Implementation and De-Implementation of Interventions in Trauma and Critical Care

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May 31, 2018
Disclosures

• Royalties from UpToDate
17 years (14% of research)

Dissemination and Implementation Studies
- Sustainment
- Implementation
- Adoption/Preparation
- Exploration
- Effectiveness Studies
- Efficacy Studies
- Preintervention

Why are some therapies slow (maybe too slow) to be implemented?

Why are some therapies quick (maybe too quick) to be implemented?
BRAND CAMP

NEW PRODUCT ADOPTION

I THINK I CAN

I THINK I CAN

I'M KING OF THE WORLD

SMOOTH SAILING

JUST WORKING OUT THE KINKS

OOF, I'M PATHETIC

WOW, BRILLIANT

I HEARD ASHTON KUTCHER HAS ONE

I FOUND IT AT SAM'S CLUB

WHAT NEW PRODUCT?

LAGGARDS

TEAM MEMBERS

INNOVATORS

EARLY ADOPTERS

EARLY MAJORITY

LATE MAJORITY

© 2007

Thanks to G. Moore

SKYDECKCARTOONS.COM

McGovern Medical School
Diffusion of Innovation (Rogers)

1. Qualities of innovation
2. Nature of the dissemination of knowledge and influence
3. Qualities of people doing the adopting and social structures
Qualities of the Innovation

- Social currency
- Triggers
- Emotion
- Public
- Practical value
- Stories
Activated Protein C

1) Marketing campaign
2) Values, Ethics, and Rationing in Critical Care (VERICC) task force ($1.8 million)
3) Surviving Sepsis Campaign

Timeline of Controlled Trials of rhAPC, Regulatory Actions, Yearly Sales, and the Marketing Initiative by Eli Lilly.
49 highly cited (> 1000 times) articles between 1990-2003:
45 (92%) described effective intervention
7 (16%) contradicted by subsequent studies
7 (16%) effects stronger than those of subsequent studies
20 (44%) replicated
11 (24%) largely unchallenged

### Nature of Dissemination: Guidelines

<table>
<thead>
<tr>
<th>EAST Guideline Recommendation</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Damage control resuscitation (DCR)</td>
<td>2017</td>
</tr>
<tr>
<td>Massive transfusion/ DCR protocol</td>
<td></td>
</tr>
<tr>
<td>High ratio of plasma and platelets to RBC</td>
<td></td>
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<tr>
<td>rVIIa</td>
<td></td>
</tr>
<tr>
<td>TXA</td>
<td></td>
</tr>
<tr>
<td>ORIF of rib fractures</td>
<td>2017</td>
</tr>
<tr>
<td>For flail chest</td>
<td></td>
</tr>
<tr>
<td>For non-flail rib fractures</td>
<td></td>
</tr>
</tbody>
</table>
Qualities of the adopters
Why might we implement ineffective/ harmful therapies?
<table>
<thead>
<tr>
<th><strong>Contagious: Why Things Catch On</strong> Author: Jonah Berger</th>
<th><strong>Ending Medical Reversal: Improving Outcomes, Saving Lives</strong> Authors: Vinayak Prasad and Adam Cifu</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Social currency</strong></td>
<td><strong>Technology effect</strong></td>
</tr>
<tr>
<td>“It’s cool”</td>
<td>“Newer is better”</td>
</tr>
<tr>
<td><strong>Triggers</strong></td>
<td><strong>Basic science in education</strong></td>
</tr>
<tr>
<td>Tip of the tongue</td>
<td></td>
</tr>
<tr>
<td><strong>Emotion</strong></td>
<td><strong>Act now, data later</strong></td>
</tr>
<tr>
<td>Feelings (positive and negative)</td>
<td></td>
</tr>
<tr>
<td><strong>Public</strong></td>
<td><strong>Direct-to-consumer advertising</strong></td>
</tr>
<tr>
<td>Popularizing of products</td>
<td></td>
</tr>
<tr>
<td><strong>Practical value</strong></td>
<td><strong>Abandoning a paycheck</strong></td>
</tr>
<tr>
<td>Good deal</td>
<td></td>
</tr>
<tr>
<td><strong>Stories</strong></td>
<td></td>
</tr>
</tbody>
</table>
Kaplan-Meier Curves Showing Cumulative Survival of Patients Who Received Intensive Insulin Treatment or Conventional Treatment in the Intensive Care Unit (ICU)

**Single center efficacy trial**

Implementation of TGC

% ICU admissions receiving intervention

Study Quarter

Reasons why we got it wrong initially?

• Confidence that pathophysiologic concepts underlying the practice were rational
• Extrapolating results to an unstudied group
• Excessive confidence in a single-center trial
• Studying only short-term but not long-term endpoints
• Applying data gathered in an era before advanced medical therapies in a later era
• Initial studies were improperly controlled
A research finding is less likely to be true when:

- The studies conducted in a field are smaller
- Where effect sizes are smaller
- When there is a greater number and lesser preselection of tested relationships
- Where there is greater flexibility in designs, definitions, outcomes, and analytical modes
- When there is greater financial and other interest and prejudice
- When more teams are involved in a scientific field in chase of statistical significance
Low sample size

Not replicable

Trial stopped early

Placebo effect

Surrogate outcomes

Flawed meta-analyses (GIGO)

Age-old adages
How can we do better at implementation?
Theory (big T): based on a body of facts repeatedly confirmed through observation and experiment (not pictured)

Model: simplified context-specific representation of a complex reality

Framework: broad set of propositions that organize diagnostic and/or prescriptive inquiry

Theory (little t): middle-range set of context-independent propositions specifying a denser and more logically coherent set of relationships

Using D&I Models to Guide Trial Design

D=I: RE-AIM

- **Reach**
- **Efficacy**
- **Adoption**
- **Implementation**
- **Maintenance**

- **Reach**
  - Proportion and representativeness of individuals who participate in intervention

- **Efficacy**
  - Degree to which intervention worked

- **Adoption**
  - Proportion and representativeness of settings, organizations, etc.

- **Implementation**
  - Level of fidelity

- **Maintenance**
  - Level of sustained use and sustained participation

Using D&I Models to Guide Implementation

Increasing specificity and visibility

Model or framework

Strategy

Tool

Implementation toolkit: a package of implementation materials that is developed, tested, and refined for dissemination for use in spreading a targeted best practice intervention or program

Implementation strategy or program: an integrated set of implementation interventions (methods or techniques to facilitate change/ adoption of best practice recommendations)

# Expert Recommendations for Implementing Change (ERIC) Project

<table>
<thead>
<tr>
<th>Implementation Strategy</th>
<th>Importance</th>
<th>Feasibility</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use evaluative and iterative strategies</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Audit and provide feedback</td>
</tr>
<tr>
<td>Provide interactive assistance</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Provide clinical supervision</td>
</tr>
<tr>
<td>Adapt and tailor to context</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Tailor strategies</td>
</tr>
<tr>
<td>Develop stakeholder interrelationships</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Identify and prepare champions</td>
</tr>
<tr>
<td>Train and educate stakeholders</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Develop educational materials</td>
</tr>
<tr>
<td>Support clinicians</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Remind clinicians</td>
</tr>
<tr>
<td>Engage consumers</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Involve patients and family members</td>
</tr>
<tr>
<td>Utilize financial strategies</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Develop disincentives</td>
</tr>
<tr>
<td>Change infrastructure</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>⭐️⭐️⭐️⭐️⭐️</td>
<td>Create/change credentialing standards</td>
</tr>
</tbody>
</table>
Context:
1. Enthusiastic leadership (implied)
2. Adequate resource commitment (implied)
3. Responsive system to identify equipment issues (implied)
# Effectiveness-Implementation Hybrid Designs

**Diagram:**

- **Efficacy Studies** → **Effectiveness Studies** → **Implementation Research** → **Improved processes, outcomes**

<table>
<thead>
<tr>
<th>Study Characteristic</th>
<th>Hybrid Trial Type 1</th>
<th>Hybrid Trial Type 2</th>
<th>Hybrid Trial Type 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research aims</td>
<td>1: determine effectiveness of a clinical intervention</td>
<td>1a: determine effectiveness of a clinical intervention</td>
<td>1: determine utility of an implementation intervention/strategy</td>
</tr>
<tr>
<td></td>
<td>2: better understand context for implementation</td>
<td>2: determine feasibility and potential utility of an implementation intervention/strategy</td>
<td>2: assess clinical outcomes associated with implementation trial</td>
</tr>
</tbody>
</table>
Why might we fail to de-implement ineffective/harmful therapies?
De-implementation of TGC

% ICU admissions receiving intervention

Study Quarter

Barriers to de-implementation: Psychological biases

- Loss aversion
- Confirmation bias
- Threat to autonomy

Barriers to de-implementation: Context

How can we do better at de-implementation?
<table>
<thead>
<tr>
<th>Factor</th>
<th>General principle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior evidence base</td>
<td>Priority should be given to practices where the present <strong>evidence base is weakest</strong></td>
</tr>
<tr>
<td>Cost/ ubiquity</td>
<td>Priority should be given to interventions with <strong>significant net financial burden</strong> on health payers</td>
</tr>
<tr>
<td>Alternative options</td>
<td>Priority should be given to practices for which there are <strong>several alternatives</strong> or of low cost bolstered by stronger evidence</td>
</tr>
<tr>
<td>Documented harms</td>
<td>Priority should be given to test practices where the <strong>harms</strong> are well documented and confer substantial morbidity</td>
</tr>
<tr>
<td>Testing the intervention</td>
<td>Priority should be given to test practices where the <strong>cost to test is far less than ongoing expenditures of the practice</strong></td>
</tr>
<tr>
<td>makes financial sense</td>
<td></td>
</tr>
<tr>
<td>Proponents are open-minded</td>
<td>Priority should be given to test practices where <strong>negative results may truly gain traction</strong></td>
</tr>
<tr>
<td>Value of information gained</td>
<td>Priority should be based on the expected value of funding a specific study that may <strong>inform de-implementation</strong> at the size and cost proposed</td>
</tr>
</tbody>
</table>

**Prioritizing testing unproven Rx’s**

*Prasad and Ioannidis. Implementation Science 2014.*
Prevention

1. Take pre-emptive steps that would allow for efficient de-implementation

2. Restrict use (i.e., use only on protocol) prior to widespread dissemination
Effective de-implementation

1. **Substitution**
   - Alternative to an innovation

2. **Disenchantment**
   - New information indicates that the benefits of the existing medical care do not justify the costs or adverse effects
How can a collaborative lead a de-implementation effort?

No difference in mortality.

Prophylactic IVC filter placement was associated with DVT (OR 1.83, 95% CI 1.15-2.93)
How can a collaborative lead a de-implementation effort?

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process Measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VTE prophylaxis ≤ 48 h (%)</td>
<td>--</td>
<td>41.6</td>
<td>47.6</td>
<td>51.3</td>
<td>58.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VTE prophylaxis w/ LMWH (%)</td>
<td>--</td>
<td>33.3</td>
<td>37.9</td>
<td>38.3</td>
<td>43.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IVC filter (%)</td>
<td>2.49</td>
<td>1.96</td>
<td>1.72</td>
<td>1.08</td>
<td>0.98</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Outcome Measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DVT (%)</td>
<td>1.51</td>
<td>1.36</td>
<td>1.17</td>
<td>0.92</td>
<td>1.04</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PE (%)</td>
<td>0.51</td>
<td>0.40</td>
<td>0.44</td>
<td>0.47</td>
<td>0.43</td>
<td>0.7</td>
</tr>
</tbody>
</table>
### How can a surgeon lead a de-implementation effort?

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Younger leaders</td>
<td>Obtain senior stakeholder buy-in</td>
</tr>
<tr>
<td>Departmental policies and economic/political factors</td>
<td>Obtain senior stakeholder buy-in</td>
</tr>
<tr>
<td>Perceived threat to autonomy</td>
<td>Collaborate and obtain buy-in (i.e. absolute versus relative indications for an innovation)</td>
</tr>
<tr>
<td>Confirmation bias or loss of aversion to an innovation</td>
<td>Conduct a trial</td>
</tr>
<tr>
<td>Relative value of RCTs versus clinical experience</td>
<td>Conduct a trial</td>
</tr>
</tbody>
</table>

Van Bodegom-Vos. 
How can a surgeon lead a de-implementation effort?

![Graph showing the rate of damage control laparotomy (DCL) per month from January 2011 to January 2016. The graph is divided into three sections:

1. Definitive laparotomy – no equipoise
2. Equipoise (“Grey Zone”)
3. Damage control laparotomy – no equipoise

The graph shows a fluctuating rate of DCL per month, with peaks and troughs throughout the years.]
Emergency abdominal operation

- Definitive: 59%
- Damage control: 17%

Random allocation

- ???: 24%
In a learning health care system, research influences practice and practice influences research.

McGovern Medical School

LEARNING HEALTH CARE SYSTEM + IMPLEMENTATION SCIENCE:
(1) Support for implementation of effective practices
(2) Contextually sensitive improvement of practices
Summary

• Methodological rigor must be balanced with efficiency in clinical trials to be able to generate and apply knowledge in real time.

• Dissemination and implementation models, strategies, and tools can facilitate uptake of effective, evidence-based practices.

• Learning healthcare systems and implementation science are complementary and necessary for achieving high-quality, high-value patient-centered care.
Questions?
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