did the stakeholders feel about the process?

Whereas the general purpose of FE is to prepare for and assess the process of implementation, the literature is replete with other identified purposes, including:

- Assessing whether a program or intervention addresses a significant need;
- Modifying a proposed program or intervention, as needed;
- Detecting and systematically documenting unanticipated events;
- Optimizing/controlling implementation to improve potential for success;
- Obtaining ongoing input for short-term adjustments;
- Documenting continual progress;
- Informing future similar implementation efforts, e.g., to other healthcare sites or to a larger system;

• Understanding the extent/dose, consistency, usefulness, context, and quality of an intervention;
• Assisting interpretation of program outcomes or worth; and
• Fostering an understanding of the causal events leading to change and the specific components of the intervention that most influenced it.

D. Data Collection Methodologies Utilized in FE

a. Quantitative

Quantitative assessments can be used to collect data regarding a broader group of participants or stakeholders (e.g., frontline providers or other staff). In many cases, the participants or stakeholders targeted are the individuals who will be using the intervention in their daily practice.

Quantitative assessments may include, but are not limited to:

- Structured surveys and tools that assess organizational culture, readiness to change (i.e., Organizational Readiness to Change Assessment–ORCA) (Helfrich, Li et al., 2009), and provider receptivity to evidence-based practices (EBPs). (See Tools and Toolkits section)
- Intervention fidelity measures offer information on the extent to which elements of the intervention are implemented in the precise way in which they are meant to be implemented. For example, an intervention may include a patient assessment and recording that patient assessment in the medical record. The completeness of the patient assessment and the way in which the assessment is recorded in the patient medical record offer potential areas where a fidelity measure might be helpful.

b. Qualitative

Qualitative assessments can offer a "deeper-dive" with a smaller group of individuals to provide specific information about barriers and facilitators, as well as strategies and best practices for utilizing facilitators and overcoming barriers.

The best way to capture this data depends on the perspective(s) you are interested in exploring. Qualitative assessments may include, but are not limited to:

- Semi-structured or open-ended interviews may be used in cases where there is a smaller group of clinical stakeholders whose individual perspectives are needed.
- Focus groups may be used in cases where you are interested in exploring group perspectives and team dynamics.

- Direct observation of clinical structure and process during site visits may provide additional insight into processes/structures that may facilitate or hinder implementation.

Of course, in many cases using a solely qualitative or quantitative assessment will not be sufficient to meet the needs of a FE. For this reason, many implementation projects also take advantage of mixed-method approaches to FE, in which multiple data collection strategies from both the quantitative and qualitative paradigms are utilized. Drawing on both quantitative and qualitative approaches supports the gathering of diverse data that can yield robust FE findings to inform a given implementation effort.

For more information on mixed methods, please refer to Creswell J., 2007) and Greene, 2007).

c. Implementation as the dependent variable

In the realm of FE, the extent to which a practice/intervention has been assimilated into an organization is what is being measured. The extent of assimilation can be framed in three broad categories:

- Widespread avoidance/non-use,
- Meager or unenthusiastic use (compliant use), and
- Skilled, enthusiastic use (committed use) of the practice/intervention.

E. FE Research Process

FE, like most any research or evaluation endeavor, is characterized by a series of choices that must be made regarding what to study and how to most effectively study it. More than likely, resources (e.g., person power, finances, time) will limit the ability to assess and understand all of the factors that could be potentially relevant to a particular implementation effort. For this reason, the ability to make thoughtful choices about what the focus of a particular FE should be is critical.

An important first step involves identifying the aims of the FE. The aims identified will depend, in large part, on the overarching goals of the broader intervention effort, including what is already known about the intervention based on the published literature and existing evidence base. Any theoretical or conceptual framework that is informing the study also is critical to consider at this stage, as it will likely represent or account for factors that could influence implementation and by extension are potential targets for the FE.

Subsequently, researchers must:

- Identify the primary questions that derive from the FE aims,
- Develop instruments and methods to collect data,
- Conduct systematic data collection, and
- Analyze and report the data collected.

As noted above, both qualitative and quantitative methods are commonly used in FE. Qualitative approaches to data collection and analysis may uncover things that are working and not working well, and the extent to which program elements are being implemented as intended. Quantitative approaches to data collection and analysis may be used to gauge the extent to which specific changes are being realized. For example, in a project that involves having providers use computerized clinical reminders, the extent to which those reminders are accessed could be tracked to determine whether change occurs following targeted educational activities.

Ultimately, what is most important is identifying and effectively applying approaches to FE data collection and analysis that are appropriate to the FE and the broader intervention effort.

F. Challenges to Conducting FE

As a unique aspect of implementation research, FE also presents its own unique set of challenges. We categorize these challenges as follows: 1) data collection considerations; 2) participant considerations; 3) regulatory considerations. Each of these challenges are addressed briefly.

Challenges associated with data collection pertain primarily to selecting and effectively applying the appropriate approaches to data collection and analysis. A related issue pertains to issues of entrée (e.g., how can rapport be established with participants? How can support of leadership be gained?) within the settings where data for the FE will be collected.

Challenges associated with participant considerations generally pertain to the engagement of special or potentially vulnerable populations in research. For example, in many cases, unions and/or other employee organizations may have to be consulted before hospital staff can be approached and asked to participate in a research or evaluation effort.

Finally, challenges associated with regulatory considerations pertain to describing FE to organizational entities like research and development committees, institutional review boards, and other bodies that may not be familiar with its purposes and associated activities.

Researchers are encouraged to consult the resources referenced at the end of this section for more information on strategies that may be effective in addressing the challenges presented here.

G. Writing about FE

When writing about FE, researchers must remember the potentially different needs and perspectives of their audiences.

In the context of proposal development and grant writing, researchers need to thoroughly describe the elements of their FE, justify their appropriateness, and cogently articulate their plans for carrying out the FE. A compelling proposal will describe FE in terms of:

- Data collection techniques to be used and the ways that the data collection techniques relate (e.g., hopefully highlighting synergies);
- Settings and participants (i.e., subjects) from which data will be collected including sampling and recruitment plans;
- Envisioned processes and procedures for collecting data; and
- Plans for processing, organizing, and ultimately, analyzing the data that is collected.

The level of detail included to address these topics should be sufficient so that potential funding agencies and reviewers can gauge the appropriateness of the proposed FE, its feasibility, and the capability of the researcher or research team to conduct the proposed FE.

In the context of research oversight and institutional review board protocol writing, researchers need to similarly address the enumerated points above, providing sufficient detail to support the assessment of participant (i.e., subject) understanding of the research, the associated burdens for participants, potential risks to participants, and the management and security of the data that is collected.

Researchers interested in the intersection of FE and writing should turn to texts on writing successful grants and proposals, and to their local institutional review boards for exemplary protocols.

H. Web-based resources related to evaluation

US Government Resources

CDC Evaluation Working Group website (http://www.cdc.gov/eval/index.htm) offers information about the work group, a framework for program evaluation, and an extensive resource listing (http://www.cdc.gov/eval/resources/index.htm).

The **National Science Foundation**'s Directorate for Education and Human Resources, Division of Research, Evaluation and Communication has a web-published *User-Friendly Handbook for Mixed Method Evaluations* (http://www.nsf.gov/pubs/1997/nsf97153/start.htm). While the examples and content are related to education and learning evaluations, the handbook has information related to evaluation that can be applied to other settings. Other features include an example evaluation plan, tips for analyzing qualitative data, and example materials – such as example observation guides, interview guides, and so forth.

The **Bureau of Justice Assistance** is committed to the importance of program evaluation and to developing and enhancing evaluation capabilities at the state and local levels. Evaluation results provide policy makers and program managers with information for future program development and can be used to modify and improve existing programs. The Evaluation Website: https://www.bja.gov/evaluation/ is designed to provide State Administrative Agency staff, criminal justice planners, researchers and evaluators, as well as local practitioners with a variety of resources for evaluating criminal justice programs, and it has a page with links to a variety of evaluation resources.

Other Resources

The **American Evaluation Association** (http://www.eval.org) is an international professional association of evaluators devoted to the application and exploration of program evaluation, personnel evaluation, technology, and many other forms of evaluation. The site includes Guiding Principles for Evaluators, meetings and events related to evaluation, and links to resources for evaluators, including a listing of online texts and books with "how-tos" related to evaluation. (http://www.eval.org/publications/guidingprinciples.asp).

RE-AIM (http://www.re-aim.org) is a systematic way for researchers, practitioners, and policy decision-makers to evaluate health behavior interventions. It can be used to estimate the potential impact of interventions on public health. The group is affiliated with Kansas State University, and the Robert Wood Johnson Foundation has provided funding for the workgroup and for developing the website. RE-AIM stands for: Reach into the target population; Efficacy or effectiveness; Adoption by target settings or institutions; Implementation—consistency of delivery of intervention; and Maintenance of intervention effects in individuals and populations over time.

Resources for Methods in Evaluation and Social Research (http://gsociology.icaap.org/methods/) is a website supported by ICAAP (The International Consortium for the Advancement of Academic Publication) and lists free resources for methods in evaluation and social research. The focus is on "how-to" do evaluation research and the methods used: surveys, focus groups, sampling, interviews, and other methods. Most of these links are to resources that can be read online. A few, like the GAO books, are available for free (via U.S. mail), as well as being available for online reading.

The **Action Evaluation Research Institute** (http://ww35.aepro.org/) is a site with information on action research and evaluation.

FE Research Associates (FERA) (http://www.feraonline.com) is an evaluation group that has 25 years of experience with non-profit organizations. The site includes general information on FE, as well as links to other resources.