FIRST
Do No Harm

Ambulatory Surgery Centers

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Quality Management System (ISO) Implementation at Boston IVF

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We all have a sense of what we mean when we say a product or service is 'high quality'. Medicine is no exception. However, simply saying that a service is high quality is not enough. You must have a system in place that promotes it, and can prove it. We discovered the International Organization of Standardization ("ISO") and implemented it into our practice in 2002. We have benefited enormously from it and I'd like to explain the highlights and the advantages it has had for us.

Boston IVF is a medical practice and Ambulatory Surgical Center with clinical, laboratory and surgical services for couples with infertility. We had started as a small medical practice and had grown quickly so, as a result, we had outgrown our systems. A colleague of mine from Europe introduced me to the concept of ISO. I asked him to visit us in Boston to explain the value for a medical practice. I invited the key players in our organization to attend.

The most common ISO standard is called "ISO 9001," which can be applied to most any business or service, including medical practices. Several hospitals and medical services have become ISO-certified. Briefly, ISO establishes a framework to neatly organize a service or business. In a sense, it is pretty basic and if I had to simplify it, it involves the following:

1. Focus on customers (patients).
2. Document what you do.
3. Communication.
4. Continually improve.

Initially, change required every level of the staff to devise their own procedures. For example, the nurses decided on how to best deal with certain patient situations. Similarly, the receptionist decided on what is reasonable in terms of hold times for patients. The staff was empowered by the ISO system to be part of the process. This is essential so that the process never appears burdensome, and allows the creativity of those on the front lines, who most often know the best way to get the work accomplished, to be part of the solution.

Another example of the benefits of ISO is training. The role of all employees is now clearly written out. In the past, new employees would not have a pre-set system for learning about our company and the role they play. They would tag along with a co-worker and simply observe. ISO forced us to clearly lay out the orientation for new employees. For example, a new nurse must read and absorb certain medical knowledge that is clearly spelled out in a manual, be questioned on it, be aware of all the policies of the company and demonstrate competences.

Although a medical practice has many 'customers,' (e.g. referring doctors, vendors, employees, etc), the main customer is our patient. It is important to stay totally focused on why we do what we do; it is to help patients. Everyone in the organization must also realize that if there are no patients, there is no company. We are as dependent on them as they are of us. Every employee must work hard to meet the expectations of patients.

Before we implemented ISO, I asked the staff to send me every piece of paper with our company's name on it. I received thousands of papers including outdated consent forms, protocols, patient instructions and brochures. What a mess! Our documents were out of control. An essential element of ISO is to get a handle on documents so that every document is tracked and updated in a particular way. For example, all consent forms for our patients are online for the patient or physician to download. This assures that the consent available is the current version. We have no confusion in our organization of what is a current document. And every document is available to the staff on our server. We only print our documents off our server and do not stock paper versions (since paper versions are uncontrolled).

In most every facet of life, many problems have their root in poor communication. ISO helps establish a way to communicate well and solve problems. Let's say an error is identified; who tells who and how is it documented and solved in a way so that errors can be tracked? ISO helps with this. We developed a 'non-conformance' database that keeps track of errors, which is essential to be sure not only are errors are identified and corrected, but also tracked over time. For example, a patient of mine had a procedure done and the consent was out of date. It was simply missed. A conformance report showed that this occurred on occasions and we implemented a system that would catch this error; the frequency of this

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'non-conformance' is tracked and fortunately, rarely occurs.

Improvement is a key element to the success of any organization. No one should be too complacent with the company's current situation since it can always be better. To improve quality, objective data is critical. We cannot say that we 'think our patients are happy with our care.' One needs to track patient experiences with surveys and hard data. One can learn a lot with this data. For example, I thought patients were more likely to want to be referred to me because of my books written, articles published and research. To my surprise, I was humbled to learn that the main reason was easy parking. (Wow!)

Quality must be objectively defined and cannot be a 'feeling.' Every department should set 'quality objectives' to monitor some aspect of its quality. For example, in vitro fertilization is a relatively complex procedure with multiple variables determining whether the patient will ultimately be pregnant. An important aspect is the technique of implanting the embryos into the uterus. This 'embryo transfer' is very sensitive to surgical technique. We have several physicians in the group performing the embryo transfer. We monitor the pregnancy rate per physician performing procedure on a quarterly bases. Our goal is to have all the surgeons' results to be within a certain variation from the mean. If a surgeon's results fall below determined variation, then we discuss it as a group. A surgeon, no matter how experienced, may be asked to observe the technique of a surgeon with the best success rate, to learn and improve. Partly related to the transparency of this approach, all surgeons strive to be at their best and the variation between surgeons has become very tight over the recent years.

To summarize, ISO has been a critical tool for our organization to control quality and improve its service. A quality management system such as ISO, leads to a more orderly company, helps keep priorities clear, reduce errors, improve patient service, and ultimately translate to better care of our patients.

WHO'S WATCHING OUR PATIENTS?

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The Cataract and Laser Center, Inc.

Mr. X had cataract surgery at our center for his second eye and as with his first eye, had an uneventful experience. Unfortunately, he did not show for his post operative evaluation the next day at his surgeon's office. After many phone calls, next of kin notification and a 911 call, Mr. X was found unresponsive at home. This prompted a review of our system to maintain our goals for providing a safe environment for surgery for our patients.

While Mr. X. fits the normal profile for length of stay at our facility, a few details varied slightly from the norm. He arrived via The Ride, part of the Massachusetts' Bay Transportation (MBTA) service. His co-morbidities classified him an ASA III. He was deemed stable on the day of surgery.

We reviewed this incident at the Board of Manager's meeting with participation by our Medical Director and our QAPI committee. It was noted that the first encounter is at the surgeon's office and dialog must begin there to establish a system of support for once the patient leaves our facility. The Center for Medicare and Medicaid Service (CMS) conditions for coverage indicates that "all patients should be discharged in the company of a responsible adult, except those patients exempted by the attending physician."[1] While we were discharging our patients with a responsible adult, we needed to be more proactive in assuring that someone was available to them for 24 hours after their surgery. This is supported by AAAHC as part of the patient rights section G3.[2] We began to change our discharge process by sending correspondence to all surgical schedulers to explain the necessity to confirm support after surgery and the need to begin the dialog with the patient to establish the necessity for assuring support after surgery, with documentation that this process has begun. We then added a line to each office's booking sheet that stated, "24 hour support has been confirmed" and by whom this support will be provided.

Our facility also needed to make changes in documentation and we began this process by revising our pre surgical assessment phone call sheet to include a reminder for the need for 24 hour support. The front sheet of our medical record was also edited to include documentation that 24 hour support has been confirmed when the patient arrives at our facility for surgery. No patient is allowed to have surgery at our center without arranging for a responsible adult to support them until their post operative next day visit. We have also amended our post operative instructions to include, in conjunction with their surgeon's emergency contact, the directive to call 911 for all emergencies. Our surgeons' offices have been provided with two links to supportive caregivers in the community should this be warranted.

On a final, but equally important note, we have reviewed CMS standard Anesthetic Risk and Evaluation, with all of our anesthesia and surgical team members.[3] This standard cites the need for accurate evaluation and documentation of surgical candidates on the day of surgery. In keeping with this standard and the American Society of Anesthesiologists (ASA), we do not allow surgical candidates with an ASA status above III to present to our center. Patients with ASA III classifications, as with

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all classifications, must be deemed stable at the time of surgery.

While the above changes seemed daunting initially, our surgeons' office managers, as well as our own surgical schedulers, worked tirelessly to accomplish this task. To date, we have not had to cancel any patients for lack of post operative support and less than a half dozen patients have been canceled for unstable ASA III or greater. This team effort has provided a safer environment for surgery for our patients with all members more aware of requirements within the surgical center, as well as those pertaining to both before and after surgery.

References

1. 42 CFR 416.52(2)(c)(3)
2. AAAHC Rights of Patients (G) (3)
3. 42 CFR 416.42 (a)

Assessing Timely Submission of Patient Preadmission Documentation—Missing Chart Items Project

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Cataract and Laser Center Associates

Our Ambulatory Surgical Center (ASC) is a single specialty cataract and laser center, with eight affiliated ophthalmic surgeons from two different practice groups. We perform approximately 2200 procedures annually. Surgical procedures are performed on Wednesdays and Thursdays. The patients' pre surgical review begins on Tuesdays. Designated nurses arrive at our center to review and transcribe charts for the Wednesday and Thursday surgical patients. An ongoing issue at the conclusion of the nurses' review was a significant list of patient information "missing" from the documentation submitted by the surgeon's offices.

To review and better understand the problem, a formal study was conducted in 2011, utilizing weekly sheets of missing items per ophthalmology practice from January through December 2010. The data collected was used to translate, quantify, and categorize the missing items. The review of 10 required preadmission data elements helped establish a baseline. Three required items emerged as the focus: 1) Missing History and Physical; 2) Missing EKGs, and 3) Patient Medication information. It was determined that an average of 26% of the pre surgical charts were affected and required follow-up at the end of Tuesday's transcription.

This issue and the data were presented to our Board of Managers. They deemed the project to be of significant importance to justify continued effort in achieving improved compliance with timely submission of required patient preadmission documentation. Timely submission would reduce the burden on surgical center staff for follow-up on missing items and eliminate their diversion from the bedside on surgical days for late transcription of data. The Office Managers of the affiliated ophthalmology practices attended the meeting and shared the information with their Surgical Coordinators.

Outreach to the ophthalmic practices was made for the following; 1) written details of the present system for collection of the needed "packet" items and, 2) proposed changes that would foster improvement. The following represent changes implemented by the ophthalmology offices:

- The delivery date by courier of "patient packets" was modified to include Thursday of the week prior to surgery and Monday, instead of Tuesday of the surgical week.
- A surgical checklist of needed items was affixed to the front of each "packet," which denoted charts that were "complete" or with specific items still "missing."
- A written "deadline" date for necessary receipt of the H&P and EKG from the Primary Care Physician (PCP) was sent along with the confirmed patient appointment slip and standardized H&P form that our Center requires.
- An additional phone call to follow-up with the PCP offices will be made by the surgical coordinators if the data does not arrive on the "deadline" date.

The effort, which is ongoing, has fostered and improved the relationship between our surgical center and surgical practices. The improved understanding of our individual systems and recognition of how they interrelate is invaluable. It has and will assist us to ensure efficiency and meet future challenges to provide continued excellent patient outcomes.

Obtaining Post Discharge Patient Information

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Cape Cod Eye Surgery and Laser Center

Though the typical age of an eye surgery center patient is 65+, it is rare that a patient has an unanticipated adverse event, and with the effort placed on pre-operative clearance for admission to the ambulatory surgery center (ASC), it is extremely rare that an event requires a transfer for emergency or supportive care outside the scope of the ASC.

What I would like to address in this article is the Quality Assurance necessity for surgery centers to obtain a copy of the care the patient received up to discharge from the hospital, when a transfer is necessary. The information allows the surgery center to follow-up on the patient, document the outcome of the transfer, and conduct a thorough review of the occurrence. However, obtaining this information has often proven difficult.

As part of the surgery center's Transfer Policy, a patient being transferred is asked to sign a Medical Record Release Form. A copy of the signed release is kept in the patient's medical record. The surgery center sends a copy of the signed form to the hospital with the patient. The form indicates that the hospital is to send a copy of its records for the care provided to the patient and the discharge instructions to the surgery center. Many hospitals honor this and release the medical records.

Despite the Medical Record Release Form being readily available at the hospital, I often do not receive the records. I learned that at some hospitals the Medical Records Department may not see the signed Release, since it is presented to the Emergency Department at the time of transfer. When I do not receive the medical records in a timely manner I send a copy of the signed Medical Release Form to the hospital to obtain the patient medical records.

Occasionally, there are transfers involving a patient not in condition to sign the medical release paperwork. During the surgery center's follow-up communications with such patients, I discuss the need for obtaining the medical record for care provided. I then mail the patient a Medical Release Form to sign and return to me. This follow-up method has resulted in only a small percentage of patients returning the form. I have considered meeting the patient in the surgeon's practice during a follow up appointment, but coordinating schedules is another challenging task.

The surgery center received an advisory from the Board of Registration in Medicine Quality Patient and Safety Division (QPSD) titled "Sharing of Patient Information for Quality Improvement Purposes," which explains that the HIPAA Privacy Rule permits disclosure of protected health information without an individual's authorization to another covered entity for certain health care operations.

Recently I called a hospital's Medical Records Department, and spoke to a staff member to request a medical record release without a signed patient consent. I was told patient consent was required for a release to be made. I then faxed the medical record release request, without the patient's signature, to the hospital with a copy of the QPSD Advisory. I did not receive a response. Then I followed-up with a letter to the Medical Records Department with a medical record release request citing the HIPAA Privacy Rule, and providing them again with the information from the QPSD. Still, there was no response to the surgery center's request.

I hit a wall! Not knowing what to do next I called the QPSD for guidance. The QPSD representative provided me with the contact information for the Hospital's Patient Care Assessment (PCA) Coordinator and suggested that I contact the PCA Coordinator directly for assistance in the matter. I followed this guidance and contacted the PCA Coordinator, who told me that he would follow-up on my request. Within 2 weeks of my call to the PCA Coordinator, I received all the medical records I requested from the hospital.

If you have found obtaining medical records on transfer patients a challenging task you are not alone. Utilize the resources available to you. The hospital's PCA Coordinator may be able to assist in facilitating your request. If you do not know the name of that individual, contact the QPSD for assistance.

A copy of the QPS Division advisory, *Sharing Information for Quality Improvement Purposes*, is available at the QPSD website: http://www.mass.gov/eohhs/docs/borim/physicians/pca-notifications/sharing-patient-info.pdf.

The QPS Division is in a unique position to support licensed Ambulatory Surgical Centers (ASCs) through gathering data and developing resources to support best practice. The development of targeted materials, such as special reports, advisories and guidelines, based on information that becomes increasingly available through reporting from ASCs can be added to a data base and targeted to outpatient procedures.

Study on Preventing Skin Tears From Surgical Drapes

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New England Eye Surgery Center

New England Eye Surgical Center (NEESC) is an Ophthalmic Ambulatory Surgical Center, which has been in existence since 1985. It is physician owned and operated. It's staff consists of 18 surgeons and combined nursing and technician staff of approximately 12. The center has 2 Operating Rooms and does approximately 3000 surgeries, annnually. We are accredited through AAAHC and have deemed Medicare status.

Quality Improvement program

Our quality improvement committee consists of the Nurse Manager, who is the quality improvement officer, staff nurses, the Anesthesiologist and the Medical Director. Our quality improvement program monitors patient care and safety, infection control, medical risks, peer review, cost containment, and staff competency. Our studies originate as a result of direct observations, tracking mechanisms, incident reports, and from recommendations from both nursing and physician staff.

NEESC evaluated skin tears, using the 10 QI step study method from AAAHC.

1. **Purpose:** To respond to incident reports and staff observations describing patient facial skin tears from removal of the surgical drape after surgery.
2. **Performance Goals:** NEESC is to have 0 % skin tears.
3. **Data Collection:** Data included review of incident reports, staff observation, physician reports and patient complaints.
4. **Results of Data Collection:** Data collection showed over 5 skin tears in 4 months. All were superficial and were treated with an antibiotic ointment.
5. **Analyze Findings:**
   - 5 cases of skin tears from removal of surgical drapes reported or observed.
   - Possible cause:
     - Fragile aging dry skin.
     - Patients on prednisone or Coumadin.
     - Technique used to remove drape from skin.
6. **Comparison of Goals:** NEESC did not meet their goal of 0% occurrences.
7. **Corrective Actions:** The QI Committee and the nursing staff proposed the following corrective actions:
   - Wet drape and skin prior to removing drape.
   - Re-educate staff in removing the drape gingerly, especially high risk patients.
   - Pad area with gauze to protect the skin when removing the drape.
   - Trial new surgical drapes that are less caustic to the skin.
8. **Restudy:** The QI Committee, along with nursing staff implemented ongoing monitoring of patients for skin tears. Patients were monitored for any occurrences of skin tears for 6 months. There were no observations or reports of skin tears from drape removal. Several surgical drapes were trialed, but were found to be less effective in adhering to the skin.
9. **Comparison of Goals:** NEESC met its goal of 0 % skin tears.
10. **Reporting and Education**: Results of study and corrective actions will be reported to Medical Advisory Committee and throughout the organization, as appropriate.

Skin tears can also occur when removing IVs or bandages, or during turning or positioning. ASCs should have protocols for prevention, and for treatment should a skin tear occur. The Pennsylvania Patient Safety Authority published an advisory on the topic of skin tears that may be a helpful resource: "Skin Tears, The Clinical Challenge" at http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2006/Sep3(3)/Pages/01b.aspx..

QPS Division Notes:

This is the first of our Ambulatory Surgery Center Newsletters. We plan to routinely publish this special newsletter and encourage ASCs to submit articles describing their quality projects, or other initiatives. We have been working with your facilities for the past year, so we expect to see an increase in submissions of Safety and Quality Review reports. Examples of types of reports we have received include: endoscopic perforations, anesthesia events and patient falls. These reports demonstrate to us that you have robust systems for identifying and evaluating unexpected patient outcomes.

Do you "know" your patients?

Some SQR reports submitted by ASCs have raised questions about whether the involved patients were appropriate candidates for surgery at the facilities, due to the patients' medical co-morbidities and surgical risks. Please ensure that your facility has carefully developed, evidence based criteria to guide your pre-operative assessment of a patient's risk factors. The following resources are provided.

QPSD Advisory Preoperative Assessment and Coordination of Care: http://www.mass.gov/eohhs/docs/borim/physicians/pca-notifications/coordination-care.pdf

Pennsylvania Patient Safety Advisory, Patient Screening and Assessment in Ambulatory Surgical Facilities: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2009/mar6(1)/Pages/03.aspx

Additional Helpful Links

Pennsylvania Patient Safety Advisory, Should patients be accompanied when discharged from ambulatory surgery? This link is at: http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2007/sep4(3)/documents/100.pdf

Here are some examples of SQR Submissions from ASCs:

fall with fracture; colonoscopy with perforation; pulmonary embolism following endoscopic surgery; wrong eye surgery; esophogeal perforation with EGD procedure; and MI post endoscopy.

CONTACT THE QPSD

To be added to the QPS Division Newsletter and advisory mailing list, update hospital contact information, submit an article, request an SQR form, or obtain additional information, contact QPSD: Jennifer.Sadowski@state.ma.us or (781) 876-8296.

Send mail to Massachusetts Board of Registration in Medicine, QPS Division, 200 Harvard Mill Square, Suite 330, Wakefield, MA 01880.

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