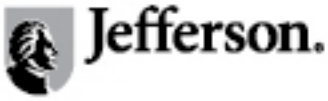


5-31-2017

Standardized Consent Forms for Surgical Procedures: An Intervention to Improve the Resident-led Informed Consent Process

C. Hodge
Abington Jefferson Health

N. Sich
Abington Jefferson Health

T. Olszewski
Abington Jefferson Health

A. Rogers
Abington Jefferson Health

R. Josloff
Abington Jefferson Health

See next page for additional authors

Authors
C. Hodge, N. Sich, T. Olszewski, A. Rogers, R. Josloff, and K. Noonan

Standardized Consent Forms for Surgical Procedures:
An Intervention to Improve the Resident-led Informed Consent Process

Hodge C, Sich N, Olszewski T, Rogers A, Josloff R, Noonan K
Abington-Jefferson Health, Abington PA 19090

Background

The core ethical principle of patient autonomy requires the patient to develop an understanding of their disease process and agree with the treatment plan. Informed consents for surgical procedures epitomize this process. Furthermore, documented informed consents carry heavy weight of legal and ethical liability. Bagnell, et al[1] used a systematic review and semistructured interviews to identify the following key components of informed consent:

- Procedure description and details
- Indications for and benefits of the procedure
- General and specific risks
- Alternative treatment options and risks
- Patient concerns and expectations
- Discussion at appropriate level for the patient

While outpatient consents at Abington-Jefferson Health (AJH) are performed with printed standardized consents by each attending surgeon's practice, inpatient or ED consents are handwritten by residents, usually interns and junior residents, on a fill-in-the-blank form. This leads to several problems, including:

- Poor legibility of consent forms
- Inadequate documentation of risks and alternatives
- Inadequate description of procedure
- Having to rewrite an entire consent if a mistake is written
- Lack of resident and patient understanding of risks and benefits
- Extra time taken to handwrite consents

Objective and Goals

To provide high quality, consistent consent forms for common surgical procedures and improve resident workflow by creating and implementing standardized printed consents for common surgical procedures.

- These consents will be used by residents consenting patients in the ED or inpatient setting.
- Consents shall include standardized procedure descriptions, risks and benefits of the procedure, and alternative treatment option descriptions, risks and benefits.

Methods

Creation

- Pilot – standard outpatient consents combined and agreed upon by all attendings
- Subsequent – initial consents used as a template for residents to create consents, which were then vetted by attendings performing the procedures

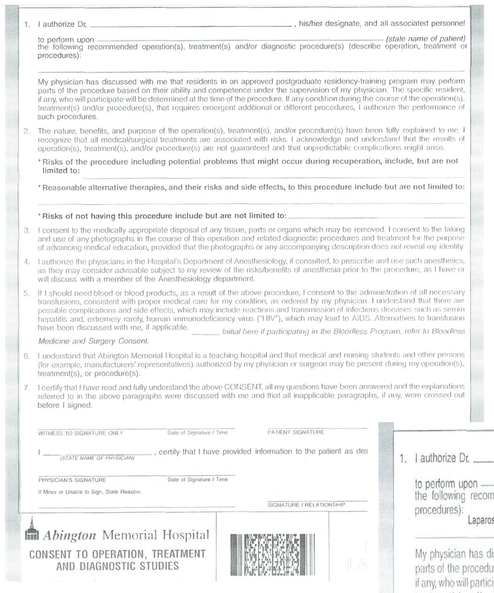
Implementation

- Consents posted on resident shared drive
- Consents are modifiable - type in patient, attending and consenting physician name
- Residents educated about the standardized consents during weekly conference

Metrics

- Surveys of attending physicians, OR staff and residents
  - Comparison of handwritten vs typed consents on legibility, correctness, completeness, errors, and resident and attending comfort with adequacy of consent now and at 1 year
- Audit of consents
  - Compare selection of consents for 3 most common procedures (laparoscopic appendectomy, laparoscopic cholecystectomy, and triple-lumen catheter placements) over 3 months prior to and 3 months after intervention for documentation of: standard risks, specific risks, alternatives, risks of not having procedure

"Fill-in-the-blank" Consent



1. I authorize Dr. _____, his/her designate, and all associated personnel to perform upon _____ *(state name of patient)* the following recommended operation(s), treatment(s) and/or diagnostic procedure(s) (describe operation, treatment or procedures):

My physician has discussed with me that residents in an approved postgraduate residency-training program may perform parts of the procedure based on their ability and competence under the supervision of my physician. The specific resident, if any, who will participate will be determined at the time of the procedure. If any condition during the course of the operation(s), treatment(s) and/or procedure(s), that requires emergent additional or different procedures, I authorize the performance of such procedures.

2. The nature, benefits, and purpose of the operation(s), treatment(s), and/or procedure(s) have been fully explained to me. I recognize that all medical/surgical treatments are associated with risks. I acknowledge and understand that the results of operation(s), treatment(s), and/or procedure(s) are not guaranteed and that unpredictable complications might arise.

*Risks of the procedure including potential problems that might occur during recuperation, include, but are not limited to:

*Reasonable alternative therapies, and their risks and side effects, to this procedure include but are not limited to:

*Risks of not having this procedure include but are not limited to:

3. I consent to the medically appropriate disposal of any tissue, parts or organs which may be removed. I consent to the taking and use of any photographs in the course of this operation and related diagnostic procedures and treatment for the purpose of advancing medical education, provided that the photographs or any accompanying description does not reveal my identity.

4. I authorize the physicians in the Hospital's Department of Anesthesiology, if consulted, to prescribe and use such anesthetics, as they may consider advisable subject to my review of the risks/benefits of anesthesia prior to the procedure, as I have or will discuss with a member of the Anesthesiology department.

5. If I should need blood or blood products, as a result of the above procedure, I consent to the administration of all necessary transfusions, consistent with proper medical care for my condition, as ordered by my physician. I understand that there are possible complications and side effects, which may include reactions and transmission of infectious diseases such as: serum hepatitis and, extremely rarely, human immunodeficiency virus ("HIV"), which may lead to AIDS. Alternatives to transfusion have been discussed with me, if applicable. _____ *Initial here if participating in the Bloodless Program, refer to Bloodless Medicine and Surgery Consent.*

6. I understand that Abington Memorial Hospital is a teaching hospital and that medical and nursing students and other persons (for example, manufacturers' representatives) authorized by my physician or surgeon may be present during my operation(s), treatment(s), or procedure(s).

7. I certify that I have read and fully understand the above CONSENT, all my questions have been answered and the explanations referred to in the above paragraphs were discussed with me and that all inapplicable paragraphs, if any, were crossed out before I signed.

WITNESS TO SIGNATURE ONLY — Date of Signature / Time — PATIENT SIGNATURE

I _____ (STATE NAME OF PHYSICIAN), certify that I have provided information to the patient as des

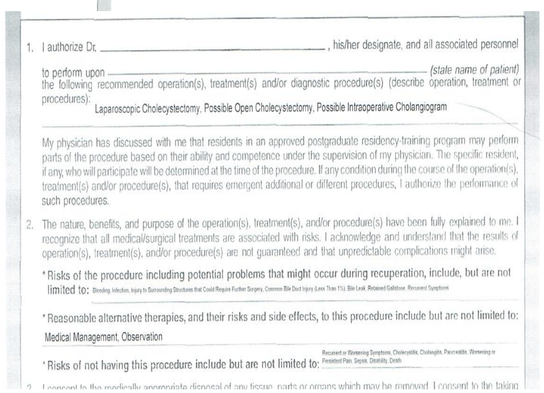
PHYSICIAN'S SIGNATURE — Date of Signature / Time

If Minor or Unable to Sign, State Reason:

SIGNATURE / RELATIONSHIP

Abington Memorial Hospital
CONSENT TO OPERATION, TREATMENT AND DIAGNOSTIC STUDIES

Standardized Consent for Laparoscopic Cholecystectomy



1. I authorize Dr. _____, his/her designate, and all associated personnel to perform upon _____ *(state name of patient)* the following recommended operation(s), treatment(s) and/or diagnostic procedure(s) (describe operation, treatment or procedures):
Laparoscopic Cholecystectomy, Possible Open Cholecystectomy, Possible Intraoperative Cholangiogram

My physician has discussed with me that residents in an approved postgraduate residency-training program may perform parts of the procedure based on their ability and competence under the supervision of my physician. The specific resident, if any, who will participate will be determined at the time of the procedure. If any condition during the course of the operation(s), treatment(s) and/or procedure(s), that requires emergent additional or different procedures, I authorize the performance of such procedures.

2. The nature, benefits, and purpose of the operation(s), treatment(s), and/or procedure(s) have been fully explained to me. I recognize that all medical/surgical treatments are associated with risks. I acknowledge and understand that the results of operation(s), treatment(s), and/or procedure(s) are not guaranteed and that unpredictable complications might arise.

*Risks of the procedure including potential problems that might occur during recuperation, include, but are not limited to: Bleeding, Infection, Injury to Surrounding Structures that Could Require Further Surgery, Common Bile Duct Injury (Less Than 1%), Bile Leak, Retained Gallstone, Recurrent Symptoms

*Reasonable alternative therapies, and their risks and side effects, to this procedure include but are not limited to:
Medical Management, Observation

*Risks of not having this procedure include but are not limited to: Recurrent or Worsening Symptoms, Cholecystitis, Cholangitis, Pancreatitis, Worsening or Persistent Pain, Jaundice, Disability, Death

2. I consent to the medically appropriate disposal of any tissue, parts or organs which may be removed. I consent to the taking

Future Directions

- Future projects could implement a resident training program to improve consent discussions, such as that created by Thompson, et al[2].
- Another area for possible improvement would be to incorporate audio-visual aids into the consent process, which has been shown to improve patient recall[3].

References

1. Bagnall NM, et al. Informing the process of consent for surgery: identification of key constructs and quality factors. J Surg Res. 2017 Mar; 209:86-92.
2. Thompson BM, et al. Informed consent training improves surgery resident performance in simulated encounters with standardized patients. Am J Surg. 2015 Sep; 210(3);578-84.
3. Farrell EH, et al. Systematic review and meta-analysis of audio-visual information aids for informed consent for invasive healthcare procedures in clinical practice. Patient Educ Couns. 2014 Jan; 94(1):20-32.