Spreading Change Locally and Nationally

Institute for Healthcare Quality,
Safety and Efficiency

SCHOOL OF MEDICINE

UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

Disclosures

None

Agenda

1. Sustainability and Spread
2. QI Writing
3. ****Asking for resources → QI Grants

BREAK

4. IRB: QI vs. Research

Learning Objectives

1. Describe the concept of diffusion of innovation.
2. Identify factors that lead to more sustainable projects.
3. Assign stakeholders on diffusion of innovation curve.
4. Describe the SQUIRE guidelines for QI manuscript writing
5. Recognize the parallels between SQUIRE 2.0 and Steps 1, 3, 4 in Kotter Change Management (Burning platform, Vision, Communicate)
6. Differentiate QI and Research for the IRB
7. Identify potential local and national sources for grant funding
8. List factors that lead to successful QI grant applications

Session	Session Overview
Patient Safety	• Historical origins of patient safety movement • Safety Culture • Case Review • Second victim and how to support caregivers when errors occur
Applied Patient Safety	• Guide the development and participation in a systems-based case review conference.
Quality Improvement & Change Management	• Basics of Quality Improvement • Step-wise, practical implementation guide • Change Management framework overview for driving change
Acquiring Data to Drive Change	• Data sources to track improvement • Data analysis and organization • Data visualization
Spreading Change Locally and Nationally	• Diffusion of innovation framework • QI vs. research • Strategies for dissemination and publication • Grant opportunities
Coaching and Teaching Quality Improvement	• How to coach QI teams • Identifying and troubleshooting common QI missteps

YOU ARE HERE


zoom

Sustainability

33% - 70% of (successful) innovations are **NOT** sustained

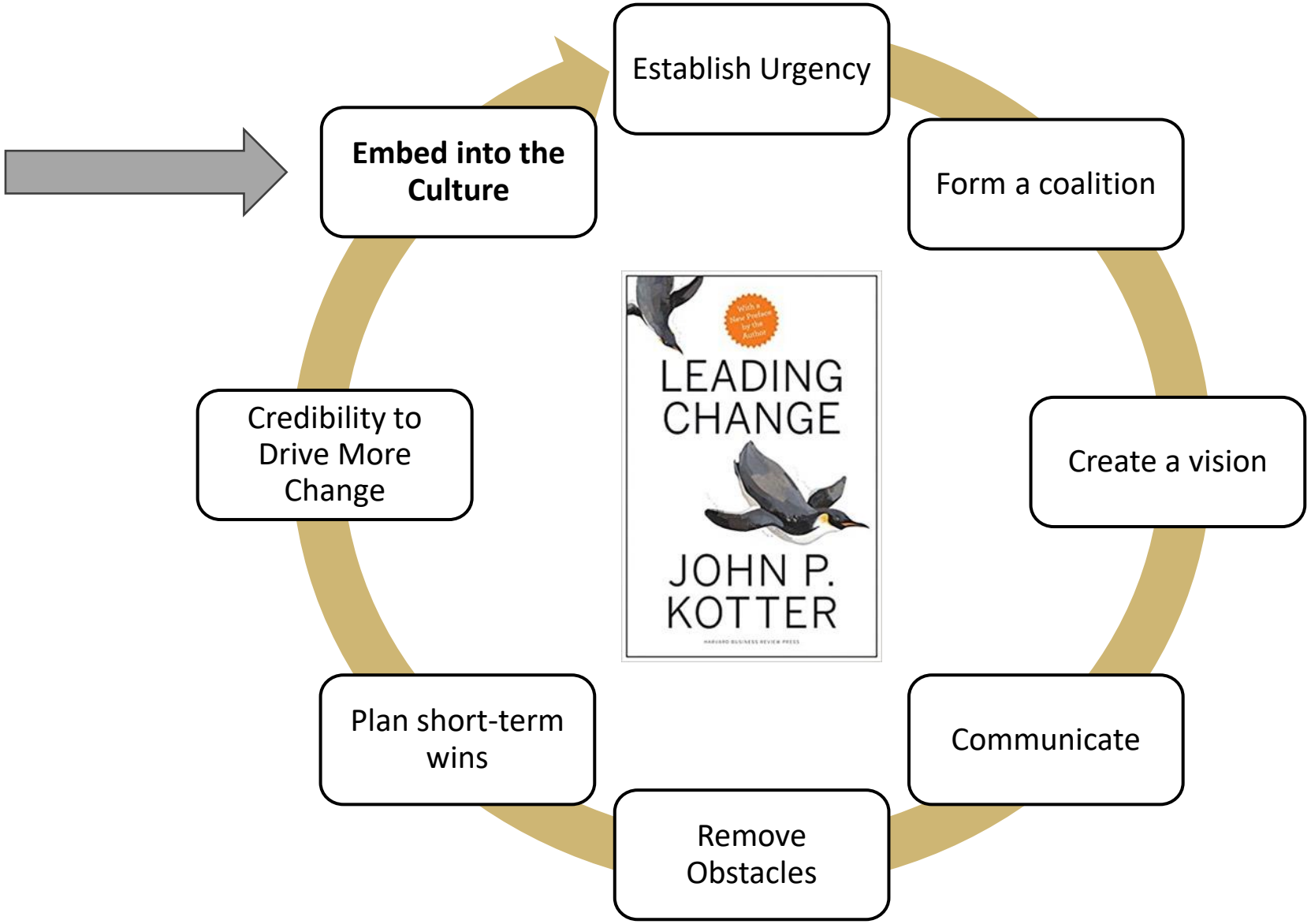
”Improvement evaporation effect"

Buchanan D., Fitzgerald L. & Ketley D. (2007) The Sustainability and Spread of Organizational Change: Modernizing Healthcare. Routledge, London, UK.

Fleiszer AR, Semenic SE, Ritchie JA, Richer MC, Denis JL. The sustainability of healthcare innovations: a concept analysis. J Adv Nurs. 2015 Jul;71(7):1484-98. PMID: 25708256.

"Sustainability occurs when **processes or improved outcomes last within an organization *after* implementation has occurred**. An improvement that has become part of the organizational culture and has been maintained **regardless of workforce turnover** is an example of a sustained improvement."

Module 6: Sustainability: Facilitator Notes. Content last reviewed March 2017. Agency for Healthcare Research and Quality, Rockville, MD.
https://www.ahrq.gov/hai/quality/tools/cauti-ltc/modules/implementation/long-term-modules/module6/mod6-facguide.html


Establish Urgency
Form a coalition
Create a vision
Communicate
Remove Obstacles
Plan short-term wins
Credibility to Drive More Change
Embed into the Culture
LEADING CHANGE
JOHN P. KOTTER

Factors important to sustainment described across numerous studies…

Intervention characteristics

Agency (institutional) characteristics

Stumbo SP, Ford JH 2nd, Green CA. Factors influencing the long-term sustainment of quality improvements made in addiction treatment facilities: a qualitative study. Addict Sci Clin Pract. 2017 Nov 1;12(1):26. PMID: 29089054

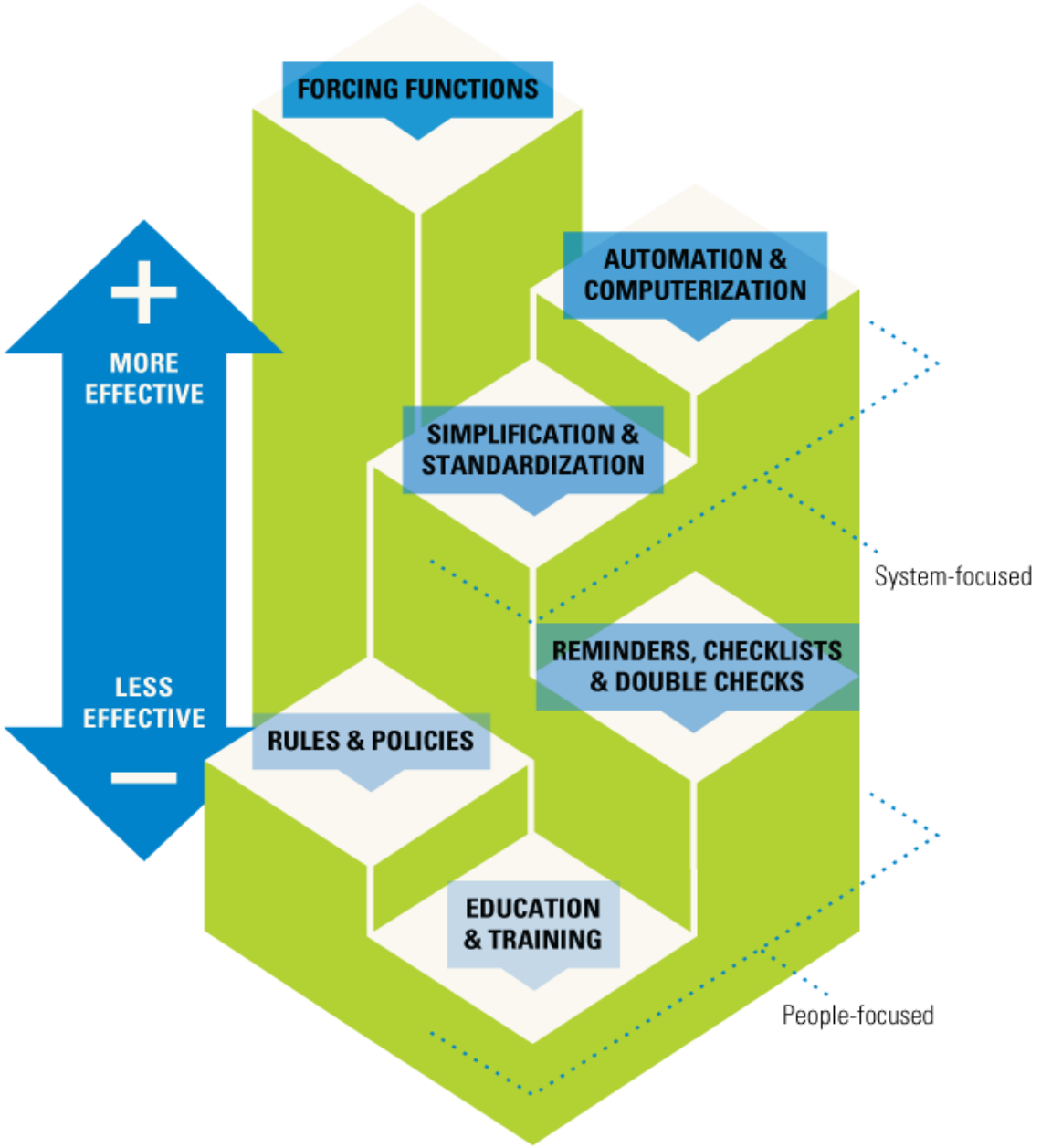
Intervention characteristics

Capacity to routinize innovations and processes

Value to the institution

Adaptability of the intervention components to fit different areas

Stumbo SP, Ford JH 2nd, Green CA. Factors influencing the long-term sustainment of quality improvements made in addiction treatment facilities: a qualitative study. Addict Sci Clin Pract. 2017 Nov 1;12(1):26. PMID: 29089054


FORCING FUNCTIONS
AUTOMATION & COMPUTERIZATION
SIMPLIFICATION & STANDARDIZATION
REMINDERS, CHECKLISTS & DOUBLE CHECKS
RULES & POLICIES
EDUCATION & TRAINING
MORE EFFECTIVE
LESS EFFECTIVE
System-focused
People-focused

Agency (institutional) characteristics

Enhance Sustainability

Alignment between business-centered and (patient)-centered practices

Early staff engagement – adds legitimacy

Embedding data integration: making the connection with quality improvement

Limit Sustainability

Lack of evidence of impact on bottom line

Data roadblocks

High levels of staff turnover

Stumbo SP, Ford JH 2nd, Green CA. Factors influencing the long-term sustainment of quality improvements made in addiction treatment facilities: a qualitative study. Addict Sci Clin Pract. 2017 Nov 1;12(1):26. PMID: 29089054

Breakout #1

10 minutes

1. **Introduce yourselves**

2. **Assess POCUS as a proposed intervention using a “New Idea” scorecard.**

Point of Care Ultrasound (POCUS)

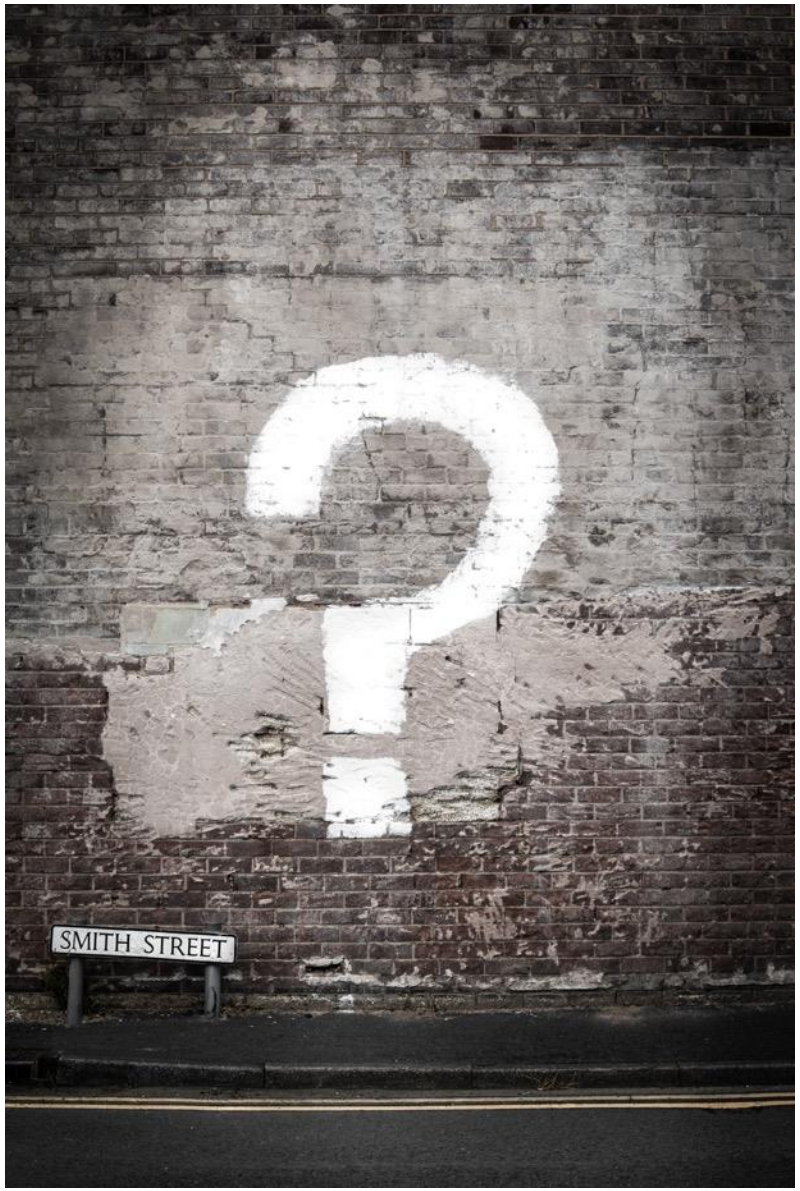
Image Source: https://aiumthescan.blog

New Idea Scorecard

Name of innovation:	Score
Relative advantage	
Simplicity	
Compatibility	
Trialability	
Observability	
Total	

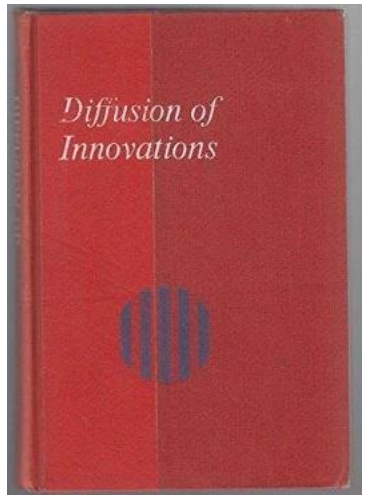
Score on 1-5 rating (1 = none, 5 = very)

- **Relative Advantage** –degree to which an innovation is perceived as better than the idea it supersedes
- **Simplicity** – degree to which innovation is perceived as being simple to understand and use
- ***Compatibility*** – the degree to which an innovation is perceived as being consistent with the existing values, experiences, beliefs, and needs of potential adopters
- ***Trialability*** – degree to which an innovation can be tested on a small scale
- ***Observability*** –degree to which use of an innovation and results it produces are visible to those who should consider it.

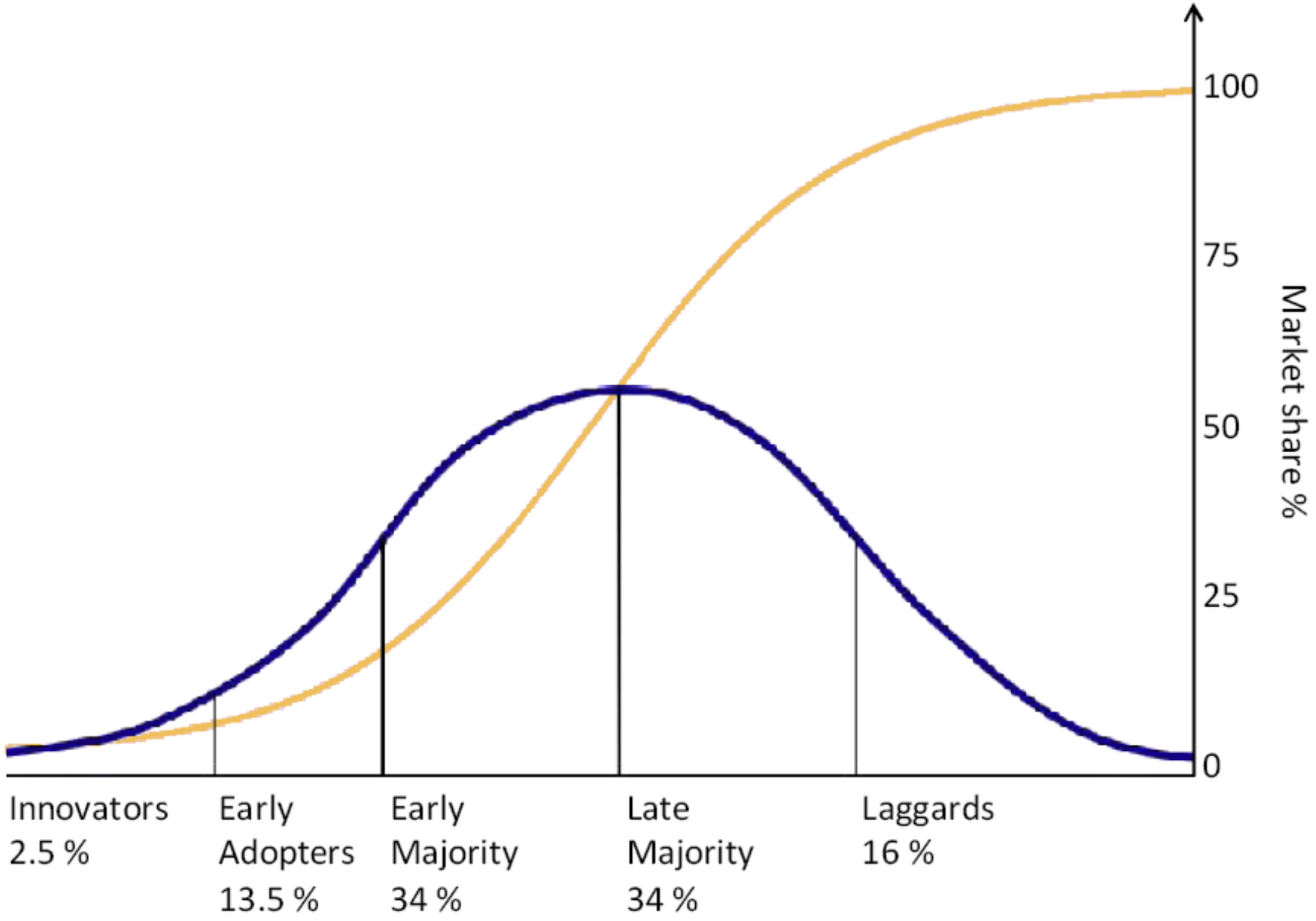


How do you know when something will be sustained?

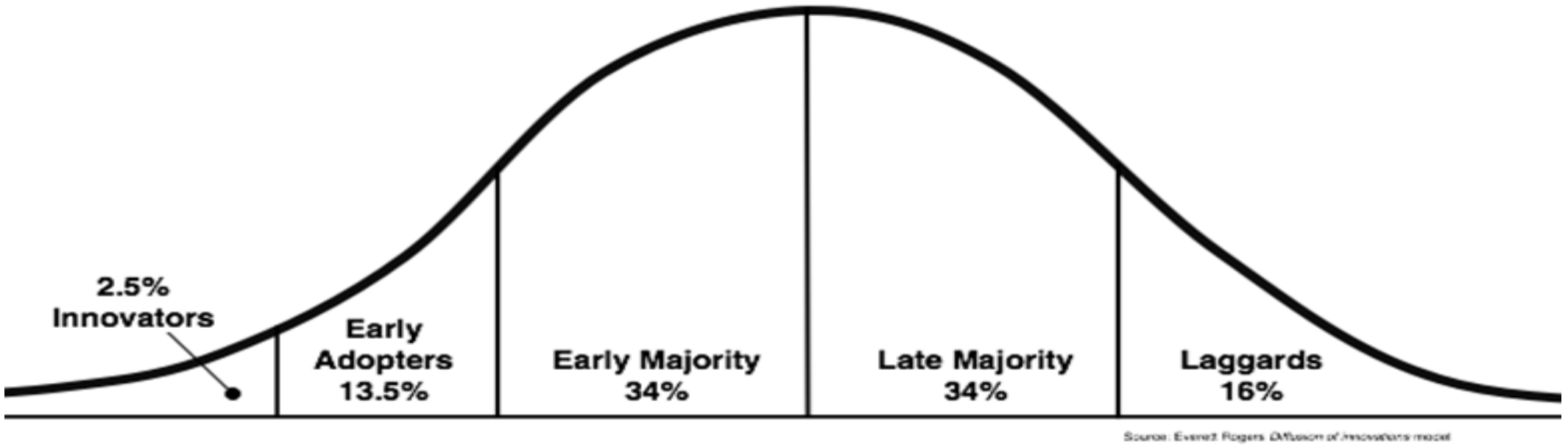
Can you predict it?



Everett Rogers, 1962



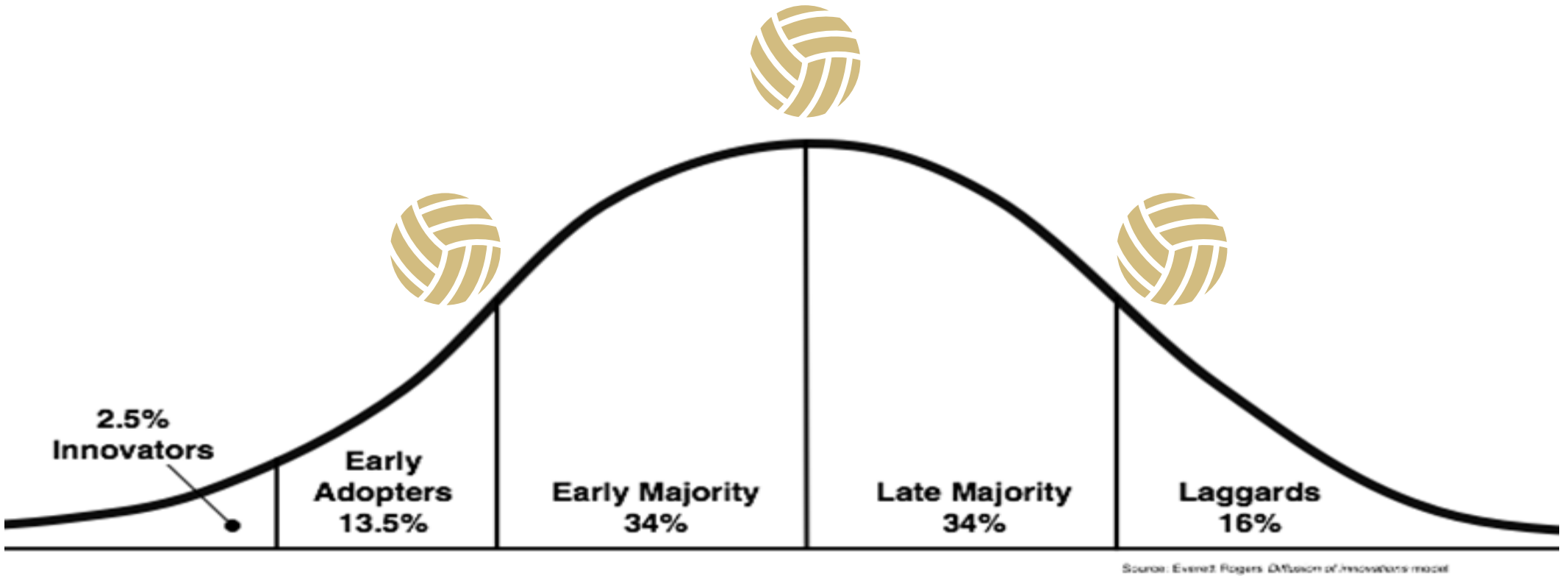
Tipping Point: % of population required before large-scale social change occurs



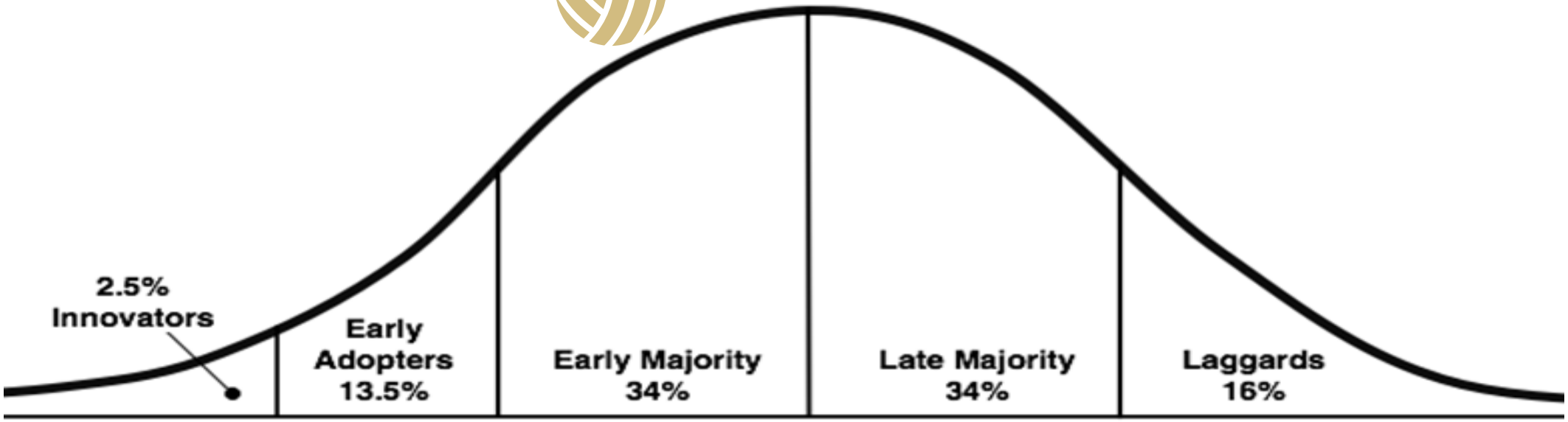
Source: Everett Rogers *Diffusion of Innovations* model

Where do you think the tipping point is?

(What percentage of the population needs to adopt the innovation before large-scale change will occur?)



25%



Source: Everett Rogers *Diffusion of Innovations* model

***

- WHY do people fall into categories? → empathy for “laggards”

Stages of Individual Adoption

1. Knowledge: exposure but no active role in seeking more information.
2. Persuasion: seeks more information.
3. Decision: weighs risk/benefits and decides whether to adopt or reject.
4. Implementation: trial and error, determining when and when to not to employ
5. Confirmation: individual finalizes behavior

Characteristics of the Innovation

Relative advantage (relative to current tools or procedures)

Compatibility with the pre-existing system

Complexity or difficulty to learn

Trialability or testability

Potential for reinvention

Observed effects

} Judged as a whole

POCUS Adoption/Diffusion

- https://pubmed.ncbi.nlm.nih.gov/25227642/

Characteristics of the Adopters

Innovators	Early Adopters	Early Majority	Late Majority	Laggards
Willing to take risks Highest social status Financial liquidity Social Closest contact to source and other innovators	More discreet than innovators Use judicious nature to maintain credibility	Average social status Contact with early adopters Rarely hold positions of opinion leadership in a system	Approach an innovation with a high degree of skepticism Below average social status Little financial liquidity	Aversion to change-agents Focused on "traditions" Low financial liquidity Socially isolated

Guiding Coalition

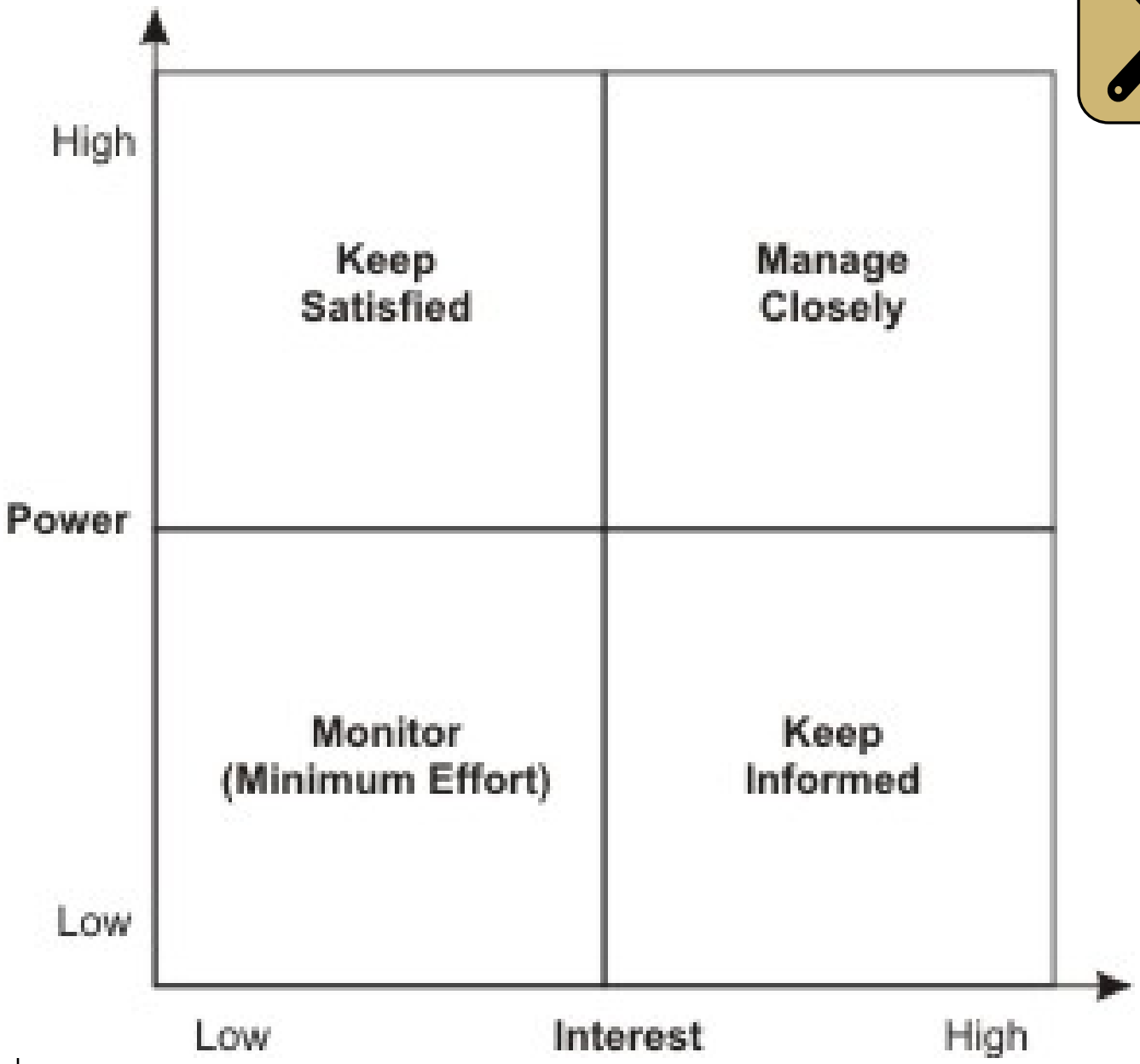
Key Partner Map

née Stakeholder

Step 1: Identify

Step 2: Prioritize

Step 3: **Understand**



Breakout #2

8 minutes

1. **Describe your project or problem you want to solve.**

2. **Determien where your key partners they lie on the Diffusion of Innovation curve** – try to list one person or group into each category.

Top (Adoption) Mistakes

We assume that evidence matters in the decision making of potential adopters.

Evidence is most important to only a subset of early adopters and is most often used by them to reject interventions.

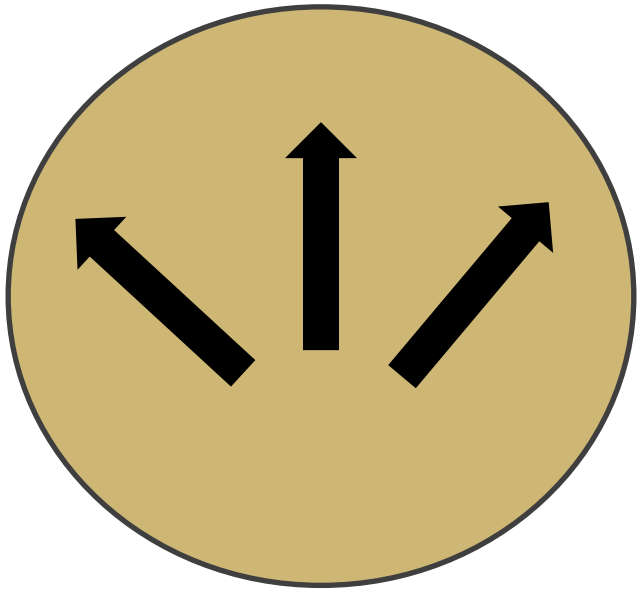
Solution: Emphasize other variables in the communication of innovations such as compatibility, cost, and simplicity.

We substitute our perceptions for those of potential adopters.

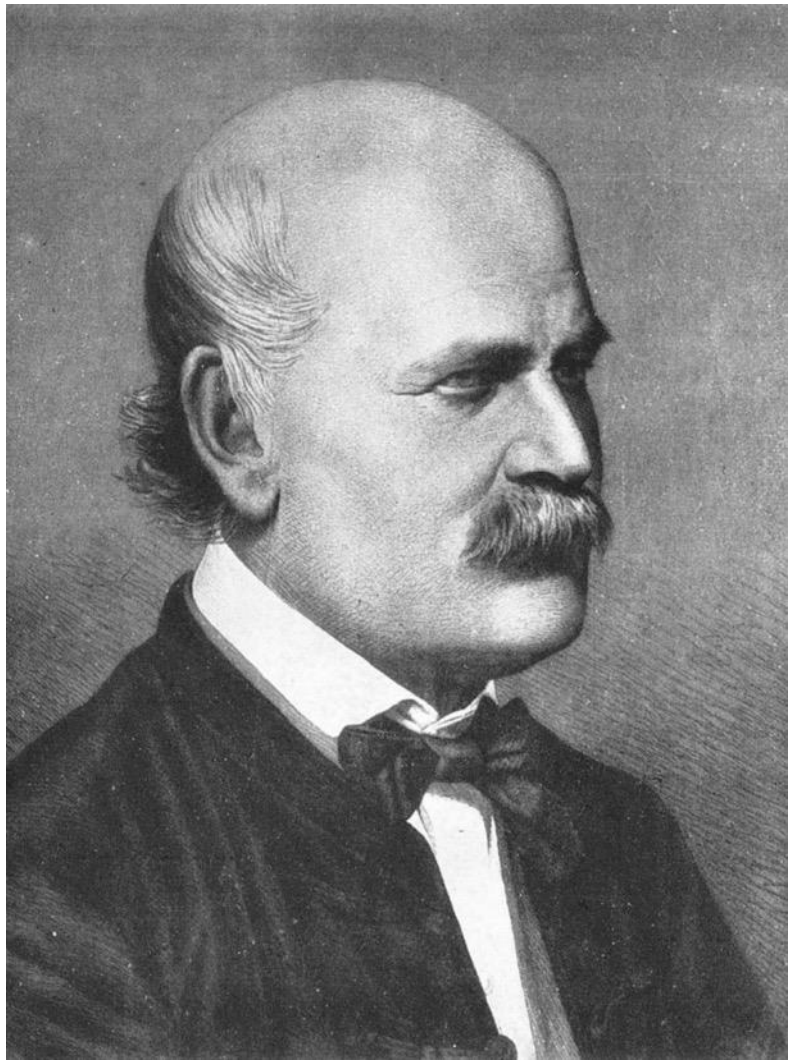
We confuse authority with influence

Solution: Seek out and listen to representative potential adopters to learn wants, information sources, advice-seeking behaviors, and reactions to prototype interventions.

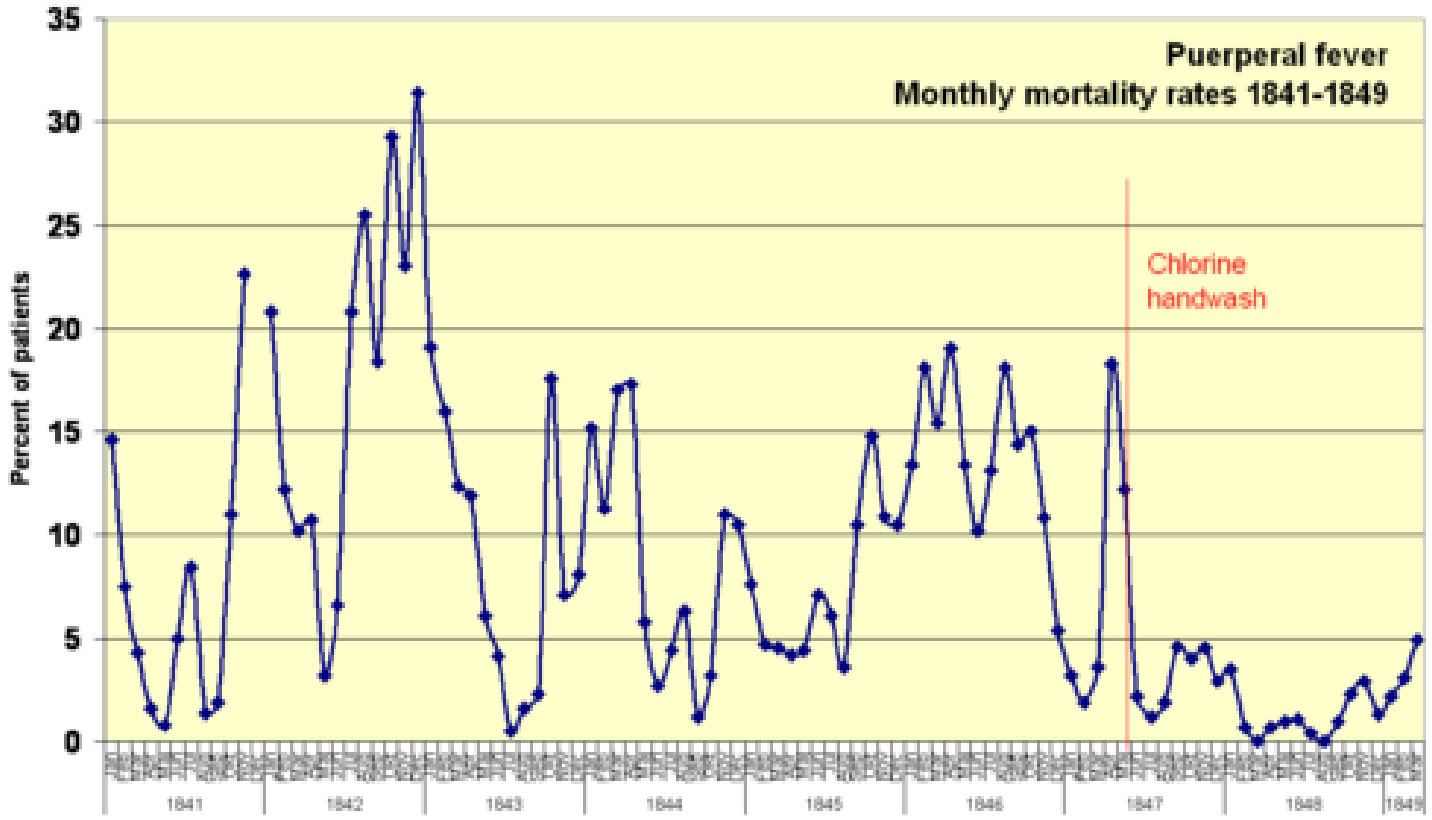
Dearing JW. Applying Diffusion of Innovation Theory to Intervention Development. Res Soc Work Pract. 2009 Sep 1;19(5):503-518. PMID: 20976022;



Spread



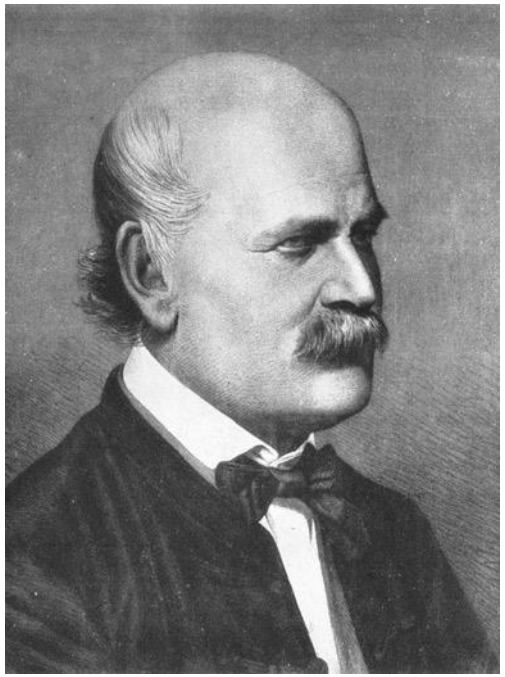
Ignaz Semmelweis, 1818 - 1865



https://www.npr.org/sections/health-shots/2015/01/12/375663920/the-doctor-who-championed-hand-washing-and-saved-women-s-lives

https://en.wikipedia.org/wiki/Ignaz_Semmelweis

You'd think everyone would be thrilled. Semmelweis had solved the problem! But they weren't thrilled.



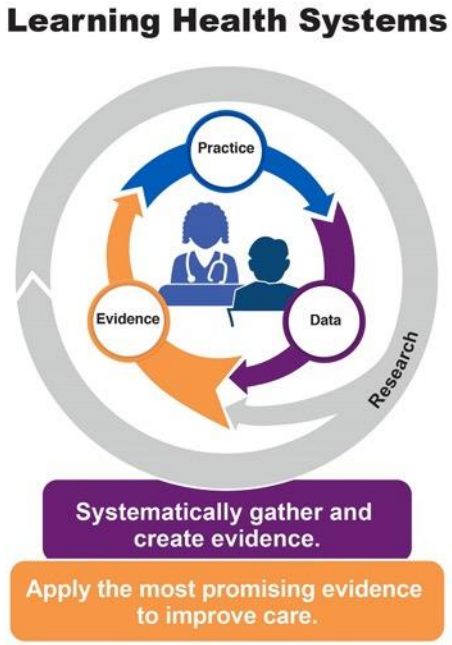
1. Doctors were upset because Semmelweis' hypothesis made it look like they were the ones giving childbed fever to the women.

2. Semmelweis was not very tactful. He publicly berated people who disagreed with him and made some influential enemies.

Eventually the doctors gave up the chlorine hand-washing, and Semmelweis — he lost his job.

https://www.npr.org/sections/health-shots/2015/01/12/375663920/the-doctor-who-championed-hand-washing-and-saved-women-s-lives

Agency for Healthcare Research and Quality



Learning health system: a health system in which internal data *and* experience are systematically integrated with external evidence, and that knowledge is put into practice.

https://www.ahrq.gov/learning-health-systems/about.html

Learning Health Systems

- Have leaders who are committed to a culture of continuous learning and improvement.
- Systematically gather and apply evidence in real-time to guide care.
- Employ IT methods to share new evidence with clinicians to improve decision-making.
- Promote the inclusion of patients as vital members of the learning team.
- Capture and analyze data and care experiences to improve care.
- Continually assess outcomes refine processes and training to create a feedback cycle for learning and improvement

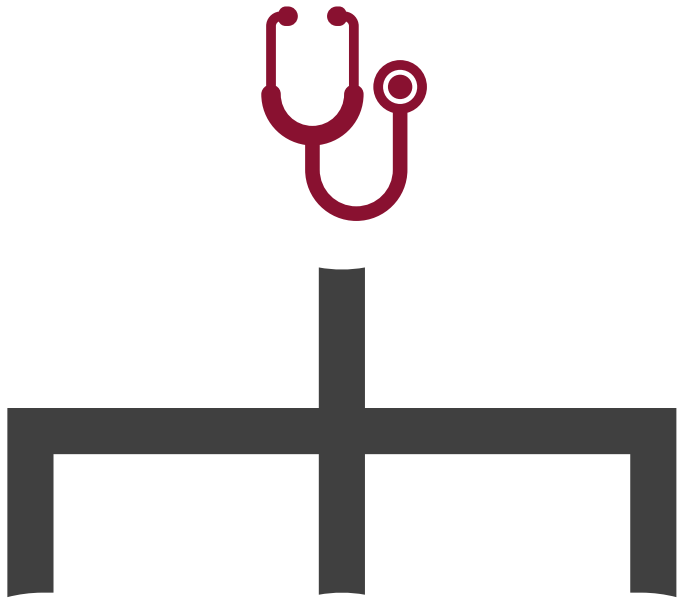
https://www.ahrq.gov/learning-health-systems/about.html

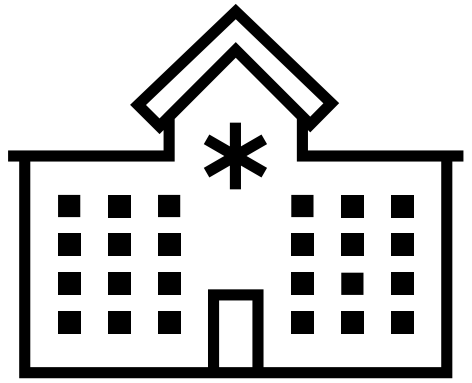

O
Rh POSITIVE
A
Rh POSITIVE
B
Rh POSITIVE
AB
Rh POSITIVE

Red Blood Cell (pRBC) Transfusion Recommendations
pRBCs are most likely APPROPRIATE in the following clinical scenarios:
• Hgb < 7 g/dL OR Hgb < 8 with CV disease AND symptoms
• Hemodynamically unstable patient with an acute bleed
• Perioperative acute blood loss anemia with expected Hgb < 7
• Cytotoxic chemotherapy with expected Hgb < 7
• Anemia with symptoms that are intolerable without transfusion
Transfuse 1 unit at a time unless Hgb <6.0 or bleeding out

COST = **~$700**
Per Unit

50% of non-OR, non-MTP, inpatient transfusions **DID NOT** meet guidelines

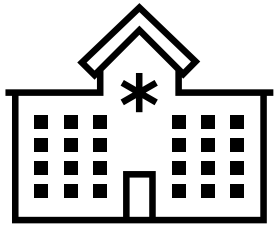




University of Colorado Hospital (UCH)

Order (Set) Modify	Order (Set) Modify + **In-line CDS**	Order(Set) Modify + **Interruptive CDS**

Mistry N, Richardson V, Carey E,…Anstett, T. General improvements versus interruptive or non-interruptive alerts in the blood order set: study protocol for a randomized control trial to improve packed red blood cell utilization. Trials. 2023;24(1):314.



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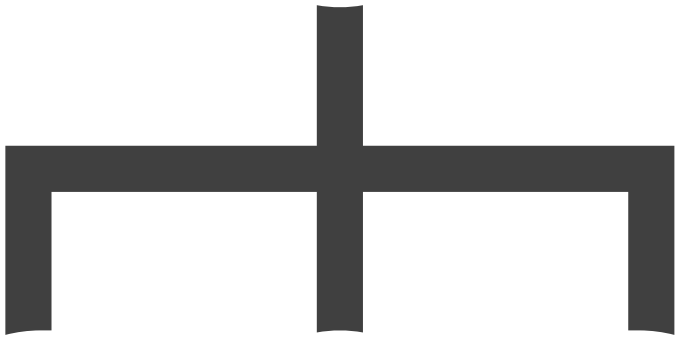


Order (Set) Modify

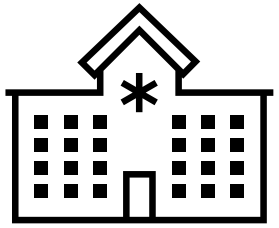
WINNER!

Order (Set) Modify + **In-line CDS**

Order(Set) Modify + **Interruptive CDS**

University of Colorado **Anschutz Medical Campus** | **IHQSE**

Mistry N, Richardson V, Carey E,…Anstett, T. General improvements versus interruptive or non-interruptive alerts in the blood order set: study protocol for a randomized control trial to improve packed red blood cell utilization. Trials. 2023;24(1):314.



UCH

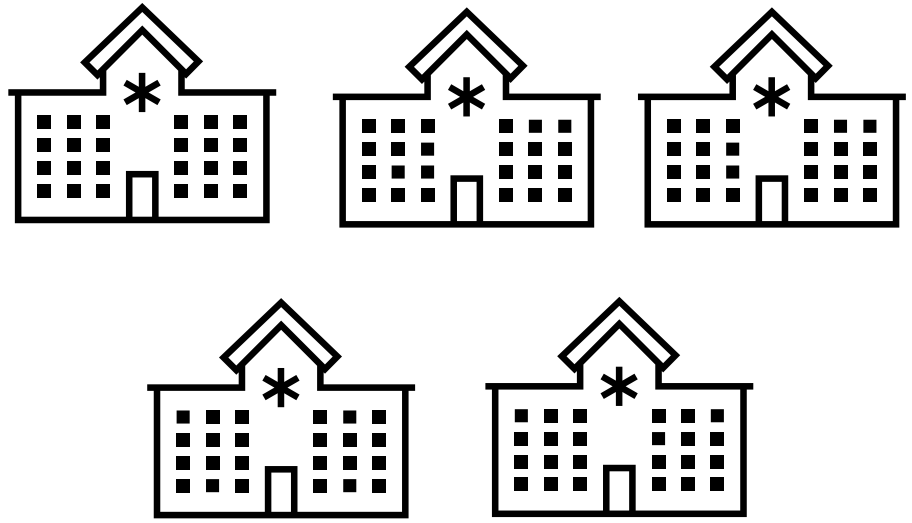
Order (Set) Modify

WINNER!

Order (Set) Modify + In-line CDS

Order(Set) Modify + Interruptive CDS

uchealth



Mistry N, Richardson V, Carey E,…Anstett, T. General improvements versus interruptive or non-interruptive alerts in the blood order set: study protocol for a randomized control trial to improve packed red blood cell utilization. Trials. 2023;24(1):314.

Communication and Support

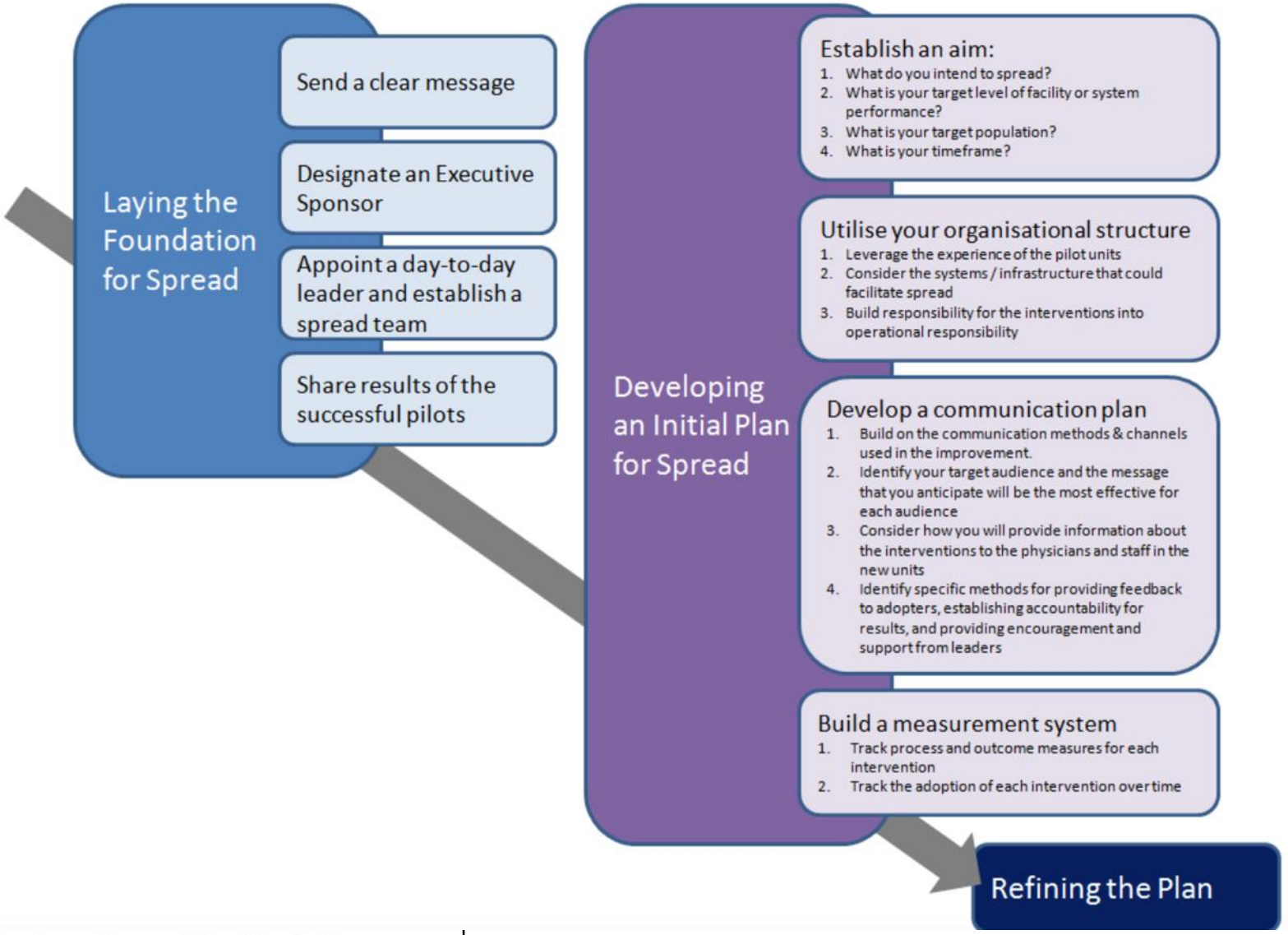


Figure 1: Figure created to visually summarise the 100,000 Lives Campaign

Local Context

- The population (e.g. clinics, units, facilities) that is the target of the spread activities
- The specific goals that are expected to be achieved
- The specific improvements to make in the target population
- The time frame for the effort.

Resources

Institute for Healthcare Improvement

A Framework for Spread: From Local Improvements to System-Wide Change

How to cite this paper:

Massoud MR, Nielsen GA, Nolan K, Schall MW, Sevin C. *A Framework for Spread: From Local Improvements to System-Wide Change.* IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2006. (Available on www.IHI.org)

Sharing your QI success
AND
Making QI Academic

Congratulations! You have a successful QI Project and want to share it with the world.

But how? Where? Who?

Photo credit: Clay Banks @ unsplash.com

Places to consider sharing your success.

- Conference Posters
- Conference Presentations
- Internal memos
- Press releases
- Papers/Manuscripts

Ready to Roll: Team Effort Bucks Sedation Trend

Cardiothoracic ICU supports awake and mobile for better patient care

6 minute read

Written by Debra Melani on July 31, 2023

Early mobilization can lead to:

- Less cognitive impairment
- Less ICU-acquired weakness
- Better quality of life

Reduced ICU sedation can decrease:

- Mortality
- Delirium
- Mechanical ventilation time
- Hospital length of stay
- Long-term consequences

UCHealth launches new virtual respiratory therapist program

The new position will focus on getting patients off of ventilators sooner.

Author: Jon Glasgow
Published: 12:18 PM MDT October 25, 2022
Updated: 12:18 PM MDT October 25, 2022

Start with the basics…

Define your objective(s)

What do you want to achieve by sharing your work?

Map your audience

Who is most affected by your work?
Who might find it most valuable?
What is it you want them to take away?

Frame your work

What they might want or need to hear from you, rather than what you want to tell them.

Ross-Hellauer T, et al. Ten simple rules for innovative dissemination of research. PLoS Comput Biol. 2020 Apr 16;16(4). PMID: 32298255;

Internal memos and press releases are great, ***and*** I really want (or need) to academically disseminate my work.

Posters/Presentations

Publications

QI project **D-O-N-E**!
Now let's publish it!

Image Credit: https://awol.com.au/ever-dreamt-of-riding-falkor-from-neverending-story/22791

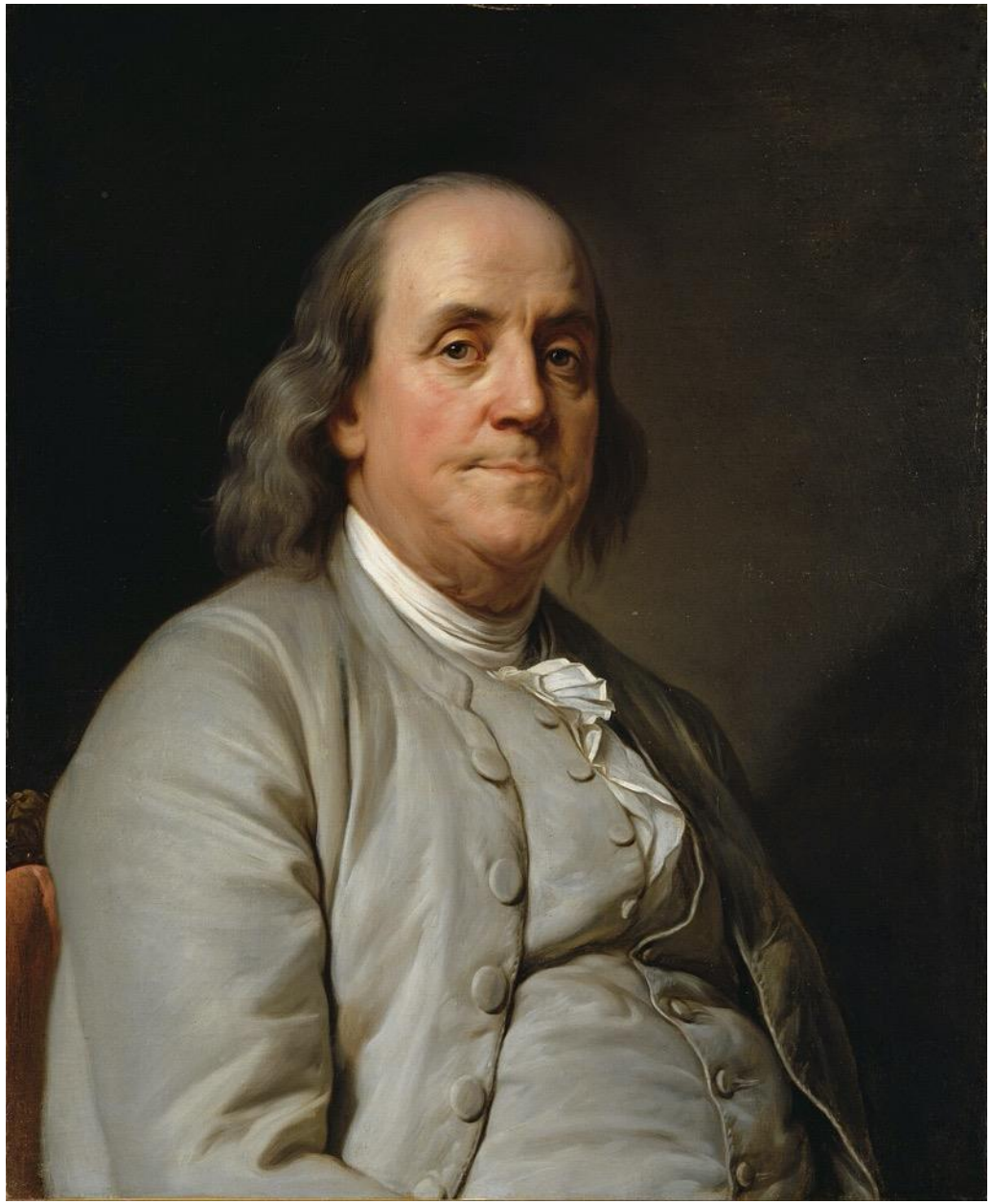
Adapted from: Valerie Vaugh, MD, MSc. University of Utah

But **sadly**…

- You forgot to collect demographics
- You can’t remember why you made decision “X” or when?
- You didn’t collect balance metrics
- There is a paper just like yours…but BETTER!

Image Credit: ww.kindertrauma.com/trauma-scene-the-neverending-story-the-death-of-artax/

Adapted from: Valerie Vaugh, MD, MSc. University of Utah



”An ounce of prevention is worth a pound of cure.”

Benjamin Franklin, 1706 - 1790

Portrait by Joseph Duplessis, 1778
Source: https://en.wikipedia.org/wiki/Benjamin_Franklin

FINER Criteria

Feasible *

Interesting

Novel

Ethical *

Relevant *

Generally used (in conjunction with PICOT), for crafting a good research question.

* Determined BEFORE you start

Adapted from: Valerie Vaugh, MD, MSc. University of Utah

Fandino W. Formulating a good research question: Pearls and pitfalls. Indian J Anaesth. 2019 Aug;63(8):611-616. PMID: 31462805

FINER Criteria

Feasible * budget, complexity of the design, recruitment, sample size, measurement time, commitment of clinicians/end-users

Interesting

Novel

Ethical * Potential risks and benefits need to be carefully weighed → **IRB**

Relevant * Are the results important? Even if negative?

Adapted from: Valerie Vaugh, MD, MSc. University of Utah

Fandino W. Formulating a good research question: Pearls and pitfalls. Indian J Anaesth. 2019 Aug;63(8):611-616. PMID: 31462805

FINER Criteria

Feasible *

Interesting Who cares? Does it benefit – patients? clinicians? system?

Novel Often the death nell of QI – but it doesn't have to be

- New setting
- New population
- Confirmation / expansion of prior study

Ethical *

Relevant *

Adapted from: Valerie Vaugh, MD, MSc. University of Utah

Fandino W. Formulating a good research question: Pearls and pitfalls. Indian J Anaesth. 2019 Aug;63(8):611-616. PMID: 31462805

SQUIRE

Promoting Excellence in Healthcare Improvement Reporting

Standards for **Qu**ality **I**mprovement **R**eporting **E**xcellence, 2.0

Framework for reporting system level work to improve quality, safety and value.

Title and Abstract	Introduction	Methods	Results	Discussion
	Why did you start?	What did you do?	What did you find?	What does it mean?

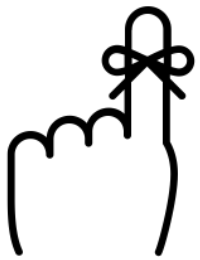
For both poster/presentation abstracts *and* papers.

Ogrinc G, et al. SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety.* Online first, September 15, 2015.

Title Describes an ***initiative to improve*** healthcare

KEY WORDS

- Quality
- Safety
- Effectiveness
- Patient-centeredness
- Timeliness
- Cost
- Efficiency
- Equity of healthcare



- Use the FEWEST words possible to accurately describe the content of the paper
- Consider thinking of what you would search for if looking for your paper.

Ogrinc G, et al. SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety.* Online first, September 15, 2015.

1. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials – BMJ, 2003

2. COVID-19: Clean up on IL-6 – AJRCMB, 2020

3. Invasive Fungal Disease Complicating Coronavirus Disease 2019: When It Rains, It Spores – CID, 2020

4. Vancomycin and the Risk of AKI: Now Clearer than Mississippi Mud – CAJSN, 2016

5. Fantastic yeasts and where to find them: the hidden diversity of dimorphic fungal pathogens – COM, 2019

6. Bats in the Bedroom, Bats in the Belfry: Reanalysis of the Rationale for Rabies Postexposure Prophylaxis – CID, 2009

7. Hogwarts Headaches — Misery for Muggles – NEJM, 2003

8. Clinical use of the polymyxins: the tale of the fox and the cat – IJAA, 2018

9. Experimental replication shows knives manufactured from frozen human feces do not work – JASR, 2019

10. Bundle in the Bronx: Impact of a Transition-of-Care Outpatient Parenteral Antibiotic Therapy Bundle on All-Cause 30-Day Hospital Readmissions – OFID , 2017

Have fun with the title – especially for posters and presentations abstracts!

https://www.idstewardship.com/best-journal-article-titles-medical-literature/

Group Activity

Craft a title for your “publication”: based on your problem, location, intervention, and your *expected* results.

When ready, put your title in the chat.

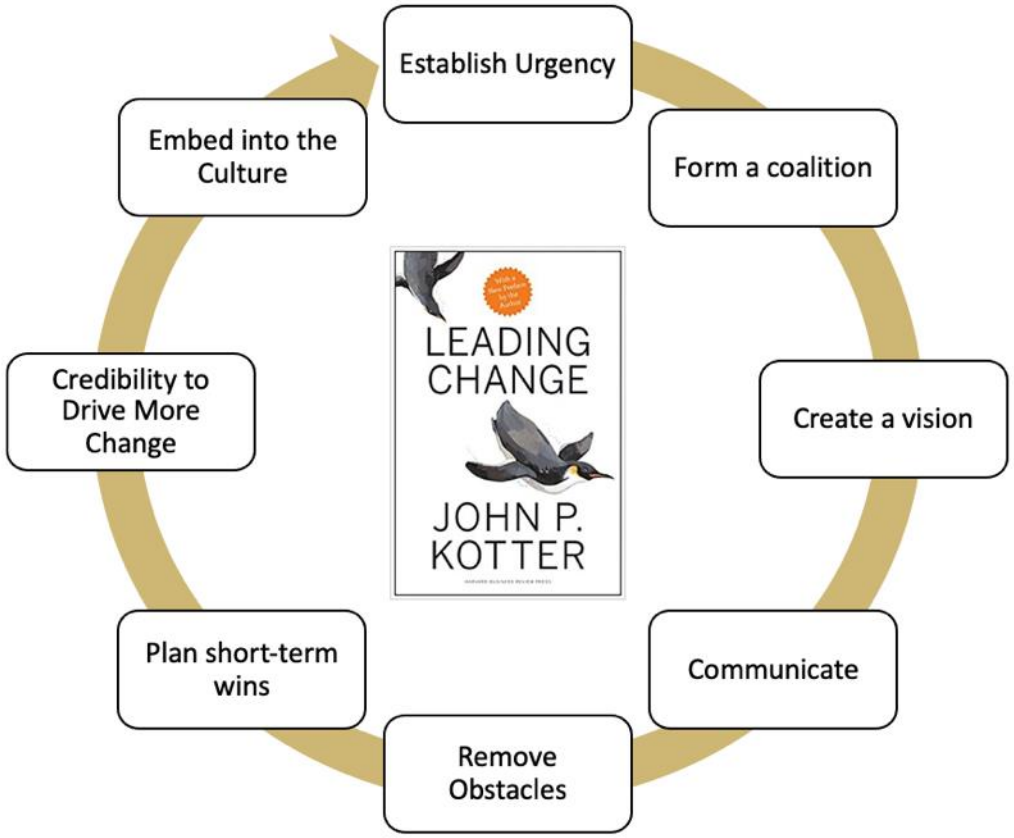
Introduction Why did you start?

Answer these questions:

- What is/was the problem?
- Why is it important (who cares)?
- What is the rationale for why it exists?
- What was your intervention and why did you think it would work?
- What was your Aim?

Can (and should) mimic your elevator pitch!

Ogrinc G, et al. SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety.* Online first, September 15, 2015.



1. Establish Urgency

3. Create a Vision

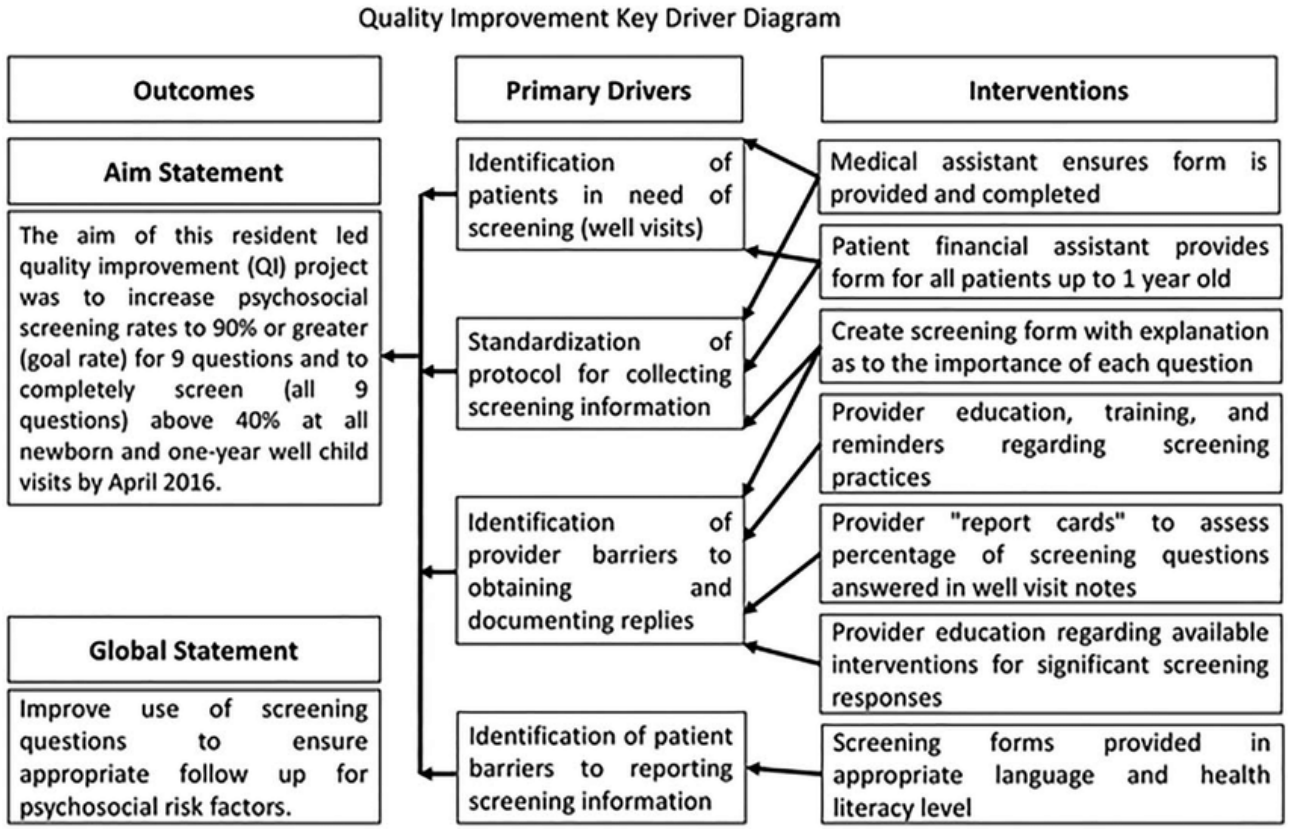
4. Communicate

Methods What (exactly) did you do?

Context of the Intervention	Setting and participants.
Intervention(s)	Detailed description of the implementation strategy.
Measurement of the intervention + impact	Rational for selection of process/outcome measures.
Analysis	Description of the approach of the ongoing assessment of the contextual elements that contributed to success/failure/efficiency.
Ethical Review	→ **IRB**

Ogrinc G, et al. SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety.* Online first, September 15, 2015.

Methods What (exactly) did you do?



All providers

Order (Set) Modify

Order (Set) Modify + **In-line CDS**

Order(Set) Modify + **Interruptive CDS**

Friedman S, et al. Improving Screening for Social Determinants of Health in a Pediatric Resident Clinic: A Quality Improvement Initiative. Pediatr Qual Saf. 2021 Jun 23;6(4):e419 PMID: 34235349

Results What (exactly) did you find?

- Steps of the intervention and evolution over time
- Process measure outcomes
- Associations
- Unintended consequences
- Missing data

Tables and Figures

Table 1: Patient +/- provider characteristics

Figure 1: Subject flow diagram (if relevant)

Figure 2: Data over time (run chart or SPC)

Ogrinc G, et al. SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety.* Online first, September 15, 2015.

Discussion What does it mean?

- **Brief** summary of the results
- Primary finding in context of established literature
- Secondary finding(s)
- Interpretation of associations between intervention and outcomes
- Impact, policy implications
- Limitations
- Strengths
- Future studies

Ogrinc G, et al. SQUIRE 2.0 (*Standards for QUality Improvement Reporting Excellence*): Revised publication guidelines from a detailed consensus process. *BMJ Quality and Safety.* Online first, September 15, 2015.

SQUIRE
Promoting Excellence in Healthcare Improvement Reporting

A few notes…

Explanation and elaboration of the SQUIRE (Standards for Quality Improvement Reporting Excellence) Guidelines, V.2.0: examples of SQUIRE elements in the healthcare improvement literature

Excellent resource with explanations and examples for each of the elements of SQUIRE 2.0

Exceptions to every rule:

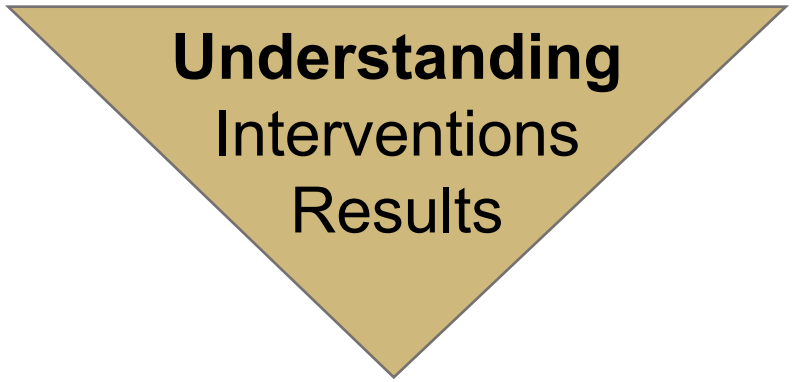
- Intervention design/rationale
- Table 1 Demographics
- Statistics

Goodman D, et al. Explanation and elaboration of the SQUIRE (Standards for Quality Improvement Reporting Excellence) Guidelines, V.2.0: examples of SQUIRE elements in the healthcare improvement literature. BMJ Qual Saf. 2016 Dec;25(12):e7 PMID: 27076505

SQUIRE
Promoting Excellence in Healthcare Improvement Reporting

A few notes…

The work focus



The publication focus

Do what works best for the story **YOU** want to tell.

Target Journals for QI work

BMJ Quality and Safety
BMJ Quality Improvement Reports
Joint Commission Journal on Quality and Patient Safety
Journal for Healthcare Quality
American Journal of Medical Quality
Journal of Clinical Outcomes Management

or….

most specialty specific journals

Jane
Journal/Author Name Estimator

Insert your title and/or abstract here: (or, click here to search using keywords)

Scramble | Clear | Show extra options

Find journals | Find authors | Find articles

Every article has a home…

Summary

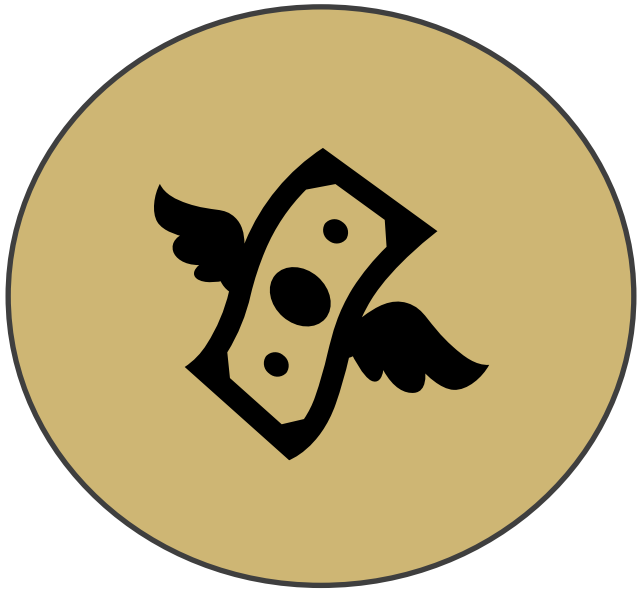
Project

(FINER)

SQUIRE 2.0

BREAK-TIME

Come back at…



QI Grant Writing

Learning Objectives

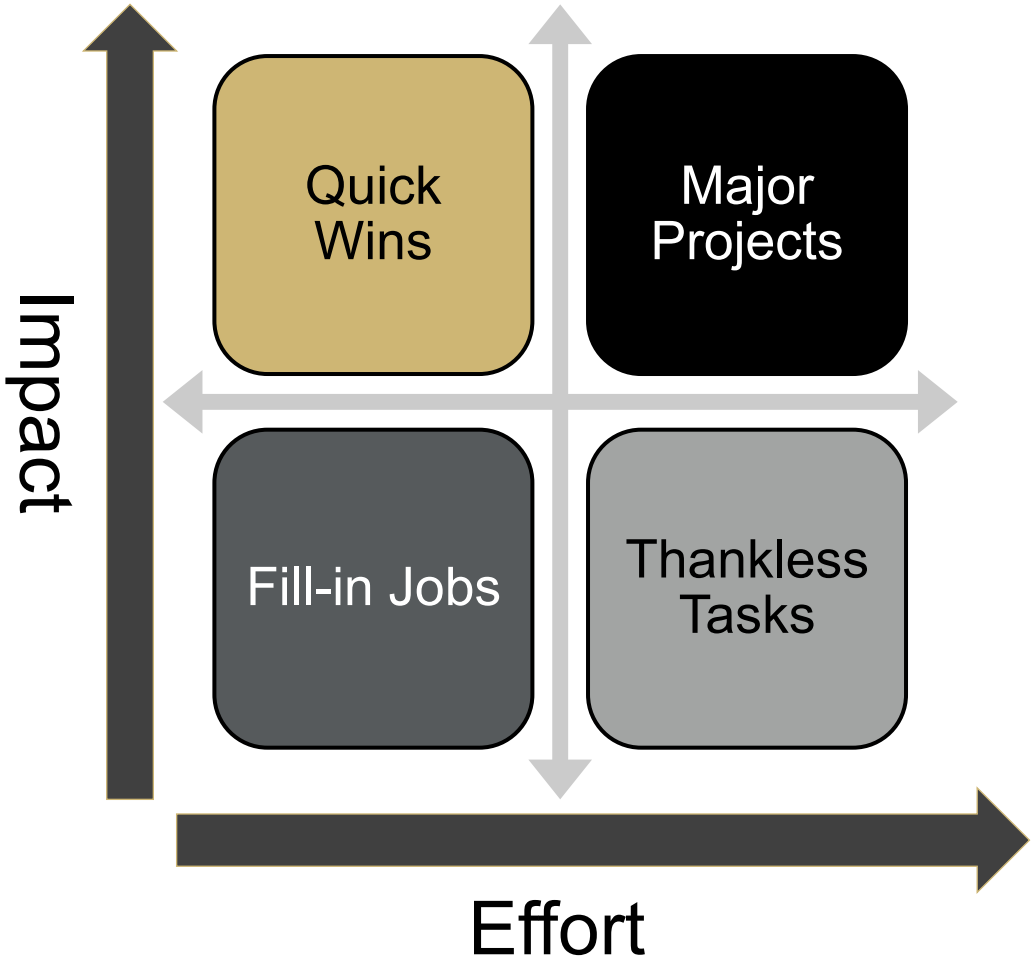
1. Identify potential local and national sources for grant funding.

2. List factors that lead to successful QI grant applications.

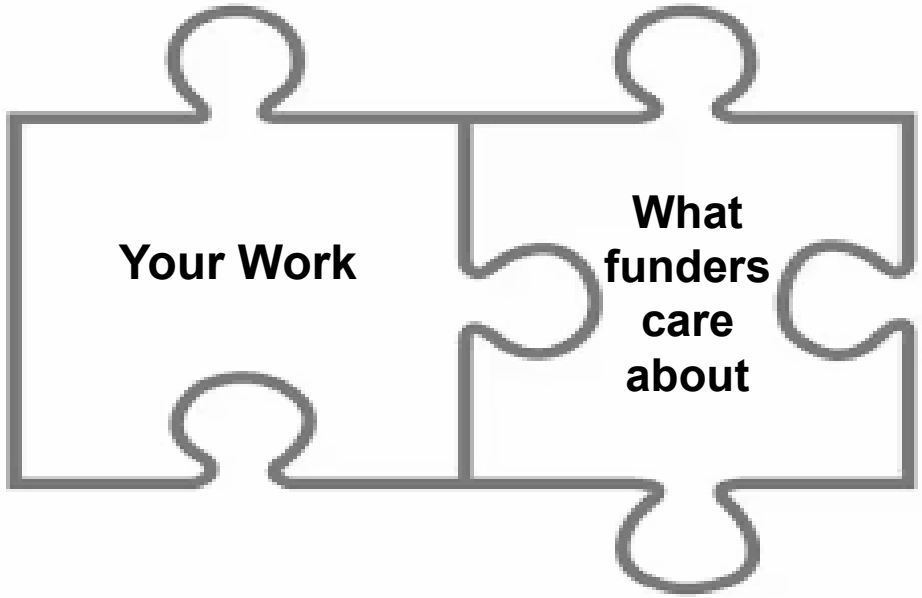
3. Understand WHY to apply for grants.

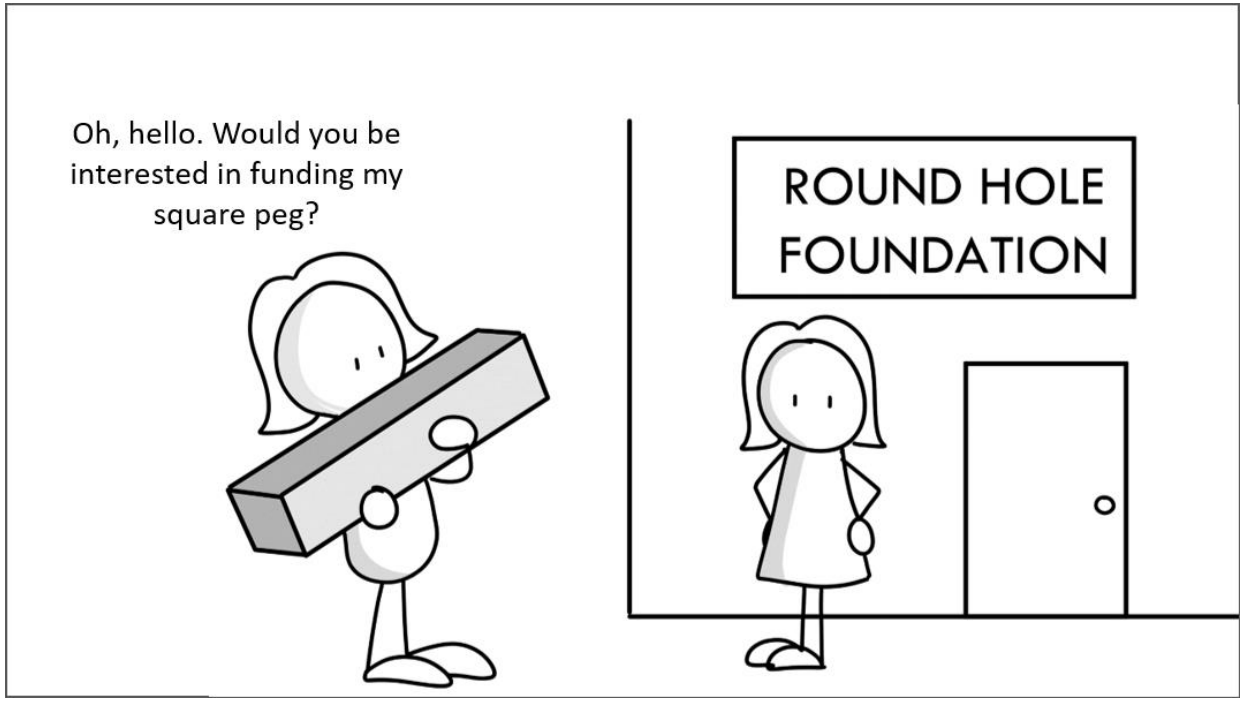
Why Do I Need to find QI Grant Funding?

- QI takes time and money
- Prestige
- Academic promotion



Unfortunately…not all grant mechanisms fund QI work

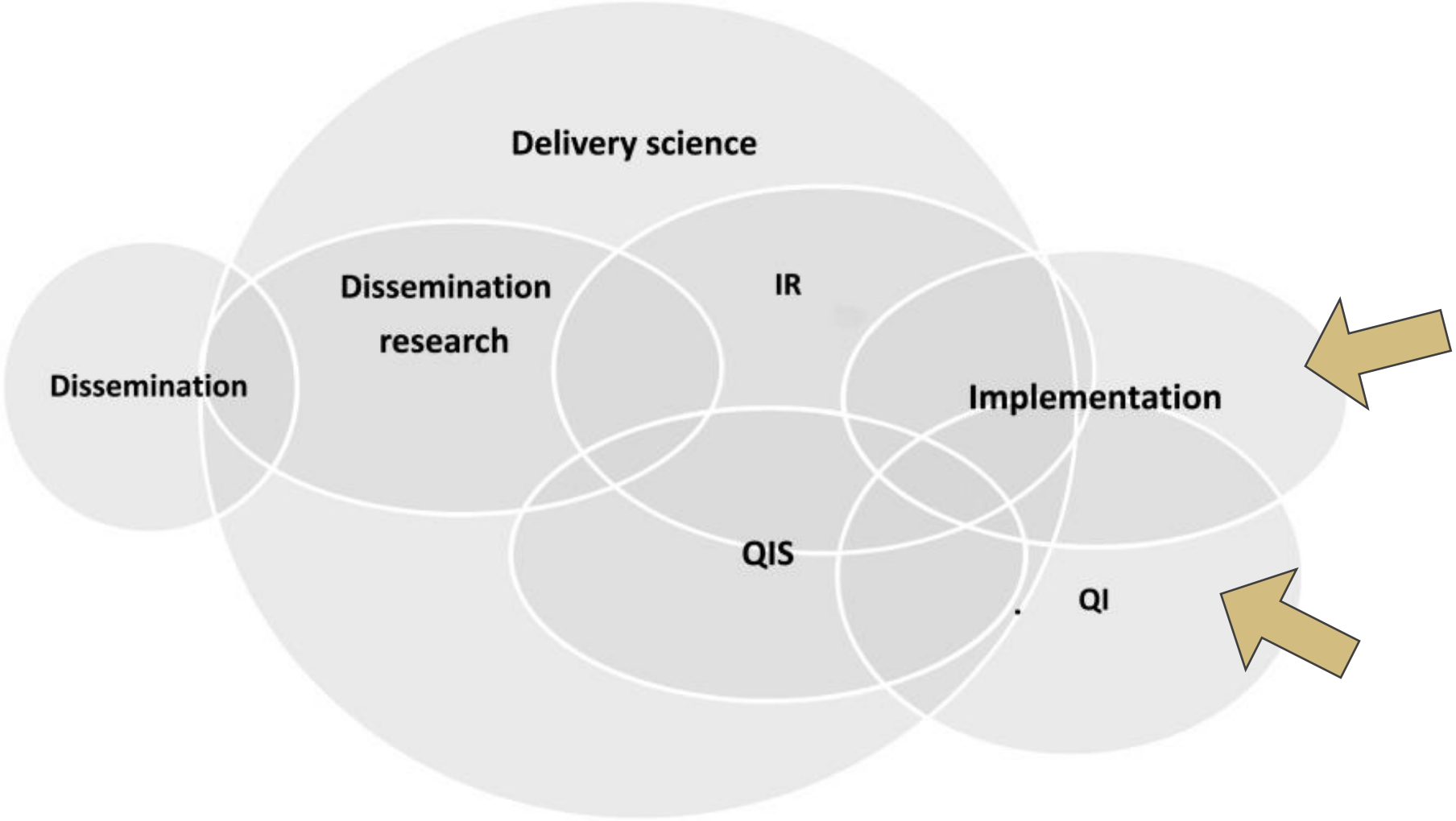




Key Terms for Finding (QI) Grants

- Quality
- Improvement
- **Innovation**
- Value
- Intervention
- IOM Dimensions of Quality Care
- Dissemination & Implementation Science (D&I)

Overlap Between D&I and QI



Tyler A et al, Hosp Peds, 202

Example

Quality Improvement

1. Understand barriers & facilitators of increasing oral (rather than IV) antibiotics for children hospitalized with pneumonia.

2. Use key driver diagram, process mapping, and subject matter experts to develop interventions to increase oral antibiotics.

3. Implement the intervention and evaluate effectiveness through statistical process control charts.

D&I

1. same…

2. Use implementation mapping to develop a set of implementation strategies to increase oral antibiotics.

3. Through an implementation trial, evaluate the feasibility, acceptability, and effectiveness of the strategies on the use of oral antibiotics through an interrupted time series analysis.

8 Tips for Writing a QI Grant

1. Spell out the need for the grant = **WHY**
2. Sell yourself/your team = **WHO**
3. Eliminate jargon from your grant application = **SIMPLE**
4. Be a good storyteller = **STORY**
5. Ensure your solutions/interventions are clear AND feasible = **WHAT**
6. Ensure your budget makes sense = **DUH, but really.**
7. Recruit an objective reviewer.
8. Pay close attention to details.

Adapted from: firespring.com/solutions-for-nonprofits/12-quick-tips-for-better-grant-writi

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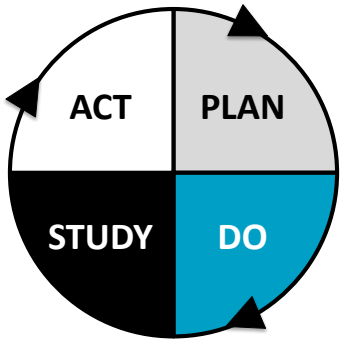

Adapted from: firespring.com/solutions-for-nonprofits/12-quick-tips-for-better-grant-writi

Project Aim: Clearly state the project's overarching goal(s) and the specific objectives for accomplishing these goals.

An aim statement should address HOW MUCH improvement (e.g.,baseline measure and targets) and by WHEN (e.g. w/in 12 months).


“I want to be a better skier.”
“By the end of the 23/24 season, I will be able to make it down a double-black diamond slope without falling.”

Make sure timeline and budget is feasible and within grant requirements

- Don’t have a 2 -year timeline for a 1-year grant
- Visuals are helpful

Table 8. Timeline of Proposed Research Activities

Aim	Activity	Y1	Y2	Y3	Y4	Y5
Aim 1	Finalize interview guides; Conduct interviews					
	Coding and analysis					
Aim 2	Identify final set of implementation strategies					
	Create implementation strategies					
Aim 3	Collect 1.5 yrs of retrospective pre-implementation data; Finalize survey & interview guide					
	Pilot pragmatic hybrid trial (deploy strategies followed by 2-month washout)					
	Conduct surveys & interviews; Analyze data (*primary outcome*)					
	Collect 1.5 yrs of retrospective post-implementation data; Analyze data (*secondary outcomes*)					
All	**First-author manuscripts:** preparation & submission of 1-2 per aim		SA1	SA2	SA3	SA3
	R01 grant: preparation & submission (initial in Y4; resubmit, if needed, in Y5)				R01	

Use Space Wisely

- Use **bolding**/<u>underlining</u> strategically
- Expensive real estate = Every word counts
- Too much text → annoy reviewers
  - Add visuals
  - Use white space

Example

5.4 Conceptual Model: The objective of this proposal is to develop and evaluate a set of strategies to increase initial *oral* (and decrease IV) antibiotics (Figure 2). By identifying barriers and facilitators to increasing oral antibiotics, we can select implementation strategies that target these barriers and facilitators. We hypothesize that a prioritized set of implementation strategies will be feasible and acceptable, enhance the reach and adoption of the intervention (i.e., initial oral antibiotics), and lead to improved reach and adoption of the intervention outcomes.

5.5 Overall Approach: We will use qualitative and quantitative methods including interviews, implementation mapping (to select evidence-based implementation strategies),[39] and a pilot hybrid trial to evaluate feasibility and acceptability of the implementation strategies and measure secondary outcomes (Figure 3). We will target *initial* antibiotic route, as that route is often continued, and focus efforts in the ED, where ~80% of antibiotics are initated.[11] Aims are related, but not dependent. The development of strategies in Aim 2 will be informed by existing barriers in the literature on related topics (e.g., clinicians feel they are providing optimal care)[65,70,71] and augmented, *but not dependent on*, findings from Aim 1. In Aim 2, we will adapt existing, evidence-based implementation strategies on related topics and populations (e.g., audit-and-feedback).[29,38,61,62] Aim 3 builds off prior aims but given that prior aims are qualitative and involve adaptation from related topics, *they will generate results and we will have implementation strategies for Aim 3.* Additionally, this sequence of aims follows a well-established approach for identifying and evaluating strategies in implementation science.[39,63]

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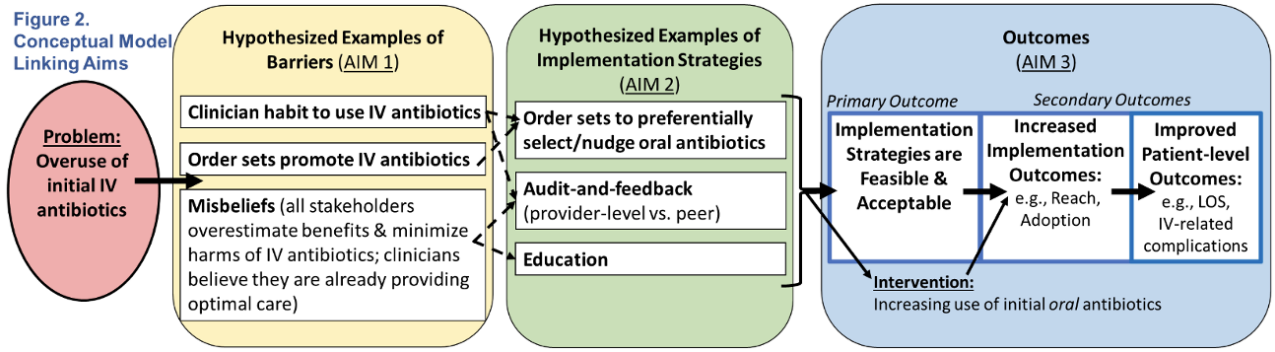

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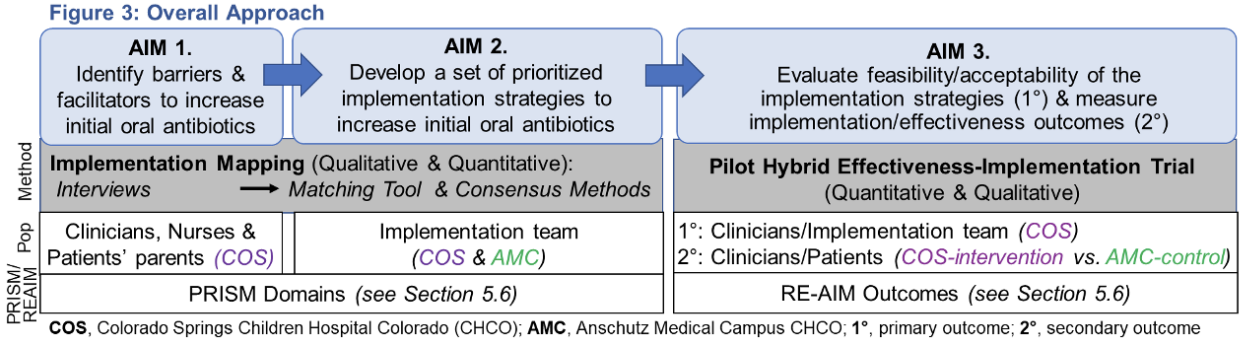


Grant Outline

Grants will be rated on the following criteria: importance (magnitude/scope, alignment with institutional goals), impact (expected outcomes, processes and cost), feasibility (PI and project team, resources, time frame) and approach (QI methodology, multidisciplinary, innovative).

This grant program will NOT support the development of new technologies and the application of them into medical practice (translational research). No grant funds may be used to offset faculty salaries, though funds may be used for consultants and research assistants. These projects should utilize multidisciplinary approaches and make use of QI methodologies (e.g., PDSA cycles) when possible.

Maximum amount awarded: $25K per project

Grant Cycle: 12 months with an option to extend NO longer than an additional 6 months

GRANT PROPOSAL #1

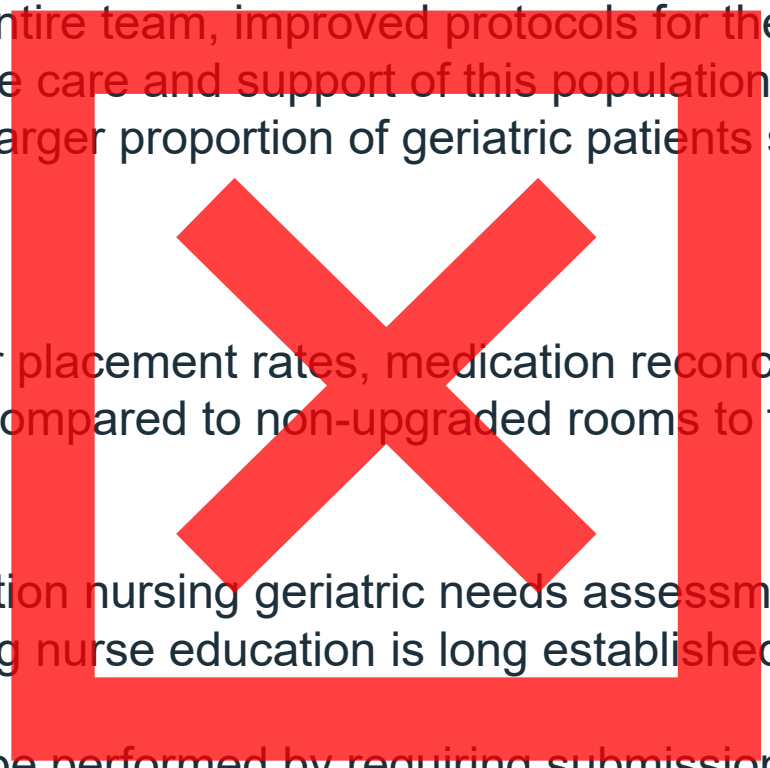
The aim of this project is to implement ERAS protocols for patients undergoing colon surgery at the University of Colorado Anschutz Medical Campus within 12 months. Our goals are to increase the use of multimodal pain management in this patient population from currently <20% to >90%. Furthermore, we aim to improve compliance with Opioid Prescribing Engagement Network (OPEN) guidelines to >90% from our current compliance rates of 50% for colon surgeries. We will be monitoring prescribed analgesics in the preoperative, intraoperative, and postoperative periods to evaluate compliance with the ERAS protocols and with OPEN guidelines for opioid prescriptions.

We will also be evaluating patients' pain scores in postoperative recovery, throughout inpatient stay, and at 48 hours after discharge from the hospital. Chart review will be utilized to evaluate pain scores while patients are hospitalized. Patients will also be called after discharge and questioned about pain score and medication use.

We will complete multiple PDSA cycles to test the implementation of the pathways, evaluate compliance with pathway components, and use what we learn to determine what modifications should be made to the pathways and the process to further refine the ERAS protocol. We will provide feedback to the multi-disciplinary team at the study step of each PDSA cycle and will generate a monthly report of prescribing practices which will be available to providers and will be presented monthly at the Colon Surgery Research Meeting.

GRANT PROPOSAL #2

The primary goal is to improve the quality of care given to geriatric patients treated at UCH. We seek to expand the knowledge base of our entire team, improved protocols for the treatment of elderly patients, and a physical environment optimized to the care and support of this population. In concert, we will launch a geriatric consult our unit, allowing a larger proportion of geriatric patients seen to receive their care in an outpatient setting.



We will also track falls, foley catheter placement rates, medication reconciliation rate, and restraint use. Rates in upgraded geriatric rooms can be compared to non-upgraded rooms to further assess the impact of this intervention.

We will perform pre- and post-education nursing geriatric needs assessment to assess the impact of the education. This process for assessing nurse education is long established in our department.

Tracking of physician education will be performed by requiring submission of CME certificates.

GRANT PROPOSAL #3

The goal of this project moving forward is to continue to collect data, perform statistical analysis of our data set and create a predictive model that will further aid in disposition decision making. Our early data review indicates that patients with longer surgery time and higher intraoperative transfusion requirements are more likely to require an ICU admission.

Additionally, members of our team hypothesize that intraoperative coagulation scores may also predict ICU admission. We need further statistical analysis by a statistician to evaluate our hypotheses. Once we have statistical analysis and we have created a predictive model, we will need time to test the model. In the last 16 months, we have decreased ICU admissions from 58% (ICU stay of more than 3 days 41%, ICU stay 2 days or less 17%) to 36% (ICU stay of more than 3 days 23%, ICU stay 2 days or less 13%).

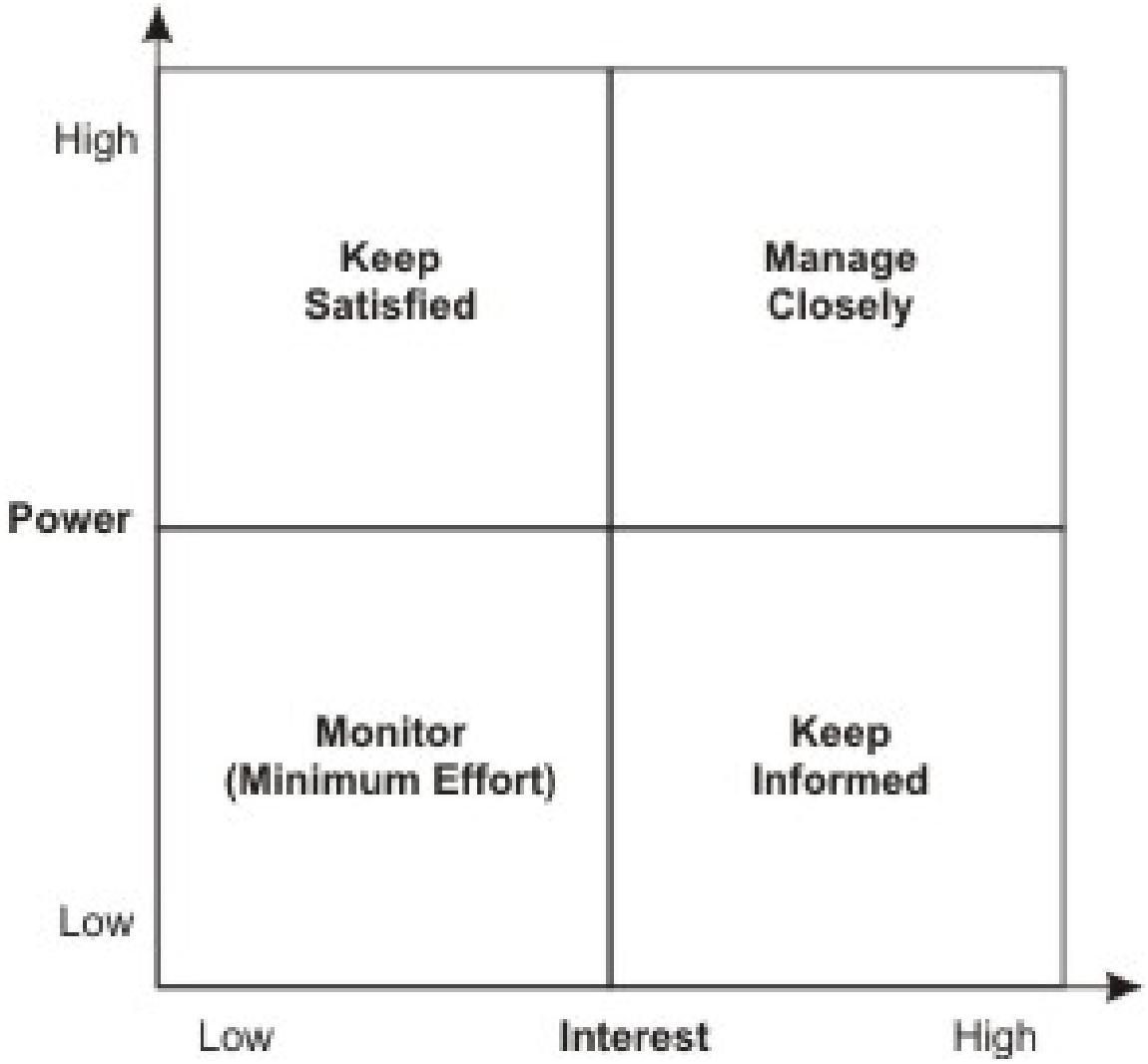
Our next step will be to work with a statistician to determine the key clinical factors that predict the need for an ICU admission post operatively.

Once we have identified these factors, we will create a predictive model and present that model to our collaborative working group for input. We will work together to agree on a predictive model and implement that model. With the creation of a predictive model, we aim to decrease the ICU stays of 2 days or less to less than 10% post-op. Once implemented, we will need at least 9-12 months of data collection with the predictive model to have an adequate data set to compare to our current baseline data.

All grants

- Application
- Internal support (ODC)
- Indirect payments
- Letters of support

#it’scomplicated



Everything we've discussed you could use to seek internal support for your work.

You (still) decide you need to look for external funding…

National

Agency for Healthcare Research and Quality

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

American College of Surgeons

Inspiring Quality: Highest Standards, Better Outcomes

Agency for Healthcare Research and Quality

- **Invests in** research that goes beyond the "what" of health care to understand "how" to make health care safer and improve quality

- **Mission** is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S.

Funding/timelines vary, but often similar application to NIH grants

- R01, K08, R03, R18 etc…

$$$ and prestigious

competitive and arduous

pcori PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Focus on comparative effectiveness & shared decision making but specific programs align more with QI

D&I - Promoting uptake of research findings to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, and others make better-informed health decisions

- $ and prestigious
- LOI first!
- Full grant if invited; competitive; less flexibility

Finding Federal Funding Mechanisms that *fit*

https://reporter.nih.gov/

E.g. Funding mechanisms for antibiotic stewardship

Reducing Overuse of Antibiotics at Discharge: The ROAD Home Trial							
1 R01 HS029482-01	VAUGHN, VALERIE MICHELE SZYMCZAK, JULIA E.	UNIVERSITY OF UTAH	2023	AHRQ	AHRQ	$500,000	View
Promoting Antimicrobial Stewardship and Patient Safety by Implementing Interventions to Evaluate and De-label Penicillin Allergy							
5 I21 HX003280-02	KAKUMANU, SUJANI S	WM S. MIDDLETON MEMORIAL VETERANS HOSP	2023	VA			View
Do inpatient antimicrobial stewardship programs help us in the battle against antimicrobial resistance?							
5 R21 AI128216-02	TARTOF, SARA	KAISER FOUNDATION RESEARCH INSTITUTE	2018	NIAID	NIAID	$205,370	View
Evaluating the Effectiveness of Alternative Implementation Strategies for Antibiotic Stewardship							
1 R01 HS025175-01	SAMORE, MATTHEW H	UNIVERSITY OF UTAH	2017	AHRQ	AHRQ	$500,000	View
Improving Antibiotic Stewardship During The Treatment of Skin and Soft Tissue Infections in The Emergency Department: A Human Factors and Systems Engineering Approach							
5 K08 HS024342-02	PULIA, MICHAEL SANTINO	UNIVERSITY OF WISCONSIN-MADISON	2017	AHRQ	AHRQ	$160,164	View

Local

CEPS Small Grant Program

$25K faculty, $10K residents/fellows

LOI Deadline: ~April 2026

Take Home Points: Finding QI grant funding

- There are national and local opportunities for QI grants
- Spend time on websites and sign up for emails
- Be **creative with search terms** (think about overlap between QI and D&I)
- NIH reporter - find federal agencies that funded similar topics
- Think about **fit** (mission/priority areas & prior funded projects) and **logistics** (pros/cons)
- When in doubt re fit, reach out

QI and the IRB

Learning Objectives

1

Describe differences and similarities between QI vs. Research

2

Recognize when an IRB application should be submitted for a project

3

Identify institutional specific considerations for QI

“QI is an integral part of good clinical practice and is designed to bring about **immediate improvements in health care in local settings**.

In contrast... Human subjects research is NOT a necessary, integral element of good clinical practice… human subjects research aims to **generate new, generalizable, and enduring knowledge about health.**”

Grady, C. Ann Intern Med 2007

	Human Subjects Research (HSR)	Quality Improvement
Purpose	Designed to contribute to generalizable knowledge	Designed to implement knowledge, assess/improve process or program within an institution compared to established standards
Design		
Benefits		
Risks		
Participant Obligation		
Goal		
Analysis		
Dissemination of results		
IRB		

Is this efficacious?	Research
How can I apply this effective intervention consistently?	QI
Are individuals randomized into intervention groups?	Research…?
Is there a new treatment?	Research
Is there deliberately delayed feedback of data in order to avoid biased interpretation of data?	Research
Does the project involve individuals with no ongoing commitment to the local institution?	Research
Is there greater than minimal risk to the patient as a result of the intervention?	Research

There is overlap…

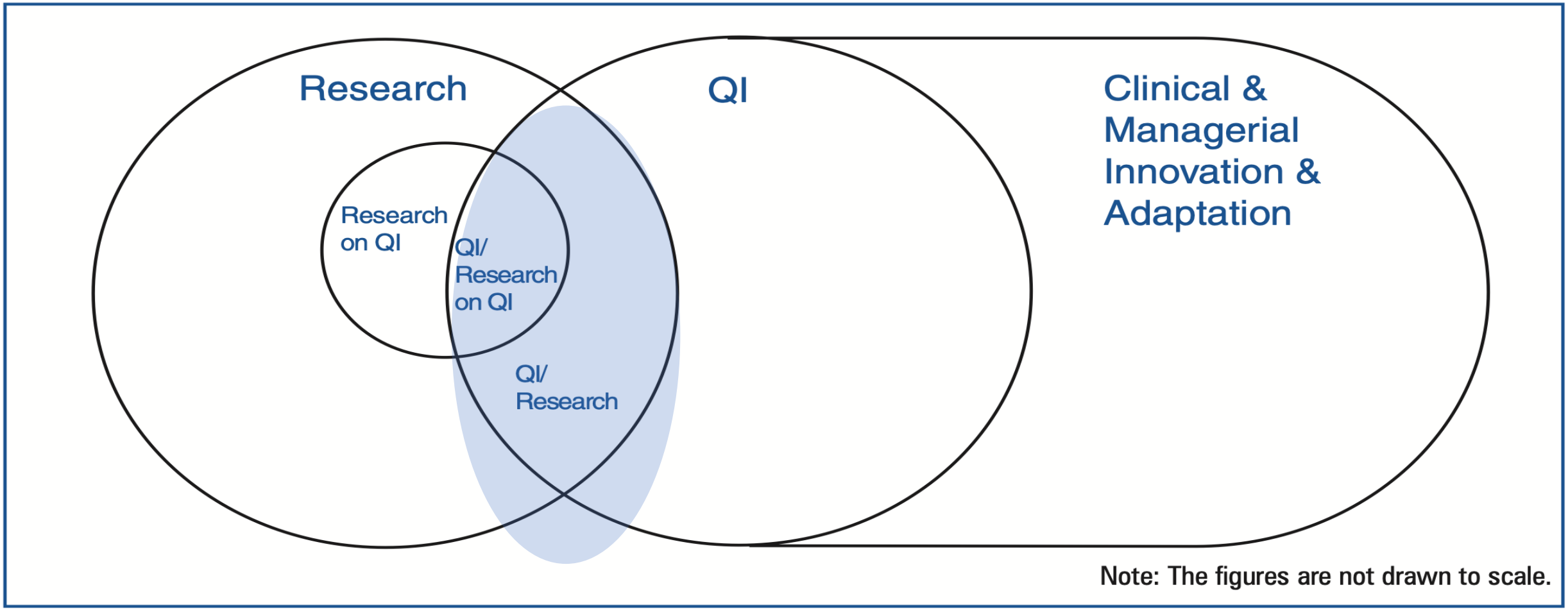


Figure 1.

What does “generalizable” mean?

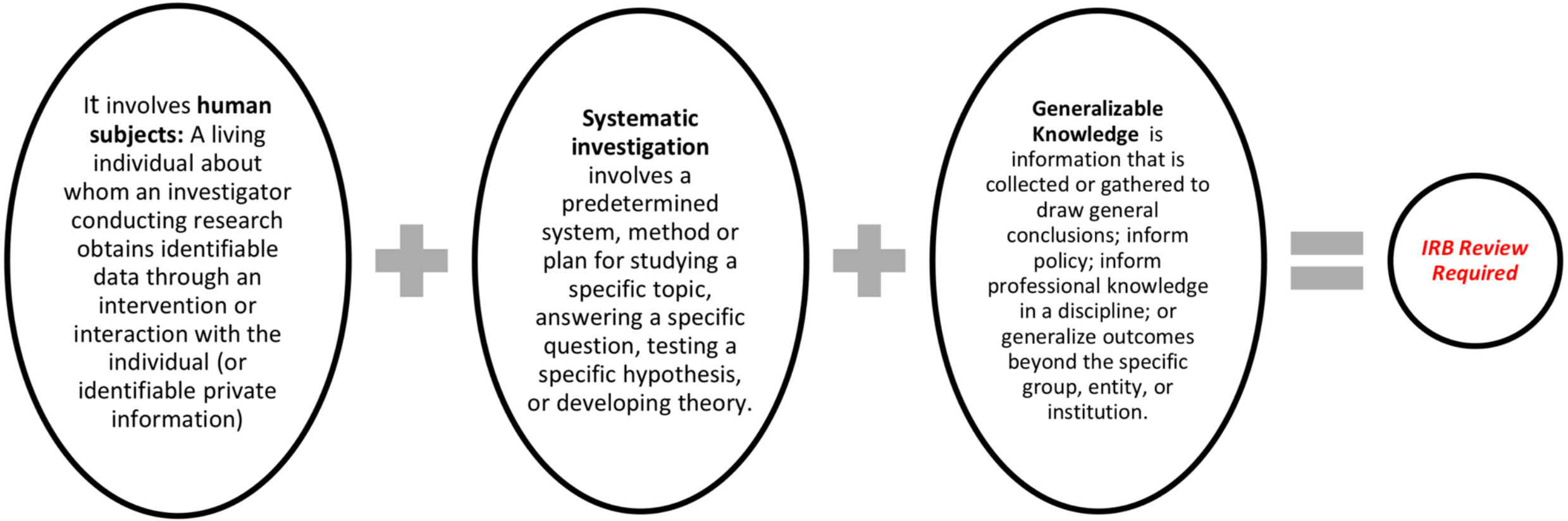
Sometimes the intent is to focus on a local institution, but the knowledge generated can be applied elsewhere (Hastings Report)

- If QI project designed scoped to be narrow
  - Not research

- If QI project is designed to improve local care and produce knowledge that could be used other places
  - QI + Research

Projects considered “research” **MUST** be approved by an IRB

Am I conducting human subjects research?



If an activity meets the definition of human subject research under 45 CFR 46.102(d), then HHS regulations apply, and IRB review is required.

Colorado Multiple Institutional Review Board (COMIRB)

"To protect human research participants' rights and welfare and to facilitate ethical research."

Do I need an IRB in order to publish QI?

Office of Human Research Protections (OHRP) response:

"Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of non-research activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results."

OHRP QI FAQ's http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/index.html

Categories of submission responses from IRB

Not HSR: The QI project is NOT research

- IRB submission only for formal determination from IRB that it is not research
- Subsequent publication should clearly state that it is QI and not research

Not HSR: The QI project IS research, but no human subjects are involved

Exempt: The QI project is research, but meets one of the exempt criteria under the regulations

Non-exempt: Expedited vs. Full Board. The QI project IS research and does not meet exempt or not HSR criteria

This study was approved by the Human Subjects Institutional Review Board (HSIRB) of the University **** and was exempt from patient consent. The work was deemed a quality improvement project and NOT a study on human subjects.

The study met the criteria for exemption from ethics review

COMPARI	PUBLICATION	This table may also be used as a tool to conduct and document a self-evaluation of the project. In that case, the project leader should indicate above where the project fits on each row. If any of the boxes in the research column are checked then the project must be submitted to COMIRB for review and approval. If the tool indicates that this is quality improvement (QI) or program evaluation (PE) only, complete the rest of this form, obtain any necessary signatures, and keep this in your project records.
Use the ch any of the research p research is		**Acknowledgment**
		I have appropriately used this tool to evaluation my project entitled: _____
FUNDING		By my signature below, I affirm that this project meets the definition of:
		Circle the appropriate term: **Quality Improvement** **Program Evaluation**
INTENT	MANDATE or ENDORSEMENT	I certify that I will conduct my project in compliance with all federal, state and local laws and policies. If during the course of the project it is amended in such a way as to meet the definition of human subject research under 45 CFR 46 or 21 CFR 56 then I understand that I must submit to COMIRB for review prior to continuing the project.
DESIGN		_____ _____ _____ _____ Signature of Project Leader Date Signature of Mentor *(if applicable)* Date
		I have reviewed this project proposal and determine that meets the criteria for quality improvement or program evaluation as outlined above and is an appropriate project to be conducted within this Division/ Department/ School/.
	IMPACT	_____ _____ _____ Signature of Appropriate Authority (*or their designee*) Title/Position Date
	POPULATION	QA Program Evaluation Research Tool CF-195, Effective 6-5-20

Case 1

In critically ill adult patients, early mobilization with physical therapy has been shown to reduce delirium, hospital length of stay and in one study mortality.

- AN plans to study the effect of a standing ICU PT order with the goal to increase the proportion of patients seen by physical therapy on HD#1 from 30% to 60% over the next 6 months.
- She additionally plans to track duration of mechanical ventilation, hospital length of stay, and mortality for these patients.
- Additionally, as it is more difficult for patients with delirium to work with PT, she intends to treat half of the patients with Haldol and assess whether those patients are able to work with PT more frequently

Case 2

There are no standardized and validated thromboprophylaxis risk tool established in the pediatric population. Despite this, local venous thromboembolism (VTE) prophylaxis guidelines exist at most major pediatric tertiary care centers

- JL performs an analysis and finds that the hospital VTE prophylaxis recommendations are only followed 55% of the time. She assembles a team to increase adherence to the recommendations to 80% in the next 4 months
- During this time, a 6 yo patient has an intracranial bleed while on recommended enoxaparin prophylaxis. JL would like to revamp the current prophylaxis guidelines to only recommend prophylaxis in children $\geq$ 12 yo
- She is not sure if this will increase the rate of VTE in the < 12 yo age group. To study this, she develops a fixed protocol with the goal to study local VTE rates in age groups before and after this change. She now intends to publish the results since the pediatric VTE body of literature is lacking.

Other QI regulating agencies on campus

Denver Health	Quality Improvement Review Committee (QuIRC)
University	COMIRB No additional procedures needed
VA	COMIRB + local VA approval
Children's Colorado	Organizational Research Risk and Quality Improvement Review Panel (ORRQIRP)

When in doubt, contact the IRB

Colorado Multiple Institutional Review Board (COMIRB)

Research Administration

Get Help | Submission Guides | Forms | Guidance and Policies | Training | IRB Members | About COMIRB

COMIRB is the IRB for the University of Colorado Denver | Anschutz Medical Campus and affiliates

Register for Office Hours

University of Colorado **Anschutz Medical Campus** | **IHQSE**

COMIRB Forms

Most Used Forms

Applications

Protocol Templates

Consent Templates

HIPAA

Approved Studies

Up-to-date COMIRB forms are listed below.

Most Used Forms

- IRB Application Form
- Secondary Research Application
- Protocol Template
- Change Form

IRB Application Form


Anschutz
IHQSE