Translating What We Have Learned into Practice Principles and Hypotheses for Interventions Addressing Multiple Behaviors in Primary Care

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Background: The evidence base regarding what works in practice for helping patients change multiple

risk behaviors is less developed than is the more basic literature on behavior change. Still, there is enough consistency of findings to present testable hypotheses for clinicians and administrators to evaluate and guide practice until more definitive evidence is available.

Methods: The behavior change principles known as the 5A's outline a sequence of support activities

(assess, advise, agree, assist, arrange) that are effective for helping patients to change various health behaviors. These same principles also apply at the clinic level for designing

activities to support behavior change.

Results: Successful practices promoting sustainable changes in multiple behaviors are patient

centered, tailored, proactive, population based, culturally proficient, multilevel, and ongoing. Often a stepped-care model can be used to provide increasingly intensive (and

costly) interventions for patients who are not successful at earlier intervention levels.

Conclusions: Contextual factors are influential in determining success at both the patient and the office

practice level. Therefore, greater attention should be paid to creating supportive family, healthcare system, and community resources and policies. We enumerate 15 hypotheses to be tested for improving patient–clinician interactions and for medical office change.

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Introduction

ittle is known about disseminating efficacious programs for promoting multiple healthy patient behaviors in clinical settings. 1,2 This is acknowledged as an important area, but due to a history of categorical funding and scientific reductionism, there are few effectiveness studies upon which to draw.^{2,3} Practitioners cannot wait for definitive evidence, but need to act on these issues each day. Therefore, after a brief review of the few directly applicable studies, we suggest both some principles and related hypotheses to be tested in clinical practice to facilitate translation from research to practice and vice versa. Although the evidence is not definitive, the emerging data are consistent enough and the need sufficiently compelling⁴⁻⁷ to develop suggestions for dissemination and improving clinical practice. We adhigh risk for disease: smoking, poor diet, sedentary behavior, and risky drinking (www.communityguide. com).^{8,9} The rationale for these four behaviors is dealt with in detail by Babor et al.⁵ and Fine et al.,⁶ and is based on their prevalence, their toll on morbidity and mortality, and the opportunity to address these issues in primary care. In addition to the literature on dissemination of intervention practices to promote multiple behavioral changes by patients, we have drawn on the related literature on single risk behaviors, general health promotion, disease management, quality improvement, theory, and clinical experience.

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The purposes of this article are (1) to present a series of general principles resulting from theory and evidence to guide multiple risk factor interventions; (2) to present a series of more specific hypotheses that can be tested in primary care settings for enhancing patient behavior change; (3) to summarize the quality improvement literature on strategies to improve behavioral counseling in clinical settings; and (4) to present a second set of hypotheses for changing healthcare office practices and healthcare professional behaviors. It is not the intent of this article to systematically review the evidence on multiple behavior change—the article by Goldstein et al.⁴ in this supplement does that. Our goal is to provide clinicians and researchers working in

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community settings with hypotheses whose support (or disconfirmation) would enhance the science of translation research.

In addition to transferring research findings into widespread delivery for individual and population health care, practice also needs to inform research. Practice-based research networks¹⁰ and similar collaborations in community settings have great potential to advance our knowledge of what works in clinical practice environments.

It is important to establish a common vocabulary to discuss the issues involved in translating research into practice (and vice versa). One of the barriers to progress in effective translation has been that different experts use the terms "diffusion," "dissemination," and "translation" differently. Since standardized definitions do not now exist, for purposes of this paper the following definitions, consistent with a recent National Cancer Institute (NCI) meeting on translation,¹¹ are used:

Diffusion: The passive process by which a program or product is absorbed into more widespread use. ¹²

Dissemination: The active promotion or support of a program to encourage its widespread adoption. This involves adaptation, evaluation, implementation, and maintenance of an intervention. Although dissemination and diffusion are sometimes used interchangeably, dissemination is considered to be a more proactive process of influencing the rate of adoption. ¹³

Translation: This term was not defined at the NCI conference, but we will define it as the process of adapting, modifying or "re-inventing" an intervention that has been previously tested and found efficacious to make it workable in a practice setting. This definition is different from that used by the National Institutes of Health (NIH) Clinical Road Map, and is closer to the second of two steps—bedside to community—in their framework.

Working Framework to Evaluate Behavior Change Counseling

It is helpful to have a framework or set of criteria against which to judge both studies and plans for translation to practice. A framework can help focus attention on key dimensions important for real-world application. We have selected the RE-AIM framework for this purpose ^{14,15} (www.re-aim.org). RE-AIM is an acronym, the key elements of which are reach, effectiveness (including quality of life and adverse outcomes), adoption, implementation, and maintenance/ sustainability. Table 1 lists RE-AIM key dimensions, questions to ask related to each of these dimensions, and suggestions for how to improve results related to each dimension.

Given this RE-AIM perspective, when considering the hypotheses below it is important to ask, "better" on what dimensions or what outcomes? Unless otherwise specified, we hypothesize that the actions recommended for real-world testing below will be superior in terms of reach (used by or with more patients), effectiveness (indicated by behavior change attempts, success at behavior change, and improvement in quality of life and patient satisfaction), and maintenance, as indicated by longer-term success on the above outcomes. Other factors being equal, we also expect superior results with respect to adoption and implementation, which reflect the ease with which an intervention can be integrated into real-world primary care settings.

As discussed in more detail elsewhere, ^{16,17} outcomes important to collect in translation research can be grouped into five categories. The first three—generalization, implementation, and economic measures—can often be collected without adding any burden to participants by keeping careful records and by conducting straightforward comparative analyses. ^{16,17}

- Generalization is at the heart of translation research and can be assessed by evaluating the participation rate and representativeness of patients, clinical settings, and staff delivering an intervention (see www. re-aim.org).
- 2. Implementation is assessed by documenting intervention delivery and by reporting the consistency with which specific staff members implement various intervention components.
- 3. Health care is a limited resource that clinicians, administrators, and policymakers must allocate every day. ¹⁸ Therefore, some basic economic measures, such as cost to develop, train, and deliver interventions should be reported routinely. ¹⁹

The final two outcomes recommended require responses from patients, but are at the heart of patient-centered primary care and behavioral counseling.

- 4. Behavior change, at both the patient and clinician/
 staff level, is the proximal target of behavioral counseling and quality improvement efforts. The specific
 behavioral measures should be relevant to the evaluation question and target behaviors being studied,
 but Hypotheses 1 through 6 below should be evaluated by measures of patient behavior change. Measures of staff and office practices or policies, as
 relevant to a given issue, are as important as are
 measures of patient behavior change, and should be
 the primary outcomes for tests of Hypotheses 7
 through 15 below.
- 5. Quality of life is the ultimate bottom line of all healthcare interventions, and should be reported to provide a common metric across studies.

Dimensions for dissemination	Questions to ask of potential programs	Strategies to enhance future translation and dissemination		
Reach (individual level)	 What percent of the target population would come in contact with your program? 	Formative evaluation with potential users Small scale recruitment studies to enhance methods		
	2. Will you reach the neediest?	Identify and reduce participation barriers		
	3. Will research participants reflect the targeted population?	Use multiple channels of recruitment		
Effectiveness (individual level)	 Will the intervention likely affect key targeted outcomes? What unintended adverse 	Incorporate tailoring to individuals Reinforce messages via repetition, multiple modalities, social support,		
	consequences may occur?	and systems change		
	3. How will impact on quality of life be assessed?	Consider stepped care approaches Evaluate adverse outcomes and quality of life for program revision and cost- benefit analysis		
Adoption (setting or organizational level)	1. What percent of target settings and organizations will use the program?	Conduct formative evaluation with adoptees and nonadoptees		
	2. Do organizations include high-risk or underserved populations?	Recruit settings that have contact with the target audience		
	Does program fit with organizational goals and capacities?	Develop recruitment materials outlining program benefits and required resources		
		Provide various cost options and customization of the intervention		
Implementation (setting or organizational level)	 Can different levels of staff successfully deliver the program? 	Provide delivery agents with training and technical assistance		
	2. What proportion of staff within a	Provide clear intervention protocols		
	setting will agree to program delivery? 3. What is the likelihood that various	Consider automating all/part of the program		
	components will be delivered as intended?	Monitor and provide staff feedback and recognition for implementation		
Maintenance (individual [I] and setting [S] levels)	Does the program produce long-term individual behavior change?	Minimize level of resources required Incorporate "natural environmental" and		
	2. Will organizations continue the	community supports		
	program over time?	Conduct follow-up assessments and		
	3. What are characteristics of persons and settings showing maintenance?	interviews to characterize success at both I and S levels		
	0 0	Consider incentives and policy supports		

RE-AIM, reach effectiveness, adoption, implementation, and maintenance/sustainability.

Principles and Testable Hypotheses for Helping Patients Change Multiple Behaviors

Principle 1. Greater use and more systematic implementation of the "5A's" model of self-management and behavior change counseling will produce superior outcomes.

The 5A's model was initially developed by NCI investigators from the literature on smoking cessation, and refined over time, ^{20–22} and has been the basis of many programs to train clinicians to intervene with other behaviors such as diet and high-risk drinking. ^{23–25} It also is consistent with more recent conceptualizations of the key steps in chronic illness self-management, ^{26,27} and evidence supporting it is presented by Goldstein et al. ⁴ in this supplement and by Glasgow et al. ²⁷ In brief, behavioral counseling is a series of five interrelated and iterative steps, each of which informs the development of a personal action plan for the patient. ⁸

This sequence begins with assessment of patient status on multiple health behaviors and their beliefs (importance, confidence, intention) related to these behaviors. Based on an individual's risk pattern, and combining information on behavior with family and personal history, personal models, and other information, the clinician then provides clear and specific, personalized advice regarding the need for the patient to change one or more behaviors. It is important that this advice be provided in an interactive manner that includes a discussion of what the patient thinks and feels about the clinician's advice and recommendations. A collaborative goal-setting process²⁸ of agreeing on a mutually negotiated, achievable, and specific plan (the what, when, where, and how of an action plan or behavior change contract) then follows.

This planning includes problem-solving assistance to identify and anticipate barriers to achieving the identi-

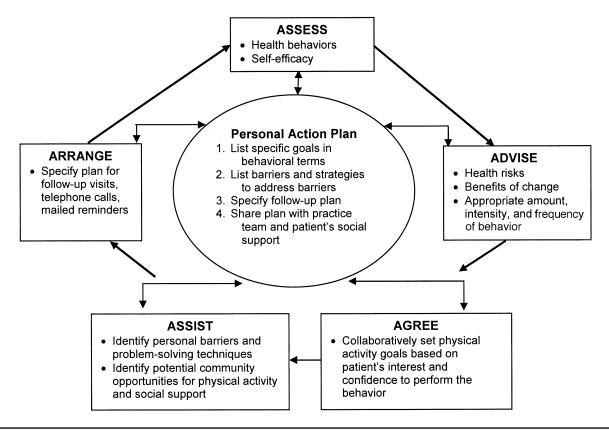


Figure 1. A schematic to direct effective multiple behavior change counseling in a primary care setting.

fied goals and generate solutions for overcoming these barriers. Problem solving ^{22,24,25,29} is increasingly being viewed as the heart of successful self-management and behavior change. ^{27,30,31} Problem solving is also one of the key behavioral strategies demonstrated to be effective in smoking cessation, as documented in the Agency for Healthcare Research and Quality (AHRQ) Tobacco Treatment Guideline. ³² Key aspects of successful problem solving are that multiple solutions are generated (any one strategy is unlikely to work in all situations), and are produced or selected by the patient based on their history, social environment, and what they are willing to do.

The final "A" is to arrange follow-up support and assistance, including connecting with community resources. This aspect of the counseling model is unfortunately often left out, but is critical to long-term success. Frequently, an initial plan does not go exactly as envisioned, but brief follow-up contact in the form of telephone calls or other types of support have been found to be very cost-effective. 33–38 A series of specific testable hypotheses related to the 5A's for primary care offices follows:

Hypothesis 1. Consistently assessing patients' behavioral changes and providing feedback to them (e.g., recording behavioral changes in patients' charts as a vital sign; having patients self-monitor and report back) will produce more success in the long term. ^{32,39}

Such periodic patient assessment and individually tailored feedback can include a health risk assessment that can be shared with the physician for use with the patient. Such risk information and recommendations need to be linked to and integrated with behavior change resources. Often, it is best to provide patients with a variety of resources because any one alternative, such as a group weight loss or exercise program, has specific access and barriers to participation issues.

Hypothesis 2. Use of more of the 5A's, and use of them in an integrated fashion, will produce superior behavior change outcomes, especially for complex cases.

The elements in Figure 1 represent an interrelated set of activities that are iterative and inform each other. It is not enough to conduct one or two of these activities in isolation. Rather these practices need to be enacted over time (they do not all need to be done at every visit or contact) in a coordinated and progressive manner. In particular, practices that provide problemsolving assistance and follow-up will especially produce better outcomes. The Assist and Arrange follow-up components are critical and are the components of the 5A's that are conducted least often. 42–44

Principle 2. A collaborative, patient-centered, and shared decision-making approach that supports the patient's role as the key decision maker will produce better long-term results.

Several theories of counseling, beginning with Roger's classic client-centered therapy, have discussed processes through which patient-centered approaches lead to greater levels of patient exploration, confidence, and satisfaction. More recent theoretical applications have included patient-centered counseling, patient-centered primary care, the transtheoretical model, and self-determination theory.

A patient-centered approach does not mean that clinicians are totally nondirective or never provide advice. It acknowledges that the patient and the physician each have important information, and that both bring important values to the encounter.⁵³ It recognizes that counseling occurs along a continuum of possibilities extending from being very directive (e.g., "It's important, given your medical and family history, that you stop smoking") to being very nondirective (e.g., when discussing reproductive choices, "There is not one right choice—it depends on your personal values"). Most counseling occurs between the two extremes of the continuum and is affected by both the strength of the evidence of the behavior's effect on health and by the patient's values and preferences.

Empirical support for this first principle comes from literature reviews and meta-analyses of the patient-provider communication literature. ^{54,55} Ockene et al. ⁵⁶ have conducted a series of studies in primary care settings with various clinical populations and diverse, and sometimes multiple, target behaviors that have supported this principle. More specific hypotheses and recommendations that follow from this general principle are listed below.

Hypothesis 3. Patients given the opportunity to set priorities in choosing the health behavior(s) to focus on at a given visit will be more likely to be successful.

Examples of programs that have such activities include those based on shared decision making, such as computer-assisted risk assessment and decision making, ^{33,57} or that explicitly provide information and time for discussion of risks and benefits. ^{58–60} With the increasing complexity of environmental, medical, and genetic risk issues, and with emerging evidence that many interventions have both positive and negative consequences, decisions are less clear-cut. They depend increasingly on what outcomes patients are most concerned about or most value. Recent reviews of shared decision making ^{61,62} indicate that this approach is efficacious and reduces both patient passivity and patient–provider conflict.

A specific experiment to test the above hypothesis might contrast a patient-centered approach that encourages patients to set priorities with an epidemiologic or risk-based set of recommendations regarding which behaviors are most important to address. It is essential that investigations of this question take a long-term, longitudinal perspective, as it is quite possible that a more directive approach might produce equivalent or better outcomes initially. But over time it would be predicted that the patient-set priorities approach would prove superior.

Hypothesis 4. When addressing multiple health behaviors: (1) if the patient is highly motivated, has good support resources, and is willing to commit to changing multiple health behaviors, it will be more effective to change multiple behaviors simultaneously; and conversely, (2) when patient self-efficacy is low or there are numerous barriers to change, changing one behavior at a time will be more successful.

This hypothesis is more speculative than others we have listed, but is an extrapolation based on what is known about goal setting, ^{28,63} and the reciprocal relationship between self-efficacy and successful behavior change. ⁶⁴ While acknowledging the complexity of this hypothesis, we feel that it reflects the clinical reality that one approach is not always superior for all patients or in all situations.

Principle 3. Interventions and quality improvement (QI) efforts that are effective in primary care will have characteristics that fit and use the unique strengths of community-based primary care, such as longitudinality, therapeutic alliance, knowledge of the patient and their social environment. ^{65–69}

The essence of primary care revolves around an iterative and ongoing relationship with a patient and his or her family within a social and environmental context. The key elements of primary care have been identified as: accessibility, continuity, comprehensiveness, integration of care, clinical interaction, interpersonal treatment, and trust. ⁶⁶ Community-oriented primary care ⁷⁰ places special emphasis on understanding and arranging supportive resources in the patient's natural environment. Thus, programs that have stronger links, better feedback systems and are better integrated with community programs and policies to support health behaviors should produce better long-term results. More specific hypotheses related to this general principle follow.

Hypothesis 5. A multilevel community-based approach that more comprehensively involves the patient's social, physical, and economic environment will produce better results, especially at follow-up, than those that provide only referrals or do not involve this community link.

This hypothesis is based on social ecologic theory, ^{71,72} and pinpoints the importance of arranging follow-up support. It also is consistent with the experience of clinicians who work with challenged and underserved populations characterized by health disparities. ^{73,74}

Hypothesis 6. Use of teachable moment interventions to relate symptoms and laboratory results to patient models of illness and to facilitate understanding of the connection of lab results and symptoms to

patient behavior will produce more patient attempts at behavior change.

This hypothesis integrates hypotheses above in that it combines a patient-centered approach with the indepth knowledge developed through longitudinal primary care. It also brings up the issue of how behavior change issues are framed for patients.⁷⁵ It is hypothesized that interventions that relate lab results and other opportunities to tie patient behavior change options and recommendations to the patient's "personal model"^{76,77} of illness should motivate more behavior change attempts than less personalized approaches.

Practice Level and Quality Improvement

Before turning to practice-level principles and hypotheses, we summarize the literature on what is known about efforts to improve the delivery of best practices in clinical settings.

Practice Improvement Literature Review

There is strong evidence that dissemination of clinical practice guidelines alone is insufficient to change practice. Received successful strategies that include audit with feedback and use of local opinion leaders have achieved moderate effects. A recent innovation, the achievable benchmark method, has shown additional promise.

Although practice efforts utilizing interventions based on total quality management (TQM) or continuous quality improvement (CQI) have produced promising results in some clinical trials, ⁸⁶ recent reviews have criticized the quality of the research designs employed. ^{81,87} Moreover, two major recent studies of a CQI intervention produced disappointing results. ^{88,89} The failure of CQI efforts in office practice have been attributed to the lack of organizational support, lack of physician commitment, and contextual or systems variables that were not adequately addressed. ^{26,81,90}

A recent structured review of interventions to improve the management of diabetes care in primary care settings concluded that organizational interventions that enhanced patient tracking and follow-up produced improvement in process outcomes, but had limited effect on patient outcomes unless combined with interventions that featured self-management support or greater involvement of nurses in follow-up care. 90 Newer TQM methods (e.g., rapid cycle improvements, monthly data reports to leadership), such as those employed by the Institute for Healthcare Improvement and the Improving Chronic Illness Care initiative's Breakthrough Series collaboratives, have been designed to address organizational and system-based challenges. 26,27,91-93 Results from initial trials of these newer methods appear promising, but controlled studies with long-term follow-up are needed.

Dissemination Strategies with Modest Impact: Interactive Educational Interventions

The impact of educational interventions on medical practice varies depending on the format. Traditional passive forms of continuing medical education (CME) are ineffective as a clinician behavior change strategy. 81,82,94,95 However, interactive educational meetings have produced promising outcomes in some settings. 81,84,95,96

A recent Cochrane review of 32 controlled trials on the impact of CME on professional practice concluded that interactive workshops can result in moderately large changes in practice.⁹⁴

Effective Dissemination Strategies: Reminders and Educational Outreach

Of all the dissemination strategies that have been studied, the use of reminders appears to be supported by the strongest evidence. The impact of interactive clinician training can be enhanced further when combined with system-based interventions. For example, the combination of training and systems-based interventions (e.g., chart reminders or prompts to clinicians to deliver counseling) is much more effective than clinician training alone. $^{96-100}$

Educational outreach, involving a personal education visit by a trained person to clinicians in their own practice setting also has produced consistent improvements in care in a number of controlled trials. §1,84,96 This type of face-to-face, on-site, in-context educational session has been referred to as academic detailing⁹⁹ or social marketing. 84,100 Educational outreach provides an opportunity for the office practice consultant to assess the needs and motivation of the targeted clinician and tailor the intervention to barriers and motivational readiness of the specific practice environment.^{54,99,101} The academic detailing approach emphasizes flexibility; assessment is key and permits tailoring of the intervention in response to clinician and practice needs. More recently, Goldstein et al. 102 reported on a controlled trial of educational outreach to promote physician-delivered, smoking-cessation treatment within a population-based sample of 259 community-based physicians. Their academic detailing intervention emphasized assessment of physician readiness for change as well as tailoring of the intervention to match physicians' level of readiness. 101,103,104 The educational outreach intervention significantly increased smoking quit rates among patients who saw a physician who participated in the academic detailing intervention. ¹⁰¹

The Benefits of a Multifaceted Approach: One Size Does Not Fit All

Reviews of strategies to enhance quality of care have stressed the importance of combining intervention methods and employing multifaceted approaches to meet the specific needs of the targeted practice, organization, or system. 81,87,90,93–97 Educational outreach is particularly attractive because it provides a process for reaching out to less motivated clinicians and practice staff who might be initially unwilling to attend an off-site workshop. It builds on the power of the relationship that develops between clinicians and practice staff over time, and also may be easily integrated with other promising approaches including interactive educational workshops, audit with feedback, reminders, and QI processes that target organizational change.

Practice Level and Quality Improvement Principles and Hypotheses

Principle 4. The principles that apply to individual-level behavior change should also apply to practice and health system levels (ongoing assessment, collaborative goal setting; individualized feedback, problem solving, follow-up assessment, and support).

The interplay between behavior change and practice design characteristics (e.g., feedback loops) should facilitate the development of successful behavior change programs at the office level. For example, at HealthPartners, a population health cycle has been implemented as an integral component of QL. 105 Components include goal setting, assessing willingness to change, health risks and health status, readiness to change, specific intervention design features, evaluation, and goal modification based on acquired data. The 4S's (size, scope, scalability, and sustainability) and the PIPE (penetration, implementation, participation, and effectiveness) impact-design and evaluation features⁴⁰ inform this approach to system-level population health improvement. Size refers to the intervention effect that a given dose of a program produces. It represents the relative aggregate volume of an intervention that an individual receives. Scope refers to the range of program operations and the extent of program activities. Scalability is the ability of the program to follow a systematically timed, planned, and graded series of steps that cumulatively account for the continuously increasing reach of a program until a critical mass is attained. Finally, sustainability refers to the long-term, ongoing support for a program in relation to an accepted value proposition that balances allocated resources against generated revenues or benefits.

Since this model brings together practice-level changes with individual patient-level changes, it represents a good example of using and aligning principles of behavior change that fit both.

The key point is that the same basic processes or principles of behavior change apply at the patient level and at the practice setting and health system levels (Figure 2). Understanding this concept is important because having an overall conceptual model of the way

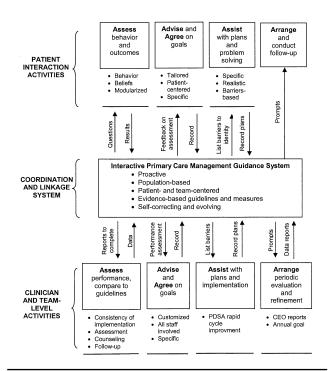


Figure 2. Illustration of applying 5A's model at multiple levels.

that successful behavior change "improvement" proceeds—regardless of whether it is individual or practice level—is illuminating and simplifying. The same issues, including using assessment and feedback, patient- or practice-centered approaches, tailoring solutions and plans to individual situations and preferences, and providing follow-up support and resources, are equally important for both practice-level and individual behavior change.

Hypothesis 7. Practices that customize behavior change plans to meet the needs of their office setting will be more successful on the "AIM" dimensions of adoption, implementation, and maintenance (institutionalization) of intervention practices than those that implement a standard program without modification.

Just as tailoring to an individual's risk, preferences, and social environment enhance success at the individual level, ^{106,107} customizing how a practice will implement the 5A's is critical. In terms of immediate results, standardized "one size fits all" office practice improvement strategies may do better, but in the long run, more flexible and tailored approaches that recognize the local expertise of practices in customizing interventions will do better. ^{39,102,108}

Table 2 presents a tool that has proven useful in assisting offices to determine which staff member in their office is in the best position to conduct each of the 5A's, and in planning how, when, and where each component should be implemented.

Hypothesis 8. Practices that specifically focus on the 4S's in planning their practice restructuring will produce better outcomes than those that do not.

Table 2. Customizing self-management 5A's action	Who	When	How (tools, etc.)	Where (be specific)	Quality control responsibility	Comments
Assess (status)						
Advise						
Agree (set collaborative goal)						
Assist (problem solve)						
Arrange (follow-up)						

As practices restructure to produce better results, it is helpful to consider guiding principles. First, it would be of benefit to consider the six aims (safety, timeliness, equity, efficiency, effectiveness, and patient centeredness) proposed by the Institute of Medicine⁶⁶ to create high-quality care. However, to do so, practices need simple rules to guide the design and development of programs. The 4S's of program design, described above, ⁴⁰ provides such a set of key principles on which to focus.

In satisfying the requirements of each of the 4S's, services are systematically linked to continually improving outcomes (as monitored by the PIPE Impact Metric). The size principle should increase chances that the program will generate the health benefit(s) desired. The scope principle should help the practice to be efficient in allocating resources. The scalability factor should ensure that all identified members of the target population will be provided access to the service(s). Finally, the sustainability factor should ensure that the program will be maintained over a sufficient period of time that health, quality, and utilization objectives can be achieved.

An example application of the 4S's method is the HealthPartners "10,000 Steps" program (www.10K-steps. com), which was originally designed to support members of the health plan to increase their daily physical activity levels. 109,110 The size principle relates to the likelihood that the program will generate a sufficiently large change in behavior, in this case a change in walking quantified by the number of steps over an 8-week period. The program design for "10,000 Steps" integrated learning from the behavior change literature and blended this with lessons learned in focus groups to ensure that the representation of the program would be appealing to members. Furthermore, the program design focused on middle-aged adults who were in a contemplation or preparation stage of readiness to increase their physical activity. The scope of the program was limited to walking as the mode of physical activity to be promoted, an 8-month time frame for the active intervention with a maintenance phase of an additional 6 months, and a target population of middleaged adults. Scalability was addressed by providing the program in two formats, mail-based and Web-based, with a modest charge (\$20) for users that would offset overall program costs. The \$20 charge for the program effectively addressed the sustainability factor of the 4S's and allows the program to be offered beyond its initial start-up investment budget.

Hypothesis 9. Practices that focus on the RE-AIM dimensions and use these for QI will produce better initial, and especially, long-term, improvements than those that do not.

This hypothesis also addresses the use of a framework for planning, implementing, and evaluating health promotion (Table 1). It is hypothesized that systematically considering—and periodically reassessing—how one's program is doing on the public health dimensions of reach, effectiveness (including quality of life and unintended or negative consequences), breadth of adoption, consistency of implementation, and long-term maintenance, will lead to corrective actions that will pay dividends. Klesges et al. [11] (www.re-aim.org) have discussed how the RE-AIM model can be applied to program planning issues, and provide example strategies that can be tested to see if they enhance performance on specified RE-AIM dimensions.

Hypothesis 10. QI efforts that employ regular panel or practice-level feedback on key counseling criteria will produce better long-term results than those that do not.

Assuming that monitoring is focused on key issues, and done in accordance with principles of goal setting and feedback, ^{28,112} assessing and providing feedback on performance should enhance practice. (Note: In some instances monitoring and feedback may be necessary but not sufficient, and incentive or other strategies may be necessary to produce substantial improvements.) A corollary to this hypothesis is that, among practices that provide regular feedback on performance, those that provide feedback on both processes and outcomes, such as Health Plan Employer Data Information Set (HEDIS) criteria or patient behavior change, will produce better outcomes than those that only provide feedback on process issues.

Hypothesis 10 is consistent with the notion of motivating practices to tailor and experiment with processes to determine how to best deliver care in their setting. Consistent with the general framework above, keeping the practices' "eyes on the prize" of improved outcomes

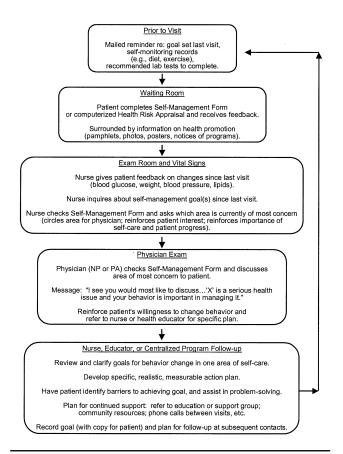


Figure 3. Examples of using entire primary care office resources to support health behaviors.

should be superior to feedback concerned only with process actions.

Hypothesis 11. Practices that employ more of the above strategies, and that integrate these strategies, will produce better outcomes as defined by larger, more generalizable and lasting behavior changes, and greater patient satisfaction and quality of life improvements than those that do not.

Figure 3 summarizes the 5A's principles in this article and illustrates their application at both the individual and the practice level. Any one of the hypothesized 5A's actions may produce modest improvement, but the consistent application of these recommendations in an integrated manner, and across different behaviors, should characterize "breakthrough" and lasting changes. Practices that employ more of the 5A's strategies embedded in the hypotheses in this section, and those that integrate the strategies, should do better than those that do not.

Principle 5. Practices that redesign their office environment and patient visits to provide behavior change support across multiple behaviors (e.g., use a consistent approach) to make interventions for these preventive behaviors more population based, more proactive, and more planned will produce better behavior change outcomes.

The characteristics above (population based, planned, and proactive) are consistent with the widely implemented, evidence-based chronic care model of Wagner et al. 92,93 It has been suggested that the chronic care model elements apply equally well to prevention activities, with the possible exception that even greater emphasis may be needed on community resources and linkages to support lifestyle behaviors in the places that patients work, live, and recreate (www.who.int/hpr/ lessons.learned.html). 93,114 In each of the six elements or "best practice principles" contained in the chronic care model, interventions are planned (rather than only responding to issues raised); informed by individually relevant assessment data; proactive (and involve scheduled outreach); focused on an entire panel of patients (rather than only those appearing in the exam room); and patient centered.

Such a consistent approach that cuts across health behaviors and chronic conditions may also be easier to adopt and implement than approaches that are restricted to individual risk factors or conditions. Although implementing a systematic approach to address multiple risks may require a greater initial investment of energy and resources, this is likely to be more cost-effective than implementing a series of distinct interventions that target single risk factors. Necessary practice restructuring steps to accomplish this would include identifying different roles for staff, transforming the delivery of care model from a physician-centered one into one that is shared among multiple staff, Web-based interventions, or telephone follow-up.

It is helpful to have a guide to the key issues to focus on in conducting QI efforts. To guide this office practice–level program design and monitoring, the 4S's framework (size, scope, scalability, and sustainability) has been proposed as discussed in Principle 4 above.⁴⁰

As data are derived from ongoing monitoring during program implementation, 40 rapid cycle improvement approaches may be applied using the 4S's model to change the way the program is implemented. 115 For example, if implementation is slow, a rapid cycle improvement may change the scalability step, and alter the manner in which marketing, outreach, or identification of appropriate patients is conducted. The 4S's model can also enhance how individuals, teams, clinics, or care systems work collaboratively toward the shared objectives of health improvement through behavior change.

Hypothesis 12. Practices that employ an outreach approach and consistently use population-based services, such as telephone counseling and repeated use of health risk assessments (HRAs), will produce better outcomes on more different behaviors than those that do not.

Population-based approaches to health improvement provide proactive outreach strategies that include methods to identify and follow up on health risks for individuals across the continuum of health states. They involve risk assessment methods that identify both disease as well as the underlying behavioral risk factors of disease. Examples are HRA surveys, disease registries, and telephone-based follow-up and referral to disease management programs or behavioral counseling. ^{92,93,105,116,117} Addressing the behavioral risk factors that place people at increased risk can be coordinated according to a review of the risk factors present as documented by an HRA, ⁵ and informed by the individual's readiness to change each of the behaviors. ⁵²

Hypothesis 13. Practices that distribute behavioral counseling activities among staff rather than rely on one member will produce superior behavior change outcomes.

Physicians often think that they are personally responsible for patient behavior. While physicians are often the most credible source of health information, they are not the only health personnel who can effectively deliver behavior change counseling. 32,118,119 Key to an effective office design is that patient assessment, intervention, and follow-up activities are distributed among various staff, and incorporated into the flow of the patient visit. 32,118-121 As illustrated in Figure 3, patient assessments can be conducted prior to the visit (or via computer in the waiting room); nurses can check on patient concerns and questions in the exam room; physicians can provide brief advice, work collaboratively with patients to set goals and answer key questions; and health educators (or other centralized staff or resource centers) can then assist the patient with problem solving and developing specific action plans. Any of a number of allied health professionals can conduct follow-up activities, and centralized resources can often be used to provide more intensive or advanced counseling.

A corollary to Hypothesis 13 is that, among those practices that involve various staff, those that implement procedures to ensure that patients receive consistent messages about behavior change goals across staff members will produce better results than those that do not.³²

Hypothesis 14. Practices that employ a rapid cycle improvement approach to QI, conduct more trials of practice change, and do more refinements of behavioral counseling to fit their setting will do better than those that do not.

Changing office practice behavior and culture is not easy. Seldom is the perfect system available from previous research or experience that can be implemented without modification to fit a given practice. Rather, practices that employ a spirit of investigation, that conduct a series of small implementation experiments, and that keep tinkering until they "get it right" are more likely to succeed in the long run. From a complexity theory perspective, it is also critical to pay attention to and even expect, potential

negative or unintended consequences of changing office practice. It is difficult to predict what these will be; but the key is to address these issues using the same open, rapid cycle improvement approach, and not to give up and revert back to "standard operating procedures" prematurely. Practices that experimented with chronic care model interventions and made successive iterations of their plans were found to do better in terms of overall success than those that spent a large amount of planning time and expected their original plan to work without modification.

Hypothesis 15. Practices that employ interactive computer technology (e.g., CD-ROM or touch-screen computer, Internet, hand-held personal digital assistant [PDA] programs) to facilitate implementation of the 5A's (e.g., output to support and encourage patient-provider goal setting and problem solving; schedule regular follow-up) will produce more change in clinician practices.

There is great potential for interactive technology approaches to enhance primary care behavior-change counseling and support. ^{124–126} Computer-based strategies can help clinicians to "systematize" repetitive aspects of practice, such as repeated assessments and identification of individual goals. Such approaches can be integrated into the flow of usual care as illustrated in Figure 2, and result in more consistent implementation of the 5A's. This can remove some time and burden from clinical staff to allow them to perform other activities and to make their interactions with patients more informed. ^{41,68,126,127}

Examples of how computer-based aids can help clinicians to deliver the 5A's include assessing patient behaviors, risks, concerns, or family history; providing immediate individually tailored feedback to patients about risk; eliciting patient preferences and readiness to change; helping to set behavior change goals; identifying likely barriers to goal attainment; presenting information on problem-solving options that have worked for other patients; providing a convenient printout for both patients and clinicians to inform discussions; and prompting or conducting follow-up contact. 40,106,127–129

Interactive computer programs are not a panacea or a way to replace clinician-patient interaction. They can backfire by de-personalizing the healthcare experience, if not implemented in ways congruent with the above principles. For example, interactive computer approaches that are regimented and do not employ the above characteristics will not produce improved outcomes and may even result in reduced patient satisfaction.

Conclusions

We have discussed actions that healthcare teams can take to change both interactions with patients and at

Patient-clinician level principles and hypotheses

- Principle 1: Greater use and more systematic use of the "5A's" model of self-management and behavior change counseling will produce superior outcomes.
- Principle 2: A collaborative, patientcentered and shared decision making approach that supports the patient's role as the key decision maker will produce better long-term results.
- Principle 3: Interventions and QI efforts that are effective in primary care will have characteristics that fit and use the unique strengths of community-based primary care, such as longitudinality, therapeutic alliance, and knowledge of the patient and his/her social environment.

Practice-level principles and hypotheses

- Principle 4: The principles that apply to individual-level behavior change should also apply to practice and health system levels (ongoing assessment, collaborative goal setting, individualized feedback, problem solving, follow-up assessment, and support).
- Principle 5: Practices that redesign their office environment and patient visits to provide behavior change support across multiple behaviors (e.g., use a consistent approach) to make interventions for these preventive behaviors more population based, more proactive, and more planned will produce better behavior change outcomes.

- H 1: Consistently assessing patients' behavioral changes and providing feedback to them (e.g., recording behavioral changes in the patient's chart as a vital sign; having patient self-monitor and report back) will produce more success in the long term.
- H 2: Use of more of the 5A's, and use of them in an integrated fashion, will produce superior behavior change outcomes, especially for complex cases.
- H 3: Patients given the opportunity to set priorities in choosing the health behavior(s) to focus on at a particular visit will be more likely to be successful.
- H 4: When addressing multiple health behaviors: (a) if the patient is highly motivated, has good support resources, and is willing to commit to changing multiple health behaviors, it will be more effective to change multiple behaviors simultaneously; and conversely, (b) when patient self-efficacy is low or there are numerous barriers to change, changing one behavior at a time will be more successful.
- H 5: A multilevel community-based approach that more comprehensively involves the patient's social, physical, and economic environment will produce better results, especially at follow-up, than those that provide only referrals or do not involve this community link.
- H 6: Use of "teachable moment" interventions to relate symptoms and laboratory results to patient models of illness, and to facilitate understanding of the connection of lab results and symptoms to patient behavior will produce more patient attempts at behavior change.
- H 7: Practices that customize behavior change plans to meet the needs of their office setting will be more successful on the AIM dimensions of adoption, implementation, and maintenance (institutionalization) of intervention practices than those that implement a standard program without modification.
- H 8: Practices that specifically focus on the 4S's in planning their practice restructuring will produce better outcomes than those that do not.
- H 9: Practices that focus on the RE-AIM dimensions and use these for QI will produce better initial and, especially long-term, improvements than those that do not.
- H 10: QI efforts that employ regular panel- or practice-level feedback on key counseling criteria will produce better long-term results than those that do not.
- H 11: Practices that employ more of the above strategies—and that integrate these strategies—will produce better outcomes, as defined by larger, more generalizable, and lasting behavior changes, and greater patient satisfaction and quality-of-life improvements than those that do not.
- H 12: Practices that employ an outreach approach and consistently use population-based services such as telephone counseling and repeated use of HRA surveys will produce better outcomes on more different behaviors than those that do not.
- H 13: Practices that distribute behavioral counseling activities among staff rather than rely on one member will produce superior behavior change outcomes.
- H 14: Practices that employ a rapid cycle improvement approach to QI, conduct more trials of practice change, and do more refinements of behavioral counseling to fit their setting will do better than those that do not.
- H 15: Practices that employ interactive computer technology (e.g., CD-ROM or touchscreen computer, Internet, hand-held PDA programs) to facilitate implementation of the 5A's (e.g., output to support and encourage patient–provider goal setting and problem solving; schedule regular follow-up) will produce more change in clinician practices.

4S's, size, scope, scalability, sustainability; H, hypothesis; HRA, health risk assessment; PDA, personal digital assistant; QI, quality improvement; RE-AIM, reach effectiveness-adoption, implementation, maintenance.

the practice level to support health behavior counseling for multiple behaviors. These strategies, based both on experimental evidence and clinical experience ^{8,27,54,68} should enhance success with multiple health behaviors, and facilitate both primary and secondary prevention (disease management). They should be especially effective for complex patients and at longer-term follow-ups.

We have stated these as hypotheses (Table 3) rather than guidelines or recommendations for two reasons. First, several of these hypotheses do not meet the standards for evidence-based medicine (e.g., multiple randomized, controlled efficacy studies), in part because funding and research have been restricted to "silos" focused on an individual risk factors (e.g., smok-

ing, physical activity).³ Second, although there are controlled studies to support these hypotheses,⁸ it is not clear whether these strategies will work in different types of real-world settings since most of the evidence for these hypotheses (and most "evidence-based medicine" recommendations) comes from studies conducted by research staff under efficacy conditions.^{1,3}

More research is clearly needed, especially on multiple risk factor change with different patient groups in settings such as practiced-based research networks. 10 We are confident, however, from QI experience and research trials, that if conducted with the context in mind, and in using rapid cycle tests with refinement, 114,115 that these strategies will prove both feasible and effective. What is needed is greater collaboration among researchers, clinicians, and patients in a manner that respects and makes maximum use of the experience and expertise of each. 130

We are cognizant that the changes advocated above are not likely to be delivered consistently or sustained in the present acute care—oriented healthcare system. A healthcare infrastructure and policies that promote patient-centered, population-based health and planned care 114,131 are needed to achieve broad, substantial and lasting improvements. The interested reader is referred to other references that discuss some of the policy changes that can support the implementation and success of the hypotheses we have enumerated. 4,5,18,40

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