

Patient Management Software

New software technology has helped many vascular centers optimize patient care while improving throughput efficiency.

BY JENNIFER PATTERSON LORENZETTI

Information is the lifeblood of a busy vascular or cardiology practice. Having the most accurate and current information at your fingertips means better patient care, better results, and more efficient patient throughput. To achieve this end, many hospitals and practices are turning to programs and software suites that track patients through an entire visit or stay.

This is the case for The Heart Center of Indiana (THCI, Indianapolis, IN), a 60-bed hospital that opened in December 2002. As home to one of the largest cardiology groups in the US, THCI has plans to expand to 120 beds. Julie Clark, RN, MS, CCNA, PMP, Director of Clinical Information Systems, oversees the technology that drives this all-digital facility. THCI uses a suite of Siemens Medical Solutions products (Erlangen, Germany) in its facility, including its imaging systems and strategic consulting functionality, tied together by an information technology component that unifies patient data and allows access to data anytime, anywhere. The system kicks into action at patient registration, and it collects data as the patient—called a “guest” at THCI—completes initial labs and educational videos.

The real utility of the system comes when the patient is in his or her room. Once there, THCI professionals can tailor the system to capture vitals and other monitored data at a frequency appropriate for the patient. For example, patients under conscious sedation have vitals recorded every 15 minutes. “The parameters can be set for how often you want [vitals collected],” said Clark. “It allows the nurse to be proactive.”

Physicians also gain some much-needed ability to be proactive from a system that allows access to data almost anywhere there is a computer. Physicians “can come out of the OR to the physicians’ lounge to view studies in real time,” Clark said. Doctors at various locations can also log into the system to collaborate on a case, allowing for better input of multiple perspectives,

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and can access patient information from a terminal inside the interventional suite when data are needed for quick decisions.

Once procedures are complete, physicians can use the system to add comments to the patient records, dictate reports, and sign off via a digital signature. This greatly reduces the amount of paper that THCI needs to process and maintain. “Our server room tends to be bigger than general records,” Clark said. Although some physicians still elect to use paper for orders, requiring personnel at THCI to scan the documents into the system, the amount of paper generated is much less than that of practices and hospitals that do not have such a system in place.

Finally, THCI uses a Siemens financials product to handle the billing procedures. Clark explained that the system allows THCI to set up parameters to charge on order or on result for various procedures and events, with a built-in discharge pathway that issues reminders if a step is inadvertently omitted. For example, the system issues a reminder that the patient needs a discharge diagnosis and care plan at the end of his stay, and THCI professionals have 48 hours to reconcile something that is not charted. The system also tracks inventory of supplies used, a function critical to proper billing. “It is very user friendly; it tells you if you forgot to do something,” Clark said.



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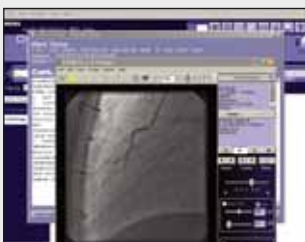
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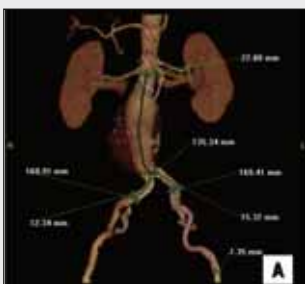
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IMPROVED PATIENT CARE

Implementation of the system has brought some very real improvements in the quality of patient care. More than 90% of patients surveyed rate THCI care as "excellent." Medical errors have also been reduced by 37% due to the implementation of information technologies such as Medication Administration Check (MAK, Siemens).

Mark Lipton, MD, FACC, Clinical Associate Professor of Medicine for NYU School of Medicine, New York, and Director of Clinical Informatics for NYU Hospitals Center, New York, who uses the Centricity physician office from GE Healthcare (Waukesha, WI), has had a similar experience. With nearly 6 years of experience using the product in his practice, he notes that such software is most useful "in high-complexity areas, where they allow decision support."

The first benefit is the elimination of paper, an improvement noted by all who are accustomed to paper charts and cumbersome file-handling procedures.

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"The [electronic medical record] is a chart; we don't really have patient charts," Lipton said.

Lipton says that the real power of the system is realized when using it to increase physician efficiency and to create an additional layer of patient safety. For example, the system allows physicians to access patient records remotely, allowing for off-site study or consultation. Consequently, the system also has built-in safeguards to protect the confidentiality of patient records even as they are accessed from off-site computers.

Indications

The AneuRx Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:

- adequate iliac/femoral access;
- infrarenal non-aneurysmal neck length of greater than 1 cm at the proximal and distal ends of the aneurysm and an inner vessel diameter approximately 10-20% smaller than the labeled device diameter;
- morphology suitable for endovascular repair;
- one of the following:
 - aneurysm diameter of >5 cm
 - aneurysm diameter of 4-5 cm which has also increased in size by 0.5 cm in the last 6 months; or
 - aneurysm which is twice the diameter of the normal infrarenal aorta.

Contraindications

There are no known contraindications currently associated with this device.

Warnings and Precautions

FDA approval of the AneuRx device on September 28, 1999 was based upon 1 year follow up data. The clinical information in this Brief Statement has been updated from the information originally submitted to the FDA for approval to include updated clinical information available to Medtronic as of August 1, 2003 (the clinical data freeze date for the 2003 PMA Annual Report).

The AneuRx Stent Graft is intended to prevent rupture of abdominal aortic aneurysms. However, this risk is not completely eliminated. Based on reports received for patients enrolled in all phases of the clinical study, through August 1, 2003, ruptures have occurred in 2/1193 (0.167%) patients during the operative period; in 3/1193 (0.251%) patients within 30 days of treatment; and in 15/1193 (1.257%) patients greater than 30 days after treatment. The one year freedom from rupture rate for patients enrolled in all phases of the clinical study is 99.5%; the two year freedom from rupture rate is 98.6%; the three year freedom from rup-

ture rate is 98.5%; the 4 year freedom from rupture rate is 97.2%, and the 5 year freedom from rupture rate is 97.2%.

The long term safety and effectiveness of this implant has not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

Exercise care in the handling and delivery technique to aid in the prevention of vessel rupture. If an AneuRx Stent Graft is placed with less than one centimeter length of non-aneurysmal tissue at the proximal or distal end attachment sites, there is potential for leaking or migration due to inadequate apposition of the stent graft.

- Inappropriate patient selection may contribute to poor device performance. Preliminary data indicate that patients with an aortic neck angle >45 degrees may have a higher likelihood of suboptimal outcomes compared to patients with an aortic neck angle <45 degrees. The same data indicate that patients with an aortic seal length of <15 mm and an iliac seal length of <25 mm may also have a higher likelihood of sub-optimal outcomes.

This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device.

- Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies.

The results of the clinical studies indicated that patients who experience an unsuccessful endovascular

repair attempt, and as a result undergo conversion to surgical Abdominal Aortic Aneurysm (AAA) repair, are likely to have increased complications arising from both procedures (i.e., cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues, and mortality).

- The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms has not been evaluated in patients:
 - with aneurysms pending rupture
 - with connective tissue disorder
 - with hypercoagulability
 - with mesenteric artery occlusive disease
 - with ilio-femoral, thoracic, or inflammatory aneurysms
 - with juxtarenal AAA
 - with pararenal AAA
 - with suprarenal or thoracoabdominal aneurysms
 - who are morbidly obese
 - pregnant or nursing
 - less than 18 years old
 - with less than one-year life expectancy.

- Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

Patient Selection, Treatment and Follow-up

- Do not use this device in patients having an active systemic infection.

- Do not use this device in patients with sensitivities or allergies to the device materials. The materials include: polyether block amide (PEBA); polyether block amide (PEBA) with tungsten filler; polyether block amide (PEBA) with barium sulfate filler; acrylonitrile-butadiene-styrene (ABS) copolymer; glass-filled acrylonitrile-butadiene-styrene (ABS) copolymer; polyetheretherketone (PEEK); polyvinyl chloride (PVC); stainless steel; ethylene propylene rubber; Nylon; silicone; polycarbonate; cyanacrylate; nickel/titanium (nitinol); tantalum; and polyester. The AneuRx Stent Graft with Xcelarent Delivery System is latex-free.

- The results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts.

- The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency may have an increased risk of renal failure postoperatively.

- Proper use of this device requires accurate fluoroscopic imaging. This device is not recommended for patients whose weight exceeds 350 lbs (150 kg) or whose weight may impede accurate fluoroscopic imaging.

- Regular follow-up including imaging of the device should be performed every 3 to 6 months for patients in the enhanced surveillance group and at least every 6 to 12 months for patients in the routine surveillance group (see IFU for patient follow-up recommendations). During the recommended follow-up imaging schedule, patients should be monitored for aneurysm size, occlusion of vessels, change in pulsatility, migration, leaks, and device integrity.

- Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:

- Aneurysm growth >5 mm (with or without leak) since last follow-up
- Change in aneurysm pulsatility (with or without growth or leak)

- Persistent endoleak with or without aneurysm growth
- Stent graft migration resulting in an inadequate seal zone

- The results of the clinical study indicate that subjects experiencing reduced blood flow through the graft limbs and/or leaks may be required to undergo secondary interventions or minor surgical procedures.

- Medtronic AneuRx Stent Graft only used in conjunction with the Xcelarent Delivery System.

Medtronic
Aneurysm Repair Systems

The system also serves as an important double-check and education tool. Physicians and staff can check for drug interactions and print information for patients to consult later. The system is also tapped to do regular reports, such as which patients are due for cholesterol screening and which patients have results that are outside acceptable limits.

Lipton finds this electronic safety net to be of critical importance in supporting the kind of multidisciplinary care his center provides. "Our patients often have many professionals involved in their care: nurses, physicians, nutritionists. [The system] increases patient safety by eliminating gaps in knowledge," he said.

Eliminating gaps in knowledge has been an important benefit for Geoffrey Rubin, MD, Associate Professor of Radiology for Stanford University, whose practice handles 15 to 20 CT, MR, and angiogram studies a day using a TeraRecon server product (San Mateo, CA). Because all of the images captured reside on the server, Rubin notes that rendering work can be done remotely from a PC or laptop. "The server feeds back the images after manipulation," he said.

By using this server system in addition to the picture archiving and communications system, Rubin and his colleagues are able to track patients through a process that can be particularly data intensive. "The datasets are the largest that we acquire, particularly with cardiac gating," he said. "We can acquire more than 4,000 images per patient." This creates significant storage needs for a hospital.

Sandy Voegler, RN, Chief Operating Officer of The Nebraska Heart Institute Hospital (NHH) in Lincoln, Nebraska, finds increased efficiencies in her hospital. She notes that her hospital's Siemens patient registration system, which captures patient demographics, is the first step in an integrated system that ushers patients from admission to release. "The demographics are interfaced to the other systems, [including] DICOM modalities and hemodynamics," she said.

Because the hospital's system collects data all during the patient's stay, a complete record is created with a minimum of hassle for hospital personnel. For example, Voegler explains that the Soarian (Siemens) cardiology system assists the catheterization lab technologists in creating documentation for physicians as procedures are performed. And the techs have proven able to multitask, which was a concern when the system was installed.

"The expectation of the tech is to view two monitors [at once], but they have been able to handle it." And, as the hemodynamics monitor continually pushes data to the Soarian cardiology system, a complete record is created at each step the patient makes. "[By] pointing and click-

ing as things are done, the tech's report is chronological," Voegler said. The physician views the report, makes corrections if needed, and signs off electronically. From these records, the patient is billed by an automatic billing system that creates an invoice electronically.

Overall, this system has had tangible benefits for NHH. Patient satisfaction is high, with more than 97% of patients indicating they would return for future treatment. Also, NHH has been able to double its throughput without increasing its staff or compromising patient safety or satisfaction. For 2003, NHH anticipated some 766 discharges, but realized more than 1,300 in that same period.

CONSIDERING A PURCHASE

If your practice or hospital is considering a purchase of software to manage patient flow, it pays to do your homework. The first step is to look at the experiences of other practices similar to your own. "Whenever you buy an electronic medical record [package], choose one for which other vascular practices have already created forms, etc., so you don't have to reinvent the wheel," Lipton said.

Lipton also recommends visiting other practices that use the software you are contemplating. "Visit installations where this [package] is up and running," Lipton said. He notes that some software packages work better for certain practices than others. "Some are [better] for pediatrics, some are good for surgeons," he said.

Once the system is in place, Voegler recommends that hospitals and vascular practices encourage their physicians to adopt some standard documentation formats. "Unique documentation for each physician is possible, but we want them to agree to a standard," she said. This agreement on a standard allows for the creation of electronic forms and minimizes the number of unique documents that must be scanned into the system.

CONCLUSION

Finally, there is much to be said for knowing one's own needs before making any purchase. Rubin urges colleagues to consider the nature of the practice first, including number of locations, number of locations at which image interpretation will be performed, how and where physicians will need to communicate, and size of practice. These are critical considerations before making any technology purchase, large or small. ■

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