Value-based Clinical Quality Improvement (CQI) for Patients Undergoing Abdominal Wall Reconstruction

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ABSTRACT

Patients with complex ventral/incisional hernias often undergo an abdominal wall reconstruction (AWR). These operations have a high cost of care and often result in a long hospital stay and high complication rates. Using the principles of clinical quality improvement (CQI), several attempts at process improvement were implemented in one hernia program over a 3-year period. For consecutive cases of patients undergoing abdominal wall reconstruction, process improvement attempts included the use of a long-term resorbable synthetic mesh (TIGR® Resorbable Matrix, Novus Scientific, Uppsala, Sweden) in place of a biologic mesh, the use of the transversus abdominis release approach in place of an open or endoscopic component separation (external oblique release) technique, and the use of a preoperative transversus abdominis plane (TAP) block using a long-acting local anesthetic (Exparel®, Pacira Pharmaceutical, Parsippany, NJ) as a part of perioperative multi-modal pain management and an enhanced recovery program. After over 60 cases, improvement in materials costs and postoperative outcomes were documented. No mesh-related complications occurred and no mesh removal was required. In this real-world, value-based application of CQI, several attempts at process improvement led to decreased costs and improved outcomes for patients who underwent abdominal wall reconstruction for complex ventral/incisional hernias. Value-based CQI could be a tool for improved health care value globally.

INTRODUCTION

The management of large midline ventral abdominal wall hernias has been challenging for general and reconstructive surgeons alike. Due to the sheer size of many of these hernias, medialization of the rectus muscles can be quite difficult. If the rectus muscles cannot be re-approximated, the placement of mesh (underlay, inlay, or overlay via open or laparoscopic approaches) can result in gross visceral protection (bowel will be separated from the subcutaneous tissues and skin by the mesh); however, this may result in poor abdominal wall functional and poor aesthetic results. The goals of an AWR are to protect the abdominal viscera, restore functional and structural continuity of the abdominal musculofascial system, provide a durable repair, and provide aesthetic improvement. If these objectives cannot be adequately achieved via more traditional methods, AWR with use of lateral relaxing incisions (release of the lateral aspects of either the external oblique or transversus abdominus musculofascial layer) may be indicated. Our hernia program has applied the concepts of clinical quality improvement (CQI) to attempt to improve outcomes by adapting the surgical techniques and perioperative care for patients undergoing repair of large midline ventral abdominal wall hernias while also attempting to reduce costs of care.

Clinical quality improvement (CQI) is real-world, real-time data collection and outcomes measurement with the application of ideas for improvement that are applied to a definable patient care process. CQI opens a new frontier for research and has the potential to identify optimal use of devices and drugs, generate presentations and publications, improve payer-pricing models, and most critically, improve patient value. Rather than using traditional clinical research — data collected in an isolated, controlled setting — employing the principles of CQI allows us to observe how devices, drugs, and methods of care affect real patients while they proceed through the actual patient care process on both a local and a global scale. Traditional clinical research is based on efforts to eliminate confounding variables and to prove or disprove a hypothesis. The CQI process recognizes that confounding variables not only continue to exist in the real world, but that it is critical to study the data that emerges from real-world patient care. In CQI, the goal is not to prove or disprove a hypothesis, but to measure and improve the value of care for a patient's entire cycle of care. A comparison of traditional clinical research and CQI is presented in Figure 1.

The CQI process arose out of the need to develop a system of healthcare management that better serves the patient and is based on the science of complex systems. CQI can potentially not only tell us where a device, procedure, or medication is safe and effective, but also help us determine the demographics of patients whom the device, procedure, or medication is most likely to benefit as well as those in whom it is most likely to harm or be wasteful. Localized data is vital to the CQI method: patients, medical practices, and hospital services, for example, are not identical across geographic and cultural locations. CQI makes it uniquely possible to evaluate outcomes by factors that vary at each local site of care. Multiple collaborations of local sites may also pool their data to look at patterns and trends from larger data sets produced by the same patient care process, in this case patients who undergo an AWR.

	Traditional Clinical Research		CQI
	Pro	Con	Comparison
Pre-market	FDA requirement	Costly	Not currently acceptable for pre-market
Human subjects research (truly experimental, high potential risk to patient)	Appropriate ethical protections	Costly, limited ability to interpret value	Not currently acceptable for pre-market
Post-market surveillance	Might help determine harmful devices	Costly, lengthy	Appropriate potential mechanism for post-market surveillance because information is gathered in real time in the real clinical world with no change in patient care.
Clinical research	Traditionally known and accepted	Costly, rarely answers clinical questions adequately	Ideal for real-world clinical research. Over time, can lead to improved value of care and opportunities to define unmet clinical needs.
CQI project	Not appropriate, may be unethical	Costly, wasteful, may be unethical	Ideal, as long as it is applied to the whole process of care, or if applied to a subprocess, the outcomes of the whole process are measured concurrently.
Off-label use/obtain additional indications	May be appropriate-industry initiated (depending on risks to the patient)	Costly, lengthy	May be appropriate - clinician initiated (depending on risks to patient)

Figure 1. A comparison of traditional clinical research with clinical quality improvement (CQI) (published with permission from Surgical Momentum).

METHODS

Our hernia program has focused on implementing CQI for patients undergoing AWR as well as other hernia patient care processes. The specific process improvement ideas we have implemented include the use of preoperative transversus abdomius plane (TAP) block with a long-active local anesthetic (Exparel®, Pacira Pharmaceuticals, Parsippany, NJ), use of long-term resorbable mesh (TIGR® Resorbable Matrix, Novus Scientific, Uppsala, Sweden), the use of the transversus abdominus release (TAR) approach for AWR, and several other process improvement ideas. Figure 2 documents some of the process improvement ideas and from where the ideas were generated. Some of these process improvement ideas were based

on published evidence from other groups.[1–5]

In line with the CQI concepts, we continuously collect many data points in the process of patient care, closely analyze the data periodically, and make changes to the delivery of care as ideas for improvement are generated from interpretation of the data and data analysis. With CQI, data collection, data analysis, determination of strength of correlations, and implementation of changes is a real-time, iterative process. Our experience of applying the principles of CQI for a ventral hernia process including patients who undergo AWR is presented.

Perioperative Management and Surgical Procedure in Detail

Preoperative preparation: During the preoperative period, patients are asked to optimize their health and emotional state in preparation for surgery. This may include weight loss, immunonutrition therapy, smoking cessation, medical optimization, exercise, and addressing any emotional issues such as anxiety or PTSD.

Multi-modal pain management: Consider pre- and perioperative multi-modal pain management, which may include preoperative and postoperative course of Gabapentin perioperative NSAIDs, TAP block with long-acting local anesthetic, intraoperative local anesthetic block, and other modalities to attempt maximal pain relief.

Incision: In most cases, an incision is made to excise a large amount of skin and soft tissue, resecting skin and abdominal wall back to healthy, well-vascularized tissue. This is commonly an elliptical vertical incision excising prior scars, but it may be an elliptical transverse incision or a fleur-de-lis (inverted T) type of incision. Typically, the umbilicus is excised and discarded during the skin and scar excision. This should be discussed with the patient preoperatively. Some people do not want their umbilicus removed. Many patients will understand when it is explained that getting to healthier, well-vascularized tissue requires removal of the umbilicus. For those patients who still do not consent to umbilectomy, working around the umbilicus, auto-transplantation of the umbilicus, or creation of a neoumbilicus by gathering skin and suturing down to the anterior fascia to create a dimple are options.

Advanced Hernia Solutions - Process Improvement Ideas

- Use of long-term resorbable mesh in place of biologic mesh **(industry)**
- Multi-disciplinary (small) team approach **(surgeon)**
- Shared decision process with patient and family (lap, open, no surgery) **(patient care manager)**
- Patient and family committee for feedback and suggestions- show mesh options, dress in jeans, casual office environment **(patient and family committee)**
- Evolution of AWR technique (open, CST, endoscopic CST, TAR) **(global collaborations)**
- Visceral reduction to ensure fascial closure **(surgeon)**
- Aggressive abdominoplasty, umbilectomy, quilting of sub Q, no drains **(plastic surgery collaborations)**
- Selective subcuticular skin closure **(team, patient feedback)**
- Multimodal perioperative management- including TAP block with long-acting local anesthetic **(anesthesia, industry, multidisciplinary collaboration)**
- Recognition of importance of preoperative management of medical, physical and emotional states **(patient care manager, team)**

Figure 2. A partial list of process improvement ideas (focus of idea generation in bold) from our multi-disciplinary hernia team (published with permission from Advanced Hernia Solutions).

Lysis of adhesions: The resection of prior mesh or resection of wound sinus tract or enterocutaneous fistula is often required. Typically, all scar tissue, hernia sac, weakened fascia, and foreign body (mesh, suture and any permanent fixation devices) are removed.

Dissection: The retrorectus space is entered medially between the posterior rectus sheath posteriorly and the rectus muscle anteriorly. The rectus muscle is dissected off of the posterior sheath to its lateral border. The posterior rectus sheath is incised very carefully just medial to the lateral border and just medial to the neurovascular bundles. This plane can be injected with long-acting local anesthetic for an intraoperative plane block if desired (Fig. 3). This injection can create a hydro-dissection plane making it easier to separate the transversus from the peritoneum (Fig. 4). This incision will divide the transversus abdominus, and the preperitoneal space will be entered lateral to the rectus muscle. The transversus abdominus can then be separated from the peritoneum back to the level of the paraspinous muscles. This dissection is then completed for the contralateral side to complete the bilateral myofascial

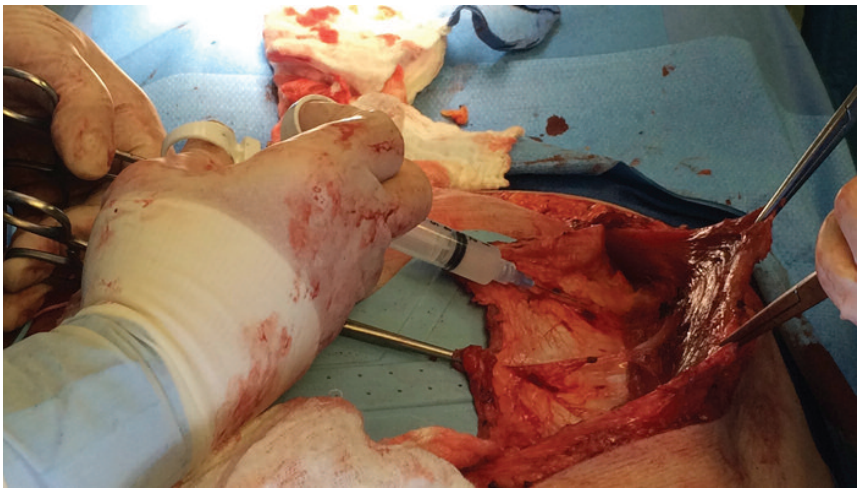

Figure 3. Injection of long-acting local anesthetic (Exparel®, Pacira Pharmaceutical, Parsippany, NJ) to the neurovascular bundles along the lateral boarder of the posterior rectus fascia.

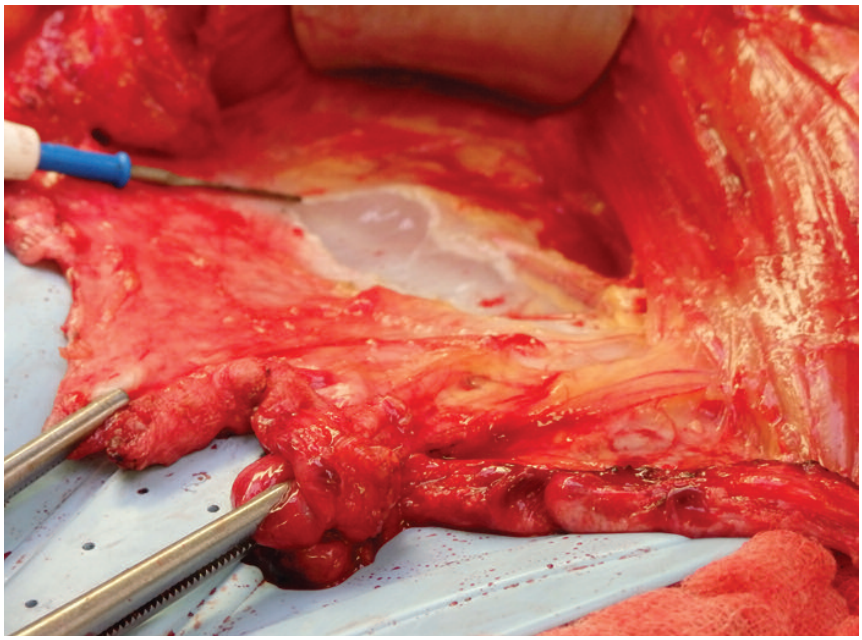

Figure 4. The hydrodissection is visible with transection of the transversus abdominus. This allows for easier dissection in the plane between the transversus abdominus and the peritoneum.

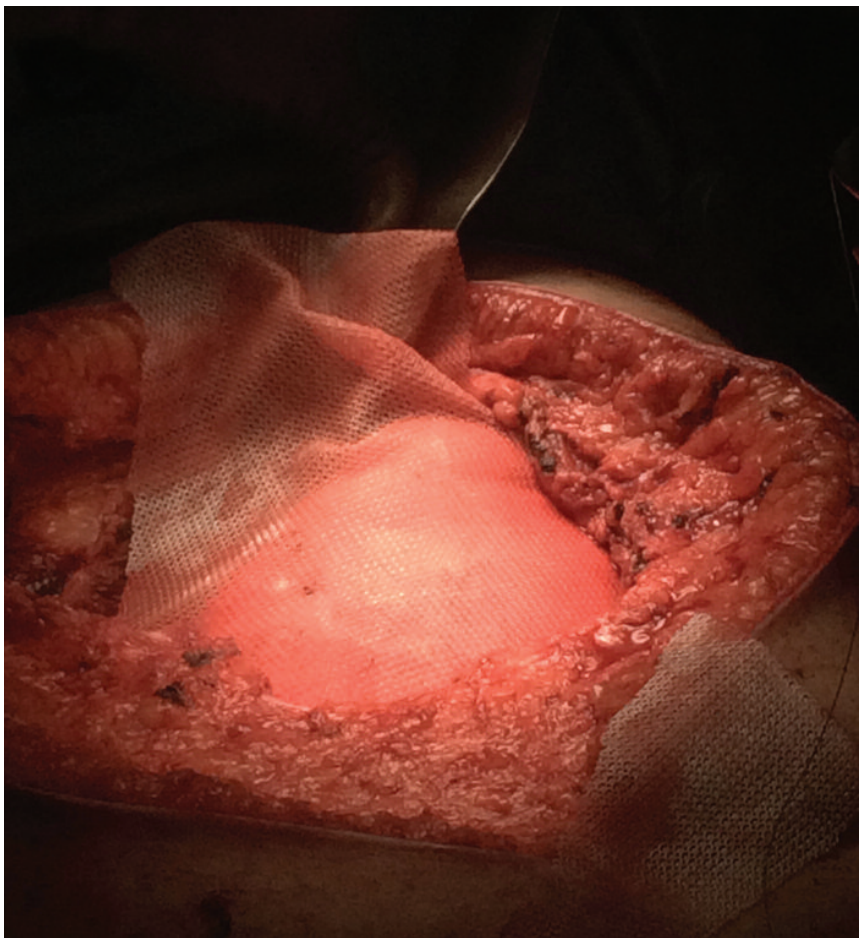

Figure 5. Long-term resorbable synthetic mesh (TIGR® Resorbable Matrix, Novus Scientific, Uppsala, Sweden) partially implanted.

advancement flaps maximizing the abdominal domain achieved and minimizing the tension on the midline closure. If loss of domain prevents midline closure despite a complete bilateral release, visceral reduction should be considered to obtain full fascial closure (omentum, colon, etc.). The posterior fascia and peritoneum (below the arcuate line) is closed with a running, long-term resorbable suture. Any holes in the peritoneum (not uncommon with the TAR approach) are closed if a macroporous mesh is used.

Mesh placement: A long-term resorbable synthetic mesh is brought onto the field and fashioned to fit the size and shape of the field to achieve a retrorectus buttress. This will typically require a vertical length of up to 30 centimeters and horizontal length of up to 20 centimeters. The shape is usually elliptical.

Mesh fixation: A 0-Vicryl stitch is used to anchor the mesh at the midline inferiorly, often to the pubis. Then, interrupted sutures are place bilaterally to the lateral cut transversus abdominus fascia maintaining the mesh taut as each suture is placed (Fig. 5). The final stitch is placed at the superior midline, often at the xiphoid process, to complete the mesh fixation (Fig. 6). If the mesh is adequately taut, the anterior fascial closure will not cause buckling or wrinkling of the mesh.

Closure: After irrigation and addressing any bleeding, the anterior fascia is closed with a running long-term resorbable stitch. The subcutaneous tissue is irrigated and many quilting sutures are placed to eliminate dead space. For patients with a thick abdominal wall, the quilting sutures are done in 2 to 4 layers working the way up from the level of the fascia to the level of the skin. This can prevent the need for drains and can decrease tension on the skin closure. The skin is closed with staples or a subcuticular running suture.

Postoperative care: The patient is usually sent to a regular floor room without abdominal drains; however, a bladder catheter is often used overnight. Early ambulation, small amounts of liquids, and small meals are encouraged within the first 24 hours. Prophylactic measures for DVT include SCDs, Lovenox® (Sanofi, Paris, France), and early ambulation. Pulmonary measures include incentive spirometry and

multi-modal pain management that results in less pain in most patients when walking, taking deep breaths, and coughing. With this enhanced recovery program, many patients are able to be discharged by the third postoperative day. Figure 7 describes many of the perioperative options for multi-modal pain management and enhanced recovery for patients who undergo AWR.

RESULTS

The impact of several attempts at process improvement for AWR patients, including the use of a long-term resorbable mesh as an attempt at value-based process improvement, are demonstrated. Thirty-nine patients were initially evaluated in the process. The mean follow-up presented for this initial group of patients was 12 months. Table I demonstrates that this was a very complex patient group with 49% having prior abdominal wall infections, 23% with active abdominal wall infections, 26% with loss of abdominal domain, 21% had intraoperative contamination, and 64% had a recurrent ventral hernia. Data in the second column compared the initial 39 patients with a published study in which AWR was employed using a biologic mesh.[6] The most recent 24 AWR patients were included in the third column for a continued evaluation. Follow-up for this patient group is between 4 to 14 months. Table II demonstrates outcome measures including wound complications, recurrence rate, and need for mesh removal compared with the referenced published study for a similar patient group and procedure. Specifically looking at costs, the total cost for mesh usage in all 63 patients was $232,434 vs. nearly $800,000 for similar-sized biologic mesh options (Table III).

DISCUSSION

Use of CQI in Health Care

Improving the value of patient care has become the challenge for health care in the 21st century. In health care, value should be defined by quality measures, patient safety and satisfaction, and the costs of care for a defined care process throughout the entire cycle of care.

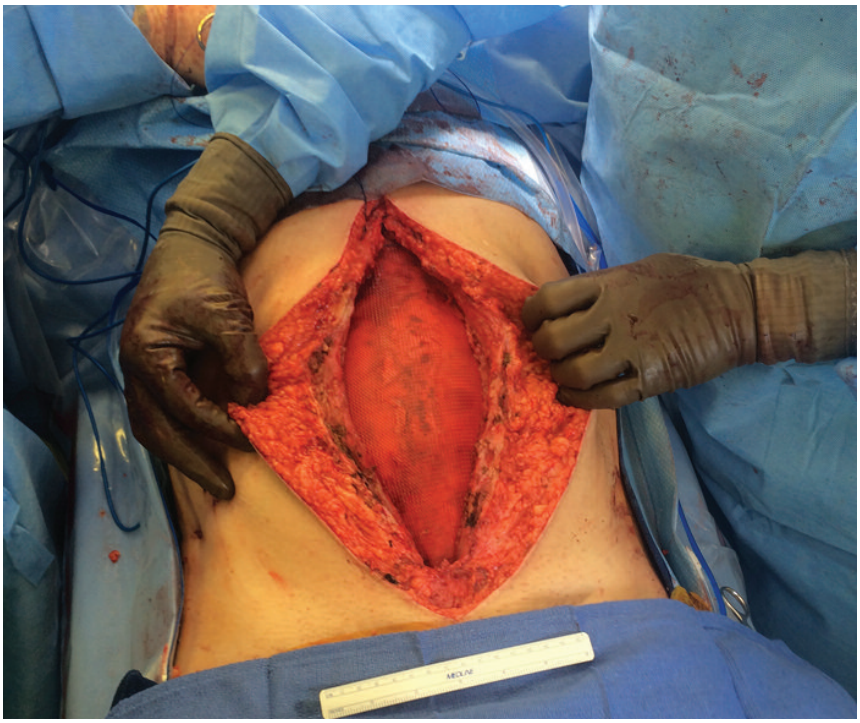

Figure 6. Long-term resorbable synthetic mesh (TIGR® Resorbable Matrix, Novus Scientific, Uppsala, Sweden) completed implant in the retrorectus/preperitoneal space, sewn laterally to the cut transversus abdominus facia.

Currently, there is no example of patient care that has a defined care process and defined outcome measures that determine value. However, publications from business experts have proposed a model for patient care that would allow for defining, measuring, and improving value.[7–9] Continuing to

	Preop	Intraop	Postop
Prep/medical/emotional Anesthesia SSI bundle for AWR	Weight loss/improve nutrition Smoking cessation AWR: consider Botox	General anesthesia Additional local infiltration	Activity as tol Many small meals Ice/heat/support DVT prophylaxis
GI function	Bowel cleansing Liquids/Colace/magnesium Entereg		Colace Magnesium Entereg
Medications (up to one week preop and postop 3-5 d)	Lyrica Neurontin		Lyrica Neurontin Opioid agonist (IV/oral)
Medications (immediately preop and postop in hospital)	Ofirmev	Toradol Ibuprofen	Ofirmev, Toradol, Entereg, Ibuprofen
Block	TAP: Exparel Decadron Bupranorphine Flank: consider epidural	Local: Intraoperative Exparel block Xylocaine gel for bladder cath	
Anti-emetic therapy		H2-blocker, Reglan, Zofran (prior to end of case), Emend (for high-risk PONV)	Zofran in PACU

Figure 7. Some options for multi-modal pain management and enhanced recovery for patients with ventral hernia undergoing AWR (published with permission from Advanced Hernia Solutions).

Table I
Some complex patient characteristics for the first 39 patients, a published comparison group of patients who underwent AWR using a biologic mesh, and the last 24 patients

Complicating factors	LTR mesh CQI n = 39	RICH study n = 85	Last 24 cases
Previous infection (abdominal wall or mesh)	49%	34%	50%
Active infection	23%	19%	25%
Stoma present	8%	39%	13%
Loss of domain	26%	20%	29%
Intraoperative contamination	21%	53%	17%
Prior ventral hernia repair	64%	64%	38%

provide patient care in a model designed over 100 years ago is no longer adequate. Our current system structural design for modern patient care includes the hospital model with hierarchy and bureaucracy as well as department silos causing fragmentation in care that is becoming more inefficient as complexity increases.[10,11] The other system structure for providing patient care is the individual physician model, which is also not sufficient in light of the exponential increase in medical knowledge.[12] Both core structures for providing patient care are inadequate given the increasing complexity of patient care and the increasing pace of change in our world in general. A complexity science view of health care, which is based on principles that describe "complex phenomena demonstrated in systems characterized by non-linear interactive components," allows us to simplify patient care by designing care around definable patient groups, diseases, and problems.[13] The information generated by the care processes can be used to improve the outcomes of care over time. This continuous improvement of the patient's entire cycle of care has the potential to lead to improved quality, safety, and patient satisfaction at the same time that costs are lowered, resulting in improved value.[7,8] There are now even peer-reviewed, evidenced-based guidelines supporting the use of CQI rather than traditional research methods for the study of ventral/incisional hernia disease.[14]

Table II
Selected outcomes for patients who underwent AWR, the first 39 patients, a published comparison group who had a biologic mesh, and the last 24 patients

Postoperative results	LTR mesh CQI n = 39 (12 month f/u)	RICH study at 12 month f/u n = 71	Last 24 cases
Seroma	15%	28%	21%
Wound infection (managed operatively)	28% (13%)	29% (16%)	8% (4%)
Recurrence	15%	19%	0%
Mesh removal	0%	0%	0%

The use of CQI for improving patient care has been supported by health care law since the HIPAA law in 1996. These principles were again supported with the Patient Safety and Quality Improvement Act of 2005. The need for human subjects research protections and the use of IRB processes has been challenged, and when true CQI efforts are implemented there is a clear distinction compared with human subjects research, which does require an IRB process. True CQI is focused on local process improvement and utilizes evidence-based medicine interpreted by the clinical team, ideally including the patient and family in a shared decision process. CQI is not appropriate for any pre-market studies, for interventions that could clearly increase risks for patients, and for efforts that intend to produce generalizable knowledge as a priority, rather than local process improvement as a priority. The intent to publish is not sufficient to classify the effort as human subjects research. This information about the distinction between human subjects research and CQI is clearly presented in the format of frequently asked questions (FAQs) on the U.S. Health and Human Services website.[15] It should be noted that the results of a CQI project in one local environment do not necessarily apply the same to another, different local environment. Local environmental variation can produce different patient results from the same process improvement intervention.

Synthetic, Biologic, and Resorbable Synthetic Mesh

In general, all types of mesh used for hernia repair provide reinforcement and a scaffold for cellular/vascular ingrowth and incorporation into surrounding structures. The tissue surrounding a hernia defect is typically weak, and attempts to close the defect with sutures only (primarily tissue repair) or to sew mesh to the fascial edges (inlay approach) commonly fail. de Vries et al. showed that the hernia recurrence rate for primary suture repair of large

abdominal wall hernias necessitating component separation has been shown to approximate 52%, versus 22% with the use of prosthetic mesh.[16] However, this study also demonstrated that wound complications, especially seroma formation and infection, were much more common with the use of prosthetic mesh. Other studies have also suggested that the risk of wound complications is unreasonably high when permanent synthetic mesh is placed in contaminated fields. For example, Cavallaro et al. argued that biologic mesh should be used in contaminated fields because 50% to 90% of synthetic meshes placed in that setting required removal.[17] In addition, synthetic mesh may undergo changes due to foreign body reaction.[18] This could result in physical alterations of the mesh including migration and contraction as well as potentially making the mesh stiffer and more brittle.

In an effort to reduce the infection rate, chronic inflammation, and foreign body reaction associated with use of prosthetic mesh for complex abdominal wall hernia repair, many surgeons began to use biologic meshes in the 1990s. Biologic meshes are derived from animal or human tissue processed to produce acellular extracellular matrices (ECM) that provide a scaffolding of collagen and elastin. The ECM scaffolding normally releases growth factors and other chemoattractants, which signal the migration of fibroblasts and other structural cells to the porous EMC. A remodeling process ensues, which eventually leads to the degradation of the biologic mesh ECM and replacement with host tissue. The balance of biologic mesh ECM degradation and replacement by host collagen influences the cellular structure, strength, and compliance of the final hernia repair. The process of production of biologic meshes varies greatly — including donor characteristics as well as the decellularization, sterilization, and cross-linking processes. In addition, many biologics require specific storage and transport protocols. All of these factors lead to many variations between the biologic meshes, and therefore, a large array of patient-mesh interactions, which may result in varying degrees of mesh incorporation, strength of repair, and foreign body reaction. The complex procurement, production, and storage/transport processes for biologic mesh also lead to significant costs. The biologics have also been associated with relatively high rates of hernia recurrence in clinical use. However, when compared with traditional prosthetic meshes, biologics have potentially been more resistant to infection and chronic inflammation.

Table III
A comparison of the mesh costs for all 63 AWR cases compared with what the costs would have been using two different biologic meshes based on actual cost of mesh purchase to the hospital

Using long-term resorbable mesh		Using biologic mesh		
			Hospital standard biologic mesh	Market-leading biologic mesh
2 patients w/ 10x15 cm	$1,950	2 15x10 cm	$6,600	$6,128
5 patients w/ 2x10x15 cm	$9,750	5 10x30 cm	$39,600	$36,768
55 patients w/ 20x30 cm	$214,500	32 20x30 cm	$726,000	$755,315
Additional mesh in 4 patients (1 pt had no macroporous LTR mesh)	$6,234			
Total mesh cost	$232,434		$780,120 (+547,686)	$805,565 (+573,131)

Because of the relatively high recurrence rates associated with primary suture repair and the high rates of infection and foreign body reaction with prosthetic meshes, as well as the high cost and relatively high recurrence rates with biologics, resorbable synthetic meshes have become more widely utilized for large ventral hernia repair and abdominal wall reconstruction. Similar to the biologics, resorbable synthetic meshes are designed to provide mechanical strength as well as a temporary scaffold structure for tissue ingrowth during the critical period of wound healing. Unlike biologic mesh, resorbable synthetics have relatively predictable mechanical properties, including compliance, elasticity, strength, and fracture, as well as rate of absorption and degradation.[19] This type of mesh has less stringent storage and transportation protocols. Resorbable synthetics have also been estimated to reduce costs by 66%, compared with biologic meshes.[3] The main options for resorbable synthetic mesh include GORE®-BIO-A® (W.L. Gore, Newark, DE), Phasix™ (Davol, a Bard Company, Warwick, RI), TIGR® (Novus Scientific, Uppsala, Sweden), Vicryl® (Ethicon, Somerville, NJ), and Seri® Surgical Scaffold (Actavis, Parsippany, NJ). TIGR® Matrix maintains its mechanical strength for 6 months, and is usually completely resorbed by 3 years after implantation. The major other types of available biosynthetic meshes (Vicryl®, GORE®-BIO-A®, and Phasix™) lose their mechanical strength and are completely reabsorbed (all by hydrolysis) much more quickly than TIGR® Matrix. Vicryl® biosynthetic mesh is completely resorbed by 2 to 3 months, GORE®-BIO-A® mesh within 6 months, and PHASIX™ mesh within 12 to 18 months.[19]

CONCLUSION

Implementing the principles of CQI can improve the value of care in a dynamic way because improvement measures are applied in real time with real patients. For abdominal wall reconstruction, use of long-term resorbable mesh demonstrated better value in this CQI project compared with published use of biologic mesh based on measures that define value (similar outcomes with decreased costs). More examples of process improvement will help demon-

strate the validity of this approach. It is important to note that when doing CQI, local variables matter and can lead to different outcomes for the same process and process improvement ideas. If the process improvement attempt described in this effort is made at another location and in a different group of patients, the results will likely be different. STI

AUTHORS' DISCLOSURES

Dr. Ramshaw receives speaking and teaching honoraria from B. Braun, Covidien, Ethicon, Surgiquest, and WL Gore; he is also a consultant for Novus, Pacira, and STS. Dr. Stephan and Ms. Forman have no financial relationships to report.

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