

Effectiveness Research & Implementation Research: From Culture Clash to Synergy

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Webinar Outline

- **Challenges & Opportunities**
- **Some definitions**
- **The landscape of progression from efficacy to public health impact**
- **Efficacy vs. effectiveness research**
- **Clinical intervention vs. implementation research**
- **Hybrid intervention-implementation research:**
 - **A proposed typology**
 - **Potential & need**
 - **Trade-offs & synergies**
 - **Design issues (next week)**



The Quality Chasm: Clinical & Health Care Challenges

- **Guideline non-concordance / EBP non-adoption:**
 - **Limited time and resources**
 - **Insufficient training**
 - **Lack of infrastructure (e.g., for feedback)**
 - **Lack of incentives & counter-incentives**
 - **Provider/system mis-perceptions**
 - **Competing demands & priorities**



The Quality Chasm: The Research Response

- **17 years to adoption of efficacious innovations:**
 - **Multiple steps...**
 - **...study by study, RCT by RCT**
 - **Unidirectional flow:**
Concept Development →
Public Health Impact



The Opportunity

- IOM
 - Quality Chasm Report
 - National Roundtable on Health Care Quality
- VA, AHRQ ongoing implementation commitment
- American Recovery & Reinvestment Act (ARRA): Implementation (*may*) link to Comparative Effectiveness Research (CER)
 - DHHS Federal Coordinating Council
 - IOM CER Report
 - Top-Quartile CER Priority: *“Compare the effectiveness of dissemination and translation techniques to facilitate the use of CER by patients, clinicians, payers, and others.”*



The Opportunity: The Research Challenge

- How to bundle agendas and goals across multiple steps in the process?
- How to establish bidirectional flow of developmental information to enhance progress?
- *How to speed the process?*



Some Terms Defined, 1

- **Clinical Intervention:** Clinical initiative, manipulation, change to be introduced into the healthcare venue
 - Cf: “Implementation Intervention,” “Implementation Process”
- **Process Measures:** *Characteristic or quality of care (e.g., guideline concordance, model fidelity)*
 - Cf: “Intermediate Outcome,” “Implementation Outcome”
- **Outcome Measures:** *Impact on individual or population health or function (e.g., symptoms, functional status, QoL)*

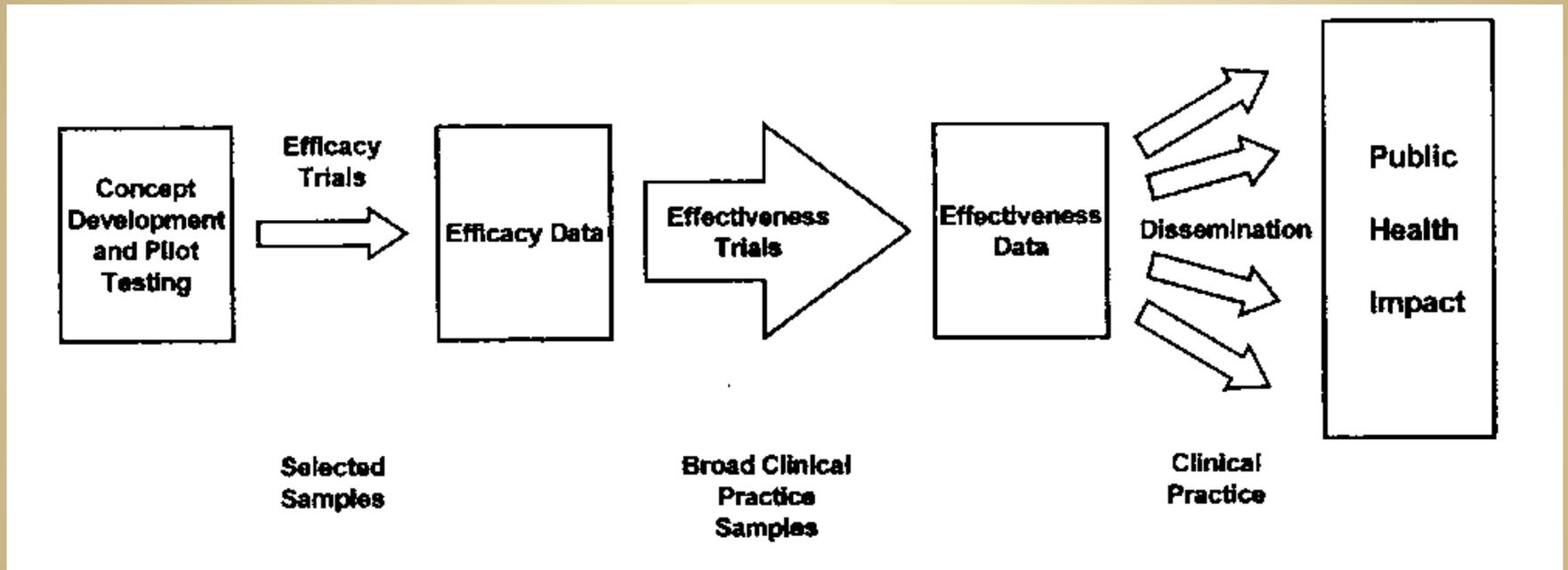


Some Terms Defined, 2

- **Implementation:** *A purposeful effort to facilitate the uptake and use of an [evidence-based] innovation*
 - Ideally: “The planned process and systematic introduction of innovation or change with proven value with goal of sustainable change” (Grol, 2004)
- **Dissemination:** *Passive spread of information or use of an [evidence-based] innovation*
 - Cf. “targeted distribution of information” (NIH PA)
- **Effectiveness Research:** *To follow...*
 - Cf. “practical clinical trials,” “large, simple trials,” “pragmatic clinical trials”



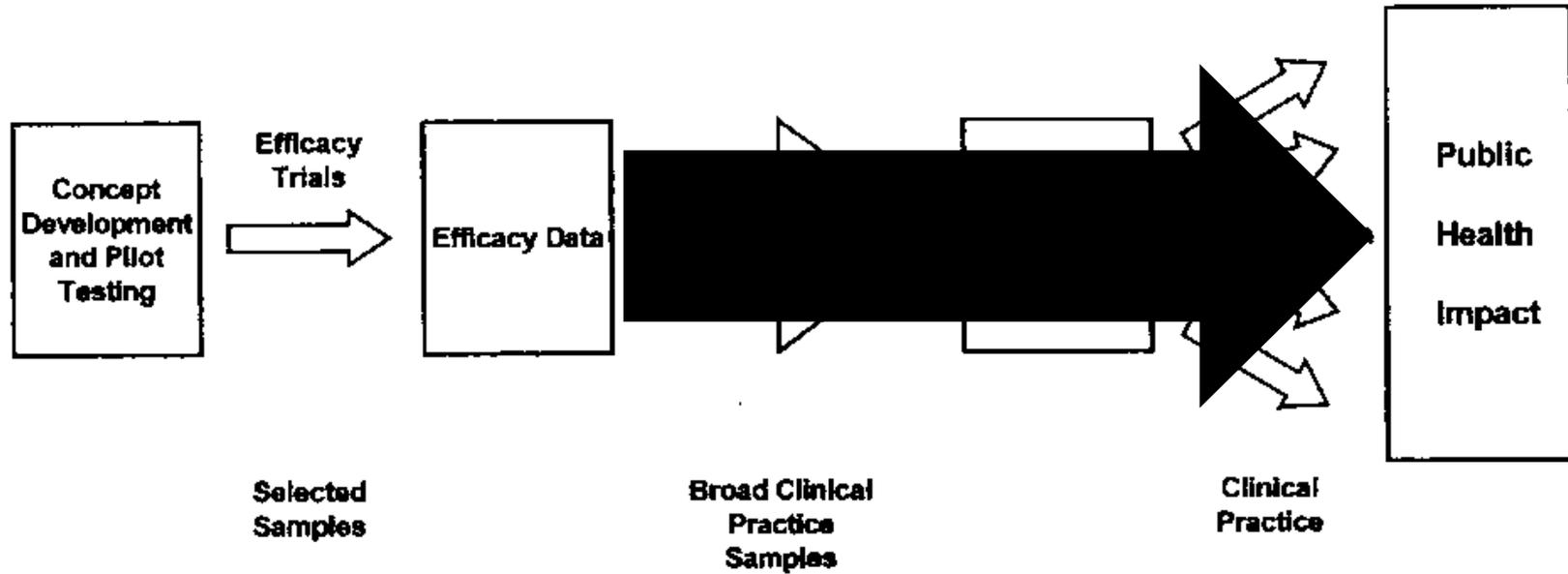
The Landscape ~ 10 Years Ago



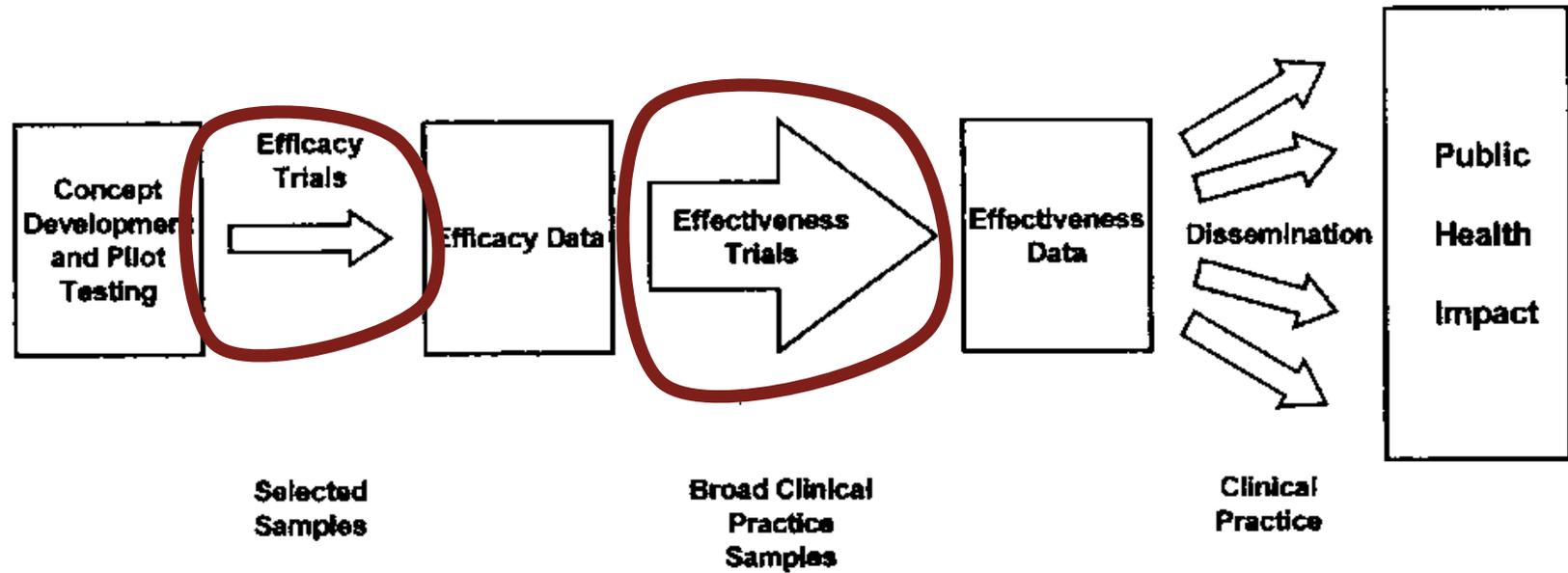
from Bauer, 2001



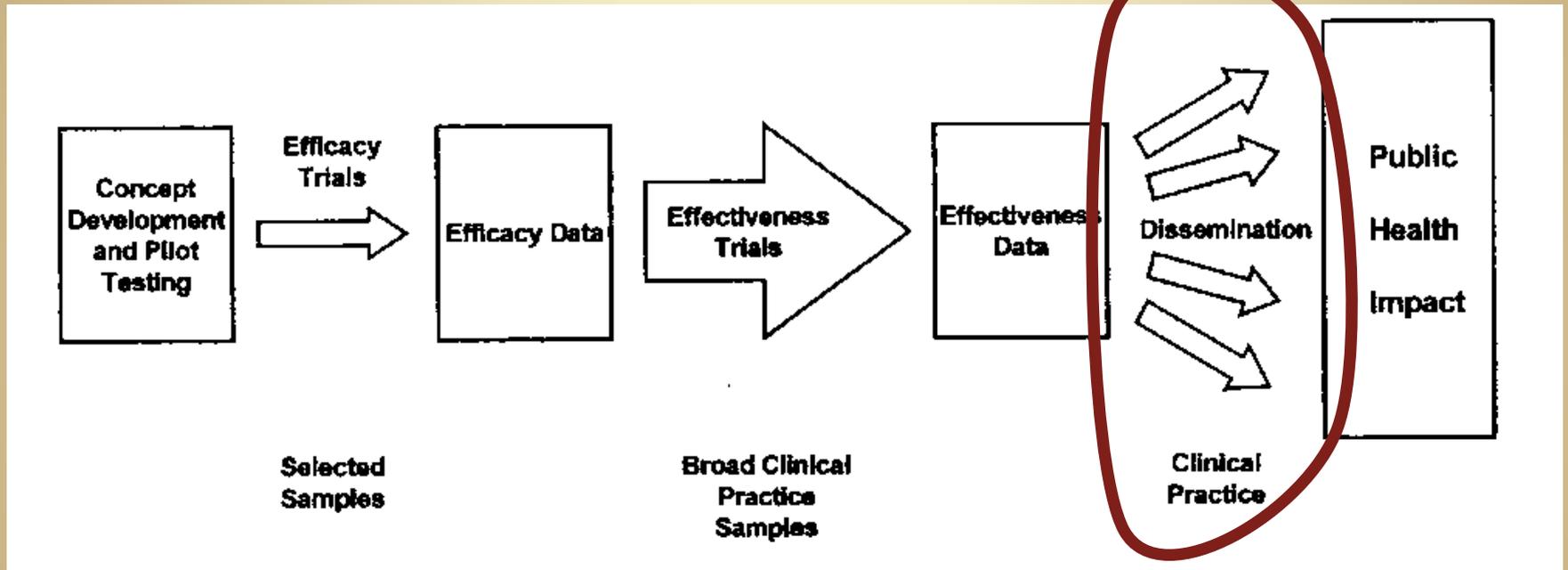
The Landscape ~ 10 Years Ago



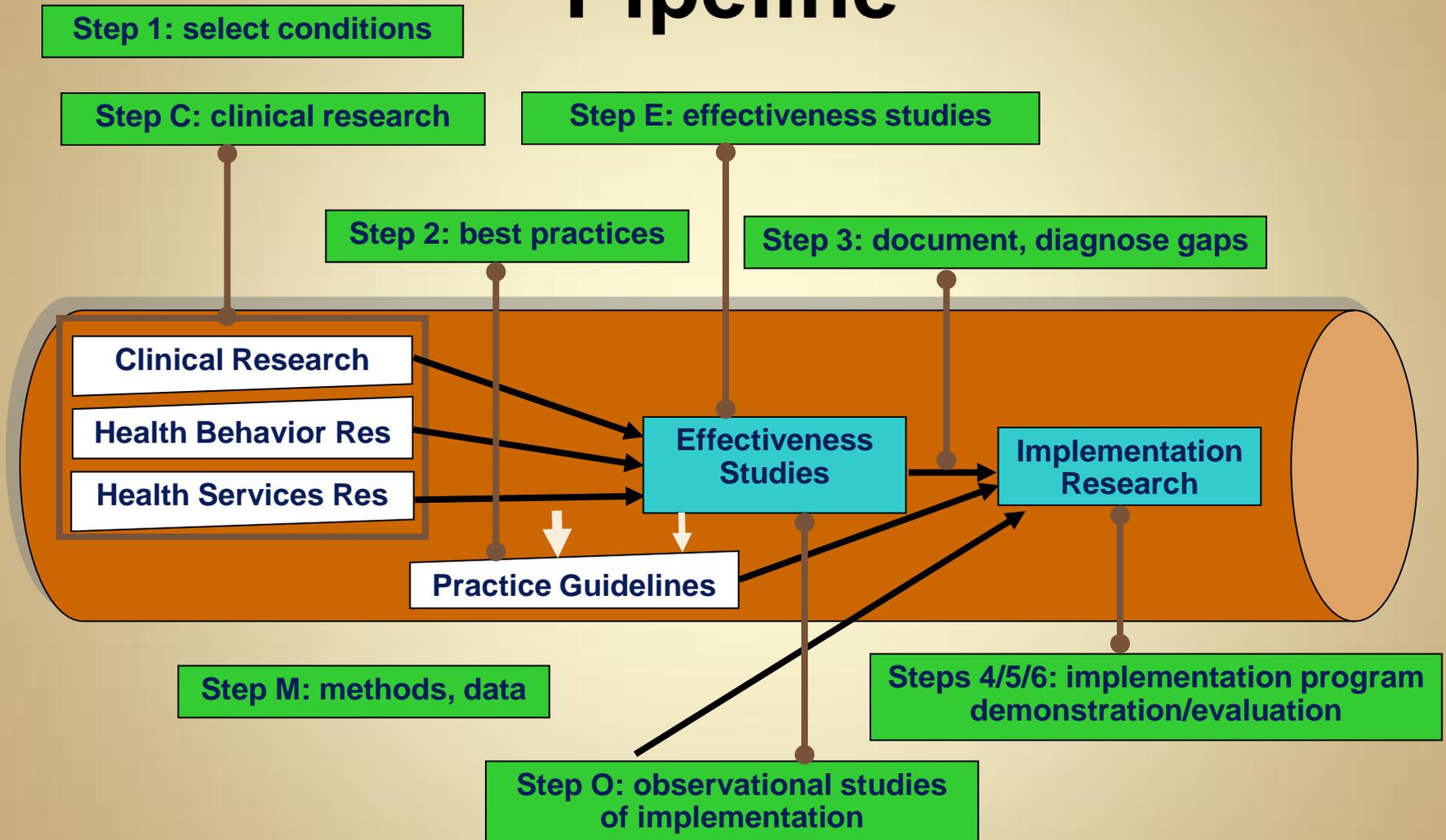
The Landscape ~ 10 Years Ago



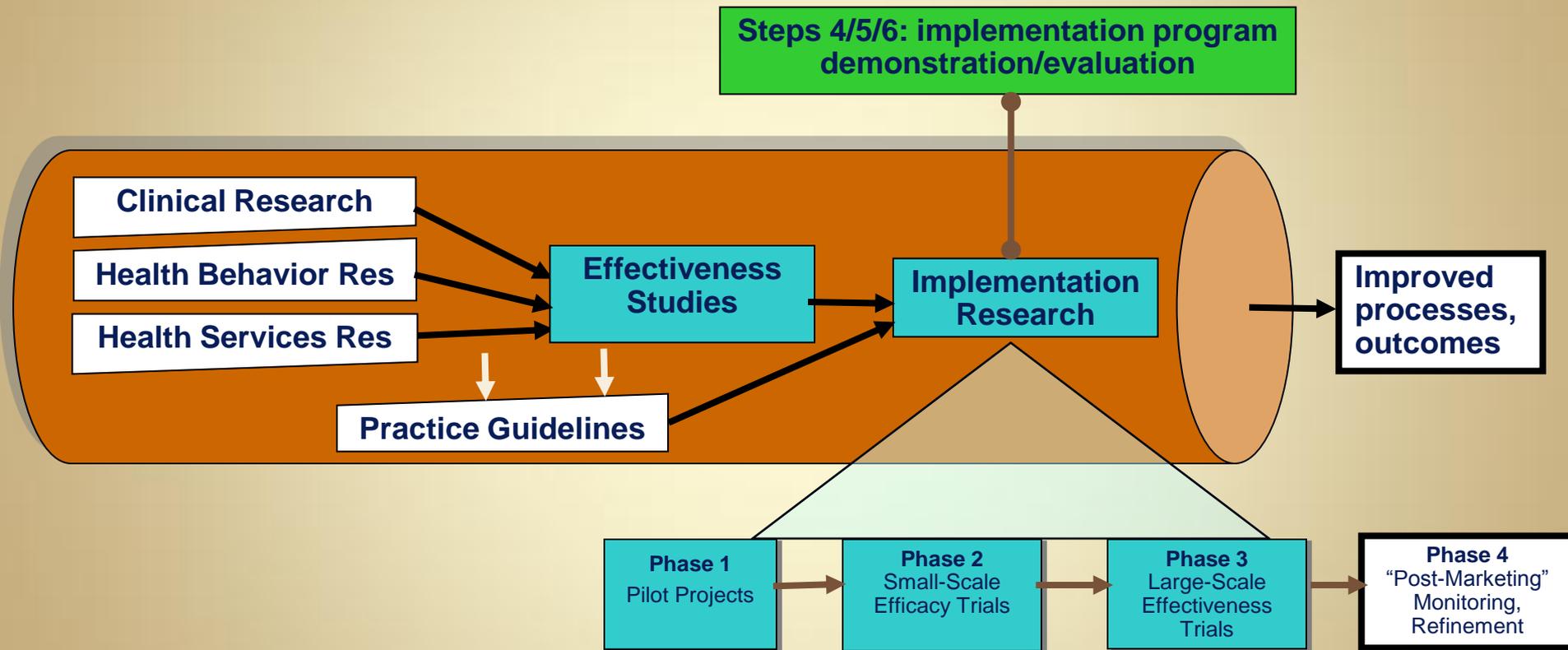
The Landscape ~ 10 Years Ago



QUERI Research-Implementation Pipeline



QUERI Research-Implementation Pipeline



Efficacy vs. Effectiveness, 1

- **Efficacy Design:**
 - Studies intervention impact under best possible conditions.
 - Isolates intervention impact.
 - Maximizes internal validity.
- **Effectiveness Design:**
 - Studies intervention impact under usual care conditions.
 - Study conditions replicate as closely as possible the conditions in the target venues to which the study results will be applied.
 - Maximizes external validity.

e.g., Wells, 1999; Bauer et al, 2001; Glasgow & Eamons 2007

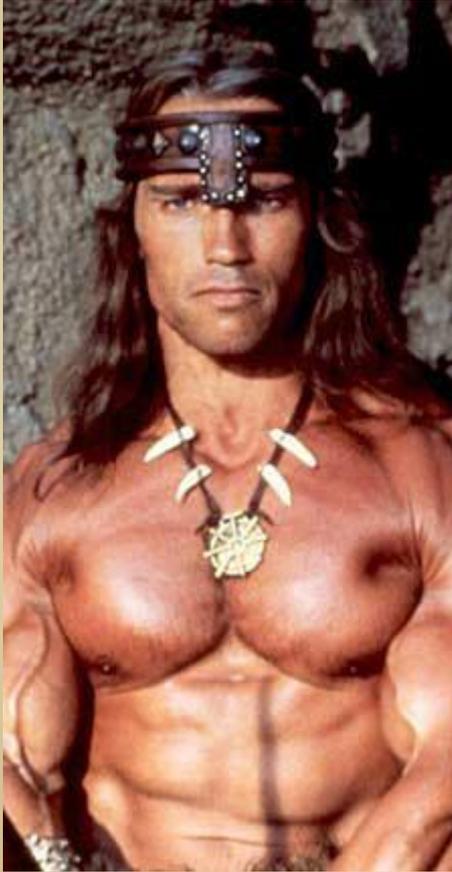


Efficacy vs. Effectiveness, 2

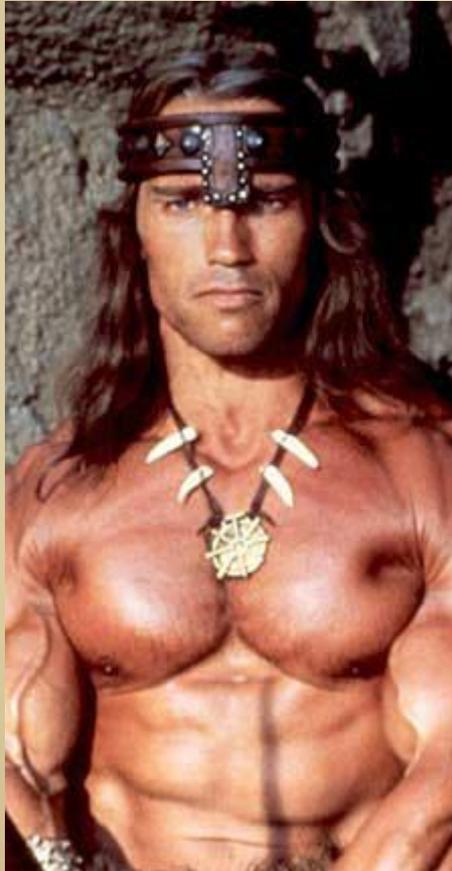
- **Internal Validity:**
 - The study tests what it set out to test.
- **External Validity:**
 - Study results are applicable to the setting in which the results are to be applied.
- **Two Key Principles:**
 - *Efficacy-Effectiveness & IV-EV are ends of a **spectrum**, not alternate categories.*
 - *Moving along the spectrum requires **trade-offs**: Every design decision is a deal with the devil.*



Efficacy & Effectiveness: Best Practice vs. Usual Conditions



Efficacy & Effectiveness: Best Practice vs. Usual Conditions



Questions?



Intervention vs. Implementation Research

- **Clinical Intervention Research:**
 - Clinical intervention *impact* is the focus.
 - Context (in large part) is noise.

- **Implementation Research:**
 - The *uptake* is the focus.
 - Context (in large part) is signal.



Intervention Research: Here it comes...



Implementation Research: Process is the Focus



Intervention vs. Implementation Research

- **Clinical Intervention Research:**
 - Clinical intervention *impact* is the focus.
 - Context (in large part) is noise.
- **Implementation Research:**
 - The *uptake* is the focus.
 - Context (in large part) is signal.
- *Is Hybrid Research possible?*



Two Types of Implementation Research, 1

• Pre-Trial / Observational Work

- 3A. **Measure** existing practice patterns and outcomes and identify variations from evidence-based practices and benchmark outcomes (quality, outcome and performance gaps)
- 3B. **Identify** determinants of current practices
- 3C. **Diagnose** quality gaps
- 3D. **Identify** barriers and facilitators to improvement
- 4A. **Identify** implementation/quality improvement strategies, programs and program components or tools (e.g., via literature reviews); assess need for design of new strategies or components
- 4B. If needed, **develop** implementation/quality improvement strategies, programs, program components or tools based on relevant theory and empirical research
- 4C. **Assess** determinants of quality gaps and barriers/facilitators to improvement within participating sites



Two Types of Implementation Research, 2

- **Implementation Trials**
 - 4D. **Implement** quality improvement strategies and programs via interventional studies



Two Types of Implementation Research, 2

- **Implementation Trials**
 - 4D. **Implement** quality improvement strategies and programs via interventional studies
- **Implementation Trial Phases (from QUERI Pipeline)**
 - Pilot projects
 - Small scale efficacy trials
 - Larger scale effectiveness trials
 - Post-monitoring marketing & refinement



Two Types of Implementation Research, 3

- ***Questions:***
 - ***Can you have efficacy or effectiveness implementation trials? (Y)***
 - ***Is there still a trade-off of internal vs. external validity? (Y)***
 - ***Are our design decisions still deals with the devil? (Y)***



Therefore...

Two Types of Hybrid Research

- Hybrid designs that test a clinical intervention while **collecting data** regarding various aspects of implementation (**Type I**)
- Hybrid designs that test a clinical intervention while at the same time **intervening** in the implementation process (**Type II**)
 - Clinical intervention rolled out to all, while two implementation processes are compared
 - Clinical intervention compared to usual practice (or other), while implementation factors adapted in real time



Two Types of Hybrid Research, Simply Stated

- **Type I** hybrid designs (**descriptive**): Typically utilize **summative** implementation data only.
- **Type II** hybrid designs (**trials**): Typically utilize **formative** as well as summative implementation data.



Two (Type II) Hybrid Research Definitions

- **“A traditional intervention design plus a descriptive formative evaluation”**
--Stetler, Mittman, & Francis 2008
- **“The use of formative evaluation with an experimental study, quasi-experimental study, or other appropriate real-world design”**
--Stetler et al, 2008



Formative Evaluation

- “[The] general intent of formative evaluation is used to describe and *monitor* the development and progress of an intervention or program. It also provides information with which to *adjust* the process, as needed, to *maximize the effect* of the translation strategy. Furthermore, formative evaluation activities can be employed *either before or during* implementation of the intervention or program.”

from QERI Implementation Guide Part I (italics added)



The Curran Query:

“How free is the intervention to fail?”

- Pure clinical intervention research:
 - ***Very***: That’s the point: disprove the null hypothesis.
- Implementation Research:
 - ***Much less so***: The point is to learn how to optimize the process of implementation



Clinical Intervention vs. Implementation Trial Designs

Design Characteristic	Clinical Intervention Focus	Implementation Focus
The Manipulation	Intervention	Implementation Process
Outcome	Health Outcomes, Quality Measures	Model Fidelity, Quality Measures
Typical Unit of Analysis	Subject, Provider, Site	Provider, Site
Randomization	By subject, Provider, Site	By Provider, Site, (or Non-)
Formative Evaluation	None	Typically
Qualitative Data	Sometimes secondary	Typically



Some Examples of Formative Evaluation

- **CHF QUERI**: individualized implementation plans with weekly teleconferences to resolve problems.
- **Substance Use Disorder QUERI**: Opioid agonist toolkit roll-out followed by ongoing follow-up to modify.
- **HIV/AIDS QUERI**: Ethnographic study identified barriers to clinical reminders that could be addressed.

from Stetler et al, 2006



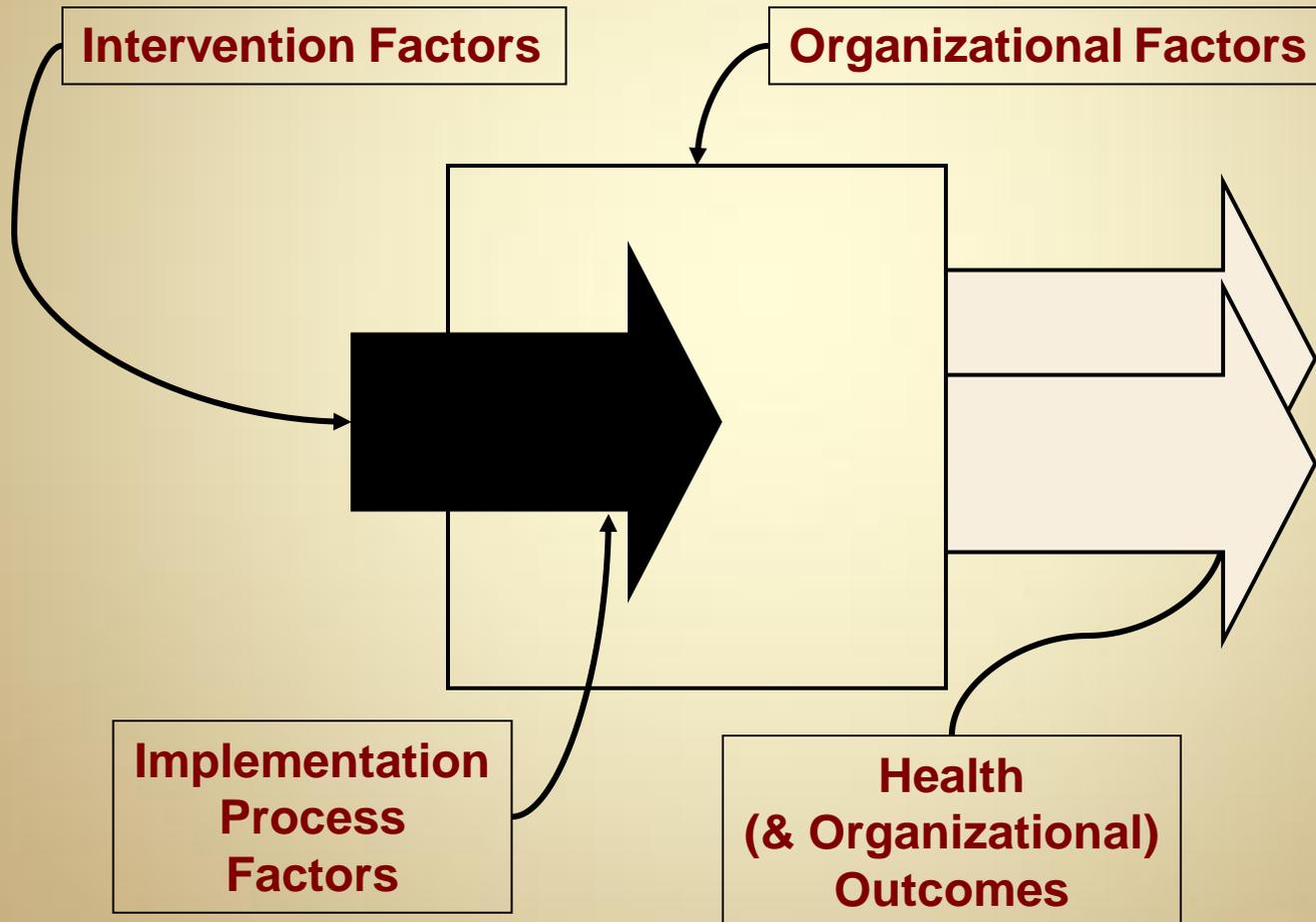
Implementation Research: Process is the Focus



Hybrid Type II (Trial) Research: Implementation plus Health Outcomes



The Comprehensive Hybrid Design: Intervention, Implementation & Organization



Why Do Hybrid Research?

(Implementation research is tough enough...)

- **Speed is of the essence!**
- **Bidirectionality of flow of information**
- **Process improvements do not necessarily mean health outcome gains**
 - **Or: Guideline concordance \neq patient improvement**
 - **Corollary of the Curran Query: *Asking how free an intervention is to fail requires knowing whether or not the intervention fails.***

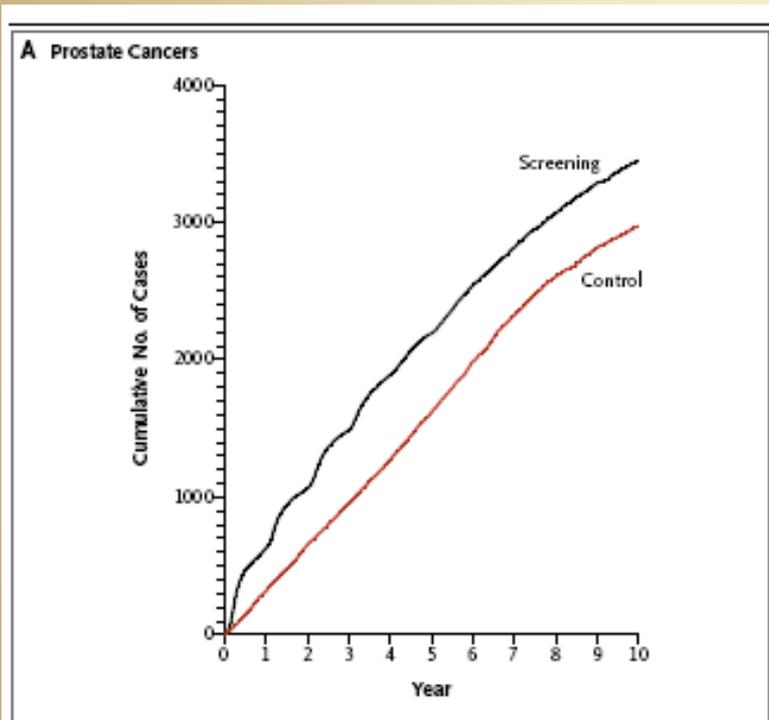


Do Process Improvements Improve Outcomes?

RCT	Dx	Intervention	↑ Outcome?
Worrall 1999	Depression	Education	No
Brown 2000	Depression	CQI or Acad Det	No (2 RCTs)
Cannon 2000	PTSD	Reminders	No
Simon 2000	Depression	Audit-Feedback	No
Thompson 2000	Depression	Education	No
Wells 2000	Depression	Care Management	Yes
Suppes 2003	Bipolar	Care Management	Yes
Miller 2004	Schizoprh.	Care Management	Yes
Thomas 2004	Depression	Computerized Templated Notes	No
Hepner 2007	Depression	Care Management	Yes (3 RCTs)



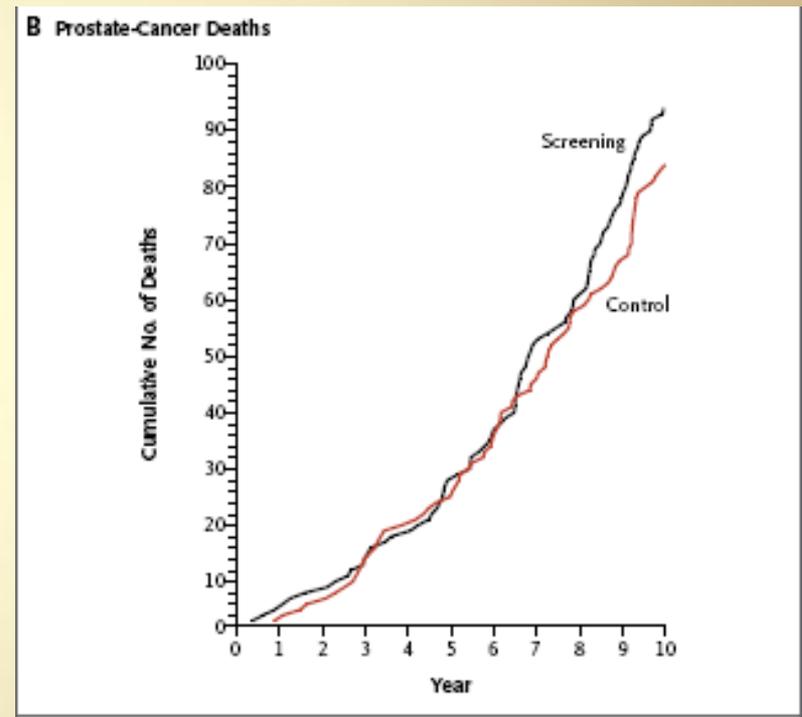
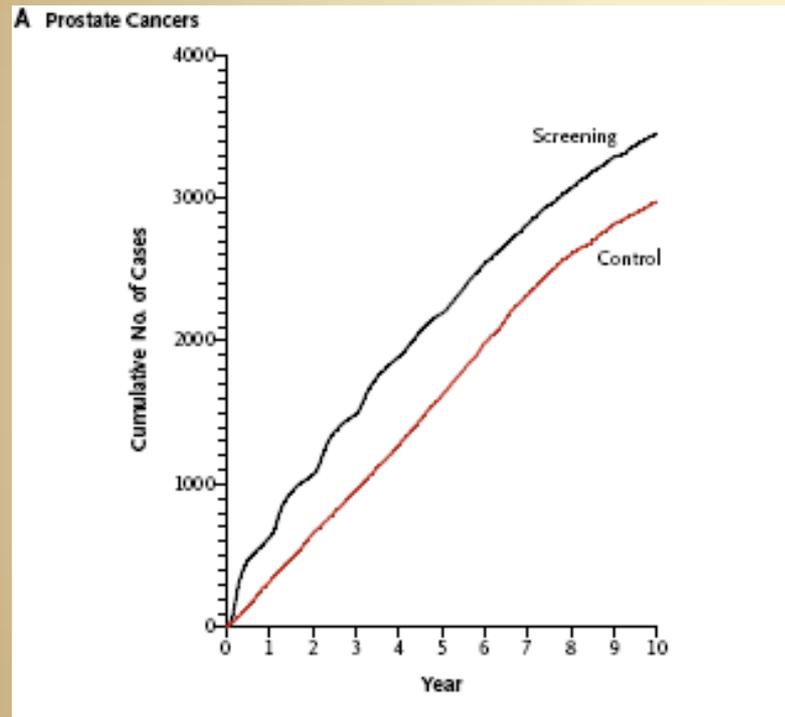
Do Process Improvements Improve Outcomes?



from Andriole et al, 2009



Do Process Improvements Improve Outcomes?



from Andriole et al, 2009



Some *Ecological* Challenges in Hybrid Research

- Lack of shared concepts, constructs, vocabulary within the field [*see above...*]
- Lack of familiarity, appreciation, impetus for implementation science issues outside of the field
 - Grant reviewer expertise along the spectrum required
 - Editorial interest/expertise among top journals
 - Academic promotion path tougher [*our business case*]
- Lack of familiarity, appreciation, impetus of clinical intervention trials complexities within the implementation field



Some *Design* Challenges in Hybrid Research

- Lack of shared concepts, constructs, vocabulary within the field
- Broader expertise required among co-investigators
 - Quantitative
 - Qualitative
 - Both interpretive & progress-focused (Stetler et al, 2006)
- Often requires larger systems, samples
- What is the unit of analysis? How to randomize?
- May require longer protocols: FE refinement → “final” implementation
- IRB complexities



Envoi:

Our Implementation Challenge

“Sure you can get them to do what you want them to do.

But can you get them to *want* to do what you want them to do?”

—Jon Borus, M.D.

