



Accelerating Adoption of Genomic Medicine Innovations: Tools and Guidance from Implementation Science

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Brian S. Mittman, PhD

Kaiser Permanente Southern California, Dept of Research and Evaluation
Dept of Veterans Affairs, Center for Implementation Practice and Research Support
UCLA Clinical and Translational Science Institute (CTSI)

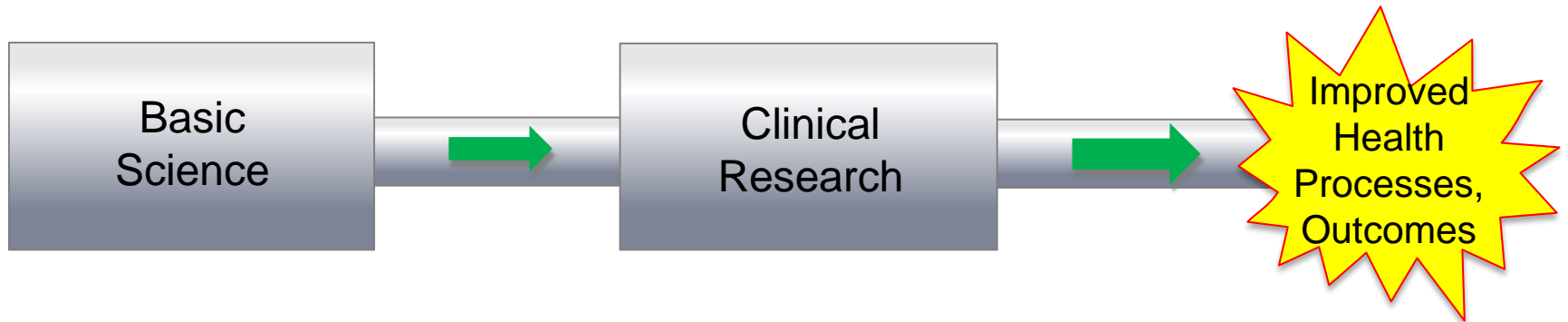
Outline

➤ Part 1: *Deep dive*: frameworks, study types

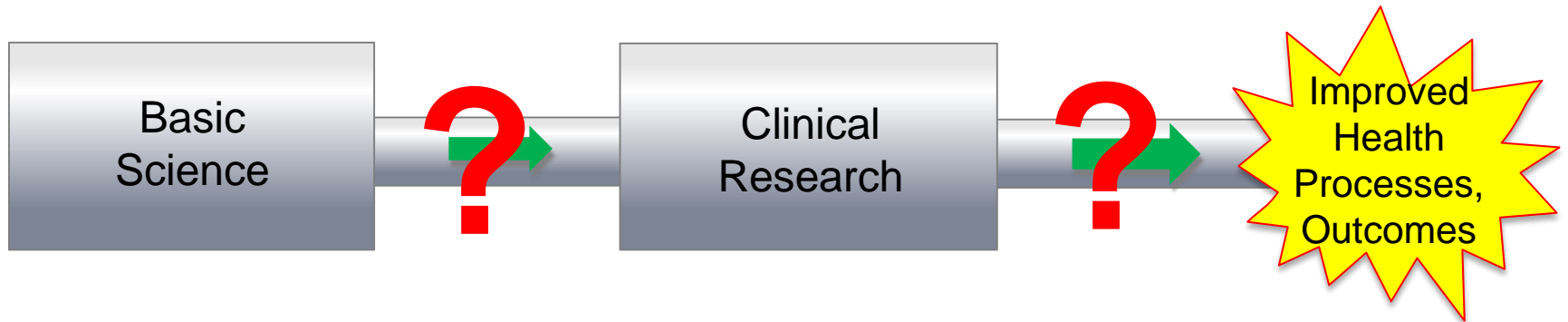
Part 2: Selected implementation science insights

Part 3: Genomic medicine implementation
research: a brief illustration

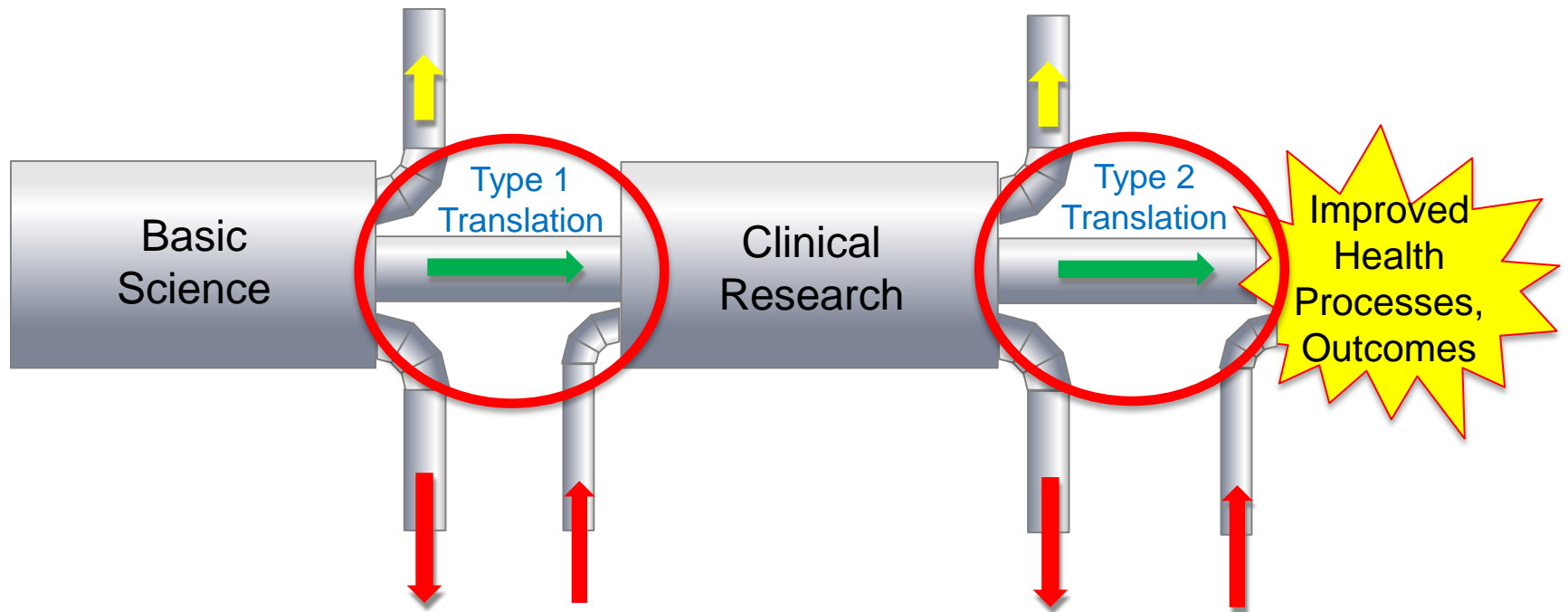
Health benefits of research



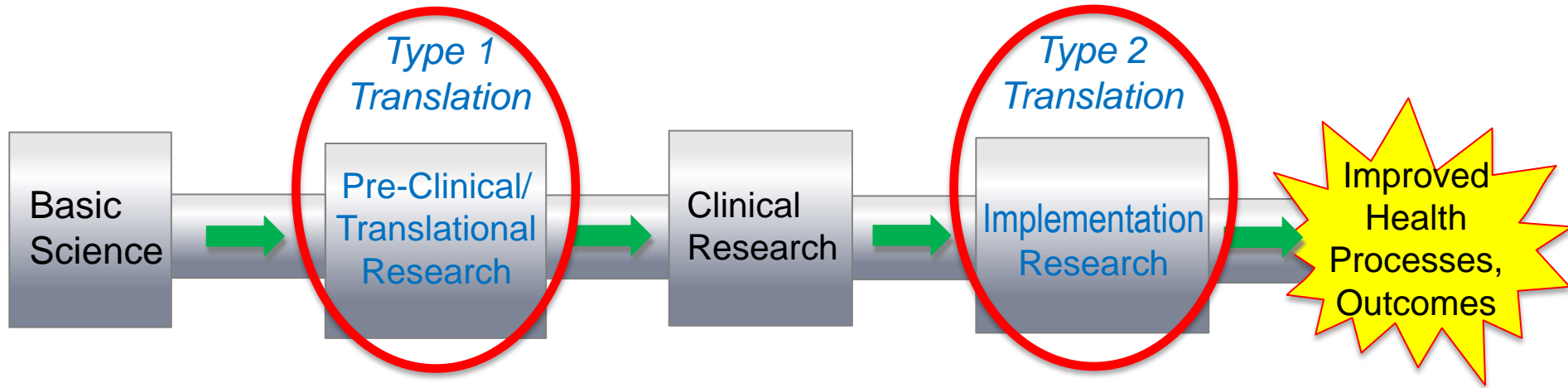
Health benefits of research



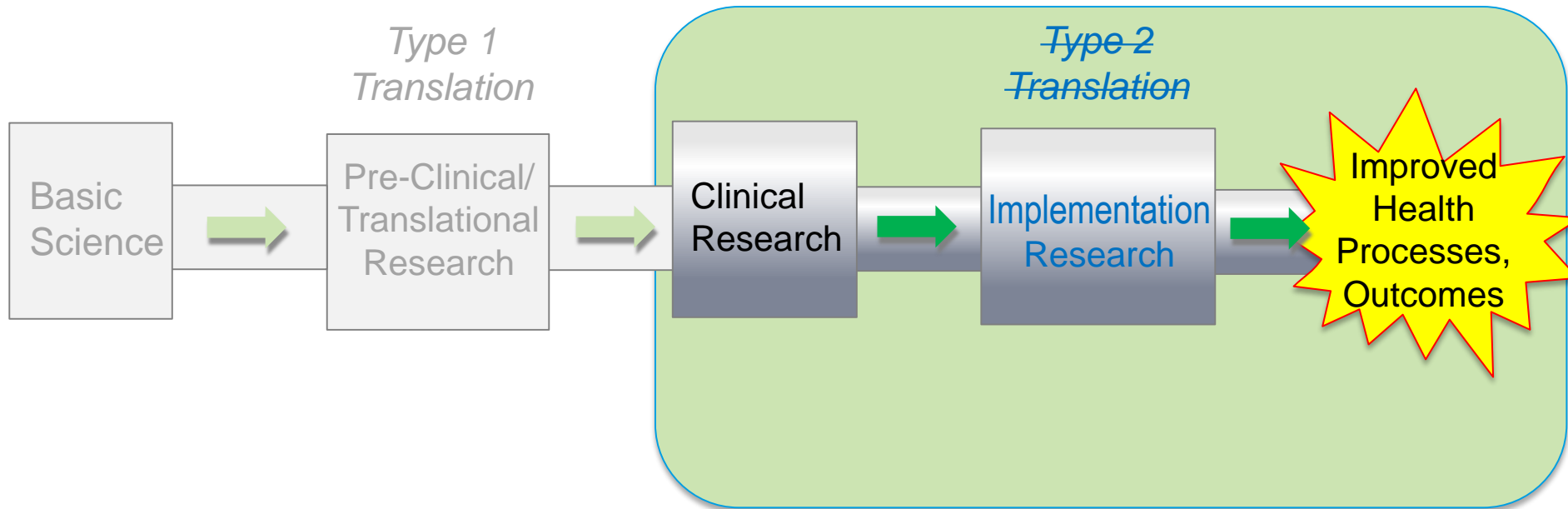
Translational research



Translational research



Implementation research



Implementation science definition

Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of **health services**.

It includes the study of influences on **healthcare** professional and organizational behavior.

Eccles and Mittman, 2006

Implementation science aims

1. Develop reliable strategies for improving health-related processes and outcomes; facilitate widespread adoption of these strategies
2. Produce insights and generalizable knowledge regarding implementation *processes, barriers, facilitators, strategies*
3. Develop, test and refine implementation theories and hypotheses; methods and measures

The *Tower of Babel* problem

- Knowledge translation, translational research
- Research utilization, knowledge utilization
- Knowledge-to-action, knowledge transfer & exchange
- Technology transfer
- Dissemination research
- Quality improvement research, improvement science
- T-1, T-2, T-3, T-4, T-5, T-6
- Etc.

Implementation research vs. QI research

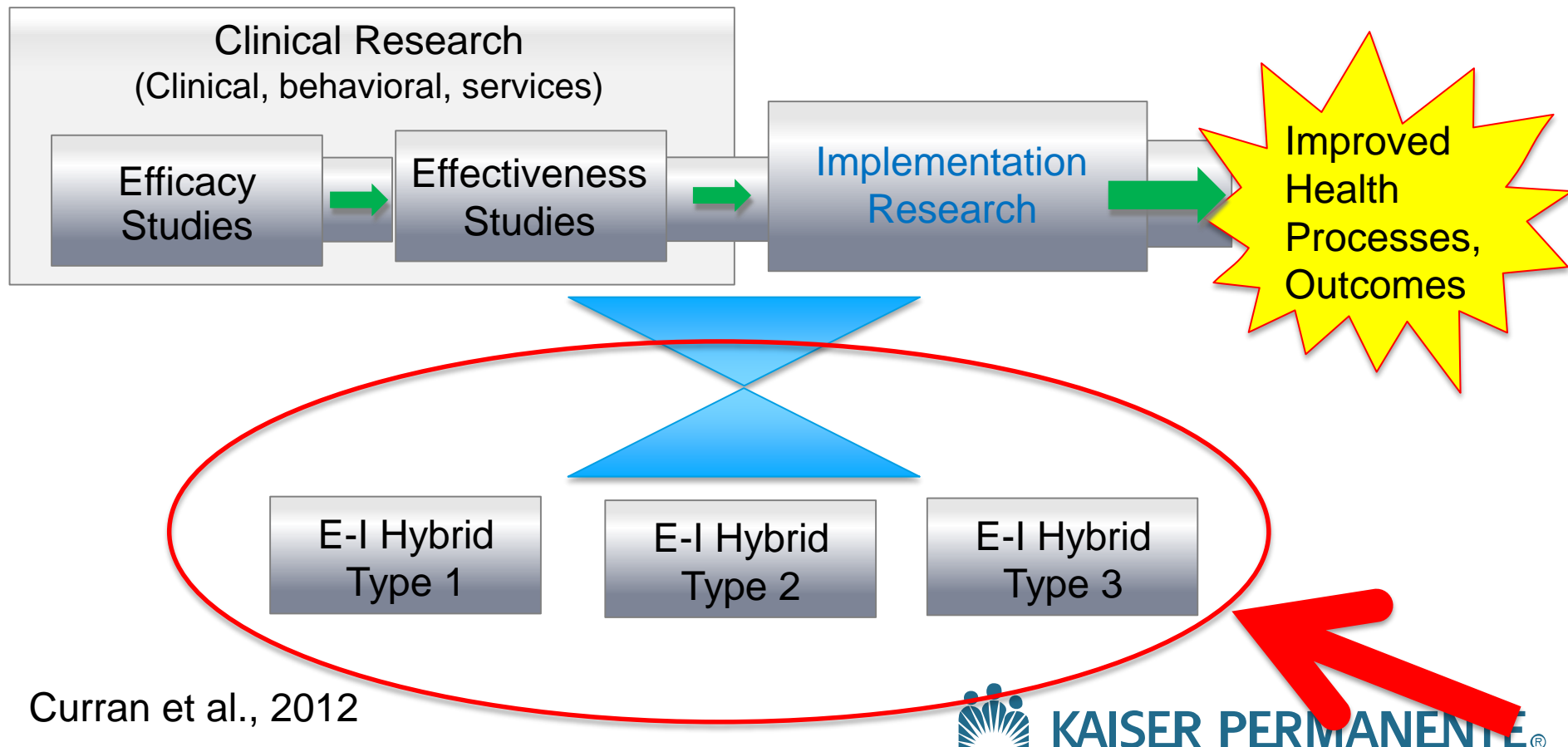
- QI generally targets specific local quality problems via rapid-cycle, iterative improvement
- IS generally endeavors to develop and rigorously evaluate fixed implementation strategies to address implementation gaps across multiple sites, emphasizing theory, contextual factors and – occasionally – mediators, moderators, mechanisms
- *IS aims to develop generalizable knowledge*

Clinical research vs. implementation research

<u>Study type</u> <u>Study feature</u>	<u>Clinical research</u>	<u>Implementation research</u>
Aim: evaluate a / an ...	clinical intervention	implementation strategy
Typical intervention	drug, procedure, therapy	clinician, organizational practice change
Typical outcomes	symptoms, health outcomes, patient behavior	adoption, adherence, fidelity
Typical unit of analysis, randomization	patient	clinician, team, facility

Combining phases:

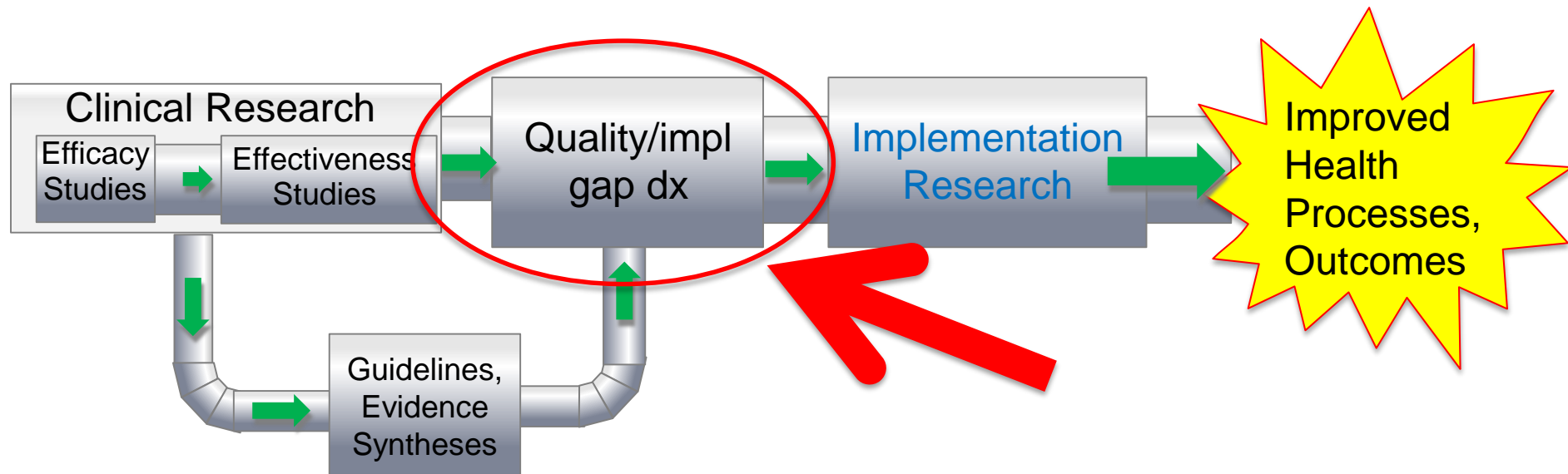
Hybrid effectiveness-implementation designs



Gaps in the pipeline:

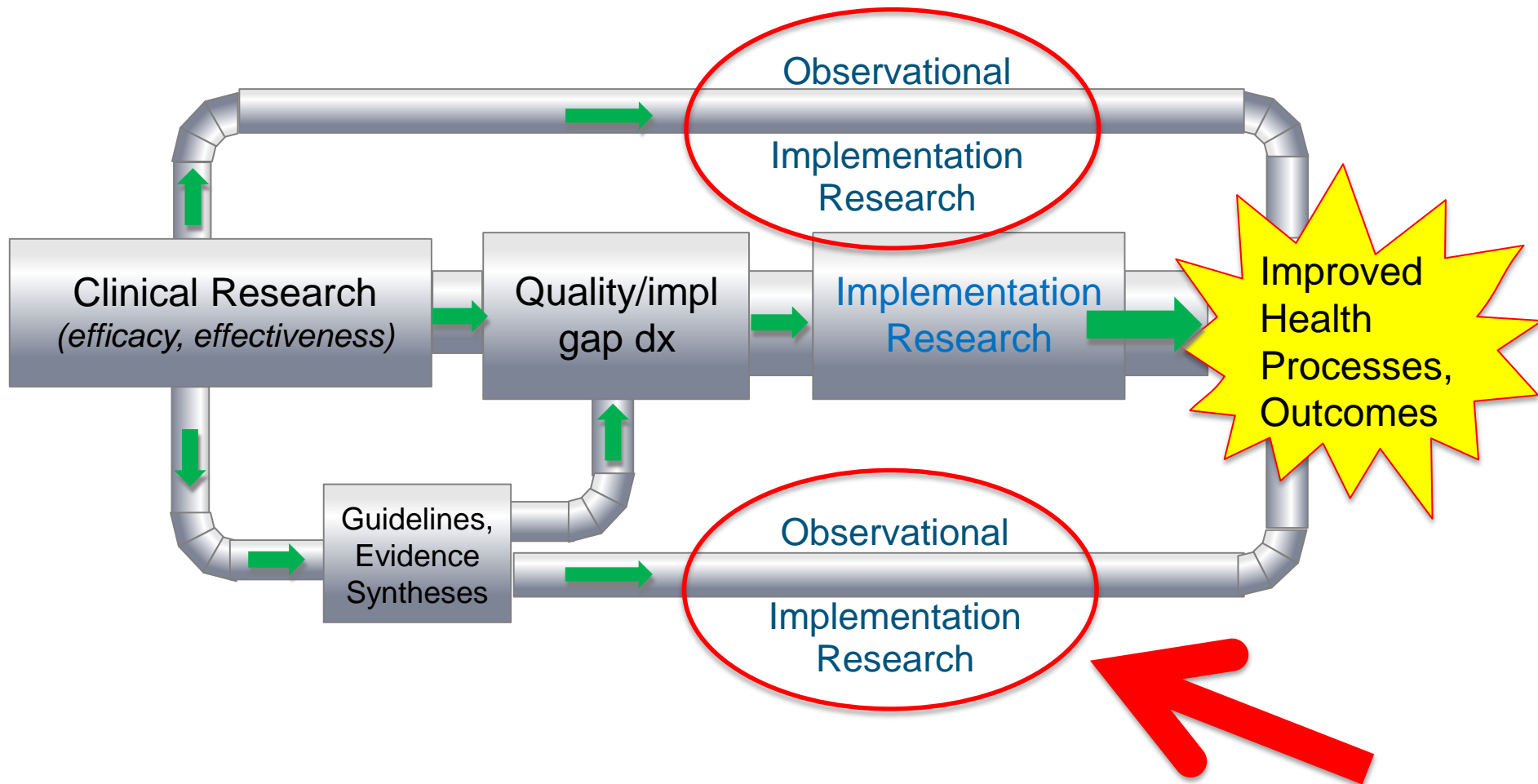
Pre-implementation studies

(document, diagnose quality/implementation gaps)

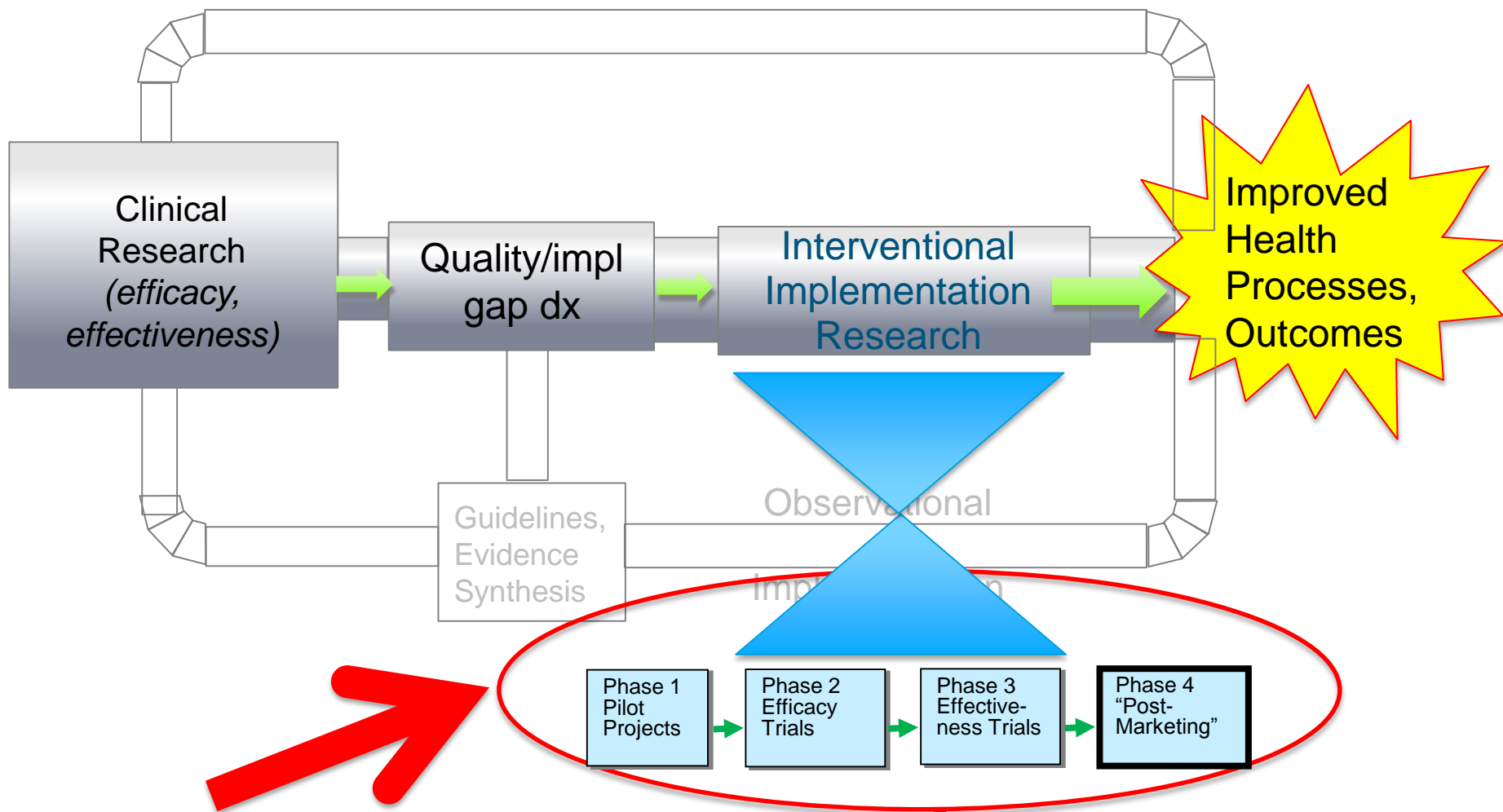


Gaps in the pipeline:

Observational implementation studies



Gaps in the pipeline: *Phased implementation trials*



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Factors influencing implementation of effective, innovative practices

1. Innovation characteristics
2. Inner setting
3. Outer setting
4. Individuals (delivering care, facilitating implementation)
5. Implementation process

Damschroder et al, CFIR, 2009

General insights, principles

Improvement and implementation science demonstrate that clinical practices and quality gaps (and solutions) are:

- Highly stable and slow to change; *clinical inertia, conservatism*
 - *With notable exceptions (e.g., CT scans, robotic surgery)*
- Variable and heterogeneous (across time, place, problem)
- Multi-faceted, multi-level
- Not responsive to simple practice change strategies

Selected barriers to implementation

- Insufficient information, knowledge, skill, time
- Too much information
- Evidence is not accepted as legitimate
- Implementation gaps not recognized
- Misaligned financial incentives
- Insufficient staff or systems support
- Lack of external pressure, expectations

Levels of influence on clinical practice

- Point of care (MD knowledge, patient demand)
- Microsystem, team (norms, culture)
- Clinic, hospital (policies, leadership)
- Delivery system (organizational/fiscal policies, leadership, resources)
- Professional norms (local, regional, national)
- Patients, businesses, other stakeholders (community, region, province/state, nation)
- Local, regional, national regulations
- *Contrast with “1950s medicine”*

A short history of quality improvement in health care

- Most QI initiatives address no more than 2-3 causes of quality gaps at 1-2 levels
- The result: considerable effort, occasional impact – typically on mediating factors – but limited change in practices
- The classic case: “intervention physicians displayed improved knowledge and attitudes but no change in clinical practices”

Requirements for practice change

1. Valid, legitimate, accepted evidence
2. Clinician/staff knowledge, skill
3. Supportive professional norms
4. External expectations, monitoring, pressure/incentives
5. Patient acceptance
6. Evidence of quality gaps
7. Etiology of practices, quality gaps
8. Feasible methods/systems

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Requirements for practice change: *Scheuner et al family history toolkit*

1. Valid, legitimate, accepted evidence
lectures; prior training
2. Clinician/staff knowledge, skill
lectures, information sheets, EHR reminder
3. Supportive professional norms
lectures, one-on-one contacts by champions
4. External expectations, monitoring, pressure/incentives
feedback (perceived importance; limited)

Requirements for practice change: *Scheuner et al family history toolkit*

5. Patient acceptance
patient information sheets
6. Evidence of quality gaps
needs assessment survey; advisory committee
7. Etiology of practices, quality gaps
*needs assessment survey; advisory committee;
partnered/practice-based research*
8. Feasible methods/systems
EHR reminder, feedback

Implications for implementation and improvement

Implementation and improvement generally require:

1. Strong evidence base, consensus regarding appropriateness
2. Clinician knowledge, training, skill, ability: *education, training*
3. Supportive norms: *social influence strategies*
4. Monitoring, expectations, pressure from key stakeholders
5. Supportive patient knowledge, beliefs, attitudes, preferences, expectations: *patient education, outreach, influence*
6. Documentation of implementation gaps: *variations studies*
7. Comprehensive understanding of barriers: *root cause analysis*
8. Requisite time, staff, space, equipment, additional resources

Implications for implementation and improvement

Implementation and improvement generally require:

Multi-level, multi-component, partnered *campaigns*

- guided by extensive *planning*
- deployed in a *planned*, explicit, systematic manner
- with continuous monitoring, feedback, refinement and adaptation (broadly and locally)