QUERI Implementation Guide

1. Applying Frameworks, Theories, and Models

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A. The Science of Implementation

Please see the following National Institutes of Health (NIH) website for a succinct definition of implementation science, as well as information on dissemination of implementation science:

http://www.fic.nih.gov/News/Events/implementation-science/Pages/faqs.aspx

Implementation is a "wickedly" complex sociological process (Conklin, 2005) that interacts significantly with multiple dimensions of the context in which it occurs. Implementation researchers seek to discover relationships between key constructs that underlie this process. Implementation science is a relatively new scientific field. In order for the science to advance and for findings to be generalizable, implementation science must incorporate the characteristics of good and/or rigorous science.

Underlying science is a theoretical understanding of the phenomena being studied. Characteristics of good science include (Sabatier, 2007):

1. Data collection and analysis methods should be presented publicly, and in a way that can be replicated by others.
2. Concepts and propositions should be logically consistent, clearly defined, and, in general, lead to empirically falsifiable hypotheses.
3. Propositions should be as general as possible and relevant uncertainties explicitly addressed.
4. Methods and concepts should intentionally be subjected to criticism and evaluation by subject area experts.

Underlying these imperatives is the need for coherent sets of propositions referred to as "theories."

The following are valuable resources that you may wish to review. They are related to the role and value of theory in implementation research and include cyberseminars, articles, and books.

- QUERI Enhancing Implementation Science Cyber Seminar 2012 (slides 8-18) http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/eis-060712.pdf

- QUERI CyberSeminar Series: *Implementation Research Theoretical Frameworks,* Cheryl Stetler & Laura Damschroder. April 2009

(http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/qi-040709.ppt , http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/qi-040709.cfm)

- Generalizing through consistent use of theory (or frameworks or models) may be more efficient than replicating specific studies in many different settings: (Foy, Ovretveit et al., 2011)
- Five roles of theory in designing and testing interventions: (Bartholomew and Mullen, 2011)
- Using theory to change individual level behavior: (French, Green et al., 2012)
- Role of theory in predicting effects of patient safety practices: (Foy, Ovretveit et al., 2011)
- Using theory to guide synthesis of findings across studies: (Damschroder, Aron et al., 2009; Gardner, Whittington et al., 2010)
- A widely cited, coherent, and accessible argument for the importance and role of theory in the scientific process, applied to the public policy domain (another highly complex scientific domain of inquiry), is offered in the book edited by Paul Sabatier: (Sabatier, 2007)
- Designing theoretically-informed implementation interventions (Improved Clinical Effectiveness through Behavioural Research, 2006). http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1436012/pdf/1748-5908-1-4.pdf
- Why you should not use theory—Designing theoretically-informed implementation interventions: Fine in theory, but evidence of effectiveness in practice is needed (Bhattacharyya, Reeves et al., 2006) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1436014/pdf/1748-5908-1-5.pdf

You also may want to browse the QUERI Implementation Cyberseminar series. Browsing this link will lead you to the audio and video links for each cyberseminar, in addition to the slides:

- http://www.hsrd.research.va.gov/cyberseminars/series.cfm#qi

B. Frameworks, Theories, and Models

In implementation science, three commonly used terms are *frameworks*, *theories*, and *models*; each comprising theoretical propositions at different levels of specificity. These terms tend to be used interchangeably in the published literature. This conundrum is complicated by the many layers and contexts in which these terms are applied. It is beyond the scope of this Guide to solve this inconsistency, but the use of terms within this section will be consistent. Elinor Ostrom provides a pragmatic and helpful conceptualization of these terms and illuminates helpful linkages between them in her chapter (Ostrom, 1999) depicted in the Figure below. Frameworks, theories, and models provide three levels of increasing specificity in theory-based research. It is important to clearly describe how theoretical constructs or techniques are defined and operationalized in your project so that others can replicate your results. Selection and use of implementation frameworks, models, or theories is critical not only for guiding data collection and analysis, but also for contributing to advancing the theory of implementation science.

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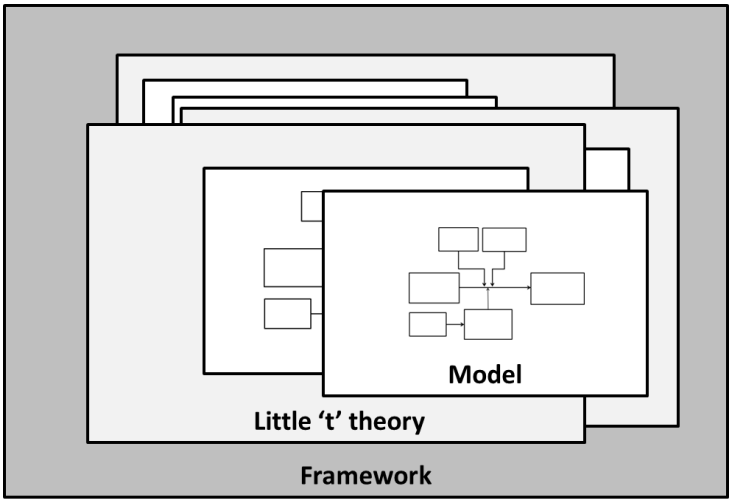
Theoretical or Conceptual Framework. A Framework provides a broad set of propositions that organize diagnostic (what is the nature of the phenomenon being studied, e.g., the context in which implementation happens) and/or prescriptive (e.g., how implementation is planned and carried out) inquiry. Frameworks provide "meta-theoretical" language that promotes comparison across theories. They attempt to identify a comprehensive set of elements that any theory related to the domain (e.g., implementation) would need to consider or include, and help to generate research questions that need to be addressed.



Theory. This is arguably the most contentious term. A "big T" Theory is one that embodies a well-substantiated explanation of some aspect of the natural world, based on a body of facts that have been repeatedly confirmed through observation and experiment. Such fact-supported theories are not unproven "guesses," but reliable accounts of the real world. The Theory of biological evolution is more than "just a theory." It provides an elegantly simple set of propositions that helps to explain the wide diversity in species over time and space. A "little t" theory is a middle-range set of context-independent propositions that specifies a denser and more logically coherent set of relationships; it may have values applied to some variables, and usually specifies how relationships vary depending on values of specific variables. Normalization Process Theory (NPT) is one of the few implementation theories explicitly characterized as a middle-range theory (May, Mair et al., 2009). Middle-range theories support more specific research questions and provide the basis for working assumptions and testable hypotheses. These theories provide assumptions that make it possible for a researcher to diagnose a phenomenon (e.g., implementation), explain its processes (e.g., the role and value of audit and feedback), and predict outcomes (e.g., more of the desired behavior). Multiple theories can be compatible with a single conceptual framework (see below).

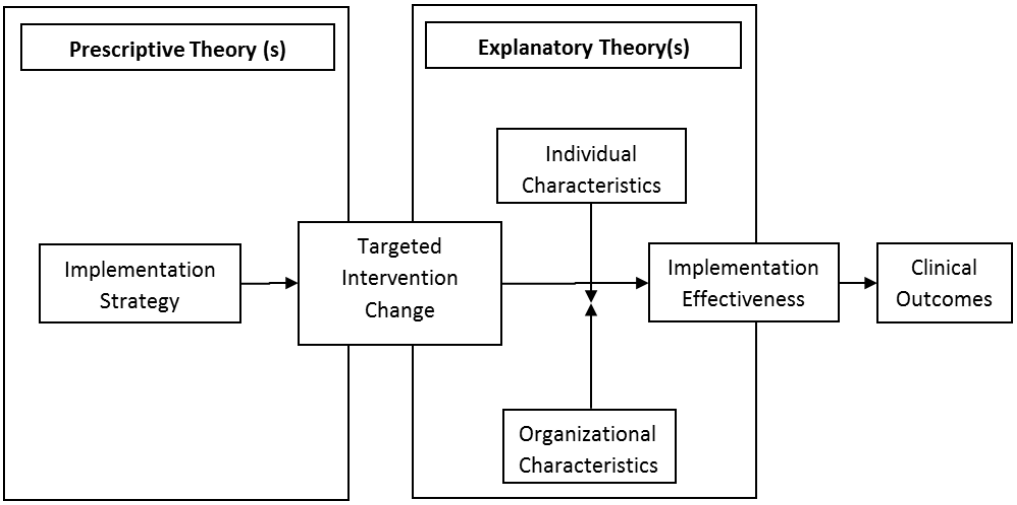
A model is a simplified representation of a complex reality. It is narrower in scope and specifies more precise assumptions; ideally, it is mathematical, though this is not necessarily the case in mixed-methods or qualitative research approaches. Models are context-specific. For example, Klein, Conn & Sorra developed and tested a model of implementation of a software system in a sample of manufacturers. A model was proposed, tested, and refined to include seven defined constructs (including expected outcomes) with defined relationships and statistical associations (Klein, Conn et al., 2001).

A conceptual framework may be broad or narrow. A broad framework might provide guidance in problem definition, purpose, literature review, methodology, data collection and analysis, while a

narrower framework might comprise a collection of constructs with or without relationships specified. For example, the Theoretical Domains Framework (TDF), developed by Susan Michie, provides a taxonomy of constructs known to influence individual-level behavior change (Michie, Johnston et al., 2005; Cane, O'Connor et al., 2012). Another example framework of constructs related to organization-level change is the Consolidated Framework for Implementation Research (CFIR) (Damschroder, Aron et al., 2009).

C. Types of Theories

Whether embodied in frameworks, middle-range theories, or models, theories may be explanatory or prescriptive (Grol, Bosch et al., 2007). *Explanatory* theories (also known as "impact," "descriptive" or "predictive") underpin hypotheses and assumptions about how implementation activities will facilitate a desired change, as well as identify potential facilitators and barriers for success. *Prescriptive* theories (also known as "process" or "planned action") guide how implementation should be planned, organized, and scheduled. The figure below provides a schematic for how these types of theories are related and can be used to guide, design, and test implementation interventions and strategies.

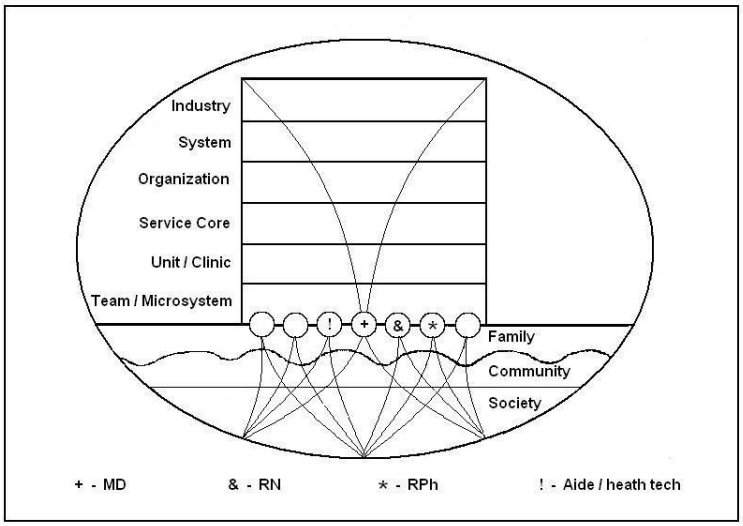


D . Levels and Theories

Another dimension by which to characterize theories is the level they are expected to operate. For example, they may be targeted at individual level change (e.g., Theory of Planned Behavior, an explanatory theory), at the collective or organizational level (e.g., Klein, Conn, and Sorra's theory and model described above), or at a systems or policy level (e.g., Rogers' Diffusion of Innovation Theory).

The figure below (based on a manuscript by Ferlie and Shortell, 2001) illustrates the way that clinics or microsystems, where individuals provide clinical care, are nested in larger organizational structures. The circle around the levels encloses the full social system, including both the levels from the provider side (top part of the diagram) and the levels within which patients are embedded (lower part). Patients and

providers meet and interact within smaller sub-units of an organization, with individual providers interacting with individual patients, as well as with each other. Theories apply at all the levels from both the provider and patient sides of the social system.



There is an expanding array of resources to help identify and select appropriate theories. A few are listed below:

- Individual-level change: Theory at a glance: http://www.cancer.gov/PDF/481f5d53-63df-41bc-bfaf-5aa48ee1da4d/TAAG3.pdf (US HHS-National Institutes of Health, 2005)
- Extensive narrative review and characterization of groundings for multiple levels (Tabak, Khoong et al., 2012)
- Comprehensive list of planned action, cognitive psychology, organizational, and quality improvement theories (see Section 4-Theories and Models of Knowledge to Action): http://www.cihr-irsc.gc.ca/e/40618.html#toc.

E. Applying Theory to Implementation Studies

Once appropriate frameworks, models, and/or theories are selected, this will guide the study's hypotheses generation, data collection, and data analysis (an example using the Normalization Process Model as a conceptual framework to inform qualitative data collection and analyses is provided by Macfarlane and O'Reilly-de Brun, 2012). As noted earlier, it is important to clearly describe how theoretical constructs or techniques are defined and operationalized in your project so that others can replicate your results. Selection and use of implementation frameworks, models, or theories is critical, not only for guiding data collection and analysis, but also for contributing to advancing the theory of implementation science. Doing so promotes systematic building of knowledge across studies and settings; see Gardner, Whittington et al., 2010; Damschroder and Hagedorn, 2011) for more on this topic and:

- General Framework for applying theory to implementation research projects: QUERI Enhancing Implementation Science CyberSeminar 2012 http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/eis-060712.pdf (see slides 33-54).

Another way of putting models and frameworks together with strategies and tools is described in Sales, Smith et al., 2006). In this paper, the authors describe how all of these interact to support planning and designing interventions, covered in more detail in the next section, and provide an example from Mental Health-QUERI http://www.queri.research.va.gov/mh/default.cfm .