

What Does It Mean to Be Pragmatic? Pragmatic Methods, Measures, and Models to Facilitate Research Translation

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Abstract

Background. One of the reasons for the slow and uncertain translation of research into practice is likely due to the emphasis in science on explanatory models and efficacy designs rather than more pragmatic approaches. **Methods.** Following a brief definition of what constitutes a pragmatic approach, I provide examples of pragmatic methods, measures, and models and how they have been applied. **Results.** Descriptions are provided of pragmatic trials and related designs, practical measures including patient-reported items for the electronic health record, and the Evidence Integration Triangle and RE-AIM practical models, each of which can help increase the relevance of research to policy makers, practitioners, and patients/consumers. **Conclusions.** By focusing on the perspective of stakeholders and the context for application of scientific findings, pragmatic approaches can accelerate the integration of research, policy, and practice. Progress has been made, especially in pragmatic trials but even more opportunities remain.

Keywords

evaluation, implementation, measurement, pragmatic trial, research design, theory

Wikipedia defines pragmatism as “a philosophical tradition centered on the linking of practice and theory” (<http://en.wikipedia.org/wiki/pragmatism>). It describes a process whereby theory is extracted from practice and applied back to practice to form what is called *intelligent practice*. Merriam Webster tells us that pragmatic approaches focus on matters of fact or practical affairs and are practical as opposed to idealistic (<http://www.merriam-webster.com/dictionary/pragmatic>). In reflecting on the current challenges facing health care, health education, and public health, I conclude that there is an increased need to be pragmatic. In this article, I overview pragmatic approaches in general and provide examples of pragmatic designs, measures, and models. The concluding section then discusses opportunities and challenges for pragmatic approaches, which I feel offer the best chance for more rapidly accelerating translation of research into practice and policy.

Both government and private funders in the United States have long supported both basic and applied scientific research. With the current health care crisis, continuing inequities in health and health care (Institute of Medicine, 2012; Starfield, Gervas, & Mangin, 2012) and demands from Congress and the public for science to be more accountable, the time seems right for adoption of more pragmatic approaches. This does not mean abandoning the scientific methods that have produced undeniable progress, but it does mean broadening our focus and placing greater priority on

some issues that have received little or no attention (Glasgow, 2008; Green & Glasgow, 2006).

At the heart of pragmatic approaches to health research is keeping our focus on issues and data relevant for making decisions and taking action. In this way, pragmatic approaches are also strongly aligned with patient-centered outcomes research (Selby, Beal, & Frank, 2012; www.pcori.org) and comparative effectiveness research (Glasgow & Steiner, 2012; Institute of Medicine, 2011a). The overall goal of pragmatic approaches is to produce results that are relevant to stakeholders as well as rigorous (Glasgow & Chambers, 2012). As can be seen in Table 1, pragmatic approaches focus on application and context.

Pragmatic Designs

Pragmatic designs have received the greatest attention of the issues discussed in this article. Leaders from Centers for Medicare & Medicaid Services and the Agency for Healthcare Research and Quality published a key article in *Journal of*

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Table 1. Key Characteristics of Pragmatic Approaches.

| Pragmatic Component | Purpose | Key Factors | What Is Not Meant | Example References |
|-----------------------|--|--|--|---|
| Approach | To address specific, practice needs and questions | Focus on application and context, usefulness | That basic science is irrelevant; just need a balance | Pawson, Greenhalgh, Harvey, and Walshe (2005); Biglan (1995); Stange, Breslau, Dietrich, and Glasgow (2012) |
| Models and frameworks | Relatively simple, focus on relationships and context | Focus attention on key issues for success | That it is atheoretical or that theory is unimportant | Glasgow, Gaglio, et al. (2012); Kessler et al. (2012) |
| Designs | Address issues of practitioners, policy makers, and patients. Are both rigorous and relevant | Focus on resources, context, replication, applicability of results | That internal validity (or RCTs) are not relevant; just need a balance | Kessler and Glasgow (2011); Klesges, Estabrooks, Glasgow, and Dzewaltowski (2005); Thorpe et al. (2009) |
| Measures | To be feasible and actionable in real-world settings | Brief, broadly applicable, sensitive to change | That traditional psychometrics are irrelevant; just other issues equally or more important | Estabrooks et al. (2012); GEM (http://cancercontrol.cancer.gov/brp/gem.html) |

the American Medical Association in 2003 that stimulated greater focus on “practical trials” (Tunis, Stryer, & Clancey, 2003). Other authors added to this literature and provided examples of practical alternatives to traditional designs that had focused almost exclusively on internal validity (Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; Solberg et al., 2010). Pragmatic methods and, in particular, pragmatic trials were given a major impetus in 2008 with the CONSORT group publication of standards for pragmatic trials (Zwarenstein et al., 2008). Pragmatic trials are designed to answer the question of whether a program works under usual conditions, compared to explanatory trials that answer the question if an intervention works under ideal conditions. This publication and related development of the Pragmatic-Explanatory Continuum Indicator Summary (Glasgow, Gaglio, et al., 2012; Thorpe et al., 2009) that highlights 10 specific dimensions along which studies are more or less pragmatic versus explanatory (efficacy focused) have also contributed to the increased recognition of pragmatic studies. As seen in Figure 1, the extent to which a study is pragmatic versus explanatory on each of the 10 PRECIS dimensions (e.g., participant eligibility criteria, level of practitioner expertise, follow-up intensity, controls for practitioner adherence) can be succinctly summarized by the distance from the center of a “hub and spoke” figure. Most of these dimensions are relatively self-explanatory, but examples are provided in Thorpe et al. (2009) and Glasgow, Gaglio, et al. (2012). On each dimension, the study is rated from 0 (*being completely explanatory*, and the score indicated by a mark for this dimension being in the center of the PRECIS figure) to 4 (*being completely pragmatic*, and a dot or mark placed at the extreme end of the “line” for that dimension in the PRECIS figure). Thus, with a glance, it can be seen that Study A on the left-hand side of Figure 1 is much more pragmatic, especially on the dimensions on the left, top, and bottom of the

diagram—for example, practitioner expertise, flexibility of the intervention, practitioner adherence—than Study B on the right-hand side of the figure, which might represent a traditional efficacy study conducted under highly controlled homogenous conditions.

Key features of pragmatic studies and important ways in which they differ from efficacy studies are that: (a) the questions, perspectives taken, and outcomes studied are those that are important to stakeholders such as policy makers, practitioners, and patients; (b) the research is conducted in multiple, heterogeneous settings similar to those in practice; (c) there are few exclusion criteria and characteristics of participants (patients) resemble those seen in typical practice; and (d) comparison conditions are real-world alternatives—for example, current standard of care, rather than no treatment or placebo controls (Glasgow et al., 2005; Tunis et al., 2003; Zwarenstein & Treweek, 2009).

The National Institutes of Health has recently announced support for pragmatic trials in the Health Care Systems Collaboratory specifically (<http://commonfund.nih.gov/hcscollaboratory/>) and more generally through other funding mechanisms (e.g., the Dissemination and Implementation Research in Health Program Announcement 13-055; <http://grants.nih.gov/grants/guide/pa-files/PAR-13-055.html>). Much of the Veteran Administration’s QUERI program and of the new research being funded by the Patient-Centered Outcomes Research Institute can be considered pragmatic research (Damush et al., 2010; www.PCORI.org).

Pragmatic Measures

Assessing outcomes that are important to key stakeholders is part of the answer to increasing research relevance (Proctor et al., 2011). However, the measures through which those outcomes are assessed also need to be pragmatic in order to

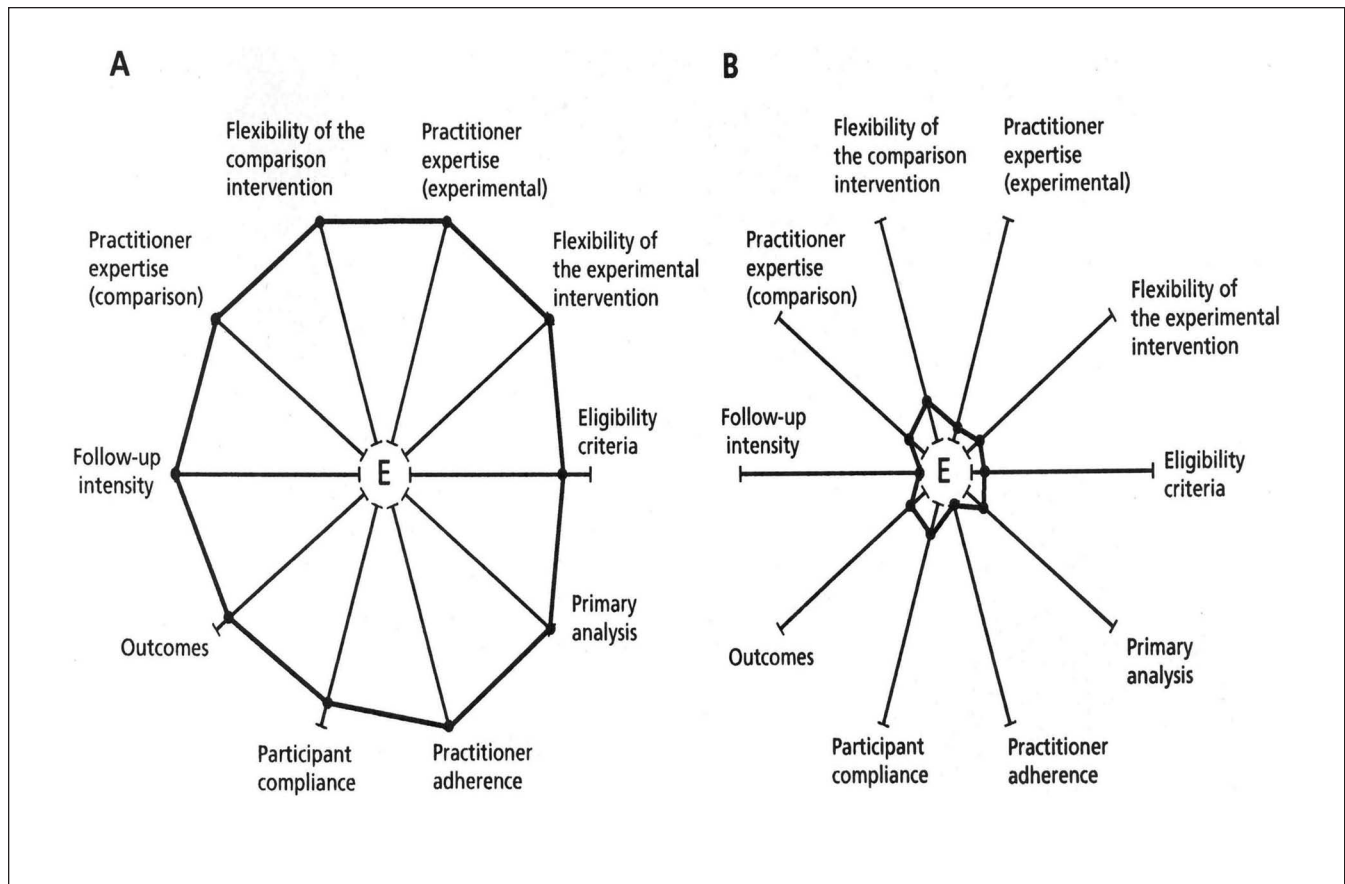


Figure 1. Illustration of application of the PRECIS criteria to characterize research studies.

be feasible to collect in typical and often busy real-world settings having multiple competing demands and for whom research is not their primary business (Mays & Hogg, 2012; Nutting et al., 1999; Stange, Woolf, & Gjeltema, 2002). Many measures in health services research are so lengthy or burdensome that they are difficult or impossible to collect in real-world settings, especially if not administered by research personnel (Glasgow, Kaplan, Ockene, Fisher, & Emmons, 2012). Recent advances in electronic health records (EHRs) offer great potential to address this situation, but there is an important gap. It is ironic in this era of the patient-centered medical home (Crabtree et al., 2010) and patient-centered care (Institute of Medicine, 2011b) that the content area least often included in any systematic, standardized, or searchable way in the EHR is patient-reported measures.

Estabrooks et al. (2012) describe an iterative, participatory process used to identify practical patient-report measures of health behaviors and psychosocial issues that are feasible to use in most adult primary care offices and be included in EHRs. As shown in Table 2, they used a series of “pragmatic measures criteria” in addition to more traditional psychometric characteristics to identify measures for this purpose. Key characteristics for pragmatic measures included features such as breadth of applicability, face validity, being

actionable, not producing adverse reactions or consequences, and sensitivity to change as important issues to consider in selecting measures.

Like pragmatic designs, pragmatic measures emphasize context and appropriateness for specific settings in which measures will be used (Stange, Breslau, Dietrich, & Glasgow, 2012). The culture change that is required for pragmatic measures is, once again, having the perspective of the user take precedence over other considerations. Frequently this means above all being brief enough and understandable enough to be administered, scored, and the results interpreted and acted on in the context of usual care and in low resource settings. Other considerations include being broadly applicable across patients (practitioners are unlikely to use different measures with different scales and interpretations for different subsets of patients) and also having to compromise on some psychometric characteristics (and usually comprehensiveness/length) to make the measure feasible to implement (Glasgow & Riley, in press).

Pragmatic Models and Frameworks

Various levels and types of theories, models, and frameworks are used in science and health (Glanz, Lewis, & Rimer, 2002;

Table 2. Recommended Characteristics of Pragmatic Measures and Metrics.

| Characteristic | Recommended Criteria |
|----------------------------------|---|
| Reliable | Especially test–retest (less on internal consistency) |
| Valid | Construct validity, criterion validity, established norms |
| Sensitive to change ^a | Suitable for longitudinal use, goal attainment tracking, repeated administration |
| Feasible ^a | Brief (generally three items or less); low respondent and staff burden; easy to score/interpret |
| Important to practitioners | Indices for health conditions that are prevalent, costly, challenging |
| Public health relevance | To address without measures, in primary care domain, related to Healthy People 2020 goals |
| Actionable ^a | Realistic actions such as reliable referral, immediate discussion, online resources |
| User friendly | Patient interpretability; face validity; meaningful to practitioners, public health officials, policy and decision makers |
| Broadly applicable | Available in English and Spanish, validated in different cultures and contexts |
| Cost | Publicly available or very low cost |
| Enhances patient engagement | Having this information is likely to further patient involvement in their care and decision making |
| Cause no harm | Does not produce unintended consequences or make clinic responsible for things it cannot address |

^aThese criteria were given special emphasis.

Source. Adapted from Estabrooks et al. (2012).

Glasgow & Linnan, 2008). The philosophical roots of modern-day pragmatism lie in objections to some features of logical positivism (Pierce, 1935) and were advanced by thought leaders such as William James and John Dewey. As used in this article, pragmatic models are concerned with application to practice. As opposed to grand theories, they are usually at a moderate level of specificity and are constructed to apply to concrete situations. To be useful, pragmatic models emphasize key issues that are important to address for successful implementation or evaluation. Like most models, pragmatic models are simplifications of reality, and as George Box is quoted as saying, “Are wrong . . . but some may be useful” (Box & Draper, 1987). Health education and implementation science employ several different types of models and frameworks. For the purpose of this article, I focus on two key implementation science conceptual needs: theories or models of intervention that guide what should be done to produce successful outcomes; and models or evaluation frameworks that guide the types of questions that should be asked to assess how successful intervention efforts have been.

What makes both types of models pragmatic (vs. explanatory) is *how useful they are in guiding action in real-world settings*. Thus, pragmatic models are generally more concrete and specific than abstract theories. There are many well-established health behavior theories (Glanz et al., 2002), evaluation models (Harris, 2010; Veney & Kaluzny, 2005), and a rapidly increasing number of implementation science models (Tabak, Khoong, Chambers, & Brownson, 2012). Many theories and models, however, are inordinately complex, consistent of a huge number of steps or component parts in an effort to be comprehensive, and often contain substantial jargon and terminology specific to the model that make them challenging to implement or to share with

community practitioners and stakeholders. Here, given space limitations, I focus on one intervention model—the Evidence Integration Triangle (EIT; Glasgow, Green, Taylor, & Stange, 2012) and one evaluation framework—the RE-AIM model (Glasgow et al., 2010; Kessler et al., 2012) with which to illustrate features of pragmatic models. This is not meant to imply that these are the best models; simply that they are the ones with which I am most familiar.

The EIT (Glasgow, Green, et al., 2012) is a recent model designed to be helpful for both stakeholder groups as well as researchers to focus attention on the need for three interconnected components for successful programs or policies. These components include—an evidenced-based intervention (which can be a policy, preventive action, or an intervention program), a practical measure or set of measures to longitudinally track progress, and ongoing implementation of partnership principles among stakeholders. Each of these three is necessary but not sufficient and must be selected to fit or align with the multilevel context (Figure 2) in which the activity takes place. The other pragmatic implication of the EIT is that programs are rarely successful as initially implemented and need to evolve and adapt to changing context in order to be successful and sustained (Glasgow & Chambers, 2012).

The RE-AIM framework is more established, having first appeared in 1999. It has been widely used to evaluate and review the literature in both health behavior change and public health areas (Jilcott, Ammerman, Sommers, & Glasgow, 2007; King, Glasgow, & Leeman-Castillo, 2010). It has been used more recently to help design programs intended to be broadly implemented (Glasgow et al., 2010; Klesges, Estabrooks, Glasgow, & Dziewaltowski, 2005) and to reduce health disparities (Bennett et al., 2012; Toobert, Glasgow, Strycker, Barrera, & King, 2012). RE-AIM focuses attention

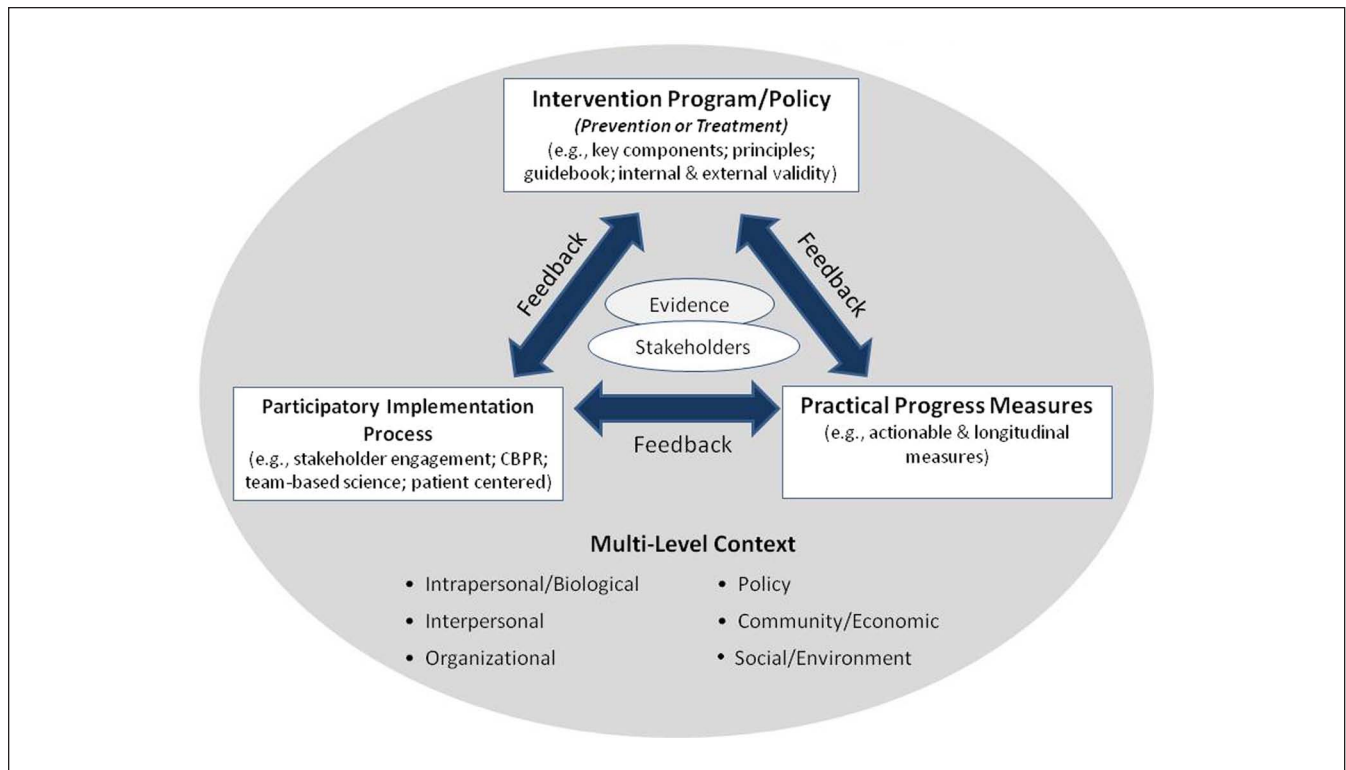


Figure 2. Evidence Integration Triangle (EIT) model.

Table 3. RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact.

| RE-AIM Element | Guidelines and Questions to Ask |
|---|--|
| Reach: Percent and representativeness of participants | Can the program attract large and representative percent of target population? Can the program reach those most in need and most often left out (i.e., older adults, the poor, low literacy, and numeracy?) |
| Effectiveness: Impact on key outcomes, quality of life, unanticipated outcomes, and subgroups | Does the program produce robust effects and across subpopulations? Does the program produce minimal negative side effects and increase quality of life or broader outcomes? |
| Adoption: Percent and representativeness of settings and staff that participate | Is the program feasible for most real-world settings (costs, expertise, time, resources, etc.)? Can it be adopted by low-resource settings and typical staff serving high-risk populations? |
| Implementation: Consistency and cost of delivering program and adaptations made | Can the program be consistently implemented across program elements, different staff, time, etc.? Are the costs—personnel, up-front, marginal, scale-up, equipment—reasonable to match effectiveness? |
| Maintenance: Long-term effects at individual and setting levels, modifications made | Does the program include principles to enhance long-term improvements (i.e., follow-up contact, community resources, peer support, ongoing feedback)? Can the settings sustain the program over time without added resources and leadership? |

Source. Adapted from Toobert, Glasgow, Strycker, Barrera, and King (2012).

on five dimensions or factors (Reach, Effectiveness, Adoption, Implementation, and Maintenance) that are common challenges to programs being successful in “going to scale” or achieving desired applied outcomes (www.re-aim.org). As shown in Table 3, common issues across the RE-AIM dimensions include representativeness of participants, staff,

and settings involved; health disparities impact across multiple levels; consistency, cost, and quality of implementation; and sustainability of both outcomes and the intervention or policy (Kessler et al., 2012). Both of these pragmatic models are intended to increase the transparency of research and results reporting to make it easier for practitioners and policy

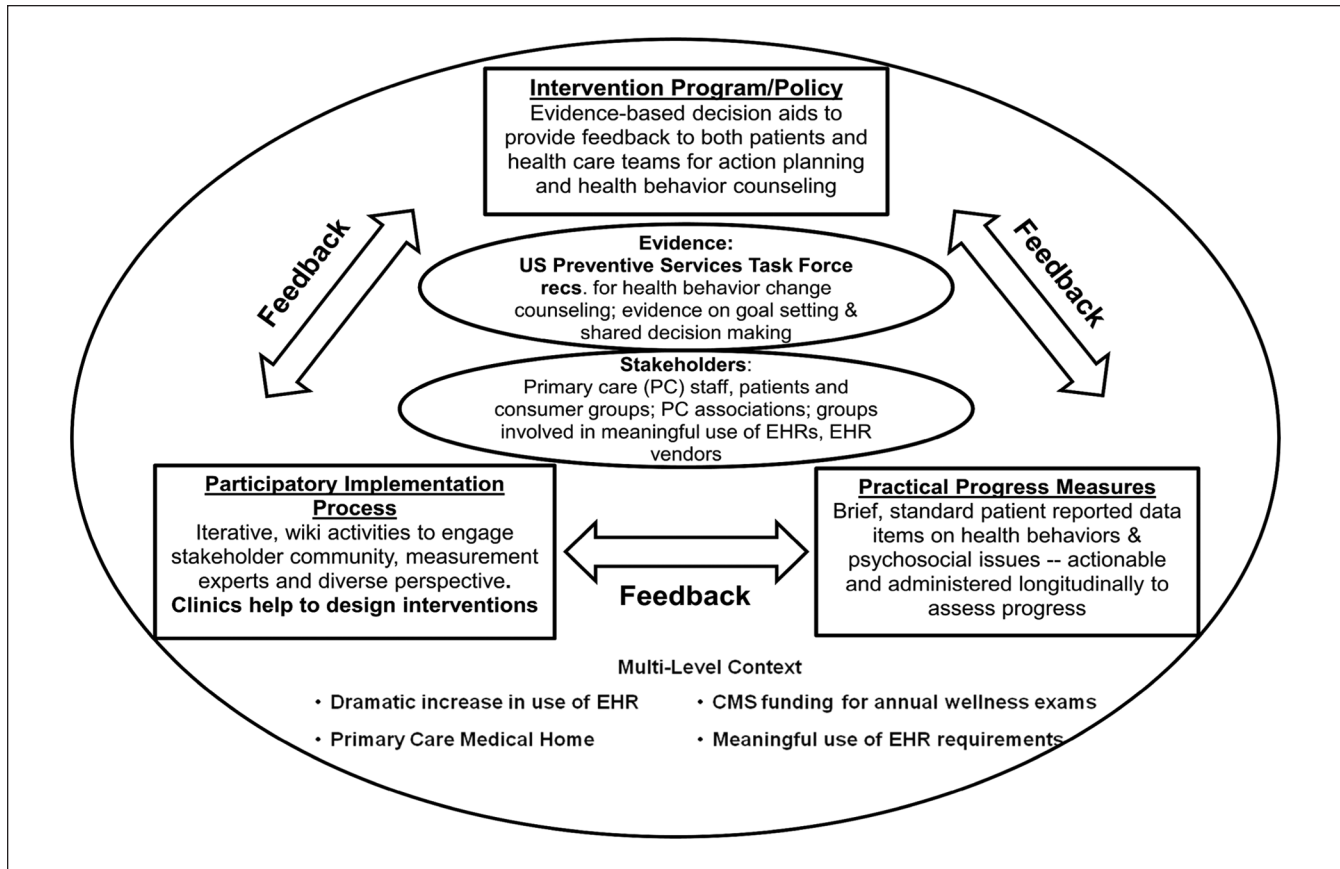


Figure 3. Application of the EIT to patient-reported health issues.

makers to determine the breadth and local applicability of a program or policy.

Integrative Example

An ongoing project serves to illustrate the integration of pragmatic models, methods, and measures. The EIT (Glasgow, Green, et al., 2012) helps conceptualize the necessary evidence-based interventions, pragmatic measures, and participatory processes needed to increase the frequency and quality with which health behavior and psychosocial issues are addressed in diverse primary care settings. As shown in Figure 3, the evidence-based interventions were taken from literature reviews and U.S. Preventive Services Task Force recommendations (<http://www.uspreventiveservicestaskforce.org/>) for primary care based health behavior counseling and treatment of depression and anxiety. A series of 17 items assessing 10 different health behavior and psychosocial issues, as well as overall quality of life, shown in Table 4 were identified using iterative expert opinion and crowd sourcing approaches described in Estabrooks et al. (2012). As can be seen, almost all of these items are very brief, have

national norms, and are practical to use in primary care settings. These items are the practical progress measures that are designed to be used longitudinally over time to evaluate patient health status and progress on these behavioral and mental health issues.

Participatory processes included formative evaluation and obtaining stakeholder input from four different perspectives—health care decision makers, practitioners, patient advocates, and primary care researchers (Estabrooks et al., 2012). In addition, participating research teams and practices were engaged in developing the final protocol, including what “essential features” needed to be implemented (e.g., the patient report survey items in Table 3, feedback to providers and patients, process and implementation measures to be collected) and what aspects of the study could be customized to the local setting (e.g., where in the clinic flow these questions were asked, who on the primary care team went over the survey results with patients, who developed the collaborative action plan with the patient, how follow-up was conducted). The practical trial design is a cluster randomized delayed intervention pragmatic implementation study being conducted in nine pairs of diverse primary care clinics in

Table 4. Domains and Items Selected for Patient Reported Health Behavior and Psychosocial Issues.

| Domain | Final Measure (Source) |
|---------------------------|--|
| 1. Demographics | Nine items: sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran's status. Multiple sources including: Census Bureau, Institute of Medicine, and National Health Interview Survey |
| 2. Overall Health Status | One item: Behavioral Risk Factor Surveillance System (BRFSS) Questionnaire |
| 3. Eating Patterns | Three items: Modified from Starting the Conversation (STC) (adapted from Paxton, Strycker, Toobert, Ammerman, & Glasgow, 2011) |
| 4. Physical Activity | Two items: The Exercise Vital Sign (Sallis, 2011) |
| 5. Stress | One item: Distress Thermometer (Roth et al., 1998) |
| 6. Anxiety and Depression | Four items: Patient Health Questionnaire–Depression & Anxiety (PHQ-4) (Kroenke, Spitzer, Williams, & Löwe, 2009) |
| 7. Sleep | Two items: (a) Adapted from BRFSS; (b) Neuro-QOL (Item PQSLP04) |
| 8. Smoking/Tobacco Use | Two items: Tobacco Use Screener (adapted from Youth Risk Behavioral Surveillance System Questionnaire) |
| 9. Risky Drinking | One item: Alcohol Use Screener (Smith, Schmidt, Allensworth-Davies, & Saitz, 2009a) |
| 10. Substance Abuse | One item: NIDA Quick Screen (Smith, Schmidt, Allensworth-Davies, & Saitz, 2009b) |

different types of health care organizations (e.g., federally qualified community health centers, practice-based research networks) in the Northeast, East, South, Midwest, Northwest, and Southwest of the United States.

Opportunities and Challenges for Pragmatic Approaches

This article has outlined initial steps and progress to date in the development and implementation of pragmatic designs and methods, measures, and models. Other examples could have been chosen: these are simply the ones with which I have the greatest familiarity. There are also several areas in which pragmatic approaches seem particularly appropriate. These include comparative effectiveness research (Glasgow & Steiner, 2012; Institute of Medicine, 2011a; Selby et al., 2012), especially the patient-centered issues addressed by Patient-Centered Outcomes Research Institute (<http://www.pcori.org/>). Another area that could benefit from concerted pragmatic research and development concerns understanding of context (Stange & Glasgow, 2012). Pragmatic studies are very context dependent, and reports of pragmatic studies should report on the multilevel context within which they are conducted to allow potential adopters determine the applicability to their setting. Although there is close to universal agreement on the importance of context, at present there are no widely accepted or standard approaches to describing or assessing context. Development of pragmatic approaches to the study of context would significantly advance the field. One reviewer for this article made the point that there is also a converse problem with non-evidence-based approaches being prematurely adopted in practice, such as the Drug Abuse Resistance Education program for substance abuse prevention. Pragmatic approaches could also be used to develop and evaluate strategies to “de-implement” such programs.

Key issues and debates about pragmatic approaches concern their size, cost, and how rapidly they should produce results. Some think that pragmatic approaches, because they are likely to encounter greater variability in both implementation and outcomes than efficacy studies, need to be large and by implication costly. Others argue that even if large in numbers, pragmatic studies need not be costly or slow, especially if pragmatic measures such as appropriately “cleaned” EHR data (Kiefe & Allison, 2012) are used as outcomes.

There are ongoing debates about research design in pragmatic trials, parallel to those concerning comparative effectiveness (Dentzer, 2012; Luce, 2010), especially concerning the advantages and limitations of randomized trials (Dentzer, 2012; Glasgow & Linnan, 2008; Kessler & Glasgow, 2011). My opinion is that we need to encourage multiple approaches to research design, consider the reasons why and when results converge and diverge across methods, and pay greater attention to issues of replication and integrating results across methods.

There are differences of opinion concerning appropriate outcomes for pragmatic research. Some grant and journal article reviewers think that biologic outcomes or biomarkers should always be included and are the ultimate outcomes and purpose of health research. In contrast, others, including myself, feel that given the current status of research, more emphasis is needed on implementation outcomes as well as the ultimate outcomes of population health and functioning.

The above are brief and possibly biased perspectives on some of the key current and emerging issues within pragmatic approaches. The opinions represented are my own, do not necessarily represent those of the National Cancer Institute or National Institutes of Health, and are intended to stimulate thinking, reflection, and discussion; not to prematurely conclude or limit debate. The field is relatively new and rapidly evolving, and I have certainly not included all the methods and issues addressed by pragmatic approaches. Pragmatic

approaches are not without their limitations and are explicitly an attempt to achieve a better balance between internal and external validity criteria, not to undermine internal validity or experimental rigor. Greater attention to pragmatic methods, measures, and models offers great potential to produce more rapid and relevant answers for research dollars expended and to help integrate research, practice, and policy.

Author's Note

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