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2.1 Introduction

The scientific paradigm shift from reductionist to complex systems science began over a century ago. Around the beginning of the twentieth century, physicists started to understand the incompleteness of Newtonian physics applied to the real biologic world. During the past century, many other disciplines have begun to make this shift. From the studies of systems biology to behavioral economics, the principles of a reductionist, rational, and static scientific understanding of our world have been found to be inadequate to explain and improve our dynamic and ever-changing world. Even the human genome project, with the unmet potential to discover the blueprint for the cause of and cure for all of our diseases, found that our genome was constantly adapting and changing and the idea that we could make a major impact on our health through only genetic engineering was naïve and misguided. Understanding healthcare as a complex biologic system and applying tools that apply to this reality will result in a global healthcare system that is based on measuring and improving the value of care we provide.

A more complete understanding of our world through the application of complex systems science will allow us to identify the factors that contribute to both positive and negative outcomes from definable patient processes and patient subpopulations. These factors are constantly changing and are interconnected with other factors that contribute to outcomes. If they are tested in isolation, as attempted in a prospective, randomized, *controlled* trial, the potential measurement of the impact of any one factor will be likely

inaccurate. It would also only apply to the selected group of people in which that factor was tested and only in the environment in which that experiment was completed. The tools we have used to attempt to discover static truths in healthcare will need to be replaced by tools from complex systems science (also known as information or data science) which should be applied to all patients (no inclusion or exclusion criteria) in many different local environments.

Where the reductionist scientific method, which attempts to prove or disprove a hypothesis, assumes the test environment is static, the complex systems tools for discovery are intended to be applied to a constantly changing world. Basic principles in complex systems science include the assumption that many factors that are constantly changing and interacting can have a variety of impacts on the subject (a person/patient) who is considering a variety of treatment options and will have a variety of potential outcomes based on the interaction of the factors related to the patient, the treatment process in that local environment at one particular moment in time. A change in any one or more of these factors can lead to a similar or potentially different outcome from the same treatment option. Rather than attempting to prove or disprove a hypothesis, tools for discovery in complex systems science are simply designed to improve whatever is measured within a definable process.

These tools for improvement have been applied and matured most famously in manufacturing, the automobile industry, for example. A variety of terms have been applied to improvement tools such as Lean and Six Sigma, but the basic concept is the same—the desire to achieve continuous improvement. One significant point needs to be made about the application of these tools in manufacturing compared with healthcare. In manufacturing, these tools are typically applied to one manufacturing process that is producing one specified product, a 2016 Ford Mustang, for example. In a manufacturing process, the steps and factors involved can be controlled and improved by eliminating variation. Statistical tools include process control charts to identify inappropriate or unexpected variation. In a biologic process, such as

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healthcare, it is impossible to control the variation. Instead, the process can be managed through iterative measurement and improvement of value-based outcomes and through the identification of patterns and subpopulations. The optimal variety of options for various subpopulations can be determined with nonlinear complex systems tools such as factor analysis and predictive analytics. Currently, many reductionist tools for improvement (like a single “best practice,” for example) are being applied to healthcare as if healthcare was composed of static, mechanical processes instead of the reality that we are dealing with complex biologic processes in healthcare.

Another way improvement tools have been generally misapplied in healthcare is their application to subprocesses without attention to the impact on the value of whole patient processes. It should be well accepted that the most important processes to improve are the entire cycles of patient care for the many definable patient processes. The concept of a whole patient process includes the time from the moment of first symptom to the return to a full quality of life (for acute, curable disease) and in some cases for the entire life of the patient (for chronic, not currently curable disease). The ultimate outcome measure for the entire cycle of care is value, a combination of costs, quality measures, and outcome measures from the perspective of the patient, such as patient and family satisfaction with the care process. Until now, essentially all process improvement attempts in healthcare, like decreasing central line infection or improving safety in the operating room, have been attempts at improving a subprocess, not the entire cycle of care for a definable patient care process. In a complex process, when a subprocess is improved without attention to the whole process, the result is suboptimization—improvement of a subprocess will not lead to improvement of the whole process and will predictably have unintended consequences.

The application of complex systems science to hernia disease is demonstrated in applying the principles of value-based clinical quality improvement (CQI) principles to the whole cycle of care for a definable patient care process. This ideally requires a multidisciplinary team to determine the appropriate factors (patient and treatment variables) that are most likely to impact the outcomes that would measure value for a specific care process. By identifying what data points and outcome measures should be collected, the team is providing the programming for what goes in to the computing—a computer program providing data analysis and data visualization. That same team then attempts to interpret the significance of the analysis and data visualizations to generate ideas to improve outcomes that measure value. This example of a team providing the programming of data, a computer program providing a variety of data analytics and visualizations from the data entered, and that same human team then interpreting the output and using that to

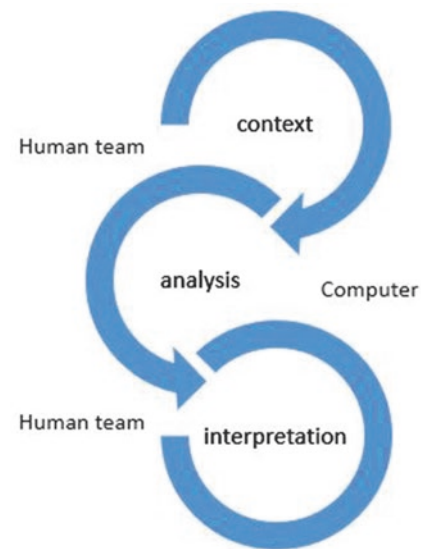


Fig. 2.1 Illustration of the human–computer symbiosis for artificial intelligence applied to healthcare. The human team identifies the context (patient care process) and programs what data and outcomes to analyze, the computer can perform a variety of analyses and produce visualizations, and the human team then interprets the analyses and visualizations to generate ideas for process improvement

generate ideas for improving the patient care process is an example of the human–computer collaboration that can be termed artificial intelligence (Fig. 2.1). Computers have become immensely powerful at beating human beings in competitions if rules and answers are known and do not change. IBM’s successful demonstration of their computer capabilities at beating the world’s best chess player (IBM’s Deep Blue vs. Garry Kasparov) and Jeopardy’s greatest champions (IBM’s Watson vs. Ken Jennings and Brad Rutter) demonstrate that computing capabilities have overtaken even the greatest human minds in these areas. But this was never meant to be the greatest potential application of artificial intelligence. The true potential for artificial intelligence is in the discovery of new ideas, innovations, and applications that have yet to be applied to improve the value of a particular process. In the case of hernia disease, we have generated many examples of attempts to improve the value of care for patients who have a ventral hernia. We will demonstrate the method and impact of having a dedicated team (including input from patients and family members) who determine what factors and outcome measures to use for the computer analytics and how to interpret the output of the data analyses and data visualizations to generate value-based ideas in an attempt to improve outcomes. This is one application of artificial intelligence, a symbiosis between human teams and computing capabilities, to healthcare. This complex systems science approach to healthcare will become more and more important as the pace of change in our world continues to accelerate.

2.2 Examples of CQI Applied to Ventral Hernia Disease

2.2.1 A Patient Centered Idea for Improvement (Eliminating the Use of Abdominal Wall Drains)

As a part of our Hernia CQI program, we have regularly obtained feedback and input from hernia patients and their family members to get ideas for improvement. A couple of years into applying CQI for the patients who underwent an abdominal wall reconstruction (AWR), we recognized that many patients had very negative experiences with the abdominal wall drains we often placed during an AWR. Patients did not like the irritation, discomfort, and hassle of drains, especially when they had to manage them outside of the hospital. We even had one patient who developed an infection at the site where the drain tubing exited the skin, with no problem at the actual incision site. In an attempt to apply a process improvement, our hernia team did a literature search and found techniques that had been developed by plastic surgeons in abdominoplasty operations that led to the elimination of abdominal wall drains which demonstrated better rates of wound complications such as infection, hematoma, and seroma.

We were already moving toward techniques to minimize the elevation of skin flaps—first using endoscopic approaches for external oblique component separation and then the transversus abdominus release (TAR) approach. We added the techniques of wide skin and soft tissue excision including excision of the umbilicus, and the use of layered quilting (also known as tension reduction) sutures to eliminate the dead space and tension on the skin closure. In some cases, this included an inverted T (fleur-de-lis) incision. Although this did increase the operative time (a new improvement opportunity), the rate of wound complications has decreased significantly without using a single drain over the past 3 years.

The primary data analytics tool we used to evaluate the impact of eliminating drains is called a factor analysis. In general, a factor analysis produces a number between positive one and negative one. The more positive the number, the more positive the correlation is between the factor and what is being measured. If the number is negative, the closer the number is to negative one the stronger the negative correlation is between that factor and whatever is being measured. A factor analysis produces weighted correlations and attempts to identify which factors contribute the most to identified outcome measures that determine the value for a particular process, ventral hernia disease in this example. In a factor analysis performed to determine what factors contributed to poor outcomes, the use of drains had a highly weighted correlation (+.875) to poor outcomes (increased

LOS, increased opioid use, and increased incidence of post-operative complications). This factor analysis supported the continued practice of not using drains in our AWR patient process after applying the technical process improvements described above.

2.2.2 Minimizing Pain and Enhancing Recovery (A Multimodal Effort)

The problem of opioid-related complications and chronic opioid use and addition is now a national epidemic and the dialogue has made it to the public press with reports of many tragic deaths related to prescription opioids. It has been estimated that approximately 1 in 12 elective surgery patients may become addicted to opioids due to the use of their post-operative prescription for pain medication.

With this motivation and the patient's perspective that it is not a good experience to feel pain from a major operation, or to feel nausea and vomit as a side effect from postoperative opioid use, our hernia team implemented many attempts at process improvement with the focus being perioperative pain management and enhanced recovery minimizing the use of opioids. Working with an anesthesiologist, we implemented preoperative transversus abdominus plane (TAP) blocks with a variety of medications including long-acting local anesthetics (liposomal bupivacaine) and short-acting local anesthetics (bupivacaine). In addition, other anti-inflammatory medications were also used as a part of the block and intraoperatively through an intravenous route. Over time, for large abdominal wall reconstruction patients, we added an intraoperative block with liposomal bupivacaine, and for laparoscopic ventral hernia repair patients, we instituted a low pressure pneumoperitoneum system to address visceral pain which would not be adequately addressed with the abdominal wall blocks which were used to address the somatic pain. Other process improvement ideas in this area included a more aggressive attempt to prepare the patient for surgery including weight loss, smoking cessation and nutritional, physical, medical and even psycho/social/spiritual and emotional optimization. The perception of pain is a very complex biologic interaction and a subpopulation of patients may experience less pain if their fears and emotional problems (like PTSD) are addressed pre-operatively. We also try to do a better job at setting expectations of postoperative pain and the appropriate attempt to minimize opioid use. Most patients understand when we explain the potential downside of using opioids as the sole or primary method for postoperative pain control. Our hernia patient care manager does the majority of this counseling and has many of examples from prior patients to help patients understand why we would want to implement these concepts in an attempt to improve outcomes.

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6
Age	-0.040	-0.040	-0.818	-0.024	0.207	0.209
BMI	-0.136	-0.137	0.230	-0.001	-0.806	0.037
Frequent Cough	-0.193	-0.604	-0.036	-0.529	-0.143	-0.106
Frequent Constipation	0.137	-0.774	0.048	0.104	-0.013	0.264
Prostate Enlargement	0.007	0.129	-0.449	-0.002	0.142	-0.049
Strain to Urinate	-0.143	-0.726	0.029	0.075	0.059	-0.214
Frequent N/V	0.030	0.067	0.034	-0.879	0.027	0.029
Pre-OP Pain	0.106	0.059	-0.134	-0.287	0.231	-0.686
C Medically	0.137	-0.212	-0.669	0.014	-0.465	-0.248
C Emotionally	0.741	0.037	0.345	-0.051	0.057	-0.286
C Surgically	0.846	0.093	-0.074	0.168	-0.205	-0.047
Recurrence	0.832	-0.115	-0.106	-0.029	0.103	0.155
Previous Infection	0.353	0.293	0.096	-0.014	-0.613	0.029
Smoke	0.014	-0.076	0.115	0.181	-0.142	-0.794
Previous Repair	0.628	0.207	-0.156	-0.519	-0.016	-0.075

Fig. 2.2 A factor analysis demonstrating the patients emotional complexity (C Emotionally) has a highly positive correlation (Factor 1 row +0.741) to poor outcomes such as increased length of stay complications and higher total opioid use

It was actually our patient care manager who identified that a patient's preoperative emotional state may be impacting the outcomes for our hernia program. Almost 5 years ago, we started to subjectively assess the emotional state of our patients—low, medium or high emotional complexity. Patients with minimal or no emotional issues were graded low, those with moderate issues as medium, and those with significant issues, such as a documented diagnosis or demonstrating severe anxiety or PTSD, were considered high emotional complexity. About a year later, when we did a factor analysis, we learned that the emotional state of our patients preoperatively was the highest weighted modifiable factor that correlated with bad outcomes, contributing much greater to those outcomes than BMI, smoking, or diabetes (Fig. 2.2). Since then, we have been implementing preoperative counseling, psychological assessments, and therapy and addressing social support needs for this subpopulation of patients. We have also worked with social scientists and other social services professionals to refine and make our preoperative tools more objective to better identify and classify these patient groups.

Through these many multimodal attempts at process improvement for opioid sparing pain control and enhanced

recovery, we have seen a significant decrease in the time in PACU, the length of stay and the total use of opioids in the PACU and for the total hospital stay. The percentage of patients not requiring opioid pain medication in the PACU has risen to about 33 % for patients who undergo abdominal wall reconstruction (AWR) and over 60 % for patients who have a laparoscopic ventral hernia repair. Similarly, a much larger percentage of patients is now discharged on the day of surgery or postoperative day 1 after laparoscopic ventral hernia repair and almost 40 % of patients are now discharged in 3 days or less (all without drains) after AWR. Prior to implementing these attempts at process improvement, only one patient went home on postoperative day 3 (less than 5 % were discharged in 3 days or less) after an AWR. As we continue to apply linear and nonlinear analytics tools, such as factor analysis, we can continue to see which factors contributed the most (or least) to the outcomes. In a recent factor analysis, several of the attempts at process improvement, such as long-acting local anesthetic blocks, the elimination of drains and low insufflation pressure had highly weighted positive correlations to the improvement of outcomes over time.

2.2.3 Understanding the Cost Component of Value (The Challenge of Measuring Real Costs)

The most difficult outcome measure to collect when attempting to define a measurement of value for a hernia patient care process has been the costs for the entire cycle of care. The majority of costs for a hernia process are typically around the operation and hospital stay. It would be ideal for the hospital to collect costs for the patient care process during the entire hospital stay (known as activity-based accounting). But hospitals use a method called cost accounting, where the costs are allocated by hospital departments, not by the patient care process. In cost accounting, the hospital will typically pool all costs into direct (actual costs of care for all patients) and indirect (nonclinical-related costs like overhead and nonclinical salaries). Hospitals will have a variety of formulas to assign direct and indirect costs to each patient for internal purposes, but the actual costs of care for each patient are not actually collected or known. The hospital bill that a patient receives after a hospital stay actually has little or nothing to do with the actual costs of care. The bill is generated from a chargemaster that generates a bill from an itemized attempt at documenting the patient's hospital stay. The patient's hospital bill is notoriously inaccurate and often lists charges for items that seem ridiculous. It is important to know that hospital charges are not related to the actual costs of care and should not be used as one of the measurement of costs to determine the value of a patient care process.

To get a true measurement of value, some reasonable estimate of costs of care will be necessary to go along with quality and patient perspective measures. Until activity-based accounting is available, the easiest way to measure costs is to combine the estimates of direct and indirect costs that a hospital assigns to each patient's hospital stay. Although costs are a challenge to obtain, a true measurement of value cannot be obtained without knowing (or at least having a reasonable estimate of) real costs. When the actual reimbursement is known and a total cost estimate is known the hospital profit margin can be calculated for a specific patient care process. For most hernia processes, the hospital margin will be negative due to the low reimbursement of hernia procedures compared to other surgical procedures and due to the costs of some hernia meshes and a relatively high rate of complications for complex ventral hernia repairs. We have found that including the measurement of hospital margin and making attempts at process improvement to improve the financial outcomes for the hospital in addition to the value for the patient can help engage the hospital administration in the CQI effort. Some people chose to look only at direct costs and not apply the nonclinical overhead (indirect) cost estimates. The measurement of direct costs subtracted from the total hospital reimbursement is called contribution margin.

We have chosen to use total costs and total margin when applying the financial measures to our CQI projects in an attempt to better partner with the hospital and recognize that all hospital costs will need to be accounted for if we are to have financial sustainability in healthcare.

2.3 Application of These Tools to a Local Hernia Program

The application of these concepts for any hernia team requires some time to meet, some understanding of where the data exists (if it exists), and some commitment on the part of the hospital to help with access to data and to allow the people who contribute to the whole cycle of care for hernia patients at each local environment (operating room staff, floor staff, etc.) to be available from time to time to look at outcomes and help contribute ideas for attempted process improvement. As discussed above, ideally the hospital will work with the hernia team to get better and better estimates of real costs for each patient within each process. This might be more realistic collecting data prospectively although if data for patients who have been cared for in the past is available, that can be a good dataset as a starting point to stimulate the first set of ideas for attempted process improvement.

Our current general method for applying these principles includes an initial multidisciplinary meeting where we define the care process we will work on, define the factors in the process that we think will contribute to the outcomes, and define the outcomes that will be a good measurement of value for each specific patient care process. For a ventral hernia process, we look at patient demographic factors, such as gender, BMI, number of prior hernia repairs, presence of an active wound, and the emotional state of the patient, for example. We also identify process or treatment factors that we believe will potentially impact outcomes such as use of local anesthetic block, type of mesh, use of an intraoperative local anesthetic block, and the pressure of carbon dioxide gas used for laparoscopic cases. Outcomes that measure value for a ventral hernia process include costs, length of stay, opioid use, wound complications, recurrence, return to quality of life, etc.

When the data points are identified, we go to all of the data repositories where they might be found—the physician and hospital EMR, the anesthesia record, the hospital financial system, etc. We typically do a 1-month dataset test to see if we think the mechanism of data collection is generating the correct patient group and produces reasonably accurate data. Usually, there are some gaps to fill in, particularly in data collected for the specific data points from the actual surgical procedure and for data from the long-term follow-up. To specifically address these two gaps, we developed forms, OR quick forms and follow-up forms, to make documenting

CQInnovation Quick OR Notes

Laparoscopic Ventral Hernia Repair

Advanced Hernia Solutions
A Surgical Momentum Clinical Team

Patient Name: _____						Date of Surgery: _____			
Total Number of Ports Placed:						Location/Type:			
1	2	3	4	5	6	RLQ	RUQ	LLQ	LUQ
Approximate Time Lysing Adhesions: _____ (Min.)						Suprapubic		Subxiphoid	
						Mid Upper		Mid Lower	
						Flank: <input type="checkbox"/> Right <input type="checkbox"/> Left		Parastomal	
						Umbilical		Spigelian	
Extent of Adhesions:									
Mild		Moderate		Severe					
Was Mesh Removed: <input type="checkbox"/> Yes <input type="checkbox"/> No									
Hernia Attribute:									
Small		Medium		Large		Swiss Cheese			
Number of Defects: _____						Total size of defect(s): _____ x _____ (cm)			
Mesh Used:									
Gore Dual Mesh			SurgiMesh XB			Composite EX			
Proceed			C- Qur			Ventral light			
Physiomesh			Duelux			Parietex Composite			
Effective Size of Mesh Used: _____ X _____ (cm)									
Tacker Used:									
ProTack		Absorb-a-Tack		Secure Strap					
Number of Tackers Used:									
1	2	3	4	5					
Suturing Technique:									
Diamond		Square		Peripheral		Other: _____			
Total Number of Sutures: _____									
Specimen Retained:									
Mesh		Bowel		None		Other: _____			
TAP Block: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Right <input type="checkbox"/> Left									

Fig. 2.3 OR quick form for laparoscopic ventral hernia repair—a method to collect gaps in data from the actual surgical procedure

data in these two areas more efficient (Fig. 2.3). After the dataset test looks good, we will collect data for a defined previous time period, 1 year or more depending of the volume of cases for each process. Meaningful insight begins to occur after analyzing as few as 20–30 cases so obtaining hundreds of past cases is not usually necessary. Finding the

data and putting it in context does require time and some resources, so getting a minimum amount of cases and data that generates actionable insight to improve value is the goal. Once the ideas for process improvement have been generated from the analysis of previous cases, then data is collected as new patients go through the process and as new ideas for

potential process improvement are implemented. Meetings to go over the outcomes and the computer-generated data analysis and visualization are held periodically to generate new ideas for improvement. Typically, we have had our meetings monthly, with a deeper study of the data through nonlinear analytics and data visualization each quarter. We will periodically also invite additional people to attend meetings and give their perspective and ideas to attempt to improve our care processes. Groups from former patients and family and industry partners that produce and sell drugs and devices that are factors in the patient care process typically attend one or two of these meetings each year. The application of CQI principles from complex systems science applied to healthcare never ends. Theoretically, there can always be improvement and change is occurring at a faster and faster pace. So it will become more and more important to understand and apply these principles in the future. When applied to hernia disease and across our entire healthcare system, the potential for a sustainable healthcare system that is based on measuring and improving value, not based on volume, will be achievable.

2.4 Summary

The application of complex systems science to hernia disease and to healthcare in general is in its infancy. But the understanding that we cannot continue to use the same

methods to care for patients that we have in the past and expect to achieve a sustainable global healthcare system is growing fast. It is becoming evident that we will need to transition from a healthcare system based on volume to one that is based on value. To do this, we will need to learn how to measure and improve value in the context of definable patient care processes. The complex system science principles applied to hernia disease described in this chapter, including the use of human–computer artificial intelligence to generate and apply ideas to improve value-based outcomes, can lead to a sustainable healthcare system.

Suggested Reading

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Textbook of Hernia

Hope, W.W.; Cobb, W.S.; Adrales, G.L. (Eds.)

2017, XV, 418 p. 272 illus., 219 illus. in color.,

Hardcover

ISBN: 978-3-319-43043-0