Implementation Science: A Primer for Pharmacists

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Objectives

- Pharmacists:
  - Describe the need for closing the evidence-practice gap in health systems
  - Define implementation science and its role in health care
  - Articulate why promoting the uptake of evidence-based medicine requires a rigorous systematic approach
  - Identify at least two specific implementation science frameworks or theories that can be applied to common pharmacotherapy utilization challenges

- Pharmacy Technicians:
  - Define the evidence-practice gap
  - Articulate some barriers to evidence-based practice in health systems
  - Identify at least two specific implementation science frameworks or theories that can help solve common pharmacy technology problems

Conflicts of Interest

- Presenters report no relevant conflicts of interest related to the content of this presentation

Rapid Change in Healthcare

Stressors in hospital and ambulatory care

- Health care reform
- Payment tied to performance
- Pressure to reduce costs, reward performance
- The price tag: **U.S. health care spending** grew 9.7 percent in **2020**, reaching $4.1 trillion or $12,530 per person[1]

Challenge to US health care system to improve quality and cost-effective care

- Do clinical trials (e.g., drugs) translate into better outcomes or lower costs for our patients?
  - "All breakthrough, no follow-through" [3]

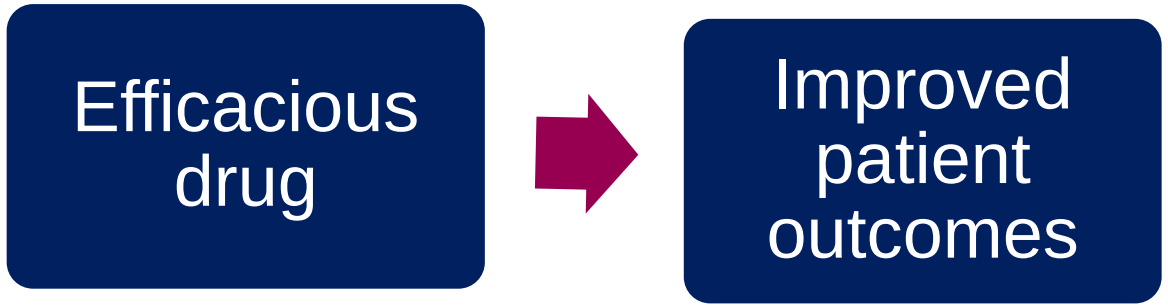
1 . https://www.cms.gov/
2. Heneghan et al. Trials (2017) 18:122
3. Steven Woolf - Washington Post

U.S. Prescription Drug Spending Estimates and Projections: 2010-2020

Source: https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/02/

Evidence vs Practice (Efficacy vs Effectiveness)

Clinical research solves this:



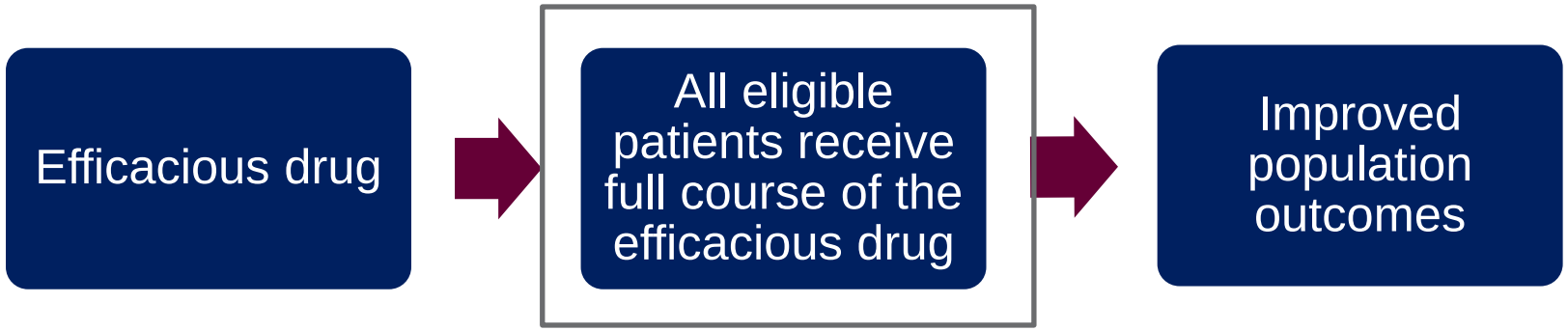
In practice, we need to solve this:

Evidence-Practice Gap

- Evidence-based practices take **17 years** to be incorporated into routine clinical care
  - To this day, **only 26%** of all adults with hypertension have it under control
  - For children with cochlear implants, device adherence is **only 50%** despite overwhelming benefit to cognitive development
- Gap is prevalent in health systems: antimicrobial de-escalation, VTE prophylaxis, reversal of neuromuscular blockade, etc.

Cochlear Implants Int. 2018 May;19(3):131-141.
BMC Psychol. 2015; 3(1): 32.
NHANES 2015–2018

Why the evidence-practice gap exists



Many barriers to this step

- Drug too costly for health system
- Drug may not work in context of other interventions
- Drug too difficult to adhere to
- Insurance sets a co-pay that's too high
- Patients experience adverse reactions to the drug
- Providers unaware of evidence for the drug
- Drug too difficult to administer
- No system in place to identify right candidates for drug
- Providers don't dose the drug correctly
- Patient does not perceive direct benefit of therapy

An Evidence – Practice Gap
A Montefiore Medical Center Experience

7/2014: Liposomal bupivacaine (*Exparel)* injection – added to MMC formulary, restricted to orthopedics

- Claimed it would improve outcomes - lower opioid consumption and decrease length of stay
- No evidence comparing to immediate release bupivacaine

3/2017: Change in MMC P&T Committee mission: Evidence-based outcomes

5/2017: Required data to confirm benefits of *Exparel* - Aggregation of internal (local RCT) and external (e.g., HSS study) literature shows no added benefit vs immediate release bupivacine

11/2018: *Exparel* removed from the MMC formulary

- Approximately $2,000,000 spent over 4 years

Could this have been prevented?

Montefiore Pharmacy-coordinated Heart Failure Program "Brown Bag" Clinic

2012: Initiated a pharmacy-driven heart failure readmission reduction program (aka "Brown Bag" Clinic)

- Patient counseling, medication reconciliation and CDTM = reduced readmissions
- Initial results ~10% reduction in readmission!

2020: Collected 8 years' worth of data to confirm results via a powered study using matched controls and accounted for confounding variables

- Upon analyzing data, realized that program's impact was negligible:
  - Most patients failed to keep an appointment
  - Those attending likely to be healthier and more motivated at baseline

Conclusion: Single post-discharge visit unlikely to have impact

Could we have intervened earlier?

"We'll educate and follow up in 6 months"

- Identify a drug over-utilization problem
- Round up the usual suspects of interventions
  - “Education”
  - Re-doubling clinical pharmacist vigilance
  - Epic screen i.e., Best Practice Alert)
- Usage slightly decreases in next two months
- Consider the initiative a “success” with no further follow up
- Initiative gets restarted a year later when the program is “out of hand” again

Trying harder….Being better……Doing gooder…

Summary: Problems with “Business as Usual”

- Challenges faced by health systems require us to maximize healthcare value
- We are not realizing the full population health impact of our costly medical interventions
- Continuing to fund ineffective interventions puts out institutions at a clinical and financial disadvantage
- Without appropriate tools for implementation, we are unable to evaluate or improve the population health impact of interventions

Introduction to Implementation Science

Theories, Frameworks, and Applications

Implementation Science

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

ImplementationSci. 2006;1:1.

Our medical culture emphasizes pharmacosurgical interventions that produce immediate results and whose dosage can be easily defined and controlled. There is little research on interventions that address whole populations, are long lasting, or become "institutionalized." Indeed, many interventions that prove efficacious in randomized trials are much less effective in the general population.

Glasgow et al.

Principles of Implementation Science

Trans-Disciplinary Approach

Patient, Provider, Organization, and Policy-level Interventions

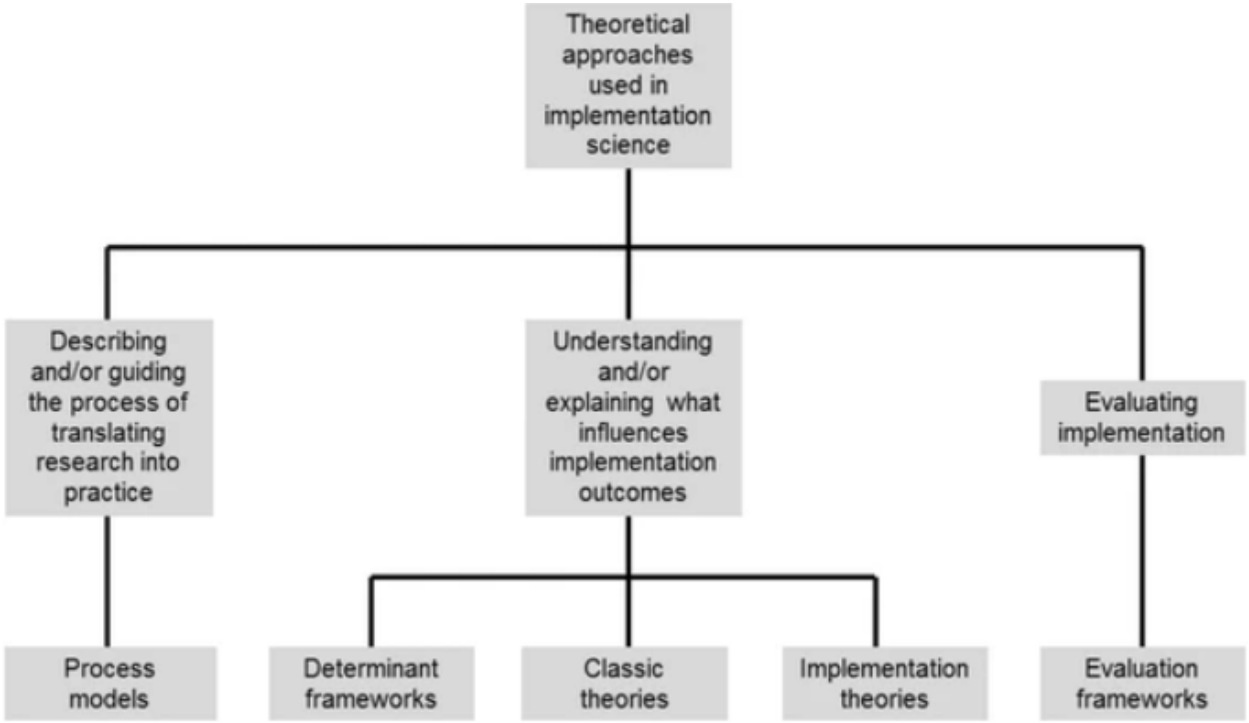
Theory-Driven

Mixed-Methods Research

Stakeholder Engagement

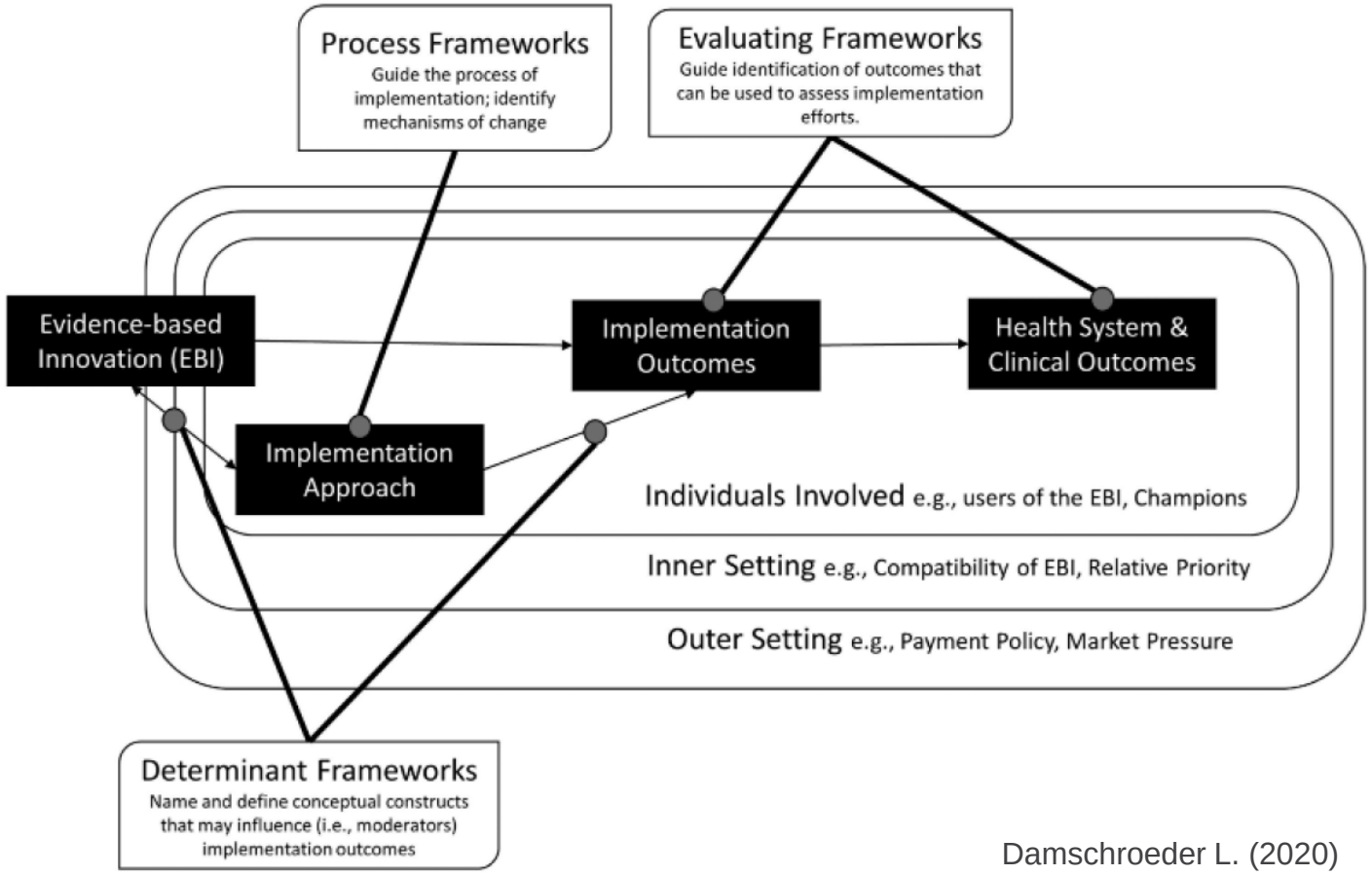
Tools of Implementation Science

Theories, Models, and Frameworks



Nilsen (2015)

Theories, Models, Frameworks and Implementation Process



Damschroeder L. (2020)

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Process Frameworks

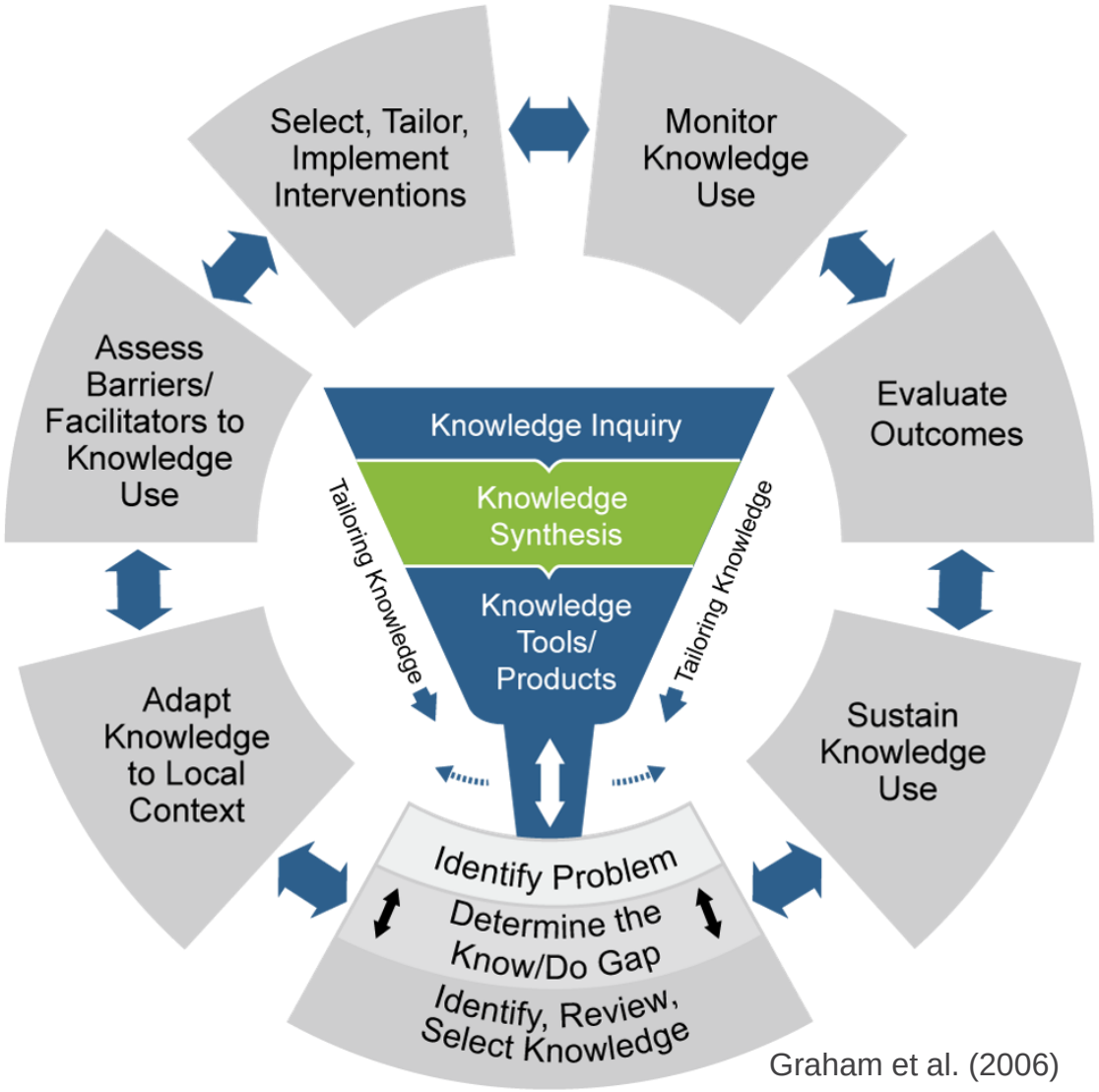
Guiding the Process of Implementation

Damschroeder L. (2020)

Established evidence for a 'proven' treatment does not ensure successful implementation

Proctor et al.

Knowledge to Action (K2A) Framework



Graham et al. (2006)

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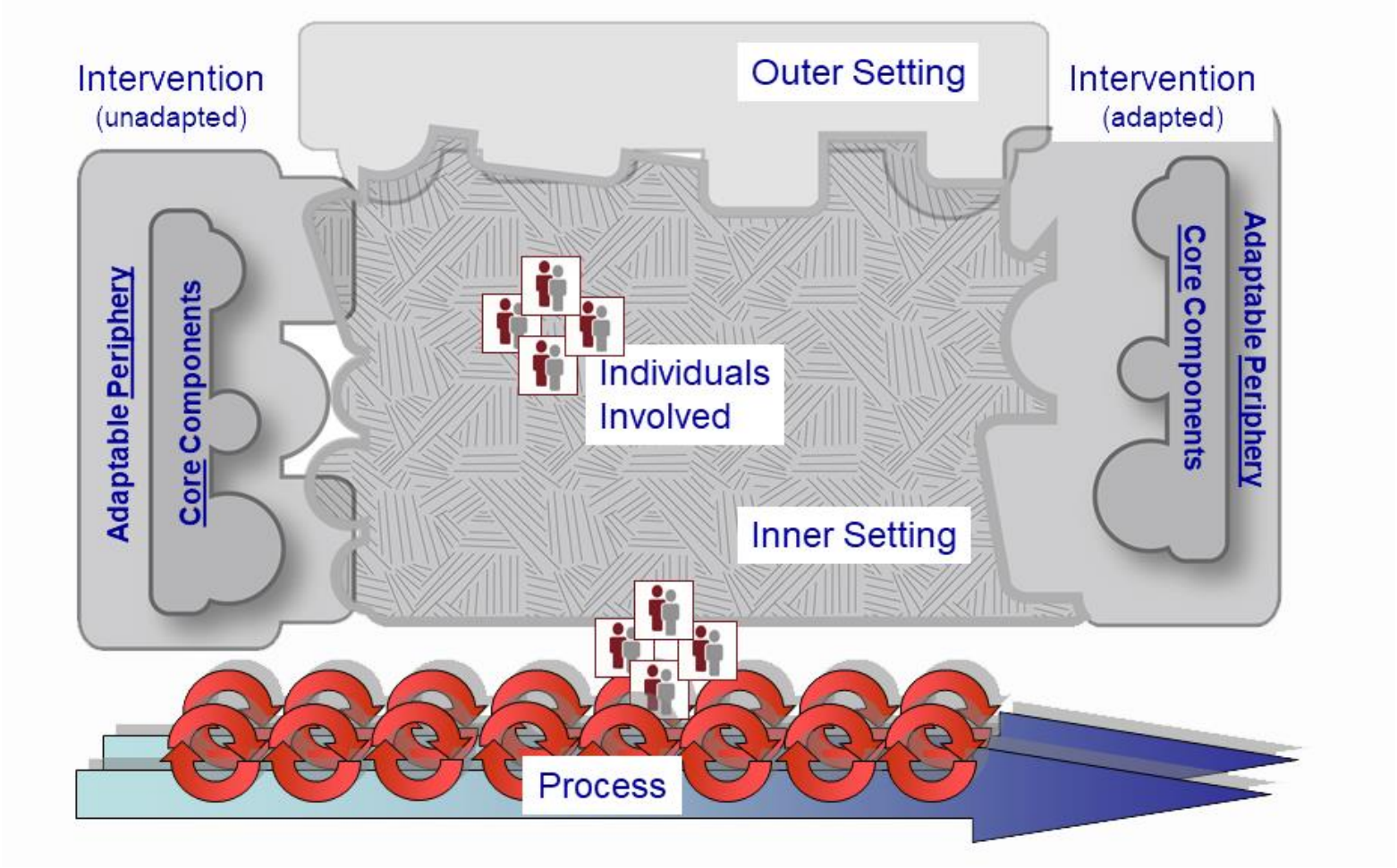
Determinant Frameworks

Define What Influences Implementation Outcomes

Many existing theories propose 'what works' but more research is needed into what works where and why

Damschroder et al.

Consolidated Framework for Implementation Research (CFIR)



Implementation Sci **4,** 50 (2009)

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CFIR - Intervention Characteristics

A	Intervention Source	Perception of key stakeholders about whether the intervention is externally or internally developed.
B	Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
C	Relative Advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
D	Adaptability	The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
E	Trialability	The ability to test the intervention on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.
F	Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.
G	Design Quality & Packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.
H	Cost	Costs of the intervention and costs associated with implementing the intervention including investment, supply, and opportunity costs.

CFIR - Inner Setting (Organization)

A	Structural Characteristics	The social architecture, age, maturity, and size of an organization.
B	Networks & Communications	The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
C	Culture	Norms, values, and basic assumptions of a given organization.
D	Implementation Climate	The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
1	Tension for Change	The degree to which stakeholders perceive the current situation as intolerable or needing change.
2	Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
3	Relative Priority	Individuals' shared perception of the importance of the implementation within the organization.
4	Organizational Incentives & Rewards	Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.
5	Goals and Feedback	The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.
6	Learning Climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.

E	Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
1	Leadership Engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.
2	Available Resources	The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time.
3	Access to Knowledge & Information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.

CFIR - Outer Setting (Organization)

A	Patient Needs & Resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.
B	Cosmopolitanism	The degree to which an organization is networked with other external organizations.
C	Peer Pressure	Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.
D	External Policy & Incentives	A broad construct that includes external strategies to spread interventions, including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.

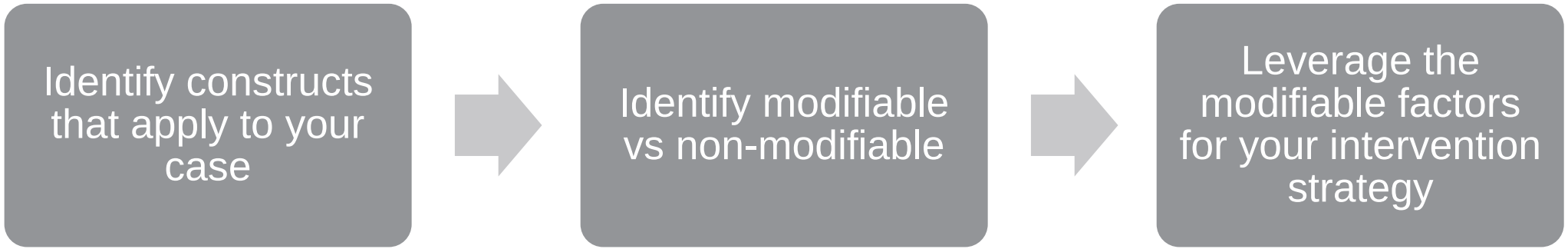
CFIR - Characteristics of Individuals

A	Knowledge & Beliefs about the Intervention	Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
B	Self-efficacy	Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
C	Individual Stage of Change	Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
D	Individual Identification with Organization	A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.
E	Other Personal Attributes	A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

CFIR – Implementation Process

A	Planning	The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance, and the quality of those schemes or methods.
B	Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
1	Opinion Leaders	Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention.
2	Formally Appointed Internal Implementation Leaders	Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
3	Champions	“Individuals who dedicate themselves to supporting, marketing, and ‘driving through’ an [implementation]” [101] (p. 182), overcoming indifference or resistance that the intervention may provoke in an organization.
4	External Change Agents	Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
C	Executing	Carrying out or accomplishing the implementation according to plan.
D	Reflecting & Evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

Applying Determinant Frameworks



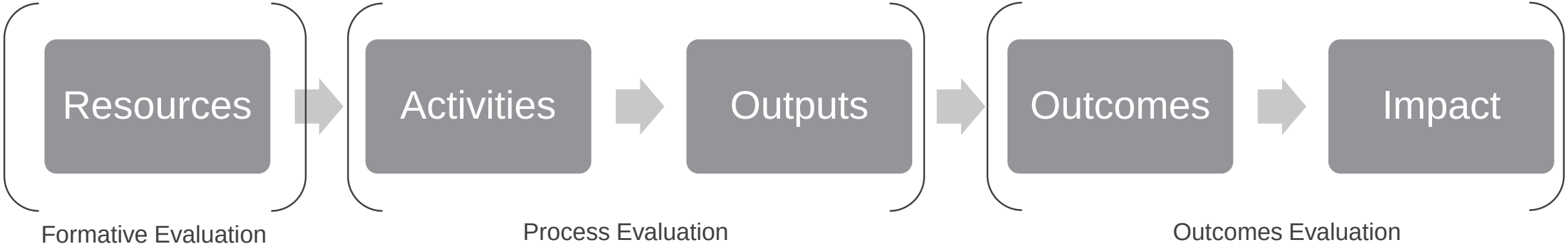
Evaluation Frameworks

Assessing Implementation Efforts

Our goal is to ensure that evaluations focus on answering not only “Does it work?” but also “How does it work?

AHRQ Patient-Centered Medical Home Framework

Logic Models



RE-AIM Framework

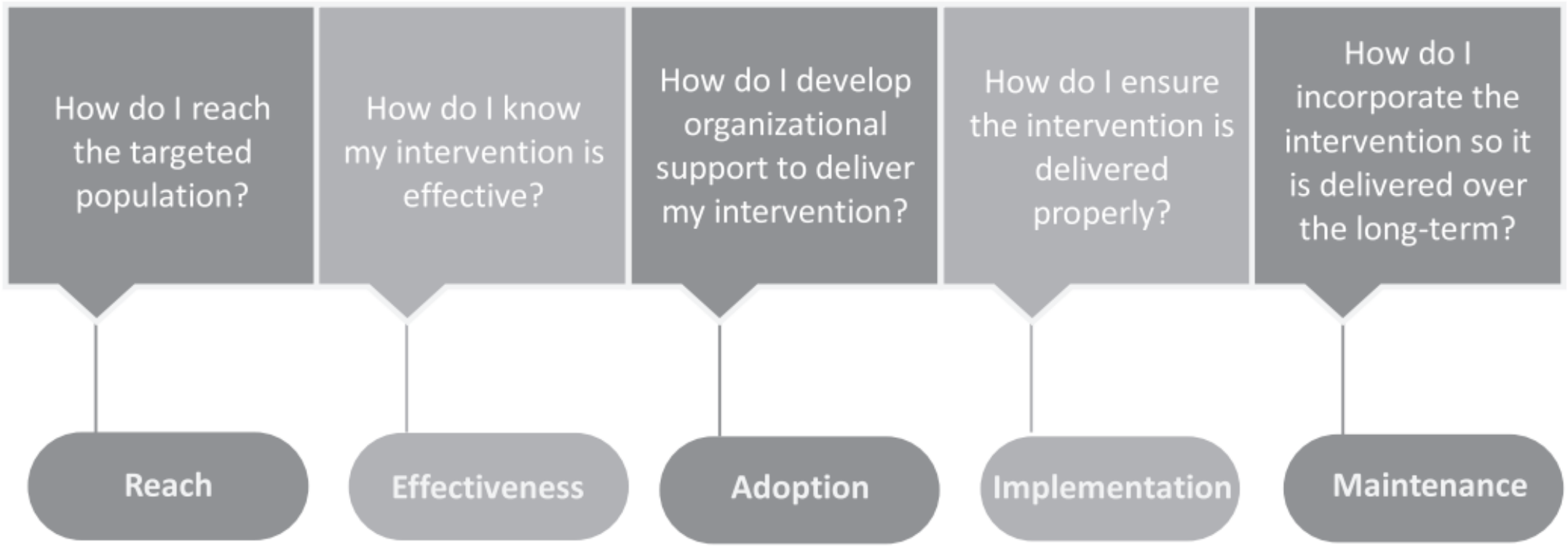


Figure 1. Elements of the RE-AIM IS Framework (Based on Glasgow et al., 1999)

Megan E. Schliep, Crystle N. Alonzo & Megan A. Morris (2017) Beyond RCTs: Innovations in research design and methods to advance implementation science, Evidence-Based Communication Assessment and Intervention, 11:3-4, 82-98, DOI: 10.1080/17489539.2017.1394807

Applying Implementation Science Toolkit

Case Study in Optimizing Neuromuscular Blockade Reversal

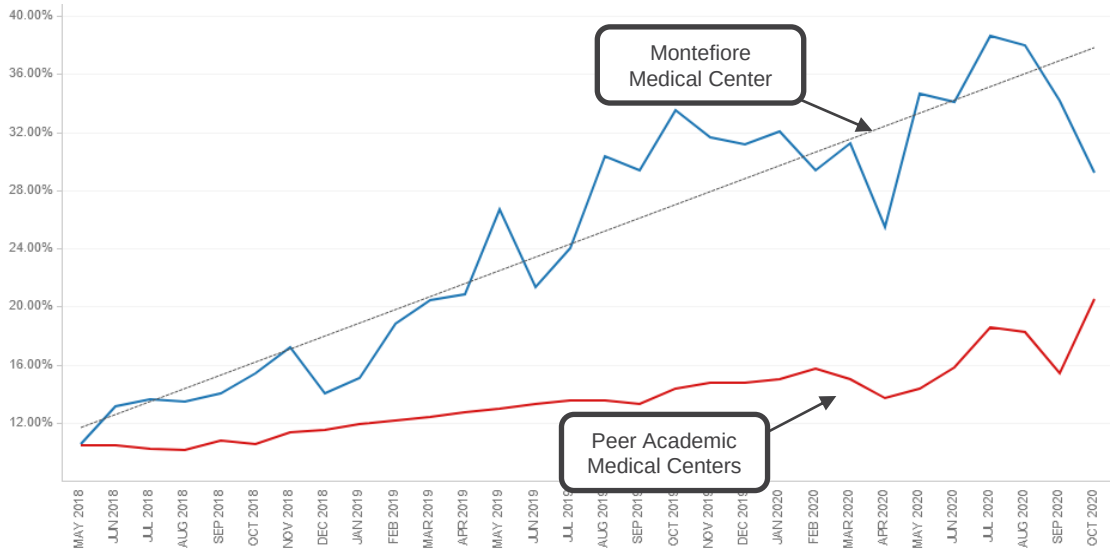
Background: Neuromuscular Blockade (NMB)

- NMB is administered during certain procedures to improve surgical conditions and ventilation

- Must be fully reversed prior to extubation to prevent complications
  - **Neostigmine**
    - Quickly reverses light degree of blockade (ineffective for deeper blockade)
    - $10-15 per reversal (with glycopyrrolate)
  - **Sugammadex**
    - Reverses any degree of blockade within <5 minutes
    - $100-200 per reversal

Problems to be Addressed

- We were utilizing significantly more sugammadex than our peers
- Studies do not demonstrate better outcomes with sugammadex
- We were not taking advantage of higher value evidence-based practices (quantitative monitoring)



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Step 1: Stakeholder Engagement

Defining evidence-based intervention requires balancing the needs of stakeholders

Pharmacy Leadership	Clinical Pharmacists	Pharmacy and Therapeutics Committee	Anesthesia Providers	Chief Medical Officer	Chair of Anesthesia
• Reducing drug budget	• Maintaining a good relationship with anesthesia clinicians	• Compliance with P&T-approved evidence-based use criteria	• Maintaining autonomy over clinical decisions	• Meeting strategic goals of the institution	• Implementing cutting-edge practices

Step 2: Define Complex Evidence-Based Practice

"Who should do what, when, and how?"

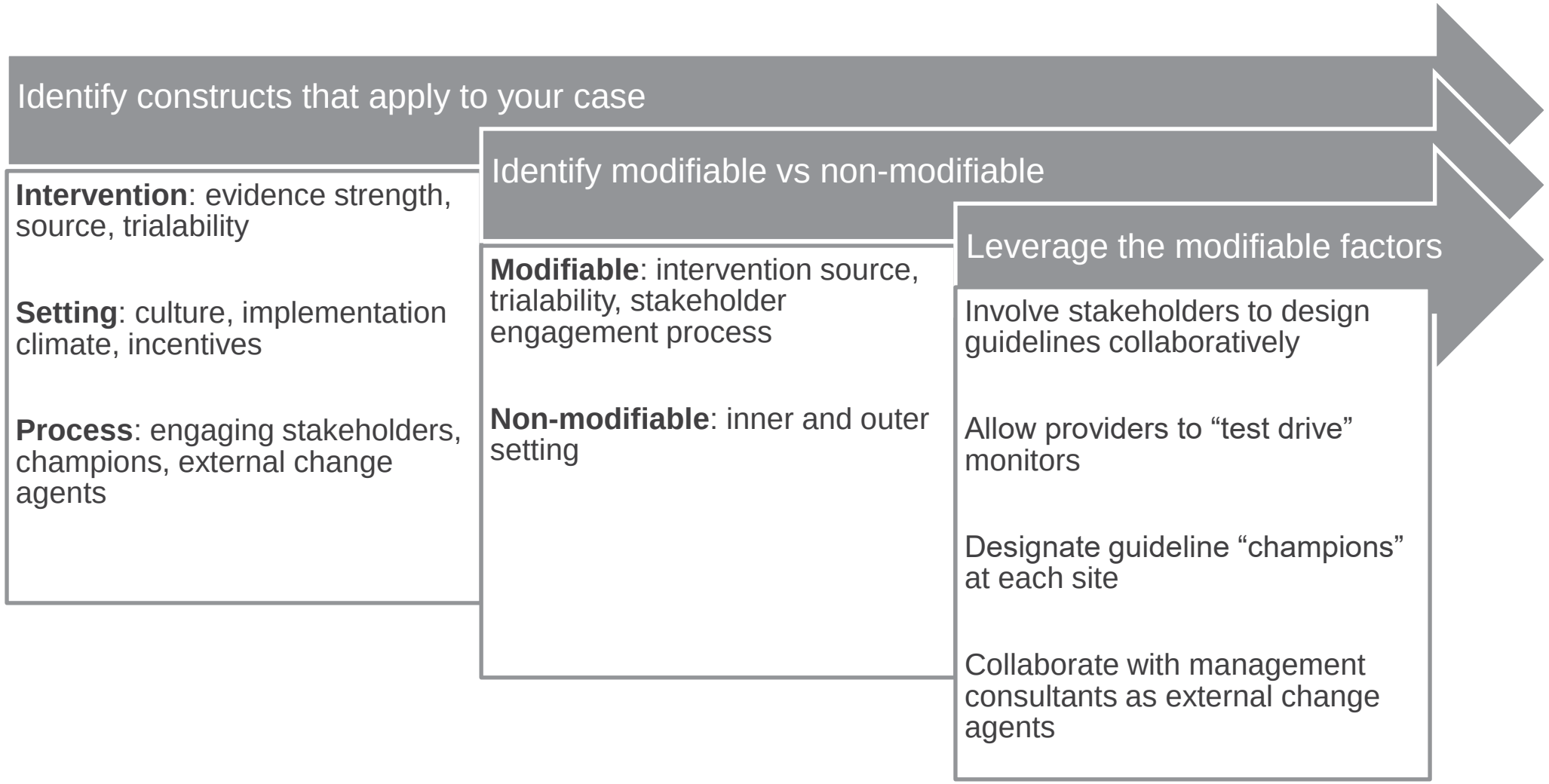
Who: Anesthesia Clinicians (Attendings, Residents, Fellows, CRNAs)

When: After completion of the surgical procedure which utilized NMB

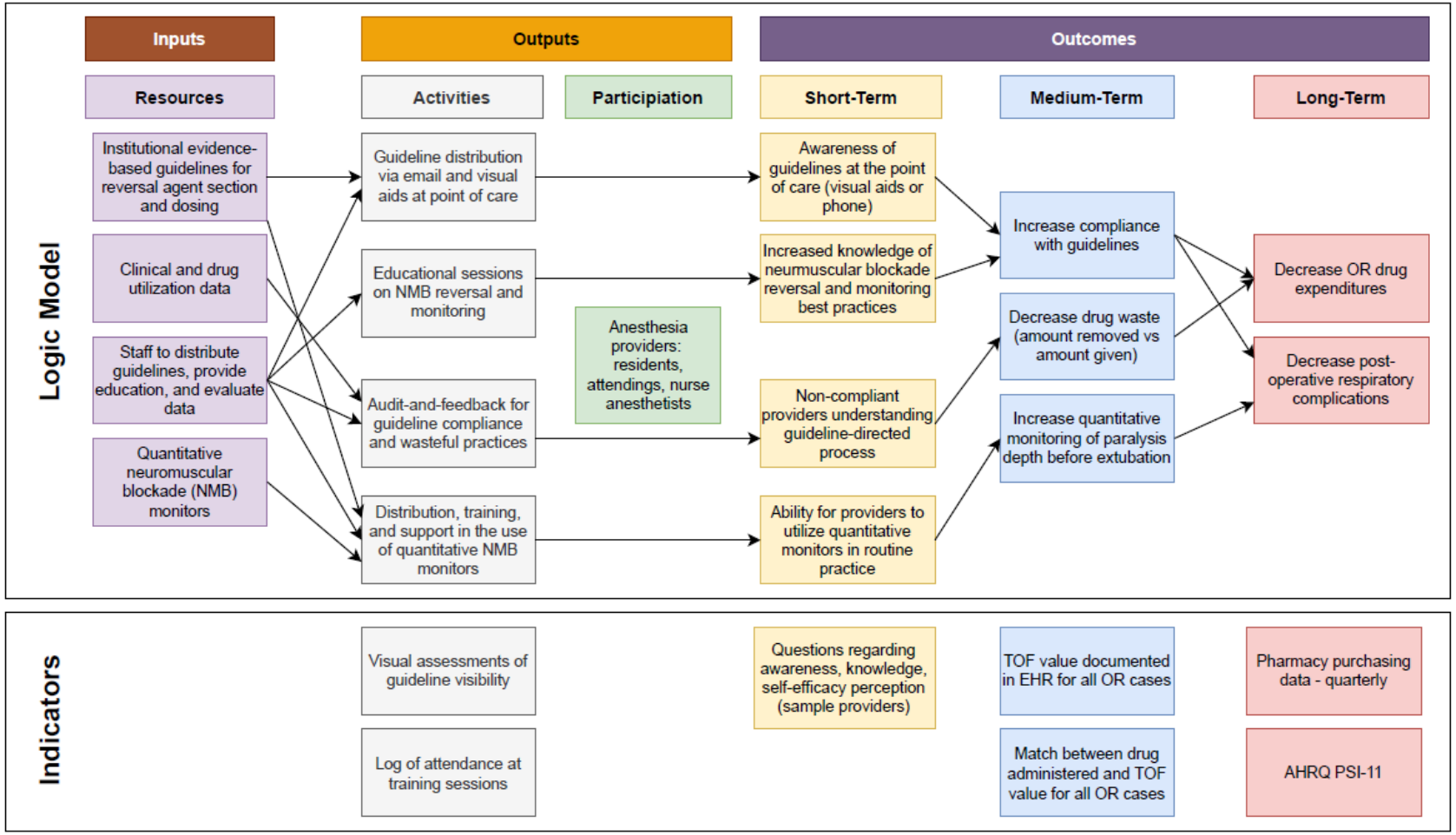
What & How:

1. Check train-of-four count
2. Select appropriate reversal agent based on train-of-four count
3. Administer correct dose of reversal agent
4. Confirm complete reversal using train-of-four ratio

Step 3. Design a Theory-Informed Implementation Strategy



Step 4: Create a Logic Model for the Program



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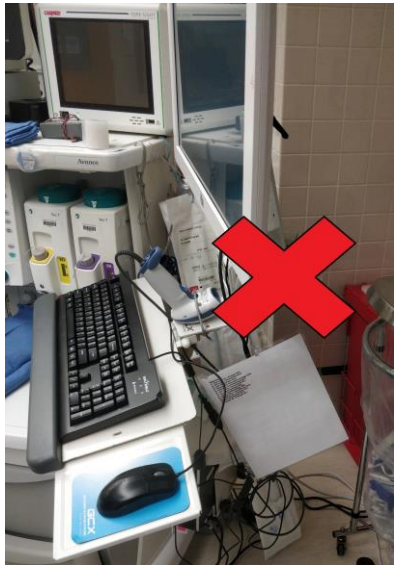
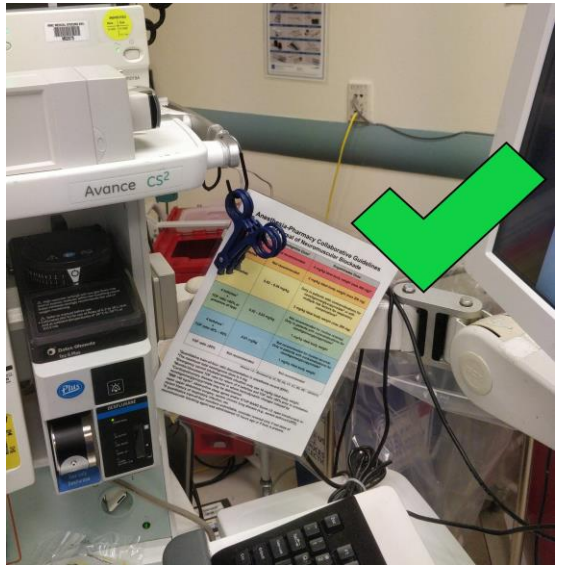
Step 5: Create an Evaluation Plan

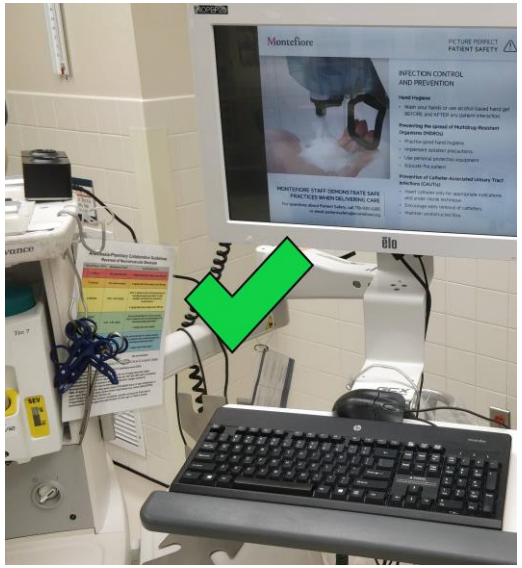
RE-AIM Component	Evaluation Questions	Measure	Data Source
Reach	What proportion of providers are aware of the new guidelines/monitors? Does awareness vary by provider type, campus, shift?	Ability to locate the institutional guidelines upon request	OR walkthroughs and observations
Effectiveness	Are providers aware of guideline recommendations? (Short-term)	Ability to recall specific recommendations in guidelines	OR walkthroughs and observations
	Are providers confident in their ability to use quantitative monitors? (Short-term)	Self-assessment of confidence with new monitors	Provider survey
	Is the program improving documentation of pre-reversal paralysis depth? (Medium-term)	Documentation of pre-reversal paralysis depth	EHR
	Can the program unintentionally lengthen the time it takes to transfer a patient from OR to PACU, and the number of cases that can be performed in a day? (Medium-term)	OR to PACU time	EHR
	Is the program decreasing postoperative complications? (Long-term)	Postoperative complication rate data	AHRQ PSI-11 for the medical center
	Is the program reducing mediation-related expenditures in the OR? (Long-term)	Total drug expenditures on neuromuscular blocking agents and reversal agents	Pharmacy purchasing data
Adoption	Does guideline and monitor utilization vary by campus/care setting/provider subspecialty?	Provider assessment of whether they or their colleagues utilize the guidelines/monitors in daily practice	Focus groups with providers OR observations
Implementation	Are certain components of the program utilized more than others? What are the barriers and facilitators for aligning the practice with guidelines?	Provider assessment of most and least utilized/useful components of the guidelines Provider assessment of barriers and facilitators of guideline compliance and sustainability	Provider survey and focus groups with providers
Maintenance	Did guideline adherence sustain over a 3, 6, and 12 month period? Does sustaining guideline adherence require additional inputs?	Guideline compliance audits	EHR

Step 5: Implement & Evaluate Program

Process Evaluation Using Qualitative Methods







"Some attendings tell us to use sugammadex anyway" – Anesthesia Resident

"CRNAs don't really get invited to the lectures" – CRNA

"The new monitors are unreliable and produce incorrect readings" – Attending Anesthesiologist

"I thought the guidelines didn't apply to cardiac cases?" – Anesthesia Resident

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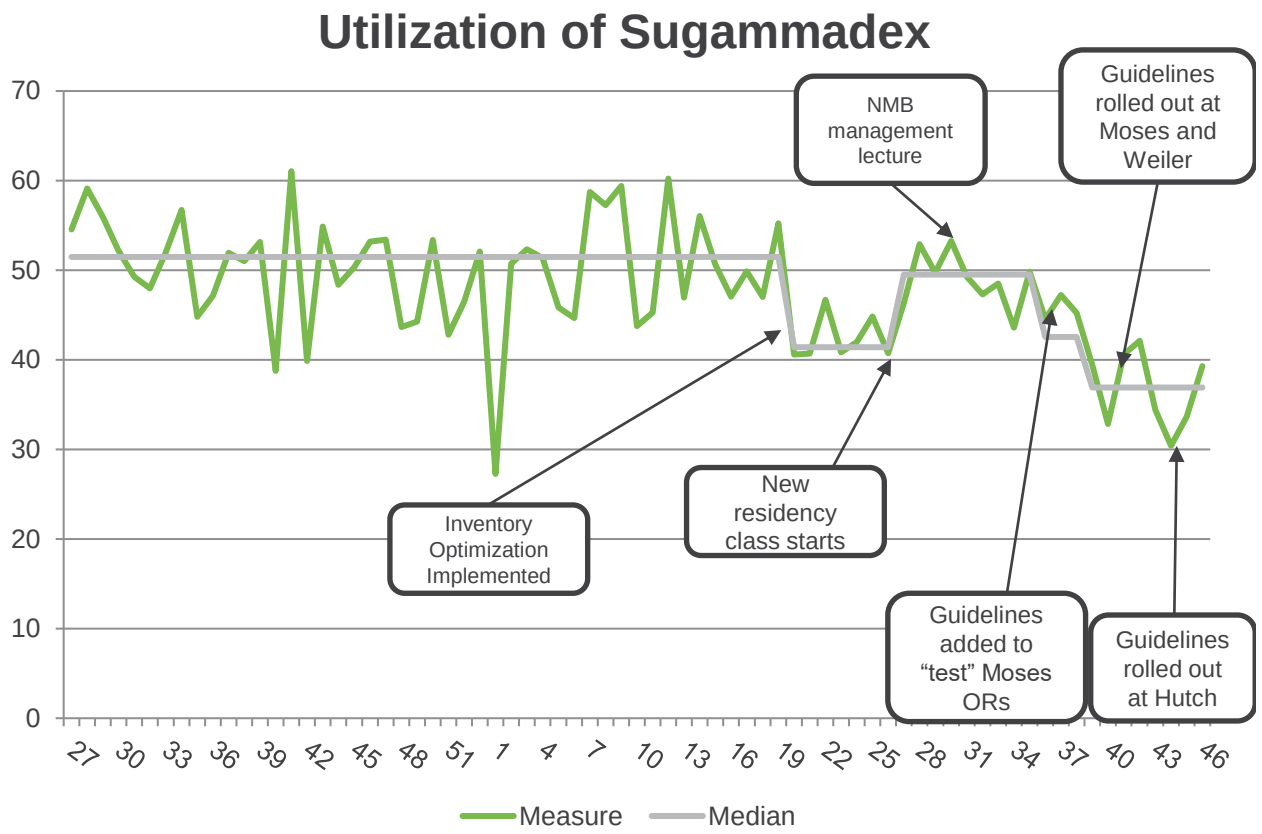
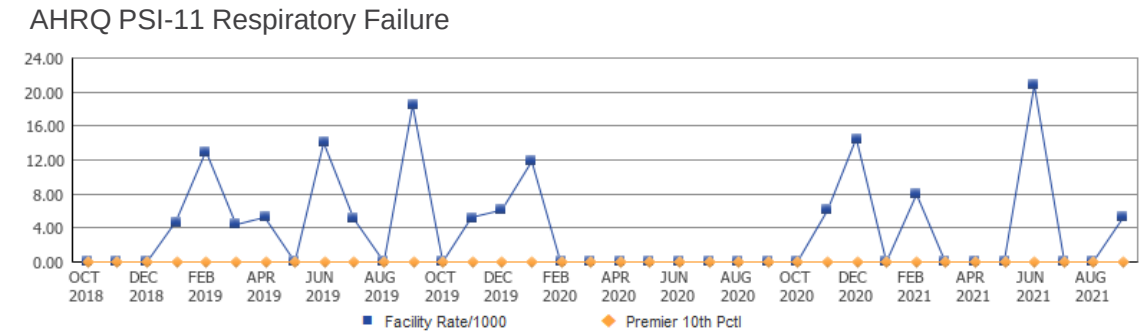
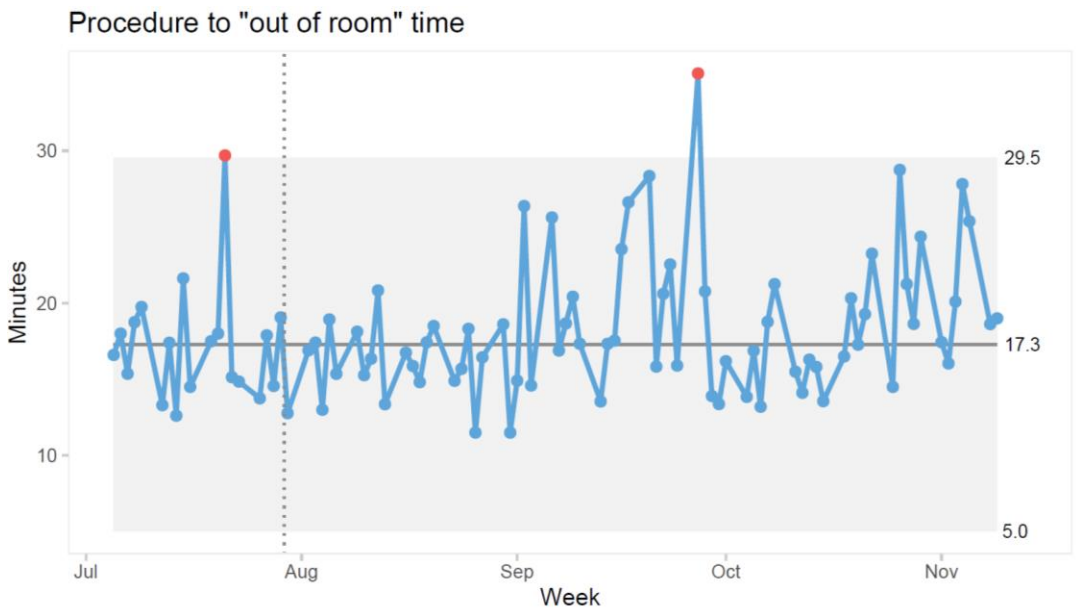
Step 5: Implement & Evaluate Program

Outcomes Evaluation Using Quantitative Methods







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Step 6: Disseminate Findings

Executive Steering Committee - Monthly	Department of Anesthesia – Yearly Grand Rounds	Health System Leadership – Montefiore Quality Council
Pharmacy Leadership – Perioperative Committee	P&T – Steering Committee Report	Scientific Community – Conference Presentations and Journal Manuscript

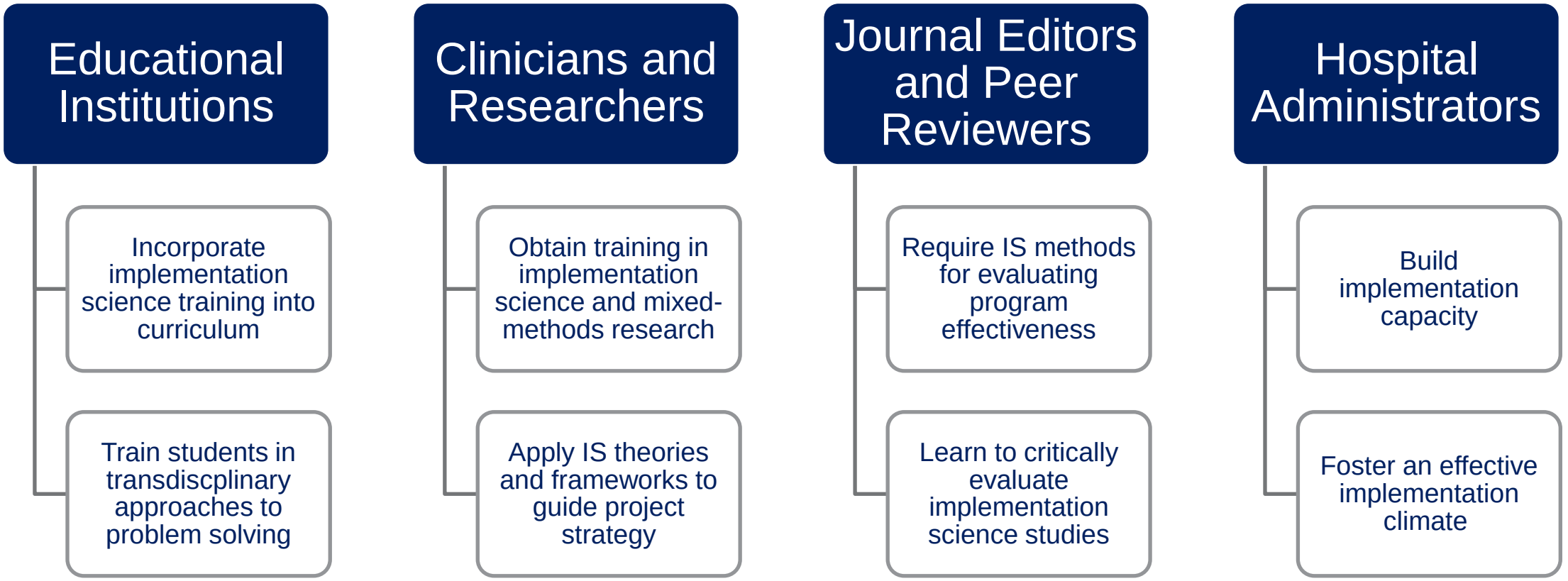
Implementation Science Research

- Implementation science methods can effectively drive the uptake of evidence-based practices locally
- They can also be used to advance the evidence-base for real-world interventions
- Goal is to develop programs that can be replicated in other settings and generalized across contexts
- Grant funders now increasingly interested in implementation science research

There is now tremendous attention paid to the “replication crisis” that exists in [medicine]. It would thus seem prudent to […] incorporate standards for replication into the primary goals of establishing what works, for whom, and under what conditions

Derzon (2018)

Implications for Pharmacy Profession



Sophisticated data-gathering systems must be paired with equally sophisticated implementation strategies if learning healthcare systems are to make good on their promise

Bauer et al.

Summary

- Closing the evidence-practice gap is a strategically important goal for health systems
- Implementation science is the study of improving the quality and effectiveness of health services through the uptake of evidence-based practices
- Implementation science relies on theoretical approaches, stakeholder engagement, transdisciplinary collaboration, and mixed-methods
- These methods can be applied to solve locally relevant problems as well as create generalizable knowledge
- Pharmacy profession should embrace this new science to maintain our relevance in health systems and the academic space

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