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Moving Toward Impact: An Introduction to Implementation Science for Gastroenterologists and Hepatologists

Implementation science (IS) is the "scientific study of methods to promote the 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."[1] IS is a burgeoning field with tremendous potential to positively impact gastroenterology and hepatology. Thus, this commentary aims to introduce gastroenterologists to the nomenclature, frameworks, and research designs of IS using relevant clinical examples.

IS has emerged to bridge the gap between "the care that is and the care that could be," which was described in the Institute of Medicine's seminal report, "Crossing the Quality Chasm."[2] Within gastroenterology and hepatology care, there are several examples of this "quality chasm," wherein evidence-based practices have not been universally implemented. For example, despite strong evidence, only 67% of persons in the United States have received guideline-concordant colorectal cancer (CRC) screening.[3] Similarly, only 32% of patients with cirrhosis receive appropriate endoscopic variceal surveillance.[4] Improving the uptake of established, evidence-based practices such as these could considerably improve the quality and decrease the costs of care.

IS and Related Disciplines

IS overlaps with, but is distinct from, several related disciplines, including intervention science and quality improvement science. Intervention science is primarily concerned with developing novel evidence-based programs and practices. In contrast, IS primarily aims to increase the uptake and maintenance of existing evidence-based programs and practices. Quality improvement efforts aim to create local change in a specific system or specific set of care processes, often using rapid cycles to create rapid change, with less focus on generalizability or theory. Quality improvement may or may not involve a focus on the uptake of evidence-based practices. In contrast, IS aims to developing theory-based, generalizable knowledge, specifically focused on the uptake of evidence-based practices that can be disseminated to several practice settings.[5] Finally, multilevel health services research focuses on the patient-, provider-, and system-level factors associated with health outcomes, whereas IS, in contrast, focuses on the use of an evidence-based practice. This difference in focus manifests in all aspects of study design, such that the hypotheses, target population, measures, intervention providers, and fidelity differ between the 2 types of research.[5] Thus, IS offers novel methods to accelerate the translation of gastroenterology and hepatology research findings into practice change and public health impact.

IS in the Research Pipeline

Implementation research can be conceptualized along the translational science spectrum,[6] in which discovery often begins with basic and preclinical research that establishes the potential of a given intervention. Candidate interventions can be tested through clinical research that can broadly take the form of efficacy trials, which assess intervention performance in a highly controlled setting, and effectiveness trials, which evaluate intervention performance in more "real-world" settings. Although clinical research focuses on whether the intervention works, implementation research focuses on methods to increase the uptake of the intervention into routine care. For example, a clinical trial may answer, "does drug X cure hepatitis C?", whereas an implementation trial answers questions like, "what supports do providers need to deliver hepatitis C treatment to the most patients in the shortest amount of time?" Whereas clinical investigation focuses on individual patients, implementation investigation focuses on the systems, clinics, and providers that are delivering the intervention.

In placing IS within the research continuum, it is important to clearly distinguish between an "intervention" and the process around its implementation (Figure 1).[7] The term "intervention" can be used broadly to refer to an evidence-based practice, program, policy, or guideline that is being implemented.[8] In contrast, implementation refers to the adoption and maintenance of evidence-based "interventions." Thus, IS primarily focuses on the implementation process, context, implementation outcomes (shaded in Figure 1), although it often also appropriate to measure clinical outcomes in implementation trials.[7]

Theories and Frameworks in IS

Theories and frameworks contribute to design, execution, and measurement in IS research. Appropriately selected theories and frameworks allow investigators to plan implementation, understand contextual factors associated with the adoption of evidence-based interventions, and evaluate implementation efforts.[9]

Planning Implementation

Implementation frameworks can be used to guide investigators through the steps of planning implementation. Most implementation planning frameworks start with defining a problem and then guide investigators or implementers through a step-by-step approach. For example, the knowledge-to-action framework is a planning framework with the following steps: (1) identify a problem of interest; (2) consider the implementation context; (3) assess implementation barriers and facilitators; (4) select and

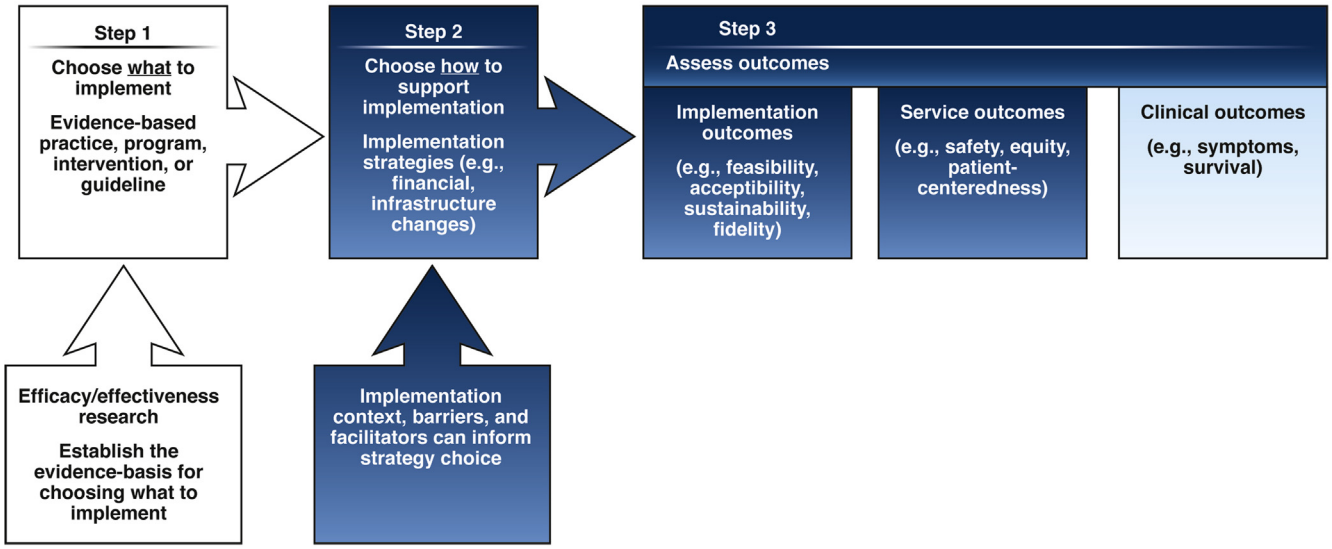

Figure 1. Conceptual Model of Implementation Research (adapted by permission from Springer Nature. *Administration and Policy in Mental Health*. Implementation Research in Mental Health Services: an Emerging Science with Conceptual, Methodological, and Training challenges. Proctor et al. Copyright 2008.)

tailor an implementation approach; (5) conduct a trial of the implementation approach; (6) evaluate implementation; (7) iterate the approach based on evaluation data; and (8) sustain the intervention.[10] Case example 1 (Figure 2) illustrates this process as applied to implementing an alcohol treatment program for patients with cirrhosis.

Understanding Implementation

A second group of IS Frameworks focuses on helping investigators understand the implementation process.[9] These "understanding" IS Frameworks include classic, implementation, and determinant theories and frameworks. Classic theories are derived from other disciplines but inform IS. For example, behavior change theories from psychology can inform efforts to change the behaviors of clinicians and health care system leaders to facilitate implementation. In contrast, implementation theories are specific to IS and address aspects of implementation (eg, implementation climate).[11]

Determinant frameworks also fall under the umbrella of "understanding" theories and frameworks and are used to delineate implementation barriers and facilitators.[9] Such implementation barriers (and facilitators) can arise at the levels of the patient, provider, organization, system, and sociopolitical context and can be addressed in implementation planning and evaluation. One commonly used determinant framework is the consolidated framework for implementation research (CFIR), which includes 5 domains: the outer and inner implementation settings, characteristics of the intervention, characteristics of the persons involved, and the implementation process itself.[12] Table 1 illustrates

Case Example 1

Implementing Treatment for Alcohol Use Disorder (AUD) in Patients With Cirrhosis

Upon reviewing statewide healthcare data, a team of hepatologists identifies a problem that they would like to address: "low AUD treatment rates among patients with cirrhosis." After defining the problem, they conduct interviews with providers, patients, and administrators in rural communities. Through this work, the team identifies implementation barriers including a lack of systematic patient tracking and inadequate transportation for treatment. Based on these findings, the team develops an implementation strategy to overcome these barriers. The strategy includes contracting with a cab company to provide transportation and developing a dashboard for providers to track patients with AUD and cirrhosis. These approaches are then trialed, evaluated, and adapted as needed, and the team makes a plan for implementation sustainment.

Figure 2. Case Example 1. Implementing treatment for alcohol use disorder (AUD) in patients with cirrhosis.

Table 1. Colorectal Cancer Screening Barriers and Tailored Exemplars of Implementation Strategies Mapped to CFIR Barriers

CFIR Domain	Constructs (Examples)	Examples of Barriers to CRC Screening	Examples of Mitigating Implementation Strategies
Intervention characteristics	Intervention source, adaptability, complexity, cost	Colonoscopy is perceived to be complex and time consuming[12]	Provide mailed CRC screening tests with step-by-step instructions[13]
Inner setting: features of the implementing organization	Networks and communications, culture, implementation climate	Low PCP-to-GI referral rates[14]	Develop clinical reminders for providers[15] Audit provider performance and provide feedback[13]
Outer setting: external context or environment	Knowledge of patient needs and resources, peer pressure, external policies and incentives	Inadequate public transportation[12]	Provide bus passes or travel vouchers.
Characteristics of individuals: clinicians and other staff within the implementing organization	Providers' knowledge and beliefs about the intervention, self-efficacy, individual stage of change	Clinicians are not confident that they can appropriately choose between/council about CRC screening modalities[16]	Provide technical assistance[16]
Implementation process	Planning, engaging, executing, reflecting and evaluating an intervention	Implementation barriers to CRC screening are not routinely assessed[17]	Use external coaching to help providers assess and address implementation barriers [17]

NOTE. where existing studies have used implementation strategies that may address stated barriers, these are provided and cited. Where such examples are not available, a hypothetical example is provided.
CFIR, consolidated framework for implementation research; CRC, colorectal cancer; GI, gastroenterologist; PCP, primary care provider.

how the CFIR framework can be used to understand known barriers to implementing CRC screening programs. An IS frameworks like the CFIR broaden the scope of inquiry beyond patients to include factors at multiple levels (eg, provider, health system). Using the CFIR to classify implementation barriers and strategies to overcome these barriers, it becomes clear that most efforts to increase CRC screening have focused on addressing patient- and provider-level barriers. This framework draws attention to the potential added benefits of considering the inner and outer settings, which may prompt investigators to assess and address system-level barriers (eg, leadership buy-in, policies). Further data collection, using semi-structured interviews with stakeholders and informed by a determinant framework such as the CFIR, could inform such an approach.

Evaluating Implementation

Implementation evaluation frameworks specify outcomes that researchers should measure to assess the extent and quality of implementation. In addition to patient-level outcomes (eg, cancer prevention), implementation researchers assess provider- and system-level outcomes. Some examples of implementation outcomes are adoption, or the extent to which providers start using a new evidence-based practice, and fidelity, or the extent to which providers use the intervention as intended.[13] Assessing implementation outcomes, in addition to clinical outcomes, allows researchers to understand the reasons for implementation success and failure. This factor is important because even the most efficacious intervention cannot help patients if it is not adopted by providers or implemented properly. For example, if a colonoscopy is completed but the withdrawal time is inadequate, then the endoscopist may miss polyps. In this example, withdrawal time is an implementation outcome (fidelity to procedural guidelines). Therefore, implementation scientists have identified and defined 8 unique implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability), which are distinct from service and clinical outcomes (Figure 1).[14]

Implementation Data Collection

Implementation researchers use a variety of data collection methods to evaluate implementation processes, outcomes, and determinants. IS often incorporates qualitative data, which adds rich contextual information and novel insights from the perspectives of multiple stakeholders, such as patient, providers, administrators, and policymakers. Mixed methods allow investigators to combine information from qualitative and quantitative sources, including medical records, interviews, surveys, and organizational data. Understanding the complex interactions between factors influencing implementation and clinical outcomes often requires such approaches. For example, an investigator may first uncover that endoscopists are not appropriately using rectal indomethacin to prevent

pancreatitis after endoscopic retrograde cholangiopancreatography using administrative data. Further data collection, using semistructured interviews with stakeholders and informed by a determinant framework such as CFIR, could inform such an approach.

Implementation Strategies

Implementation strategies are "methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice."[13] These strategies include a variety of activities that can occur across ecological levels, such as infrastructure changes, developing stakeholder interrelationships, and changing policy.[15,16] Table 1 shows examples of implementation strategies that have been used to address barriers to CRC screening. Thus, although there are a number of implementation strategies, IS aims to help stakeholders be deliberate in their strategy choices.[17] For example, in the Veterans Administration's national hepatitis C virus elimination program, technical assistance and direct patient outreach were associated with higher treatment rates.[18] Applying these strategies, rather than more expensive but potentially less successful strategies (eg, increasing physician reimbursement), may help other similar efforts. Purposefully examining and addressing implementation barriers with thoughtfully chosen, supportive implementation strategies can increase the reach of evidence-based practices.

Case Example 2

Using Implementation Science to Improve Adherence to Endoscopic Triaging Guidelines in the Context of COVID-19

Gastroenterologists working in a system of clinics are interested in implementing a need-based triage process to catch up with COVID-related endoscopic procedure delays. They first clearly define the problem as: "patients are receiving their procedures in the order they were requested and not in order of need." They conduct a needs assessment with local stakeholders, including patients, referring providers, gastroenterologists, nurses, staff, and administrators. Through this work, the primary barriers to implementing the new guidelines are: 1.) Ordering clinicians cannot track and triage patients whose tests were ordered pre-COVID; and 2.) Schedulers are not incentivized to ensure that patients have <30 day wait times for procedures.

The investigators conduct a randomized-control trial, testing head-to-head implementation strategies. Clinics are cluster-randomized to receive either 1.) a change to the incentive structure such that providers and schedulers are incentivized according to guideline adoption and adherence, or 2.) a population management tool that allows providers to track and triage patients. The team assesses which implementation strategy is associated with improved adoption of the new triage guidelines.

Figure 3. Case Example 2. Using implementation science to improve adherence to endoscopic triaging guidelines in the context of the novel coronavirus disease-2019.

Implementation Study Design

Implementation studies use a number of study designs. Most IS studies occur at the level of the clinic or health care system, but even single-clinic studies can include observational data collection about implementation (eg, intervention fidelity, implementation barriers). Multisite IS studies can be observational or experimental in nature. There are several commonly used IS trial designs, such as randomized controlled trials, stepped-wedge trials, and factorial designs. In randomized controlled IS trials, sites, systems, or clinics may be randomized to receive implementation strategies versus usual care or versus other strategies.[19] Stepped-wedge designs randomize health care settings to receive implementation strategies at different times.[8] Factorial designs allow investigators to vary multiple implementation strategies and efficiently assess a number of factors within a single study. An example of factorial design, a Multiphase Optimization Strategy Implementation Trial[8] randomizes sites to evolving strategies with the goal of optimizing implementation and clinical outcomes. Sequential Multiple Assignment Randomized Implementation Trials similarly use multiple sequential randomizations throughout the study.[8] Within each of these study designs, IS investigators can assess clinical outcomes, but primarily focus on questions related to implementation of an evidence-based intervention, such as "which implementation strategy best supports equitable access to CRC screening" or "to what extent can health care settings adapt the IBD home model and still achieve improved clinical outcomes?"

Hybrid-type Designs

Most IS studies assess how evidence-based interventions can be best implemented, presupposing that strong effectiveness data support the implementation of the intervention in question. However, health care settings may choose to implement programs and practices that do not yet have established efficacy. Likewise,

investigators may desire to evaluate implementation factors early in the development of interventions. Given the benefits of considering intervention effectiveness and implementation factors in the same study, IS experts have developed hybrid-type approaches within the aforementioned study designs.[20] Type I hybrid designs focus predominantly on effectiveness, while also collecting data on the barriers and facilitators to implementation. Type II hybrid designs focus equally on implementation and effectiveness, and type III includes effectiveness measures but predominantly focuses on assessing the impact of implementation strategies. Using these hybrid approaches to assess implementation and efficacy and effectiveness elements, IS can accelerate the time from discovery to implementation.

Potential Areas of Implementation Inquiry in the Fields of Gastroenterology and Hepatology

IS provides a roadmap that helps investigators, providers, and policymakers to advance research from the benchtop or clinical trial to the community. Within gastroenterology and hepatology, there are numerous examples of evidence-based practices that have not been widely implemented. Potential gastroenterology implementation studies could address expanding hepatitis C virus treatment with the goal of population-level hepatitis C virus eradication, providing evidence-based alcohol use disorder treatment to persons with cirrhosis, avoiding or "de-implementing" opioid medications in persons with inflammatory bowel disease, or implementing evidence-based fluid management strategies for acute pancreatitis, to name a few. Case example 2 (Figure 3) demonstrates how a gastroenterology practice can use IS to address novel coronavirus disease-2019–related endoscopy delays. As practice guidelines and evidence evolve within the field, an IS approach can also guide efficient and effective dissemination and implementation of new findings and recommendations.

Conclusions

IS is a rapidly developing field that presents significant opportunities to improve the uptake of existing evidence-based practices. This primer is meant to introduce this valuable, emerging discipline to hepatologists and gastroenterologists.

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Conflicts of interest

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