Implementation Science
Approaches &
Outcomes Measurement

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Associate Professor of Surgery, Anesthesiology &
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#TraumaVTE22 CNTR4u
Disclosures

• Some of this work has been funded by
  – Patient Centered Outcomes Research Institute (PCORI)
Implementation Science
“Practical Guide to Implementation Science”

- Implementation science is the study of methods and strategies to promote the adoption and integration of proven clinical treatments, practices, organizational, and/or management interventions into routine practice and hence to improve health.

Neuman, Kaji, Haut. *JAMA Surg* 2020
1. Actively design and evaluate interventions with implementation and future dissemination in mind.
2. Create a transdisciplinary research team with key stakeholders from all relevant groups.
4. Consider using the hospital floor, outpatient clinic, hospital, or practice as the randomized implementation unit, rather than randomizing individual patients.
5. Assess outcomes via an established framework (ie, the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework) using mixed methods.
6. Manuscripts should follow standard reporting requirements (ie, Strengthening the Reporting of Observations Studies in Epidemiology, Standards for Reporting Qualitative Research).

Neuman, Kaji, Haut. JAMA Surg 2020
Conclusions

Implementation science can promote the uptake of evidence-based surgical interventions into clinical practice and improve the consistency of high-quality care after surgery. The ability of surgeons to appreciate and use implementation science in their own research will be greatly facilitated by training, stakeholder engagement, and funding opportunities.
Rigorous Scientific Approaches to Changing Practice
Translating evidence into practice: a model for large scale knowledge translation

Changes that can improve patients’ health are often difficult to get into practice, even when backed by good evidence. Peter Pronovost, Sean Berenholtz, and Dale Needham describe a collaborative model that has been shown to work.

Our model combined culture change and evidence with rigorous measurement... clinicians (especially doctors) perceived the measures and results as valid.

- About 350 citations
- JAMA, Ann Surg, BMJ, Chest, PlosOne, Circulation, CCM, Health Affairs
Overall concepts
Envision the problem within the larger healthcare system
Engage collaborative multidisciplinary teams centrally (stages 1-3) and locally (stage 4)

1. Summarise the evidence
Identify interventions associated with improved outcomes
Select interventions with the largest benefit and lowest barriers to use
Convert interventions to behaviours

2. Identify local barriers to implementation
Observe staff performing the interventions
“Walk the process” to identify defects in each step of implementation
Enlist all stakeholders to share concerns and identify potential gains and losses associated with implementation

3. Measure performance
Select measures (process or outcome)
Develop and pilot test measures
Measure baseline performance

4. Ensure all patients receive the interventions
Implement the “four Es” targeting key stakeholders from front line staff to executives

**Engage**
Explain why the interventions are important

**Evaluate**
Regularly assess for performance measures and unintended consequences

**Educate**
Share the evidence supporting the interventions

**Execute**
Design an intervention “toolkit” targeted at barriers, standardisation, independent checks, reminders, and learning from mistakes
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Consolidated Framework for Implementation Research (CFIR)

- “Provides a menu of constructs that have been associated with effective implementation”
- Barriers and Facilitators

https://cfirguide.org/
### Consolidated Framework for Implementation Research (CFIR)

<table>
<thead>
<tr>
<th>Intervention characteristics</th>
<th>Outer setting</th>
<th>Inner setting</th>
<th>Characteristics of Individuals</th>
<th>Process of implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Intervention source</td>
<td>- Patient Needs &amp; Resources</td>
<td>- Structural Characteristics</td>
<td>- Knowledge &amp; Beliefs about the Intervention</td>
<td>- Planning</td>
</tr>
<tr>
<td>- Evidence Strength &amp; Quality</td>
<td>- Cosmopolitanism</td>
<td>- Networks &amp; Communications</td>
<td>- Self-Efficacy</td>
<td>- Engaging</td>
</tr>
<tr>
<td>- Relative advantage</td>
<td>- Peer pressure</td>
<td>- Culture</td>
<td>- Individual Stage of Change</td>
<td>- Opinion Leaders</td>
</tr>
<tr>
<td>- Adaptability</td>
<td>- External Policy &amp; incentives</td>
<td>- Implementation Climate</td>
<td>- Individual Identification with Organization</td>
<td>- Formally</td>
</tr>
<tr>
<td>- Trialability</td>
<td></td>
<td>- Tension for Change</td>
<td>- Other Personal Attributes</td>
<td>- Appointed</td>
</tr>
<tr>
<td>- Complexity</td>
<td></td>
<td>- Compatibility</td>
<td></td>
<td>- Internal</td>
</tr>
<tr>
<td>- Design Quality &amp; Packaging</td>
<td></td>
<td>- Relative Priority</td>
<td></td>
<td>- Implementation</td>
</tr>
<tr>
<td>- Cost</td>
<td></td>
<td>- Organizational Incentives &amp; Rewards</td>
<td></td>
<td>Leaders</td>
</tr>
</tbody>
</table>

Van Oers, Qual Life Res 2021
Dissemination, implementation, and de-implementation: the trauma perspective

Ho, Dicker, Haut, TSACO 2020
# Implementation Science Outcomes

## Table 1  Outcomes for implementation science

<table>
<thead>
<tr>
<th>Implementation outcomes</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Acceptability**               | The perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory  
    *Synonyms*: Satisfaction with various aspects of the innovation (eg, content, complexity, comfort, delivery, and credibility) |
| **Adoption**                    | The intention, initial decision, or action to try or employ an innovation or evidence-based practice  
    *Synonyms*: Uptake; utilization; initial implementation; intention to try |
| **Appropriateness**             | The perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem. “Appropriateness” is conceptually similar to “acceptability,” and the literature reflects overlapping and sometimes inconsistent terms when discussing these constructs  
    *Synonyms*: Perceived fit; relevance; compatibility; suitability; usefulness; practicability |
| **Implementation costs**        | Cost impact of an implementation effort, dependent on three components: variation in complexity of treatments, variation for complexity of implementation strategy, variation by setting and overhead  
    *Synonyms*: Marginal cost; cost-effectiveness; cost–benefit |
| **Feasibility**                 | The extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting. Actual fit or utility; suitability for everyday use; practicability |
| **Fidelity**                    | The degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the programme developers  
    *Synonyms*: Delivered as intended; adherence; integrity; quality of program delivery |
| **Penetration**                 | Integration of a practice within a service setting and its subsystems  
    *Synonyms*: Level of institutionalization; spread; service access |
| **Sustainability**              | The extent to which a newly implemented treatment is maintained or institutionalized within a service setting’s ongoing stable operations  
    *Synonyms*: Maintenance; continuation; durability; incorporation; integration; institutionalization; sustained use; routinization |

Ho, Dicker, Haut, TSACO 2020
So what does this all have to do with VTE?
A Big Assumption

• As physicians, we assume that medication orders we place are consistently delivered.
• But is that truly the case?
• Does prescription = administration?
Steps to Optimal Pharmacologic VTE Prophylaxis

Provider Prescription → Nurse Administration → Patient Acceptance
Missed Doses of VTE Prophylaxis Matter

Association Between Missed Doses of Chemoprophylaxis and VTE Incidence in a Statewide Colectomy Cohort

Rhami Khorfan, MD, MS,* Lindsey Kreutzer, MPH,† Remi Love, MA,‡ Cary Jo R. Schlick, MD,* Matthew Chia, MD,* Karl Y. Bilimoria, MD, MS,* and Anthony D. Yang, MD, MS*†‡

(Ann Surg 2021;273:e151–e152)

Original Investigation | PACIFIC COAST SURGICAL ASSOCIATION

Correlation of Missed Doses of Enoxaparin With Increased Incidence of Deep Vein Thrombosis in Trauma and General Surgery Patients

Scott G. Louis, MD; Misa Sato; Travis Geraci, MD; Ross Anderson, BS; S. David Cho, MD; Philbert Y. Van, MD; Jeffrey S. Barton, MD; Gordon M. Riha, MD; Samantha Underwood, MS; Jerome Differding, MPH; Jennifer M. Watters, MD; Martin A. Schreiber, MD

Patterns of Non-Administration of Ordered Doses of Venous Thromboembolism Prophylaxis: Implications for Novel Intervention Strategies

Kenneth M. Shermock, Brandyn D. Lau, Elliott R. Haut, Deborah B. Hobson, Valerie S. Genetsky, Peggy S. Kraus, Leigh E. Elkind, Christoph U. Lehmann, Brian L. Pinto, Patricia A. Ross, Michael B. Streiff

All Patients Prescribed Pharmacologic Venous Thromboembolism (VTE) Prophylaxis

<table>
<thead>
<tr>
<th>One Academic Hospital (n=24,709)</th>
<th>Three Community Hospitals (n=18,355)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of VTE Prophylaxis Does Not Administered (p=0.011)</td>
<td>Proportion of Patients who Miss ≥ 1 Dose (p=0.852)</td>
</tr>
<tr>
<td>10.9% 33,291/311,204</td>
<td>13.6% 21,500/158,608</td>
</tr>
<tr>
<td>43.7%</td>
<td>43.6%</td>
</tr>
</tbody>
</table>

Lau, et al. JGIM 2017
Copyright © 2017 American Society of Internal Medicine. All rights reserved.
Published by Springer Nature
Nurse Education Improves VTE Prophylaxis Administration
Nurse Education Improves Missed Doses of VTE Prophylaxis

Adult Medical and Surgical Nurses at The Johns Hopkins Hospital (n=933)

Nurses Cluster Randomized by Floor to Receive One of Two Education Modules about Venous Thromboembolism (VTE) Prevention

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>Any Education</th>
<th>VTE Prophylaxis Non-Administration (p=0.002)</th>
<th>12.4% → 11.1% OR: 0.87, 95% CI: 0.80-0.95</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dynamic Scenario-based Education</td>
<td>10.8% → 9.2% OR: 0.83, 95% CI: 0.72-0.95</td>
<td>VTE Prophylaxis Non-Administration (p=0.26)</td>
<td>14.5% → 13.5% OR: 0.92, 95% CI: 0.81-1.03</td>
</tr>
<tr>
<td>Linear Static Education</td>
<td>Satisfaction (p&lt;0.05)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Lau, et al. PLOS ONE 2017

Copyright 2017 PLOS. All rights reserved. Published by Public Library of Science
Success of a Patient Education Bundle on VTE Prophylaxis
Patient Education Bundle

- One-on-one, face-to-face engagement with a nurse educator
- 2-page patient education sheet
- 10-minute patient education video

Haut, JAMA Network Open 2018
What Do Patients Want?
Paper Form (2-pages)

**The Johns Hopkins Hospital Patient Information**

<table>
<thead>
<tr>
<th>What is a blood clot or Venous Thromboembolism (VTE)?</th>
<th>How Do I Prevent Blood Clots?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood clots are called Venous Thromboembolism (VTE). There are 2 main types:</td>
<td>Venous Thromboembolism (VTE)</td>
</tr>
<tr>
<td>- Deep Vein Thrombosis (DVT) is a clot in a deep vein, usually an arm or leg</td>
<td>Deep Vein Thrombosis (DVT)</td>
</tr>
<tr>
<td>- Pulmonary Embolism (PE) is a clot that has broken off and traveled to the lungs. This can cause death.</td>
<td>Pulmonary Embolism (PE)</td>
</tr>
</tbody>
</table>

- [www.hopkinsmedicine.org/armstrong/bloodclots](http://www.hopkinsmedicine.org/armstrong/bloodclots)

They spoke, we listened

Video

>275,000 views on YouTube
### Patient Education Bundle Study Results

**Adult Medical and Surgical Patients at The Johns Hopkins Hospital Prescribed Pharmacologic VTE Prophylaxis**

<table>
<thead>
<tr>
<th>Control Floors</th>
<th>Intervention Floors</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=14,319</td>
<td>N=5,333</td>
</tr>
</tbody>
</table>

**No Alert**

- **Usual Care**
  - 13.6% → 13.3%
    - Conditional OR: 0.98 (95% CI: 0.91-1.07)
  - 8.7% → 8.5%
    - Conditional OR: 0.98 (95% CI: 0.89-1.08)

**VTE Prophylaxis Non-Administration (p<0.001)**

- 9.1% → 5.6%
  - Conditional OR: 0.57 (95% CI: 0.48-0.67)

**Patient Refusal (p<0.001)**

- 5.9% → 3.4%
  - Conditional OR: 0.53 (95% CI: 0.43-0.65)

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Haut ER, et al. *JAMA Network Open*. 2018

Generalizability (D&I) Award #2 PCORI

- Consortium of Leaders in the study Of Traumatic Thromboembolism (CLOTT)

- Project funded by PCORI Dissemination and Implementation (D&I) Award
CLOTT 3

@elliotthaut

#TraumaVTE22 #CNTR4u
Stakeholder Organizations

- National Blood Clot Alliance
- North American Thrombosis Forum
- Patient Safety Movement Foundation
- Society of Trauma Nurses
- American Trauma Society
- American College of Surgeons Committee on Trauma
- Coalition for National Trauma Research Board of Directors
- Coalition for National Trauma Research Scientific Advisory Council
- Eastern Association for the Surgery of Trauma
- Trauma Surgery & Acute Care Open
- American Association for the Surgery of Trauma
Multi-Center Study

Coalition for National Trauma Research Network

Principal Investigator
Elliott Haut MD, PhD, FACS

Study Overview
The primary objective is to help nurses and patients make informed decisions regarding VTE prevention and reduce the occurrence of blood clots in injured patients.

1. University of Maryland
2. Oregon Health & Science University
3. Medical College of Wisconsin (Froedtert Hospital)
4. Stanford University (Stanford Health Care)
5. University of California – San Diego
6. University of California – San Francisco (Zuckerberg San Francisco General Hospital)
7. University of Utah
8. Medical University of South Carolina
9. Penn Medicine – Lancaster General Hospital
10. Christiana Hospital
Facilitators

- Engaged leaders
- Involved multidisciplinary teams
- Standardized nurse education
Venous Thromboembolism Prevention: The Nurse's Perspective

This module focuses on the nurse's role in VTE prevention. It provides an overview of the latest information regarding VTE: prophylaxis, appropriate delivery of pharmacologic and mechanical methods, how to educate patients on VTE, and how to address missed and refused doses. It includes interactive cases, video, and real-time knowledge assessment, and provides nurses with the skills to enable patients to make educated decisions.
## Nurse Education Module
(Percent complete by site)

<table>
<thead>
<tr>
<th>Site</th>
<th>Completers</th>
<th>Percent of all Completers</th>
<th>Each Site's Target #</th>
<th>Percent Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>212</td>
<td>21%</td>
<td>235</td>
<td>90%</td>
</tr>
<tr>
<td>B</td>
<td>111</td>
<td>11%</td>
<td>131</td>
<td>85%</td>
</tr>
<tr>
<td>C</td>
<td>127</td>
<td>12%</td>
<td>157</td>
<td>81%</td>
</tr>
<tr>
<td>D</td>
<td>30</td>
<td>3%</td>
<td>172</td>
<td>17%</td>
</tr>
<tr>
<td>E</td>
<td>49</td>
<td>5%</td>
<td>117</td>
<td>42%</td>
</tr>
<tr>
<td>F</td>
<td>105</td>
<td>10%</td>
<td>115</td>
<td>91%</td>
</tr>
<tr>
<td>G</td>
<td>53</td>
<td>5%</td>
<td>60</td>
<td>88%</td>
</tr>
<tr>
<td>H</td>
<td>49</td>
<td>5%</td>
<td>58</td>
<td>84%</td>
</tr>
<tr>
<td>I</td>
<td>88</td>
<td>9%</td>
<td>126</td>
<td>70%</td>
</tr>
<tr>
<td>J</td>
<td>72</td>
<td>7%</td>
<td>118</td>
<td>61%</td>
</tr>
<tr>
<td><strong>Project Total</strong></td>
<td><strong>896</strong></td>
<td>-</td>
<td><strong>1339</strong></td>
<td><strong>67%</strong></td>
</tr>
</tbody>
</table>

Data as of 4/27/2022
Facilitators

- Validated patient education materials
- Toolkit materials for roll-out
Implementation Materials

How To Talk to Patients About VTE Prevention
- Let’s talk about how to keep you safe in the hospital.
- Your doctor looked at your individual risk factors for blood clots.
- Medicine is the best practice for blood clot prevention.
- Walking has NOT been shown to prevent blood clots.
- Bruising and burning can happen, but we can lessen that by giving the shot slowly.
- Do you have questions about the handout or video? bit.ly/bloodclots

Strategies for Refused Doses
- Provide Education Bundle
  - Talk to Patient
  - AND
  - Provide Education Handout
  - AND
  - Show “How Do I Prevent Blood Clots?” Video
- Still Refusing
  - Document and Notify Provider

Strategies for Missed Doses
- Patient Off Floor
  - Give dose when patient returns
- Patient Being Discharged
  - Give dose before discharge
- Upcoming Procedure
  - Give dose unless held ordered by prescriber
- Condition Not Appropriate
  - Confirm with prescriber to hold dose
- Duplicate Orders
  - Ask provider to correct

What to Know
- Your blood clot risk
- What your provider has ordered
- How to prevent blood clots

Learn More
- Video
- Handout
- Visit this site for more info: bit.ly/bloodclots
Implementation Materials

What to Know

- Your blood clot risk
- What your provider has ordered
- How to prevent blood clots

Learn More

- Video
- Handout
- Visit this site for more info: bit.ly/bloodclots
Barriers

- Competing Priorities
  - COVID-19
The COVID-19 Effect

COVID-19: The dark side and the sunny side for patient safety

Patient Safety and Quality Improvement Adaptation During the COVID-19 Pandemic

Robert S. Sterling, MD, FAAOS, FAOA\(^1\), Stephen A. Berry, MD, PhD\(^2,3\), Carrie A. Herzke, MD, MBA\(^2\), and Elliott R. Haut, MD, PhD, FACS\(^3,4,5\)

The Effect on Trauma Care Secondary to the COVID-19 Pandemic

Collateral Damage From Diversion of Resources

Elliott R. Haut, MD, PhD, FACS, Ira L. Leeds, MD, MBA, ScM, and David H. Livingston, MD, FACS

Keywords: COVID-19, injury, quality, surgical care, trauma

(Ann Surg 2020;272:e204–e207) left most hospitals in high prevalence areas to treat every trauma patient as potentially COVID positive. Although this may not yet be true outside of previous hotspots, it is becoming more apparent that
Barriers

• Research Hurdles
  • Variation in IRB approvals

• Informatics Barriers
  • Lack of interoperability
  • Multiple alert options

• Hospital Policies / Culture
  • Differential approaches to holding VTE prophylaxis
  • Variation in medication formularies
  • Diverse workflows
Be Ready to Change PARTS of an Intervention

• Your proposed intervention may not be accepted “as-is”
• Original project had dedicated nurse educator
• How can it be adapted to the real world?
• Who has the final say?

• Issues of Acceptability, Adoption, Cost, Fidelity
Get It In Writing

• Look back at letters of support (or emails, meeting minutes, etc.)
• Be prepared for leadership and management turnover
• New team may not know what was promised or agreed to
Be Prepared to Battle with Bureaucracy

• Many committees need to approve education roll out
• At what level is the decision made?
  • Health system, hospital, functional unit, floor, nurse
• Different pathways for different hospitals?
• Informatics, Electronic Health Record (EHR) System
Be Ready to Advocate for Long-Term Continuation

- What happens after the funded “research” phase is over?
- Who takes over control for sustainability?
- Who pays the costs?
- Can you still stay involved and have a voice to push for fidelity?
Changing Practice is a Team Effort

@elliotthaut

#TraumaVTE22 #CNTR4u
For More Info
@elliotthaut (Twitter) or ehaut1@jhmi.edu

• Hopkins VTE Website
  – http://www.Hopkinsmedicine.org/Armstrong/bloodclots

• Patient Education Video and Paper Handouts

• Nurse Education
  – https://www.hopkinsmedicine.org/armstrong_institute/training_services/eLearning/ or bit.ly/NurseEducationVTE

• CNTR Website
  – https://www.nattrauma.org/research/research-policies-templates-guidelines/clott-3-project-page/