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IMPACT ASSESSMENT PAPER

Reducing Perioperative Blood Transfusion in Gynecologic Oncology Patients at Mayo Clinic

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Reducing Perioperative Blood Transfusion in Gynecologic Oncology Patients

Standardized surgical practices and new medication show promise

Someone needs blood every two seconds in the United States.¹ An estimated 5 million patients receive blood annually and there are 14.6 million transfusions per year.² Blood transfusions are a necessary element of healthcare, and while most patients experience no side effects from receiving blood, there can be unfavorable outcomes: e.g., a reaction to the transfusion, increased infection rates, and increased blood clot/venous thromboembolism (VTE) rates. Unnecessary blood transfusions also can lead to patient dissatisfaction and increased healthcare costs. With healthcare industry changes toward value-based purchasing, a high transfusion rate compared to industry benchmarks can potentially negatively impact reimbursements in the future (a single transfusion costs as much as \$750 per unit at Mayo Clinic).

The blood transfusion rate at the Mayo Clinic in Rochester was higher than national benchmarks using the National Surgical Quality Improvement Program (NSQIP). Mayo Clinic examined blood transfusion rate data for the GYN Surgery Division, and found the rate to be exceptionally high for the Current Procedural Terminology (CPT) code category of malignant abdominal hysterectomies (MAH): 57 percent (double the national average and down from a high of 77 percent).

Gynecology surgery cases can be very involved and blood loss is expected, says Dr. Sumer Wallace, Fellow, Gynecologic Oncology. But there did not appear to be a good standard in the department for when to transfuse. During the lengthy and often complex conditions of the operating room, transfusion decisions often came down to provider preference.

The realization within Mayo Clinic was that something needed to change, and standardizing blood-transfusion practices became a goal. The GYN Surgery Department would be the focus of an improvement project, and blood-transfusion best practices and standards would be implemented.

Mayo Clinic

Mayo Clinic was founded in 1889 and consists of more than 3,300 physicians, scientists, and researchers. Mayo Clinic in Rochester, Minn., is one of four major Mayo Clinic campuses in the United States, and consists of:

- 794-bed Mayo Clinic Hospital, Methodist Campus
- 1,265-bed Mayo Clinic Hospital, Saint Marys Campus
- 85-bed Mayo Eugenio Litta Children's Hospital.

Mayo Clinic aims to deliver the highest quality and most affordable care. All Mayo Clinic locations serve only Mayo Clinic patients and are staffed only by Mayo Clinic doctors. Mayo Clinic has been recognized as one of the finest academic medical centers in the United States, including:

- U.S. News Best Hospitals Honor Roll
- U.S. News Best Hospital Common Care
- U.S. News Best Children's Hospital
- Consumer Reports hospital safety
- UHC Quality Leadership Award
- The American College of Surgeons National Surgical Quality Improvement Program.

¹ American Red Cross, 2016.

² Centers for Disease Control and Prevention, 2016.

Two Departments Investigate Blood Transfusion Rates

A cross-functional team from the Division of Surgical Gynecology and Department of Anesthesiology attended training in June 2015 at the Academy for Excellence in Healthcare (AEH) at The Ohio State University. Dr. Christopher Jankowski, anesthesiologist, had received a Master of Business Operational Excellence from OSU and was familiar with the AEH program. “Our anesthesia group and GYN surgery groups had done some process improvement in other areas over the last couple years,” he says. “I thought the AEH would be a fantastic way to get this project off the ground because it was clearly going to require multidisciplinary efforts across various specialties.”

The improvement team learned about and improved their understanding of lean tools and techniques, such as process mapping, Five Whys investigation, and data analysis. Dr. Wallace says that AEH increased the organization of the team and “gave us a little bit more motivation and momentum.”

Dr. Jamie Bakkum-Gamez, Gynecologic Oncologist, says AEH offered tools to help them evaluate their data regarding key decision points when patients should be transfused as well as potential interventions based on evidence available in literature and/or best practices. AEH also was beneficial in that it brought together all the necessary parties, including surgeons and anesthesiologists.

The improvement team was sponsored by Bradley J. Narr, MD, chairman of Anesthesiology and head of the Surgical and Procedural Committee for the entire Mayo Clinic system, and Bobbie Gostout, MD, the head of OB-GYN, member of the Board of Governors, and Vice President for Mayo Clinic. Dr. Sean Dowdy, Division Chair for GYN surgery, was a member of the improvement team.

At Mayo Clinic, the improvement team developed “swim lanes” (process flow maps), showing a patient’s entire journey, from entering Mayo Clinic to postoperative release to a floor. The team found that most transfusions occurred in the operating room and postoperatively (measured as 48 hours after the procedure to coincide with NSQIP data).

The team also developed intraoperative and postoperative cause maps to identify if transfusions occurred only when necessary and at appropriate amounts, and if not, why (see *Intraoperative Cause Map* on next page). The definition used for “inappropriate” was established by the team with Anesthesiology

Mayo Clinic Improvement Team

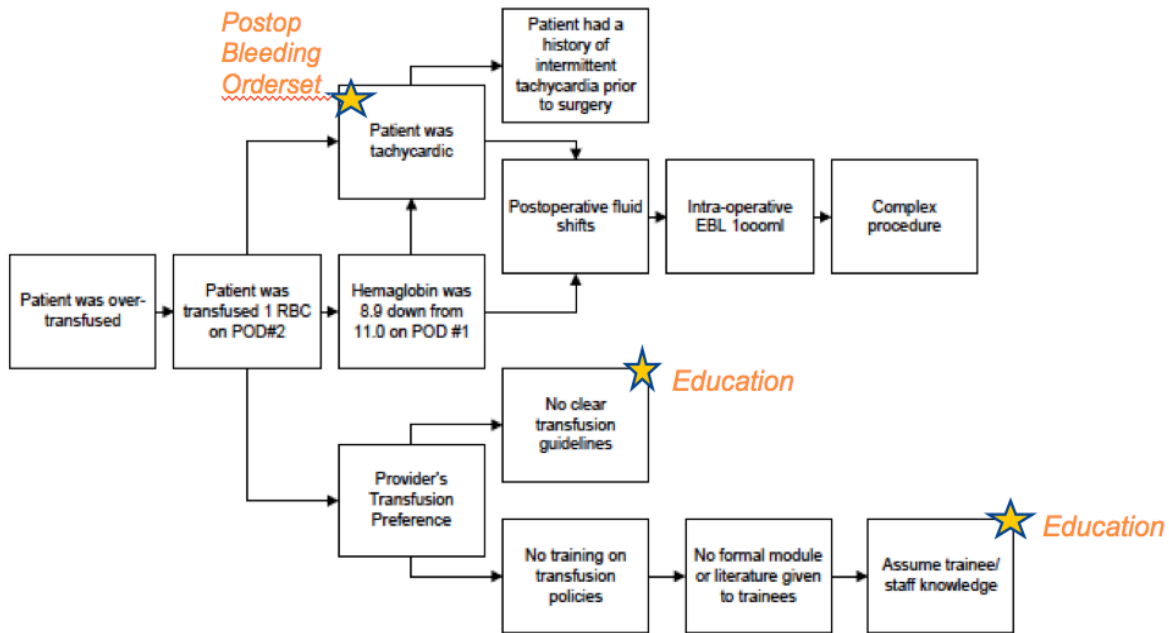
GYN Surgery:

- Jamie Bakkum-Gamez, MD
- Sean Dowdy, MD
- Sumer Wallace, MD
- Meg Ince, PA
- Steph DeJong, MD
- Pam Grubbs, RN Administration
- Hilary Otto, OR RN
- Megan Weinhold, Clinic RN
- Sue Bothun, Floor RN
- Ginny Kulsrud, Secretary

Anesthesia:

- Christopher Jankowski, MD, MBOE
- Gerard Kamath, MD
- Mark Keegan, MD
- Jessica Halverson, CRNA

Intraoperative Cause Map

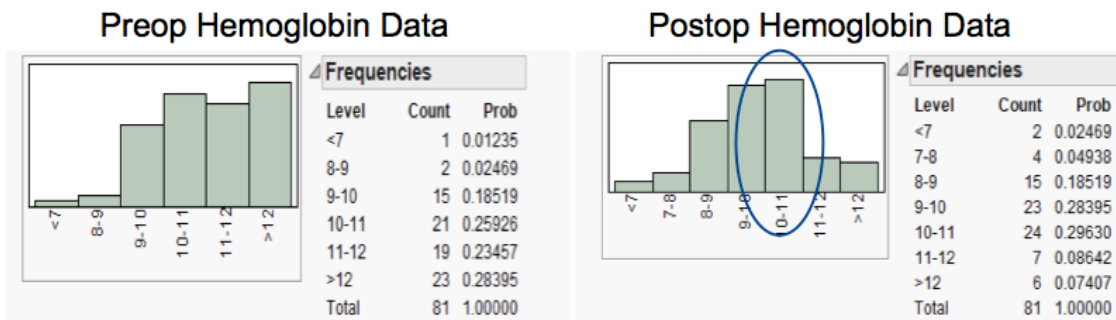


Source: Mayo Clinic

colleagues and was standardized across Mayo Clinic. The team decided that the post-transfusion hemoglobin goal should be 8.5-9.5 g/dL (grams per deciliter). If a patient rose to a level above that goal, then they were probably overtransfused. The team reviewed data on 145 ovarian cancer procedures from 2013-14 that required a blood transfusion. They also examined frequency of transfusions by the preoperative and postoperative hemoglobin levels: 81 patients (56 percent) had been transfused, and many resulted in hemoglobin levels above 9.5 g/dL (see details below).

“We didn’t have anything that was standard as far as guidelines go for transfusion, both intraoperatively and postoperatively,” says Dr. Wallace. “When a patient was being transfused was based on provider opinion, which varies across the departments and the practices in general.”

Ovarian Cancer Procedures Requiring Blood Transfusion (2013-14)



Source: Mayo Clinic

The cause maps and data helped the improvement team to identify root causes related to unnecessary transfusions:

- Non-standardized approach to blood transfusions
- Issues related to being a large academic center with many different care providers and many learners
- Transfusion often consisted of two units at a time
- Hemoglobin level to trigger transfusion higher than evidence suggests it should be
- Transfusions likely to occur with high-blood-loss procedures
- No standardized education on transfusions

Developing Countermeasures and Standardized Work

The improvement team established a goal to reduce the transfusion rate by 30 percent. They had initially considered a 50 percent reduction when training at AEH, but were encouraged to set a more feasible initial target that could still greatly impact patient care and hospital costs.

The improvement team had developed a wealth of Level 1 evidence (evidence from a systematic review of all relevant randomized controlled trials or evidence-based clinical practice guidelines based on systematic reviews of such trials) in order to develop their countermeasures. Based on their study and analysis, the team proposed three medical algorithms (decision trees) for care across the value stream of a GYN surgical procedure and prudently established facts and reasoning to secure colleague buy in. The algorithms addressed three periods when blood transfusions occur, with countermeasures proposed for each period:

Preoperative:

- *Tranexamic acid*: The team proposed that tranexamic acid be given when applicable. Tranexamic acid can decrease the rate of blood loss. Dr. Wallace says tranexamic acid is typically cited in literature as a medication for multiple reasons, such as trauma and obstetrics for hemorrhages. In recent years it has been used for other specialties, such as Urology surgery, Cardiac surgery, Orthopedic surgery, and GYN surgery. Contacts of Dr. Bakkum-Gamez in London also pointed to evidence that it has been used for GYN cancer patients and effectively decreased their transfusion rates without increasing harm or risk. “So we had good Level 1 evidence to bring to our department to say that this is a safe medication,” says Dr. Wallace. “It has been shown to work in the past.”

Intraoperative:

- *Implement institution-wide transfusion guidelines*: GYN Surgery was not the only surgical department at Mayo Clinic whose transfusion data was an outlier compared to national averages. As such, the overall institution had begun to also address the transfusion issue, and had developed a video — required viewing for those involved with transfusions — that described nationally accepted transfusion guidelines. For example, the guidelines indicate that a transfusion should be considered if the hemoglobin level falls below 7 g/dL. Dr. Wallace says the guidelines and

standard of care had been vetted by the Mayo Clinic through various societies and organizations that examine such practices, and were comparable with what the improvement team had found in their review of literature.

- Improve communication during critical junctures:* The improvement team developed a list of intraoperative communication checkpoints that serve as reminders to all in the operating room. Because GYN surgery cases can be long, staff can lose track of time and the precise amount of blood loss. “We often weren’t communicating with our anesthesia colleagues. We thought that that was a good point to make a change,” notes Dr. Wallace. Checkpoints review estimated blood loss (EBL) based on what has been collected in a suction canister as well as the patient status and if a transfusion is being considered.
- Use of a hemostasis checklist:* This form of surgery standardization includes tasks such as examining all sites on the body that were addressed with surgery for bleeding or other issues. Dr. Bakkum-Gamez says, “I don’t think everybody was really doing that, and there wasn’t a formal process to remind each surgeon to do that. Given the expansiveness of the operation, being in the pelvis and in the upper abdomen, there are times when you’re not looking at the whole process at the same time. You’re not looking at the whole space at the same time, so that was very helpful.” She says that when meeting with Mayo Clinic surgical experts, one had commented on the need for such a checklist and was planning to implement one.

Hemostasis Checklist

Site	Hemostatic			Intervention if not
	Yes	No	N/A	
Right:				
Cardinal pedicle				
Pelvic lymph nodes				
IP pedicle				
Peritoneal biopsy sites				
Common lymph nodes				
Para aortic lymph nodes				
Left:				
Cardinal pedicle				
Pelvic lymph nodes				
IP pedicle				
Peritoneal biopsy sites				
Common lymph nodes				
Para aortic lymph nodes				
Vaginal Cuff				
Bladder/Peritoneum				
Sacrum				
Sigmoid colon				
Colon resection/reanastomosis				
Small bowel resection/reanastomosis				
Mesenteric biopsies				
Omentum				
Splenic flexure				
Hepatic flexure				
Liver				
Spleen				
Right diaphragm				
Left diaphragm				

Source: Mayo Clinic

Postoperative:

- Postop bleeding order set:* The team put in place a postop bleeding order set that included admission/conditions, medications, vital signs, laboratory, and notification conditions. For this the team incorporated best practices developed by another Mayo Clinic department.
- Training:* The team began to implement trainee and staff education for residents, fellows, and nursing.
- Blood draws:* The team brought attention to the timing and the amount of blood draws, which can affect the need for a postoperative blood transfusion.

An action plan culminated in the gradual rollout of countermeasures, development of a control plan, and the start of data collection to ascertain effectiveness. The countermeasures would be trialed for patients scheduled to undergo an ovarian cancer staging procedure, an exenteration procedure, or an open procedure for stage III/IV endometrial cancer.

By October, the team's bundled approach to reducing blood transfusion had been implemented, and the team had conducted an email survey to gauge staff reaction to the countermeasures: 83 percent indicated they had used tranexamic acid for a surgical case, and no one (0 percent) had issues with the use of the tranexamic acid. Two-thirds of respondents indicated that opinions or practices had changed regarding blood transfusions after the guidelines were implemented.

Initial Results and Lessons Learned

In late September, all countermeasures for the project were underway and the team started collecting data for the entire project, with an initial goal of getting three months of data. The improvement team conducted interim analysis to evaluate VTE rate, cardiac event rate, ICU transfer, RRT frequency, cost, timing of blood draws, amount of blood draws, and 30-day complications (Accordion Severity Grading System). Coming out of meetings with GYN Surgery staff and working with statisticians, the improvement team also established a stopping rule for the use of tranexamic acid — an objective measure was set based on VTEs and cardiac-event rate to ensure that this practice change would not cause harm.

As of February 2016, Dr. Wallace says there have not been any events related to the tranexamic acid, but adds that the data is preliminary (three months) and not yet able to be analyzed for significance. “We do have a quite substantial drop in the transfusion rate, but the sample size is low, so that it's hard to say [what has caused it]. We'll collect for three more months, and then reevaluate at that time. Of course, during that timeframe, I'll be looking to make sure that we're not having any events. At the end of that will be a total of six months of [data for] the practice change. We'll look back, reevaluate, assess for significance, and, hopefully, be able to publish our experience so that it can be used for others. This is the first project of its kind that we know of in the United States, so, hopefully, it will be able to expand from there.”

“One of the things that we struggle with in healthcare is that there's very little standardized work, and you can't improve a system if you don't even have a system,” says Dr. Jankowski. “What we basically tried to do with this project is to implement some standardized work, and now we've got some stability. Even though our preliminary results are very encouraging, now we can begin to evaluate our practice in a much more logical fashion to see if we can improve even more. This is the first of many PDSA cycles related to this problem.”

During the course of the improvement project, the team repeatedly encountered transfusion practices that were the result of provider preferences. Their countermeasures would need to decrease blood transfusion rates, but they also needed to be flexible enough to allow Mayo Clinic specialists to apply their knowledge specific to individual cases and patients. Because of this, members of the improvement team

expected and prepared for resistance. Dr. Wallace advises, “Have your evidence. Have a lot of evidence for anything. Try to know what questions will be asked and what issues will be raised, and just know the evidence for that, so that you can present that to people.”

“We put a couple of skeptics on our team ... because we knew if we got buy in from them, we’d be able to get buy in from others,” notes Dr. Jankowski. “Physicians, if nothing else, are data driven. And when shown literature that’s compelling, we’re willing to make changes.” Dr. Bakkum-Gamez similarly prepared for resistance with her GYN Surgery staff. She says the preparation and presentation of Level 1 data and literature by Dr. Wallace helped to reassure many.

Dr. Jankowski says the project and its emphasis on gathering, analyzing, and continually checking data and literature speaks to process-improvement issues throughout healthcare. “We’re all really good at identifying problems and implementing plans to address them. But often, after the initial data demonstrates improvement, nobody looks at it again. We established in this particular service line a culture of continuous data collection and reevaluation. That’s something that we can begin to export to other areas of the clinic. There’s some institutional enthusiasm for this approach, but it’s heavy lifting to do that sort of work. Hopefully, our success will give people more encouragement to begin to do that.”

Dr. Bakkum-Gamez and Dr. Jankowski recognize, though, that still more can be accomplished with this project, such as building in audits and developing leading indicators to sustain the changes and continuously improve the procedure. “We haven’t matured to the point where we have a daily visual management system for this, and, ideally, we ought to have one,” adds Dr. Jankowski.

As more data is gathered and changes studied further, the project — considered quality improvement within Mayo Clinic — will likely be presented as a peer-review publication to a societal journal. There also are opportunities to disseminate the blood-transfusion practice changes beyond Rochester, across the entire Mayo Clinic enterprise, and throughout healthcare. “This is an opportunity that our colleagues who do GYN oncology surgery in Florida and Arizona would likely want to join with once we have institutional data for support,” says Dr. Wallace.

AEH Commentary

Process improvements in healthcare seldom venture deep into the physician/patient interaction. The AEH project to decrease blood transfusion rates at the Mayo Clinic shows that such improvements may be necessary when analysis reveals that physician decisions are among the root causes of the problem. As important, it illustrates the thoroughness and due diligence required to get buy in from physicians to implement changes to their personal practices.

The Mayo Clinic project also illustrates that rigorous collection and analysis of data is critical to making informed decisions, assessing the outcomes of countermeasures, sustaining change, and protecting the welfare of patients. Many organizations and individuals want to jump to the next project or improvement;

the improvement team from the Mayo Clinic is building six months of data before they even declare the effectiveness of their changes.

Lastly, the Mayo Clinic project reveals that an issue as complex as blood-transfusion rates throughout a surgery procedure — preoperative, intraoperative, and postoperative — involves many causes and requires a range of countermeasures that touch a variety of roles and specialties. Rarely when dealing with healthcare value streams is there a single, simple solution.

About AEH

The Academy for Excellence in Healthcare blends in-person class time with hands-on project work, interactive simulations, and recurrent coaching, all aimed at helping healthcare teams spark actionable change at their organization. At the heart of this program is a real-world workplace problem each participant team selects and commits to solving through five intensive days on campus, followed several weeks later by two days of project report-outs and lean leadership training. This project-based approach pays immediate dividends and lays the groundwork for transformational change.



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