Integrating Regulatory Requirements in the IP Program

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Objectives

1

IP will be able to implement regulatory requirements

2

IP will be able to provide expected oversight

3

IP Program will be able to measure and sustain success

Process

Who

What

When

Where

Why

How

Who

Everyone

For this conversation we will focus on

- Infection Prevention and collaborators

What Regulatory Requirements

Federal

- CMS / CDC / FDA
  - Joint Commission
  - DNV

State / City DOH

National Standards

- AORN
- ASHRE
- AAMI
- USP
- FGI
- Others

When

- From Start to discharge and beyond
- Facility Design (FGI, ASHRAE, USP)
- Operations (AORN, AAMI)
- Products (FDA, UL)
- Patient Care (CMS / CDC / DOH)
- Outpatients and Discharge (DOH)

Where

Infection Prevention oversight

- Roof top / Basement
- OR
- ICU
- Pharmacy
- Patient Care floors
- Staff offices
- Kitchen

Oversight

Physical Environment

- Isolation
- Operating Rooms
- Pharmacy
- Construction
- Water
- HVAC

Oversight

Processes

- Instrument Reprocessing
- Medication Compounding
- Environmental cleaning
- Hand hygiene
- Personal protective equipment (PPE) use
- Surveillance, HAI prevention
- Injection Safety
- Food Handling

Oversight

Preparedness

- Outbreaks
- Disasters
- Drills

Why

- Because it is required
- Because it makes patient care safe
- Because it makes patients safe
- Because it minimizes risk
- Because it standardizes care

It takes a Village .....

How

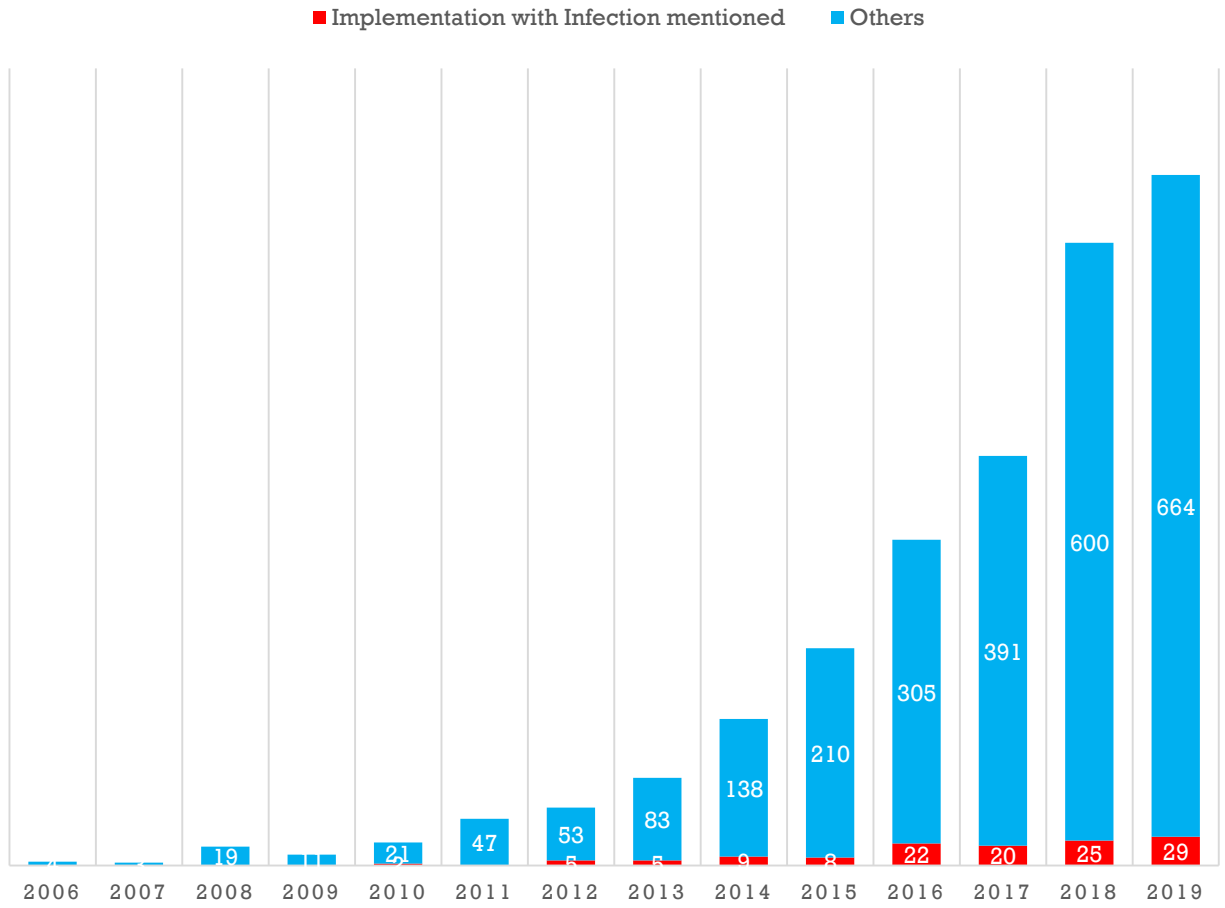
How

Implementation

Sustainability

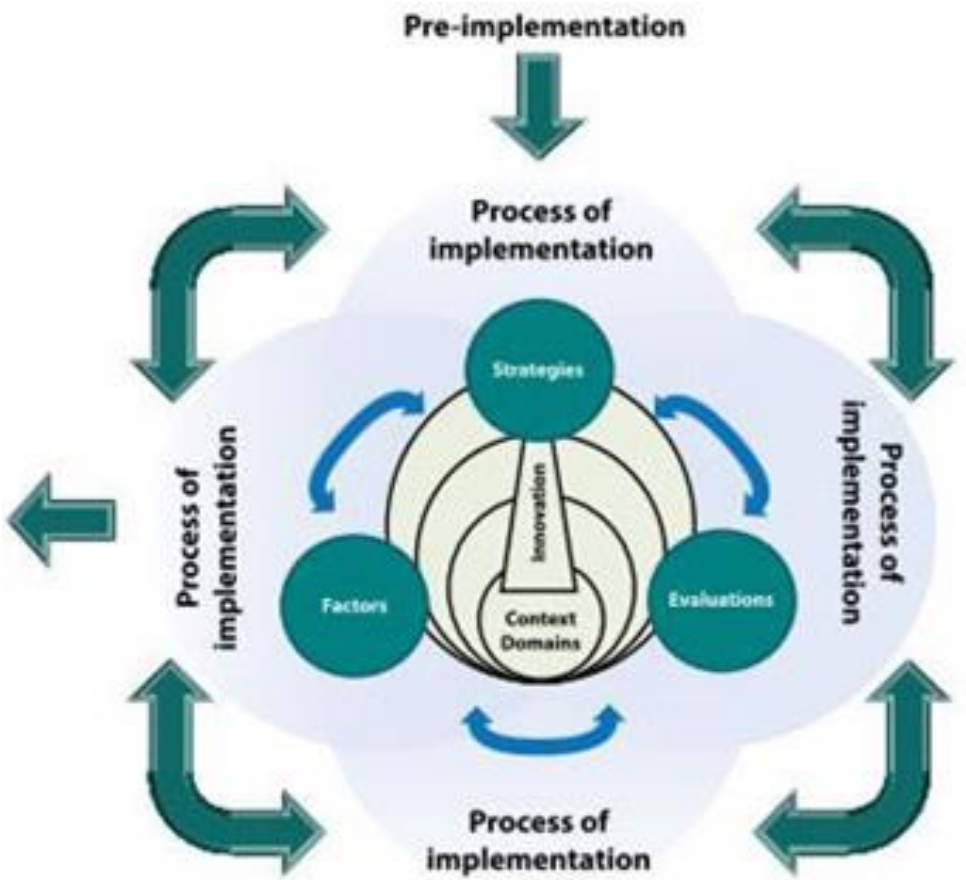
Implementation Science

PUBMED SEARCH ON ARTICLES PUBLISHED ON IMPLEMENATION SCIENCE



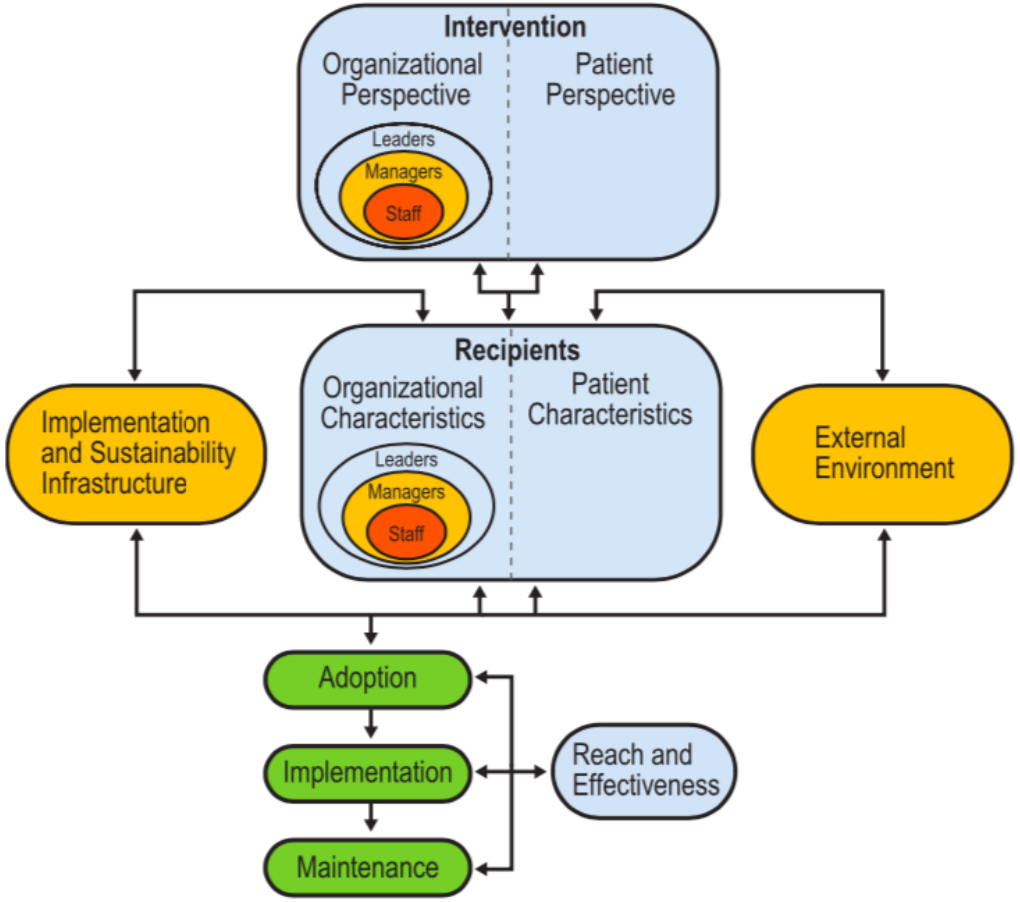
Implementation

- Top arrow points from pre-implementation to process of implementation.
- Overlapping circles show process of implementation, and depict circular relationships between strategies,
evaluations and factors.
- They surround concentric circles labeled context domains, and a box labeled innovations.
- Arrows show all components work together to comprise the process of implementation.
- Final arrow point left to post-implementation.



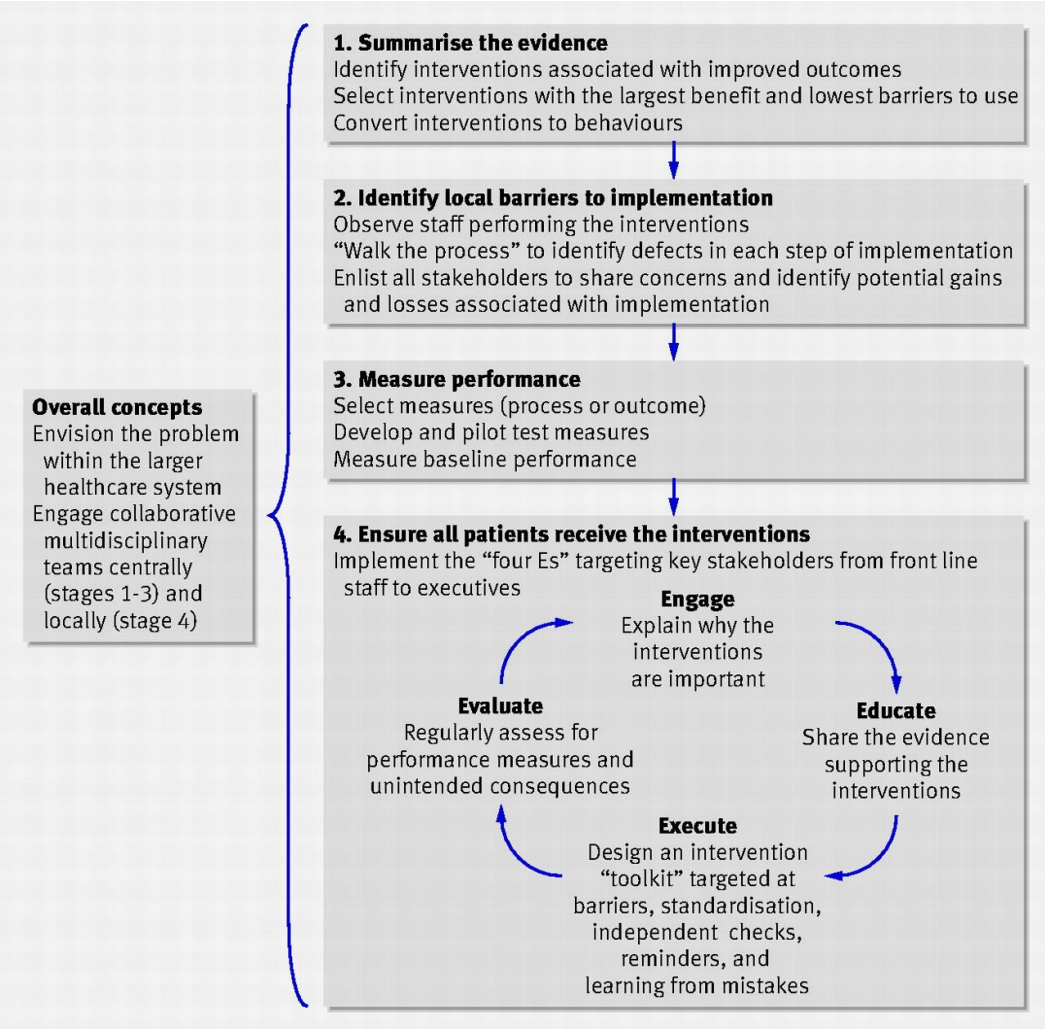
Implementation

- Top intervention box includes organizational (leaders, managers, staff) and patient perspective.
- Intervention flows into and out of recipients box, which contains organizational (leaders, managers, staff) and patient characteristics.
- Recipients affected by implementation and sustainability structure, and external environment, which impact and are affected by the recipients.
- Below, adoption, implementation, and maintenance flow out of relationships between recipients, implementation and sustainability infrastructure, and external environment; and interact with reach and effectiveness



Feldstein, A. C., & Glasgow, R. E. (2008). A Practical, Robust Implementation and Sustainability Model (PRISM) for Integrating Research Findings into Practice. *Joint Commission Journal on Quality and Patient Safety*, *34*(4), 228–243. https://doi.org/10.1016/S1553-7250(08)34030-6

Strategy for translating evidence into practice.



Peter J Pronovost et al. BMJ 2008;337:bmj.a1714

Plan:

- Recognize an opportunity and plan a change.

Do:

- Test the change. Carry out a small-scale study.

Check:

- Review the test, analyze the results, and identify what you've learned.

Act:

- Take action based on what you learned in the study step.
- If the change did not work, go through the cycle again with a different plan.
- If you were successful, incorporate what you learned from the test into wider changes.
- Use what you learned to plan new improvements, beginning the cycle again.

Implementation Process

Planning

- Conducting a needs assessment

Educating

- Hosting educational sessions

Financing

- Offering incentives

Restructuring

- Revising professional roles

Managing quality

- Audit and feedback

Attending to policy context

- Changing licensure requirements

Example

The 797 Standard

- "The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from:
- Microbial contamination (nonsterility)
- Excessive bacterial endotoxins
- Variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see "official" and "article" in the *General Notices and Requirements*) or 10% for nonofficial articles,
- Unintended chemical and physical contaminants
- Ingredients of inappropriate quality in compounded sterile preparations (CSPs)

Planning

What is the Standard

Who is involved in implementation

- Joint commission
- Pharmacy

Who is providing oversight

- Infection prevention
- Internal team

Education and Learning

Know

- Understanding standard requirements pertaining to Infection prevention

Disinfection

- Which surfaces and with what

Cultures

- When, what and how often

Cleaning

- With what standards and how often

Financing

Reporting

- Process may already be in place but not reported out

Implementation

- If no process in place, it is critical to implement to sustain pharmacy practice

FTE requirements

- If pharmacy program is extensive, may require additional IP FTE % allocation

Restructuring

Need for improvement

- Working with pharmacy leadership to find areas including:
  - Cleaning / Disinfection
  - Culturing
  - Recordkeeping

Need for reporting

- Having ASP pharmacist report 797 standard compliance during ICC

Managing Quality

Audit

- Regular review of pharmacy processes
  - Cleaning
  - Competency
  - Culture results

Feedback

- During rounds
- During ICC
- During Pharmacy meetings

Attending to policy context

Changing licensure requirements

- Other Pharmacy standards (chapters including 800, 795 etc)

Joint commission

- In 2018, The Joint Commission enhanced its process for evaluating sterile compounding

Sustainability

- Training and Competency
- Checklists
- IP skill enhancement
- Rounding
- Reporting

Training and Competency

How are the staff trained

- Educators or Certifications

How often are they retrained

- Yearly, Quarterly or never?

What signifies competency

- Once and done, or have to perform 3 times?

Who ensures competency

- Nursing Education? Managers? Infection Prevention

Checklists

Tool

- Helpful to ensure standard review occurs every time

Scalability

- Can be implemented at unit level, department level or during IP review

Status

- Need to make sure checklists are relevant and up-to-date

IP competency

Baseline

- Infection prevention staff knowledge regarding standards

Enhancement

- Any additional training required?

Competent

- Are they able to understand, review, overview, educate as needed?

Rounding and Reporting

Regularity

- IP should developing regular rounding schedule to review physical environment

Reports

- Reporting strategy for pharmacy compliance to 797 standards
  - The pharmacy can report out during infection control committee meeting there compliance and culture results

Urgency

- An urgent Infection prevention report and consult is required if there is any breech in compliance or an positive cultures

To Recap

Oversight

- Important and expected

Implementation strategy

- Needs to be simple and effective

Sustainability

- Needs to be planned from the beginning

Questions?