Title

Getting Everyone on the Same Page: Key Components of an Implementation Process for a Large Pragmatic Randomized Trial Across Three Health Systems (RP312)

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Conclusion(s). Older patients at two academic centers were generally interested in life-prolonging therapies, including enrollment on cancer clinical trials, despite not explicitly stating this to their oncologist. The majority of patients deferred to their oncologists for the next steps in their management.

Impact. This study suggests that oncologists should assess patients' and caregivers' treatment preferences and have a discussion about the role of clinical trials in order to clarify any misconceptions.

Testing the "Extra Layer of Support" (ELOS) Mobile Application to Engage Cancer Patients Around Palliative Care (RP311)

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Objectives
- Describe how usability testing of digital health is performed.
- Conclude usability of the ELOS platform after results are shared from the research testing.

Importance. Despite the immense growth of palliative care clinical services, only a minority of cancer patients and their oncologists have a robust understanding of palliative care's utility. This leads to underutilization of available palliative care services.

Objective. We aimed to develop and test an educational tool for patients with advanced cancer to clarify misconceptions.

Method(s). We used a panel of physicians, nurses, patients, and caregivers to develop the Extra Layer of Support (ELOS) mobile application (app). The app was designed to introduce patients and caregivers to palliative care, patient navigation, cancer basics, symptom management, and advance care planning. We then conducted usability testing of ELOS from October 2018 through October 2019. Patients with advanced gastrointestinal or genitourinary cancer at Duke University and University of North Carolina – Chapel Hill were enrolled. We collected demographics and assessed system usability scores, willingness to use and recommend, and patient preparedness.

Results. 100 patients were enrolled. 65% were male, 27% racial minorities, and 61% with less than a Bachelor's degree. The mean usability score was 82.6, putting ELOS usability in the 93rd percentile of all mobile health tools. When asked if the patient was likely to consider using the services introduced in the tool (palliative/supportive care services), 75% of patients responded they were either somewhat likely or very

likely. When asked how likely the patients were to recommend the tool on a zero to ten Likert scale, the average response was 8.74.

Conclusion. Our testing indicates that a novel, mobile tool designed to educate and introduce patients to palliative care is highly usable, and study participants were both likely to utilize palliative care services and recommend it to others. Larger trials are needed to evaluate efficacy.

Impact. Electronic tools to educate and engage cancer patients around palliative care services are usable, even among a diverse population.

Getting Everyone on the Same Page: Key Components of an Implementation Process for a Large Pragmatic Randomized Trial Across Three Health Systems (RP312)

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Objectives
- Understand key components necessary for the implementation of a large ACP pragmatic trial.
- Understand how to effectively achieve multi-disciplinary stakeholder engagement across multiple sites.

Importance. Pragmatic trials that implement scalable advance care planning (ACP) interventions in real-world setting are needed.

Objective(s). To determine system-level changes needed to implement three scalable ACP interventions: (1) advance directive (AD) alone vs. (2) AD + PREPAREforYourCare website vs. (3) AD + PREPARE + lay navigator for a large cluster-randomized pragmatic trial across three University of California (UC) health systems.

Method(s). The trial includes patients with serious illness from primary care clinics at UC Los Angeles, UC San Francisco, and UC Irvine. Interventions are automatically sent through the electronic health record (EHR, Epic) patient portal and mail. We convened a multi-disciplinary stakeholder advisory board including state/national leaders and, from

each site, health system/Population Health leaders, Epic coders, clinicians, patients/caregivers, analysts, and payers. We obtained input from stakeholders and monitored secular trends to determine the key components required to launch this large pragmatic trial.

Results. Required key components included: (1) obtaining several administrative, privacy, Epic/patient portal approvals at each site; (2) standardizing local ACP documentation practices and providing education; (3) developing a validated SI algorithm; (4) developing site-specific EPIC code, based on local site structure, to identify patients prior to clinic appointments to receive the intervention while maintaining intervention fidelity; (5) obtaining privacy approvals for mail vendors; (6) obtaining buy-in from over 100 stakeholders to standardize ACP messaging; (7) monitoring ongoing secular trends (e.g., local Epic updates and changing Population Health priorities); and (8) requiring constrained randomization to ensure age and prior AD completion were equal among arms. We have randomized 50 clinics across the three sites, obtained all needed permissions, finalized Epic builds, and launched the trial. The trial will include approximately 7,000 patients.

Conclusion(s). Implementing a large pragmatic trial, with automated, EHR-based cohort identification and intervention delivery, requires a high level of multidisciplinary stakeholder engagement, standardization, and coordination between sites.

Impact. These key components provide guidance for the implementation of other large ACP pragmatic trials.

The Influence of Neoliberalism on Burdensome Life Sustaining Treatments Near the End of Life (RP313)

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Objectives
- Explain the relevance of systems-level influences on the quality and intensity of end-of-life care.
- List at least three factors that arise from a culture of consumerization and neoliberalism that might

contribute to burdensome, overly aggressive end-of-life care.

Importance. Burdensome, overly aggressive life-sustaining treatments (LST) near the end of life (EOL), such as mechanical ventilation and resuscitation, have the potential to create ethical challenges where treatments can cause harm and suffering with little chance of benefit. Interventions to reduce inappropriate LST have met with limited success, raising the possibility that the social context within which clinical decisions are made may play a role in the persistence of burdensome care. One such contextual factor is neoliberalism, characterized by free-market capitalism, which encourages a culture of consumerization and unlimited choice.

Objective(s). The objective of this study is to understand the broader macro-sociological factors that influence institutional culture and individual behavior that impact burdensome care.

Method(s). We conducted 37 semi-structured in-depth interviews with clinicians and administrators at two hospitals in California rated by the Dartmouth Atlas as high-intensity and low-intensity for aggressiveness of end-of-life care. Transcripts were analyzed using thematic analysis.

Results. Interviews reveal different practice patterns and behaviors in response to ethical challenges around burdensome LST, which reflect different support structures that mitigate the influences of neoliberalism at an institutional level. Stronger systems-level support structures at the low-intensity hospital appear to support clinicians in making decisions in a patient's best interest that modulate the aggressiveness of end-of-life care. In contrast, the high-intensity hospital reflected a culture of consumerism, which encourages clinical momentum towards burdensome LST. This was characterized by a prioritization of an unreflective reverence to patient autonomy; extreme deference towards consumerization; clinician powerlessness to act ethically; a focus on metrics and in particular, patient satisfaction; and the coopting of ethics committees into a regulatory body.

Conclusion(s). These results suggest that neoliberal ideology might shape organizational culture and clinical practice in ways that may have implications for burdensome LST.

Impact. Understanding how macro-sociological phenomena influence clinical practices and behaviors have the potential to inform the development of systems-level interventions to mitigate burdensome care.