
Fidelity Versus Flexibility

Translating Evidence-Based Research into Practice

Deborah J. Cohen, PhD, Benjamin F. Crabtree, PhD, Rebecca S. Etz, PhD,
Bijal A. Balasubramanian, MBBS, PhD, Katrina E. Donahue, MD, Laura C. Leviton, PhD,
Elizabeth C. Clark, MD, MPH, Nicole F. Isaacson, PhD, MSS, Kurt C. Stange, MD, PhD, Lawrence W. Green, MD

Background: Understanding the process by which research is translated into practice is limited. This study sought to examine how interventions change during implementation.

Methods: Data were collected from July 2005 to September 2007. A real-time and cross-case comparison was conducted, examining ten interventions designed to improve health promotion in primary care practices in practice-based research networks. An iterative group process was used to analyze qualitative data (survey data, interviews, site visits, and project diary entries made by grantees approximately every 2 weeks) and to identify intervention adaptations reported during implementation.

Results: All interventions required changes as they were integrated into practice. Modifications differed by project and by practice, and were often unanticipated. Three broad categories of changes were identified and include modifications undertaken to accommodate practices' and patients' circumstances as well as personnel costs. In addition, research teams played a crucial role in fostering intervention uptake through their use of personal influence and by providing motivation, retraining, and instrumental assistance to practices. These efforts by the research teams, although rarely considered an essential component of the intervention, were an active ingredient in successful implementation and translation.

Conclusions: Changes are common when interventions are implemented into practice settings. The translation of evidence into practice will be improved when research design and reporting standards are modified to help quality-improvement teams understand both these adaptations and the effort required to implement interventions in practice.
(Am J Prev Med 2008;35(5S):S381–S389) © 2008 American Journal of Preventive Medicine

Introduction

Difficulties exist in developing, documenting, and reproducing complex interventions, such as those directed toward healthcare professionals to improve clinical care.¹ Implementation is the

means by which evidence-based clinical research is translated into practice.^{2,3} However, few studies describe the process of implementing change in healthcare settings,^{4,5} and, as a result, little is known about how to translate good ideas and evidence into practice.^{6–8}

From the Department of Family Medicine (Cohen, Crabtree, Etz, Balasubramanian, Clark, Isaacson), University of Medicine and Dentistry of New Jersey–Robert Wood Johnson Medical School, Somerset, the Department of Epidemiology (Crabtree), University of Medicine and Dentistry of New Jersey School of Public Health, New Brunswick, the Robert Wood Johnson Foundation (Leviton), Princeton, New Jersey; the Department of Family Medicine, University of North Carolina at Chapel Hill (Donahue), Chapel Hill, North Carolina; the Departments of Family Medicine, Epidemiology and Biostatistics and Sociology at Case Western Reserve University and the Case Comprehensive Cancer Center (Stange), the AAFP-funded Center for Research in Family Medicine and Primary Care, (Cohen, Crabtree, Etz, Balasubramanian, Isaacson, Stange), Cleveland, Ohio; and the Department of Epidemiology and Biostatistics, Society, Diversity and Disparities Program, School of Medicine and Comprehensive Cancer Center, University of California San Francisco (Green), San Francisco, California

Address correspondence and reprint requests to: Deborah J. Cohen, PhD, Department of Family Medicine, Research Division, University of Medicine and Dentistry of New Jersey–Robert Wood Johnson Medical School, 1 World's Fair Drive, Somerset NJ 08873. E-mail: cohendj@umdnj.edu.

Treatment fidelity, or the degree to which an intervention maintains its original form, is fundamental to the implementation of complex interventions and effectiveness research.^{2,9–13} In efficacy studies, adherence to intervention protocols is carefully monitored. But in effectiveness studies, where interventions are tested in real-world practice settings, adherence is more challenging. This has serious implications for evaluating study results. Currently, there are two views about how to manage treatment fidelity in effectiveness research.² One view is that strict adherence to program protocol is necessary under all circumstances.^{9,12} A second view is that adaptation is necessary, but must be done cautiously to avoid compromising validity. In this latter view, fidelity refers to maintaining adherence to key intervention components while other modifications,

particularly those that help the integration of the intervention into the practice, are encouraged.^{3,14,15}

Little is known about the kinds of changes made to behavioral interventions as they are translated into medical practice. This article addresses the question *What type of issues prompt changes to interventions during the implementation process in primary care settings?* and aims to open the black box of implementation by exploring the tension between treatment fidelity and flexibility in practice-based health promotion research.

Methods

Prescription for Health: Promoting Healthy Behaviors in Primary Care Research Networks was an initiative funded by the Robert Wood Johnson Foundation (RWJF) in collaboration with the Agency for Healthcare Research and Quality (AHRQ) in response to a growing body of scientific evidence recognizing the importance of lifestyle on health and well-being, and acknowledging the potential role that primary care clinicians can play in preventing morbidity and mortality through counseling and other interventions.^{16–23} Grant funding was provided to primary care practice-based research networks (PBRNs) to conduct effectiveness studies to improve health promotion for tobacco use, unhealthy diet, physical inactivity, and risky alcohol use.^{17,24–29} This paper examines ten independent studies funded in Round 2 of this initiative (July 2005–June 2007). Table 1 provides a brief overview of the interventions tested.

As part of the Prescription for Health initiative, an independent analysis team (A-team) was established to conduct an evaluation. Because of the complexity inherent in changing and improving healthcare delivery systems,^{30–35} the evaluation was designed to observe the implementation process across projects. This paper presents the findings of the A-team's cross-project analysis. For clarity in this article, the individual project research teams (grantees) are referred to as investigative teams or research teams.

Data Collection

Table 2 provides an overview of the data-collection timeline. All projects funded in Prescription for Health were required to participate in the cross-project assessment and to collect standardized data. A detailed discussion of the data-collection strategy is described elsewhere.^{36,37} Briefly, a multimethod assessment was performed that included survey data, interviews, site visits, and project diaries. Survey data were collected at the PBRN and practice levels; interviews and site visits were conducted with each investigative team to gain PBRN-, project-, and practice-level insights. Interactive online project diary rooms were created on the AHRQ-sponsored PBRN secure extranet. Members were selected from each investigative team (e.g., principal investigators, health educators, facilitators) to post implementation experiences in their diary room bi-weekly. The A-team monitored, analyzed, and responded weekly to diary postings. Diaries functioned both as a data-collection tool, providing real-time insights into implementation processes, and as a communication mechanism, facilitating interaction between investigative teams and the A-team.

Data Management

The ATLAS.ti version 5.2 was used for data management and analysis. Data were de-identified and saved on a password-protected network maintained by the University of Medicine and Dentistry of New Jersey–Robert Wood Johnson Medical School, whose IRB approved the study protocol.

Analysis

Real-time process analysis. The A-team conducted a real-time analysis that involved reading and reflecting on data as they were collected.^{38,39} Diary entries were read aloud and discussed during weekly meetings. Other data (e.g., grant applications, survey data, notes from interviews and site visits) were discussed when relevant to understanding the projects' reported implementation experiences. The group decided how

Table 1. Project overviews

Project	Research question
1	Can interactive voice recognition and web-based tools be used in primary care to improve patients' health behaviors?
2	Can built-in EMR prompts and referrals to pre-identified resources be used in primary care to improve patients' health behaviors?
3	Can a telephone-based, voice-activated counseling system be used in primary care to improve patients' health behaviors?
4	Can a PDA-based HRA completed by adolescent patients in the waiting room be used in primary care to improve adolescent patients' health behaviors?
5	Can referrals to a lifestyle counselor be used in primary care to improve patients' health behaviors?
6	Can medical assistants be used in primary care to improve patients' health behaviors?
7	Can a community liaison (a community-based person who assists patients in finding behavioral resources) be used in primary care to improve patients' health behaviors?
8	Can practice-developed and -tailored systems to identify and connect at-risk patients with community resources via the web be used in primary care to improve patients' health behaviors?
9	Can facilitation and prevention collaboratives be used in primary care to improve patients' health behaviors?
10	Can collaborative links among practices and public health and community resources be used in primary care to improve patients' health behaviors?

EMR, electronic medical record; HRA, health risk assessment; MA, medical assistant; PDA, personal digital assistant

Table 2. Prescription for Health evaluation timeline^a

Date	Action
July 2005	Start of Prescription for Health Round-2 initiative First National Program Office (NPO)-sponsored Prescription for Health Meeting. This and subsequent NPO meetings brought together funded research teams, members of the NPO and analysis team (A-team), and consultants and experts A-team interviews all research teams A-team and research teams begin using online diaries
November 2006	Practice-survey data collection (baseline) begins
January 2006	Second NPO-sponsored Prescription for Health meeting A-team interviews all research teams
March 2006	Practice survey data collection (baseline) completed
May 2006	Site visits with grantees begin
October 2006	Site visits with grantees completed
November 2006	Practice-survey data collection (follow-up) begins
January 2007	Most interventions underway; some nearing completion A-team begins single-case analysis
March 2007	A-team begins cross-case comparative analysis
May 2007	Third NPO-sponsored Prescription for Health meeting A-team interviews all investigative teams A-team reports preliminary findings
June 2007	Prescription for Health ends
September 2007	Practice-survey data collection (follow-up) completed

^aThis timeline describes the research activities of the analysis team (A-team).

to respond to each week's diary entries, and questions and comments were posted to each diary room.

Comprehensive analysis. Comprehensive individual project analyses used an immersion-crystallization approach,³⁸⁻⁴⁰ beginning with an examination of all available data (e.g., diaries, grant applications, interview and site-visit notes, survey data, communications, and other artifacts) for a project and proceeding iteratively. Team members initially read and coded data together, and then divided the remaining data by project, meeting weekly to discuss emerging themes. Once the individual project analyses were developed, the A-team transitioned to a cross-case comparative analysis and engaged in a second immersion-crystallization cycle to understand how themes were manifesting across projects. Each team member analyzed a single theme, with weekly group meetings to discuss emergent insights.

Treatment fidelity and flexibility analysis. During the project-specific analyses, aspects of the Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) model were coded. RE-AIM is the framework that Prescription for Health grantees used for planning and assessing the external validity, adoption, and sustainability of research.^{41,42} Through the pro-

cess of coding RE-AIM, intervention change emerged as an important theme. So that this theme might be better understood, grant proposals were re-examined to identify each project's proposed intervention and how it had changed. All data were re-examined within and across projects to identify the changes that research teams had made to intervention protocol during the implementation process. Quotations from raw data were identified that exemplified the observations and analytic claims. Findings from this analysis were organized into a table that identified (1) the key features of each intervention as originally proposed (this was the standard against which intervention fidelity was assessed); and (2) the change(s) to intervention protocol during implementation. Minor revisions were made to the table based on the feedback of each project's principal investigator. Quotations from raw data exemplify these observations and analytic claims. Data segments in this study have been de-identified; all names have been changed.

Results

All Prescription for Health interventions changed as they were integrated into practice. Table 3 describes each project's essential intervention components and the changes that occurred during implementation. While all interventions eventually stopped changing, what the intervention was at stasis was often different from what had been proposed in the grant application. The one apparent exception to this rule was Project 8, which reported no changes to the proposed intervention. However, this project used a unique intervention approach in which practices were asked to improve a clinical target and were given significant flexibility to develop their own intervention for making the improvement (DJC, unpublished findings, 2008). The intervention was, therefore, predicated on allowing adaptation across practices. In all other projects, practices adapted predefined interventions during implementation.

Changes to the Intervention

Accommodating practice circumstances. Research teams made changes to proposed interventions to accommodate practices' circumstances. For example, a number of projects intended to have practices administer a health risk assessment (HRA) as part of the intervention, and found that the proposed delivery method (e.g., kiosk or health information system) did not fit well with a practice's routines. For example, one research team changed the HRA delivery method to better fit with practice routines:

We changed our method of health behavior assessment from using a kiosk to using a tablet PC. We felt that the tablet PC would be more mobile in case the patient was called back to the exam from the waiting room. (Project 10, RWJF 6-month report)

Modifications like these fostered flexibility. Other alterations were observed to enhance the function of an

Table 3. Essential intervention components and protocol change(s) during implementation

Project	Essential intervention components	Protocol change(s) during implementation
1	Letter prompts patient to initiate contact with telephone- or web-counseling system Patient initiates contact with system, and system guides HRA-referred to web or IVR counseling, as needed Physicians updated on patient's progress	Actively recruit patients with posters and handouts Clinician to use tool in encounter with patient
2	1-hour training in how to use EMR prompts EMR prompts physician through brief counseling based on HRA and 5A's Patients offered four referral options: web-based, telephone, group counseling, or usual care Patients proactively contacted (usually within 24 hours) by counseling service	Research team changed EMR system they modified. Practice's region and health system changed Changes community resources offered No health educator hired. Partner with Weight Watchers and health system Wellness Center
3	Implementation workshop for provider teams Physician identifies patients, and provides educational materials, brief message, and referral to telephone system. Telephone system conducts HRA and offers counseling. Physicians receive progress report.	Actively recruit patients with posters and handouts Research team initiates counseling system; most patients do not self-initiate.
4	Physicians receive two training sessions on brief motivational interviewing. Patient completes HRA in waiting room using PDA. Results are printed and placed in patient's chart. Clinician reviews results, discusses risk, and offers brief counseling. Patient receives community resource card and referral, as appropriate. LISTSERV for physicians to share successful strategies	Offer monetary incentive for finishing exit survey Add summary report to HRA output Extend data-collection period Discontinue LISTSERV
5	Physicians receive one workshop on brief counseling intervention. Rooming or nursing staff complete HRA during well visit of child aged 2 years. HRA triggers physician to engage in brief behavioral counseling, goal setting, and referral to lifestyle counselor. Front-desk staff schedule visit with health educator. Health educator meets with patient to assist with goal attainment.	Recruitment through calls to eligible families Hired health educator rather than lifestyle counselor Amount of exposure to counselor at each practice decreased Most counseling done via telephone as opposed to face-to-face
6	Three 1-hour training workshops for medical assistants Medical assistant reviews HRA, assesses patient's readiness to change, offers referral to health system resources with minimal physician assistance	Retraining of medical assistants when there was staff turnover and to foster medical assistants' buy-in Implementation of new EMRs made old HRA difficult to use; instead, medical assistants do HRA Referral accepted by fax only
7	3-week training for community liaison Practice develops plan for process of referral to liaison. Practice identifies at-risk patients, provides information, and sends referral to liaison Liaison conducts HRA; offers brief counseling, referral to community resource; monitors patient's progress; and provides feedback to practice. Practice reviews feedback from liaison.	Additional liaison hired Liaisons spent more time with patients than expected. Liaisons do more in-house counseling and less referral to community resources than expected.
8	Assessment to determine practice's approach for addressing health behaviors Practice chooses change, and facilitator guides change process to foster use of assessment tools and expand nonclinical staff's role in screening and referral to behavior-change resources	No changes reported
9	Physicians' training session for each behavior and for motivational interviewing Facilitated PDSA cycles to produce incremental improvements in processes—changes involve screening as part of vital signs, printed handouts and referrals as appropriate, brief physician counseling for patients ready to change Facilitators conduct monthly performance audits. Regional practices share performance data and lessons learned.	Eligibility expanded to include adolescents Some patient recruitment via posters at practice's request Some EMRs prevented changes to vital-signs process
10	Practice participates in state-level prevention collaborative. Team PDSA cycles that involve (1) implementing self-HRA at waiting room kiosk, (2) brief counseling and referral by physician, (3) relationships/links with community resources	Tablet PC replaced kiosk for self-HRA. IT support shifted locations. Area health educators added to collaborative to strengthen connection

EMR, electronic medical record; 5A's, ask, advise, assess, assist, arrange; HRA, health risk assessment; IT, information technology; IVR, interactive voice recognition; MA, medical assistant; PC, personal computer; PDSA, Plan-Do-Study-Act

intervention component for a practice's members, as shown in the example below:

Our programmer has modified the HRA in order to provide a summary report to the providers. This report makes it easier to quickly see priority area (where the problems are). (Project 4, RWJF 6-month report)

Additionally, practices sometimes requested study changes. For example, the goal of Project 5 was to improve healthy eating and physical activity by speaking with the parents of children aged 2–3 years about these issues during well-child visits. This project tested an intervention that included (1) a parent's completion of a health screener; (2) brief counseling by a physician, goal setting, and referral to lifestyle counselor; and (3) counseling sessions. One practice requested a change in the patient-recruitment plan that involved referring families that had an overweight older sibling:

At Practice 5, the idea of referring families based on an overweight older sibling made sense to me and to the medical director. I like it because it is true to the goal of engaging families, and it is a very legitimate point of entry. But ____ is right that the process has to look different when it starts this way. . . . [S]he will need to administer the screener (unlikely that the doc will do this in these situations). And we will have to note in her documentation the source of the referral so we can keep track of how many came this way and how they played out. And she will have to be the first goal setter. I guess I see it as backwards—instead of the doc setting a goal and the lifestyle counselor addressing it and maybe then expanding to other goals, she will set a goal and feed that back to the doctor by documenting in the children's charts. (Project 5, diary entry)

The change to the recruitment plan proposed by the practice altered the original intervention by shifting the responsibility for administering the health screener and engaging in goal setting with patients from the doctor to the health educator.

Accommodating patients' circumstances. Patients' circumstances and reactions to interventions also affected the interventions. For example, Project 3 conducted an effectiveness trial of a telephone-based, voice-activated counseling system previously shown to be efficacious in several RCTs.^{43–47} Primary care practices offered the telephone-counseling tool to patients, providing them with instructions for initiating contact with the system. However, few patients actually initiated contact, and one research team member had to initiate the system for the majority of patients:

There has been no real change in the rate of patients initiating the system on their own. Over-

all, I've initiated the system for about 83% (236/285) of the patients that have enrolled. So far 123 patients have completed their baseline HRA. This is a low rate of completion considering we need this data for all patients who participate. (Project 3, diary entry)

When a patient did not initiate contact, the research team input the patient's information into the telephone-counseling system, and modified the system so it would initiate contact with the patient. This modification solved a recruitment problem, but changed the intervention from a patient-initiated to a telephone system-initiated referral approach.

Patient preferences also affected Project 5, the intervention that offered families access to a lifestyle counselor. In Project 5, the research team learned that the patients who were referred to the lifestyle counselor resisted face-to-face meetings, because this option involved returning for a second appointment. The intervention was changed to accommodate patients by offering most counseling sessions over the telephone. The health educator said that, at all of the sites, patients rarely show up for their appointments; she ends up counseling over the phone. It seems that the patients do not take their appointments with the health educator as seriously as they take their appointments with physicians (Project 5, site-visit notes).

A similar implementation experience was observed in Project 7, which tested the effectiveness of a community liaison—someone who would be located in the community, accept referrals from practices, and assist referred patients with finding community resources for health behavior counseling and support. Most community liaisons (all were qualified counselors) reported providing more counseling to patients themselves than referral to community resources for behavior-change support, as was originally proposed. This change was in response to patients' needs: Patients required more up-front counseling, and few affordable community resources were found to provide intensive behavioral counseling:

When I went into this originally I thought that I was really going to hook patients up with community resources. I knew there was going to be some in-house counseling, but I . . . thought that we had a lot of good resources in the community. But as I got into actually referring people and figuring out what . . . they truly needed, I ended up switching a lot of them to the in-house counseling. Even if I referred them to a website or referred them to Weight Watchers, they still wanted the one-on-one interaction. (Project 7, interview data)

The community liaison was an essential component of the intervention being tested, and modifications to how the liaison interfaced with practices and patients

was considered an important change to intervention protocol.

Accommodating personnel costs. Higher-than-expected costs to recruit key study personnel could also result in changes to an intervention. For example, the lifestyle counselor hired in Project 5 cost more than expected, and this resulted in changes to the proposed intervention:

The role of lifestyle counselors are more expensive than planned and available in the practices only half a day per week, which appears to limit their ability to both maintain visibility in the practice and to have effective face-to-face counseling with patients. (Project 5, diary entry)

Underestimating the cost of hiring personnel is a common research problem and generally not considered to affect the intervention per se. However, in Project 5 the lifestyle counselor was an essential component of the intervention, and hiring costs led to an intervention change: Practices and patients had less exposure to the counselor than originally anticipated.

The Work of Research Teams: Active Ingredients in Implementation Research

The work of research team members, although not typically considered an essential component of interventions, was crucial for intervention uptake and implementation. The three research team member activities described (the use of personal influence, the dissemination of effective techniques through staff retraining, and the provision of instrumental assistance and enforcement of protocol) were critical for intervention implementation across Prescription for Health studies.

Use of Research Team Member Influence

In Project 10, the aim was to establish and test the effectiveness of developing and strengthening collaborative links among practices and state and county health departments, county cooperative extension agencies, and other community resources. To make this happen, the research team had to identify the extension agents in each community and then elicit their participation. In one community, the research team's facilitator used her influence to get buy-in from the county extension agent:

The facilitator . . . was not acquainted with the County Extension Service (CES) and couldn't get them to talk with her The facilitator knew the state-level health promotion consultants and elicited their support for the project. They then met with the local CES health promotion coordinator and reworked the county plan to make local practices part of outreach activities. (Project 10, site-visit notes)

The facilitator worked with the state-level consultant to reshape both the county's agenda and the allocation of funds to include working with primary care practices. As a result, the health promotion coordinator and the adult nutritionist and outreach/resource worker went to the practice and met practice members, volunteering to provide information from parks and recreation; they also displayed a willingness to teach classes after-hours. (Project 10, site-visit notes).

The role of the facilitator, while not considered an essential component of this intervention, was the force that created the link between primary care practice and community resources, and accomplished a key intervention goal.

Dissemination of Effective Techniques Through Staff Retraining

Less-dramatic examples show how pervasive and crucial research team activities were. For instance, research teams provided extensive retraining during implementation to facilitate intervention uptake. In Project 6, a project designed to extend the medical assistant's role in practices to include the HRA and referral to community resources, the research team found recruitment numbers low at some practices. Several medical assistants were identified who had effective ways of talking with patients to identify health risk and make a referral. The research team disseminated and retrained less-successful medical assistants in this expert approach:

In an attempt to gain more uniformity across our six clinic sites regarding medical assistant enrollments, I spent some time discussing the enrollment approach used by the medical assistant who is the most productive one across all clinic sites. We will be passing along this expert approach. (Project 6, diary entry)

Provision of Instrumental Assistance and Protocol Enforcement

In addition to retraining, investigative teams provided instrumental assistance with implementation. For example, in Project 5, the lifestyle counselor developed tools to help practice members remember to do the HRA, and she stocked rooms with assessment forms:

I will make fluorescent yellow stickers to put on upper corner of docs' computers reminding them to complete the assessment form. I will stock forms in every exam room. I will make a short script for desk staff so they can better explain the intake form to patients. (Project 5, diary entry)

In Project 9, the research team helped practices obtain information about the functionality of their electronic medical record (EMR) systems, and often tailored the systems for practices:

The principal investigator asked if her EMR would allow her to add items to the vital sign section. She said no. The principal investigator volunteered to get in touch with the EMR company to see if something could be done. After the meeting, our information technology person contacted the company . . . (Project 9, diary entry)

This project also identified and alerted physicians to staff members' resistance, allowing practice members to enforce the new protocols implemented as part of the project's intervention:

Today I spent my time between recruitment and editing the EMR for Prescription for Health purposes. I am trying to satisfy all involved with chart recording. This has been harder than it should be. The nurse is having problems with the change even though it only changes her duties by adding a few extra clicks during her initial vital sign collection. I will speak to the doctor so he will enforce the change . . . and that it is not just me. (Project 9, diary entry)

Motivating a practice to change, retraining a practice's members, and assisting with the development of tools to deliver the intervention were some of the activities that research teams performed to help the practices implement an intervention.

Discussion

Effectiveness research is a messy process.^{48,49} All Prescription for Health interventions arrived at stasis, but during implementation, research teams worked with practice members to tinker with interventions, adapting them to fit local circumstances. The need to adapt does not indicate a poor intervention or an inexperienced research team; it is a common part of the research process. It is the journey of translating evidence-based research into practice.⁴⁸

Multiple reasons have been identified for the poor translation of evidence-based research into practice (e.g., insufficient training in translation research, systems barriers such as competing demands, short patient visits, lack of financial incentives, over-reliance on the RCT). A number of solutions to this problem have been proposed, including (1) conducting more effectiveness, or practical, clinical trials in real-life settings^{6,8,50-58}; (2) collecting data to expand the understanding of an intervention's external validity (e.g., RE-AIM)^{15,59-62}; and (3) working closely with those in the local study settings through, for example, participatory and community-based research.⁵⁴ These solutions aid translation by expanding knowledge of the variations that manifest at the population and practice levels. While such solutions are important steps beyond the traditional approaches that control and treat varia-

tion as mediating and moderating variables in research, they may not be enough. A study can be replicated multiple times and achieve excellent external validity, and yet if the adaptations that interventions undergo during the implementation process are not observed and understood, then important knowledge necessary to translate interventions into practice is lacking.

Project 3 provides an excellent example of this issue. Although the telephone-counseling system tested in this project had been previously shown to change patient behavior in efficacy studies, the use of this tool in the primary care settings failed because patients failed to initiate contact with the telephone system. Of note is that the RCTs establishing the efficacy of the telephone-counseling system made extensive use of research assistants who conducted home visits to help participants initiate contact with the telephone system.⁴³⁻⁴⁵ Thus, the hands-on support provided by the research team during the efficacy trials turned out to be crucial to patients' initiating use of the telephone-counseling system.

Additionally, in the case of the effectiveness study reported here, the research team testing the telephone-counseling system recruited geographically dispersed practices, and could not be onsite to help practices adapt this intervention, which might have fostered better uptake. This observation underscores another important finding of this study: The work that research teams do during implementation, while often taken for granted, may be an essential feature of the intervention. Recognizing these invisible but essential features may help as attempts are made to translate evidence-based research into clinical practice.^{6,63}

This new way of understanding the essential features of interventions has implications for how cost effectiveness is considered. Many of the intervention changes documented in this article improve the flow and logistics of an intervention in the practice. Shifting from face-to-face to telephone counseling with patients, for example, may be more cost effective. However, this study also reveals the extensive work that research teams can do to support implementation efforts. The hands-on support that Project 3 provided, as described above, could be a hidden cost for a practice undertaking this intervention. This work, while typically invisible, is crucial for intervention uptake and needs to be considered when intervention costs are calculated.

This study's findings must be understood in the context of its limitations. As outside evaluators, the A-team had both a physical and emotional distance from projects that fostered critique and reflection. The geographic distance, however, was also a limitation. Because practices were located nationwide, the A-team was unable to observe practices directly as they implemented interventions; instead, they relied on grantees to observe and report these experiences. The online diaries were extremely useful in this regard, but there was variability

in the depth and frequency of diary postings across projects.^{36,64,65} This limitation was mitigated by making diary postings a condition of award, showing grantees the value of this data source, and not relying exclusively on diaries for implementation insights. Site visits and interviews provided additional opportunities for understanding intervention implementation. However, due to variability and biases associated with self-report data, it is not possible to quantify how often projects made the types of changes described above and to test for statistical association between these findings and relevant practice-level outcomes. Nonetheless, this study's findings lay the foundation for future work that is hypothesis-driven and investigates how the changes to interventions during effectiveness research can affect relevant clinical outcomes.

Despite these limitations, the study's findings underscore the need both for flexibility when evidence-based research is translated into practice and for a shift in how the essential features of practice-based interventions are conceptualized. Making this shift requires facilitating implementation in a way that gives practices the flexibility to adapt and define interventions to fit their own settings. Needed are research designs that foster reflection and rigorously evaluate not only the research outcomes but also the process for achieving those outcomes.^{33,49,66–68} Also needed are modifications to the Consolidated Standards of Reporting Trials criteria to include the reporting of changes during implementation (www.consort-statement.org/). Together these changes may help to more effectively translate good evidence-based ideas into practice.

This research was funded by grants #047075 and #053221 from the RWJF. It was also supported in part by an American Cancer Society Clinical Research Fellowship grant to Dr. Stange.

No financial disclosures were reported by the authors of this paper.

References

- Campbell M, Fitzpatrick R, Haines A, et al. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694–6.
- Dusenbury L, Brannigan R, Falco M, Hansen WB. A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Educ Res* 2003;18:237–56.
- Berman P, McLaughlin MW. Implementation of educational innovation. *The educational forum* 1976;40:345–70.
- Mittman BS. Creating the evidence base for quality improvement collaboratives. *Ann Intern Med* 2004;140:897–901.
- Ovretveit J, Bate P, Cleary P, et al. Quality collaboratives: lessons from research. *Qual Saf Health Care* 2002;11:345–51.
- Glasgow RE, Emmons KM. How can we increase translation of research into practice? Types of evidence needed. *Annu Rev Public Health* 2007;28:413–33.
- Horn SD. Performance measures and clinical outcomes. *JAMA* 2006;296:2731–2.
- Green LW, Glasgow RE. Evaluating the relevance, generalization, and applicability of research: issues in external validation and translation methodology. *Eval Health Prof* 2006;29:126–53.
- Dumas JE, Lynch AM, Laughlin JE, Phillips Smith E, Prinz RJ. Promoting intervention fidelity. Conceptual issues, methods, and preliminary results from the EARLY ALLIANCE prevention trial. *Am J Prev Med* 2001;20:38–47.
- Orwin RG. Assessing program fidelity in substance abuse health services research. *Addiction* 2000;95:S309–27.
- Resnick B, Inguito P, Orwig D, et al. Treatment fidelity in behavior change research: a case example. *Nurs Res* 2005;54:139–43.
- Spillane V, Byrne MC, Byrne M, Leathem CS, O'Malley M, Cupples ME. Monitoring treatment fidelity in a randomized controlled trial of a complex intervention. *J Adv Nurs* 2007;60:343–52.
- Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. *Implement Sci* 2007;2:40.
- Rogers E. Diffusion of innovations. 4th ed. New York: The Free Press, 1995.
- Glasgow RE, Klesges LM, Dzawaltowski DA, Bull SS, Estabrooks PA. The future of health behavior change research: what is needed to improve translation of research into health promotion practice? *Ann Behav Med* 2004;27:3–12.
- McGinnis JM, Foege W. Actual causes of death in the U.S. *JAMA* 1993;270:2207–12.
- McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the U.S. *N Engl J Med* 2003;348:2635–45.
- Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the U.S., 2000 [published erratum in *JAMA* 2005;293(3):293–4]. *JAMA* 2000;284(291):1238–45.
- Woolf SH, Glasgow RE, Krist A, et al. Putting it together: finding success in behavior change through integration of services. *Ann Fam Med* 2005;3:S20–7.
- Stange KC, Woolf SH, Gjeltema K. One minute for prevention: the power of leveraging to fulfill the promise of health behavior counseling. *Am J Prev Med* 2002;22:320–3.
- Whitlock EP, Orleans CT, Pender N, Allan J. Evaluating primary care behavioral counseling interventions: an evidence-based approach. *Am J Prev Med* 2002;22:267–84.
- Center for the Advancement of Health. Integration of health behavior counseling in routine medical care. Washington DC: Center for the Advancement of Health, 2001.
- Green LA. The view from 2020: how family practice failed. *Fam Med* 2001;33:320–4.
- USDHHS. Treating tobacco use and dependence: a clinical practical guide, 2000. Washington DC: NIH, 2000.
- U.S. Preventive Services Task Force. Behavioral counseling in primary care to promote healthy diet: recommendations and rationale. *Am J Prev Med* 2003;24:93–100.
- U.S. Preventive Services Task Force. Behavioral counseling in primary care to promote physical activity: recommendations and rationale. *Ann Intern Med* 2002;137:205–7.
- U.S. Preventive Services Task Force. Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: recommendations and rationale. *Ann Intern Med* 2004;140:554–7.
- IOM. Crossing the quality chasm: a new health system for the twenty-first century. Washington DC: National Academy Press, 2001.
- Glasgow RE, Orleans CT, Wagner EH. Does the chronic care model serve also as a template for improving prevention? *Milbank Q* 2001;79:579–612, iv–v.
- Stetler CB, Legro MW, Wallace CM, et al. The role of formative evaluation in implementation research and the QUERI experience. *J Gen Intern Med* 2006;21:S1–8.
- Cohen D, McDaniel RR Jr, Crabtree BF, et al. A practice change model for quality improvement in primary care practice. *J Healthc Manag* 2004;49:155–68; discussion 169–70.
- Grol R, Baker R, Moss F. Quality improvement research: understanding the science of change in health care. *Qual Saf Health Care* 2002;11:110–1.
- Miller WL, McDaniel RR Jr, Crabtree BF, Stange KC. Practice jazz: understanding variation in family practices using complexity science. *J Fam Pract* 2001;50:872–8.
- McDaniel R, Driebe DJ. Complexity science and health care management. In: Blair JD, Fottler MD, Savage GT, eds. *Advances in Health Care Management*, vol 2. Stamford CN: JAI Press, 2001.
- Stange KC. The paradox of the parts and the whole in understanding and improving general practice. *Int J Qual Health Care* 2002;14:267–8.
- Cohen DJ, Leviton LC, Isaacson N, Tallia AF, Crabtree BF. Online diaries for qualitative evaluation: gaining real-time insights. *Am J Eval* 2006;27:163–84.

37. Cohen DJ, Tallia AF, Crabtree BF, Young DM. Implementing health behavior change in primary care: lessons from Prescription for Health. *Ann Fam Med* 2005;3:S12-9.
38. Crabtree BF, Miller WL, eds. *Doing qualitative research*. 2nd ed. Thousand Oaks CA: Sage Publications, Inc., 1999.
39. Miller WL, Crabtree BF. The dance of interpretation. In: Crabtree BF, Miller WL, eds. *Doing qualitative research*. 2nd ed. Thousand Oaks CA: Sage Publications, Inc., 1999.
40. Borkan J. Immersion/crystallization. In: Crabtree BF, Miller WL, eds. *Doing qualitative research*. 2nd ed. Thousand Oaks CA: Sage Publications, Inc., 1999.
41. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1322-7.
42. Kaiser Permanente Colorado Region Institute for Health Research. re-aim.org/.
43. Friedman RH. Automated telephone conversations to assess health behavior and deliver behavioral interventions. *J Med Syst* 1998;22:95-102.
44. Friedman RH, Kazis LE, Jette A, et al. A telecommunications system for monitoring and counseling patients with hypertension. Impact on medication adherence and blood pressure control. *Am J Hypertens* 1996;9:285-92.
45. Friedman RH, Stollerman J, Rozenblyum L, et al. A telecommunications system to manage patients with chronic disease. *Medinfo* 1998;9(Pt 2): 1330-4.
46. Ramelson HZ, Friedman RH, Ockene JK. An automated telephone-based smoking cessation education and counseling system. *Patient Educ Couns* 1999;36:131-44.
47. Delichatsios HK, Friedman RH, Glanz K, et al. Randomized trial of a "talking computer" to improve adults' eating habits. *Am J Health Promot* 2001;15:215-24.
48. Woolf SH. The meaning of translational research and why it matters. *JAMA* 2008;299:211-3.
49. Davidoff F, Batalden P. Toward stronger evidence on quality improvement. Draft publication guidelines: the beginning of a consensus project. *Qual Saf Health Care* 2005;14:319-325.
50. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. *JAMA* 2003;290:1624-32.
51. Glasgow RE. Translating research to practice: lessons learned, areas for improvement, and future directions. *Diabetes Care* 2003;26:2451-6.
52. Glasgow RE. Practical, practice, and policy relevant trials. *Curr Diab Rep* 2004;4:111-2.
53. Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *Am J Public Health* 2003;93:1261-7.
54. Green LW. From research to "best practices" in other settings and populations. *Am J Health Behav* 2001;25:165-78.
55. Green LW. Public health asks of systems science: to advance our evidence-based practice, can you help us get more practice-based evidence? *Am J Public Health* 2006;96:406-9.
56. Green LW, Kreuter MW. Fighting back or fighting themselves? Community coalitions against substance abuse and their use of best practices. *Am J Prev Med* 2002;23:303-6.
57. Green LW, Mercer SL. Can public health researchers and agencies reconcile the push from funding bodies and the pull from communities? *Am J Public Health* 2001;91:1926-9.
58. Green LW, Ottoson JM. From efficacy to effectiveness to community and back: evidence-based practice vs. practice-based evidence. In: *From clinical trials to community: the science of translating diabetes and obesity research*. Bethesda MD: National Institutes of Diabetes, Digestive and Kidney Diseases, NIH, 2004.
59. Dziewaltowski DA, Estabrooks PA, Glasgow RE. The future of physical activity behavior change research: what is needed to improve translation of research into health promotion practice? *Exerc Sport Sci Rev* 2004;32: 57-63.
60. Dziewaltowski DA, Estabrooks PA, Klesges LM, Bull S, Glasgow RE. Behavior change intervention research in community settings: How generalizable are the results? *Health Promot Int* 2004;19:235-45.
61. Dziewaltowski DA, Estabrooks PA, Klesges LM, Glasgow RE. TREND: an important step, but not enough. *Am J Public Health* 2004;94:1474; author reply 1474-5.
62. Dziewaltowski DA, Glasgow RE, Klesges LM, Estabrooks PA, Brock E. RE-AIM: evidence-based standards and a Web resource to improve translation of research into practice. *Ann Behav Med* 2004;28:75-80.
63. Glasgow RE, Green LW, Klesges LM, et al. External validity: we need to do more. *Ann Behav Med* 2006;31:105-8.
64. Cretin S, Shortell SM, Keeler EB. An evaluation of collaborative interventions to improve chronic illness care. Framework and study design. *Eval Rev* 2004;28:28-51.
65. Pearson ML, Wu S, Schaefer J, et al. Assessing the implementation of the chronic care model in quality improvement collaboratives. *Health Serv Res* 2005;40:978-96.
66. Baker GR. Strengthening the contribution of quality improvement research to evidence based health care. *Qual Saf Health Care* 2006;15:150-1.
67. Batalden P, Davidoff F. What is "quality improvement" and how can it transform healthcare? *Qual Saf Health Care* 2007;16:2-3.
68. Berwick DM. Broadening the view of evidence-based medicine. *Qual Saf Health Care* 2005;14:315-6.