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
2. Manuscript Writing

BREAK

3. QI Grants: Writing and Sources
4. IRB: QI vs. Research

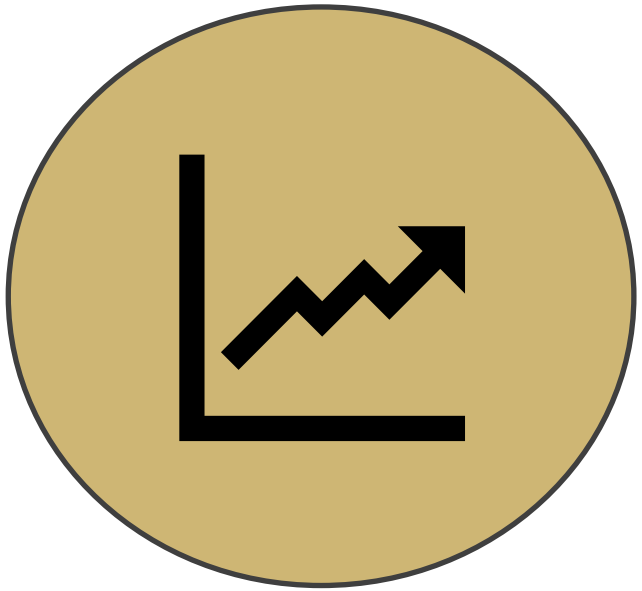
Learning Objectives

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. Recall the existence of SQUIRE 2.0 guidelines
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

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

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

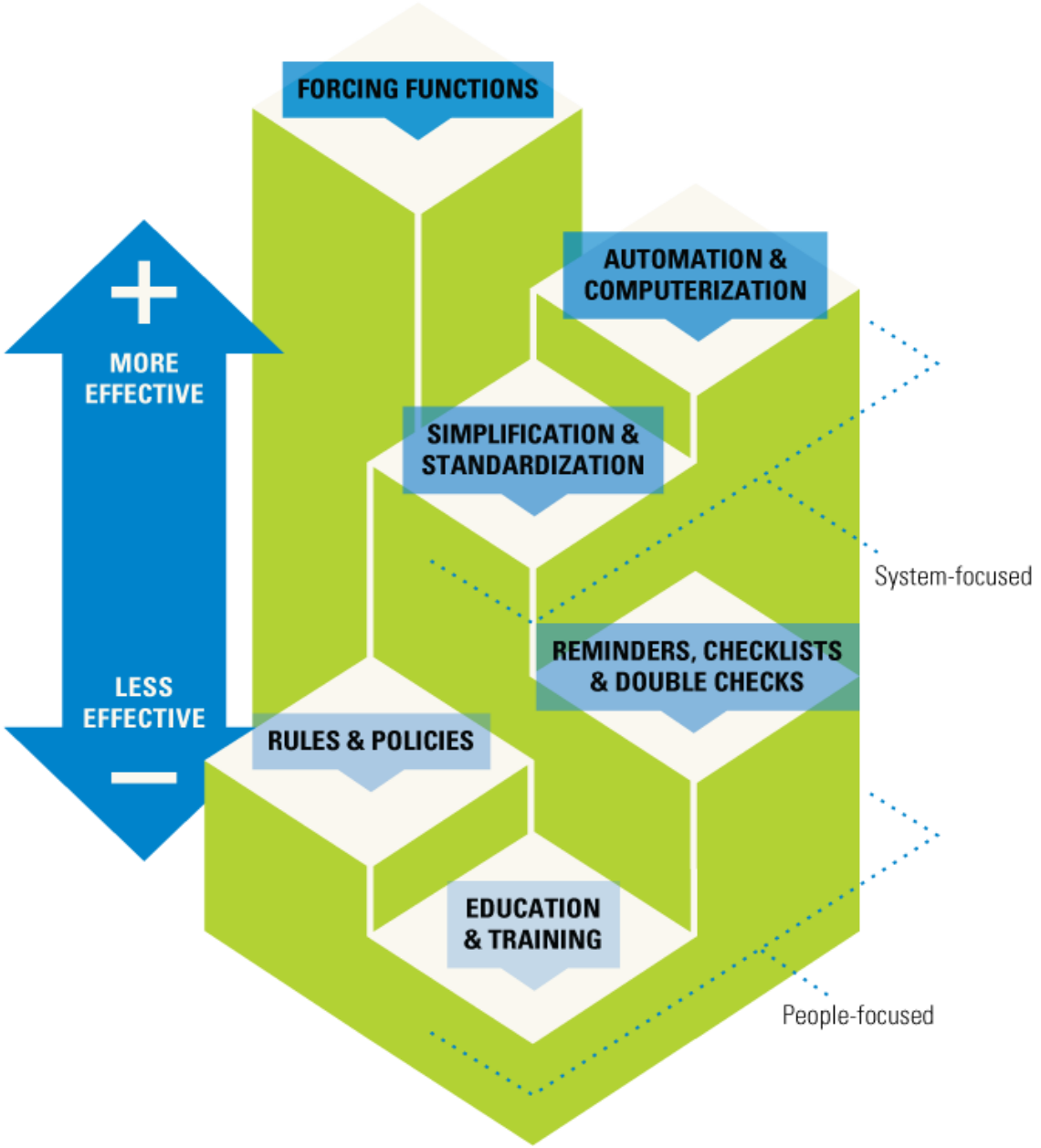
Limit Sustainability

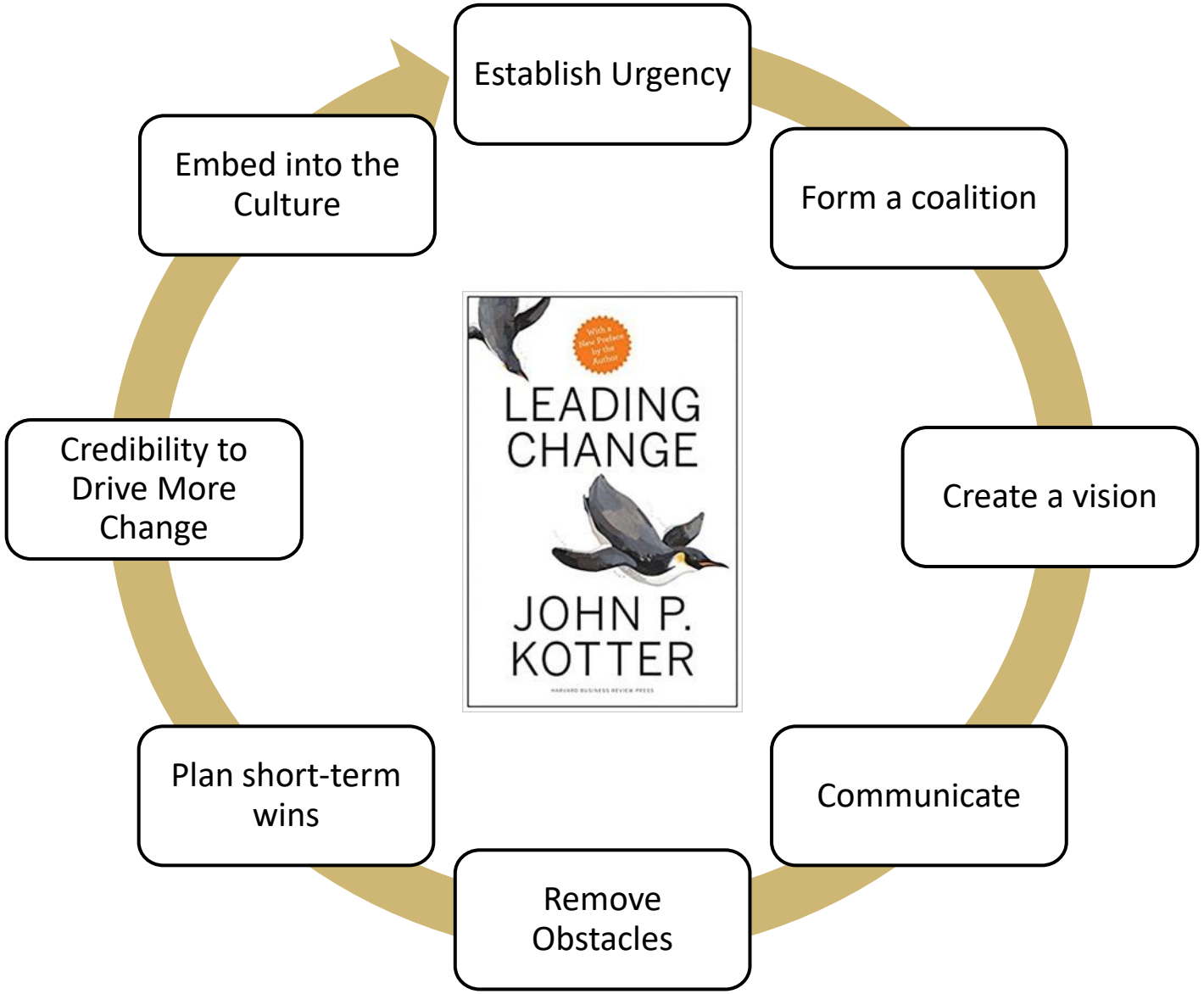
Lack of evidence of impact on bottom line

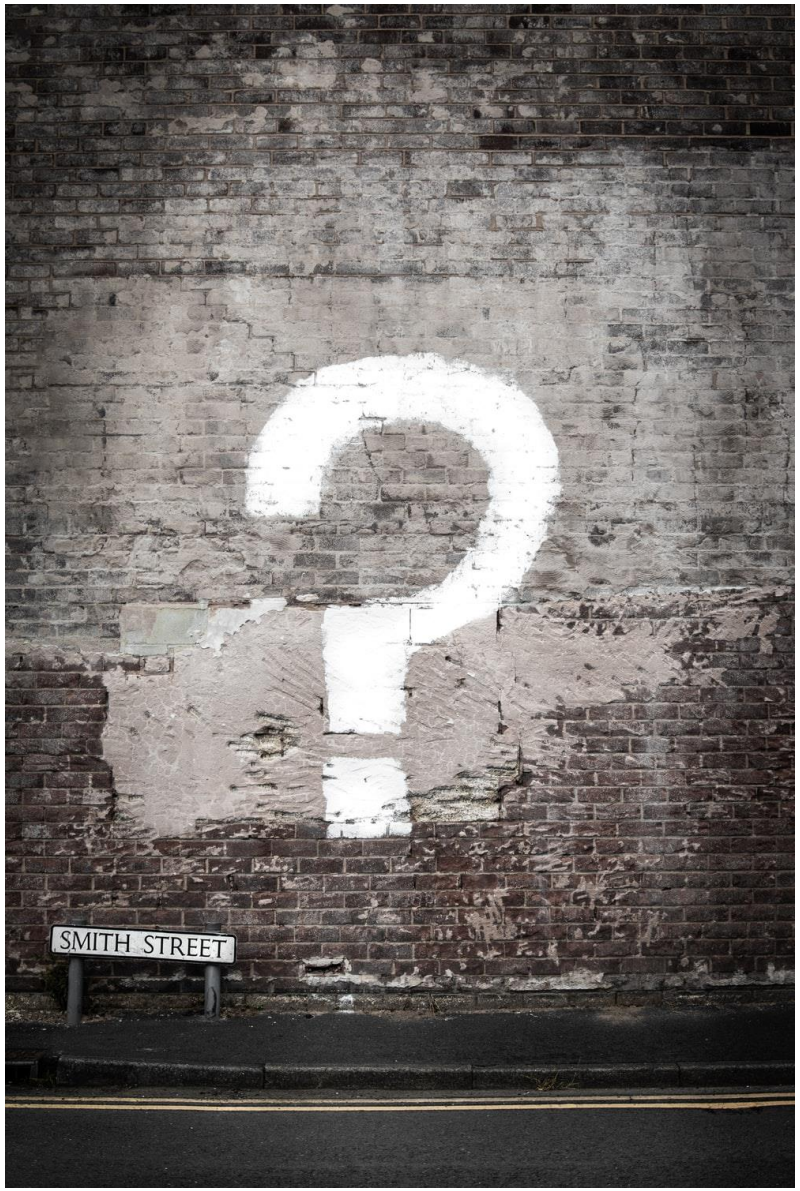
Data roadblocks

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

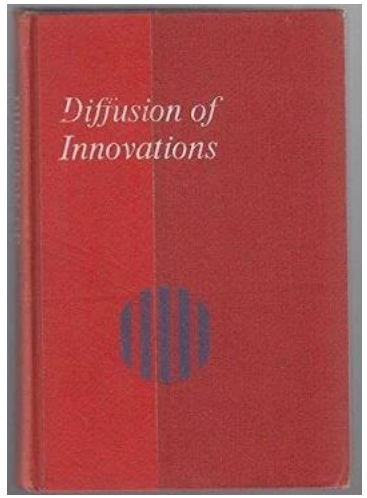

FORCING FUNCTIONS
AUTOMATION & COMPUTERIZATION
SIMPLIFICATION & STANDARDIZATION
REMINDERS, CHECKLISTS & DOUBLE CHECKS
RULES & POLICIES
EDUCATION & TRAINING
MORE EFFECTIVE
LESS EFFECTIVE
System-focused
People-focused


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

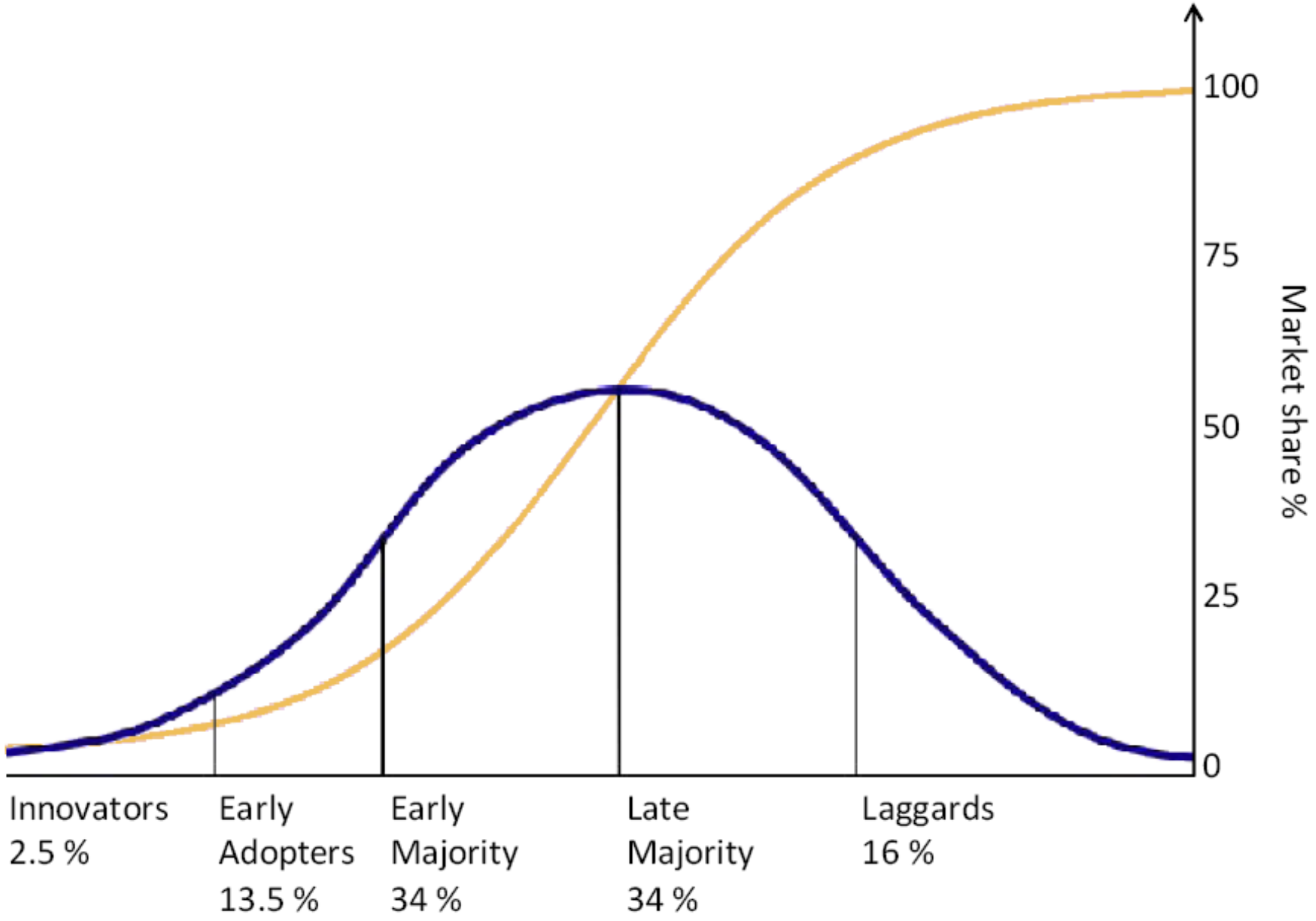


How do you know when something will be sustained?

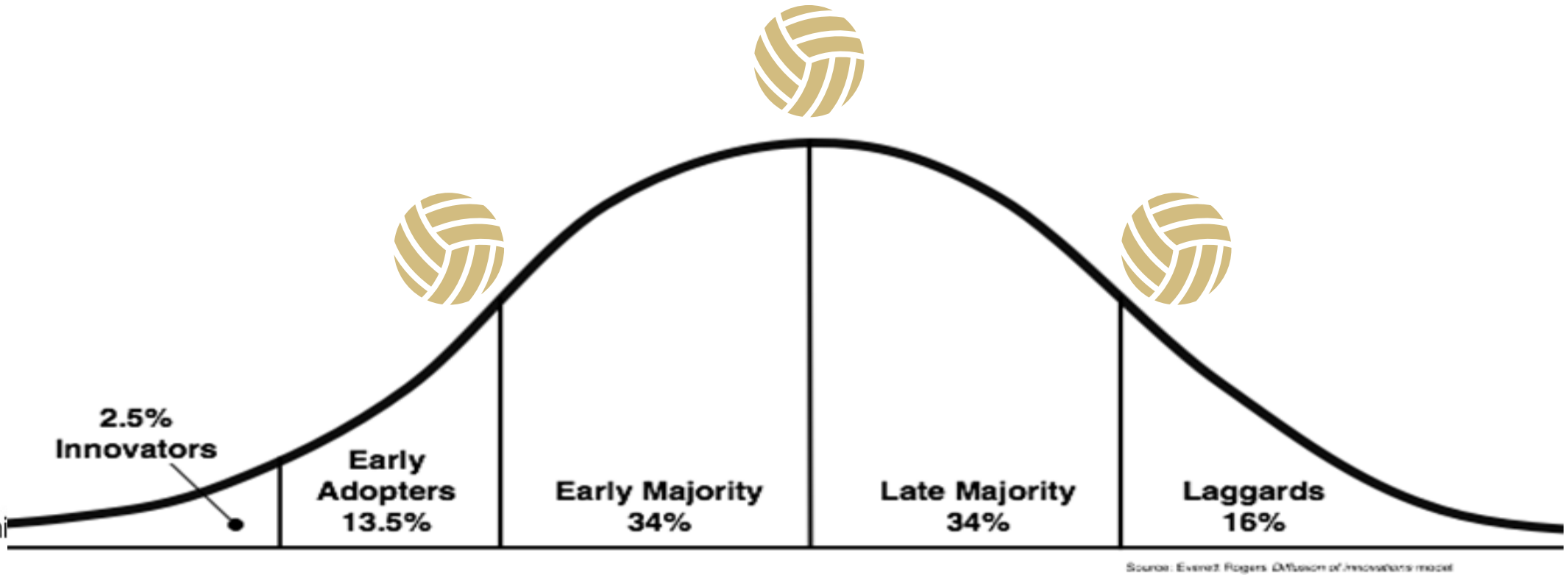
Can you predict it?



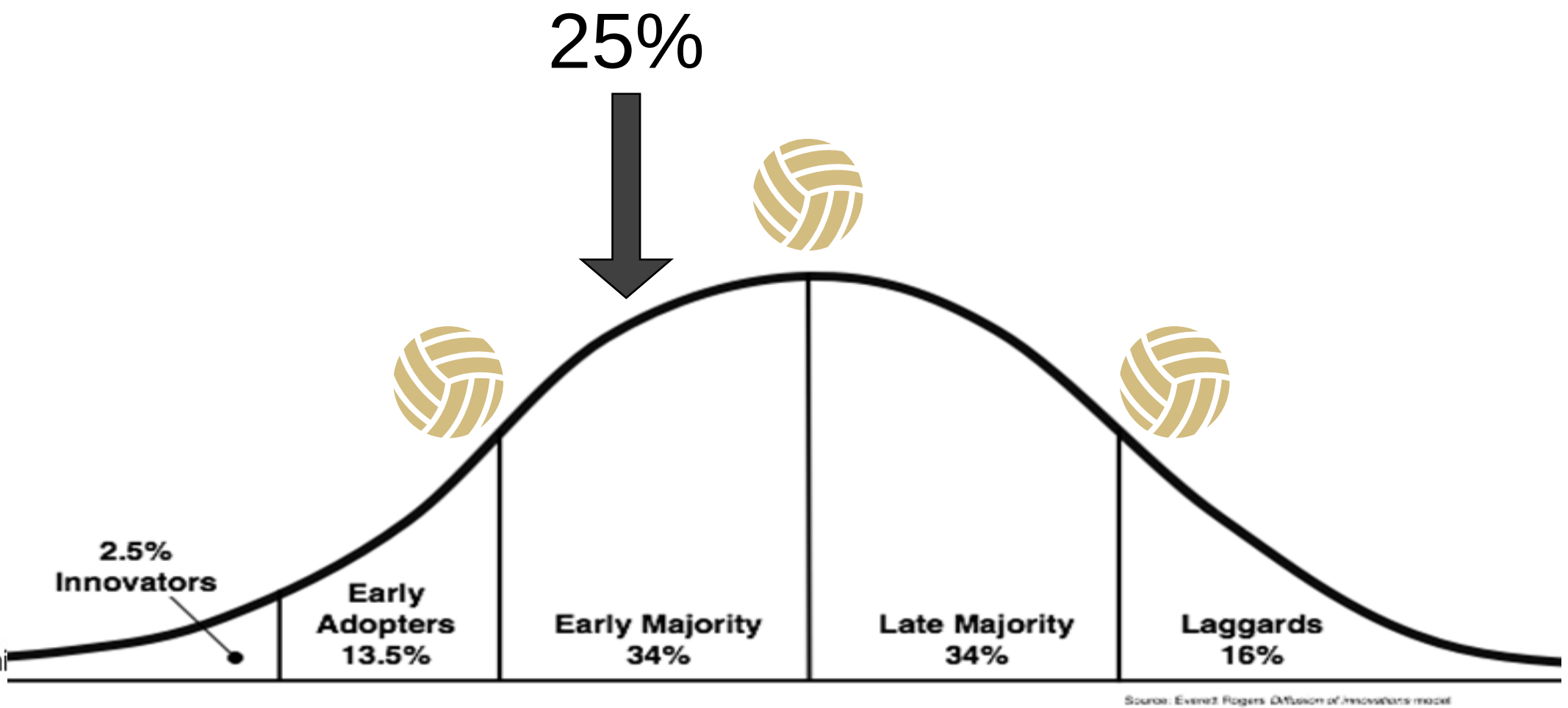
Everett Rogers, 1962



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



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



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

Stages of Individual Adoption

1. Knowledge: exposure but no active role in seeking more information.

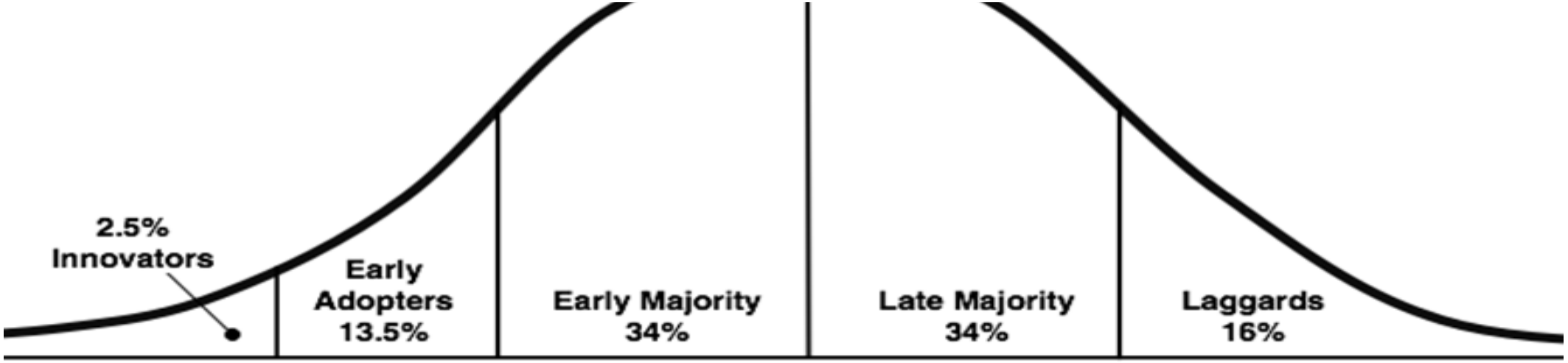
2. Persuasion: seeks more information.

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 Adopters



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

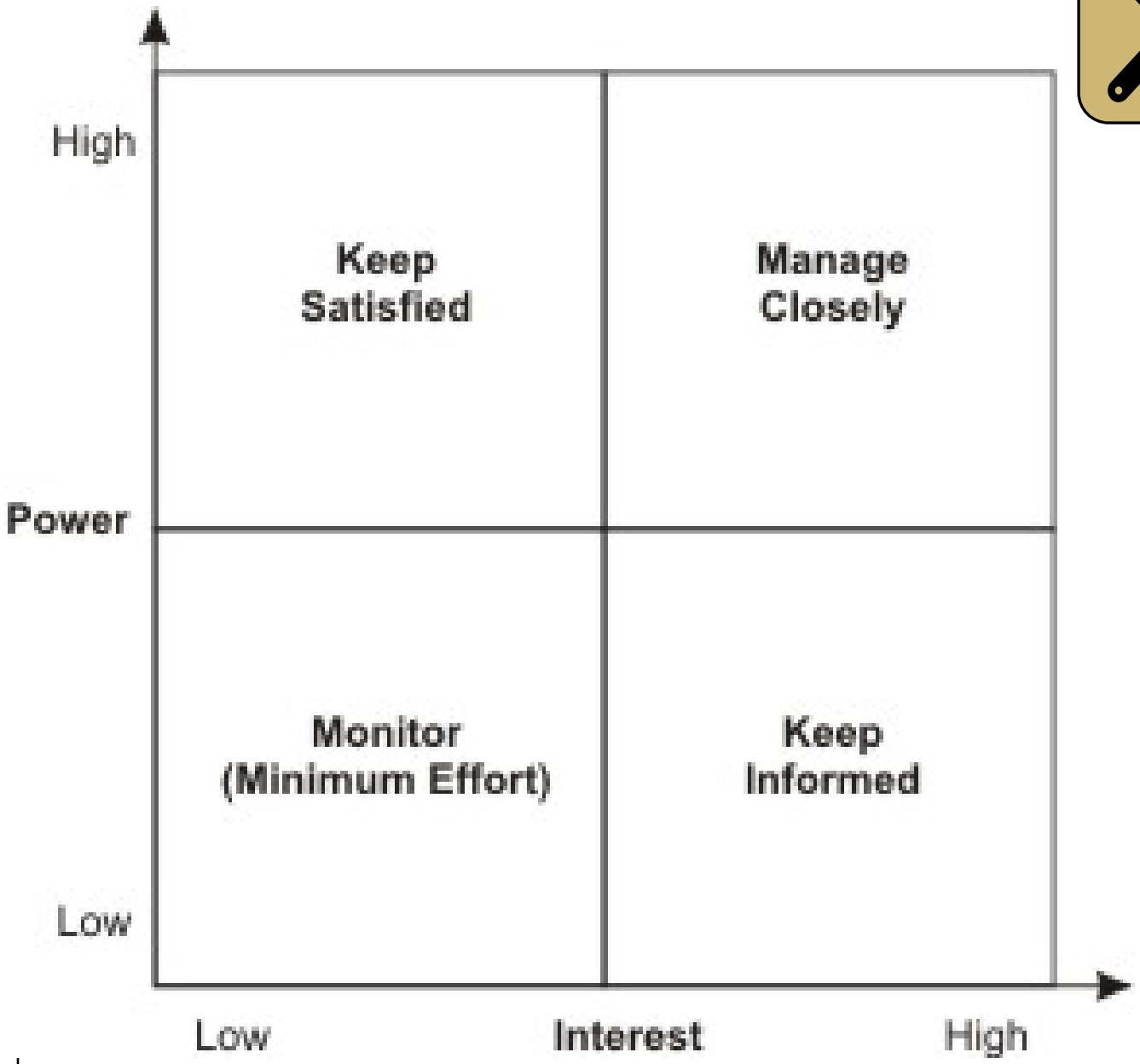
Key Partner Map

née Stakeholder

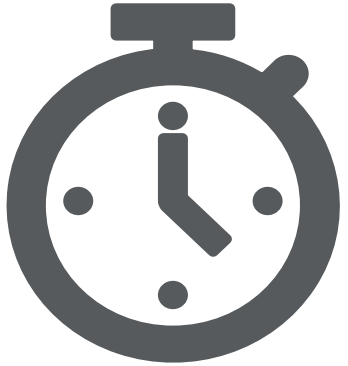
Step 1: Identify

Step 2: Prioritize

Step 3: **Understand**



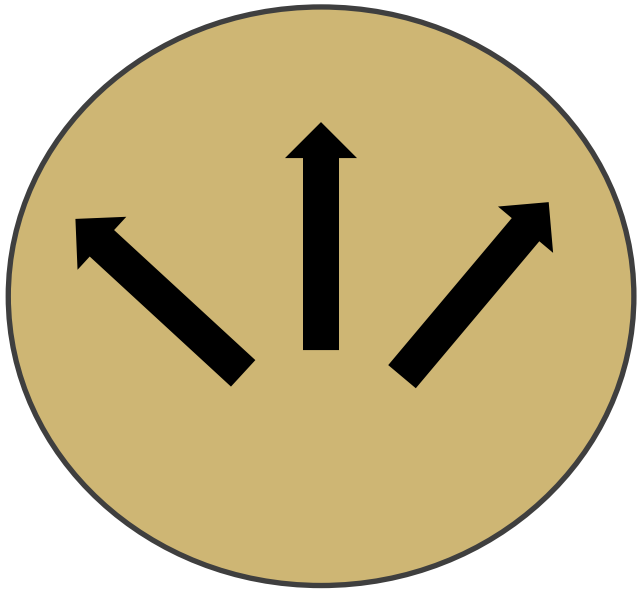
Breakout #1



15 minutes

1. Introduce yourselves and your current QI work

2. Determine where your key partners they lie on the Diffusion of Innovation curve



Spread

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

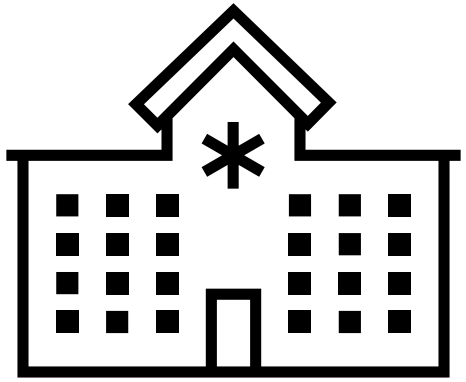
https://www.ahrq.gov/learning-health-systems/about.html


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

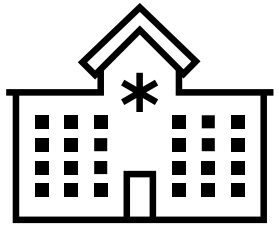
50% of non-OR, non-MTP, inpatient transfusions **DID NOT** meet guidelines



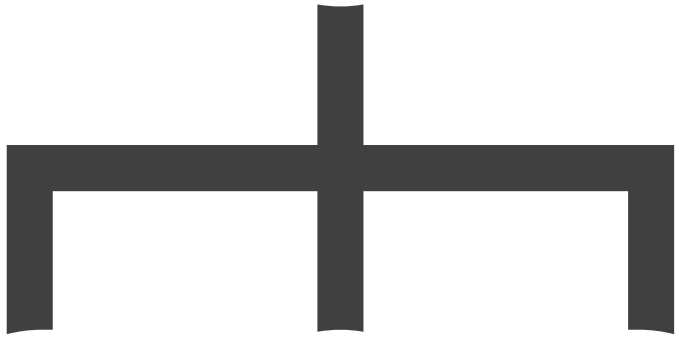
University of Colorado Hospital (UCH)

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.



UCH



Order (Set) Modify

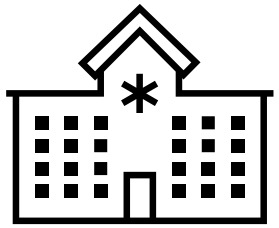
WINNER!

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

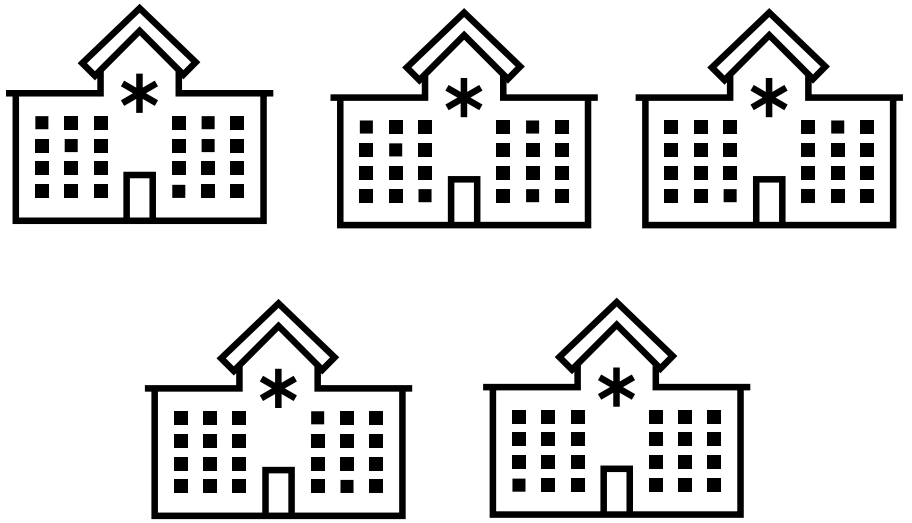
Order (Set) Modify

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

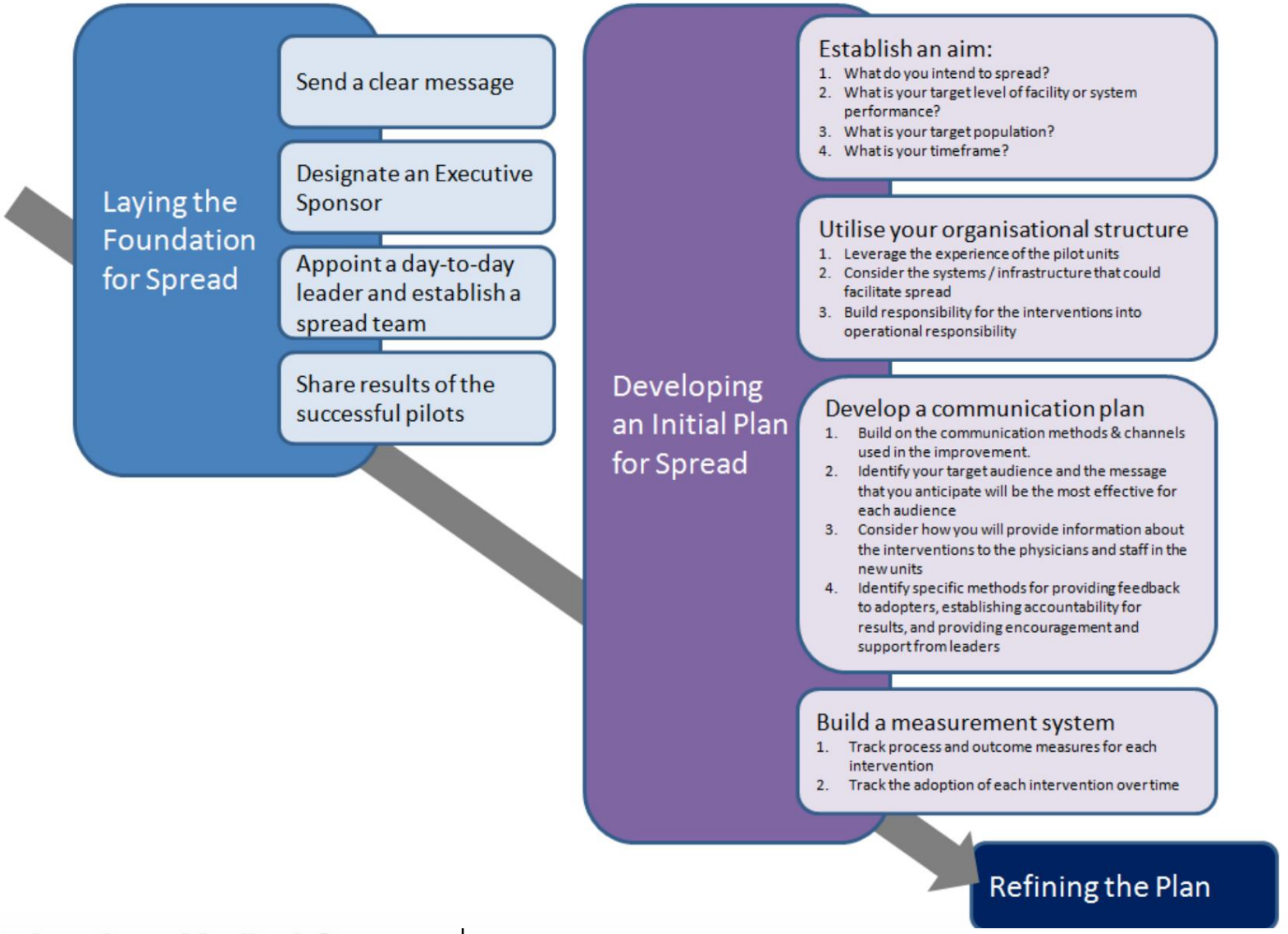


Figure 1: Figure created to visually summarise the 100,000 Lives Campaign

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)

NHS Improving Quality

QI Manuscript Writing

SQUIRE

Promoting Excellence in Healthcare Improvement Reporting

Standards for
Quality
Improvement
Reporting
Excellence

- Framework for reporting system level work to improve quality, safety and value
- Can be used during the project design phase

SQUIRE

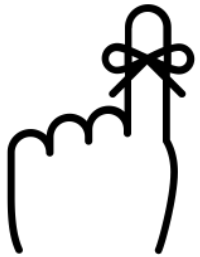
Promoting Excellence in Healthcare Improvement Reporting

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

Title

Describes an ***initiative to improve*** healthcare which includes:

- *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 if looking for your paper.

BRIEF REPORT

Effectiveness of SIESTA on Objective and Subjective Metrics of Nighttime Hospital Sleep Disruptors

Vineet M Arora, MD MAPP[1]*; Nolan Machado, BA[2]; Samantha L. Anderson, BA[1]; Nimit Desai, MD[1]; William Marsack, MSN[1]; Stephenie Blossomgame, MSN[1]; Ambrosio Tuvilleja, RN[1]; Jacqueline Ramos, RN[1]; Mary Ann Francisco, MSN[1]; Cynthia LaFond, PhD, RN, CCRN[3]; Edward KY Leung, PhD[3]; Andres Valencia, BA; Shannon K Martin, MD, MS[1]; David O Meltzer, MD, PhD[1]; Jeanne M Farnan, MD, MHPE[1], Jay Balachandran, MD[4], Kristen L Knutson, PhD[5], Babak Mokhlesi, MD, MSc[1]

[1]University of Chicago Medicine, Chicago, Illinois; [2]Pritzker School of Medicine, Chicago, Illinois; [3]Children's Hospital Los Angeles, Los Angeles, California; [4]Columbia-St. Mary's, Mequon, Wisconsin; [5]Northwestern University, Chicago, Illinois.

Abstract

2 PURPOSES:

- Summarize **all key** information
- Indexing/searching

STRUCTURE:

- Background about the local problem
- Methods
- Interventions
- Results
- Conclusions

We created Sleep for Inpatients: Empowering Staff to Act (SIESTA), which combines electronic "nudges" to forgo nocturnal vitals and medications with interprofessional education on improving patient sleep. In one "SIESTA-enhanced unit," nurses received coaching and integrated SIESTA into daily huddles; a standard unit did not. Six months pre- and post-SIESTA, sleep-friendly orders rose in both units (foregoing vital signs: SIESTA unit, 4% to 34%; standard, 3% to 22%, $P < .001$ both; sleep-promoting VTE prophylaxis: SIESTA, 15% to 42%; standard, 12% to 28%, $P < .001$ both). In the SIESTA-enhanced unit, nighttime room entries dropped by 44% (−6.3 disruptions/room, $P < .001$), and patients were more likely to report no disruptions for nighttime vital signs (70% vs 41%, $P = .05$) or medications (84% vs 57%, $P = .031$) than those in the standard unit. The standard unit was not changed. Although sleep-friendly orders were adopted in both units, a unit-based nursing empowerment approach was associated with fewer nighttime room entries and improved patient experience.

Journal of Hospital Medicine 2019;14:38-41.

Aim: Examine the effectiveness of SIESTA, a sleep protective program, on medical inpatient units

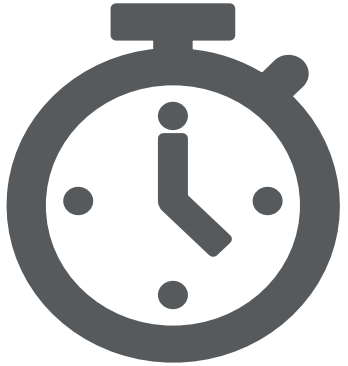
Intervention:

- Program consisted of electronic nudges and interprofessional education.
- Two medical inpatient units (one SIESTA-enhanced unit, one control)

Results:

- SIESTA integrated unit patients reported less nighttime sleep interruptions and better patient experience
- Both units noticed an increase in sleep friendly orders

Breakout #2



15 minutes

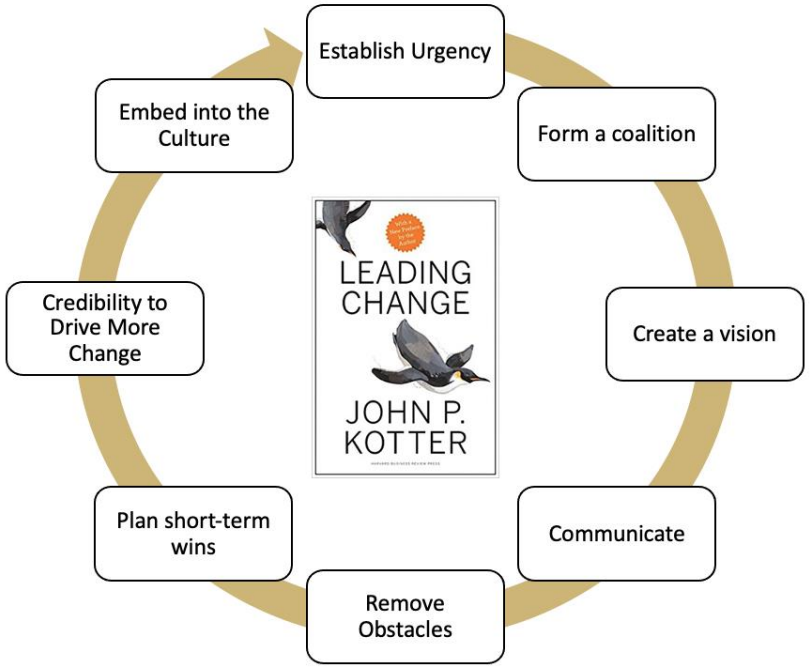
1. 5 min – craft a title for your manuscript/poster
2. Put in the the chat for others to read.
3. Share and give feedback to each other

Introduction

<u>Answer these questions:</u>

- What is the problem?
- Why is it important (who cares)?
- What is the rationale for why it exists?
- What is your Aim?

Can (and should) mimic your elevator pitch!



1. Establish Urgency

3. Create a Vision

4. Communicate

Introduction (SIESTA)

What is the importance?

- Hospitalizations are not restful
- Sleep deprivation is associated with poorer health outcomes
- American Academy of Nursing “Choosing Wisely Campaign recommends reduction in unnecessary nocturnal care

Rationale?

- Interventions to improve inpatient sleep are not widely used
- Targeting routine nighttime disruptions could be a cost-effective way to improve patient sleep

AIM?

- Evaluate a protocol called SIESTA and test its effectiveness in decreasing nocturnal sleep disruptors

Methods: What and how did you do it?

Context of the Intervention	Setting and participants
Intervention(s)	Detailed description of the implementation strategy Theory for why the intervention was chosen
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)	

Methods

What did you do?

Context of the Intervention

Two 18 room general medicine units in Chicago. Included physicians, nurses, awake English-speaking patients with intact

TABLE. **Demographics of Patients (N = 1,083)**

Characteristic	SIESTA-Enhanced Unit Pre n = 329, 30.3%	SIESTA-Enhanced Unit Post n = 293, 27.1%	Standard Unit Pre n = 252, 23.3%	Standard Unit Post n = 209, 19.3%
Age (years) Mean, SD	54.3, 19.1	55.1, 20.8	59.0, 19.2	62.3, 16.1
Gender (% female)	58.6%	60.1%	57.9%	54.6%
Length of Stay (days) Median (IQR)	4 (2-7)	5 (2-8)	4 (2-8)	5 (3-8)
Race (% African- American)	64.4%	62.8%	67.1%	75.1%
Outcomes				
Sleep-Promoting Order Set Usage				
Vital Signs n = 168 uses	11, 6.5%	104, 62%	7, 4.2%	46, 27.4%
Heparin n = 147 uses	23, 15.6%	73, 49.7%	16, 10.9%	35, 23.8%
Patients Reporting a Sleep Disruption n = 201 surveyed	48, 59%	11, 34%	27, 56.3%	21, 56.7%

No major differences in demographics among patients admitted before and after SIESTA in each unit were observed. Although the difference is clinically small, patients admitted to the standard unit were older than those admitted to the SIESTA-enhanced unit in both periods ($P < .05$).

Methods

What did you do?

Context of the Intervention	Two 18 room general medicine units in Chicago. Included physicians, nurses, awake English-speaking patients with intact cognition
Interventions	In SIESTA enhanced unit: Nursing education/empowerment about sleep interventions, Physician education, EHR changes (behavioral nudges in EPIC, batched lab orders for non sleep hours, changing heparin ppx regimen for BID), signs/materials, identification of patients at nursing huddle
Measurement of the intervention impact	SiESTA related orders in EPIC Nocturnal room entries (Hand hygiene trackers and heat sensors Patient reported sleep disruptors survey
Analysis	Objective and Subjective measures of sleep disturbances pre/pc intervention via multivariable logistic regression
Ethical review (IRB)	Not required for this journal's brief report

Methods

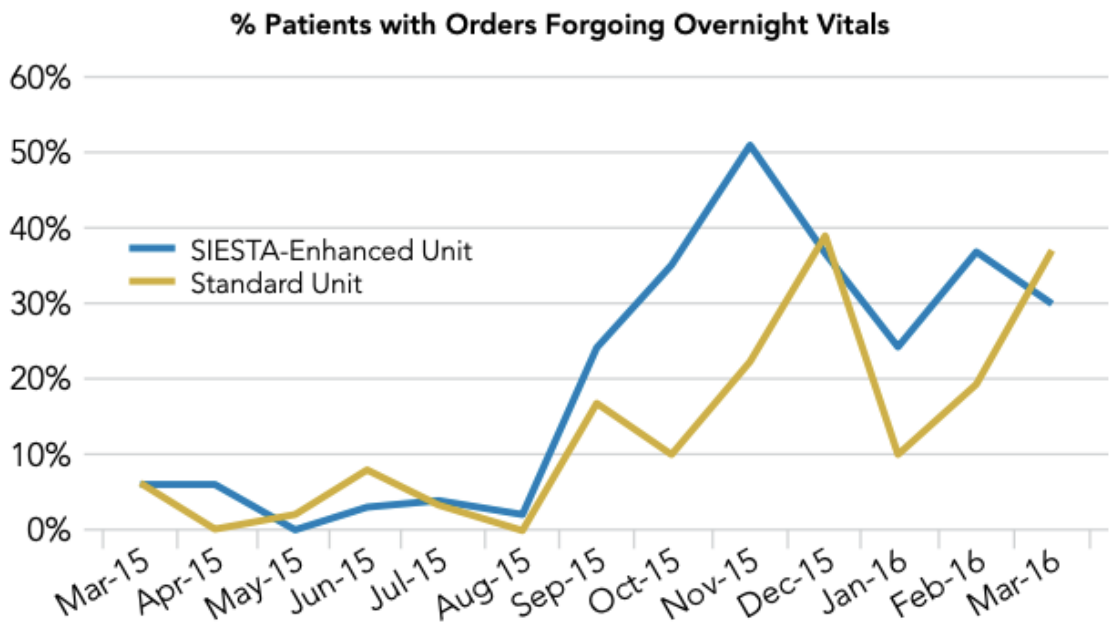
What did you do?

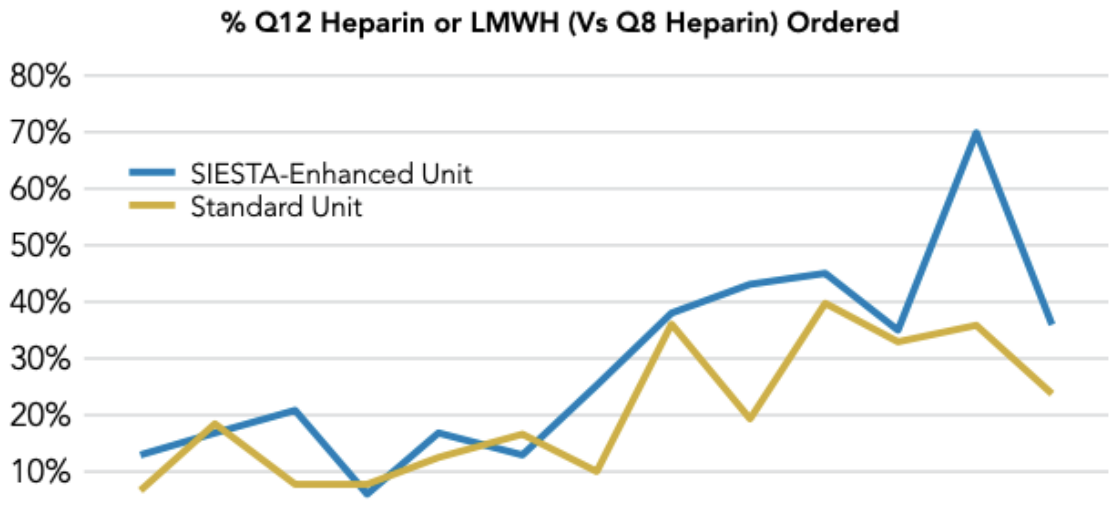
All providers

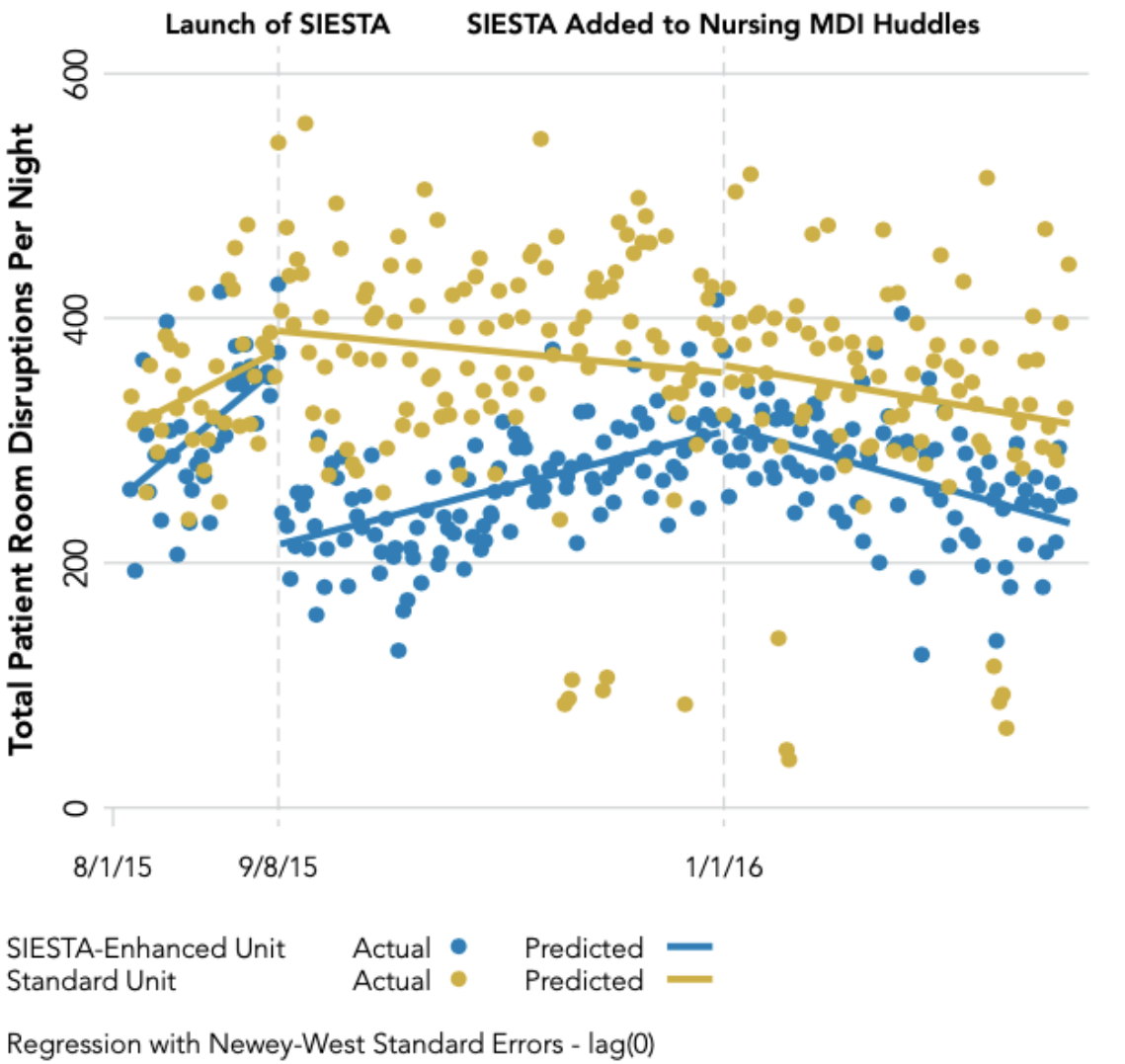
Order (Set) Modify	Order (Set) Modify + **In-line CDS**	Order(Set) Modify + **Interruptive CDS**

Results: What did you find?

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


% Patients with Orders Forgoing Overnight Vitals
60%
50%
40%
30%
20%
10%
0%
SIESTA-Enhanced Unit
Standard Unit
Mar-15
Apr-15
May-15
Jun-15
Jul-15
Aug-15
Sep-15
Oct-15
Nov-15
Dec-15
Jan-16
Feb-16
Mar-16


% Q12 Heparin or LMWH (Vs Q8 Heparin) Ordered
80%
70%
60%
50%
40%
30%
20%
10%
SIESTA-Enhanced Unit
Standard Unit


Launch of SIESTA
SIESTA Added to Nursing MDI Huddles
Total Patient Room Disruptions Per Night
600
400
200
0
8/1/15
9/8/15
1/1/16
SIESTA-Enhanced Unit Actual Predicted
Standard Unit Actual Predicted
Regression with Newey-West Standard Errors - lag(0)

Discussion: What does it mean?

1	Key Results summary relevant to study objectives
2	Interpretation of associations between intervention and outcomes. Opportunity costs.
3	Reasons for differences observed/ comparison to other projects
4	Impact, policy implications
5	Limitations, strengths, future studies

1	Key Results summary relevant to study objectives
2	Interpretation of associations between intervention and outcomes. Opportunity costs
3	Reasons for differences observed/ comparison to other projects
4	Impact, policy implications
5	Limitations, strengths, future studies

SIESTA can be effectively implemented in this context decrease sleep disruptions as well as increase patient satisfaction

Altering default settings in EHR influences physician behavior, but full culture change requires multiple types of interventions

Limitations: Non-randomized, single center, providers worked in both units, low survey response rates, could not measure objective sleep duration.

Strengths: robust data, resourceful use of available technology, multidisciplinary, focus groups

Future studies- extending to other units.

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

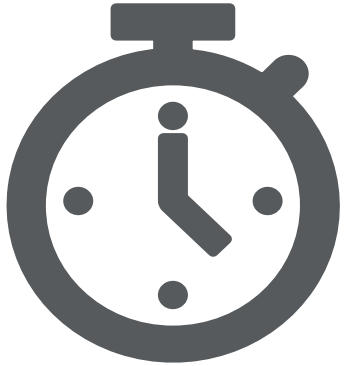
Insert your title and/or abstract here: (or, click here to search using keywords)

Scramble | Clear | Show extra options

Find journals | Find authors | Find articles

Every article has a home…

Breakout #3



15 minutes

Identify ONE target journal OR conference you will submit to.

NOTE: dates of conference, location, deadlines, etc.

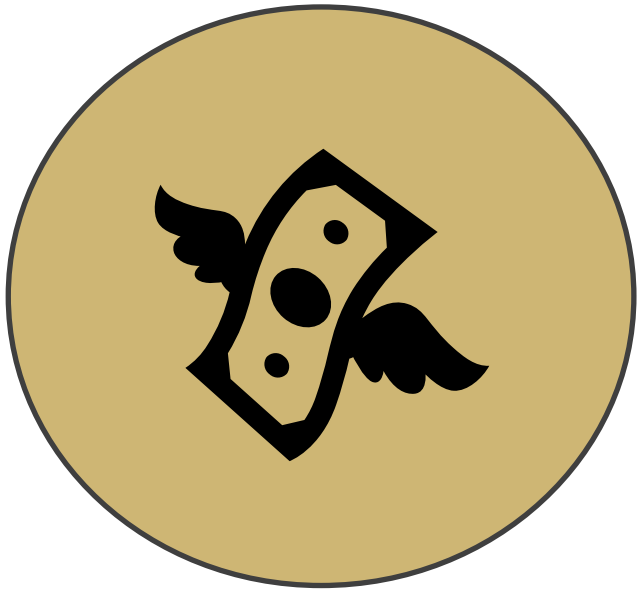
Summary

Achieving meaningful improvement in healthcare requires dissemination of quality improvement projects through publication.

The SQUIRE guidelines

- provide a framework to report system level work to improve quality, safety and value of healthcare
- demonstrate that observed outcomes were due to interventions
- Have value in project design as well as reporting stage


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

National

Hint: “Innovation”

Agency for Healthcare Research and Quality

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

American College of Surgeons

Inspiring Quality: Highest Standards, Better Outcomes

Local

CEPS Small Grant Program

LOI Deadline: SPRING 2024

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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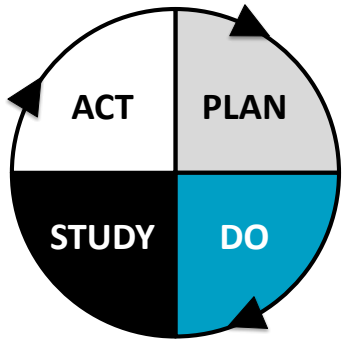


Adapted from: firespring.com/solutions-for-nonprofits/12-quick-tips-for-better-grant-writi

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.”

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

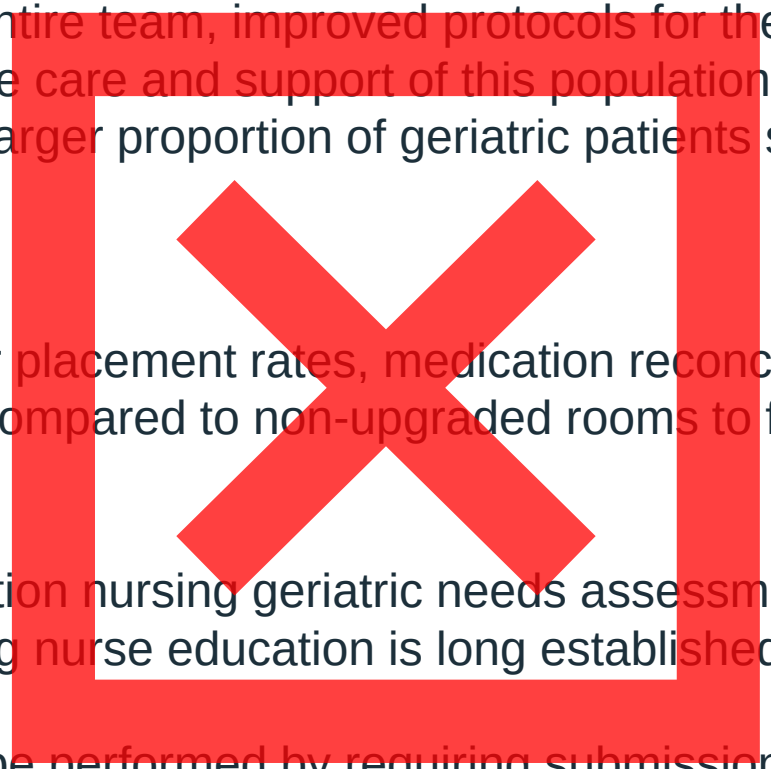
The aim of this project is to implement ERAS protocols for patients undergoing colon surgery at the University of Colorado Anschutz Medical Campus within 12 months. Our goals are to increase the use of multimodal pain management in this patient population from currently <20% to >90%. Furthermore, we 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.

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…

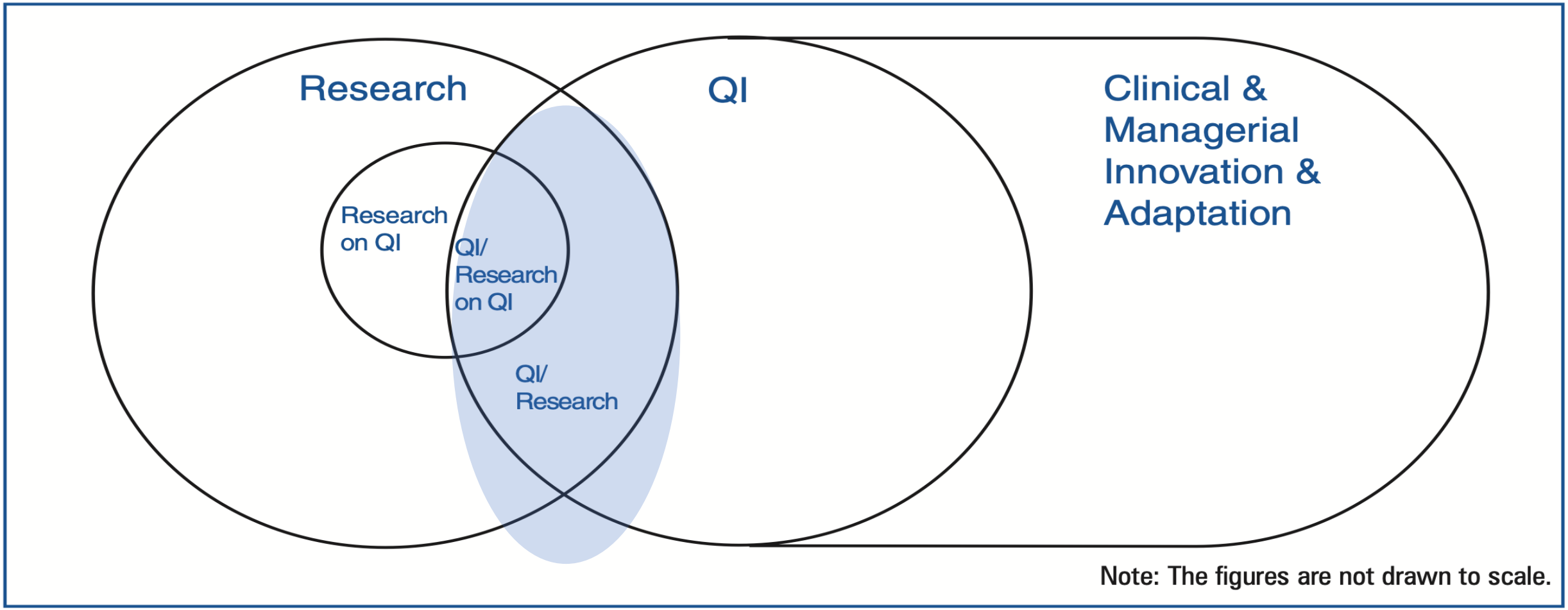


Figure 1.

What does “generalizable” mean?

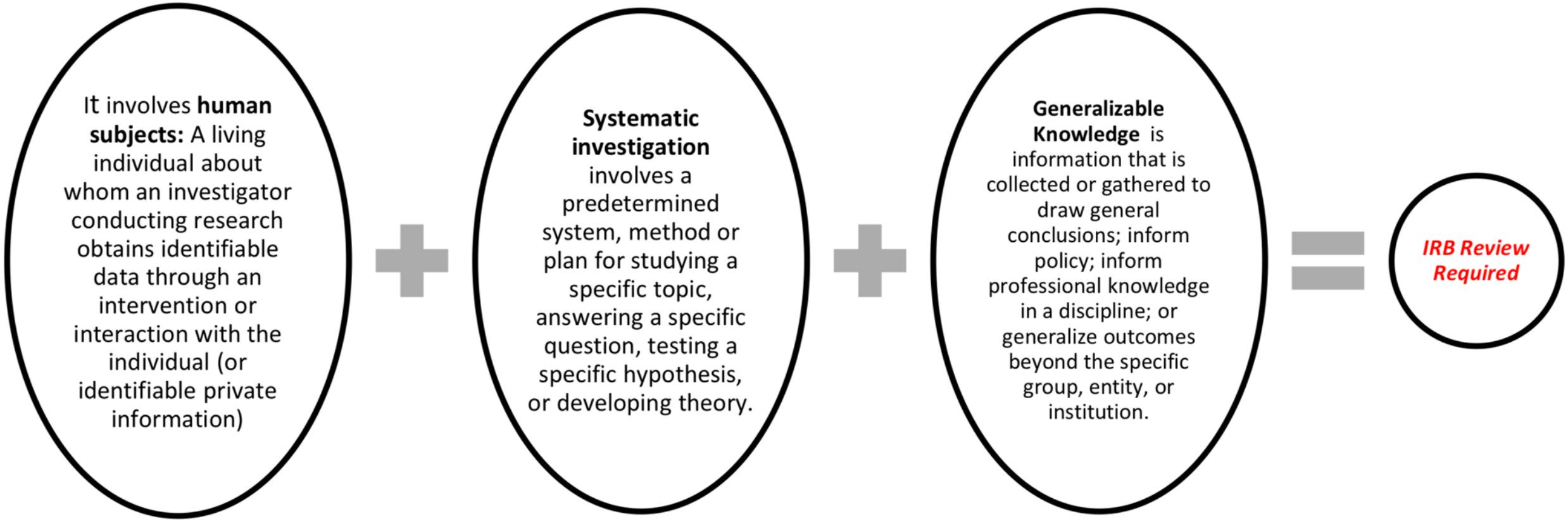
Sometimes the intent is to focus on a local institution, but the knowledge generated can be applied elsewhere (Hastings Report)

- 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	
Use the ch any of the research p research is	PUBLICATION
FUNDING	
INTENT	MANDATE or ENDORSEMENT
DESIGN	
	IMPACT
	POPULATION

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.

Acknowledgment

I have appropriately used this tool to evaluation my project entitled: _____

By my signature below, I affirm that this project meets the definition of:

Circle the appropriate term: **Quality Improvement** **Program Evaluation**

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.

_____ _____ _____ _____

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/.

_____ _____ _____

Signature of Appropriate Authority (*or their designee*) Title/Position Date

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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