Patient safety is near the top of every healthcare facility’s list of priorities these days. Individual providers, clinics, and hospitals alike are closely examining their operational processes and technology systems with the goal of preventing medical errors.

Automation has provided several solutions for reducing medical errors, including computerized provider order entry (CPOE) and electronic pharmacy orders. One area of care that has resisted automation is the informed consent process. This persists in spite of the fact that fully understood informed consent has been recognized as a major patient safety opportunity by the AHRQ, National Quality Forum, and the Leapfrog Group.

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Aside from providing generic or blank consent-for-treatment forms, most facilities have limited standardization for managing the informed consent process. As a result, patients often are not properly educated about conditions, treatment alternatives, or the benefits and risks of a procedure. Obviously, this poses significant risks to patient safety for patients, facilities, and physicians.

Healthcare facilities can make great strides in eliminating this risk by utilizing technology to standardize, automate, and improve the informed consent process. Establishing a safe healthcare environment that encourages both patients and providers to communicate openly about medical procedures enables these facilities to not only improve overall patient safety, but also increase patient satisfaction and enhance the delivery of care. The communication aspect is critical.

Patients as Partners
Patients increasingly are becoming concerned consumers of healthcare, as opposed to passive recipients. Patient empowerment and consumerism initiatives are being widely undertaken with the goal of creating partnerships between providers and patients so that the highest level of care can be delivered in the most efficient manner. Forming the foundation of these programs are two core concepts: open communication between patient and provider and comprehensive patient education.

The notion of “patient as partner” is an idea whose time has come. Patients have never been more proactive in researching their symptoms, conditions, and treatment options than they are today. This is partly a result of the abundance of information available and the easy access patients have to this information via the Internet. Most patients have embraced the idea of educating themselves about their health, including many senior citizens, who have become known as “the wired retired.”

But too much of a good thing can become a bad thing. Not all healthcare resources are created equal, and there is plenty of misinformation being presented as credible. Even
when patients consult reliable information sources, they may be swayed by arguments and alternatives that are not appropriate for their case.

For example, I recently had a 65-year-old patient come to me for a second opinion on his prostate cancer. He had been told that his prostate was large, and he was having some difficulty urinating. Worried, he researched his treatment options on the Internet and was certain that radioactive seed implantation was his best available option. However, this was not the best solution for his condition. I was in the position of needing to “re-educate” him about the best course of treatment.

Fortunately, my practice uses an automated informed consent application that gave me the educational resources I needed for this patient. Before he arrived for his appointment, I was able to send him materials that detailed characteristics of poor candidates for seed implantation. When he read the materials, he could see that he fell into that category and, after a brief discussion during his appointment, he had a better understanding of what treatment options were most appropriate. As a result, he was much more satisfied about the course of his treatment, and his positive attitude impacted his response.

**Paper-based Processes Fall Short**

Unfortunately, few providers have moved to an automated informed consent process that includes these types of patient education tools. Typically, providers use processes that fail to include the key elements of informed consent—benefits, risks, alternatives, and patient education. Most often, they involve hastily prepared “fill in the blank” forms, loaded with handwritten notes and medical jargon, or generic “consent for treatment” documents that are not specific to the given procedure.

Unfortunately, these approaches leave providers vulnerable to a variety of problems. Safety and satisfaction may be diminished because patients may not make knowledgeable decisions and may be dissatisfied with outcomes.

"Automating this ubiquitous process enables providers to supply better care, enhance their relationships with patients and generate comprehensive documentation while saving time."

The best software applications, on the other hand, rely upon rich, continually updated, procedure-specific libraries that let a provider standardize clinical communication while still customizing materials for each patient. As the provider and patient discuss treatment options, the provider accesses a computer database of relevant materials. Depending on the situation, the provider prints out educational materials on the patient’s condition or disease, as well as alternative treatment modalities. These procedure-specific informed consent documents include explanations of risks, benefits, procedure descriptions, prognosis if the patient elects not to undergo treatment, and other relevant topics. The most effective materials are written in a style that is easily understood by the layperson, avoiding complicated medical or legal jargon. Ideally, software applications also include a library of anatomical diagrams that enable the provider to better explain the diagnosis and treatment plan.

As a result, patients receive comprehensive information, can make better choices, and are more satisfied with the informed consent process. A study of one specific informed consent application that was conducted at a large teaching university’s outpatient urology clinic found that both patients and clinicians were very satisfied with the automated process when compared with the traditional paper-based informed consent process.

Automating this ubiquitous process enables providers to supply better care, enhance their relationships with patients and generate comprehensive documentation while saving time. A study in two Veteran’s Administration medical centers found the incidence of lost or misplaced consent forms were totally eliminated through the implementation of the VA’s Electronic Support for Patient Decisions initiative, an automated informed consent solution, compared with 8 percent the previous year. Electronically generating and storing consent documents offers the VA a wealth of operational and financial benefits, including a significant reduction in lost operating room time as a result of locating or replacing missing paper consent forms.

**Other Benefits**

Besides these primary patient safety benefits, providers have found that automated informed consent applications give them the opportunity to:

- **Improve the quality of care.**

  Practices using these applications have found that informed patients are more compliant with medical advice and maintain reasonable expectations regarding their treat-
ment. The technology approach also enables family members to review the consent and relevant education materials, helping them become better informed as well.

- **Compile, record, and manage patient information.** Advanced software applications facilitate the digital capture of patient and provider signatures on a final informed consent document.

- **Access patient information in real time.** Providers can quickly confirm that informed consent documentation is on file so they can eliminate potential treatment delays.

- **Simplify documentation.** A progress note, fully documenting the informed consent discussion with a patient, is automatically generated and filed with the patient’s electronic medical record.

- **Enhance compliance with standards.** Standardization facilitates compliance with JCAHO and other organizational requirements.

- **Improve reimbursement.** CMS and other payers have established improved patient consent and education goals, and have implemented regulations governing the process. As a result, providers with electronic consent applications will receive fewer claim disputes, repayment demands, or penalties.

Without a doubt, patient safety will increase as a result of any efforts a practitioner makes to provide comprehensive education and engage patients in an ongoing informed consent process. These activities help ensure that the right treatment options are considered and that inappropriate alternatives are avoided. Software applications can be a provider’s most effective tool in achieving these ends.

**About the Author**

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