

The Complete EMR: Leveraging Informed Consent Capability

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ABSTRACT

Informed consent is the cornerstone of medical documentation. This process impacts every patient who enters a healthcare facility to receive a treatment or procedure. Inadequate informed consent can have a negative impact upon patient safety, medical malpractice liability, operating room efficiency, and key accreditation requirements.

The critical process of informed consent may be improved via utilization of an automated informed consent application (AICA). Further, embedding an AICA within an electronic medical record (EMR) system can have a dramatic impact upon the efficiency of the organization, upon institutional compliance, and upon the quality of patient care. The availability of signed consent forms in a service-oriented architecture (SOA) affords a unique opportunity for electronic communication with other clinical software applications. This integration facilitates confirmation of correct patient, correct procedure, and correct site, prior to surgery; and it ensures the presence of all required documentation prior to the initiation of treatment.

ORIGINS OF CONTEMPORARY INFORMED CONSENT

Informed Consent – The Process

In 2007 the Joint Commission on Accreditation of Healthcare Organizations added a new National Patient Safety Goal: *Encourage patients' active involvement in their own care as a patient safety strategy.*¹ Potentially the most significant opportunity for a patient to become actively engaged in the design of his or her care plan occurs during the informed consent discussion that a patient has with his or her physician. The American Medical Association advises that this communication process contain the following elements:²

- The patient's diagnosis, if known;
- The nature and purpose of the proposed treatment or procedure;
- The risks and benefits of the proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing the treatment or procedure.

Legal Origins of Informed Consent

Healthcare professionals have not always been so enlightened in their approach to the informed consent process. It is only in the last century that the concept of informed consent has been recognized as a requirement as opposed to a courtesy or custom. The original case law that laid the foundation for mandatory informed consent was based on the finding that physicians who operated on patients without the patient's permission or knowledge committed an act of battery.³ In the late 1950s, rulings by courts in North Carolina, California, and Minnesota found that physicians had an affirmative duty of disclosure.⁴ This requirement to proactively disclose relevant information, and to thus allow patients to make an informed decision regarding their treatment options, is the essence of contemporary informed consent.

The requirements for informed consent are now spelled out in the statutes and case law in all 50 states. Some states have taken steps to provide physicians with guidance on what reasonable risks should be disclosed to patients prior to a contemplated procedure. The states of Texas and Louisiana have established Medical Disclosure Panels (MDPs) whose purpose is to determine which hazards related to specific surgical procedures and treatments must be disclosed by physicians or healthcare providers. Effectively these MDPs have established procedure-specific risks for hundreds of surgical procedures.^{5,6}

Applicable Standards and Requirements

Aside from state requirements, most hospitals craft their informed consent policies to comply with the standards set forth by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO standard RI.2.40 states that a hospital's informed consent policy must detail the following:⁷

- The procedures that require informed consent.
- The process used to obtain informed consent. Further, the informed consent process must include a discussion of the following elements:
 - Nature of the proposed treatment or procedure;
 - Benefits of the contemplated treatment or procedure;
 - Risks of the planned treatment or procedure;
 - Likelihood of achieving goals;
 - Alternatives to the proposed treatment or procedure, including the risks and benefits of the alternatives;
 - Patient’s prognosis if treatment is declined; and
 - Any limitations on the confidentiality of patient information.
- How informed consent is documented.
- When surrogate decision-makers may provide informed consent on the patient’s behalf.
- The circumstances under which care or treatment may be provided with obtaining informed consent (typically for emergent care).

JCAHO has established other standards that may impact the informed consent process including: Standard RI.2.50 (consent for recording or filming) and Standard PC.6.10 (requirement to provide sufficient information to allow patient to make decisions).

The Centers for Medicare and Medicaid Services (CMS) has also established guidelines for the informed consent process. CMS charges State healthcare agencies with ensuring institutional compliance with Conditions of Participation (CoPs). CoPs are minimum health and safety standards that hospitals must meet in order to participate in the Medicare and Medicaid programs. CMS publishes a State Operations Manual (SOP) that guides State surveyors on how to interpret the CoPs. Appendix A of the CMS SOP moves beyond a discussion of the informed consent process – it specifies the elements that must be present on the informed consent form itself.⁸

- Name of patient, and when appropriate, patient’s legal guardian;
- Name of hospital;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues);
- Risks;
- Alternative procedures and treatments;
- Signature of patient or legal guardian;
- Date and time consent is obtained;

- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

Providers and hospitals have found the requirement to list the names of practitioners and specific surgical tasks to be challenging. The greatest concern has been expressed by teaching institutions who may not readily know the identity of Residents who might participate in a given procedure.⁹

CMS has issued other opinions related to the informed consent forms that must be generated for specific types of procedures. Institutions that wish to provide bariatric surgery for Medicare beneficiaries must have a written informed consent process that informs each patient of national-, center- and provider-specific rates for potential surgical risks, hospital lengths of stay, 30-day mortality, and other relevant outcome measures.¹⁰

STATUS OF INFORMED CONSENT

Failure to Fully Inform

Fully informed consent is a rare occurrence. One large study of 3,552 patient decisions found that only 9 percent met the criteria for a completely informed decision and an analysis of the subgroup of complex decisions found that only 0.5 percent were completely informed.¹¹ This situation may not be abetted by the presence of a written consent form – they too are typically incomplete. A review of consent forms from 157 hospitals found that only 26 percent of the forms contained the four basic elements of informed consent (procedure description, benefits, risks, and alternatives).¹² Also of concern is the potential for a lack of action when specific items are disclosed on the consent form. A recent study of 89 patients undergoing radical prostatectomy procedures found that 89 percent of those patients were apprised of the risk of requiring supplemental blood products yet only 26 percent of the patient actually gave their consent to receive blood products. In following those cases, 92 percent of the subjects went on to require a transfusion.¹³

Medical Malpractice Risk

Failure to obtain informed consent is one of the top ten reasons for medical malpractice that are filed against hospitals.¹⁴ The reasons for claims involving inadequate documentation of informed consent can vary significantly. A recent Risk Analysis report prepared by ECRI, a nonprofit health services research agency, detailed several representative jury awards:¹⁵

- \$150,000 award for failing to disclose an alternative treatment to a urology procedure (Pennsylvania).
- \$547,000 award for a missing consent form for laparoscopic gynecologic surgery (Maryland).
- \$1.8 million award for failing to disclose relevant risks prior to spinal surgery (New Jersey).

Key to minimizing the risk of a lawsuit is good communication between the physician and his or her patient.¹⁶ Other factors regarding where informed consent is obtained, and how the informed consent discussion is documented, are also critical. A recent study of 28 lawsuits alleging inadequate informed consent yielded two statistically significant findings:¹⁷

- Consent should be obtained in the physician's office as opposed to being obtained in the preoperative holding area.
- The informed consent discussion should be documented in the office or operative notes, in addition to being documented on the signed consent form.

The recommendation to have a contemporaneously prepared note that details the informed consent discussion has been echoed by other experts – a signed consent form alone does not provide adequate documentation of the informed consent process.^{18,19}

A Patient Safety Opportunity

Improving the informed consent process has been recognized as a significant patient safety opportunity. The Agency for Healthcare Research and Quality (AHRQ) released an evidence report in 2001 identifying 79 patient safety practices. Eleven of those practices were rated highest based on the strength of evidence supporting their adoption. One of those eleven most highly rated practices was to improve the informed consent process. The authors of the AHRQ report noted that “informed patients are less likely to experience medical errors by acting as another layer of protection.”²⁰

The impact that enhanced informed consent can have on improving patient safety has led to the concept of improved informed consent commanding attention on key patient safety initiatives. Ensuring patient comprehension during the informed consent process is one of thirty National Quality Forum-endorsed safe practices.²¹ Verifying that hospitals have taken steps to improve the quality of the informed consent process is a component of The Leapfrog Group 2006 Hospital Quality and Safety Survey.²²

Avoiding Wrong Site Surgery

Informed consent can play a key role in reducing the incidence of wrong patient/wrong procedure/wrong site surgeries. The informed consent discussion affords providers an exceptional opportunity to confirm the patient's understanding of the planned procedure and the specific anatomical location(s) that will be affected. By employing a procedure-specific consent form, providers are afforded a unique opportunity to corroborate the patient's expectations for procedure type and surgical location. It has been estimated that 45 percent of wrong-site surgeries could be eliminated simply by having a properly completed consent form.²³

Certain opportunities exist for leveraging the use of an automated informed consent application (AICA) to assist with the “Time Out” process specified by the Universal Protocol For Preventing Wrong Site, Wrong Procedure,

Wrong Person Surgery™ (Universal Protocol™).²⁴ A note, automatically generated by an electronic informed consent application, can be used by the surgical team to verify the patient, the procedure, and the operative site. The OR team can review that note on a computer monitor that affords convenient access to the Electronic Medical Record (EMR) or on paper printout prior to the start of a case.²⁵

The Cost of Paper Consent

Many costs are associated with a paper-based informed consent process. An analysis of the expenses associated with scanning both consent forms and advance directive documents in three VA Medical Centers found the average annual cost per facility to be approximately \$80,000.²⁶ Another significant cost is the cost of unused OR time resulting from lost or misplaced consent documents. Although occurring only 8 percent of the time in one study, the expenses associated with lost revenue and inefficient use of OR resources is estimated to be \$580,000 per year for the average U.S. hospital.²⁷ Another benefit of an improved informed consent process may be a reduced number of cancellations. A large teaching facility, after implementing a program of verifying patient comprehension during the informed consent process, found their cancellation/delay rate drop from 8 percent to 0.8 percent.²⁸

COMPUTER-ASSISTED INFORMED CONSENT

Components of Computer-Assisted Informed Consent

An AICA will typically consist of two components: the software application itself and the clinical content library. The application will typically be customized for a given institution to facilitate connection with other software applications and systems. Meanwhile, the clinical content library will typically reflect the standard-of-care for informed consent that is practiced by thousands of physicians. This use of the same clinical content, consistently throughout the enterprise and across the country, is thought to convey “herd immunity” against claims of inadequate informed consent.²⁹

Software Application

An AICA should consist of a core subset of features and functionality that affect the following:

- Interface with key hospital applications including the EMR, OR scheduling system, document management system and patient information systems.
- Support distributed use of the application in the remote offices of those physicians with privileges at the subject hospital.
- Facilitate the reconciliation of patients for whom consent is obtained, and who do not have a medical record in place at the facility.
- Provide for the confirmation and documentation of patient understanding of what is discussed during the informed consent process.

- Support the documentation of the presence of multiple providers and documentation of their specific surgical tasks for complex procedures.
- Allow for the customization and automation of common hospital forms (HIPAA forms, Advance Directives, history and physical forms, etc.)
- Facilitate the documentation of the presence of an interpreter.

Clinical Library

The clinical library of an AICA typically includes the following elements:

- Procedure-specific informed consent documents.
- Patient education documents.
- Pre- and post-procedure patient instructions.
- A gallery of anatomical and procedure-specific images.
- Standard patient forms for use in the practice or hospital.
- Patient information sheets for prescription and over-the-counter medications.

It is essential that the clinical library be comprehensive – if a facility elects to standardize on an electronic means of obtaining informed consent, it is imperative that consent documents and other materials be available for all procedures performed in the institution. It is also critical that the clinical content library be updated on a regular basis and that the content meet the needs of patients with low medical literacy and patients for whom English is not their primary language.

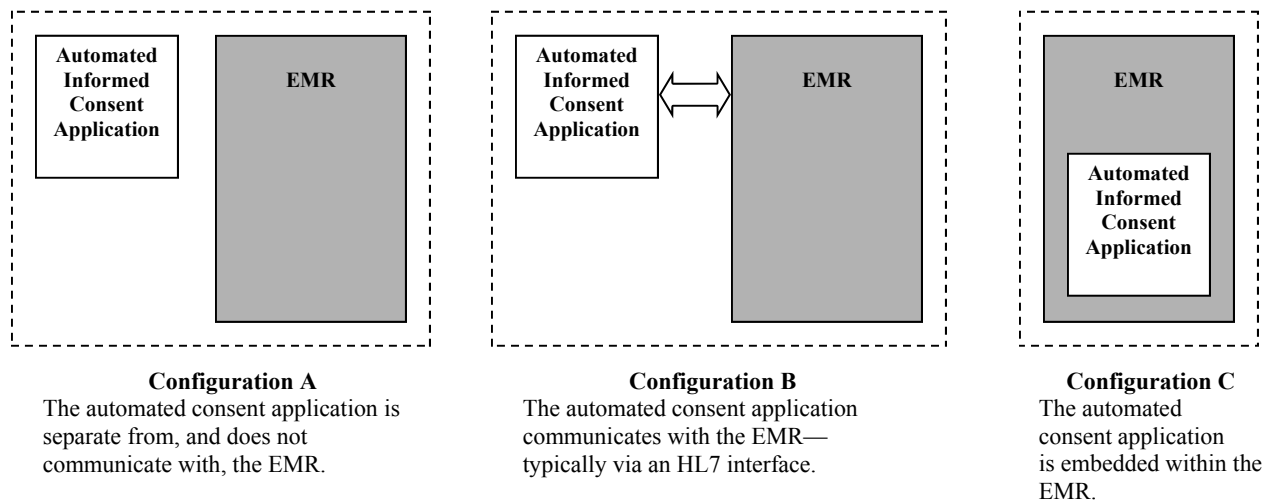
AUTOMATED INFORMED CONSENT MEETS THE EMR

The Integration Continuum

AICAs can exist in one of several configurations. In some implementations an AICA will operate as a standalone application (see Figure 1 – Configuration A). This is common for physician practices that employ an AICA to generate procedure-specific informed consent documents in a paper-based environment.³⁰

A more sophisticated implementation is typically employed when AICAs as deployed in hospitals. Hospitals will typically deploy an AICA in an arrangement where that software communicates with the hospital’s EMR (see Figure 1 – Configuration B). The AICA may also communicate with a document management system and/or a patient registration system or hospital information system (HIS). The interface for communications between the AICA and the other software applications is typically accomplished via HL7 interfaces. This configuration is characteristic of the solution employed in all 162 Department of Veterans Affairs (VA) medical centers. The VA Health System employs an AICA in an HL7 Clinical Context Management Specification (CCOW) architecture where the AICA is launched as a “tool” from within the Computerized Patient Record System or CPRS – the VA’s EMR.³¹

Figure 1



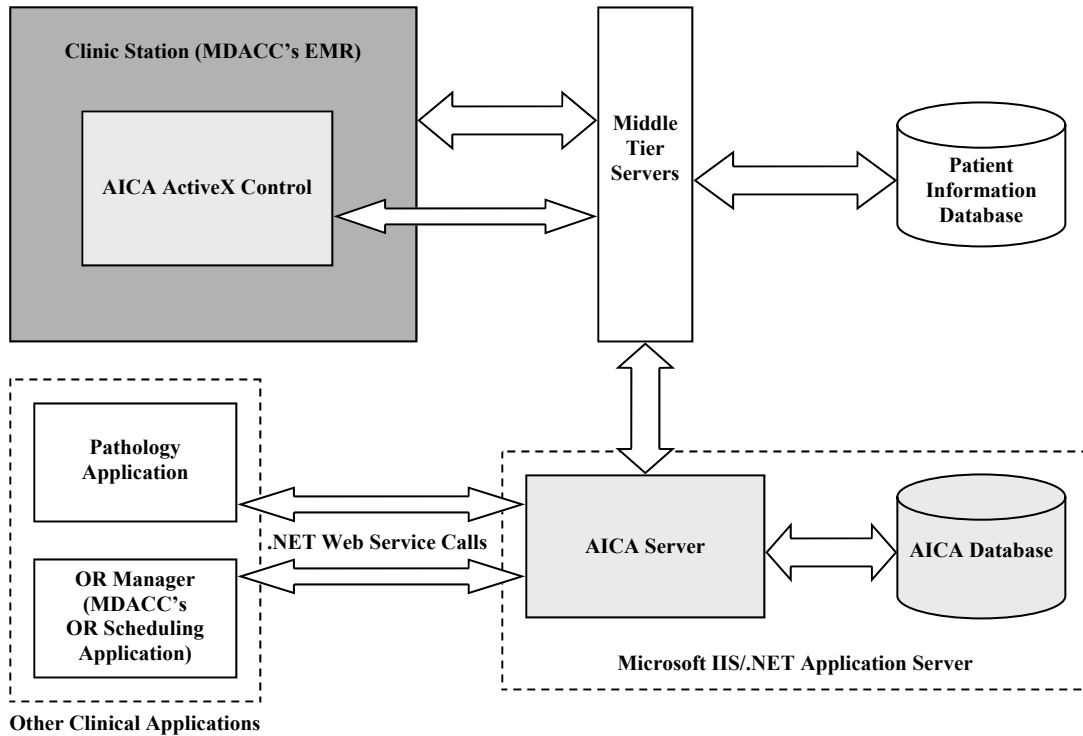
A third means of deploying an AICA is to integrate it within the EMR itself (see Figure 1 – Configuration C). M. D. Anderson Cancer Center (MDACC) sought an AICA that could be integrated into Clinic Station – MDACC’s homegrown EMR.³² This embedded approach provides the EMR with the content and functionality that are inherent to an AICA while simultaneously minimizing the impact to the user experience of healthcare providers that utilize the EMR.

EMR Integration

At MDACC the AICA (iMedConsent™ Application, Dialog Medical, Duluth, GA) exists in two key locations: as an ActiveX control within the EMR application and as a Microsoft IIS/.NET Application Server (see Figure 2). When a patient is selected within the Clinic Station EMR, the EMR retrieves information from the Patient Information Database. If the provider elects to prepare a consent document, certain data elements are then made available to the AICA (e.g. patient name, date of birth, medical record number, etc.). When a procedure is selected, the ActiveX control within the AICA will retrieve information about that procedure (description, risks, benefits, alternatives, etc.) from the AICA clinical library which resides in the AICA database. After entering other relevant data (e.g. diagnosis, laterality, etc.) the informed consent document is either “stored” for later retrieval and modification, or signatures are collected and the document is permanently “saved.” A “saved” document may be printed for the patient; it is also retained in the AICA server in XML format with embedded e-signatures or embedded digitally-captured signatures.

Figure 2

Implementation of an Automated Informed Consent Application (AICA) Utilizing a Service-Oriented Architecture



The presence of signed consent forms in a Service-Oriented Architecture (SOA) facilitates the exchange of that information with other clinical applications. The following are examples of queries that may be made to the AICA database:

- Does a consent form(s) exist for a particular patient?
- What procedures are enumerated on the consent form?
- What anatomical location or laterality for the surgical or treatment site(s) are specified on the consent form?
- Has the patient provided consent for tissue banking?
- Does the procedure(s) for which the patient is scheduled match the procedure(s) specified on the consent form?

The inherent flexibility of the SOA approach affords the institution significant opportunities to leverage the AICA.

Hardware Requirements

For institutions with an EMR in place, the incremental hardware requirements to implement an AICA are minimal.

The typical requirements for the Microsoft IIS/.NET Application Server are:

- Dual 32-bit, 2.8GHz or higher, Pentium 4 or Xeon processor (single core or dual core)

- 2GB RAM
- 240GB Hard Drive (supports the clinical library and short-term storage – additional capacity required for long-term storage of digitally signed consent documents)

Other required hardware such as workstations, computer carts, and wireless tablet PCs, typically exist as a result of the infrastructure required to support the EMR. The only incremental expense is typically the need to obtain digital signature capture pads for those areas of the institution where signature consent is obtained. These inexpensive, USB-enabled pads are of the types that are ubiquitous in retail locations and employed for credit card transactions.

LEVERAGING THE SYSTEM

Moving the informed consent process and resulting documentation into electronic format opens many opportunities to leverage this information within the enterprise. Consent is usually one of the initial process steps as a patient moves down a therapeutic pathway. As such, it creates the opportunity to build additional workflow support for processes that impact patient safety and institutional compliance. As clinical workflow is redesigned to take advantage of comprehensive electronic documentation, dramatic improvements in process efficiency can be realized by the institution.

Patient Orders

The volume of documentation found in patients' records continues to increase. The paradigm in clinical medicine is focused on physician-directed care underpinned by order sets and procedure-based documentation. For issues dealing with consent, this model is reversed. Patients create "high level" orders that direct treating entities with regard to a broad range of personal issues. These patient orders include:

- Financial arrangements;
- Control over personal health information;
- Informed consent for surgical procedures and treatments; and
- Disposition of surgical and laboratory blood and tissue samples.

As tuned as health care organizations are to accurate execution of provider orders through sweeping initiatives such as CPOE, they are not well equipped to execute patient orders as provided through informed consent forms and other written instructions and permissions. For most institutions this is a manual process with very poor integration into the medical record. To find clarity in the current state of patients' directives requires a manual review of paper documents. As with all paper-driven processes, the possibility of documentation delay, documentation in process, or completely misfiled information is always possible. Just as critical as physician order accuracy, patient consent accuracy is a safety imperative. As organizations move toward exclusive electronic origination of these documents, certainty in compliance increases dramatically. Within the electronic order management context, routine audit-ability of consent documentation becomes essential.

OR Scheduling

The operative environment is one of healthcare's most tightly managed and controlled resources. With high fixed costs, hospital management is constantly focused on improving throughput, resource utilization, and efficiency. Customers of this unique environment are diverse and include patients, surgeons, anesthesia providers, and nursing personnel. Within these competing pressures throughput and efficiency is a high stress, high acuity environment with recognized ongoing risk of catastrophic medical error (e.g. wrong site surgery, wrong person surgery, wrong procedure surgery). Moving a patient safely and quickly through this process is complex and difficult. The ability to capture the surgical consent electronically via an AICA enabled MDACC to streamline case posting and booking by wrapping additional surgical information into the EMR.

Booking a case correctly and completely is critical for streamlined patient flow on the day of surgery. Elements necessary for complete booking include those found on the informed consent form:

- Description of the surgical procedure;
- Laterality;
- Anticipated surgical length;
- Special equipment needs;
- Preferred time of the procedure; and
- Agreement to allow observers and photography for teaching purposes.

Using the information communicated during the informed consent encounter as a starting point, MDACC is building an on-line workflow that enables the posting surgeon to add all the additional elements within a single process. The result is an electronic document containing the surgical posting with links to the surgical consented procedure. Using this workflow support tool, the case posting always reflects the procedure for which the surgeon has obtained consent. If changes or additions are required, the surgeon is alerted that the informed consent record no longer supports the posted procedure. Thus, the informed consent record becomes the arbiter of the actual posted procedure.

Changing Patient Desires

When patients present to a health care system, one of the first steps is completion of forms and consent documents including the consent to treat, HIPAA form, financial authorizations, and tissue banking consent. Although viewed as mundane, these agreements underpin the patient's legal relationship with the institution. It is not uncommon that over the course of treatment the patient will need to amend or revoke some of these permissions and authorizations. With paper or scanned documentation, the ability to ascertain the current patient preferences is time consuming and difficult. In the area of tissue banking, patient tissue and specimens, obtained as the result of a surgical procedure, are stored for bench study, genetic profiling and other research interests. As genomic technologies improve, the use of these archives of tissues, in the context of pathologic and therapeutic medical record information, to create new and more effective molecular therapies for the treatment of cancer and other chronic diseases will continue to increase.

In the current environment, patients understand that these specimens contain their DNA and as such could in the future reveal health data not only for themselves but also for close biological relatives. Patients must have the ability to grant, and at any time revoke, the institution's right to use these specimens. The ability to track the use and disposition of these specimens exists in most electronic pathology management systems. Paper-based workflow for revocation or modification of institutional rights, however, is slow, error-prone, and expensive. With the availability of electronic consent records in an AICA, the ability to ascertain the exact state of patient directives is seamless and instantaneous. As changes with consent for tissue banking and information release occur, these changes flow back to the pathology databases into their patient specimen tables. The ability to have a constantly updated status of all patient specimens increases transparency and ensures compliance with federal regulations as well as with patient directives.

Charge Capture

Informed consent is obtained from patients for all procedures that present with more than minimal risk. The policy of most institutions is that signature consent be obtained for all procedures that are more invasive or entail more risk than collection of a blood sample or placement of an IV line. Thus, the number of clinical procedures performed within an institution requiring informed consent is fairly significant. With these more invasive procedures, sound financial management requires consistent charge capture for both the provider and for the institution. Oftentimes, these procedures such as thoracentesis, advanced wound care, or small biopsies can be performed outside the operating rooms in a clinic environment. However, just as with procedures carried out within the OR, JCAHO's Universal Protocol™ requires a formal, documented "Time Out" to confirm correct site, correct patient, and correct procedure. Audit-ability of this process is critical to support institutional compliance with these regulations. Use of the electronic consent record produced by the AICA as a starting point enables the creation of a documentation template. That documentation template records the consent encounter, and as the patient moves through the care process, contains documentation of "Time Out," the procedure note, and the equipment charge sheet – all of the information required to facilitate consistent charge capture.

Using the electronic consent record as the starting point enables the creation of a workflow support system within the EMR that meets the clinical needs of the provider as well as the documentation needs of the institution. It is anticipated that this project will enable MDACC to track clinical procedures with high accuracy and in near real time. This will enable the organization to also quickly identify deficiencies and support a robust quality improvement program.

CONCLUSIONS

Informed consent discussions form the basis of patient – facility relationships. The records of these discussions are created when patients contemplate undergoing procedures that present them with increased personal risk. As such,

these documents mark an important event in the evolution of the patient's care. Bringing the informed consent information into the EMR presents opportunities for institutions to support improved workflow for providers. Embedding an AICA within the EMR enables professionals to enhance document care and perform as per the institutional policies. This automation of processes creates standardization of documentation and empowers institutions with the ability to implement robust quality and performance improvement programs.

In academic institutions, providing leading edge therapies and moving research into the clinical arena as quickly and as safely as possible is a critical priority. Simultaneously, the ability to follow patient directives and assure that they are being complied with is paramount. As institutions such as MDACC are driven to be more efficient, flexible and adaptive to a constantly evolving and competitive environment, they must focus on those critical leverage points upon which to apply technology and resources to deliver superior care and higher quality. The informed consent process is one of these leverage points.

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