



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.^{1,2} Even where evidence-based guidelines are available, they are often underused in primary care.³

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.”⁴ 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).^{5,6} 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).^{7–9} 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.

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,¹⁰ an instructive IS primer found on the University of North Carolina website,¹¹ and several available books about IS.^{12–14} Commonly used theoretical frameworks and models include Reach Effectiveness Adoption Implementation Maintenance (RE-AIM),¹⁵ the Consolidated Framework for Implementation Research,¹⁶ Promoting Action on Research Implementation in Health Services,¹⁷ and Theory of Diffusion.¹⁸ 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^a

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.

^aContent in parentheses has been only partially completed.

maintenance organizations, federally qualified health centers, independent practices). In this diverse and complex world of patients and health care delivery, pragmatic controlled trials, interrupted time series, step wedge, and pre-to-post study designs may better answer the questions being posed.¹²

IS theoretical frameworks help researchers think not only about immediate clinical outcomes (eg, symptom control, health care use) but also about the process of implementation, including intervention mediators (variables that explain how a treatment produces its effect) and moderators (variables that explain on whom and under what conditions a treatment produces its effect).¹² Evaluation of the process of implementation often uses qualitative assessment techniques, such as interviewing key stakeholders on their views of the intervention either individually or in focus groups. The Asthma Toolkit has used a relatively simple SurveyMonkey tool to gather physician feedback.

New IS researchers may want to select other outcome variables that are easiest and least costly to measure. This “low-hanging fruit” can produce insightful information and set the stage for more ambitious evaluations in subsequent studies. Initial assessment of Asthma Toolkit program effectiveness included medical record audits to document inclusion of elements of evidence-based guidelines during clinic visits (eg, severity assessment, spirometry, action plans). In some cases, physicians reviewed their own medical records before and after the Asthma Toolkit training. Physician self-audits correlate reasonably well with third-party assessments; added advantages include focusing physician attention on guideline adherence and setting up a mechanism for physicians to complete their Maintenance of Certification for board renewal,^{19,20} thus providing another incentive for participation. Several years into the Asthma Toolkit program, additional low-cost measures of effectiveness in the form of state and Medicaid use data were introduced. Evaluation of implementation was also expanded to examine baseline physician characteristics and attitudes as potential predictors of intervention effect. Future measures will include stakeholder surveys and long-term (1–5 years) sustainability (Table 1).

Take 1 Step at a Time

The Asthma Toolkit program was developed in a series of 7 separate projects, each of which provided important information about successful implementation that in turn allowed further refinement of the intervention. In response to physician feedback and requests, the program has increased from an asthma focus toward a wider respiratory objective that includes COPD training and expanded measures to more broadly address outcomes within an IS theoretical framework (Table 1). This stepwise approach to IS has 5 distinct advantages over a single, large IS trial by providing IS investigators with (1) an opportunity to learn about and adopt IS theories and strategies; (2) an ongoing, adaptive process that informs a constantly evolving intervention; (3) growth that can accelerate, slow, and then accelerate again as dictated by available funding; (4) engagement with new stakeholders and communities over time; and (5) mentoring opportunities for young scientists wishing to learn about IS.

Obtain Funding

Funders of the Asthma Toolkit program have included the Caring for Colorado Foundation, Colorado Department of Public Health and Environment, COPIC Medical Foundation, GlaxoSmithKline, Jessie Ball DuPont Fund, Kaiser Permanente Community Grants Program, NIH, and Pfizer. The size of each phase of this program has expanded or contracted to fit the amount of funding received. Smaller projects have assembled as few as 5 practices into a training unit, whereas larger projects have included as many as

57 practices in a large rural area. Smaller supplemental grants have allowed development of community information programs and the Asthma Toolkit website.

Many nonprofit foundation funding programs place emphasis on building community health programs but explicitly exclude bench research projects or, in some cases, those using an RCT design. Many nonprofit funders explicitly exclude RCTs but nonetheless expect measurement of outcomes to determine whether the project has achieved its stated goal. This emphasis on effective outcomes allows for measurement of the implementation process. For example, the Caring for Colorado Foundation instructs applicants, “The Foundation is committed to learning from grants, whether they meet expectations or not. Grants that don’t achieve desired outcomes provide opportunities to learn about what doesn’t work. Learning about what does and what doesn’t work helps the foundation fine-tune and improve its grantmaking.”²¹ In effect, these funders are encouraging applicants to use an IS model to evaluate the success of their implementation project and to examine with whom and under what circumstances the intervention was successful. Investigators seeking to initiate an IS program may wish to look for foundations whose priorities match the investigator’s interests. For example, the Asthma and Allergy Foundation of America, the American Asthma Foundation, the American Lung Association, and the COPD Foundation offer small grants aimed at respiratory diseases. The Foundations Center funds programs in Native American health, the Steele-Reese Foundation supports rural health, the Aetna Foundation provides grants to improve community health, and the Kresge Foundation funds programs to improve the health of low-income peoples, to name just a few. Investigative web searching can help zero in on potential funders, including lesser known foundations and funds.

Scale Up

Having begun on a smaller scale while accumulating stakeholder experience, outcome data and overall familiarity with IS research, many IS investigators will want to consider larger IS projects. *Scaling up* is an important objective in IS research as investigators seek to establish more widespread implementation of the intervention into a variety of health care settings to solve health-gap problems at a population level. Future scaling-up goals in the Asthma Toolkit program will include partnering with rural critical access hospitals, federally qualified health centers, school-based clinic programs, and Indian Health Service clinics to bring training into all Colorado counties and eventually to other states. Large research programs typically require submission of research grant applications to major funders, such as the NIH, Patient-Centered Outcomes Research Institute, Agency for Healthcare Research and Quality, the Veterans Administration Health Services Research and Development, William T. Grant Foundation, and the Robert Wood Johnson Foundation.

Conclusions and Final Recommendations

New and experienced clinical researchers may find the pathway into the field of IS lined with formidable barriers. Young scientists with primary clinical responsibilities and minimal research time in particular require a nontraditional approach to creating a practical research program. Rather than attempting to immediately launch a large IS research program, investigators may find more satisfaction and success with a bootstrap approach. This developmental model includes a series of steps: identifying small starting projects that can feed into larger projects, harvesting no-cost health data from large public databases, and deciding on a theoretical framework to help guide both the development and assessment of the IS project. Building relationships with key stakeholders to help define projects, interventions, and target outcomes is essential and requires

the investigator's commitment to regular communication with stakeholders and a willingness to make changes in response. Creativity and innovation should be embraced, producing strategies to identify low-cost stakeholder partnerships and data sources to power the initial stages of research. As occurred with the Asthma Toolkit program, small-scale IS projects can be developed over several years, generating manuscripts and pilot data, leading to the application for larger support from competitive funding sources. Finally, new IS investigators are encouraged to work with an experienced IS mentor. Mentoring programs are often available through the investigator's home institution, affiliated graduate or medical school programs, and national organizations.

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