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Review Article

Quality improvement in gynecologic oncology: Current successes and future promise

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HIGHLIGHTS

- Quality improvement methodology can be applied to gaps in healthcare to improve patient outcomes and safety.
- Successful examples of quality improvement in gynecologic oncology include ERAS and blood transfusion reduction.
- Common frameworks for quality improvement include Six Sigma and Lean.
- Quality improvement outcomes should be disseminated to the greater healthcare community.

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ABSTRACT

Quality improvement in healthcare has accelerated over the past two decades, including in gynecologic oncology. Improvements have been made on a practice, institution, system and national scale, and efforts have focused on improving safety, efficiency, and cost of care. Gynecologic oncology practitioners ought to engage in this work to improve patient outcomes, comply with federal regulation, and continue to meet required educational requirements of training programs. In gynecologic oncology there are already many examples of successful quality improvement initiatives that have resulted in improved patient care, including the implementation of enhanced recovery after surgery programs, reduction in blood transfusion, and increases in guideline adherent cancer care. Quality improvement methodology is born out of industrial engineering and includes Six Sigma and Lean; both are frameworks for implementing quality improvement as a process and can be adopted in healthcare settings to achieve the desired outcomes. Six Sigma is a system that aims to have a 99.9997% defect free process, and uses the DMAIC (Define-Measure-Analyze-Improve-Control) framework to guide stakeholders in their work. Lean is a concept aimed at reducing waste in process. Regardless of methodology used, the most important aspect of successful quality improvement is the use of change-management theory to achieve stakeholder buy-in and institutional participation. The physician champion is a key element to this. Finally, once a project has been completed, successfully or not, it is important to disseminate the experience. This will allow for adoption and replication in other institutions. It also can serve as a mechanism for academic recognition and advancement. Quality improvement is an important and growing field in medicine, and has an important role in the future of gynecologic oncology.

Contents

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1. Introduction

Since the publication of the landmark Institute of Medicine report in 1999, To Err is Human, healthcare sciences have acknowledged the imperative to redesign our medical systems to meet the needs of patients [1]. The subsequent Institute of Medicine report in 2001, Crossing the Quality Chasm: A new health system for the 21st century, invigorated health systems across the nation to utilize the principles and structure of quality improvement science to meet the 6 aims listed in the report: safe, effective, patient-centered, timely, efficient, and equitable care [2]. This review will briefly discuss the ways in which gynecologic oncology as a field has embraced quality improvement, describing examples of successful quality improvement endeavors. We will describe the framework of quality improvement and change management and recommend tools that can be used by healthcare. And finally, we will focus on how successful quality improvement efforts can be disseminated and describe the relationship between quality improvement and research utilizing quality improvement data. We hope that this paper will serve as a resource for the field of gynecologic oncology.

2. Why quality?

The most important reason to focus our efforts on quality improvement is to improve patient safety, healthcare outcomes, and value of care. Matching the needs of patients to the reality of healthcare delivered is a challenge for every system, and quality improvement offers tools to address identified gaps. While patient health and safety is the main driver of healthcare quality improvement work, there are other reasons to pursue this type of work in your own setting, including the need to comply with government regulation, optimize reimbursement, and comply with educational mandates. The American Society of Clinical Oncology (ASCO) and the Society of Gynecologic Oncology (SGO) have both convened task forces that focus on quality and value, with specific recommendations regarding the provision of high value care. New models of healthcare are emerging, and reimbursement will be tied to the value of overall oncology care rather than just volume of services provided [3]. The Merit-based Incentive Payment System (MIPS) is an incentive/disincentive program in which reimbursement is tied to a composite metric including quality, resource use, clinical outcomes, and the electronic medical record [3]. Under MIPS, providers will collect performance data and report to Medicare for reimbursement adjustment. The alternative payment model (APM) approach is another quality-based payment reform that is now incorporated into Medicare reimbursement. Participation in quality improvement and quality outcomes measurement is now essential and part of every practice's business model.

In medical education, the Accreditation Council for Graduate Medical Education (ACGME) has made quality improvement a priority for training programs by including quality milestones within residency and fellowship requirements. Specifically in obstetrics and gynecology residency, similar to other specialties, there is a problem-based learning and improvement milestone focused on quality improvement processes [4]. In gynecologic oncology fellowship, there is a similar milestone where level 1 (entry level) is identifying a gap in healthcare and level 4, (graduation level) is "completes a QI project, either as an individual or team member" [5]. Additionally, after training, the American Board of Obstetrics and Gynecology includes quality improvement participation as a requirement of on-going maintenance of certification, reenforcing the importance of career-long quality improvement.

3. Quality improvement v. research

It is important to understand what constitutes a quality improvement project and what qualifies as research. The difference between quality improvement and research centers around knowledge. Research generates new, generalizable knowledge while quality improvement in healthcare is the translation of existing knowledge, generated initially by research, into clinical practice with the goal of improving the quality of health care in specific populations. Research is specifically defined by 45 CFR 46.102(d) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [6]." The interpretation of knowledge as "generalizable" to other similar populations typically drives the determination as to whether a project is quality improvement or research. As it may not always be clear, most Institutional Review Boards (IRB) have a tool, such as a quality improvement v. research checklist, as a guide. Quality improvement protocols usually do not require IRB review and, if reviewed, would be deemed to be not research if truly quality improvement. Some institutions also have a separate Quality Review Board (QRB) that functions to review quality improvement protocols.

Where to Start: Identifying a Gap.

A key aspect in quality improvement is to identify an area of practice in which there is a gap among the ideal treatment, experience and outcomes and the healthcare reality. The gap may be institution or system wide, or may be specific to a department or division. Before embarking on a quality improvement project, this gap must be identified clearly. In gynecologic oncology, complex oncologic care often requires multidisciplinary approaches, handoffs of care, and shifts in goals of care. For example, following the new diagnosis of ovarian cancer numerous processes of care are essential for optimizing patient outcomes (Fig. 1). At any point along the continuum of care, practice gaps may occur and opportunities for quality improvement may be recognized.

4. Addressing the gap

Once a gap in quality has been identified, the next step is identifying the approach that best addresses it. Numerous tools, theories, and methodologies exist within quality improvement and selecting those that are most appropriate is important to the success of the initiative. Quality improvement theories were formed as early as the 1920s, when Walter Shewhart's work with statistics, control charts, and operational definitions was used to increase the reliability of processes at Western Electric Company [30]. His work was followed by the work of individuals such as W. Edwards Deming, who is credited with developing the Plan-Do-Study-Act (PDSA) cycle and Joseph Juran, who is known for his work in quality control [30]. Their work, along with the work of many others, paved the way to the development of two of the more popular methodologies used today: Six Sigma and Lean. While the majority of these theories and methodologies were developed in

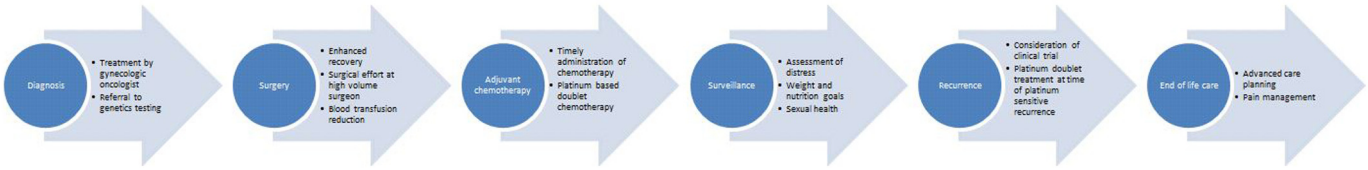

Fig. 1. Flow of care processes following a diagnosis of ovarian cancer.

manufacturing, they have become more widely adopted for use in healthcare over the past 20 years.

The Motorola Corporation is credited with developing the Six Sigma methodology in the mid-1980s [31]. It's based on the statistical measure of variation and aims to develop processes and systems that are 99.9997% defect free or 3.4 defects per million opportunities (DPMO). There are two methodologies that form the basis for Six Sigma: 1) Define, Measure, Analyze, Improve, and Control (DMAIC) and 2) Define, Measure, Analyze, Design, and Verify (DMADV) [31]. DMAIC is the more commonly used methodology and is the one focused on in this review. While the goal of achieving 3.4 DPMO may not be applicable to most healthcare quality efforts, the DMAIC framework is useful in the majority of quality improvement projects. The DMAIC approach provides a framework for projects and when followed, increases the chance of success for the team. A summary of each phase of DMAIC, including suggested tools to accomplish each step is listed in Table 1.

Lean is the other commonly used quality improvement methodology in healthcare and other industries. Lean focuses on the elimination of waste within a process and focuses on reduction of non-value-added activities. Non-value-added activities are defined by the American Society for Quality (ASQ) as "a process step or function that is not required for the direct achievement of process output" [32]. These activities are known as waste in a system and can be viewed as any activities that do not add value to the final product or service and are not activities the consumer would be willing to pay for. The methodology identifies 8 categories of waste: 1) unnecessary services or overproduction, 2) mistakes or defects, 3) delays or waiting, 4) unnecessary motion or movement, 5) over-processing, 6) excess inventory, 7) excess transport, and 8) unused creativity [33]. Although originally developed for manufacturing, Lean methodology fits well within healthcare. It has been estimated that for every dollar spent on healthcare, over 75 cents is spent on non-patient care activities [33]. The tool most commonly associated with Lean is the value stream map. Value stream mapping is an activity where a process is mapped from beginning to end and visually displays the flow of materials, consumers/patients, and information. Data collected includes process and wait times, first time quality, and improvement opportunities. Value stream maps are typically done in current and future state, using the information gathered in the current state to eliminate waste and design more efficient, effective future state processes.

While both Six Sigma and Lean methodologies had separate beginnings and different focuses, it has become increasingly common to use a combination of both when addressing opportunities for quality improvement. The term "Lean Six Sigma" has become popular and recognizes the fact the two methods and their associated tools can be blended together for an even more effective approach, especially in the healthcare setting. ASQ recognizes the overlap and has defined Lean Six Sigma as "a fact-based, data-driven philosophy of improvement that values defect prevention over defect detection. It drives customer satisfaction and bottom-line results by reducing variation, waste, and cycle time, while promoting the use of work standardization and flow, thereby creating a competitive advantage. It applies anywhere variation and waste exist, and every employee should be involved" [32].

5. Define, measure, analyze, improve, and control (DMAIC)

As mentioned above, the use of the DMAIC framework can help increase the likelihood of success for a project by providing a structured format for a team to follow. This format can be used with any quality improvement methodology chosen. While each step is important, two steps – Measure and Control – are worth highlighting in more detail.

The Measure phase serves several purposes that are beneficial to a team before, during, and after a project. Measures are selected in order to establish a baseline and assess current performance prior to implementing change, to measure and verify improvements as they are implemented, and to measure the maintenance of the improvement in the control phase [30]. The number of measures used is dependent on the project and the data can be collected from existing sources or through new data collection methods created specifically for the initiative. Measures are frequently categorized as process, outcome, or counterbalance. Process measures capture data specific to a step in a process that is a part of the quality improvement project. Outcome measures, as the name suggests, measure the overall outcome, or endpoint of a process. Relying on outcome measures alone can be limiting since it can be hard to draw conclusions as to the reason(s) for a change in the data. Process combined with outcome can often give more information. Counterbalance measures are important for ensuring the implemented changes don't create an unwanted effect in another area. The tools used in the measure phase can range from simple check or tally sheets, to more complex statistical analysis. Often several tools are used throughout the duration of the project.

Measures remain an important part of a project through every phase, including the Control phase. In this phase, the team monitors the data to ensure the changes are maintained and the project sustains the gains made. The Control phase can be challenging for multiple reasons, including the loss of momentum after completing the project and resistance to change by those who are affected. Teams should be

Table 1
DMAIC and tools to accomplish each step.

Step	Define	Measure	Analyze	Improve	Control
Purpose	• Define the purpose and scope • Gather background information on the gap in quality	• Identify measures to capture baseline data • Measure the current state problem	• Analyze the data collected • Identify root causes	• Develop and try solutions to address identified root causes	• Maintain the gains achieved in the previous steps • Adjust processes as needed
Potential Tools	• Project charter • Communication plan • Process maps	• Data collection and analysis plans • Control and run charts • Flowcharts	• Cause-and-effect diagrams • Scatter diagrams • Hypothesis testing	• PDSA cycles • Gantt charts • Failure mode and Effect analysis (FEMA) • Control charts	• Communication plans • Control and run charts • Process management charts

aware these common pitfalls and design plans early in the project to help avoid them.

6. Examples of quality improvement in gynecologic oncology

In gynecologic oncology, there are many examples of successful implementation and dissemination of quality improvement projects. Efforts to date have targeted adherence to guideline-based cancer care, perioperative care, and more. The implementation of enhanced recovery after surgery (ERAS) protocols is a prime example of successful quality improvement efforts that have been widely adopted in gynecologic oncology. Work done at our institution focused on implementing evidence-based practices to guide perioperative management in both benign and oncologic gynecologic surgery [7]. By assembling a multidisciplinary team of stakeholders, identifying gaps in need of improvement, and implementing a bundled evidence-based and best practice intervention that spanned the whole perioperative course, patient postoperative outcomes were improved with regards to pain control, return of bowel function, length of stay, and costs [7]. Specifically, a gap in perioperative care was identified in our institution, noting variability among surgeons in perioperative care and length of postoperative hospital stays. The relevant group of stakeholders was assembled including gynecologic oncology faculty and trainees, urogynecology representatives, perioperative, outpatient clinic and postoperative floor nursing staff, anesthesiologists, and pharmacists. The group employed quality improvement methodology (described below) to create and implement a bundled pathway addressing preoperative oral intake, perioperative fluid management, analgesia, nausea and vomiting prophylaxis, postoperative diet, and activity with the ultimate goal of reducing length of hospital stay following three complex gynecologic surgical procedures —ovarian cancer debulking, ovarian cancer staging, and vaginal prolapse surgery. Through the development and implementation process, stakeholders met monthly to discuss barriers, successes, and outcomes, addressing issues that arose in real-time. Measures and countermeasures were predefined and also followed in real-time. At the end of the implementation period, the intervention cohort was assessed for outcomes and compared to a historic cohort to assess achievement in the pre-defined quality metrics. As per quality improvement methodology, following the initial successful implementation of the ERAS pathway, a control phase was undertaken to monitor on-going compliance and progress. The process and success of this quality improvement project was then also leveraged retrospectively as a research study and the work has been disseminated over the course of the past several years. The process used at Mayo Clinic Rochester was adopted by the larger Mayo Clinic enterprise. Similar successes with ERAS have been reported by many other institutions and these successes demonstrate the power of the quality improvement process described above [8–12].

Blood transfusion reduction has also been a particular focus in gynecologic oncology surgery. Prescott, et al. demonstrated an increase in morbidity associated with increased blood transfusion use in a gynecologic oncology population using the National Surgical Quality Improvement Program (NSQIP) database [13]. Additionally, transfusion has been shown to be associated with increased risk of cancer recurrence in ovarian cancer as well as other solid tumors [14–16]. As such, there appears to be great value in sparing cancer patients transfusions. Through the implementation of a bundle of interventions including administration of preoperative tranexamic acid, practitioner education on guideline-based transfusion practices, and an intraoperative hemostasis checklist, transfusion rate reduction was effectively achieved and is described by Wallace, et al. [17]. Using quality improvement approaches, an assembled group of stakeholders identified a higher than national average rate of blood transfusion as a practice gap within gynecologic oncology surgery. The group utilized cause-mapping and swim lanes to identify targeted opportunities and sites along the process of patient care where interventions had the greatest potential for impact. They reviewed evidence based guidelines from the American Society of Anesthesiologists (ASA) and the American Association of Blood Banks (AABB), Level 1 evidence supporting specific interventions, and best surgical practices specific to the target patient population to design an intervention bundle. The implementation of the bundle followed quality improvement methodology including regular intervals of monitoring and communication. In the end, the project resulted in a 56.4% reduction in transfusion rate in the overall cohort [17]. Again, in this example, the experience has been leveraged in other patient populations and institutions, and the data from the quality improvement project was utilized retrospectively as an IRB-approved research project for publication. In this particular bundled approach, the introduction of tranexamic acid as a practice change is an excellent example of the translation of Level 1 evidence from a published randomized controlled trial [18] to practice.

The impact of adherence to guideline-based cancer care has been examined in multiple cancer types; and itself can be thought of as a quality measure. Adherence to National Comprehensive Cancer Network (NCCN) guidelines in ovarian cancer occurs more often in higher volume centers and with higher volume physicians, and more importantly, is associated with improved survival [19]. Several studies have confirmed these results, demonstrating the improved oncologic outcomes in centers and with providers with high volume [3,20–24]. After the publication of LAP2 in which laparoscopy was compared to traditional laparotomy in the surgical staging and treatment of endometrial cancer [25], the utilization of minimally invasive approaches to hysterectomy became the standard of care surgical approach for endometrial cancer and has been a Commission on Cancer endometrial cancer quality metric since 2015 [26].

The above are just a few examples of successful quality improvement efforts in gynecologic oncology; other examples include improving the rate of genetic counseling referral among women diagnosed with ovarian cancer, shortening the time between ovarian cancer debulking and initiation of chemotherapy, improving the rate of chemotherapy platinum doublet use, reducing surgical site infection rates, and increasing the rate of use of sensitizing chemotherapy with radiation for cervical cancer [27–29]. All are circumstances in which the application of quality improvement methodology has led to improved outcomes for gynecologic oncology patients.

7. Implementing change

Perhaps one of the most challenging aspects of a quality improvement initiative is managing the associated change. Even when a project has been supported and successful, implementing and sustaining changes can be difficult. This can limit the success of the project if the changes are not managed effectively. There are numerous change management theories and resources available and a change management plan should be developed early in the project planning. Fig. 2 demonstrates the resulting impacts when key components of change management are missing or inadequate [34]. Tools such as a communication plan, stakeholder analysis, and control plan can help teams identify potential barriers and areas of resistance before reaching the Improve and Control phases. Early identification and management will help increase the likelihood the change is accepted and implemented.

8. Physician champions and stakeholder identification

As physician leaders, there are great opportunities and responsibilities to be champions of change. Implementing the evidence-based and best practice content of a quality improvement project requires leadership vision, buy-in of all key stakeholders, anticipation of hurdles and plans to address them, and establishment of a mutually respectful culture that fosters a team approach to the project. Change management not only requires logistics and planning, it also requires trust and emotions which can feel at odds with objectivity. Successful quality improvement initiatives in gynecologic oncology have all included a

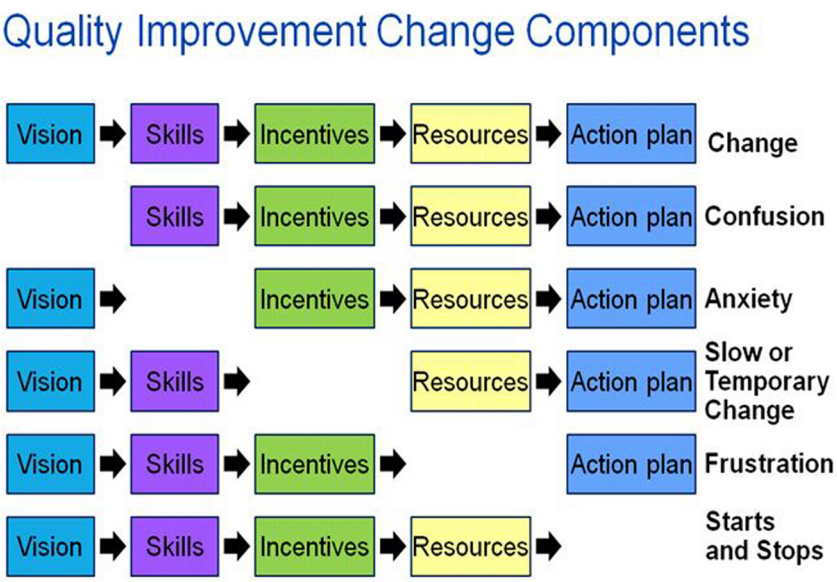

Fig. 2. Essential components of change management and outcomes when a component is missing.

multidisciplinary approach with one or more physician champion and each stakeholder group represented by respected leaders within each discipline that are committed to seeing the project succeed.

9. Publishing quality improvement efforts

Similar to research, the impact of a successfully implemented quality improvement project should be disseminated. This can be at a local level through standardizing the practice change to a broader local patient population, at a regional level through health system practice standardization, or a national or international level through presentation or publication. The dissemination of successful quality improvement effort outcomes in gynecologic oncology has provided a platform that supports appropriately contagious efforts to replicate success and/or tackle a new practice gap. As such, and also similar to research, quality improvement project outcomes can and should be published. And while publication is one way to broaden the reach in dissemination, it also has the potential to enhance one's academic portfolio.

Guidelines exist for reporting quality improvement work. Analogous to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for clinical trial result reporting [35], the Standards for QUality Improvement Reporting Excellence (SQUIRE) 2.0 guidelines [36,37] provide a standard framework for reporting system level applications that improve the quality, safety, and/or value of healthcare. Journals that publish quality improvement work may require the use of SQUIRE 2.0 reporting guidelines. Additionally, quality improvement science can employ traditional research approaches and CONSORT, STROBE, and other reporting guidelines can apply as well [38]. There are well-established and ever-emerging peer-reviewed, indexed journals committed to publishing quality improvement project outcomes. Additionally, many clinical journals, including journals with high impact factors such as the Journal of the American Medical Association (JAMA), The BMJ, The Lancet, and the New England Journal of Medicine (NEJM), have begun publishing quality improvement manuscripts in recent years [39].

Publication of quality improvement data may also occur ultimately as an original research publication. Sometimes during the process of a quality improvement project or in response to the project outcome, a research question is generated. Such generation of research questions in the setting of a quality improvement project is not uncommon, but when a question arises that meets criteria of the 45 CFR 46.102 (d) definition of research [6], to address that question requires IRB approval. However, one can utilize already existing quality databases for IRB-approved retrospective research. ERAS was discussed earlier as an example of one of the first structured quality improvement projects our multidisciplinary gynecologic oncology team championed. While ERAS was implemented as a quality improvement project in our institution and our IRB deemed ERAS to be not research, the favorable impact of the project on our outcome measure generated additional questions that met the definition of research. As such, the results of our findings after implementing ERAS were ultimately published as an IRB-approved retrospective cohort study [7].

Regardless of how the outcome of a quality improvement effort is shared, dissemination provides a platform for replication at other institutions, inspires development of approaches that further refine the evidence-based interventions, and generates momentum to identify the next gap needing improvement.

10. Conclusion

Quality improvement is an important aspect of practicing gynecologic oncology and should be a part of everyone's practice, regardless of their practice setting. The reasons for participating in quality improvement are clear and range from complying with governmental and educational requirements to, most importantly, improving the value of care for women with gynecologic cancers. While there have been many examples of successful quality improvement projects in the field, there are many aspects of gynecologic cancer care yet to be addressed. The use of quality improvement and change management methodologies has been shown to improve the success of quality improvement initiatives in healthcare and can be used to guide healthcare providers in their efforts. Both successes and failures should be disseminated in order to inspire growth in the field and promote novel opportunities for improved care across the spectrum of gynecologic oncology practice settings.

Author contributions

1. Amanika Kumar, MD: review article outline, manuscript writing and editing, approval of final manuscript
2. Katherine M. Nesbitt: review article outline, manuscript writing and editing, approval of final manuscript
3. Jamie N. Bakkum-Gamez, MD: review article outline, manuscript writing and editing, approval of final manuscript

Conflict of interest statement

The authors declare that there are no conflicts of interest.

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