Implementation Science: A Primer

Jennifer N. Hill, MA
Implementation Science Research Scientist, Patient-Centered Research
Evidera, a PPD business

Larissa Stassek, MPH
Senior Research Associate, Patient-Centered Research
Evidera, a PPD business

Emma Low, PhD
Senior Research Associate, Patient-Centered Research
Evidera, a PPD business

Sonal Mansukhani, PhD, MBA, BPharm
Former Senior Research Associate, Patient-Centered Research
Evidera a PPD business

Elizabeth Bacci, PhD
Senior Research Scientist, Patient-Centered Research
Evidera, a PPD business

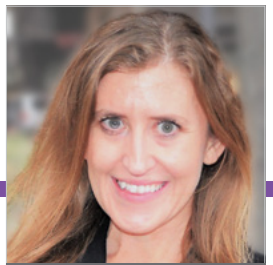
What is Implementation Science?

The hook that implementation scientists often use to drive home the importance of their work is that it takes an average of 17 years for evidence to be implemented into practice and only 14% of original research will reach patients.[1,2] But what is implementation science?

While there are several different definitions of implementation science, it is broadly defined as the scientific study of methods to promote systematic uptake of research findings and other evidence-based practices into routine practice, and hence, to improve the quality and effectiveness of health services and care.[3] It is also referred to as dissemination and implementation research or knowledge translation.[4]

Who are the stakeholders and what is the value proposition?

Everyone benefits from implementation science, including hospital administrators, providers and other healthcare professionals, pharmacists, health insurers, policymakers,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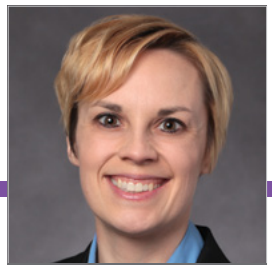

Elizabeth Bacci

regulators, pharmaceutical companies, caregivers, and, most importantly, patients.

The value of implementation science is becoming clearer as we deal with resource constraints. Utilization and evaluation of evidence-based strategies is essential to ensuring that investments in research are contributing to increased use of evidence while maximizing healthcare value and improving public health.[5,6,7]

Implementation Science Study Designs

What does an implementation science study look like?

Clinical research and implementation science share similarly rigorous approaches to scientific study. While clinical trials are largely focused on establishing effectiveness (tolerating), implementation science is focused on understanding and addressing barriers and facilitators to the uptake of evidence-based practices and interventions in the context in which they are being introduced.[8]

Implementation can be considered throughout the research pipeline, but implementation science studies may come after, or in combination with, effectiveness studies (See Figure 1). These combination studies are considered hybrid designs and there are three different types.[9] Hybrid designs are usually most appropriate for studies with minimal risk interventions (i.e., those with at least some evidence of effectiveness and strong face validity, to support use of the intervention in a new way such as setting, population, or method of delivery).[10]

- **Hybrid Type I** designs are primarily focused on testing and collecting evidence of the clinical intervention while gathering some data on implementation, such as acceptability or feasibility.
- **Hybrid Type II** designs typically place an equal emphasis on testing the clinical intervention and the implementation strategy.
- **Hybrid Type III** designs are typically focused on testing the implementation strategy, such as fidelity and adoption, while collecting some data on effectiveness.

Selecting a hybrid design depends on the level of evidence available on the intervention, the trial population and information available to support the implementation strategy. In an implementation trial, the scientists have an evidence-based intervention or practice that needs uptake, and the implementation expert is testing hypotheses regarding modified strategies for uptake in a new setting, as well as fidelity to those plans.[11]

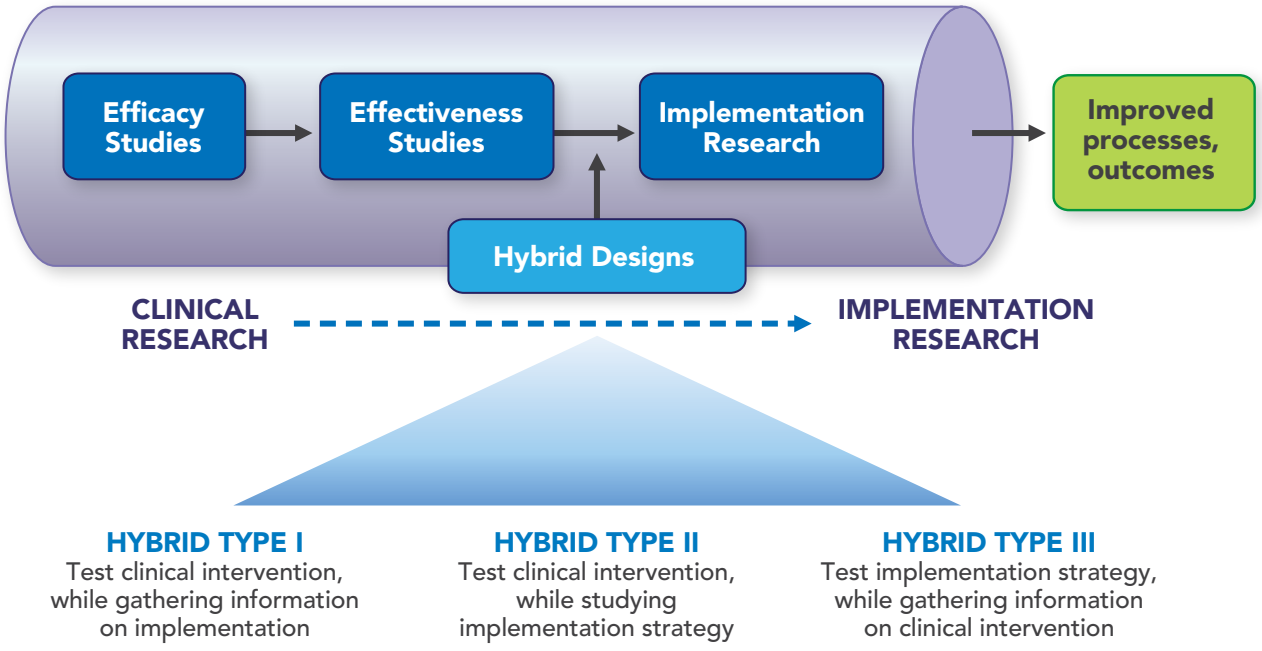
The Role of Continuous Quality Improvement

Continuous Quality Improvement (CQI) involves incremental and iterative assessments of improvement based on small and/or large changes to processes or delivery of evidence-based practices or interventions. Goals may include, but are not limited to:

- Improvement of processes (e.g., system or clinic levels)
- Individual-level outcomes (e.g., patient, clinician)
- Regulatory outcomes (e.g., improved safety)[13]

Designs or methodologies for these types of improvement studies may include Plan-Do-Study-Act (PDSA)[14] cycles or Six Sigma (which follows the problem-solving process

Figure 1. Research Pipeline and Hybrid Designs[8,12]



of Define, Measure, Analyze, Improve and Control [DMAIC]).[15] In CQI studies, improvements are made, the effect of those improvements are assessed, and the cycle is repeated until the desired outcome is achieved.[13] Data collection strategies used in this study are similar to program evaluation or implementation studies, but the cycle for analysis is typically much quicker as the feedback is fed directly back into the study and immediately acted upon.[16,17]

Methods and Data Collection

Implementation science studies can be retrospective (e.g., large scale comparative case studies or retrospective assessment of factors impacting implementation) or prospective in design, (e.g., collecting data during an implementation trial for the purposes of testing specific hypotheses) or may be a combination of both. These studies may also be guided by a framework or theory that informs the design and conduct of the study, the design of data collection instruments, and the reporting of study findings.

Implementation science studies typically employ a mix of methods such as use of quantitative data (e.g., administrative data or data produced from databases or systems, closed-ended survey questions or measures, source documents, etc.) and qualitative data (e.g., interviews or focus groups, open-ended survey questions, meeting notes/minutes, etc.). Due to the diverse nature of implementation study designs and objectives, a variety of analytic approaches may be used to assess data from these various sources, including traditional statistical and/or qualitative approaches, rapid analysis techniques,[16,17] or triangulation of the data from the various data sources.[18,19]

Data collected within an implementation study are often complex and may be collected at several different levels such as system level (governmental or policy), organizational level, site level (provider team or group level), and the patient level.[20] Outcomes may include, but are not limited to, knowledge or attitude change, behavior change, health-related outcomes or changes, process-related changes, and policy or system-related changes.

How does program evaluation fit in?

Program evaluation can be, and often is, considered under the umbrella of implementation science. Program evaluations may be designed retrospectively, prospectively, or both, and are usually guided by an evaluation framework. Program evaluations typically involve engaging stakeholders, sometimes from multiple groups, in describing and establishing the design of an evaluation. They include identifying key questions, indicators to measure key outcomes, and collection of data from many different sources such as existing data/documents or newly collected data from surveys, focus groups, or interviews. Program evaluation requires a synthesis of the findings while considering the needs of the stakeholder, as well as a review and agreement of the conclusions of the evaluation among the stakeholder groups. This review of conclusions is a critical step to ensure that the results of the evaluation will be used for program improvement. It is important that the results produced from a program evaluation tie back to the purposes identified early in the evaluation and that the results are provided in a way that can be used and shared broadly with other stakeholder groups.

Example Implementation Science Studies

The following sections provide examples of how to utilize implementation science to address different research needs.

DAILY ORAL (AT-HOME) TREATMENT VS. INJECTABLE (IN-CLINIC) TREATMENT

Population: Two studies, both of patients and providers, with one undertaken in the United States and one in Europe

Challenge: How to most effectively implement a new, long-acting injectable treatment that requires regular visits to the clinic, as opposed to daily oral medication self-administered at home, which is the current standard of care. Due to the different route of treatment and the need for more frequent clinic visits, the sponsor was interested in identifying barriers and facilitators involved in making this treatment shift.

Approach: Both studies utilized implementation science frameworks within their design. The US-based study used the Consolidated Framework for Implementation Research (CFIR)[21] whereas the European-based study utilized the Exploration, Preparation, Implementation and Sustainment Framework (EPIS) alongside outcomes guidelines developed by Proctor et al.[22] Similarly, both studies utilized a mixed methods approach involving individual surveys and one-on-one interviews. The US-based study adopted a single arm approach with all sites receiving the same implementation support, including eight monthly facilitation calls with clinic staff. The European-based study used a two-arm study design in which the standard arm sites received traditional implementation support, and the enhanced arm sites received additional meetings and trainings. The latter arm also participated in CQI calls involving the development of plans to address challenges.

Stakeholders: Patients, doctors, nurses, and administrative clinic staff responsible for implementing the treatment, and the sponsor.

Key Findings: Through the surveys, interviews, and facilitation or CQI calls, stakeholders offered feedback on facilitators and barriers to successful implementation. This has allowed the research team and sponsor to better understand who is best suited for the new treatment, what types of clinics and settings may need additional support in implementation, and strategies for patients and clinics to be more successful in the transition to this new treatment. The study findings will be used to help advise and support clinical sites in the effective implementation of this new treatment in a real-world setting.

CAN A HEALTHCARE APP IMPACT CLINICAL OUTCOMES?

Population: Patients attending a specialty care clinic and providers at the speciality care clinic.

Challenge: Evaluate a new app designed to track potential patient symptoms and exacerbations of new symptoms over time, provide resources to patients, and increase the ability of patients to communicate with their care team.

Approach: The patient interface is linked to a clinician dashboard where patient responses are tracked and responded to by the patient's clinical team in real time. Using a mixed methods design, including techniques such as one-on-one qualitative interviews with patient and clinical site users, patient surveys, and other quantitative usage metrics, evidence can be evaluated with the hope of improving the quality of the electronic system in clinical practice and determining if the app impacted clinical outcomes.

Key Findings: The results of this study will be disseminated in early 2022.

STUDYING PROGRAM IMPACT THROUGH RETROSPECTIVE AND PROSPECTIVE DATA

Population: Individuals from funding partner's organization, individuals from leadership at program partner, and individuals from the field involved in the program

Challenge: Evaluate a program to understand its impact since inception (retrospective data) as well as at the current stage (prospective data). Though the program has been funded for nearly five years, efforts to study the impacts have been largely informal. A dedicated evaluation was requested to support decisions that would inform future funding.

Approach: The evaluation followed the Centers for Disease Control and Prevention framework for program evaluation[23] which focuses on producing results that are the most salient while reinforcing the integrity and quality of the evaluation. The framework involves engaging stakeholders, describing the program, focusing the evaluation design, gathering credible evidence, justifying conclusions, ensuring use, and sharing lessons.

Stakeholders: The funding partner that provided guidance on aspects of program development and the partner responsible for the conduct of the program.

Key Findings: The evaluation provided key information on areas of strength and challenge within the program and areas of greatest impact. The findings and recommendations produced from the program evaluation were immediately used in presentations to high-level decision makers for the purpose of informing conversations about priorities for future focus.

Conclusion

Implementation science studies often consider multiple factors that may serve as barriers and/or facilitators at the system level, site level, or individual level. Analyses may include a mix of existing data or data collected specifically for the purposes of the assessment. Data may also be collected from a variety of sources, over multiple timepoints throughout an assessment and may carry over into a long-term assessment of sustainability. Implementation science plays a critical role in producing evidence-based strategies and supporting the uptake of evidence-based practices and interventions, with the goal of improving healthcare and patient outcomes. ■

For more information, please contact Jennifer.Hill@evidera.com, Larissa.Stassek@evidera.com, Emma.Low2@evidera.com, or Elizabeth.Bacci@evidera.com.

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