Center for the Study of
Healthcare Provider Behavior

QUERI

Quality Enhancement
Research Initiative

Designing a Successful*
Dissemination/Implementation Study

Brian S. Mittman, PhD
Senior Social Scientist

VA/UCLA/RAND Center for the Study of
Healthcare Provider Behavior

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Selected views of implementation research

- Implementation research lacks rigor

- Implementation studies employ "black box" methods

- Implementation research is atheoretical

- Implementation research inappropriately emulates clinical research

- Implementation research sacrifices external for internal validity

- Implementation research is not research

Implementation research goals

- Generate new insights and generalizable knowledge regarding dissemination/implementation *processes*, *barriers*, *facilitators*, *strategies*

- Apply, test and refine models, theories, hypotheses, principles

- Improve health-related processes and outcomes within participating settings and groups

- Produce reliable strategies for improving health-related processes and outcomes in other settings and groups

Available frameworks, guidelines

- Clinical research

- Program evaluation

- Health behavior/health promotion research

- Implementation science ("translation type 2")
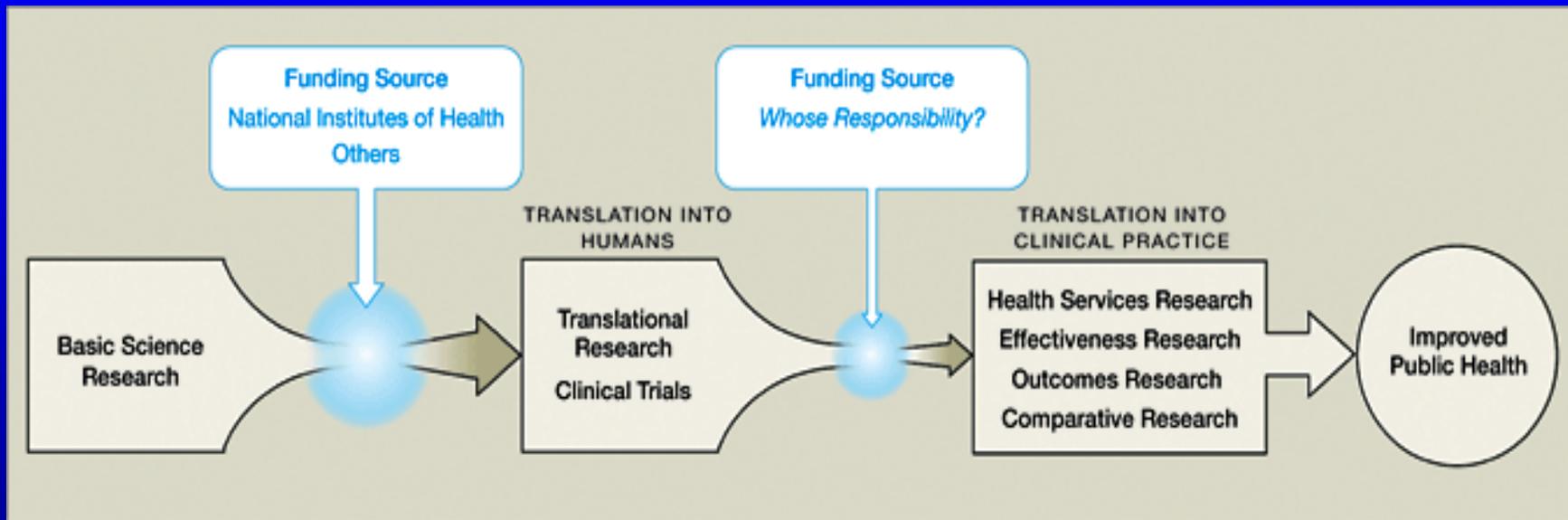
- Phase models, CONSORT-like statements, templates

Key implementation research frameworks

- Health-related research / implementation pipeline

- QUERI Six-Step Process

- 4-phase implementation research framework (clinical trials, UK MRC complex interventions, QUERI)

- Elements for an implementation research "CONSORT extension" (Green/Glasgow external validity criteria, QUERI Service-Directed Project template)

* This list is incomplete; the views expressed here are the author's rather than those of VA, NIH or *Implementation Science.*
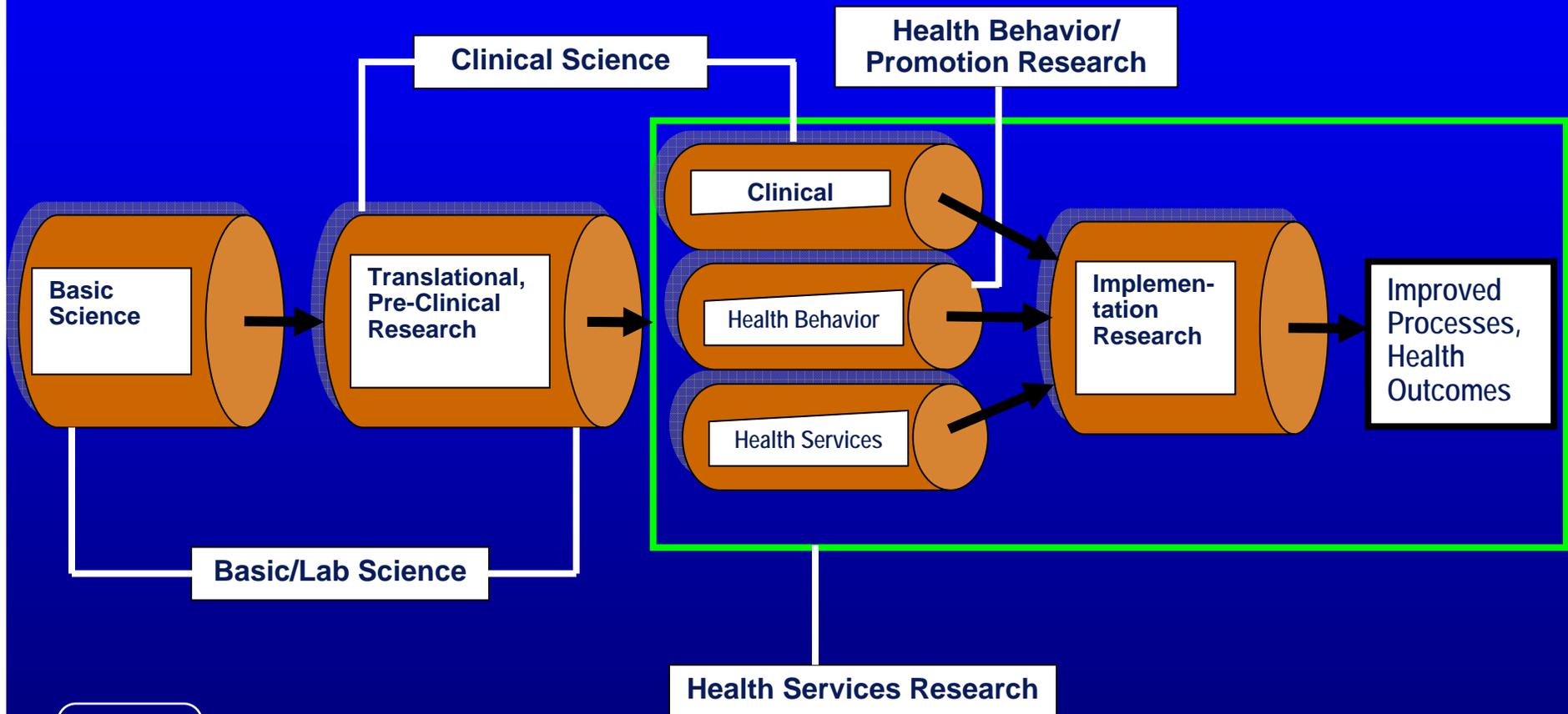
IoM Clinical Research Roundtable:
Two translational roadblocks

Crowley WF, et al. Clinical Research in the United States at a Crossroads. *JAMA.* 2004. 291: 1120-1126
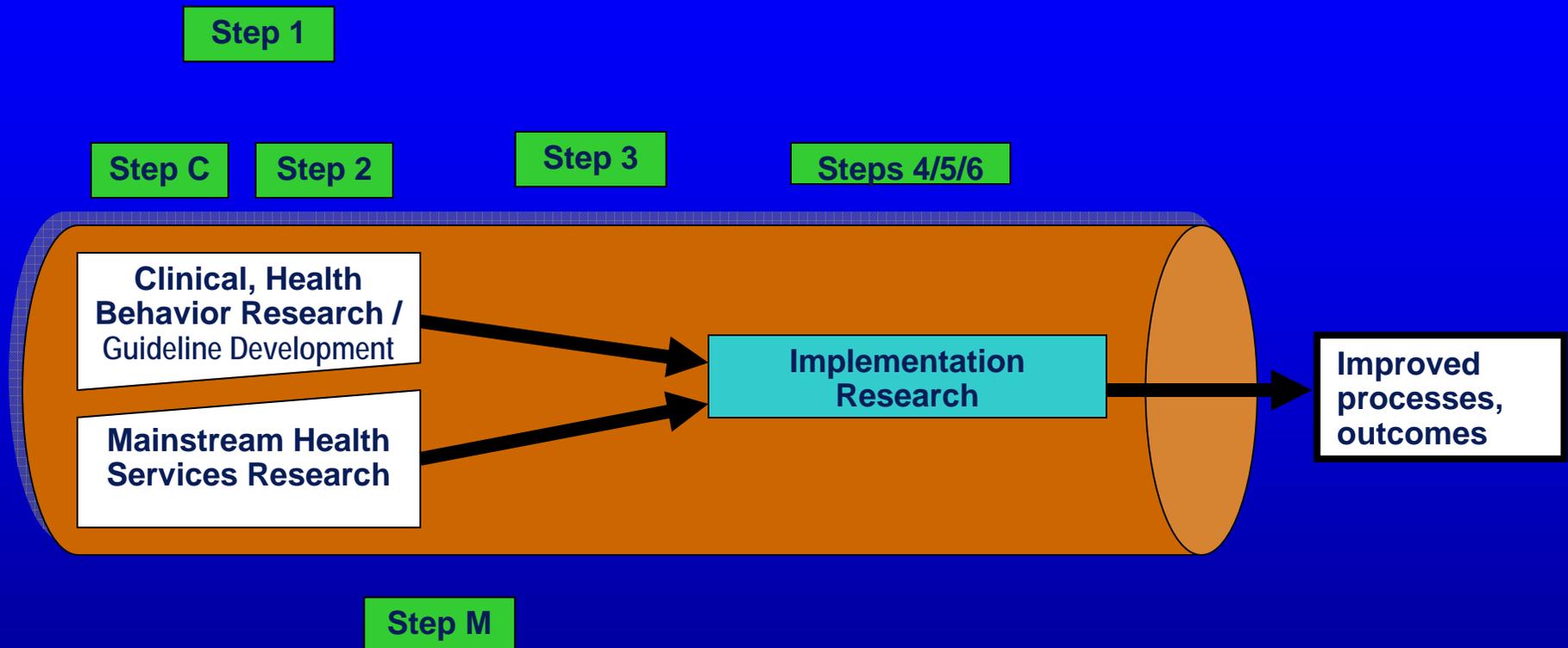
The *Classic* Six-Step QUERI Process

1. Identify high risk/high burden conditions

2. Identify best practices

3. Define existing practice patterns in VA and variations from best practices

4. Identify (or develop) and implement programs to promote best practices

5. Document outcome and system improvements

6. Document improvements in health related quality of life

Annotated QUERI Six-Step Process

Step 1: Select Diseases/Conditions/Patient Populations

   1A. Identify and prioritize (via a formal ranking procedure) high risk/high burden clinical conditions

   1B. Identify high priority clinical practices/outcomes within a selected condition

Step 2: Identify Evidence-Based Guidelines/Recommendations

   2A. Identify evidence-based clinical practice guidelines

   2B. Identify evidence-based clinical recommendations

Annotated QUERI Six-Step Process

Step 3: Measure and Diagnose Quality/Performance Gaps

   3A. Measure existing practice patterns and outcomes across VHA and identify variations from evidence-based practices (quality, outcome and performance gaps)

   3B. Identify determinants of current practices

   3C. Diagnose quality gaps and identify barriers and facilitators to improvement

Annotated QUERI Six-Step Process

Step 4: Implement Improvement Programs

> 4A. Identify quality improvement strategies, programs and program components or tools to address quality gaps
> (e.g., via literature reviews)
>
> 4B. Develop or adapt quality improvement strategies, programs, program components or tools (e.g., educational resources, decision support tools)
>
> 4C. Implement quality improvement strategies and programs

Step 5/6: Evaluate Improvement Programs

> 5. Assess improvement program feasibility, implementation and impacts on patient, family and system outcomes
>
> 6. Assess improvement program impacts on health related quality of life (HRQOL)

Annotated QUERI Six-Step Process

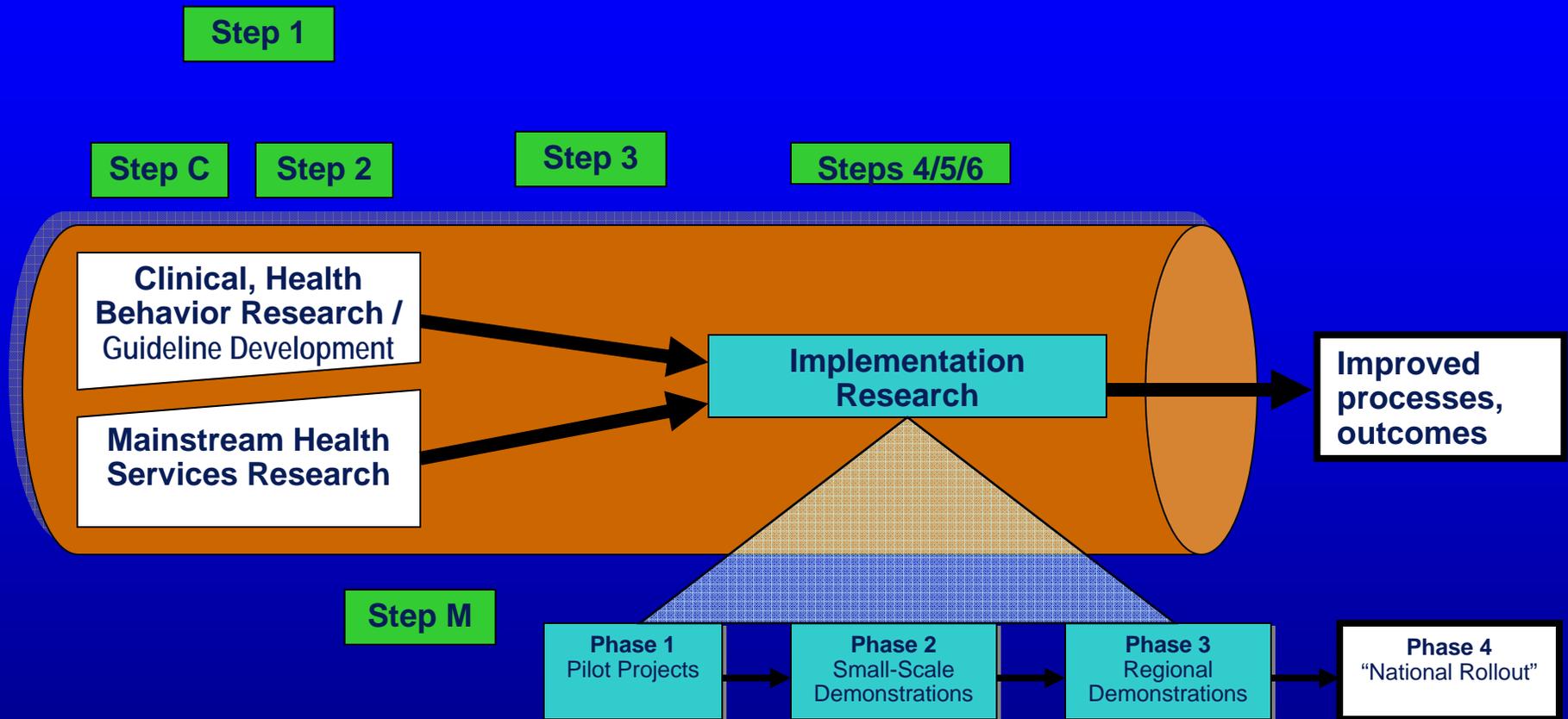Step M: Develop Measures, Methods and Data Resources

  M1. Develop and/or evaluate patient registries, cohort databases, data warehouses

  M2. Develop and/or evaluate case-finding or screening tools

  M3. Develop and/or evaluate structure, process or outcome measures

  M4. Develop and/or evaluate organizational structure/system, clinical practice, utilization or outcome databases

Step C: Develop Clinical Evidence, Effective Practices

  C1. Develop evidence-based clinical interventions, recommendations (clinical research)

  C2.   Develop evidence-based health promotion/prevention programs (health behavior/health promotion research)

  C3. Develop evidence-based health services interventions (health services research)

QUERI's research/implementation pipeline

Step 1

Step C   Step 2   Step 3   Steps 4/5/6

Clinical, Health Behavior Research / Guideline Development

Mainstream Health Services Research

Implementation Research

Improved processes, outcomes

Step M

Phase 1 Pilot Projects

Phase 2 Small-Scale Demonstrations

Phase 3 Regional Demonstrations

Phase 4 "National Rollout"

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QUERI Four-Phase Implementation Research Framework

Phase	Study Type	Form of Evaluation
Pre-trial	Design	Conceptual design of implementation program and underlying program (logic) model from theory, prior empirical research
Phase 1	Pilot / Formative	Pilot test, assess feasibility, formative evaluation and refinement, develop intervention/evaluation protocols
Phase 2	Efficacy	Small-scale rigorous trial in controlled settings with ongoing intervention support
Phase 3	Effectiveness	Large-scale rigorous trial under routine conditions in varied settings
Phase 4	Monitoring	Ongoing monitoring and feedback

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Elements of a CONSORT-like statement (extension) for implementation research

Motivation

- implementation projects are hybrid research/practice initiatives

- implementation projects require a unique set of design features, methods, skills and competencies

Goal

- provide guidance in designing, conducting and documenting implementation projects

QUERI Service-Directed Project Template

A. Specific aims
- Implementation aims: short- and long-term (phases)
- Science aims: theory/models, empirical insights
- Hypotheses: intervention impacts, influences

B. Background and significance
- Clinical issue: morbidity, mortality, burden
- Clinical evidence (effective practice): strength, acceptance, implementation gaps (magnitude, potential to close)
- Implementation processes, knowledge

QUERI SDP Template

C. Previous studies

–   Current practices: determinants, barriers and facilitators to change

–   Implementation strategy: theory, empirical evidence base and status (phase)

QUERI SDP Template

D. Design and methods

- Intervention overview (conceptual framework, approach)
- Intervention details (components, operational details):
  - Legitimacy of evidence
  - Motivation for change, external expectations, pressure
  - Norms (organizational, professional, consumer)
  - Clinician, staff, consumer education and skills
  - Financial, administrative, logistical facilitation
  - Organizational redesign, as needed
  - Tailoring and adaptation
  - Monitoring and refinement

QUERI SDP Template

D. Design and methods (continued)
  – Evaluation details

  - Experimental design
  - Usual care condition
  - Randomization protocol

  - Diagnostic analysis: practice determinants; barriers and facilitators to change
  - Formative evaluation: overall plan, details
  - Impact (summative) evaluation: overall plan
  - Process evaluation

  - Project sites, site recruitment
  - Subjects, subject recruitment

QUERI SDP Template

D. Design and methods (continued)
  – Evaluation details, impact evaluation

  • Outcomes (clinical practices, patient outcomes, system outcomes): variables, measures, data collection protocols
  • Contextual factors: variables, measures, data collection protocols
  • Analysis plans and methods; interpretation (research, policy, practice)

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QUERI SDP Template

D. Design and methods (continued)
  – Evaluation details, process evaluation

  - Identify mechanisms of impact and measures: variables, measures, data collection protocols
  - Influences on mechanisms: variables, measures, data collection protocols
  - Analysis plans and methods

  – Evaluation details, other
    - Sustainability

QUERI SDP Template

D. Design and methods (continued)

– Management plan

- Intervention management plan
- Evaluation management plan
- Staff qualifications: intervention, evaluation

Implementation research resources

- Northstar, RE-AIM, UK MRC, etc.
- Phase models, efficacy/effectiveness studies
- Green/Glasgow external validity criteria
- Experimental/quasi-experimental designs, cluster RCTs
- Stetler et al, formative evaluation, process evaluation
- Economic evaluation
- CONSORT-like statements, templates
- Diffusion, dissemination, implementation theories, models
- Qualitative research methods
- Publication guidelines (protocols, main and supporting)