What is Implementation Science? Implications for Conducting Antimicrobial Stewardship Research

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Nothing to disclose
Objectives

• To review how implementation science can advance the goals of antimicrobial stewardship.
• To introduce a classification scheme for implementation strategies.
• To understand the rationale for and measurement of implementation outcomes.
• To apply our new understanding of implementation strategies and outcomes to a real-life example of antimicrobial stewardship across a large healthcare system.
The Need to Study Implementation

On average, it takes 17 years for evidence-based practices to be incorporated into routine care.

Efficacy and effectiveness trials → Lack of awareness → Sustained application in routine care

- Competing demands
- Limited resources and skills
- Misalignment of priorities

Another Example of Time-Lag: Translating Research Evidence and Public Health Priorities into Local Stewardship Practice

1957
NEJM report: 52.5% of antibiotics were not indicated

1981
2 single-center studies showed cost-savings from restricting cephalosporins

1988
IDSA publishes “Guidelines for Improving the Use of Antimicrobial Agents in Hospitals”

1995
CDC’s National Campaign for Appropriate Antibiotic Use in the Community

1997, 2001
2 RCTs show that audit-and-feedback can reduce unnecessary antibiotic use

2015
NHSN survey: All 7 core elements present at 48% of hospitals

2017
Joint Commission mandate

2011
Survey of children’s hospitals: Only 38% had a ASP

Strategies to promote the uptake of evidence-based practices for stewardship are needed

Defining Implementation Science

**Definition:** “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”  (Eccles MP, Mittman BS. Implement Sci 2006; 1:1.)

Implementation scientists want to know:
1) why evidence-based practices are adopted,
2) how they’re adapted to fit a specific context, and
3) how the pace of adoption can be accelerated.
Establish evidence-based practice

Identify and develop implementation strategies

Conduct trial of implementation strategies

*Watch for an upcoming ICHE paper that uses the QUERI process to identify high-priority stewardship research targets.
## A Fine Line: The Difference between Quality Improvement and Implementation Science

<table>
<thead>
<tr>
<th></th>
<th>Quality Improvement</th>
<th>Implementation Science</th>
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<tbody>
<tr>
<td><strong>Focus</strong></td>
<td>A specific patient-level problem within a single healthcare system</td>
<td>An evidence-based practice that is under-utilized across healthcare</td>
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<tr>
<td><strong>Goal</strong></td>
<td>To fix the specific problem within a single healthcare system</td>
<td>To generate generalizable knowledge while also improving healthcare quality</td>
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<tr>
<td><strong>Approach</strong></td>
<td>Design and trial strategies to improve the problem</td>
<td>RE-AIM</td>
</tr>
<tr>
<td><strong>Models</strong></td>
<td>Toyota Lean Six Sigma</td>
<td>PARiHS framework</td>
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Another significant [research] gap is the dearth of implementation research in this area….little effort and limited research funding have been allocated to study how best to achieve large-scale implementation [of ASPs].
Implementing an Antibiotic Stewardship Program: Guidelines by the Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America


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“Qualitative assessments that can examine the impact of factors such as organizational culture, prescriber attitudes, and the self-efficacy of the antibiotic steward...are lacking and are important to establish the context in which ASP implementation occurs.”

Evidence-based guidelines for implementation and measurement of antibiotic stewardship interventions in inpatient populations including long-term care were prepared by a multidisciplinary expert panel of the Infectious Diseases Society of America and the Society
The Importance of Context in Antimicrobial Stewardship

Using implementation outcomes, we can understand...

- If the protocol failed at a site, was it because of an inherent flaw of the protocol or a failure of implementation?
- How can the protocol be modified to fit the context?

Adapted from Don Goldman’s talk, “QI Research vs. Implementation Science” 7/24/2014.
Available online (accessed 11/7/17).
Think about the last time you tried to implement an antimicrobial stewardship intervention at your practice site. What was the major barrier to the intervention being as effective as possible?

A. The intervention lacked buy-in from key stakeholders
B. The intervention was too time-consuming
C. The intervention was not sustainable
D. The intervention was not well-suited to the practice site where it was implemented
E. All of the above
F. None of the above
What will create the change?
Implementation Strategies

  - 73 implementation strategies labeled and defined
  - Includes:
    - Create new clinical teams
    - Audit and provide feedback
    - Identify and prepare champions
    - Use capitated payments
    - Mandate change
  - Suggests combining them based on innovation and conceptual model
Concept Map of Implementation Strategies

Did the change occur and why?
How/Why Will Antimicrobial-Prescribing Change?

Antimicrobial stewardship interventions
- Prior authorization
- Prospective audit-and-feedback
- Facility-specific guidelines
- Education
- Selective/cascade reporting
- Rapid diagnostic testing with real-time feedback

Implementation outcomes
- Acceptability
- Appropriateness
- Adoption
- Costs
- Feasibility
- Fidelity
- Penetration
- Sustainability

Antimicrobial stewardship outcomes
- Antimicrobial appropriateness
- Antimicrobial usage
- Antimicrobial resistance
- *Clostridium difficile*
- Re-admissions

Multi-level framework predicting implementation outcomes, Chaudoir, Dugan, Barr IS, 2013, 8:22.
<table>
<thead>
<tr>
<th>Dimension</th>
<th>Description</th>
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<tbody>
<tr>
<td>Acceptability</td>
<td>Perception among implementation stakeholders that a given evidence-based practice is <em>agreeable or satisfactory</em></td>
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<tr>
<td>Appropriateness</td>
<td><em>Perceived fit, relevance, or compatibility</em> of the evidence-based practice for a given practice setting, provider, or consumer; perceived fit to address problem</td>
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<tr>
<td>Adoption</td>
<td><em>Intention, initial decision, or action</em> to try to employ an evidence-based practice</td>
</tr>
<tr>
<td>Cost</td>
<td><em>Cost impact</em> of an implementation effort</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Extent to which a new evidence-based practice can be <em>successfully used or carried out</em> within a given agency or setting</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Degree to which an evidence-based practice was <em>implemented as it was prescribed</em> in the original protocol or intended by the practice developers</td>
</tr>
<tr>
<td>Penetration</td>
<td><em>Integration</em> of a practice within a service setting and its sub-systems.</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Extent to which a newly implemented evidence-based practice is</td>
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Let’s apply it.
A Report of the Efforts of the Veterans Health Administration National Antimicrobial Stewardship Initiative

Allison A. Kelly, MD, MSOH;¹,²,³ Makoto M. Jones, MD, MS;⁴,⁵ Kelly L. Echevarria, PharmD;⁶,⁷,⁸ Stephen M. Kralovic, MD, MPH;¹²,³ Matthew H. Samore, MD;⁴,⁵ Matthew B. Goetz, MD;⁹,¹⁰ Karl J. Madaras-Kelly, PharmD, MPH;¹¹,¹² Loretta A. Simbartl, MS;¹ Anthony P. Morreale, MBA, PharmD, BCPS;¹³ Melinda M. Neuhauser, PharmD, MPH;¹⁴ Gary A. Roselle, MD¹,²,³

Objective. To detail the activities of the Veterans Health Administration (VHA) Antimicrobial Stewardship Initiative and evaluate outcomes of the program.

Design. Observational analysis.

Setting. The VHA is a large integrated healthcare system serving approximately 6 million individuals annually at more than 140 medical facilities.

Methods. Utilization of nationally developed resources, proportional distribution of antibiotics, changes in stewardship practices and patient safety measures were reported. In addition, inpatient antimicrobial use was evaluated before and after implementation of national stewardship activities.

Results. Nationally developed stewardship resources were well utilized, and many stewardship practices significantly increased, including development of written stewardship policies at 92% of facilities by 2015 (P < .05). While the proportional distribution of antibiotics did not
Timeline of VHA Antimicrobial Stewardship Initiative

**May 2011**
VHA Antimicrobial Stewardship Taskforce was created

**May 2010-Nov 2011**
Regional educational conferences
250 ASP champions identified

**Oct 2011**
Electronic Sanford Guide made available at all sites
Needs assessment survey: What activities and resources might be most useful?

**Jan 2012**
Launched internal SharePoint site with intervention tools and example policies
Started monthly webinars

**July 2012**
Informational letter from VA Under Secretary for Health

**Sep 2013**
VA Memorandum encouraged local administrators to provide institutional support for stewardship

**Jan 2014**
VHA Directive for each hospital to implement and maintain an ASP
Monthly use of nationally provided stewardship resources across all VHA hospitals

Frequency of reported stewardship activities at VHA hospitals based on a voluntary survey in 2011 and mandatory surveys in 2012 and 2015

Inpatient antimicrobial use at VHA hospitals before and after the VHA Antimicrobial Stewardship Initiative.

Concept Map of Implementation Strategies

15) Conduct educational meetings
29) Develop educational materials
19) Conduct ongoing training
31) Distribute educational material
35) Identify and prepare champions
18) Conduct local needs assessment
23) Develop a formal implementation blueprint
21) Create new clinical teams
30) Develop resource sharing agreements
32) Facilitate relay of clinical data to providers
Concept Map of Implementation Strategies

44) Mandate change
Which implementation outcomes did Kelly et al. report regarding the VHA National Antimicrobial Stewardship Initiative?

A. Acceptability
B. Adoption
C. Cost
D. Penetration
E. B and D
F. All of the above
G. None of the above
<table>
<thead>
<tr>
<th>Category</th>
<th>Methodology</th>
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<tbody>
<tr>
<td>Acceptability</td>
<td>Conduct qualitative interviews with physicians; Survey of physician satisfaction with antimicrobial stewardship activities</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Conduct qualitative interviews with ASP pharmacists and physicians re: fit of program to culture of hospital</td>
</tr>
<tr>
<td>Adoption</td>
<td>Survey of number of policies/tools that were implemented; tracking utilization of resources (e.g., webinar attendance)</td>
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<tr>
<td>Cost</td>
<td>Tracking ASP staff time and salaries</td>
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<tr>
<td>Feasibility</td>
<td>Qualitative interviews regarding barriers and facilitators to implementation; Survey + antimicrobial outcomes</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Observation of how stewardship practices were implemented; utilization measures</td>
</tr>
<tr>
<td>Penetration</td>
<td>Survey documenting number of sites implementing certain interventions; utilization measures</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Tracking both implementation and outcome measures</td>
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VA Antimicrobial Stewardship Initiative

Antimicrobial stewardship interventions

- Intravenous to oral conversation tool
- Avoidance of double anaerobic coverage
- Intervention to improve outcomes for patients with CDI
- Stewardship monitoring of outpatient parenteral antibiotic therapy
- Vancomycin de-escalation

Implementation Strategies

- Conduct educational meetings
- Develop educational materials
- Conduct ongoing training
- Distribute educational materials
- Create new clinical teams

Implementation outcomes

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Chaudoir, Dugan, Barr, IS, 2013, 8:22; Kelly et al, ICHE, 2017
## Study Design Considerations

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<tr>
<th>Research Questions</th>
<th>Hybrid Type I</th>
<th>Hybrid Type II</th>
<th>Hybrid Type III</th>
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<tbody>
<tr>
<td><strong>Primary Question:</strong> Will a clinical treatment work in this setting/these patients?</td>
<td><strong>Primary Question:</strong> Will a clinical treatment work in this setting/these patients?</td>
<td><strong>Primary Question:</strong> Which implementation strategy works better in the implementation of the clinical treatment?</td>
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<tr>
<td><strong>Secondary Question:</strong> How was the clinical treatment implemented?</td>
<td><strong>Secondary Question:</strong> Does the implementation strategy show promise?</td>
<td><strong>Secondary Question:</strong> Was the clinical treatment effective?</td>
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Conclusions

• Large-scale implementation of antimicrobial stewardship will require tailoring stewardship processes to a wide variety of unique practice settings on the local level.

• Understanding gaps in practice and the reasons for these gaps is a key prerequisite for developing a successful implementation strategy.

• The measurement of implementation outcomes can help explain why and how a clinical intervention works. This can help distinguish intervention failures from implementation failures.

• Hybrid study designs facilitate the measurement of both clinical effectiveness and implementation outcomes.