Section 6.1

Methodologies to Evaluate the Effectiveness of Knowledge Translation Interventions

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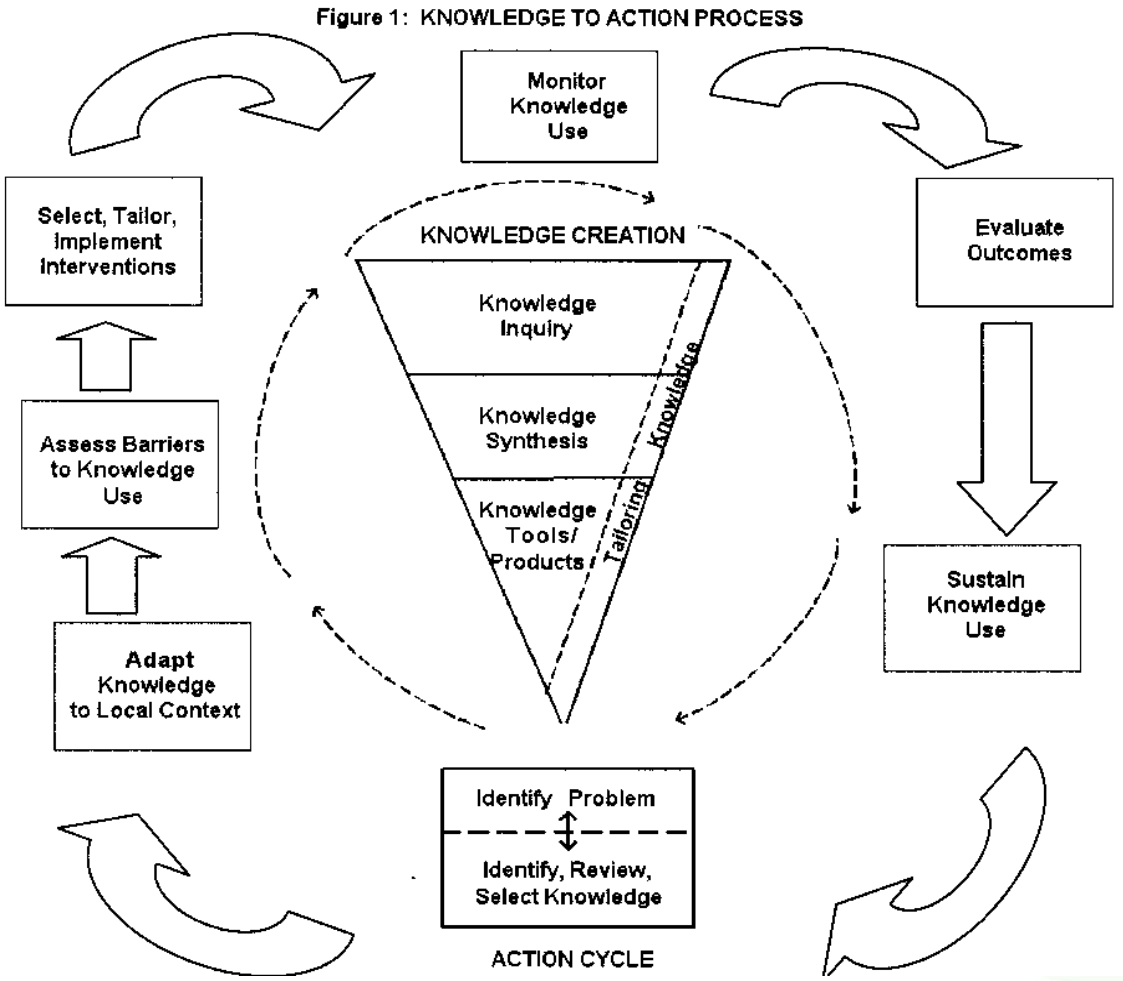
Overarching Framework: The Knowledge to Action Cycle

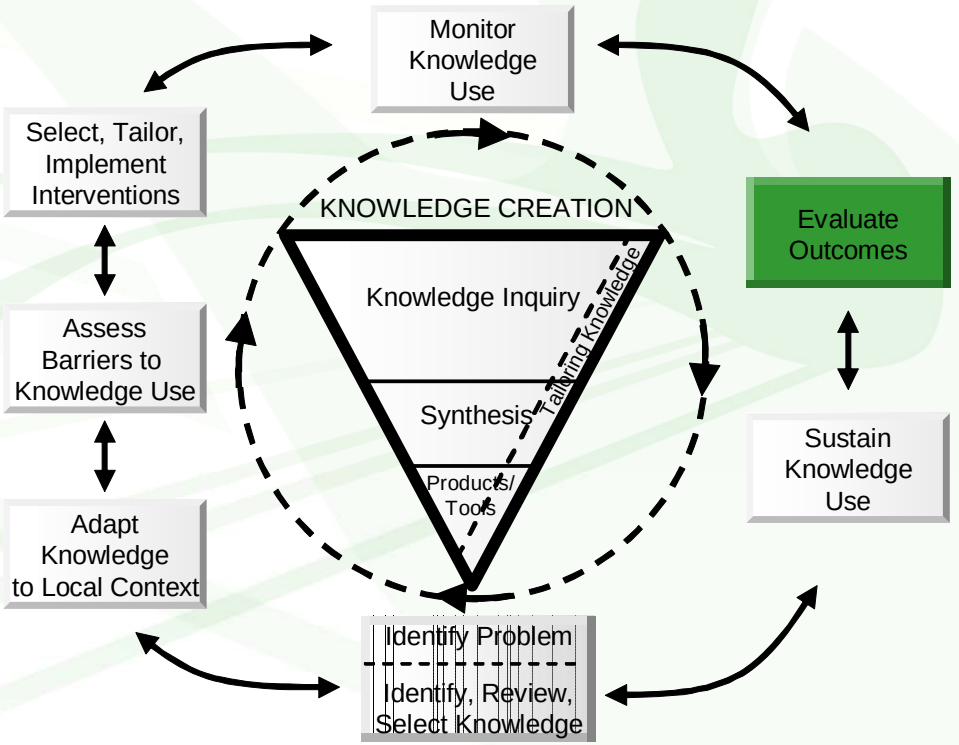


From: Graham et al. *Lost in Knowledge Translation: Time for a Map?*
http://www.jcehp.com/vol26/2601graham2006.pdf

Topic Focus:

Evaluate Outcomes

- Context & rationale: the need for evaluation
- Evaluation study designs
  - Randomized
  - Non-randomized
- Pragmatic study designs
- Successes and failures
- Conclusion



Context

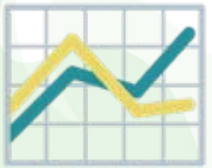
- Challenges of implementation research
  - KT promotes evidence-based medicine (EBM), but methods used to promote EBM are not evidence based
  - Pressure to improve quality of care, but dearth of information on which interventions work
  - 350,000 RCTs in clinical medicine vs. 2,400 experimental trials of interventions to improve health care delivery

Shifting Focus…

- From developing new treatments to developing approaches to deliver what is already known to work
- To create and evaluate interventions from evidence-based knowledge

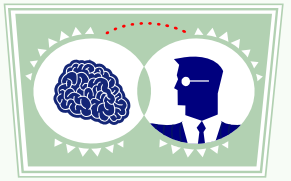
The Need for Evaluation

- Evaluation of quality improvement (QI) initiatives is important to help:
  - Determine the effectiveness of their efforts



  - Reduce wasted resources

  - Create knowledge that may benefit others



Evaluation Study Designs

- Local vs. Generalizable knowledge
  - **Local** = managers responsible for QI in an institution
  - **Generalizable** = knowledge translation researchers studying QI in general

Internal Validity

Def^{n}: relationship between intervention and impact has been accurately measured

Purpose of evaluation is to determine if:

1. There has been an improvement in the outcome of interest
2. This improvement is due to the intervention under study

When an intervention appears to be effective…but is not?

Example: The common cold

A treatment for the common cold may appear to work because a person is cured a few days after taking it. However, the clinical improvement may be due to the effect of the treatment or the natural course of a self-limited disease that lasts a few days.

Study Designs

1. **Randomized → gold standard**
   - Randomized controlled trial (RCT)
2. **Non-randomized or quasi-experimental**
   - Controlled before-after
   - Interrupted time series
   - Uncontrolled before-after

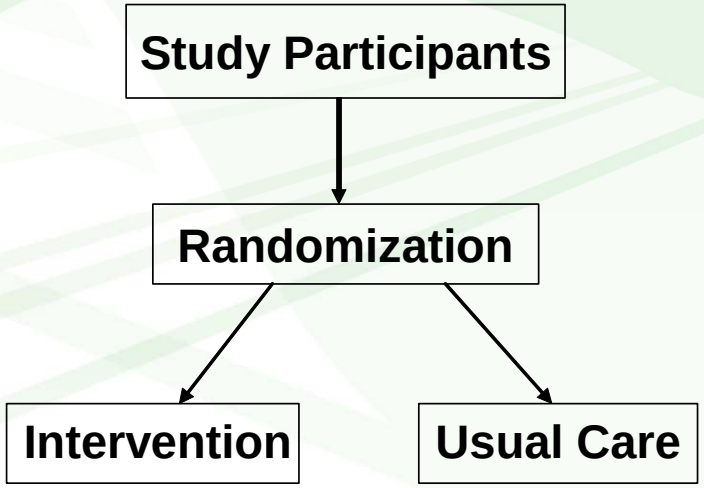
Randomized Controlled Trials

- Large sample size enables accurate assessment of intervention effect
- Increases the chance that groups will have similar distribution of known and unknown confounders

RCT Designs

Number of comparison arms:

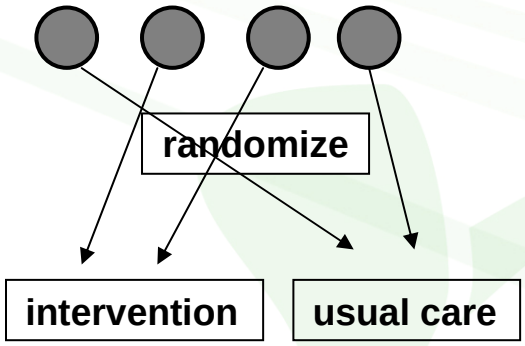
Two arm trials most common



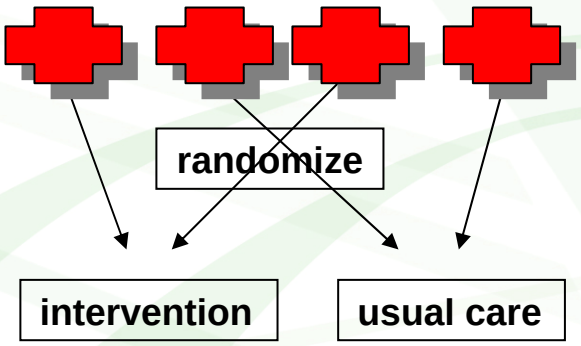
RCT Designs

Units of randomization:

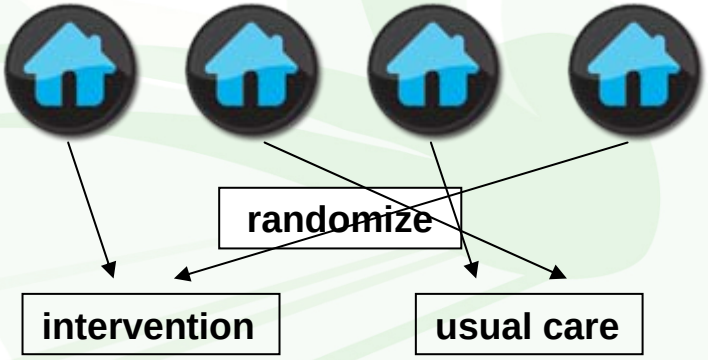
Individuals:



Providers:



Clinics/Communities:



Sample size:

- Large sample size increases ability to determine that there was no impact
- Important when effect size is small; clustering requires further adjustment

Non-Randomized Designs

- More subject to bias
- Require fewer resources
- Logistics simpler

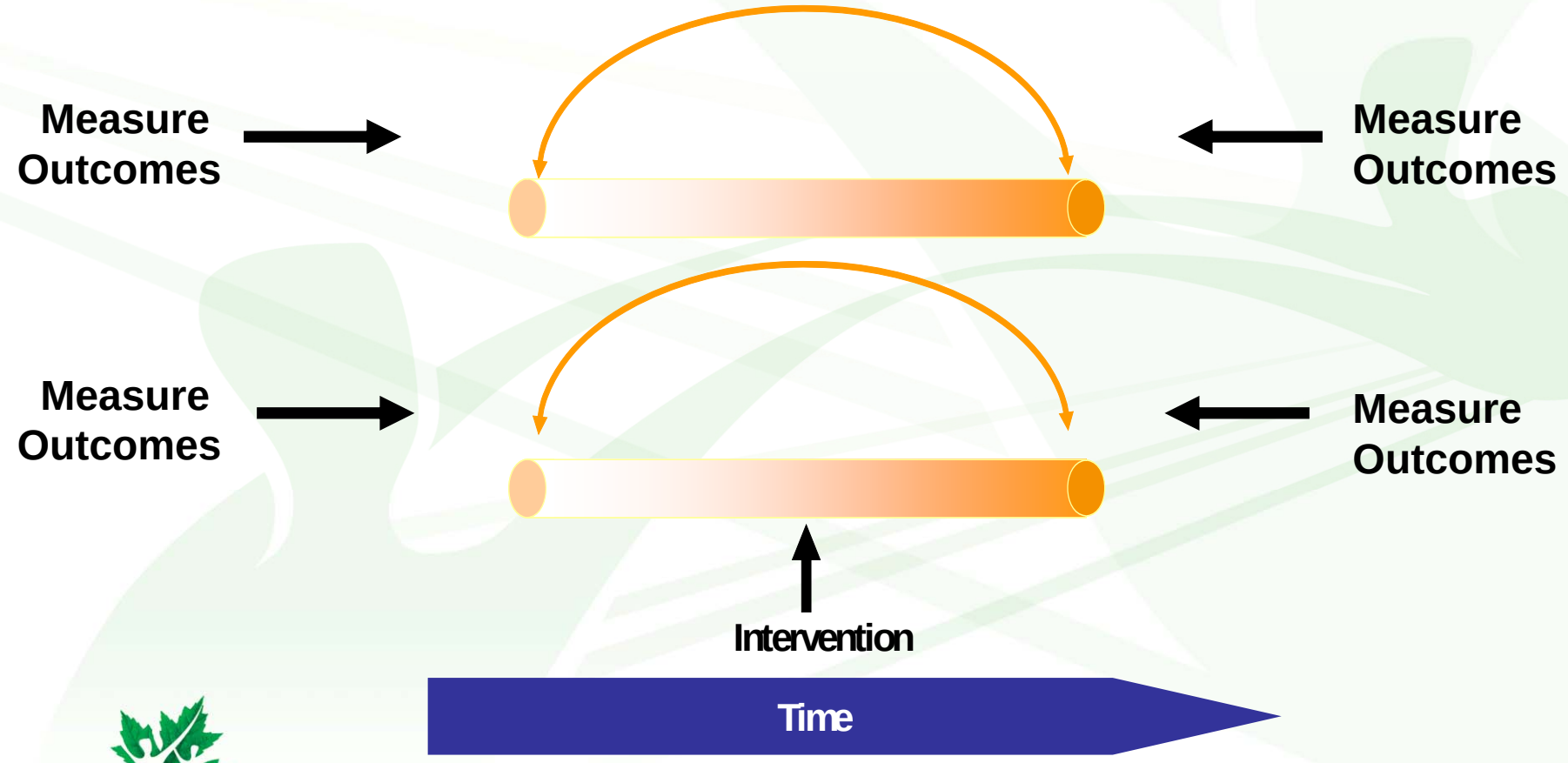
TYPES:

1. **Controlled before-after**
2. **Interrupted time series**

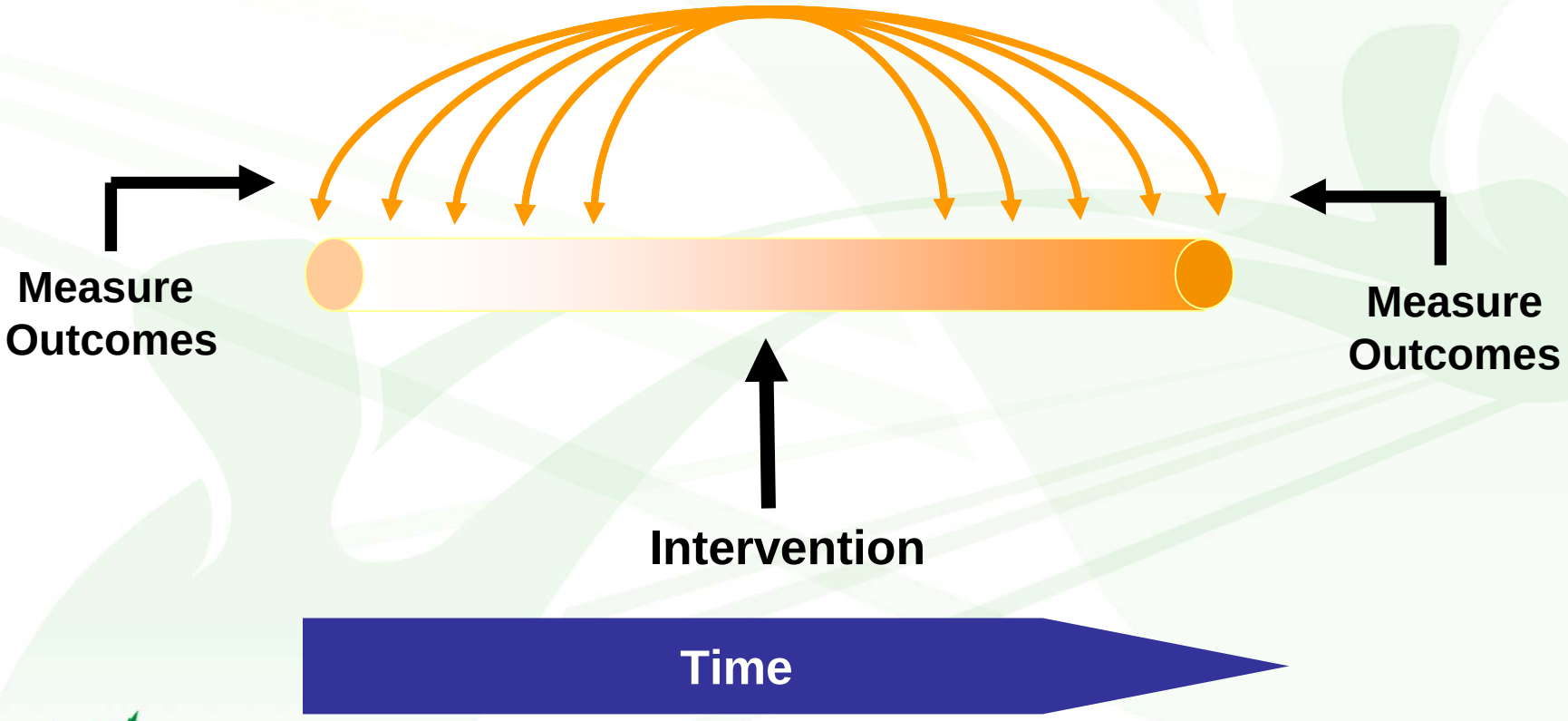
Also:

3. Uncontrolled before-after

Controlled Before-After Studies



Interrupted Time Series



Generalizability

- **Internal validity** = rigorous design, sufficient sample size, blinding of assessors and participants (where possible) to group allocation
- Perfectly valid study may not allow us to determine the degree to which results are applicable to regular practice conditions
- **Pragmatic trials** designed to maximize the relevance of the results for real world decision making

Pragmatic Study Designs

Pragmatic vs. Explanatory trials

- **Pragmatic** = designed to help choose options of care
- **Explanatory** = designed to test causal research hypotheses

Pragmatic Study Designs

	Explanatory	**Pragmatic**
Purpose	To examine efficacy	To examine effectiveness
Setting	"Ideal" conditions; environment monitored	Normal practice
Participant selection	Careful selection process and monitoring	Clinical indication
Interventions	Strict enforcement and monitoring of adherence	Flexible application; suited to normal practice
Outcomes	Short term surrogates or process measures	Outcomes with relevance to participants, funders, healthcare providers, decision makers, and other stakeholders
Relevance to practice	Indirect – little effort made to match trial design to needs of decision makers	Direct – efforts to link study design to everyday practice

Successes and Failures

- Randomized and non-randomized studies help us understand the “what”, but not the “why”
- Qualitative studies can fill this gap by answering the “why” questions
- Despite a significant number of studies investigating KT interventions, we still know very little about what works and what doesn’t
    - Rigorous evaluation of quality improvement initiatives needed to increase our knowledge of KT and to improve quality of care

Conclusion

- Implementation is inherently complex
- Despite large number of studies, many knowledge gaps remain
- The choice of evaluation design depends on what you want to know
  - What works in **your** setting or what works in **most** settings
  - Consider rigour in study design and pragmatic approaches
- Using qualitative and quantitative studies help understand **if** something works and **why**
- Given cost of implementation, evaluation is an imperative and need not be difficult

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