A Multi-Stakeholder Dialogue Enhanced Recovery Protocols for Surgical Patients: Challenges and Opportunities

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EXECUTIVE SUMMARY

On June 10, 2014, the Center for Medical Technology Policy (CMTP) hosted a multi-stakeholder forum in Baltimore, MD to discuss potential challenges and opportunities to accelerate the adoption of enhanced recovery protocols (ERPs) in the United States. The fundamental concern at issue is that 25% of patients who undergo surgery in the United States have post-surgical complications.¹ Goal-directed fluid therapy, a key component of enhanced recovery, has been demonstrated to reduce these complications by anywhere from 32% to 55%.²,³ With annual inpatient surgeries of approximately 10 million patients in the U.S., hundreds of thousands or even millions of patients can be spared surgical complications each year through the implementation of ERPs. Yet this approach to surgical patient care remains grossly underutilized in U.S. hospitals.

For this reason, leaders representing surgeons, anesthesiologists, nurses, patients, medical products companies, health system administrators, payers, quality organizations, and researchers gathered to discuss potential strategies and programs to improve outcomes for patients undergoing major surgery. Speakers shared lessons learned from implementing enhanced recovery programs at their own institutions, while the group discussed the potential barriers to accelerating adoption of such programs in the U.S. and brainstormed potential strategies to overcome those barriers.

One of the clear insights from the June 10th meeting was the recognition that continuing to support ongoing work in silos will not produce the order of magnitude change in the pace of adoption that is needed to significantly reduce preventable complications and deaths for future surgical patients in the U.S. However, given the different challenges and conflicting interests posed by a market-driven, highly fragmented healthcare system, and the complexity and rapid evolution of reimbursement models (which creates potential conflicts between surgery and anesthesiology), a general consensus among meeting attendees was that a new impartial entity bridging differences across this landscape could be extremely helpful. By providing a forum for collaboration and leadership that works across key groups and individuals that are already active in the U.S. ERP space, this entity could facilitate multi-stakeholder dialogue in a neutral environment, and would be an important vehicle to build broad support and specific plans and activities to accelerate ERPs in the U.S. and drive rapid, significant change. At the end of the day, meeting participants expressed a high level of excitement and energy, as well as a strong sense of trust and partnership, emphasizing the need to rapidly capitalize on the success of the meeting to build momentum for work to accelerate adoption of ERPs.

Feedback from Participants on Overall Goals of the June 10th Stakeholder Forum and Subsequent Work to Establish a National Partnership to Accelerate Adoption of ERPs

- The timing seems very good to provide a forum and catalyst in the ERP space. Much promising but ad hoc work is underway; a national partnership will need to build a sense of urgency nationally that emphasizes a responsibility to U.S. patients between now and the next 10 years to address avoidable complications and deaths.
- Raising awareness among providers, payers, hospitals, patients and nurses about the value of ERPs is critical, and a simple message that focuses on improving patient outcomes will be key.
  - For example, get patients home faster, fitter, and at lower cost.
- The group needs to think carefully about how to overcome the upfront costs of ERP implementation which will occur before any clinical and economic benefits are seen.
- Additional lessons are yet to be learned by careful assessment of UK and U.S. programs.

With ongoing tension between standards and innovation, promoting a set of standardized practices to accelerate the adoption of ERPs may not be the best short term approach.

There is a need for robust quality measures that reflect more than just the typical clinical outcomes (length of stay, unadjusted mortality, readmission rates, complications) to support implementation of a bundled payment model necessary to incentivize and accelerate the adoption of ERPs (e.g., these may include metrics from the patient’s perspective).

**Progress since June 10th, 2014**

In order to maintain momentum and capitalize on the energy coming from the June 10th Stakeholder Meeting, CMTP has been working with several groups to rapidly secure funding to establish and launch a formal National Enhanced Recovery Partnership, of which all June 10th attendees are automatically invited to participate as members.

In addition, CMTP has:

- Circulated the first press release (June 17, 2014)
- Launched a SharePoint site for National Partnership members (July 11, 2014)
- Released the June 10th Meeting Summary (July 11, 2014)
- Developed a proposal* for funding to establish and launch a National Enhanced Recovery Partnership (proposed start date: August 1, 2014)

*The Specific Aims of this proposal are, as follows:

1. To establish and manage a formal National Enhanced Recovery Partnership that supports ongoing dialogue and activities to accelerate the adoption of ERPs in the U.S. This partnership will own a concrete goal, to see adoption of ERPs by 80% of U.S. hospitals by 2020.
2. To design a demonstration project to develop and test quality measures that will support the acceleration of ERP adoption in the U.S. (in collaboration with Avalere Health).

**Next Steps**

Over the next 6-8 weeks, CMTP will be meeting with key stakeholders from CMS and several professional societies to discuss overlapping priorities and potential for collaboration with the new National Partnership. They will also be working closely with Prof Monty Mythen, who presented on June 10th on the NHS Enhanced Recovery Programme in the UK, and who will be visiting the U.S. for several weeks and working closely with the group to share his expertise. CMTP will also be reaching out to June 10th meeting attendees to have follow-up conversations and explore certain recommendations in depth.

Over the next 6 months, CMTP intends to do the following:

- Release a white paper and press release
- Conduct case studies, site visits, and key informant interviews with UK and U.S. experts
- Outreach to funding organizations for the new National Enhanced Recovery Partnership
- Ongoing management of National Partnership membership and online discussion space
- Develop a Strategic Plan, including mission, model and governance for the National Partnership
- Launch National Enhanced Recovery Partnership and convene first “official” meeting
MEETING SUMMARY
Enhanced Recovery Protocols for Surgical Patients: Challenges and Opportunities
A Multi-Stakeholder Dialogue
June 10, 2014
Baltimore, Maryland

Background and Meeting Objectives
Approximately 30 million operations are performed annually in the U.S. Despite advances over recent years, a large portion of surgical patients continue to have undesirable levels of morbidity, mortality, and the need for prolonged hospitalization. The costs of surgical complications are also substantial. ERP offers a potential solution to improve patient length of stay (LOS) and surgical complication rates. By reducing surgical stress and maintaining postoperative physiological function, ERPs are designed to lead to reduced morbidity, faster recovery, and shorter LOS.

Edwards Lifesciences approached the Center for Medical Technology Policy (CMTP) about hosting a multi-stakeholder meeting to discuss the potential for ERPs in the U.S. The meeting took place in Baltimore on June 10th, 2014 and included a diverse group of nearly 50 participants representing physicians, nurses, patients, payers, industry, and government. Dr. Sean Tunis, President and CEO of CMTP, welcomed the participants and explained the objectives for the meeting: (1) to obtain the multiple perspectives of stakeholder participants on the potential value of and challenges to accelerating adoption of ERP in the U.S.; (2) to better understand factors for success and key barriers by sharing experiences to date; and (3) to share ideas about essential domains of additional work and how to accelerate progress, including the potential value of maintaining a forum to support continued dialogue and collaboration.

Clinical and Economic Background: Overview of Challenges
In the first session, Dr. Tony Senagore, Professor of Surgical Disciplines at Central Michigan University, discussed factors to consider in developing an ERP program. One theme was that it is better to use outcome measures than process measures in evaluating performance. Different institutions have different problems and there is no one process that will optimally fit all institutions – therefore, he argued, institutions should have flexibility in determining what processes they adopt. The best single outcome measure is probably LOS, ideally index plus readmission (total bed days). A second theme involved comparing the cost of a complication to the ability to mitigate the risk of the complication occurring. Complications drive cost and decreasing complications is beneficial for both patients and institutions. Nevertheless, if it is not possible to prevent the complication or the complication is not a cost-driver, it may not make sense to expend a lot of effort trying to prevent it (e.g., surgical site infections (SSIs) if oral antibiotics are already being given). Dr. Senagore reviewed some of the particular elements of his ERP but reemphasized that each institution should examine its own data to determine what elements of a plan it needs.

Dr. Frederic Michard from Edwards Lifesciences discussed the economic burdens of surgical complications and the potential role of goal-directed fluid therapy (GDFT) as an element of an ERP. Complications can increase LOS by nearly a factor of five and the cost of treating complications is often more than the cost of the initial surgery. Although hospitals may receive increased payments for treating complications, the payments do not cover the costs of treatment. Changing perioperative fluid management can reduce complication rates by 25% to 50%. At present there is tremendous variability in fluid management despite the fact that there have been >30 randomized controlled trials that have shown GDFT can improve post-surgical outcomes. Quality improvement programs have demonstrated
similar results. GDFT is just one potential element of an ERP, along with optimizing nutrition and hydration pre-surgery, using regional anesthesia, and early mobilization, but it seems to be an important part. Using an administrative database to determine the costs of complications for 10 selected surgical procedures, Dr. Michard estimated that changing from standard care to GDFT could result in savings of $1,000-$1,500 per patient for colectomies.

Discussion following these presentations focused on why ERPs were not already adopted in the U.S. if almost every stakeholder appears to benefit. Barriers that were identified included: (1) dips in performance that accompany movement from one paradigm to another; (2) lack of awareness among clinicians; (3) the challenges of coordination among anesthesiologists, surgeons, nurses, and administrators, among others; and (4) misalignment of burdens, benefits, and risks (e.g., benefits accrue primarily to parties who do not bear the financial burdens).

U.K. Experience in Addressing Challenges
Professor Monty Mythen, an anesthesiologist and critical care physician from the U.K., shared the experience of a national roll-out of ERP in the U.K. The National Health Service (NHS) was experiencing financial hardships and examining the variation in LOS following major elective surgery. The NHS determined that the groups with the shortest LOS and best results were practicing some sort of ERPs and concluded that ERPs should be adopted nationally in order to decrease LOS, complications, and costs. They gathered together the groups with the best results and asked them to share their best practices. The result was a pathway from pre-admission to discharge with 35 bullet points. Not every group addressed each bullet point the same way, but each group had an approach to all 35 points. The NHS made these best practices available on the internet along with other relevant information. At its core, described Prof Mythen, an ERP means that within 24 hours of surgery, a patient is ideally dressed in his or her own clothes, has no tubes, drips, or drains, is walking around, and eating and drinking.

Prof Mythen also noted the costs of change in terms of equipment, time, and personnel. These costs must be budgeted for, though the return on investment should result in net savings. In implementation, it was critically important for all team members to understand the objectives and importance of their roles. It also was important to set realistic goals – the NHS selected only a few procedures to start with (including colectomy and major joint replacements), showed the LOS data to the relevant parties, and set a goal to move the median LOS to what the top 10% of providers were achieving at the time. They achieved 85% adoption of ERP within two years, LOS dropped, tens of thousands of bed days were saved resulting in increased productivity as more procedures were performed, complications were decreased, readmissions went down, and patient satisfaction went up. Some elements of ERPs have been difficult to achieve (e.g., carbohydrate loading and GDFT) but after three years, >95% of providers have adopted some form of an ERP. In 2012, every key national body signed a statement that ERPs should be considered standard practice for most patients undergoing major surgery across a range of procedures and specialties. Dr. Mythen closed by examining some U.S. data on LOS and fluid utilization, which displayed the sort of variability that characterized the U.K. prior to widespread adoption of ERPs.

Following Prof Mythen's presentation, discussion topics included whether bundled payments would provide sufficient incentive to drive change or whether a market approach in which the best practice wins would work better in the U.S. It was pointed out that one barrier to adoption was the lack of guidelines or standards for anesthesiologists, although the existence of guidelines would not mean there would be sufficient incentive to follow them. It was observed that the UK seemed to follow an approach of advocacy for the right thing to do, followed by sequelae for failure to perform (e.g., loss of surgical procedures or takeover/closure), whereas the U.S. approach seemed to be mandatory checklists that may or may not be appropriate and no sequelae for becoming better or worse.
U.S. Experience in Enhanced Recovery
Dr. Elizabeth (Liza) Wick, a colorectal surgeon at Johns Hopkins Medicine, presented on her institution’s experience adopting an ERP for colorectal surgery. The adoption of an ERP in the practices was built on the team’s earlier experiences reducing wound infections for colorectal surgery using a comprehensive unit-based safety program (CUSP) approach. The goal of CUSP is to improve patient safety and awareness and systems thinking at the unit level, by empowering staff to identify and resolve defects. For the ERP program, the team at Johns Hopkins wanted to implement a standardized patient-centered protocol and to integrate the preoperative, intraoperative, postoperative, and post-discharge phases of care. Elements of their program included: a nurse-led preoperative education program; a liberalized NPO (nil per os, or “nothing by mouth”) policy; multi-modal pain management; reduced intraoperative fluids; and nurse-driven postoperative orders that focused on mobility and feeding. Executive support was critical in implementing the Johns Hopkins ERP program because of both the financial support for new resources (e.g., in the pre-anesthesia clinic and pain service) and the ability to overcome bureaucratic barriers. Involvement and feedback from the frontline providers was also crucial. They audited their performance and continued to adjust the processes. In just a few months and without complete adoption they reduced LOS by two days and increased patient satisfaction.

In the group discussion, participants emphasized that integrating the whole care spectrum is difficult and requires resources (e.g., providing non-clinical time) that smaller hospitals may not be able to support. Patient education and engagement is a key element of an ERP. Some commenters believed that having a checklist or standardized order set would encourage compliance, while others noted that because of the ability to opt out it was more critical to get all providers to buy into the program.

Dr. Tong Joo (TJ) Gan, an anesthesiologist at Duke University Medical Center, shared his experience instituting an ERP program for colorectal surgery. He agreed that a lot of the challenge is in coordinating all the involved parties. He also recommended starting small and then expanding the program (e.g., starting with colorectal surgery and then expanding to other procedures), being sure to collect data on the effect of the ERPs in order to demonstrate the value to skeptical stakeholders. He reviewed some key elements of their ERP but agreed that hospitals are different and should decide what elements of an ERP make sense for them. There were some upfront costs in terms of epidurals, hemodynamic monitoring, and the carbohydrate drink, but they probably saved costs with 85% of patients while lowering LOS by two days and reducing some complications. In closing, Dr. Gan emphasized the importance of engaging all stakeholders and developing a team across the care continuum, as well as continuing to audit and provide feedback in order to continually improve and maintain momentum.

In the group discussion, commenters agreed that ERPs with different elements could be different but equally effective. Lack of agreement on the specific elements should not be allowed to become a barrier to ERP adoption and implementation. Patient care is fragmented and different stakeholders have different financial incentives. It may be possible to build teams by focusing on the common interest of improving patient care.

Stakeholder Perspectives on Enhanced Recovery for Surgical Patients
Molly Clopp, Strategic Leader for Patient Safety at Kaiser Permanente Northern California described their approach. Their region started using the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database in 2011 to help determine where they should focus improvement efforts and selected colorectal and hip fracture surgeries. They believed that ERP would reduce complications, improve pain management, and reduce LOS, among other things. They selected two pilot sites, each site instituting an ERP for a single type of surgery and then sharing its protocol with the other site. The focus of the pilot program has been not only clinical outcomes but also feasibility, to
identify problems and issues that could occur as they roll out the ERPs more broadly. Some of their challenges have included optimizing multi-modal pain management, organizing early ambulation workflow, and ensuring adherence without a standard order set. Early results with LOS and complications appear to align with existing literature, and KP Northern California anticipates rolling out the ERPs more broadly and developing protocols for other types of surgery.

Victoria Nahum from the Safe Care Campaign discussed ERPs from a patient perspective. Her advocacy grew out of her family’s negative experiences with the health care system, including her son’s death. Because ERPs focus on getting patients in their best health preoperatively, receiving best care during surgical procedures, and obtaining best outcomes, she argued, patients should support it. In order to achieve best outcomes, however, patients must be involved in and informed about the process. Among the many reasons for involving patients and families, she noted that patients and families could also inadvertently compromise the best care plans if lacking a communicative partnership with providers.

Karen Johnson, Director of the American Association of Critical Care Nurses (AACN), explained the organization’s interest in being involved in the process. AACN is dedicated to creating a healthcare system driven by the needs of patients and families where acute and critical care nurses can make their optimal contribution. They are mission-driven to ensure that nurses have the appropriate knowledge and are empowered to give patients and families what they need. To that end, they sponsor a National Teaching Exposition each year, establish standards of practice, and award grants for quality improvement projects. Their members cover pre-, intra-, and postoperative phases of care and their involvement in projects from the beginning can help promote optimal patient care.

Martha Sewell, Vice President of Clinical Marketing and Scientific Affairs at Smith Medical, discussed how ERPs affected her organization. Thirty percent of Smith Medical products are used in the perioperative space. They want to understand what is happening with clinicians and patients in order to better design products that are needed. They are funding research in a number of relevant areas, including pain management techniques, airway management techniques, fluid management, and medication delivery. Through listening they hope to understand the products and tools they will need to provide.

The stakeholder discussion again highlighted the need for multiple pathways to achieving better outcomes, as well as for guidelines and incentives to follow them. There seemed to be consensus on the importance of involving patients. Patients were key partners in developing educational materials in the UK, and some commenters believed activated consumers could become the primary driver for adoption of ERPs in the U.S. Participants were informed that an American Society of Enhanced Recovery will be forming within the upcoming year.

U.S. Policy Environment and Efforts to Facilitate Adoption of Enhanced Recovery Protocols through Quality Improvement

Kristi Mitchell, Senior Vice President at Avalere Health, opened up the afternoon by outlining the objectives for a session on the U.S. policy environment and ongoing efforts to facilitate adoption of ERPs through quality improvement programs. She described several models of quality improvement programs, how quality improvement might be a tool to facilitate adoption of best practices, and outlined several buckets of work that would be addressed by the panelists, including: strategic partnerships, data generation, development of quality measures, demonstration projects, and payment and delivery models. The overall objectives for this session were threefold:

1. To establish how quality improvement may be an effective strategy to advance the adoption of ERPs
2. To provide a case study to showcase the value of quality improvement
3. To hear real world experiences from the surgery and anesthesiology communities in using quality improvement as a strategy to advance the adoption of best practices

Dr. Richard (Rick) Dutton, Executive Director of the Anesthesiology Quality Institute, spoke about the American Society of Anesthesiologists’ (ASA) current activities. The ASA is sponsoring a learning collaborative relating to the perioperative surgical home (PSH) – a broad philosophy of coordinated care from start to finish for the surgical patient. Thirty to fifty hospitals will gather to share their best practices, which will be made available through the ASA website. Measures for the PSH or ERPs will have to relate to the entire care team because of the shared accountability for the patient. Patient satisfaction, LOS, clinical outcomes, and resource utilization will all need to be measured, cautioned Dr. Dutton. Although change is difficult, ERPs must be adopted one doctor, one nurse at a time. Finally, the ASA will try to coordinate with CMS or AHRQ to study a new payment initiative that could drive adoption of ERP.

Dr. Mark Ott, Medical Director of the Surgical Services Clinical Program at Intermountain Health, spoke about NSQIP and Intermountain’s approach to quality improvement. NSQIP evolved in the Veterans Health Administration and demonstrated that measuring surgical outcomes and reporting them back to providers could result in drops in morbidity and mortality. It spread to the private sector, and currently around 10-15% of hospitals participate, mostly the bigger hospitals that can afford the $150,000 or so it requires. NSQIP allows comparisons with other delivery systems across the country, and Intermountain determined that it was underperforming with respect to SSIs. They adopted a six-element plan to reduce SSIs, measured results over six months, and achieved a dramatic drop in infection rates.

With respect to ERP, they instituted an optional protocol in 2008 for intestinal surgery. They educated nurses throughout the system but left it to the surgeons’ discretion whether or not to use the protocol. They built dashboards that were available to doctors and nurses that tracked LOS, complications, and costs on a rolling basis. Patients who follow the ERP have low rates of complications and readmissions and the department has saved millions of dollars. One-third of the savings are returned to the surgical department for discretionary spending.

Finally, Dr. Ott reviewed their approach to tonsillectomies. There are five different methods in their system for removing tonsils, with different costs and complication rates – and the most expensive method has one of the worst complication rates. They presented their data to the surgeons along with each surgeon’s individual outcomes and costs. They said they would not tell the surgeons which method to use, but in a number of months they would reexamine the data and make them public so patients would have a basis for deciding who would perform their surgery.

The stakeholder discussion focused primarily on the role of the media in accelerating adoption of ERP. Currently patients are not aware of ERPs and are not clamoring for them. If patients created a demand, ERPs would be more widely adopted. It was also observed that the financial benefits seem to accrue to payers, not to patients.

**Breakout Session: Potential Strategies to Accelerate Adoption of ERP in the U.S.**

For the breakout session, participants were divided into four groups, attempting to maintain diversity of perspectives within each group. Dr. Tunis explained that the goal was to identify some broad strategies and specific tasks that would help accelerate broader adoption of ERPs within the next few years. To help guide discussion, Dr. Tunis reiterated the five broad domains of work to consider, as presented in the previous session: strategic partnerships, data generation, quality measures, demonstration projects, and new models of care including reimbursement models.
The following thoughts emerged from the groups:

- ensure that all stakeholders, including patients, are involved in strategic partnerships
- create an interactive website to bring together all the primary clinical associations as well as patients to share best practices and experiences
- develop a consensus guideline among all stakeholders and translate it into real world clinical practice
- develop a brief message that all stakeholders could adopt such as “home faster, fitter, and at less cost”
- create a small ERP-based data set with standardized definitions and measures that hospitals could join and use similar to NSQIP
- use LOS, perhaps with readmissions, as the primary outcome measure
- provide feedback data to providers as part of an audit, feedback, improvement loop
- develop deeper tool sets through demonstration projects for procedures other than colorectal surgery and include not just checklists but how the protocols were implemented
- explore use of bundled payments and value-based risk sharing
- pay for outcomes but don’t mandate how to achieve them/what elements to adopt
- persuade payers to change their methods or requirements and somehow mandate that ERPs should be adopted
- use the media to create awareness among all stakeholders, but particularly patients – they will drive adoption
- use preceptorships at centers of excellence to drive awareness across multiple practice levels of practitioners
- focus efforts on large institutions/networks and there will be a spillover effect into the marketplace

Meeting Wrap-up and Next Steps
Dr. Tunis reviewed the objectives of the meeting. There was a general consensus in the room that continued work to drive adoption of ERPs in the U.S. had great value, strong support to continue with a multi-stakeholder forum to further define next steps. CMTP offered to prepare a press release, meeting summary, and white paper, including perhaps a publishable version of a white paper. Dr. Tunis thanked the participants for their engagement and observed that the acceleration of the adoption of ERPs in the U.S. is an issue for which progress needs to continue.

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