

Informed Consent: Policy, Procedure and Staff Education

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Abstract

Informed consent is an important process in medicine that allows the patient the right to autonomy or the right to make decisions related to his/her health care. The current project seeks to assist Adelante Healthcare in revising their current informed consent policy by verifying each part of the policy with legal and clinical resources. Additionally, a survey was created to assess the knowledge of the Adelante Healthcare providers regarding the informed consent process and address any concerns they might have. The survey had a 43% response rate with all providers correctly naming three procedures that require informed consent. Seventy percent (70%) of the providers gave a time period for the amount of time spent explaining a procedure to a patient, averaging 6.36 minutes. Seventy-eight percent (78%) of the providers use the “teachback method” to ensure patients understand the provider’s explanation of the procedure. Of those surveyed, 26% stated correctly that the patient, provider and a witness should sign the informed consent form. All sections of the current policy and procedure were verified using legal and clinical resources. An educational poster was developed for the providers to use as a quick reference, listing all procedures requiring written or verbal informed consent. It is recommended that Adelante Healthcare distribute the poster to their providers and incorporate the suggested changes into their current policy.

Keywords: Informed consent, Minor, Incapacitated Adult, Medical Emergency, urinalysis, autonomy, Adelante Healthcare

Introduction

Informed consent is an important aspect of provider interactions with patients. Not only does the provider use the informed consent process to educate the patient on their current condition and offer treatments for that condition, it builds the trust needed in the physician-patient relationship. Furthermore, informed consent upholds the essential ethical obligation of patient autonomy or the idea that "...each individual has the right to make decisions affecting his or her health" (Paterick, Carson, Allen & Paterick, 2008).

Informed consent has several components including explaining the proposed medical procedure to the patient, giving possible alternatives to that procedure, explaining the risks and complications associated with the procedure and then giving the patient a chance to assent or refuse the treatment (Arizona State Board of Nursing, 2012). Additionally the patient must also understand the diagnosis they have been given and how the proposed procedure can be used to treat that diagnosis (Hartman & Liang, 1999).

Currently all healthcare organizations are required to have policies and procedures related to the informed consent process. Adelante Healthcare is currently revising their informed consent policy and procedure and needed assistance in verifying all the legal requirements and clinical best practices related to the informed consent process. The organization also had a need for surveying their providers to see how well they understood the informed consent process and how they used the process with their patients. A survey was used to identify areas of training needs for staff members and based on answers to the survey questions an educational piece was developed to address the training.

Background

The idea that surgeons needed to gain permission from a patient before completing a procedure dates back to eighteenth century England (White, Rosoff & LeBlang, 2006). Over time informed consent became a legal and ethical obligation, developing from an intentional tort of “battery”. This law was supposed to protect people from having any unwanted touching from the physician without express consent (Paterick et al, 2008). Now, most courts agree that failure to obtain informed consent from a patient is considered to be negligence on the part of the medical provider. Negligence is established when a provider has some kind of obligation to a patient and fails to follow that obligation. Because of this, the patient experiences some kind of negative effect such as injury caused by the negligence. If informed consent is not obtained the injury would be caused by failure to fully explain the risks of a procedure to a patient so they could make a knowledgeable decision.

Only in 1957 was the idea developed that consent for a procedure needed to be “informed” in order for it to be valid. In a California case Salgo vs. Leland Stanford Jr., the patient was given an aortogram and not informed of the risks involved in using the contrast medium (White et al, 2006). Thus, now physicians must inform patients of all risks involved with a proposed procedure and given an opportunity to refuse treatment or ask for an alternative treatment. Once the patient is taken through the consent process and can repeat back what the provider has explained to him/her, the patient is said to be fully “informed.”

Methodology

A survey was developed using the Survey Monkey online services with Adelante Healthcare’s account. Questions were developed using examples from a Temple Health project designed for healthcare organizations to survey their providers and improve informed consent

procedures. The survey consisted of six items, two specifically designed for providers to express how long they take to explain procedures to patients and how they ensure the patient understands their explanation. One question asked respondents to name three procedures that require informed consent. Another question asked who is required to sign the informed consent form. The third question asked what procedures with adolescents do not require parental consent. The last question allowed staff to express any concerns or questions they currently have regarding the informed consent process.

In total the survey was sent via email to 12 administrative directors and 41 providers employed with Adelante Healthcare. Three emails were returned and the email addresses had to be corrected and resent three days later. A reminder email was sent three days after the initial email invitation, and then again five days later. The full survey is included in Appendix A.

In addition to the survey, research was conducted using Google search to verify each portion of the current Adelante Healthcare policy on informed consent. Common search terms included “informed consent AZ statutes,” “CMS requirements on informed consent,” and “informed consent medical emergency.” The quality department at Adelante Healthcare had specific questions on some sections of the policy they wanted verified. Their first concern was whether using a urinalysis for medical reasons needed verbal or written informed consent. Secondly, they wanted to understand the order of guardianship in the state of Arizona for incapacitated adults needing procedures that require a legal guardian’s informed consent. Third, Adelante Healthcare requested legal verification on which situations with minors do not require a parent’s consent. These questions were answered by looking up specific Arizona State Statutes and clinical best practices of other healthcare organizations.

Results

A total of 23 out of 53 responses were collected, with a response rate of 43%. For the first survey question, all responders correctly named three procedures that required either written consent, verbal consent or both. The highest response was twelve respondents or 52% listed incision and drainage as requiring informed consent. Other common answers included IUD placement, biopsies, wart or mole removal using cryotherapy, and ingrown toenail removal. The distribution of procedures named is found in Appendix B. For question two, 26% of the respondents correctly stated that the patient (or legal guardian), provider and a witness are all required to sign the informed consent form. An additional 22% of the respondents stated that at least the patient (or legal guardian) and provider needed to sign the form. Ten of the respondents only listed the patient or legal guardian as a required person to sign the informed consent form.

Question three of the survey asked when it was appropriate when working with adolescents to bypass parental consent. Forty-three percent of the respondents stated correctly that adolescents can receive treatment for a pregnancy or contraception without parental permission. Another 17% correctly stated in an emergency situation the adolescent can be treated without waiting for parental permission. Other answers included treatment for Sexually Transmitted Infections, regular pelvic exams and treatment for possible rape or sexual assault.

Questions four and five were specifically geared towards providers and the process of educating patients about the procedures to be performed. Seventy percent (70%) of the providers gave a specific time frame for the average amount of time they used to educate patients. The total average time spent explaining the proposed procedure to the patients was 6.36 minutes. The remaining 30% of the providers stated that times varied depending on the patient or the procedure and they would use as much time as necessary to educate the patient. When surveyed

on how they ensure the patient understands the procedures proposed, 78% of the providers stated they use the “teachback” method, a method in which the patient repeats the provider’s explanation back in their own words. Other common responses included asking if the patient had any questions and getting the patient’s acceptance.

Question six was specifically designed to collect the providers’ concerns or questions related to the informed consent process. The most common answer was that providers were not sure which procedures needed informed consent and specifically which required written consent. Other answers included having difficulty remembering to do informed consent for minor procedures, remembering to scan the forms into the electronic medical record, and confusion with minors and which procedures do not need parental consent.

Answers were found to all of the legal questions posed by the Adelante Healthcare quality department. Currently there are no legal obligations of the provider to get informed consent for a urinalysis test for medical purposes (Warner, Walker & Friedman, 2003). Primary care physicians will often request urinalysis not only to determine if drugs of abuse are being used by a patient, but also how that could affect their medical treatment. Frequently if patients present to the emergency room and are under the influence staff would be unable to obtain informed consent. Clinical recommendations caution the use of urinalysis without informed consent. Even though the provider is not legally obligated to get consent, once the patient learns a urinalysis for substances of abuse was done without their knowledge, they could feel betrayed by the provider and the patient-physician relationship would be weakened (Warner et al, 2003).

In the state of Arizona there is a certain order of guardianship assigned to an incapacitated adult on who is allowed to give informed consent in their stead. According to the Public Fiduciary, a court-appointed legal guardian would have first priority in giving informed

consent. This is followed by a power of attorney, spouse of the incapacitated person, the person's adult child, parent of the person, a relative with whom the person has lived more than six months, and if none of these are available, a public fiduciary can give informed consent (Strickland, 2011). Of course in the case of an emergency and none of these persons can be reached in a reasonable amount of time, informed consent can be bypassed and treatment given to the person immediately (Hartman and Liang, 1999).

The last question posed by the quality department asked to verify when an adolescent can receive treatment without informed consent from their parents. Services that do not require a parent's consent include testing for HIV and STIs, if care is related to possible sexual assault or abuse, treatment for substance abuse, pregnancy or contraception (Arizona Medical Association, 2011). In addition, if a minor has a certain legal status, the parent is not required to give consent. This includes legally emancipated minors, homeless minors (those living away from their parents who lack a regular night sleeping location), or adolescents who are married.

Discussion

Although the response rate for the survey was low at 43%, the data still gives a depiction of the providers' extent of knowledge of the informed consent procedures. The providers consistently use the "teachback" method for ensuring that patients understand their explanations of procedures. They are also familiar with situations in which parental consent is not needed to treat an adolescent. Training is needed in certain areas, such as needing a witness's signature to the informed consent form in addition to the patient and provider.

Based on the responses to the final question of the survey, most providers seemed to have difficulty remembering to complete an informed consent form for minor procedures or did not recall which procedures required written or verbal informed consent. An educational poster was

developed for the providers to address this concern. It was a double-sided document on 8.5x11 inch paper outlining all procedures requiring written informed consent on one side and the procedures requiring only verbal consent on the opposite side. This poster was designed to be a quick reference for providers in cases where they were unsure which procedures needed consent or to serve as a reminder for which minor procedures required informed consent. The list of procedures included on the poster is displayed in Appendix C.

Recommendations

My current recommendations for Adelante Healthcare include distributing the educational poster to all of the current providers working for the organization. The providers have the option of leaving it electronically on their computer, printing it out and posting it in their office, or giving copies of it to their medical assistants in order to have a quick reference guide for all procedures requiring informed consent and whether the consent needs to be verbal or written.

After completing my research I added my notes in red onto the current draft of the informed consent policy for the quality department to review. Next to each note or suggestion made, I gave the specific reference from my research. I recommend they make the changes suggested and also sent them my full list of references if they wish to research my notes themselves.

Lastly, since the project was limited to a six week time period, I recommend the quality department do a post-test using my same survey once the informed consent policy has been finalized and providers have been given proper training regarding the policy. They have been given the data and results from the current survey and are free to compare the data between the pre- and post-survey periods with their providers.

Conclusion

Informed consent is an integral part of primary care and providers must understand this process in order to preserve a patient's autonomy and ability to make their own decisions with regards to their medical care. Adelante Healthcare now has the legal and clinical references necessary to finalize their informed consent policy. Based on provider answers to the informed consent survey, proper training can be conducted and the educational poster can be distributed to the providers to assist in this training process. The quality department is free to use the survey to reassess the providers' knowledge of informed consent after the policy has been finalized and training completed. They can compare data from the two surveys to ensure training was effective for the providers.

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Appendix A

Adelante Staff Survey on Informed Consent

1. List three procedures where patients need to sign an informed consent form.

2. Who is required to sign the informed consent form?

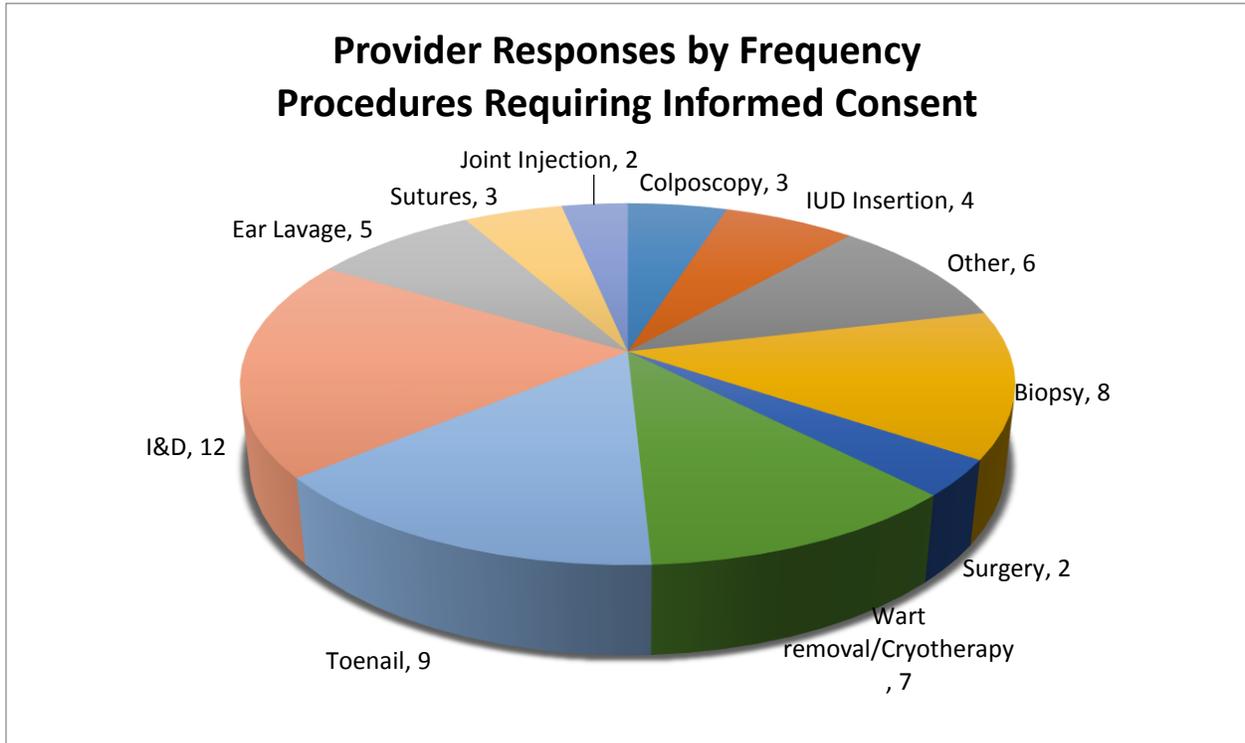
3. Name a situation with a minor patient in which it is acceptable to NOT get informed consent from the parents.

4. How do you verify that patients understand your explanation? (For Providers Only)

5. How much time do you spend explaining a procedure to a patient? (For Providers Only)

6. What is the biggest difficulty you have (or a question you have) with the informed consent process?

Appendix B



Appendix C

Written Informed Consent

- Any procedure requiring anesthesia (topical, injectable)
- Any procedure that involves skin incision or puncture including injection of a subcutaneous or intradermal lesion
- Laceration repair
- Tissue biopsy (excludes hair or nail removal for diagnostic purposes)
- Joint or bursa aspiration and/or injection
- Abscess incision and drainage
- Destruction of a lesion (Cryotherapy, Electrocautery, Curettage, Excision)
- Removal of a foreign body
- Removal of cerumen (Irrigation, Curettage, Suction)
- Insertion of ear canal wicks
- Circumcision
- Body piercing
- Nail removal
- Colposcopy
- IUD insertion and removal
- Vasectomy
- Endoscopy (Anoscopy)
- Dental procedures including extraction and gingival biopsy
- Administering blood products (Rhogam injection)
- Immunizations
- Subcutaneous allergy testing
- Participation in research, investigation or clinical trials
- Complementary and alternative medicine
- Psychotropic medications

Verbal Informed Consent

- Venipuncture
- Otoscopy
- Intravenous fluid administration
- Intradermal, subcutaneous or intramuscular injections (except immunizations)
- Osteopathic manipulation therapy
- Use of telemedicine
- Vaginal examination with speculum
- HIV Testing
- Urine drug screening for medical purposes