

# Catalyzing the Translation of Patient-Centered Research Into United States Trauma Care Systems

## A Case Example

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**Background:** The expedient translation of research findings into sustainable intervention procedures is a longstanding health care system priority. The Patient-Centered Outcomes Research Institute (PCORI) has facilitated the development of “research done differently,” with a central tenet that key stakeholders can be productively engaged throughout the research process. Literature review revealed few examples of whether, as originally posited, PCORI’s innovative stakeholder-driven approach could catalyze the expedient translation of research results into practice.

**Objectives:** This narrative review traces the historical development of an American College of Surgeons Committee on Trauma (ACS/COT) policy guidance, facilitated by evidence supplied by the PCORI-funded studies evaluating the delivery of patient-centered care transitions. Key elements catalyzing the guidance are reviewed, including the sustained engagement of ACS/COT policy stakeholders who have the capacity to invoke system-level implementation strategies, such as regulatory mandates linked to verification site visits. Other key elements, including the encouragement of patient

stakeholder voice in policy decisions and the incorporation of end-of-study policy summits in pragmatic comparative effectiveness trial design, are discussed.

**Conclusions:** Informed by comparative effectiveness trials, ACS/COT policy has expedited introduction of the patient-centered care construct into US trauma care systems. A comparative health care systems conceptual framework for transitional care which incorporates Research Lifecycle, pragmatic clinical trial and implementation science models is articulated. When combined with Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE), employed as a targeted implementation strategy, this approach may accelerate the sustainable delivery of high-quality patient-centered care transitions for US trauma care systems.

**Key Words:** Patient-Centered Outcomes Research Institute Transitional Care Evidence to Action Network, trauma care systems policy, comparative effectiveness trials, pragmatic clinical trials, Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE)

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Catalyzing the expedient translation of clinical trial findings into health care system policy and practice has received increasing attention over the past 2 decades.<sup>1–6</sup> Multiple health services research areas, including learning health care systems, pragmatic clinical trials, and dissemination and implementation fields, have emphasized the need to shorten the 17-year translational gap.<sup>1</sup>

The Patient-Centered Outcomes Research Institute (PCORI) supports comparative effectiveness research with a central tenet that key stakeholders, including patients, be engaged in all aspects of the research process.<sup>4,7,8</sup> PCORI supported greater stakeholder involvement in research to speed adoption of meaningful research findings, yet early formulations of the PCORI mission acknowledged that this tenet remained to be formally assessed.<sup>4,9</sup> Due in part to this unique stakeholder-driven approach, PCORI has a reputation for “research done differently.”<sup>8,10,11</sup> Few examples in the literature exist, however, that articulate the processes by which this stakeholder-driven approach has expedited translation of research results into practice in US health care systems. As part of the *Transitional Care Evidence to Action Network (TC-E2AN) Medical Care Supplement*, this article examines how novel stakeholder-driven research within the

Transitional Care Evidence to Action Network (TC-E2AN) has directly impacted regulatory policy for the delivery of patient-centered care within US trauma care systems.<sup>9</sup>

This narrative review works inductively from a PCORI TC-E2AN case example that has evolved over the past decade, tracing the steps that influenced the historical development of an American College of Surgeons Committee on Trauma (ACS/COT) guidance regarding the delivery of patient-centered transitional care. The approach linking pragmatic comparative effectiveness trials to end-of-study policy summits, while capitalizing on the unique opportunities for trauma surgery policy stakeholder engagement and incorporation of patient perspectives facilitated by PCORI, is also outlined. A comparative health care systems conceptual framework for transitional care which incorporates Research Lifecycle, pragmatic clinical trial, and implementation science models is articulated. When combined with Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE),<sup>5</sup> employed as a targeted implementation strategy, this approach may accelerate the sustainable delivery of high quality patient-centered care transitions for US trauma care systems.

**BACKGROUND: PATIENTS TREATED WITHIN UNITED STATES TRAUMA CARE SYSTEMS**

Between 2013 and 2018, ~2.5 to 3.0 million Americans annually were so severely injured that they required inpatient hospital admission.<sup>12</sup> Injured patients treated within US trauma care systems are a vulnerable patient population with regard to recurrent emergency department visits/hospitalizations and health disparities; in addition, the evolving coronavirus disease 2019 (COVID-19) pandemic has impacted injury survivors in ways that are just beginning to be appreciated.<sup>13-16</sup> For example, initial studies suggest that the COVID-19 pandemic has further exacerbated the fragmentation of care transitions for vulnerable injured populations.<sup>15,16</sup>

**THE AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA REGULATION OF UNITED STATES TRAUMA CARE SYSTEMS**

The ACS/COT develops national policy requirements and clinical best practice guidelines that inform the integrated operation of US trauma centers and affiliated trauma care systems.<sup>17,18</sup> The ACS/COT has successfully linked trauma center designation to verification site visits and other quality indicators.<sup>17,18</sup> Through this link to designation, the ACS/COT can mandate practice improvements based on an evolving pragmatic comparative

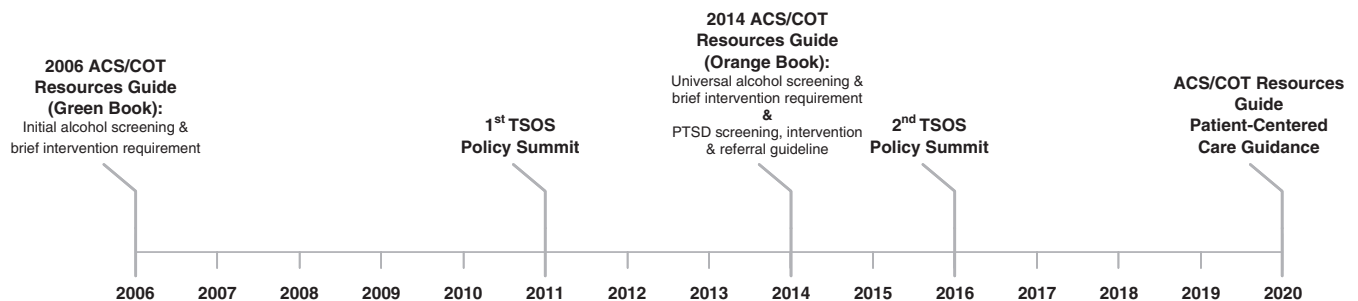
effectiveness trial evidence base. This capacity to mandate and verify practice improvements constitutes a health care system-wide implementation strategy.<sup>5,17-20</sup> Of note, the ACS/COT has the capacity to produce guideline-level recommendations when the evidence base does not warrant a regulatory mandate.<sup>5</sup> Non-mandate clinical guidance's can encourage innovator/early adopter centers to uptake novel practices, thus facilitating later widespread adoption.<sup>5,21</sup>

Over the past 2 decades, the investigative team has established a partnership with the ACS/COT whereby the results of behavioral health pragmatic clinical trials can be directly translated into policy requirements and best practice guidelines.<sup>17-19,22</sup> The historical development of this collaboration is outlined in Figure 1.

**PRAGMATIC COMPARATIVE EFFECTIVENESS TRIALS INFORMING THE AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA ALCOHOL AND POSTTRAUMATIC STRESS DISORDER SCREENING AND INTERVENTION POLICY**

In 2006, the ACS/COT delivered a policy mandate for screening and intervention for alcohol-related disorders as a requisite for level I trauma center verification (Fig. 1).<sup>17</sup> This constituted the first time that substance use/mental health screening and intervention was addressed as a requirement in the resource guide. Prior single-site comparative effectiveness clinical trials by the study team provided evidence supporting the ACS/COT alcohol mandate,<sup>23</sup> first to establish<sup>17</sup> and then refine alcohol screening and brief intervention requirements.<sup>18</sup> At a 2011 policy summit, the study team advocated that the ACS/COT extend the initial 2006 requirement for screening and intervention to all level I and II trauma centers (Table 1), based in part on emerging multisite comparative effectiveness trial results.<sup>24</sup> This recommendation was ultimately incorporated into the 2014 ACS/COT resource guide (Fig. 1).<sup>18</sup> Of note, patients did not substantially contribute to the dialog regarding the alcohol screening and brief intervention requirement, nor did PCORI trials contribute to the 2006 or 2014 ACS/COT alcohol policy requirements.

In addition to recommending universal alcohol screening and brief intervention, the investigators presented results from effective NIH/NIMH-funded single-site posttraumatic stress disorder (PTSD) intervention trials at the 2011 policy summit (Table 1).<sup>25,26</sup> Unlike alcohol screening and brief intervention, the study team believed the evidence base did not support



**FIGURE 1.** American College of Surgeons Committee on Trauma (ACS/COT) and Trauma Survivors Outcomes and Support (TSOS) Policy Timeline. PTSD indicates posttraumatic stress disorder.

**TABLE 1.** American College of Surgeons’ 2011 Policy Summit Agenda

Time	Topic
8:30–9:40 AM	Introduction and Overview
9:40–10:40 AM	Alcohol, Posttraumatic Stress Disorder and Drug Screening and Intervention at Trauma Centers: The relevance of implementation science and methods
10:40–10:50 AM	Break
10:50–11:50 AM	Alcohol discussion
11:50 AM–12:50 PM	Posttraumatic stress disorder discussion
12:50–1:20 PM	Working lunch
1:20–2:20 PM	Substances of abuse discussion
2:20–2:30 PM	Break
2:30–3:30 PM	Patient and family centered care discussion
3:30–4:30 PM	Next steps

Implementing screening and intervention programs for alcohol, posttraumatic stress disorder, drugs of abuse and other psychosocial issues at trauma centers.

requirement-level mandates for PTSD, but did suggest verbiage for a PTSD screening, referral and intervention guidance at US trauma centers. The ACS/COT incorporated this verbiage into their 2014 resource guide as a best practice recommendation.<sup>18</sup> A current multisite comparative effectiveness trial aims to contribute data to refine the current policy and potentially inform an ACS/COT mandate for PTSD screening and/or intervention.<sup>22</sup>

### A DECADE OF PATIENT-CENTERED CARE POLICY DISCUSSIONS WITH THE AMERICAN COLLEGE OF SURGEONS COMMITTEE ON TRAUMA

Building upon this established precedent of stakeholder engagement in alcohol and PTSD screening and intervention, the study team has participated in a decade-long dialog regarding patient-centered care policy in US trauma care systems. Patient voices have been a strong presence in the process, with patient-stakeholders transitioning to positions of increasing leadership.<sup>10</sup>

At the 2011 ACS/COT policy summit, the study team included stakeholders to voice patient-centered policy perspectives (Table 1). In contrast to the alcohol policy requirements and PTSD best practice guidelines, no patient-centered care guidance followed the 2011 ACS/COT policy summit. The study team surmised that the lack of pragmatic comparative effectiveness trial data impeded establishing patient-centered policy.

With the advent of PCORI, the study team developed a 3-year pragmatic comparative effectiveness trial targeting the delivery of patient-centered care transitions. The initial PCORI contract included funding for an end-of-study ACS/COT policy summit, modeled after the 2011 summit but predominantly focusing on patient-centered care delivery across US trauma care systems.

The PCORI-funded comparative effectiveness trial randomized 171 acutely injured trauma survivors with high levels of emotional distress to a patient-centered care transition intervention versus enhanced usual care control conditions.<sup>27</sup> The patient-centered care transition intervention successfully reduced the percentage of patients endorsing any severe postinjury concerns. Although underpowered for assessment of changes in utilization, the trial also detected clinically significant reductions in emergency department utilization among intervention patients.

**TABLE 2.** American College of Surgeons’ 2016 Policy Summit Agenda

Time	Topic
8:00–8:30 AM	Breakfast
8:30–9:30 AM	Patient-Centered and Psychosocial/Psychiatric Care at US Trauma Centers Policy Summit Agenda
9:30–10:00 AM	The Importance of Patient-Centered Care for US Trauma Care Systems: Patient Perspectives
10:00–10:15 AM	Break
10:15–11:15 AM	Trauma Survivors Outcomes and Support Study: Randomized Trial of Optimal Patient-Centered Care
11:15–11:45 AM	Peer Mentoring Randomized Trial in Spinal Cord Injury Rehabilitation
11:45–12:45 PM	Psychiatric and Substance Related Disorders and Traumatic Brain Injury
12:45–1:15 PM	Working lunch
1:15–1:45 PM	The American Trauma Society Patient-Centered Care Program
1:45–2:15 PM	Trauma Survivors Peer/Group Network Study Results (DOD Sponsored)
2:15–2:45 PM	Peer Support Case Study
2:45–3:15 PM	Trauma Center Providers and the Delivery of Patient-Centered Care
3:15–3:30 PM	Break
3:30–4:30 PM	Discussion and Next Steps

Patient-centered and psychosocial/psychiatric care at US trauma centers. DOD indicates Department of Defense.

During the first PCORI trial, the investigators joined the developing PCORI TC-E2AN,<sup>9</sup> which facilitated interactions with other study teams conducting PCORI-funded care transition interventions. One such team from the Sheppard Center in Atlanta demonstrated the effectiveness of a peer-led intervention in enhancing self-efficacy and reducing hospitalization days in spinal cord injury patients.<sup>28</sup>

Building upon TC-E2AN-facilitated interactions, the study team summarized key patient-centered injury intervention findings at the 2016 policy summit (Table 2).<sup>27–31</sup> Patient voice was key to the summit’s success; patient-stakeholders commenced the summit with personal narratives of injury and recovery before comparative effectiveness trial data were presented (Table 2). The ACS/COT reviewed these presentations, leading to a novel 2020 policy statement that included patient-centered care as a key consideration in national trauma center guidelines (Table 3).

### SUMMARY: CRITICAL ELEMENTS OF THE EXPEDIENT TRANSLATION OF PATIENT-CENTERED RESEARCH

Pragmatic trials are designed to inform decision makers of the comparative benefits and burdens of the intervention under study.<sup>32</sup> The study team has leveraged a series of pragmatic comparative effectiveness trials to target specific policy decisions regarding the nationwide implementation of psychosocial screening and intervention procedures for US trauma care systems.

The initial PCORI-funded study, for example, harnessed a pre-existing health care system implementation strategy to introduce a patient-centered care guidance into US trauma care systems during a single grant cycle. The inclusion of a stakeholder-driven policy summit at the conclusion of the

**TABLE 3.** American College of Surgeons’ Guidance on the Relevance of Patient-Centered Care for United States Trauma Care Systems (2020)

“The core of a patient-centered approach is the acknowledgment that patients’ perspectives can be integrated into all aspects of the planning, delivery and evaluation of trauma center care.<sup>29</sup> A series of clinical trials conducted in US trauma care systems<sup>27,28,30</sup> suggest that patient-centered care transition interventions can address patients’ postinjury concerns, enhance patient self-efficacy, and are associated with clinically relevant reductions in postinjury inpatient and emergency department health service use. Level I and II trauma centers should adopt a means of facilitating the transition of patients into the community using any of several different patient-centered strategies including: (i) peer to peer mentoring; (ii) a trauma survivors program; (iii) participation in the American Trauma Society’s ‘Trauma Survivors Network’ program<sup>31</sup>; or (iv) continuous case management that elicits and addresses patient concerns and links trauma center services with community care. Patient-centered trauma care is an area that can benefit from ongoing integration of research findings and evolving expert opinion.”

study was critical to this strategy, ensuring the ACS/COT policy group’s commitment to incorporating any findings into practice before trial funding and rollout. The summit built upon a decade of study team collaboration with the ACS/COT policy group and prior experiences from NIH-funded pragmatic comparative effectiveness trials that produced actionable findings resulting in ACS/COT policy statements. Established partnerships with injured patient-stakeholders, who worked with clinician-scientists to articulate the patient-centered perspective and provide patient voice at the 2016 policy summit, were essential to this process. In addition to patient coinvestigators and clinician-scientists, a full spectrum of front-line clinical providers, trauma surgical policy makers, and quantitative and qualitative research methodologists were included on the study team (Fig. 2).

**FURTHERING THE EFFICIENT TRANSLATION OF PATIENT-CENTERED CARE TRANSITION RESEARCH INTO SUSTAINABLE REAL-WORLD PRACTICE: NEXT STEPS**

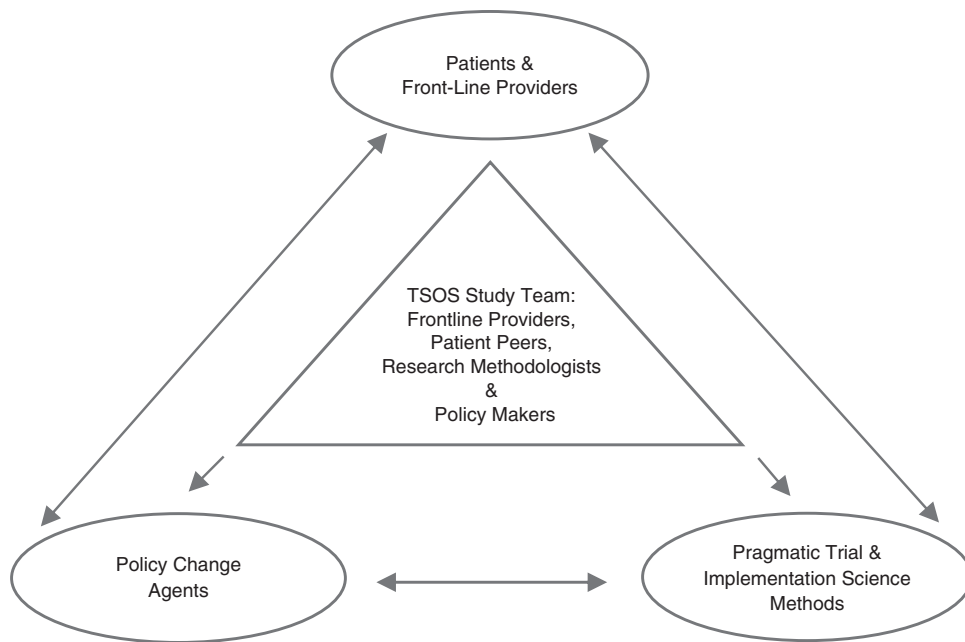
The second portion of this narrative review describes the comparative health care system conceptual framework underlying the study team’s ongoing efforts to integrate pragmatic comparative effectiveness trial data into ACS/COT guidelines for US trauma care systems. The overarching goal of these efforts is to further accelerate the sustainable delivery of patient-centered transitional care into US trauma care systems.

To achieve this goal, members of the study team obtained a second PCORI award in 2018 that builds upon and extends the investigation completed in the first 3-year trial.<sup>33</sup> The second pragmatic trial compares a multidisciplinary team collaborative care intervention that integrates front-line trauma center staff with peer interventionists versus enhanced usual care.

In designing the trial, the study team was aware that the prior ACS/COT alcohol policy mandate had not resulted in comprehensive, sustained quality of care improvements across all US trauma centers.<sup>5</sup> The discussion below identifies factors that must be addressed to optimally harness pragmatic comparative effectiveness trial results for sustained changes in US trauma care practices.

**A COMPARATIVE APPROACH THAT RANKS THE IMPORTANCE OF THEORETICAL AND APPLIED CONCEPTUAL FRAMEWORKS FOR A SPECIFIC HEALTH CARE SYSTEM CONTEXT**

Over the past 2 decades, the study team has diligently reviewed and incorporated myriad frameworks to inform the design of pragmatic comparative effectiveness trials. These



**FIGURE 2.** Trauma Survivors Outcomes and Support (TSOS) embedded multidisciplinary teams efficiently generate and iteratively translate observations from pragmatic comparative effectiveness trials.



multiple, evolving theoretical and applied models derive from and include care transition, organizational behavior, and clinical ethnographic approaches, as well as implementation science classic theories and determinant and evaluation frameworks.<sup>5,9,21,34–36</sup>

Given the proliferation of models over the past 2 decades, the study team has prioritized frameworks with applied value for expediently translating trauma care system research into sustainable practice changes. An optimal approach in this theoretical synthesis has been to order/rank the explanatory relevance of specific models for applied clinical translation. The study team has utilized logical typing as a methodologic approach for prioritizing the explanatory relevance of specific models.<sup>37,38</sup> Logical typing enables the categorization of models hierarchically, positing that theoretical confusion can be avoided by moving to increasingly higher levels of conceptual abstraction.<sup>37,38</sup> This overarching comparative approach has been applied throughout the discussion below.

### INITIAL COMPARATIVE HEALTH CARE SYSTEM APPROACHES TO INFORMING THE TRANSLATION OF RESEARCH INTO PRACTICE CHANGES

The initial frameworks informing the translation of research to practice in trauma care systems were derived from Greenhalgh et al's<sup>39</sup> model of the diffusion of innovations through health care organizations. This model posited that innovation could spread through health care organizations and systems by either passive diffusion, active assistance, or as is the case in US trauma centers, regulatory mandates.<sup>39</sup> A key idea derived from Greenhalgh and colleagues is that sustained leadership engagement for a comparative effectiveness trial from the inception of the contract/grant submission through an end-of study policy summit is superordinate to the rollout of a pragmatic comparative effectiveness trial. Thus, the integration of patient-centered care within US trauma care systems is occurring in a unique regulatory “make it happen” implementation context, in contrast to a negotiated “help it happen” implementation context that exists in other US medical settings.<sup>39</sup> From a comparative health care systems perspective, the study team's efforts to link PCORI-funded and NIH-funded comparative effectiveness trial data to regulatory policy in the United States are similar to the dialog between the National Institute for Clinical Excellence (NICE) Guidelines and National Health Service (NHS) policy; in the United Kingdom, clinical trial data summarized in the NICE Guidelines are targeted to inform NHS policy guidelines for the delivery of real world care.<sup>39–41</sup>

### CONTEMPORARY COMPARATIVE APPROACHES TO ACCELERATING THE TRANSLATION OF RESEARCH INTO REAL-WORLD HEALTH CARE SYSTEM PRACTICE

Kilbourne et al,<sup>42</sup> in the October 2019 *Medical Care* supplement, articulated the “Research Lifecycle” model intended to directly increase the real-world impact of research. Many themes articulated in the model resonate with the study

team's experiences collaborating with the PCORI TC-E2AN and ACS/COT to translate patient-centered care research into practice within trauma care systems.

The model derives from Kilbourne and colleagues' experiences with the research-to-real-world gap within the Veterans' Administration (VA) system. Their paper focuses on a key problem that the study team, TC-E2AN and ACS/COT have grappled with: the lack of sustained alignment between research investments and health care system priorities. Kilbourne and colleagues eloquently describe how closing the research-to-real-world gap requires a comprehensive approach with increased focus on staged research to health care system translation. The model incorporates the need to better measure research innovations' impact on relevant public health outcomes, as well as the need to better articulate the role of sustained leadership engagement for facilitating the research-to-practice translation.

The Research Lifecycle initiative begins with obtaining sustained health care system leadership engagement and prioritization of a particular research activity. Next, a discovery science phase ensues. A validation phase follows, in which innovations identified in the discovery phase are developed and further tested as clinical interventions. The next phase is scale-up and spread, involving research investments that refine interventions for rollout in multiple settings. The VA Research Lifecycle model emphasizes that effective implementation strategies targeting discrete health care system changes are essential to scale-up and spread. The final stage is sustainment, defined as the process of ensuring that interventions continue after research studies end.

Although Kilbourne and colleagues acknowledge that the VA health care system is uniquely positioned to initially implement the Research Lifecycle approach, a stated objective of the article is to influence adoption of the approach by the broader community of health care systems and associated research funders. A key challenge in the VA and elsewhere, anticipated by the authors, is the lack of formal infrastructure to promote the diversity of approaches and funding scenarios required for the phased translation of research innovation into real-world practice.

From a comparative health care systems perspective, careful examination of the Research Lifecycle approach yields important insights for further incorporation of patient-centered care transitions in US trauma care systems. To begin, central to the VA Research Lifecycle approach is the ability at the health care system-level to require clinical service delivery based upon comparative effectiveness trial evidence. The approach is predicated on initial and sustained leadership engagement and support, which in turn facilitates the potential for health care system-level implementation strategies, including regulatory policies.<sup>42,43</sup> The study team capacity to engage the ACS/COT policy group, who commit upfront to a policy summit, to review study findings requires a similar system-level capacity for sustained leadership buy-in. This system-level leadership engagement facilitates system-level implementation strategies, including regulatory mandates linked to verification site visits.

Of note, prior work within the VA characterizing the effectiveness of specific, targeted implementation strategies

appears to have occurred within the same context of this superordinate capacity for sustained leadership buy-in and system-level regulatory policy. For example, Kirchner et al<sup>43</sup> describe the effectiveness of the targeted facilitation implementation strategy within the VA system. Closer examination of this body of research reveals that reports of facilitation's effectiveness were occurring within the context of sustained leadership buy-in and regulatory policy capacity that aimed to integrate primary care and mental health services across the VA system.<sup>43</sup>

Finally, Kilbourne and colleagues note that the VA has substantial funding available, particularly for the initial phases of the Research Lifecycle approach. In contrast, US trauma care systems and the safety net hospitals in which trauma centers are often located frequently lack any sustained funding to support this approach. Given this lack of funding, trauma care system adoption of a staged research-to-practice approach may require the introduction of innovative efficiencies. Other investigative groups have taken approaches similar to the Research Lifecycle with what appears to be the introduction of potential efficiencies. For example, the deployment-focused approach of the NIMH Recovery After an Initial Schizophrenia Episode (RAISE) initiative purposefully bridged gaps between scientific discovery, stakeholder concerns, and policy to target reductions in the research-to-practice gap.<sup>6</sup>

### COMPARATIVE HEALTH CARE SYSTEM EXAMPLES: CONTRASTING AUSTRALIAN TRAUMA CARE SYSTEM IMPLEMENTATION STUDIES WITH UNITED STATES INVESTIGATIONS

A cross-national comparative perspective of 2 different approaches to hybrid effectiveness-implementation spectrum trials<sup>44</sup> further elucidates system-level strategies that can assist in identifying potential efficiencies for the translation of trauma care systems research to real-world practice. A series of theoretical papers and applied effectiveness-implementation hybrid trial articles now characterize the fastidiously planned rollout of traumatic brain injury screening and intervention in Australian acute care emergency department systems.<sup>45–48</sup> The Australian effectiveness-implementation hybrid approach utilizes targeted implementation strategies within the trials to “help” facilitate health care system-level practice changes.<sup>39</sup> In contrast, Trauma Survivors Outcomes and Support (TSOS) study team hybrid designs in the US trauma care system context aim to use effectiveness data to influence ACS/COT policy to catalyze a regulatory mandate linked to verification site visits. The description of effectiveness-implementation hybrid trials has not routinely included the aim of directly impacting health care policy change, linked to a verification site visit, as a potential system-level implementation strategy.<sup>20,44</sup> This comparative health care system approach yields a crucial ability to rank, and therefore distinguish, system-level implementation strategies from targeted strategies that focus on understanding implementation processes associated with a specific trial.

### RAPICE AS A METHODOLOGY OPTIMALLY SUITED FOR USE AS A TARGETED IMPLEMENTATION STRATEGY

The previously articulated RAPICE approach may be an ideal flexible, targeted strategy for understanding implementation processes associated with a specific pragmatic comparative effectiveness trial.<sup>5</sup> RAPICE is multifaceted and includes the embedding of participant observation within front-line clinical providers, who log field notes and jottings during routine activities and regularly present these observations to an external consultant.<sup>5</sup> RAPICE has the capacity to function as an efficient targeted implementation strategy when embedded within a health care system context that includes sustained leadership buy-in and regulatory capacity.<sup>5,39,42</sup> For example, RAPICE is ideally suited to provide organizational and provider-level feedback during the development and rollout of pragmatic comparative effectiveness trials; here, RAPICE can be honed as a targeted strategy to better understand trial implementation processes, and the relation of these processes to a practice's maintenance and sustainability. In the current context, RAPICE observations can be presented along with clinical effectiveness trial data at end-of-study summits to inform ACS/COT patient-centered policy guidances.<sup>33</sup> When linked with system-level implementation strategies that include regulatory requirements and verification site visits, RAPICE can facilitate the key objective of reducing the time lag on evidence-based intervention integration into health care systems.

### SUMMARY AND IMPLICATIONS FOR ACCELERATING THE EFFICIENT TRANSLATION OF PATIENT-CENTERED RESEARCH INTO UNITED STATES TRAUMA CARE SYSTEMS

A central tenet of this review is that research approaches that directly address the sustainable, rapid movement of findings into practice need to be prioritized to expediently address the research-to-practice gap. A planned end-of-study policy summit is one mechanism that, when combined with system-level implementation strategies such as regulatory mandates linked to verification site visits, can accelerate sustained real-world practice change. Resource-efficient and time-efficient targeted implementation strategies, such as RAPICE, can also be helpful in understanding how barriers and facilitators identified during pragmatic trials influence services subsequently delivered as part of policy requirements, catalyzing the research-to-practice translation. An additional efficiency relevant to US trauma care systems is that pragmatic comparative effectiveness trial team members may simultaneously function in multiple roles, including front-line clinician/patient-peer interventionist, policy maker and clinical-investigator (Fig. 2).

The review of effectiveness data by the ACS/COT from multiple studies was key in catalyzing initial policy guidance, such as the recent recommendations for patient-centered care. National requirements for alcohol screening and brief intervention met with substantial pushback when derived from an evidence base comprised of only single-site studies.<sup>49,50</sup> Later universal alcohol screening and brief intervention requirements were derived from national US multisite investigations.<sup>18,24</sup>

Future research efforts could strive to incorporate requirement-level recommendations derived from definitive multisite pragmatic studies and also periodically reexamine the evidence-base for ACS/COT policy requirements.<sup>50</sup>

Finally, for future patient-centered ACS/COT care transition policy, a key observation is that the prior ACS/COT alcohol policy mandate has resulted in variable quality of care improvements across US trauma centers.<sup>5</sup> If subsequent PCORI-funded investigations demonstrate that variability in implementation is associated with treatment effect heterogeneity in multisite studies, then the verification component of the system-level strategy should be honed to address implementation variability in the wake of regulatory mandates. Thus, incorporation of higher quality verification standards may be a key adjustment for the ACS/COT system-level implementation strategy. Optimally, RAPICE-derived pragmatic trial observations could be incorporated into verification site visit standards postmandate. This approach may enable the ACS/COT to address important health care system practice changes related to patient-centered care over the course of a single 5-year contract/grant cycle, thus substantially accelerating the translational gap for patient-centered care delivery within US trauma care systems.<sup>1–6</sup>

## REFERENCES

- Balas EA, Boren SA. Managing clinical knowledge for health care improvement. In: Bommel J, McCray AT, eds. *Yearbook of Medical Informatics 2000: Patient-Centered Systems*. Stuttgart, Germany: Schattauer Verlagsgesellschaft; 2000:65–70.
- Chambers D. Foreword. *Dissemination and Implementation Research in Health: Translating Science to Practice*, 2nd ed. New York, NY: Oxford University Press; 2018:ix–xv.
- Institute of Medicine; Committee on the Learning Health Care System in America. *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Smith M, Saunders R, Stuckhardt L, McGinnis JM, eds. Washington, DC: Institute of Medicine; 2013.
- Selby JV, Beal AC, Frank L. The Patient-Centered Outcomes Research Institute (PCORI) national priorities for research and initial research agenda. *JAMA*. 2012;307:1583–1584.
- Palinkas LA, Zatzick D. Rapid assessment procedure informed clinical ethnography (RAPICE) in pragmatic clinical trials of mental health services implementation: methods and applied case study. *Adm Policy Ment Health*. 2019;46:255–270.
- Goldstein AB, Heinszen RK, Azrin ST. Accelerating science-to-practice for early psychosis. *Psychiatr Serv*. 2015;66:665.
- Frank L, Basch E, Selby JV. The PCORI perspective on patient-centered outcomes research. *JAMA*. 2014;312:1513–1514.
- Broitman M, Sox HC, Slutsky J. A model for public access to trustworthy and comprehensive reporting of research. *JAMA*. 2019;321:1453–1454.
- Parry C, Johnston-Fleece M, Maurice Johnson J, et al. Patient-centered approaches to transitional care research and implementation: lessons from PCORI's transitional care portfolio. *Medical Care*. In Press.
- Carman KL, Dardess P, Maurer M, et al. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. *Health Aff*. 2013;32:223–231.
- Gelinas L, Weissman JS, Lynch HF, et al. Oversight of patient-centered outcomes research: recommendations from a Delphi panel. *Ann Intern Med*. 2018;169:559–563.
- Web-based Injury Statistics Query and Reporting System (WISQARS). Centers for Disease Control and Prevention. 2010. Available at: <https://wisqars-viz.cdc.gov:8006/non-fatal/home>. Accessed August 3, 2020.
- Moore M, Conrick KM, Fuentes M, et al. Research on injury disparities: A scoping review. *Health Equity*. 2019;3:504–511.
- Tsosie U, Nannauck S, Buchwald D, et al. Staying connected: a feasibility study linking American Indian and Alaska Native trauma survivors to their tribal communities. *Psychiatry*. 2011;74:349–361.
- Palinkas LA, Whiteside L, Nehra D, et al. Rapid ethnographic assessment of the COVID-19 pandemic April 2020 'surge' and its impact on service delivery in an Acute Care Medical Emergency Department and Trauma Center. *BMJ Open*. 2020;10:e041772.
- Moloney K, Scheuer H, Engstrom A, et al. Experiences and insights from the early US COVID-19 epicenter: a rapid assessment procedure informed clinical ethnography case series. *Psychiatry*. 2020;83:115–127.
- American College of Surgeons Committee on Trauma. *Resources for Optimal Care of the Injured Patient: 2006*, 4th ed. Chicago, IL: American College of Surgeons; 2006.
- American College of Surgeons Committee on Trauma. *Resources for Optimal Care of the Injured Patient: 2014*, 6th ed. Chicago, IL: American College of Surgeons; 2014.
- Love J, Zatzick D. Screening and intervention for comorbid substance disorders, PTSD, depression, and suicide: a trauma center survey. *Psychiatr Serv*. 2014;65:918–923.
- Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci*. 2015;10:21.
- Rogers EM. *Diffusion of Innovations*, 4th ed. New York, NY: The Free Press; 1995.
- Zatzick D, Russo J, Darnell D, et al. An effectiveness-implementation hybrid trial study protocol targeting posttraumatic stress disorder and comorbidity. *Implement Sci*. 2016;11:58.
- Gentilello LM, Rivara FP, Donovan DM, et al. Alcohol interventions in a trauma center as a means of reducing the risk of injury recurrence. *Ann Surg*. 1999;230:473–480.
- Zatzick D, Donovan DM, Jurkovich G, et al. Disseminating alcohol screening and brief intervention at trauma centers: a policy-relevant cluster randomized effectiveness trial. *Addiction*. 2014;109:754–765.
- Zatzick D, Roy-Byrne P, Russo J, et al. A randomized effectiveness trial of stepped collaborative care for acutely injured trauma survivors. *Arch Gen Psychiatry*. 2004;61:498–506.
- Zatzick D, Jurkovich G, Rivara FP, et al. A randomized stepped care intervention trial targeting posttraumatic stress disorder for surgically hospitalized injury survivors. *Ann Surg*. 2013;257:390–399.
- Zatzick D, Russo J, Thomas P, et al. Patient-centered care transitions after injury hospitalization: a comparative effectiveness trial. *Psychiatry*. 2018;81:141–157.
- Gassaway J, Jones ML, Sweatman WM, et al. Effects of peer mentoring on self-efficacy and hospital readmission after inpatient rehabilitation of individuals with spinal cord injury: a randomized controlled trial. *Arch Phys Med Rehabil*. 2017;98:1526–1534.
- Institute of Medicine Committee on Quality of Health Care in America. In: *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington (DC): National Academies Press (US); 2001.
- Major Extremity Trauma Rehabilitation Consortium (METRC). Early effects of the trauma collaborative care intervention: results from a prospective multicenter cluster clinical trial. *J Orthop Trauma*. 2019;33:538–546.
- American Trauma Society. 2020. Available at: [www.amtrauma.org/](http://www.amtrauma.org/). Accessed August 3, 2020.
- Califf RM, Sugarman J. Exploring the ethical and regulatory issues in pragmatic clinical trials. *Clin Trials*. 2015;12:436–441.
- Scheuer H, Engstrom A, Thomas P, et al. A comparative effectiveness trial of an information technology enhanced peer-integrated collaborative care intervention versus enhanced usual care for US trauma care systems: Clinical study protocol. *Contemp Clin Trials*. 2020;105970.
- Zatzick CD, Zatzick DF. The effect of perceived person-job fit on employee attitudes toward change in trauma centers. *Health Care Manage Rev*. 2012;38:115–124.
- Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. 2015;10:53.
- Glasgow RE, Vinson C, Chambers D, et al. National Institutes of Health approaches to dissemination and implementation science: current and future directions. *Am J Public Health*. 2012;102:1274–1281.
- Bateson G. *Mind and Nature: A Necessary Unity*, 4th ed. New York, NY: Bantam Books Inc; 1979.
- Whitehead AN, Russell B. *Principia Mathematica*. Cambridge: University Press; 1910.
- Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q*. 2004;82:581–629.



40. Gafni A, Birch S. NICE methodological guidelines and decision making in the National Health Service in England and Wales. *Pharmacoeconomics*. 2003;21:149–157.
41. Claxton K, Sculpher M, Palmer S, et al. Causes for concern: Is NICE failing to uphold its responsibilities to all NHS patients? *Health Econ*. 2015;24:1–7.
42. Kilbourne AM, Braganza MZ, Bowersox NW, et al. Research lifecycle to increase the substantial real-world impact of research: accelerating innovations to application. *Med Care*. 2019;57:S206–S212.
43. Kirchner JE, Ritchie MJ, Pitcock JA, et al. Outcomes of a partnered facilitation strategy to implement primary care-mental health. *J Gen Intern Med*. 2014;29(suppl 4):904–912.
44. Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50:217–226.
45. Green SE, Bosch M, McKenzie JE, et al. Improving the care of people with traumatic brain injury through the Neurotrauma Evidence Translation (NET) program: protocol for a program of research. *Implement Sci*. 2012;7:74.
46. Bosch M, McKenzie JE, Mortimer D, et al. Implementing evidence-based recommended practices for the management of patients with mild traumatic brain injuries in Australian emergency care departments: study protocol for a cluster randomised controlled trial. *Trials*. 2014;15:281.
47. Tavender EJ, Bosch M, Gruen RL, et al. Developing a targeted, theory-informed implementation intervention using two theoretical frameworks to address health professional and organisational factors: a case study to improve the management of mild traumatic brain injury in the emergency department. *Implement Sci*. 2015;10:22.
48. Bosch M, McKenzie JE, Ponsford JL, et al. Evaluation of a targeted, theory-informed implementation intervention designed to increase uptake of emergency management recommendations regarding adult patients with mild traumatic brain injury: results of the NET cluster randomised trial. *Implement Sci*. 2019;14:4.
49. Field CA, Baird J, Saitz R, et al. The mixed evidence for brief intervention in emergency departments, trauma care centers, and inpatient hospital settings: what should we do? *Alcohol Clin Exp Res*. 2010;34:2004–2010.
50. Kodadek LM, Freeman JJ, Tiwary D, et al. Alcohol-related trauma reinjury prevention with hospital-based screening in adult populations: an Eastern Association for the Surgery of Trauma evidence-based systematic review. *J Trauma Acute Care Surg*. 2020;88:1.