

# Pragmatic dissemination and implementation research models, methods and measures and their relevance for nursing research

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## ABSTRACT

**Background:** Pragmatic dissemination and implementation (D&I) research approaches can benefit patient care because they emphasize real-world settings and populations. Nurse scientists have an opportunity to reduce the gap between science and practice by using pragmatic D&I research and sustainability strategies.

**Purpose:** This article discusses pragmatic models, methods, and measures used in D&I research and their relevance for nursing research and enhancing population health.

**Methods:** Summary of pragmatic D&I models and related methods for designing a pragmatic studies. We discuss the RE-AIM framework and the PRECIS-2 planning aid and figure in detail. A case study is provided and application to nursing research is discussed.

**Discussion:** Successful translation of pragmatic D&I research demands an approach that addresses external validity, and customization at multiple levels including the patient, clinician, and setting. Context is critically important, and it is never too early to design for dissemination.

**Conclusions:** Pragmatic D&I approaches are needed to speed research translation, reduce avoidable waste of funding, improve clinical care, and enhance population health. Pragmatic D&I research is an area of tremendous opportunity for the nursing science community.

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## Background

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The American Academy of Nursing (AAN), through the Council for the Advancement of Nursing Science (CANS), has recently set forth a blueprint of nursing science priorities that is “relevant to nurse scientists and nurses who transform and translate our science to meet the healthcare needs of individuals and populations” (Eckardt et al., 2017). The nursing science community is poised to address this research agenda by developing effective, patient-centered interventions that inform clinical practice, promote health, and improve patient outcomes (Grady & Gough, 2015; King & Thompson, 2008). Although generating new knowledge is critically important, it is not enough. Nurse scientist must consider implementation, dissemination and sustainability strategies to transform and translate science to improve health, at both individual and population levels (Grady & Gough, 2015).

In the current research environment, there is enormous pressure to accelerate the translation of evidence-based findings into practice. National networks such as the Department of Veterans Affairs (VA) Quality Enhancement Research Initiative (QUERI) has been supporting rapid implementation of research into clinical practice since 1998 and serves as an example of how to promote the uptake of effective practices into routine care (Kilbourne, Elwy, Sales, & Atkins, 2017). To successfully meet their mission, QUERI programs apply pragmatic models and methods when designing research and quality improvement projects. Other institutions including Agency for Healthcare Research and Quality, the National Institutes of Health (NIH) Pragmatic Trials Collaboratory and Clinical Translational Science Awards, the Patient Centered Outcomes Research Institute, as well as various foundations and institutes have also made major commitments to implementation science research. Given the clinical focus of nursing science, nurses have an unprecedented opportunity to impact individual and population health outcomes along the care continuum (The NINR Strategic Plan, 2016). The AAN, CANS, and National Institute of Nursing Research (NINR) support training and career development to advance the benefits of nursing science on health (Eckardt et al., 2017; Fawcett & Ellenbecker, 2015; Stone, Cohen, & Pincus, 2017; The NINR Strategic Plan, 2016).

Although efficacy randomized controlled clinical trials (RCTs) have traditionally been considered the gold standard for conducting intervention studies, results from these trials have often not translated well or rapidly into clinical practice. Many reasons have been cited for this lack of uptake (Chalmers & Glasziou, 2009; Moher et al., 2016), but the most common reason for non-adoption is that the research being conducted is not seen as relevant to patients or clinicians (Rothwell, 2005). Rarely, do such “gold standard” efficacy RCTs produce findings that are generalizable to clinical practice or low resource community settings

or vulnerable populations. These trials are interested in determining if an intervention will work for carefully selected populations under optimal conditions (Glasgow, Brownson, & Kessler, 2013; Loudon et al., 2015). Pragmatic dissemination and implementation (D&I) research, sometimes called practice-based research or clinical effectiveness research (King & Thompson, 2008), and including some types of comparative effectiveness research (CER) designs (Glasgow & Rabin, 2014; Glasgow & Steiner, 2012) are fundamentally different from efficacy RCTs. By pragmatic we mean research conducted under close to real world condition's including settings, staff, patients, resources, and measures. Since pragmatic D&I research is a relatively young field with national and international roots, terminology can be confusing for those in the field since it has not been standardized. In this article, we will use terms common to the U.S. research field. Terminology for D&I research is summarized (See Glossary) and discussed in great length in Rabin and Brownson (2018). Pragmatic D&I research is designed to be more relevant to clinical and/or policy decisions since they are based in real-world settings and address whether an intervention or program will work under usual and diverse conditions (Ford & Norrie, 2016; Glasgow, 2013; Loudon et al., 2015). In the UK, the term process evaluation has been used to address similar issues, most notably in the Medical Research Council guidance on process evaluation of complex interventions (Moore et al., 2015).

Nursing science tackles complex research questions spanning the care continuum that have a significant impact on the health of populations. Translating this science into real-world settings with diverse and complex populations is within the skillset of nurse scientists. We will describe approaches to pragmatic D&I research that overcome the challenges experienced with traditional study designs. Secondly, we will discuss pragmatic D&I research models, methods, and measures used in D&I research. A case study is provided; application to nursing research and population health will be discussed; and a list of supplemental resources is provided for readers interested in learning more.

## Pragmatic Dissemination & Innovation (D&I) Models

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Pragmatic research trials have several key characteristics that distinguish them from traditional efficacy RCTs (Pragmatic Trials Workshop Handbook, 2014). Pragmatic trials are appropriate for conducting and synthesizing research that compares the feasibility, generalizability, and effectiveness of different interventions to improve health outcomes (Stone et al., 2017). Pragmatic trials address questions important to stakeholders, which include patients, clinicians, and decision-makers (administrator and policy makers).

They take place in settings where typical patients usually receive care or a given intervention and usually compare different real-world alternatives, rather than using placebo, no treatment, or usual care controls (Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; Krist et al., 2013). Table 1 summarizes key differences between pragmatic trials and traditional clinical efficacy trials such as stakeholder engagement, research design, and outcomes measures (Krist et al., 2013). We should note, no study is completely pragmatic or completely an efficacy trial (or explanatory in different countries' terminology) but for information purposes, Table 1 presents the characteristics of completely pragmatic and efficacy trials as exemplified by traditional pharmacological trials. We acknowledge there has been movement over recent years to have at least some level of stakeholder involvement even in traditional clinical efficacy trials, much of it spurred by the Patient Centered Outcomes Research Institute (PCORI).

Highly controlled efficacy RCTs emphasizing procedures that minimize variability (in settings, staff, patients, and outcomes studies) can be challenging to generalize or sustain in practice or communities. In fact, many interventions do not realize their full potential when implemented outside of this controlled environment. This "voltage drop" in effectiveness maybe due to reduced fidelity of the intervention when disseminated to other settings, lack of guidance in customizing interventions to the local context, and often inadequate resources (Chambers & Norton, 2016; Chambers, Glasgow, & Stange, 2013; Kilbourne, Neumann, Pincus, Bauer, & Stall, 2007; Rothwell, 2005). It is never too early for researchers to think about designing for dissemination since stakeholders will need detailed guidance when implementing and customizing an intervention.

Tabak, Khoong, Chambers, and Brownson (2012), presented 61 models used in D&I research. Today, there are well over 100 models and/or frameworks available along with detailed information about what models are most focused on what settings, which constructs, and for what purposes (Birken et al., 2017; Dissemination & Implementation Models in Health Research & Practice). Although many commonalities exist across models and frameworks in D&I science, there are three main reasons for using them: (a) describing the process of translating research into practice, (b) explaining what influences implementation outcomes, and (c) evaluating implementation (Nilsen, 2015). Birken et al. (2017) reported the most common reason for using a conceptual model or framework was to identify key constructs that may serve as barriers or facilitators. Importantly, using a model throughout the research process contributes to the study's success (Tabak et al., 2012). A useful guide to selecting and adapting D&I models is provided at [www.dissemination-implementation.org](http://www.dissemination-implementation.org).

In recent years, there has been a ground-swell of interest in learning more about pragmatic research due to the release of the Consolidated Standards of Reporting

**Table 1 – Differences Between Pragmatic D&I and Clinical Efficacy Trials**

	Pragmatic D&I Trials	Clinical Efficacy Trials
Multi-level stakeholder involvement	Engaged various stakeholders including providers, leadership, and patients in all study phases including design, data collection, study conduct, interpreting results, and disseminating findings	Limited engagement, often only selected individuals in response to investigator ideas or to help with recruitment only
Research design	Includes internal and external validity, both fidelity and local adaptation, real life settings and populations, contextual assessments	Focus on limiting threats to internal validity and minimizing variability; typically uses randomized controlled trials; participants and settings are frequently selected to be homogenous
Outcomes	Reach, effectiveness, adoption, implementation, comparative effectiveness, costs, sustainability	Efficacy, mechanism identification, component analysis
Measures	Brief, sensitive to change, actionable with rapid clinical utility, feasible in real world and low-resource settings	Validated measures that minimize bias, focus on internal consistency and theory rather than clinical relevance
Costs	Assessments include intervention costs and replication costs in relation to outcomes	Frequently not collected or reported
Data source	Often includes existing data (electronic health records, administrative data) and brief patient reports	(Gaglio et al., 2013; Harden et al., 2015; Proctor et al., 2011) Data generation and collection part of clinical trial; usually involves additional visits for data collection
Analyses	Process and outcome analyses relevant to various stakeholders; use mixed methods	Specified, a priori, and typically restricted to investigator hypotheses
Results	Feasible for broad implementation	Usually a delayed implementation cycle

Adapted from Krist et al. (2013).

Trials (CONSORT) statement ([Consolidated Standards of Reporting Trials](#)). This checklist was originally intended to improve reporting of RCTs, but in 2008 was expanded to include pragmatic trials ([Zwarenstein et al., 2008](#)). Additional guidance, especially contributing to this interest, was the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) tool to help design pragmatic trials ([Thorpe et al., 2009](#)). The PRECIS and expanded CONSORT checklist may also be used for reporting on and evaluating the published literature ([Gaglio, Phillips, Heurtin-Roberts, Sanchez, & Glasgow, 2014](#); [Loudon et al., 2015](#); [Zwarenstein et al., 2008](#)). Below we discuss three models that may be of interest to readers, which are more pragmatic than many others; providing more detail for the RE-AIM model ([Glasgow, Vogt, & Boles, 1999](#); [Glasgow & Estabrooks, 2018](#)) since we have worked most closely with it.

The Knowledge to Action framework ([Wilson, Brady, & Lesesne, 2011](#)) is a process model and is used to guide the process of translating the research into practice by specifying stages involved in the translation process ([Nilsen, 2015](#)). Many such process models originated in the field of nursing research and facilitate implementation by providing “how-to” guidelines for planning and executing implementation strategies as well as foster translation, communication, and collaboration ([Nilsen, 2015](#); [Wilson et al., 2011](#)). Related Knowledge to Action frameworks have been widely used in Canadian pragmatic research ([Graham et al., 2006](#)).

Replicating Effective Programs (REP) is another framework that provides a roadmap for implementing evidence-based interventions into community-based settings through a combination of intervention “packaging,” training, technical assistance, and other strategies to maximize the chances for sustaining the interventions ([Kilbourne et al., 2007](#)). There are four phases to REP: pre-conditions, pre-implementation, implementation, and maintenance or evolution. The main idea behind the REP is for the research team to work with stakeholders at each phase to develop a “package” that provides enough details so the stakeholders can customize the intervention to meet the local needs. REP packages are distinctly different from “toolkits” because they provide specific details regarding the intervention as well as operationalized options for adapting delivery of an intervention to local organizations in a way that does not compromise the intervention’s core elements ([Kilbourne et al., 2007](#)). REP has been widely used in programs sponsored by the [Centers for Disease Control and Prevention \(2017\)](#).

## RE-AIM

The RE-AIM framework is close to 20 years old and was designed for all stages of research from planning through evaluation and reporting ([Glasgow et al., 1999](#)). RE-AIM focuses attention on five dimensions (Reach, Effectiveness, Adoption, Implementation, and Maintenance) that influence population health outcomes and follow a logical sequence, beginning with

reach and adoption, followed by implementation and efficacy or effectiveness, and finishing with maintenance ([Gaglio, Shoup, & Glasgow, 2013](#); [Glasgow, 2013](#)).

Recent reviews have documented that RE-AIM has been extensively used in both publications and grant applications. Researchers found that RE-AIM was the D&I model most often used between 2000 and 2016 for NIH and CDC grant applications ([Vinson, Stamatakis, & Kerner, 2018](#)). Other reviews also documented the widespread use of RE-AIM, which has been used in over 440 publications ([Gaglio et al., 2013](#); [Harden et al., 2015](#); [Tinkle, Kimball, Haozous, Shuster, & Meize-Grochowski, 2013](#); RE-AIM). A detailed review of their findings is beyond the scope of this paper, but one finding is that it is often not possible to employ all aspects of the RE-AIM model (or most other models). This is especially true in community and clinical applications that are not supported by large research and evaluation budgets ([Ory et al., 2014](#)). These reviews have found that effectiveness and implementation (fidelity) are most frequently assessed, and that maintenance and costs (of implementation) are the least often reported ([Gaglio et al., 2013](#); [Harden et al., 2015](#); [Kessler et al., 2013](#)).

[Kessler et al. \(2013\)](#) found that there was often confusion between the RE-AIM concepts of reach and adoption in their review of grant proposals. Reach represents the participation and representativeness at the individual (consumer or patient) and adoption addresses participation and representativeness at multiple setting and staff levels. Representativeness of participants, settings, and the practitioners can be accomplished by comparing demographic characteristics and other relevant variables between participants and nonparticipants and by reporting the most common reasons for declining participation ([Kessler et al., 2013](#)).

[Glasgow and Estabrooks \(2018\)](#) have addressed the issue of “what is pragmatically possible and what should be expected when using RE-AIM?” They recommended: (a) that all projects consider all RE-AIM dimensions when planning an intervention or study evaluation; (b) that the research team, including multiple stakeholders, decides which dimensions are most important to that application; (c) which dimensions should be targeted for intervention (e.g., focus on enhancing reach); and (d) which dimensions should be assessed. Furthermore, they argued that pragmatic application of RE-AIM does not require comprehensive measurement of each dimension and all issues within that component, but that the sequence of decisions be explained and justified a priori to enhance transparency; and be practical ([Glasgow & Estabrooks, 2018](#)). [Table 2](#) presents a pragmatic translation of key RE-AIM dimensions and user friendly *who, what, where, why, when* type questions to which stakeholders can more likely relate.

The RE-AIM framework can also be used to enhance translation and dissemination ([Tabak et al., 2012](#)). [Table 3](#) provides a definition for each RE-AIM

**Table 2 – Pragmatic RE–AIM Questions**

RE-AIM dimension	Key pragmatic questions
Reach	WHO is (was) intended to benefit and who actually participates or is exposed to the intervention?
Effectiveness	WHAT is (was) the most important benefits you are trying to achieve and what is (was) the likelihood of negative outcomes?
Adoption	WHERE is (was) the program or policy applied and WHO applied it?
Implementation	HOW consistently is (was) the program or policy delivered; HOW will (was) it be adapted; HOW much will (did) it cost; and WHY will (did) the results come about?
Maintenance	WHEN will (did) the initiative become operational; how long will (was) it be sustained (Setting level); and how long are the results sustained (Individual level)?

Adapted from [Glasgow and Estabrooks \(2018\)](#).

dimension and examples of strategies a project could employ to accelerate the translation and dissemination processes. The pragmatic questions shown in [Table 2](#) can help the research team anticipate likely challenges, as well as plan and evaluate the interventions and implementation strategies that are more likely to be feasible and broadly applicable to produce lasting, generalizable results ([Glasgow & Estabrooks, 2018](#); [Klesges, Estabrooks, Dzewaltowski, Bull, & Glasgow, 2005](#)).

A key element of translating research into practice is context. Context is multilevel and may include characteristics and representativeness of participants, staff, and setting involved. An extension of RE-AIM, the Practical, Robust Implementation and Sustainability Model (PRISM) ([Feldstein & Glasgow, 2008](#)) specifies that contextual factors often influence outcomes along RE-AIM dimensions. It can be used to understand the success or failure of the study by describing the context in which the study was implemented ([Gaglio et al., 2013](#); [Kessler et al., 2013](#)). Other important, and less often reported elements of a full RE-AIM application are cost and quality of implementation, qualitative measures, and sustainability of the intervention ([Gaglio et al., 2013](#); [Glasgow, 2013](#); [Harden et al., 2015](#)).

### Pragmatic D&I Methods

It is critical that researchers make design decisions that are consistent with the stated purpose of their study ([Gaglio et al., 2014](#); [Thorpe et al., 2009](#)). When an investigator is interested in determining the effects of an intervention under usual conditions to optimize adoption, implementation and sustainability, then a pragmatic design is more appropriate. The original PRECIS framework was developed to help researchers design studies and assess where their study was positioned along the pragmatic-explanatory continuum based on 10 domains. The 10 domains identified the following criteria that distinguished the design from being more or less pragmatic vs. explanatory ([Thorpe et al., 2009](#)):

1. Eligibility criteria of participants
2. Flexibility with which the experimental intervention applied
3. Practitioner expertise in applying and monitoring the experimental intervention
4. Flexibility with which the comparison intervention applied
5. Practitioner expertise in applying and monitoring the comparison intervention
6. Intensity of follow-up of participants
7. Nature of the primary outcome
8. Intensity of measuring participants' compliance with the prescribed intervention, and whether compliance-improving strategies used
9. Intensity of measuring practitioners' adherence to the study protocol, and whether adherence improving strategies used
10. Specification and scope of the analysis of the primary outcome

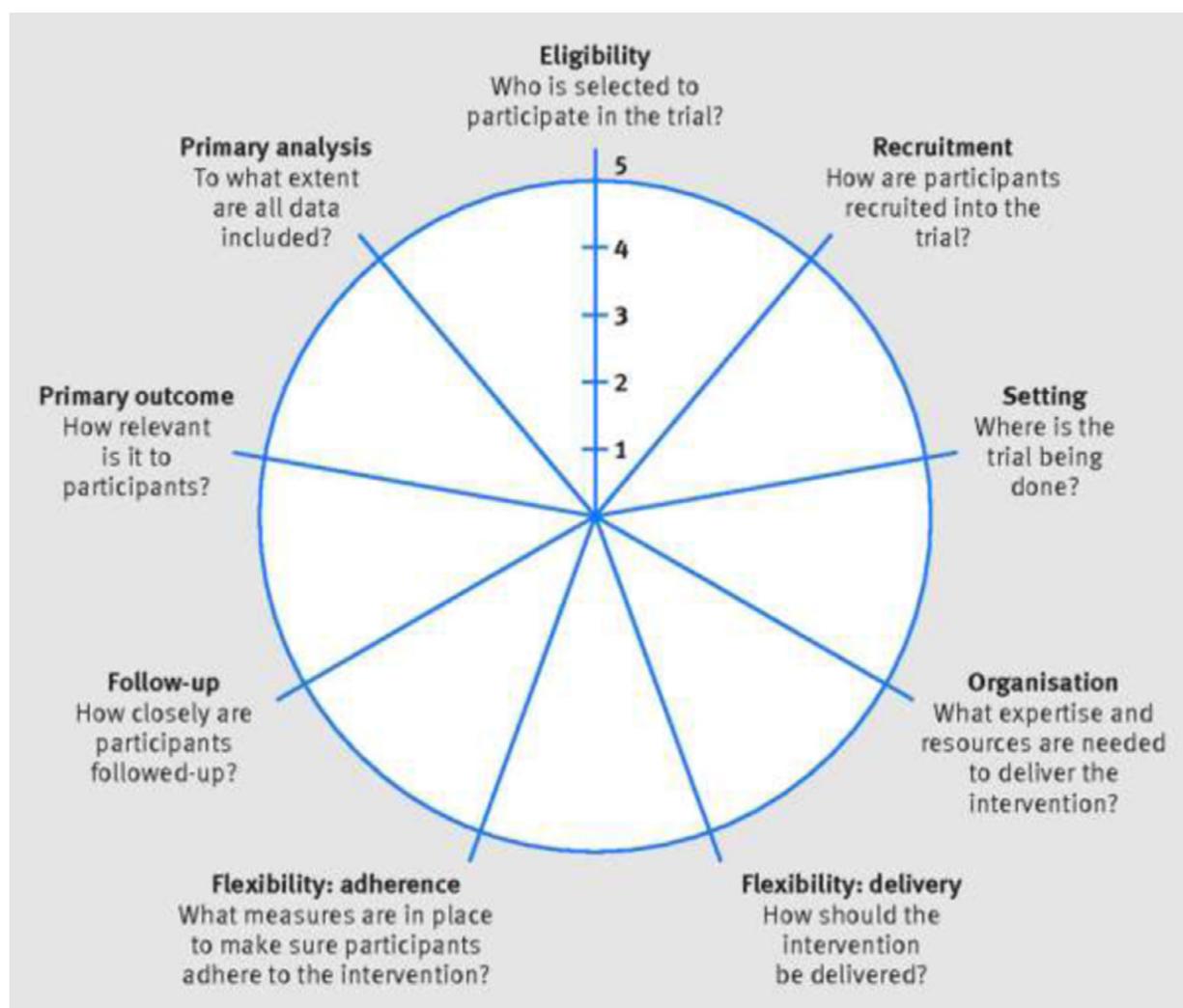
The PRECIS was revised in 2015 (PRECIS-2) to include a five-point Likert rating scale representing where each domain is positioned along the pragmatic-explanatory continuum ([Loudon et al., 2015](#)). The domains were also revised in the PRECIS-2 to provide added guidance, clarification and definitions, and modify the number of domains to nine ([Loudon et al., 2015](#)). Key elements included recruitment of participants, setting, intervention, delivery, and follow-up as well as trial methodology ([Ford & Norrie, 2016](#); [Loudon et al., 2015](#); [Thorpe et al., 2009](#)). The spoke and hub diagram depicted in [Figure 1](#) provides a visual summary of how each domain can be plotted, where one represents a very explanatory (i.e., efficacy in U.S. terminology) trial (close to the center) and five represents a very pragmatic trial (outer edge of wheel) ([Loudon et al., 2015](#); [Pragmatic Trials Workshop Handbook, 2014](#); [Thorpe et al., 2009](#)).

Pragmatic studies have fewer exclusion criteria and include populations that are like individuals with the given condition being studied (e.g., are medically complex and have multiple conditions). Pragmatic trials also use existing care procedures and settings to recruit potentially eligible patients and conduct these studies in settings similar to ones in usual care. A study would be more explanatory when it required increased resources, or specialized provider knowledge or environment to deliver the intervention ([Thorpe et al., 2009](#)). This continuum helped investigators realize that no trial is completely pragmatic or completely explanatory.

**Table 3 – RE-AIM Framework to Enhance Translation and Dissemination**

RE-AIM dimension	Definitions	Strategies to enhance future translation and dissemination
Reach (individual level)	The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative.	<ul style="list-style-type: none"> <li>• Formative evaluation with potential users, and those who decline to participate</li> <li>• Small-scale recruitment studies to enhance methods</li> <li>• Identify and reduce participation barriers</li> <li>• Use multiple channels of recruitment</li> </ul>
Effectiveness (individual level)	The impact of an intervention on outcomes, including potential negative effects, quality of life, economic outcomes, and subgroup effects.	<ul style="list-style-type: none"> <li>• Incorporate tailoring to individuals and settings</li> <li>• Reinforce messages via repetition, multiple modalities, social support, and systems change</li> <li>• Consider stepped care approaches</li> <li>• Evaluate adverse outcomes and quality of life for program revision and cost-to-benefit analysis</li> </ul>
Adoption (setting, staff or organizational level)	The absolute number, proportion, and representativeness of settings and intervention agents who are willing to initiate a program. Similar to reach only at the participant level: the percentage of settings and staff approached that participate.	<ul style="list-style-type: none"> <li>• Conduct formative evaluation with both adoptees and non-adoptees</li> <li>• Recruit settings that have contact with the target audience</li> <li>• Develop recruitment materials outlining program benefits and required resources</li> <li>• Provide various cost options and customization of the intervention</li> </ul>
Implementation (setting, staff or organizational level)	The intervention agents ‘fidelity’ to the key elements of an intervention. This includes consistency of delivery as intended, adaptations made, and the time and cost of the intervention.	<ul style="list-style-type: none"> <li>• Provide delivery staff with training and technical assistance</li> <li>• Provide clear intervention protocols, and guidance on what can and cannot be adapted. Consider automating all/part of the program</li> <li>• Monitor and provide staff feedback and recognition for implementation</li> </ul>
Maintenance (individual and setting levels)	The extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. At the individual level, sustainment of improvement.	<ul style="list-style-type: none"> <li>• Minimize level of resources required</li> <li>• Incorporate “natural environmental” and community supports</li> <li>• Conduct follow-up assessments and interviews to characterize success at both individual and setting levels</li> <li>• Consider incentives and align with policy support</li> </ul>

Adapted from [Klesges et al. \(2005\)](#).



**Figure 1 – Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) Wheel** (Loudon et al., 2015).

Another pragmatic method to consider is trial design. Traditionally, researchers have used a linear, step-wise approach to determine the effectiveness of an intervention before it was ready for clinical practice that began with efficacy research, then clinical effectiveness research, and only then D&I or “demonstration” research (Greenwald & Cullen, 1985). Others have suggested combining the clinical efficacy and effectiveness phases to accelerate translation into practice (Curran, Bauer, Mittman, Pyne, & Stetler, 2012; Glasgow, Lichtenstein, & Marcus, 2003; Wells, 1999). Curran et al. (2012) developed the effectiveness-implementation hybrid design terminology to facilitate implementation of these concepts instead of the longer, more traditional step-wise progression by blending design components. Figure 2 illustrates the distinct types of hybrid designs:

Type 1 – Primarily testing for clinical outcomes while gathering information on its delivery during the

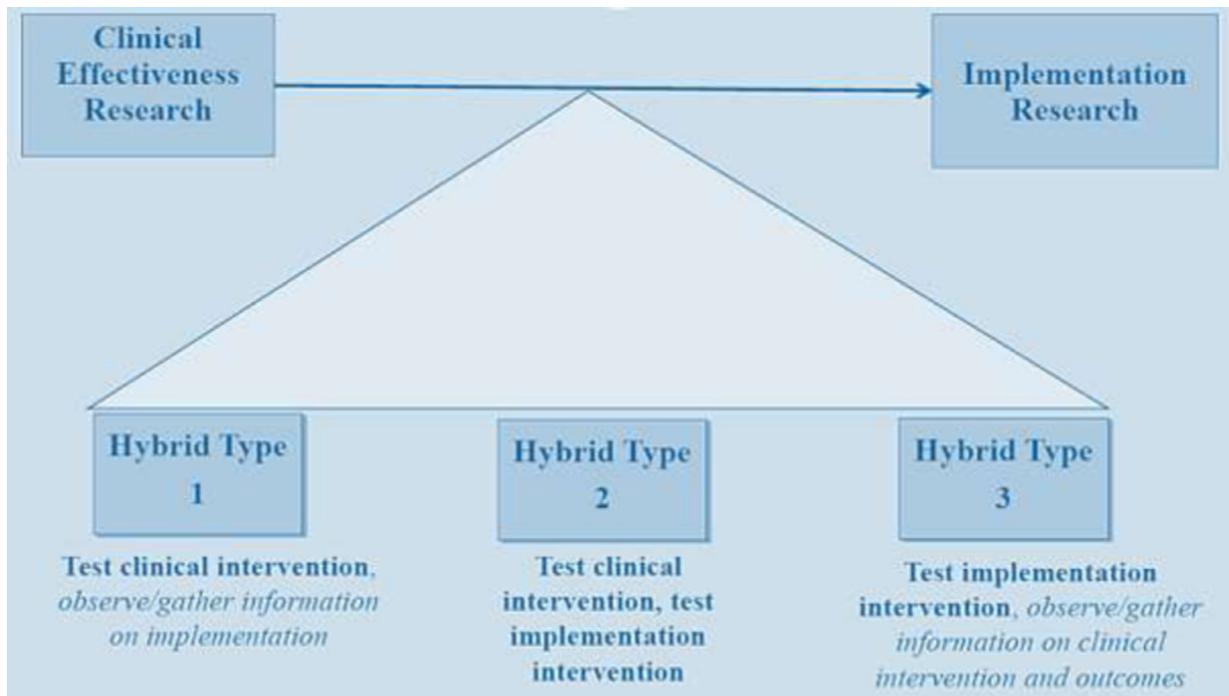
effectiveness trial and/or its potential for implementation in the real-world setting.

Type 2 – Simultaneously testing a clinical intervention and an implementation intervention or strategy.

Type 3 – Primarily evaluating the implementation intervention or strategy while gathering information on the clinical results of the intervention.

Below are examples of how a research question would vary depending on type of hybrid design being used:

- Type 1: *Primary question*: Will a clinical treatment work in this setting and/or these patients? *Secondary question*: What are potential barriers/facilitators to a treatment’s widespread implementation?
- Type 2: *Co-primary question*: Will a clinical treatment work in this setting and/or these patients? *Co-primary question*: Does the implementation method show promise (either alone or in comparison with



**Figure 2 – Types of Hybrid Designs.**  
Adapted from Curran et al. (2012).

another method) in facilitating implementation of a clinical treatment?

- Type 3: *Primary question:* Which method works better in facilitating implementation of a clinical treatment? *Secondary question:* Are clinical outcomes acceptable?

Cluster randomization is a study design often appropriate for pragmatic research. In this design, randomization occurs at the setting or group level rather than the individual level. This group level may represent clinics, hospitals, or communities. Cluster randomized designs have frequently been applied to public health and clinical evaluation studies. These designs are now becoming more popular with pragmatic research because of the increased efficiency, decreased risk of experimental contamination, and likely greater participation by settings and individuals (Donner & Klar, 2004). However, there can be a loss of statistical precision with this type of study design due to the potential imbalance between groups, especially when randomizing a small number of clusters and when there is high variability within settings (Donner & Klar, 2004).

The stepped wedge cluster randomized trial design is a type of cluster randomization; except that it involves a sequential roll-out of an intervention. This pragmatic study design is useful in situations where all settings and participants want to get the intervention (Hemming, Haines, Chilton, Girling, & Lilford, 2015). This design involves a randomized sequential crossover of clusters (e.g., clinics) from control to intervention until all clusters receive the intervention. Early adopters are

not chosen to go first, and the order is randomly assigned at regular intervals or “steps”. This design can be particularly appealing for quality improvement studies or when the intervention is anticipated to be beneficial (Dreischulte, Grant, Donnan, & Guthrie, 2013), making a parallel design unattractive to potential participating settings or even unethical since there is no crossover capability with the parallel designs (Brown & Lilford, 2006; Pragmatic Trials Workshop Handbook, 2014). A critique of the stepped wedge design is that it can be vulnerable to time varying confounding often requiring careful planning so changes to the intervention are not being made as it is rolled out (Dreischulte et al., 2013).

It is imperative for effective pragmatic D&I research to study reasons for the success or failure of implementation efforts. Understanding the context in which interventions are implemented is an essential element in designing for dissemination. Mixed methods research can provide a deeper understanding of implementation efforts (Albright, Gechter, & Kempe, 2013; Hamilton et al., 2018). Many contextual factors are best assessed using qualitative approaches. Specific guidance on the use of qualitative measures with RE-AIM has been provided by Holtrop, Glasgow, and Rabin (2018). Application of mixed methods in pragmatic D&I research is still evolving. Guidance and lessons learned have recently been provided in several sources (Holtrop et al., 2018; Palinkas & Cooper, 2017; The QUALRIS Group Learning Community, 2017).

A final issue for pragmatic D&I research concerns the use of comparison groups or control conditions. Unlike

traditional efficacy RCTs, pragmatic trials, along with CER studies, use alternative interventions that are felt to be effective, at least to some extent, as comparisons. This is consistent with the purpose to test real-world alternatives. The alternatives tested often differ in intensity, content, cost, modality or other dimensions to allow researchers to understand the comparative and incremental value of an intervention compared to one or more alternatives. One strategy used in pragmatic studies is a Minimal Intervention Needed for Change or MINC (Glasgow et al., 2014). An MINC control condition is designed to be as lean and economical as possible, so that it is maximally feasible and broadly applicable. MINC evaluations allow assessment of whether more complex and costly interventions are worth the incremental cost.

### **Pragmatic D&I Measures and Implementation Outcomes**

Both process and outcome measures in pragmatic D&I research are different than those in traditional clinical research. Instead of focusing almost exclusively on a clinical, usually biological, outcome; implementation science is concerned with evaluating the context, the implementation strategies, the process and the implementation outcomes in a project. Outcomes for D&I science have been well articulated in a series of articles (Proctor et al., 2011; Proctor, Powell, & McMillen, 2013). Proctor et al. (2011) proposed a taxonomy of implementation outcomes (e.g., acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability). Many of these outcomes (Proctor et al., 2011) are very similar or the same as the RE-AIM dimensions. Certain strategies may target one or more of these implementation outcomes or other outcomes not identified in Proctor et al. (2011). For instance, training or educational strategies typically target fidelity, while financial and policy strategies likely enhance feasibility and acceptability. More information about implementation outcomes can be found in other sources (Brownson, Colditz, & Proctor, 2012; Proctor et al., 2011; Proctor, Powell, & Feely, 2014). We direct readers to the D&I section of the Grid Enabled Measurement Initiative (GEM-Dissemination and Implementation Initiative) as well as The Society For Implementation Research Collaboration measures project for repositories of implementation outcome measures. Researchers or practice leaders who develop, design, and test implementation strategies should explicitly state the implementation outcomes targeted by the strategy.

The concept of pragmatic measures has received far less attention than those of pragmatic models, and especially pragmatic D&I research methods and designs. By a pragmatic measure, we mean an assessment strategy that is feasible to use in busy real-world settings, is brief, low cost, actionable, produces rapid or immediate feedback, is not burdensome, yet still broadly applicable, and sensitive to change (Glasgow &

Riley, 2013). Pragmatic measures are key, especially if we are to conduct practical, actionable research. They are most helpful when used in an ongoing and sustained basis to guide quality improvement, adaptations, performance evaluations, and dissemination strategies.

There has been an increasing number of papers on pragmatic measures (Glasgow & Riley, 2013; Kroenke, Monahan, & Kean, 2015; Powell et al., 2017; Weiner et al., 2017) over the past few years. While there are some differences across these conceptualizations, there is broad consensus about the core elements of pragmatic measures and that they are fundamentally different than the type of psychometrically sophisticated measurement approaches in which most researchers were trained. In contrast to the pragmatic criteria above, traditional psychometric measures have high internal consistency above all, which is usually accomplished by having an extremely long set of many items. In the future, there will likely be a strong emphasis on pragmatic patient report and computer adaptive measures (Cella et al., 2016), as well as pragmatic staff observation systems, that can be integrated into electronic health records.

### **Pragmatic D&I Research Example: My Own Health Report**

The My Own Health Report (MOHR) study was a pragmatic D&I trial whose primary purpose was to study clinical implementation of and patient experience with the use of an automated, interactive health risk assessment and feedback system to help clinics focus on patient-centered care issues (Krist et al., 2013). The MOHR trial used a paired, cluster randomized delayed intervention design with nine pairs of diverse and heterogeneous primary care clinics. The trial combined elements of pragmatic trials, implementation science, systems science (Sterman, 2006), and mixed methods approaches with practical outcome measures (Glasgow & Riley, 2013). Research teams identified and selected matched clinics that were similar in type (e.g., federally qualified health center, practice based research network, family practice, or internal medicine), and clinical characteristics including geographic region, approximate size and level of electronic health record integration. One clinic in each pair was randomized to early implementation while the second clinic was assigned to the delayed implementation condition.

The online MOHR assessment and feedback system (My Own Health Report) included patient-reported items on health risk behaviors, mental health, substance use, demographics, and patient preferences (Krist et al., 2013). RE-AIM was used to plan, adapt, and evaluate the system using a low-cost pragmatic implementation strategy. RE-AIM was used in the planning stages to develop strategies feasible for low-resource settings with patients most in need (e.g., federally qualified health centers and other diverse clinics

including rural, suburban, and urban clinics). Inclusion criteria were purposively broad for clinics and patients, and time demands on patients and staff were kept to a minimum. The implementation plan involved a high degree of flexibility and allowed each clinic to recruit patients, administer the MOHR, simultaneously provide feedback, use assessment/feedback modalities, select languages (English or Spanish), and place in their clinic workflow. In terms of RE-AIM, this plan addressed reach, effectiveness, adoption, and implementation issues (Glasgow et al., 2014; Peek et al., 2014). As summarized in Table 4, MOHR was pragmatic across many dimensions.

RE-AIM was used iteratively to monitor and adjust recruitment strategies (reach) and feedback and goal setting print-out delivery to patients and health care team members (implementation). Content on print-outs was reinforced by practical webinars providing training in motivational interviewing and collaborative goal setting. The intervention was purposefully brief, low-cost (publicly available), and addressed impact (effectiveness) through standardized assessment and feedback content (Krist et al., 2013).

Results are summarized elsewhere, (Krist et al., 2016) but in brief, the intervention produced high levels of reach (49% of all eligible patients, including those not contacted), adoption (18 of 30 diverse, low-income clinics approached participated), implementation (all eight risk factors were assessed significantly more often in intervention patients; assessment and print-outs were delivered consistently), and effectiveness (intervention was superior to randomized paired control clinics on goal setting for six of eight behaviors, and improvement on five of eight health behavior and mental health issues). The program was not, however, maintained in any of the settings following conclusion of the study.

To achieve high-levels of reach, adoption and implementation, it was necessary to allow considerable flexibility and customization about how the MOHR was delivered while keeping the content of the intervention standard (Glasgow et al., 2014; Krist et al., 2016). The study was conducted very inexpensively and rapidly by the standards of controlled trials (Glasgow et al., 2014) and demonstrated use of RE-AIM for planning, adaptation, and evaluation. The lack of setting maintenance was due to the inability to integrate the intervention into the existing health records (several

different electronic health record systems were used) and intervention costs that, while modest (primarily staff time), still exceeded reimbursement amounts provided by Medicare for annual wellness exams.

## Discussion

Pragmatic D&I research approaches are needed as pressure mounts to meet the healthcare needs of complex individuals and populations, and to improve health outcomes. Although there are many challenges in real-world application of research, pragmatic D&I research approaches are needed in nursing science if we are to shorten the time lag between discovery and application. Pragmatic D&I research is messy, complex and contextual and has both similarities and differences with traditional efficacy RCTs as shown in Table 1. However, the crosscutting difference is that while variability is minimized and viewed as bad in traditional efficacy research, variability—across settings, staff, conditions, patients and other study factors—is embraced and studied in pragmatic D&I research.

As experience using the PRECIS framework has taught us, being more or less pragmatic is not necessarily good or bad—it depends on the question, state of science, and purpose of a given study. If, however, the goal is to produce population impact and to translate to real-world, diverse settings; then research needs to more closely approximate those conditions. As Lawrence Green has stated, “If we want more evidence-based practice, then we need more practice-based evidence” (Green, 2006).

Pragmatic D&I research is contextual. To understand variability and how contextual factors influence outcomes, qualitative and mixed methods approaches are almost always needed to supplement quantitative and “objective” measures such as behavioral and biologic outcomes. Understanding the rationale for and benefits of mixed methods research is increasingly important in today’s competitive funding environment, and many funding agencies now expect applicants to include mixed methods in proposals. The increasing demand for qualitative and mixed methods research necessitates broader methodological training and deepened collaboration between medical, clinical, and

**Table 4 – Pragmatic Features of MOHR**

Pragmatic characteristic	How pragmatic characteristic was operationalized
Relevant	Diverse, real-world primary care settings, and staff who do all the interventions
Rigorous	Cluster randomized, delayed intervention design
Rapid	Completed within one year from concept, planning, and execution
Resource Informative	Low cost, studying costs and cost-effectiveness under different delivery conditions
Recursive	Data on recruitment results used to modify recruitment procedures
Transparent	Reported on adaptations, failures, lessons learned

Adapted from Glasgow et al. (2014) and Peek et al. (2014).

social scientists (Albright et al., 2013) and seems especially applicable for nursing research.

As summarized above, we have used RE-AIM throughout as an example pragmatic D&I model that is aligned with pragmatic methods and measures, and supports and helps guide pragmatic D&I research. However, RE-AIM is not always the best model for a given situation, and certainly not the only one that is useful. It is the pragmatic model that we are most intimately familiar with, and we recognize that all models are wrong (because they over simplify reality). Readers might also want to explore REP and Knowledge to Action frameworks, among others, and the dissemination-implementation website ([www.dissemination-implementation.org](http://www.dissemination-implementation.org)) can be helpful in identifying models for different purposes.

Although pragmatic research approaches, including pragmatic models, methods and measures, are most closely associated with D&I studies, they have also been used frequently in CER (Glasgow & Rabin, 2014; Glasgow & Steiner, 2012). The term pragmatic to describe research studies is being used more frequently recently, including for some more basic pharmacotherapy trials. The pragmatic approaches we have presented here would be classified as pragmatic by almost all reviewers, but the field of pragmatic research is relatively young and still evolving (Glasgow, 2013; NIH Collaboratory Living Textbook of Pragmatic Clinical Trials). As would be expected and as implied by PRECIS research, there is not complete consensus about designs, measures and outcomes that are pragmatic (e.g., are all electronic health records based measures pragmatic, or only those that are actionable and able to be reproduced and made available in typical settings?). These issues are discussed in more detail in Gaglio et al. (2014) and in the “living textbook” from the NIH Pragmatic Trials Collaboratory (NIH Collaboratory Living Textbook of Pragmatic Clinical Trials).

This paper and pragmatic D&I research in general, have limitations as well as provide tremendous opportunity for nurse scientists. From some perspectives, pragmatic D&I methods are not considered rigorous enough because they do not exert high levels of researcher control to rule out all or most extraneous variables. While this is a defensible position, it is also helpful to remember that one person’s confounders are another researcher’s key independent variables and topic of study. Although pragmatic D&I research is usually faster than traditional effectiveness research, especially in multisite studies (Glasgow et al., 2014), it is still relatively slow compared to the need of many clinical and community settings for prompt, relevant and reliable answers. Some authors are beginning to explore the interface between implementation science that produces generalizable knowledge, and quality improvement that produces rapid, local answers (Perla, Provost, & Parry, 2013).

Future directions in pragmatic D&I research will likely involve more specific pragmatic models for specific situations and problems when addressing research questions pertaining to promoting health, symptom management,

or end of life care. More rapid and iterative use of measures and digital technology (e.g., computer adapted technology) assessment procedures are needed to make designs and interventions more adaptable and measures more streamlined. Fast Healthcare Interoperability Resources technology to integrate measures into the electronic health record (Alterovitz et al., 2015; Fast Healthcare Interoperability Resources) are imminent and should substantially enhance the ability to conduct pragmatic research.

In conclusion, nurse scientists are well-prepared to lead and participate in multidisciplinary teams conducting D&I research using pragmatic approaches (Tinkle et al., 2013). Given the clinical focus of nursing science, nurses must ask pragmatic research questions such as “What program/policy components are most effective for producing what outcomes for which populations/recipients when implemented in what settings using what implementation strategies by what type of persons/modalities under what conditions, with how many resources and how/why do these results come about?” These questions are more suitable to inform more rapid and complete translation of science to practice.

## GLOSSARY\*

- Dissemination and Implementation Research is an emerging field in the United States (U.S.); however, “other countries and international organizations use terms as knowledge translation and integration, population health intervention research, or scaling-up to define this area of research.”
- Dissemination Research is the “systematic study of processes and factors that lead to widespread use of evidence-based interventions by the target population.”
- Implementation Research seeks to “understand the processes and factors that are associated with successful integration of evidence-based interventions within a particular setting.”
- Knowledge Translation is a term used by the Canadian Institutes of Health Research (CIHR) and is defined as a “dynamic and iterative process that includes synthesis, dissemination, exchange, and ethically sound application of knowledge.”
- Comparative Effectiveness Research is “the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat, and monitor health conditions in real-world setting.”
- Implementation outcomes are defined as “the effects of deliberate and purposive actions to implement new treatment, practices, and services.”
- Mixed Methods approaches “involve the collection and analysis of multiple, both quantitative and qualitative data in a single study to answer research

questions. Mixed methods can generate rich data from multiple levels and a number of stakeholders to answer complex questions.”

## SUPPLEMENTAL RESOURCES

### Book

\*Rabin and Brownson (2018)

1. Brownson R. C., Colditz, G. A. & Proctor, E. K. (Eds.) (2018). *Dissemination and Implementation Research in Health: Translating Science to Practice* (Second edition). Oxford; New York: Oxford University Press.
2. Bartholomew, L. K., Parcel, G. S., Kok, G., Gottlieb, N. H. & Fernández, M. E. (2011). *Planning Health Promotion Programs: An Intervention Mapping Approach* (Third edition). San Francisco: Jossey-Bass.
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### Websites

- NIH Collaboratory - <http://www.rethinkingclinicaltrials.org/>
- Dissemination & Implementation Models – [www.dissemination-implementation.org](http://www.dissemination-implementation.org)
- ACCORDS (The Adult and Child Consortium for Outcomes Research and Delivery Science) D&I Program - <http://www.ucdenver.edu/academics/colleges/medicalschoo/programs/ACCORDS/sharedresources/Dandi/Pages/Dissemination%20and%20Implementation.aspx>
- RE-AIM – [www.re-aim.org](http://www.re-aim.org)
- Consolidated Framework for Implementation Research (CFIR) – <http://Cfirguide.org>

- National Institute of Nursing Research - <https://www.ninr.nih.gov>
- National Cancer Institute Implementation Science - <https://cancercontrol.cancer.gov/IS/>

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### Supplementary materials

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