

Intervention design, implementation, and evaluation

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Interventions shown to be efficacious in clinical research are not routinely translated into practice. Therefore, there is a need for research that tests both the effectiveness and adoptability of evidence-based interventions in practice settings. Various issues inherent in the clinical research continuum explain the lack of research translation into practice settings.

There has been growing concern about the failure of scientific findings to influence routine practice in a timely and efficient manner. The sizable gap between evidence-based research results and their real-world application has been widely documented across various health disciplines.¹⁻⁷ It takes an average of 17 years to turn 14% of original research findings to the benefit of patient care.⁸ Bringing the findings of biomedical and clinical investigations into practice is a concept that seems to have been “lost in translation.”⁹

The clinical research continuum has been described as the progress of scientific discovery from basic biomedical research (bench) to clinical investigations with human participants (bedside) to health care and

Purpose. Strategies to improve the design, implementation, and evaluation of interventions in pharmacy practice-based research are discussed.

Summary. Various issues inherent in the clinical research continuum explain the lack of research translation into practice settings. The RE-AIM model is used to frame descriptions of strategies to design, implement, and evaluate practice-based research interventions. A major feature of RE-AIM is the shift in focus from short-term efficacy among restricted samples in controlled settings to longer-term effectiveness among more diverse samples in practice settings. The RE-AIM model consists of five dimensions: reach, effectiveness, adoption, implementation, and maintenance. Various strategies are suggested to optimize an intervention's reach. In addition to clinical measures, economic, humanistic, and process measures are recommended for measuring and optimizing the effectiveness of an intervention. Adoption is considered an assessment of an intervention's reach at the organizational level. Assess-

ment of representativeness among participating settings should also be conducted based on key characteristics relevant to a study. Several strategies are suggested to improve stakeholder buy in, thereby increasing the likelihood of intervention adoption. Intervention fidelity is important for maximizing a study's internal validity and consists of two components: integrity and differentiation. Several factors influence the likelihood and degree of intervention maintenance, including the use of existing personnel to deliver an intervention and evaluation measures that are meaningful to institutional stakeholders.

Conclusion. Application of the RE-AIM model's dimensions can enhance the reach, effectiveness, adoption, implementation, and maintenance of interventions, thus improving the quality and impact of practice-based research.

Index terms: Interventions; Methodology; Pharmacists; Pharmacy; Research

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decision-making (practice) (Figure 1).² Between each stage in the continuum, translation must occur to move scientific advancements forward, ultimately improving public health.

Type 1 translation involves the application of discoveries generated in laboratory and preclinical research to the testing of diagnostic, treatment, and preventive methods in human

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The Research Fundamentals section comprises a series of articles on important topics in pharmacy research. These include valid research design, appropriate data collection and analysis, application of research findings in practice, and publication of research results. Articles in this series have been solicited and reviewed by guest editors Lee Vermeulen, M.S., and Almut Winterstein, Ph.D.

participants. Type 2 translation aims to improve patient health by enhancing the adoption of evidence-based recommendations into everyday practice and health care decision-making and by identifying problems that contribute to the gap between recommended and actual care.¹⁰ The translational process is bidirectional between each stage; for example, findings from clinical trials can direct further biomedical research in a specific area, while problems with the implementation of treatment guidelines in community-based settings can influence the direction of clinical research. This article focuses on strategies for improving interventions in practice-based research, namely type 2 translational efforts.

Given the need for type 2 translational research, it is important for pharmacists to consider representativeness and replicability, among other factors, when designing, implementing, and evaluating interventions in practice-based settings. Evidence-based recommendations resulting from interventions tested in clinical trials are sometimes of limited relevance to practicing clinicians and administrative decision-makers.¹¹ Clinical trial participants are often highly motivated individuals without any health conditions other than the one being studied. This approach contributes to the internal validity of the findings, whereby the influence of extraneous factors is reduced so that results can be attributed to the efficacy of the intervention under investigation. However, external validity is weakened and results are not representative of an intervention's effectiveness when applied to patients in actual practice settings.¹²⁻¹⁴ Similarly, in the quest for achieving clinically significant outcomes, study interventions are often intensive, complex, expensive, and demanding of patients and pro-

viders. These interventions generally occur in academic health settings or specialty clinical settings and are performed by research staff or highly specialized clinical experts. Such conditions do not address how an intervention would work if implemented by providers in health systems or community-based settings that are accessible by larger patient populations.¹⁵

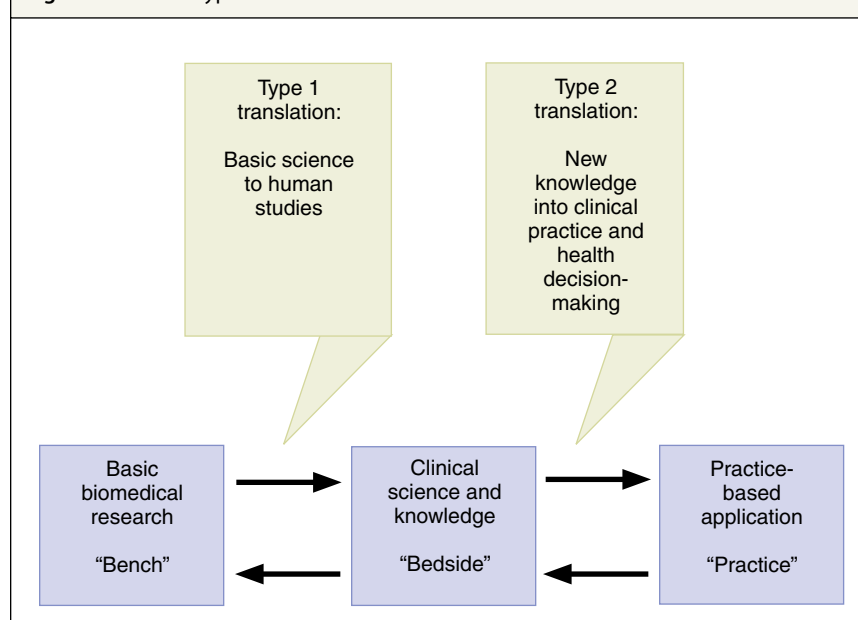
Pharmacists are well positioned to conduct research to (1) identify problems encountered in daily practice that contribute to the gap between recommended care and actual care and (2) demonstrate whether treatments with proven efficacy are truly effective and sustainable when used in practice.¹⁶ This article describes strategies to improve the design, implementation, and evaluation of interventions in pharmacy practice-based research. Specific issues related to intervention reach, effectiveness, adoption, implementation, and maintenance are discussed.

RE-AIM model

The RE-AIM model is a planning and evaluation framework used to conceptualize the public health or population-based impact of an intervention.¹⁷ The model is compatible with systems and social-ecological thinking in that it accounts for both individual and organizational factors that influence an intervention's impact.^{18,19} A major feature of RE-AIM is the shift in focus from short-term efficacy among restricted samples in controlled settings to longer-term effectiveness among more diverse samples in practice settings.^{14,20}

The model expands on Abrams and colleagues'²¹ definition of the impact of an intervention as the product of a program's reach (R), defined as the percentage of a population that receives the intervention, and efficacy (E), adding three dimensions related to research settings—adoption (A), implementation (I), and maintenance (M).¹⁷ The five RE-AIM di-

Figure 1. The two types of translation in the clinical research continuum.²



mensions are summarized in Table 1. These dimensions, along with issues related to pharmacy practice-based research, are described below.

Reach. The “reach” dimension is an individual-level measure of patient participation and representativeness. It is measured by comparing numbers of study participants with sample or census information for a target population. Calculation of patient participation rates can be conducted by dividing the number of participants by the number of persons in the target population.

The choice of a target population is influenced by the problems or questions to be investigated in the research project, including medications, diseases, and disease risk factors. Access to patient data is a determining factor in the specific criteria used to define a target population. For example, for cases in which health care utilization data are used to evaluate the effectiveness of an intervention, one criterion generally used to define a target population is continuous enrollment during the study period.

One method of identifying a target population is to screen a pool of potential participants for eligibility and then contact them via mail, e-mail, or telephone. Two examples of target populations include (1) all patrons of a pharmacy who have received an antihypertensive pre-

scription in the past month and (2) all diabetic members of a managed care organization within a specific geographic area whose most recent hemoglobin A_{1c} level was not at goal ($\geq 7.0\%$).²² Early identification of a potentially eligible pool of participants is advantageous for planning purposes; however, a lack of face-to-face contact when initially informing potential participants about a study can be a disadvantage.

Another method of identifying a target population is the screening and recruiting of potential participants in real-time encounters, such as during pharmacy or clinic visits. In such cases, initial contact regarding the study occurs in person, which gives potential participants opportunities to ask questions and receive immediate answers. Face-to-face recruitment generally yields the highest recruitment rate and the lowest attrition rate. This approach, however, can be hindered by the long recruitment periods sometimes required to accumulate expected numbers of participants and the limited personnel resources available to screen and recruit eligible participants.

Deciding how many participants to recruit is an issue that influences the potential for an intervention’s reach. If too few participants are recruited, a study may have inadequate statistical power to detect a difference between groups, otherwise known

as a type II error. During a study’s planning phase, an analysis should be conducted to determine how many participants are needed to ensure statistical power to detect a desirable effect size or intervention magnitude.

The reach dimension of the RE-AIM model also refers to whether participants are representative of the target population. Assessing representativeness can be challenging when describing nonparticipants. These individuals typically have not consented to be in a study; therefore, privacy concerns exist. Actions to address this issue include asking individuals who decline to participate to provide brief background information, conducting deidentified data retrievals from existing administrative databases, and using publicly available information such as census or Behavioral Risk Factor Surveillance System data.²³

Eligibility criteria that include individuals with common comorbid illnesses will also enhance representativeness because the study sample will be more similar to the individuals for whom the intervention is intended. It is also important to use a systematic method of participant screening, especially if more than one individual or practice site is recruiting patients. In such cases, the use of a screening protocol will help avoid selection bias among different recruiters.

Demographic and socioeconomic characteristics, such as ethnicity, educational background, and income level, should be considered when assessing participant representativeness. There is a need for increased minority participation in research to reflect the changing demographics of the U.S. population and address minorities’ historical underrepresentation in research and health disparities.²⁴⁻²⁶ Recruitment and retention of minority participants can be challenging for a number of reasons, including a lack of trust in health institutions and research, health

Table 1. RE-AIM Dimension Definitions and Levels

| Dimension | Definition | Level |
|----------------|---|-----------------------|
| Reach | Participation rate and representativeness of participants | Individual |
| Effectiveness | Effects on primary and multiple outcomes of interest, including negative outcomes | Individual |
| Adoption | Participation rate and representativeness of settings | Setting |
| Implementation | Extent to which intervention is delivered as intended | Setting |
| Maintenance | Long-term effects of intervention and extent of continuation of intervention | Individual Setting |

literacy issues, language barriers, cultural beliefs and values, and logistic considerations.²⁷

Various strategies can be used to optimize an intervention's reach. If possible, a pilot or feasibility study should be conducted to estimate the number of eligible patients and to test recruitment methods. Barriers to patient participation should be identified and reduced, and the ease of contacting eligible participants and their willingness to enroll should be considered. If participant recruitment efforts do not result in anticipated numbers, it is advisable to use multiple channels of recruitment and modified eligibility criteria that are within the scope of the study. These latter approaches are especially helpful if additional recruitment activities are conducted to obtain representative numbers of minority or underserved patients.

Effectiveness. This dimension of the RE-AIM model is an individual-level measure of intervention efficacy or effectiveness. Efficacy is a measure of how an intervention performs under optimal conditions, while effectiveness is a measure of how it performs under real-world conditions. Efficacy and effectiveness have been described as attributes of health care quality.²⁸ For reasons previously described, some efficacious interventions are not effective when implemented under less-controlled conditions. Therefore, measures of effectiveness are more appropriate in practice-based research settings.

The range and scale of interventions in practice-based research vary immensely (e.g., from a one-time telephone intervention for patients taking antibiotic therapy²⁹ to a comprehensive diabetes care program with repeated patient visits³⁰). Regardless of these differences, some basic elements of intervention design are recommended for measuring and optimizing effectiveness.

Outcomes measures. While clinical outcomes are often considered pri-

mary measures of effectiveness, the inclusion of other types of outcomes measures expands what is known about an intervention's impact.^{17,31} Outcomes selected for measurement should be relevant to patients, providers, administrators, and other stakeholders.¹¹

Economic outcomes of interventions can provide valuable information to policymakers and decision-makers regarding whether a service is worthwhile to adopt, maintain, or reimburse. Evaluation of total health care costs provides a more comprehensive view of the economic impact of an intervention than do silo-based evaluations, which typically consider medical and pharmacy claims separately.

Health organizations use various types of cost and disease classifications, such as *Current Procedural Terminology* codes,³² diagnosis-related groups,³³ and the *International Classification of Diseases, Ninth Revision, Clinical Modification* codes.³⁴ It is critical to verify the format in which health organizations maintain this information and how they would provide it for analysis purposes.

Humanistic outcomes, such as health-related quality of life (HRQL), patient satisfaction, and other patient-reported outcomes, are also important to measure. Some researchers believe that improving HRQL is the ultimate purpose of health care and pharmaceutical care.^{35,36} Well-validated HRQL measures, such as the Medical Outcomes Study Short Form-36³⁷⁻³⁹ and Short Form-12,⁴⁰ provide a common metric for comparing patient-reported outcomes, regardless of the specific diseases and interventions under investigation. The effect of pharmacist interventions on HRQL has been inconsistent, primarily due to short study periods, insufficient sample sizes, and a lack of intervention influence on HRQL.⁴¹ When possible, disease-specific HRQL measures should be administered because they

are more sensitive to changes in a patient's health status.^{42,43}

Patient satisfaction is another humanistic outcome that is indicative of the perceived quality of health care services and can be used to measure aspects of an intervention's effectiveness. Patient satisfaction questionnaires used in pharmacy research vary in focus and the inclusion of items related to structure, process, and outcomes.⁴⁴ No single standard of patient satisfaction is applicable to all pharmacy situations; therefore, whichever measure is chosen should contain items that are representative of the intervention.⁴⁵

One way to demonstrate the relevance of outcome variables while maintaining the ability to attribute effect is to measure intermediate outcome variables such as patient behaviors, health beliefs, and knowledge. Examples of patient behaviors include medication adherence and self-monitoring. Factors such as patients' perceptions of their illness and their knowledge of medication attributes have been shown to influence reports of medication adherence and HRQL.⁴⁶⁻⁴⁸ Health beliefs and patient knowledge of drug therapy can be assessed before and after an intervention to measure changes in health beliefs and learning that occur.

Intervention evaluations tend to focus on improvements in targeted health outcomes; however, interventions delivered to patients can have unintended negative consequences. For example, assessing disease severity, detecting the presence of a new illness, or recommending additional drug therapy for a current illness may have negative psychosocial and behavioral effects on patients. Furthermore, interventions that result in patients using additional medications may lead to those patients experiencing adverse effects, drug-drug interactions, or treatment failures. Hence, negative outcomes that are relevant to a study should be measured.

Process measures. Documenting processes of care and linking them to outcomes are necessary to make inferences about the effectiveness of an intervention.⁴⁹ Therefore, the processes used in an intervention should be clearly delineated and feasible to document. For interventions that involve drug therapy monitoring, it is advantageous to document any drug therapy problems identified, as drug therapy problems are part of the process of care.⁵⁰ Classifications of drug therapy problems that have been reported and evaluated in the literature ought to be used to allow comparisons with other research and provide further validation of measures.⁵¹⁻⁵³

Adoption. The adoption dimension of the RE-AIM model is a function of the participation rate among settings and the representativeness of these settings. Therefore, adoption is considered an assessment of an intervention's reach at the organizational level. Setting participation rates can be calculated as the proportion of approached settings that adopt an intervention. Representativeness of participating settings should also be assessed based on key characteristics relevant to a study.

Although settings include practice sites and health organizations, they comprise key individuals such as providers, supervisors, and administrators, all of whom collectively influence adoption. These individuals are stakeholders in a study's design, implementation, and evaluation. It is imperative to develop interventions that stakeholders are willing to adopt.

Rogers⁵⁴ diffusion of innovation theory provides some guidance on the five stages that individuals and organizations progress through when deciding whether to adopt a new activity, such as an intervention in a research program: (1) knowledge, (2) persuasion, (3) decision, (4) implementation, and (5) confirmation. This is known as the

innovation-decision process. In the knowledge stage, individuals and organizations become aware of an innovation's existence and functions. In the persuasion stage, individuals and organizations form favorable or unfavorable attitudes about an innovation. During the decision stage, a choice is made to adopt or reject an innovation. Engagement in activities to put the innovation into use and maintenance of the innovation occur in the implementation and confirmation stages, respectively.

Because they precede the decision to adopt an innovation, the knowledge and persuasion stages of the innovation-decision process are vital for ensuring that stakeholders participate in a research program. Several strategies can be used to improve stakeholder buy in, thereby increasing the likelihood of adoption.⁵⁴

Before planning a study, it is important to cultivate collaborative relationships with potential stakeholders. Consequently, when an opportunity to plan a study presents itself, stakeholders are already aware of mutual benefits from working together. While planning a study, stakeholders should be consulted to generate support and consensus on study design, measures, and procedures, as sharing control over research design and implementation helps to decrease potential barriers.⁵⁵

Stakeholders should agree with the overall goal of the study and find the study's purpose and protocol appealing. Potential benefits to stakeholders as a result of study participation should be clear and outweigh costs, resource expenditures, and potential risks. If a study has been designed to measure multiple types of outcomes, then the potential benefits of study participation can be justified from various perspectives.

Interventions should have a relative advantage over current practices but be compatible with existing practice culture, norms, and values.⁵⁴ Interventions should also be easy to un-

derstand and feasible to implement, since those that have a low impact on practice flow and do not adversely interfere with other clinician-patient relationships are more likely to be adopted.^{20,56} Collaborating providers, such as physicians, nurses, and dietitians, should concur with the aspects of the study protocol that will require their involvement. Flexibility when planning interventions is important. Study protocols may have to be modified before a stakeholder will agree to participate. If pharmacists need time away from usual work activities, they could present their supervisors with a plan consisting of issues they are attempting to address, the intervention's goal, activities involved, expected outcomes, estimated time required, feasibility of the plan, and how expected outcomes will benefit the organization. Intervention delivery to a limited number of patients could also be negotiated to demonstrate effectiveness and commitment before requesting time away from usual work activities.

In the case of experimental studies, stakeholders, such as collaborating providers and health organizations, may feel uncomfortable having a control group of patients who do not receive an intervention. Some researchers have called for studies that compare clinically relevant alternative interventions instead of comparisons of an intervention with no intervention.^{5,11,57} These types of comparisons more closely represent the decisions that policymakers face on a daily basis.

Stakeholders may not perceive a need to conduct a study. In such cases, access to relevant baseline performance data may be requested to raise awareness of areas needing improvement or for comparison with external benchmarks.⁵⁵

The adoption dimension of the RE-AIM model also addresses the representativeness of settings in which interventions are adopted. The representative aspect of adoption is

related to the replicability of an intervention. Investigations conducted in specialty settings that rely on high levels of resources or that can only be delivered by a small number of leading experts are unlikely to be replicated outside a research environment.^{57,58} Thus, interventions that can be implemented with existing staff and resources are more likely to be adopted.²⁰

Implementation. The implementation dimension of the RE-AIM model refers to intervention fidelity—the adherent and competent delivery of an intervention as proposed in a research plan.⁵⁹ Intervention fidelity consists of two components: integrity and differentiation. Intervention integrity is the extent to which providers deliver an intervention as planned to its intended recipients. Intervention differentiation is the extent to which participant exposure to an intervention differs as intended.⁶⁰

Intervention fidelity is important for maximizing a study's internal validity, or the soundness of conclusions about an intervention's effect on outcomes. If an intervention evaluation yields significant results but intervention fidelity was not measured, the inference that the intervention was effective is weakened. In contrast, if the results are not significant, it is unclear if this is due to an ineffective intervention or to a lack of intervention fidelity. The latter has been termed a type III error (i.e., evaluating an intervention that has not been adequately implemented).⁶¹

The primary focus of intervention fidelity is on the provider. Interventions delivered by multiple pharmacists or at multiple practice sites can present additional challenges to intervention fidelity. Therefore, much of this section includes strategies for implementing interventions and optimizing intervention fidelity in studies in which a pharmacist researcher designs and implements an intervention to be delivered by

multiple pharmacists or at multiple practice sites.

Training. Pharmacists can bring a wide range of skills and expertise to a study, which can ultimately increase variance in intervention delivery. Having a high degree of structure in intervention design and providing standardized training can increase the likelihood that interventions will be delivered consistently across pharmacists. The intent is to decrease the likelihood of provider influence on the intervention, thus reducing variance in intervention delivery and minimizing differential outcomes by providers. Despite the emphasis on standardized training, provider training should remain adequately individualized to account for different levels of education and experience among pharmacists.⁶⁰

Providers should be trained at multiple times during a study. Offering periodic booster training sessions can minimize decay of skills and straying from the study protocol.⁶⁰ Challenging patient cases, questions, and problems that providers have identified can also be used during training sessions. Such interactions foster interest, collegiality, and ownership in a research project.

To address possible study setbacks due to provider drop out, it is advantageous to train extra providers beyond those initially needed.⁶⁰ This strategy will result in a pool of potential providers from which to select replacements when needed. In addition, it will alleviate rushed training of additional providers.

Ensuring skill acquisition can be accomplished by training providers to fulfill specific performance criteria. Recommended methods include pretests and posttests, case analyses, role-playing with standardized patient cases, and checklists for scoring provider adherence. Areas that should be assessed for provider competence include application of current standards of care, clinical decision-making, interpretation

of protocol requirements, use of monitoring equipment, documentation of intervention delivery, and communication with patients and physicians. To ensure adequate levels of provider training and skills application, initial instances of intervention delivery should be supervised whenever feasible.

Monitoring. In general, monitoring intervention fidelity includes ensuring the standardized delivery of an intervention and evaluating protocol adherence. The following specific areas should be monitored: the extent of overall intervention implementation, changes in intervention implementation during the study, consistency of intervention delivery among different providers, and diffusion of intervention activities to participants in control or modified-intervention groups.

The gold standard for monitoring intervention fidelity is to observe realtime, videotaped, or audiotaped intervention encounters and code them based on predetermined criteria.⁶⁰ Observations can be selected at random or at specific times in a study (e.g., weekly, monthly). This approach, however, can be time-consuming and expensive. An alternative approach is for providers to complete process-evaluation forms or checklists after encounters with study participants. Lastly, selected components of intervention documentation can be reviewed for protocol adherence.

The extent of overall intervention implementation can be assessed by estimating the proportion of interventions that were conducted. Changes in intervention fidelity over the course of a study can be estimated by comparing intervention delivery during the first and second halves of a study or on a quarterly basis. If particular intervention components are deemed worthwhile to assess individually, these completion rates can also be reported. Completion rates can take into account errors of omis-

sion (e.g., missing data) and commission (e.g., incorrectly reported data) in intervention delivery. For example, a study to assess the effectiveness of a pharmaceutical care program for patients with reactive airways disease found that pharmacists accessed patient data only about half of the time and documented actions related to these data about half of the time.⁶²

Consistency of intervention delivery among multiple pharmacists should be monitored, as should participant dropout rates for differential occurrences based on provider.⁶⁰ Offering periodic forums for providers to discuss cases and review skills needed for intervention delivery can facilitate consistent intervention implementation and protocol adherence across providers. Individualized coaching is also useful when a small number of providers have been identified as exhibiting low adherence to intervention delivery.⁶³ These one-on-one sessions should also be used for providers to voice barriers to intervention delivery and seek input on ways to overcome them.

Monitoring of intervention fidelity also includes reviewing the extent of intervention delivery to its non-intended recipients, such as control or modified-intervention groups in experimental research. One strategy to optimize intervention differentiation is to have separate intervention and control practice sites. This approach lessens opportunities and temptations for providers at the control site to offer components of an intervention to its participants. Exit interviews with participants in the control group can also be conducted to determine if participants received any component of an intervention.⁶⁰

Analysis considerations. It is typical for studies to compare outcomes between control and intervention group participants or to compare data for participants before and after receiving an intervention. The intervention or postintervention designation assumes that patients received

an intervention as it was intended; intervention fidelity is not considered. As previously discussed, failure to consider intervention fidelity can result in incorrect conclusions about the effectiveness of an intervention. To address this issue, intervention fidelity can be measured to supplement statistical analyses and determine the extent of an intervention's influence on study results. By using intervention fidelity as a covariate in analyses, an intervention's relative effect can be better estimated based on the degree to which it was implemented.^{59,60}

Optimizing intervention fidelity during a single study can also improve the chance of achieving significant results. For example, detection of providers drifting from a study protocol could warrant retraining of these individuals and thereby augment a study's internal validity.⁶⁰ Improving intervention fidelity in studies over time can help bolster statistical power due to an increase in effect size from reducing random and unintended variability. This increase in effect size will reduce the number of participants who need to be recruited in future studies. Lastly, the use and reporting of intervention fidelity strategies are useful for research dissemination and translation because they establish guidelines for replicating and implementing interventions in other studies and practices.⁶⁰

It is essential to design measures for intervention fidelity during the planning phase of a study and to consistently monitor intervention fidelity throughout a study period.

Maintenance. The final dimension of the RE-AIM model operates at both the individual and setting levels. At the individual level, the maintenance dimension refers to the long-term effects of an intervention on its recipients. At the setting level, it refers to intervention institutionalization, or the extent to which an intervention becomes a stable part of routine care within an organiza-

tion. A maintenance period of two or more years has been suggested, with assessments at recurring time periods based on goals for a particular intervention and setting.¹⁷

Several factors influence the likelihood and degree of intervention maintenance. The manner in which an organization or a practice site is initially approached to participate in intervention research affects the long-term sustainability of an intervention. The nature of research can undermine intervention maintenance. If a project is presented as research with a defined beginning and end, administrators and providers may view it as self-limiting. In contrast, if a project is marketed as a practice improvement effort, it may be viewed more as a permanent change.⁶⁴

The same principle holds true for patients. Relapses in health behaviors and outcomes after study participation can occur, particularly after short study periods and the loss of provider care and support. For example, a significant reduction in medication adherence was observed among a group of elderly patients with coronary risk factors who were assigned to six months of usual care after undergoing six months of a medication adherence intervention by pharmacists.⁶⁵ The effects of a short-term intervention on patient outcomes are likely to be just that—short term.

The use of existing personnel to deliver an intervention is critical for its maintenance. Adding personnel, such as research assistants, to a practice to conduct study activities rather than relying on current personnel decreases the likelihood of intervention maintenance. In these cases, practice change is less likely because the practice continues to function as before the intervention was implemented. After the study ends, the practice is left without the means to maintain the intervention.

Intervention evaluation measures that are meaningful to an

institution's stakeholders may positively influence decisions to sustain an intervention. This approach may be accomplished, for example, by reporting cost savings. Another intuitive measure is the number needed to treat (i.e., the number of patients who need to be treated with a particular intervention to have one patient achieve a particular treatment outcome or avoid a particular adverse event).^{66,67} It is the reciprocal of the absolute risk reduction derived from a study and offers information that can help providers and administrative decision-makers distinguish between statistical and clinical significance. The number needed to treat can be used to strengthen support for maintaining a study intervention by making it available to other patients within a setting, such as those formerly in a control group or those who had not been sampled for study participation.

The Asheville Project is an example of intervention maintenance. The program researchers reported the persistence of improved outcomes for up to five years among patients with diabetes and asthma.^{68,69} The programs were designed as quasi-experimental, longitudinal pretest-posttest studies. Interventions consisted of disease education by certified educators, scheduled visits with specially trained community pharmacists for monitoring, and recommendations for physicians.

Various factors contributed to the maintenance of the Asheville Project interventions. The two self-insured employer groups, the City of Asheville and the Mission-St. Joseph's Health System, were able to evaluate the program's economic impact across the spectrum of total health care costs.⁷⁰ This viewpoint was important because, although costs associated with inpatient and outpatient medical services decreased while medication-associated costs increased, there was an overall

cost saving after the inception of the program's interventions.^{68,69}

Long-term patient participation in program interventions were largely influenced by waived copayments for program-related medications and supplies. Program participants reported the ongoing relationships with pharmacists and disease educators as critical to their involvement in the program. These relationships helped instill a trusting environment for patients in which they received encouragement and felt hopeful about managing their disease.⁷¹

Open and timely communication between providers and the employer groups was also essential to the project's maintenance. The City of Asheville originally agreed to participate in the diabetes project for one year to determine if the intervention would lower total health care costs. The overwhelming cost saving seen six months into the program resulted in a decision to reimburse pharmacists earlier than anticipated.⁷¹

The community-based pharmacists who delivered pharmaceutical care services were integral to the project's longevity. The provision of pharmaceutical care services was incorporated into their usual care processes, thus enabling sustained service delivery. Coordination of care and referrals among pharmacists, physicians, and disease educators was also important to the project's sustainability. All of these factors likely influenced decisions that led to institutionalization of the Asheville intervention and long-term outcomes improvement among patients.

Intervention maintenance is perhaps the most challenging and certainly the least measured RE-AIM dimension.⁷¹ Yet it is the dimension most closely tied to translation of clinical research into practice because institutionalization of an intervention and sustainability of its effects on patients are necessary for long-term improvements in patient care.

Discussion

It has been stated that "if we want more evidence-based practice, we need more practice-based evidence."⁷² Future translation of clinical research findings into practice will rely heavily on studies conducted in practice settings addressing problems relevant to practices and intended to improve practice.¹⁶ Practice-based interventions must be designed, implemented, and evaluated to determine if they are truly effective and sustainable when provided in real-world settings. Toward this end, pharmacists should ask questions related to reach, effectiveness, adoption, implementation, and maintenance when planning practice-based interventions.

The dimensions of the RE-AIM model provide a comprehensive set of criteria for intervention design, implementation, and evaluation that should be relevant to various stakeholders. Two strengths of the framework are its emphasis on external validity (reach and adoption) and internal validity (effectiveness and implementation), as well as its perspective of both individual and institutional levels.²⁰

Decision-makers and stakeholders may place greater emphasis on one or more of these dimensions. Some may be concerned primarily with reaching the largest number of patients, while others may focus on an intervention's effectiveness or the likelihood of it being consistently implemented. It is advisable to consider these issues and multiple perspectives when planning an intervention.

Funding agencies should consider inclusion of the RE-AIM model's dimensions in requests for proposals.¹⁴ For example, innovative ways to enhance reach, adoption, implementation, and maintenance should be funded, since all of these have been historically deemphasized in relation to effectiveness. Agencies should require plans for institutionalization of an intervention once the funding

period has ended. Funding for long-term effects and sustainability of initially successful interventions should be offered. Lastly, measurement of intervention fidelity and process measures ought to be encouraged.

Conclusion

Application of the RE-AIM model's dimensions can enhance the reach, effectiveness, adoption, implementation, and maintenance of interventions, thus improving the quality and impact of practice-based research.

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