



## Perspective

## A bootstrap approach to implementation science

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**Introduction**

A troubling gap exists between scientific breakthroughs and clinical practice. New discoveries and evidence-based guidelines are typically slow to fully penetrate all levels of health care delivery. The long-standing assumption that interventions tested in randomized clinical trials (RCTs) will disseminate into day-to-day practice is largely incorrect; only 14% of new scientific information becomes part of widespread clinical practice within 17 years after its discovery.<sup>1,2</sup> Even where evidence-based guidelines are available, they are often underused in primary care.<sup>3</sup>

Fortunately, the National Institutes of Health (NIH) has recognized that “closing the gap between research discovery and clinical and community practice is both a complex challenge and an absolute necessity if we are to ensure that all populations benefit from the nation’s investments in scientific discoveries.”<sup>4</sup> The rapidly expanding field of implementation science (IS) aims to study and guide health interventions that work in real-world public health, clinical, and community service systems. In the model of research translation from basic science to clinical practice, T3 and T4 research seeks to use new scientific information to change health care delivery across a diverse range of clinical settings to improve public health (Fig 1).<sup>5,6</sup> Despite the increasing emphasis on IS, new and experienced asthma researchers often encounter significant barriers to entering the field of IS because of insufficient training, lack of available mentors, and intense competition for available funding. Furthermore, early career clinical scientists interested in using IS in the clinical care setting may not have dedicated time for research or anticipate a likelihood of launching a large research program, but nonetheless they may have a passionate commitment to improving care delivery and patient health. For these individuals, an alternative pathway is suggested: a bootstrap approach to developing an IS program that embraces the innovative and resourceful adoption of strategies to expand their program with whatever time and economic resources are available.

**Lessons From the Asthma Toolkit Program**

The Colorado-based Asthma Toolkit program provides an example of the bootstrap approach to IS. This program, initiated in 2007 to train rural primary care physicians in the delivery of evidence-based asthma care, included in-office team-based instruction, spirometry equipment and training, and patient educational materials. The overall objective of this 8-year program has been to develop a method for introducing evidence-based guidelines into primary care settings that treat low-income and medically underserved patients with asthma and chronic obstructive pulmonary disease (COPD).<sup>7–9</sup> Most Asthma Toolkit training has occurred in rural settings where asthma specialty care is not available and effective management rests in primary care settings. Key lessons for new IS investigators from the Asthma Toolkit program include the following.

*Start Small*

Even without dedicated time and research funding, gathering information, building relationships, and exploring funding options may proceed at relatively low cost. The Asthma Toolkit program began with discussions between investigators and the leadership of the High Plains Research Network, a practice-based research network in eastern rural Colorado. Information about health disparities and gaps in care was gathered by High Plains Research Network leadership and online using state government and nonprofit websites. Investigators interested in a particular community need, care gap, or health disparity can similarly begin by identifying the organizations with similar interests, including public health departments, insurers, and nonprofit groups. Existing databases that may be accessed at no cost to evaluate health care needs, write manuscripts, and develop grants include the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the US Library of Medicine, the State Inpatient Databases, and [healthdata.gov](http://healthdata.gov).

*Engage Stakeholders*

Most IS research projects begin by identifying and meeting with key people and organizations who share a stake in the overall study

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Figure 1. T1–T4 clinical and translational phases.

objective. Investigators enter into a partnership with these stakeholders to designate study objectives, interventions, and outcomes. This is a major paradigm shift for researchers most comfortable with maintaining complete control of all elements of a study but essential to ensuring that the target community is fully on board and in support. It is particularly important that communities be able to sustain the intervention after the study ends.

Ideally, a stakeholder advisory group will meet regularly with the investigator team. However, connecting with and maintaining that group may involve travel and providing meals and time compensation, which can add considerably to costs. Existing community action groups can often be engaged more rapidly and at relatively lower cost than initiating a study-specific stakeholder group. For example, the Asthma Toolkit Program was able to form relationships with existing stakeholder groups, including 3 Area Health Education Centers (federally funded nonprofit organizations whose goal is to bring new health initiatives into the community) and 1 practice-based research network. These groups were composed of community members, including patients, physicians, business leaders, teachers, and ranchers who were committed to improving community health.

#### Think about your IS framework

Most IS research is guided by 1 of several conceptual frameworks that can provide models for implementation and strategies to evaluate the success of a project and accelerate the movement of science into practice. However, the number of IS theories and frameworks has increased to produce an unwieldy array of choices. Helpful resources include a review by Nilsen,<sup>10</sup> an instructive IS primer found on the University of North Carolina website,<sup>11</sup> and several available books about IS.<sup>12–14</sup> Commonly used theoretical frameworks and models include Reach Effectiveness Adoption Implementation Maintenance (RE-AIM),<sup>15</sup> the Consolidated Framework for Implementation Research,<sup>16</sup> Promoting Action on Research Implementation in Health Services,<sup>17</sup> and Theory of Diffusion.<sup>18</sup> The Asthma Toolkit began adopting the RE-AIM framework in its first 3-year study, first assessing reach (the number of practices and physicians who participated) and adoption (the degree to which physicians bring guidelines care into their daily practice), proceeding later to effectiveness (capacity to change

health care outcomes), implementation (factors that influence its adoption and effectiveness), and maintenance (Table 1).

#### Identify the Study Designs and Outcomes You Want to Use

The chosen theoretical framework will help investigators consider study design and the outcomes they wish to measure. In turn, the outcomes of most interest may direct the selection of a theoretical framework. IS research can be conducted in a RCT, but an RCT may not work well for all IS studies. IS studies aim to be more inclusive than many RCTs at the level of patients (eg, including wide age ranges and comorbidities), clinicians (eg, allergists, family physicians, internists, pediatricians, nurse practitioners, physician assistants), and settings (eg, large health

Table 1

The Asthma Toolkit: An Evolving Program of Implementation Research in Respiratory Medicine<sup>a</sup>

Variable	Year				
	2006	2008	2010	2014	2016
Target diseases					
Asthma	X	X	X	X	X
COPD			X	X	X
Stakeholder engagement	X	X	X	X	X
Training content					
Emphasis on spirometry		X	X	X	X
Training in the community		X	X	X	X
In-practice follow-up		X	X	X	X
Webinar follow-up				X	X
Study design					
Pre-post		X	X	X	
Step wedge					X
Cluster RCT					X
RE-AIM IS outcomes					
Reach			X	X	X
Effectiveness			(X)	(X)	X
Adoption			X	X	X
Implementation				(X)	X
Maintenance				(X)	X

Abbreviations: COPD, chronic obstructive pulmonary disease; IS, implementation science; RCT, randomized clinical trial; RE-AIM, Reach Effectiveness Adoption Implementation Maintenance.

<sup>a</sup>Content in parentheses has been only partially completed.

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