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Consent for Emergency Treatment: Emergency Department Patient Recall and Understanding

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Clinical Research Track

Scholarly Project Final Report

By checking this box, I indicate that my mentor has read and reviewed my draft

proposal prior to submission

Abstract

Informed consent is an important ethical and legal requirement that underlies the concept of patient autonomy. This prospective survey study was conducted to assess patient recall and understanding of consent for treatment in adult emergency department (ED) patients at an urban level 1 trauma center with annual volume of 95,000, Miami Valley Hospital. Out of a total 293 patients, most individuals reported only receiving a verbal explanation of the consent document (45%) or not reading the document at all (36%). About half of the patients recalled consenting to treatment (N=144, 49%) and over one third of patients could not recall anything that they consented to during the consent process. These results demonstrate poor understanding of the informed consent document.

Key Words: Informed consent, patient autonomy, treatment, emergency department

Introduction

In medicine today, informed consent is an important ethical and legal requirement to document patient consent to medical treatment. It underlies the concept of patient autonomy and ensures patients know and understand their rights, options, and consequences of those options. However, it was not until the 1950's and 1960's that informed consent was legally recognized¹ Informed consent should be obtained prior to patient treatment, and specific consent is obtained prior to specific medical interventions. However, ensuring patient comprehension has remained difficult.^{2,3,4} For example, a study by Braddock and colleagues examined 1057 patient-physician encounters including 59 primary care physicians and 65 general and orthopedic surgeons. Out of 2553 clinical decisions analyzed, criteria for complete informed consent was met only 9% of the time.⁵ As a result of this continued issue, inadequate informed consent has remained a significant allegation in many medical malpractice claims.⁶

The definition of informed consent requires several essential elements. The process of informed consent includes: patient decisional capacity, delivery of information and voluntariness, A patient must also be informed that he or she can revoke the consent at any point in time.⁷

Exceptions to informed consent include: situations in which patients choose to waive the right to informed consent, situations where patients need emergent treatment and consent may not be possible to obtain, situations in which disclosure of information would severely harm the patient or undermine decision-making capacity, or if the patient lacks decision-making capacity.⁸

In recent years, efforts have been made to improve patient comprehension regarding informed consent for treatment with the use of multimedia elements. In 2015, a study was conducted in a pediatric emergency department examining the effects of incorporating a multimedia presentation into the process of informed consent prior to sedation with ketamine. The results of this study showed a positive correlation between parental understanding and using the multimedia presentation.⁹ Another study conducted in 2014 studied the effect of using multimedia program in-line exercises during the informed consent process on enhancing patient understanding prior to their cardiac catheterization procedure. The results of the study showed those who used the multimedia program in-line exercises had significantly better understanding compared to those in the standard verbal and written process (8.3 ± 2.4 vs 7.4 ± 2.5 , respectively, 0-12 scale where 12=complete understanding, $P < 0.05$).¹⁰

However, not all recent efforts have led to improved patient comprehension. A more recent prospective randomized controlled trial was done involving use of a video in the informed consent process before cataract surgeries. In contrast to earlier studies, the study found no significant difference in comprehension among patients who watched a preceding educational video with a face-to-face surgeon informed consent, compared to patients who received only a face-to-face surgeon informed consent. Taking the variable results of studies done improving readability and studies regarding multimedia incorporation into account, finding a method improving patient comprehension remains challenging.¹¹

Currently much of the research that has been done regarding informed consent for treatment has been conducted in specific specialties, making their findings difficult to apply to all areas of medicine. With this study, we attempt to analyze the process of informed consent for treatment among adult patients in the ED. Currently the ED consent for treatment document at Miami Valley Hospital includes details regarding consent for treatment, release of medical information and privacy, photography, financial agreement and assignment, cooperation with billing, Medicare, patient assistance program, personal property, and attending physicians.

Hypothesis/Specific Aims/Research Questions

This study was conducted to assess patient recall and understanding of consent for emergency treatment, among Emergency Department (ED) patients. The null hypothesis was that there is no difference of understanding of consent by demographic groups, triage level, or chief complaint. Research questions attempted to be answered by this study include:

- 1) Do patients recall what they are consenting to when they sign a consent for treatment document?
- 2) What aspects of the consent for treatment are recalled and what aspects are not recalled?

Methods

The prospective survey study was conducted at Miami Valley Hospital’s Emergency Department, an urban level 1 trauma center, with an annual volume of 95,000. Research assistants collected data from the electronic medical record and then verbally collected prospective data via a verbal survey during the patient’s ED visit. (Appendix A, Data Collection Form; Appendix B, patient survey). Inclusion criteria included ED patients 18 and older. Exclusion criteria included individuals in-distress, did not speak English, or unable to communicate. Verbal consent was obtained in private patient treatment rooms. No changes to medical care were instituted. Data obtained were entered into a spreadsheet using Microsoft Excel without patient identifiers. A priori power analysis calculated a minimum sample size of 197, based on a population of 400, confidence interval of 95% and 5% margin of error. Data were analyzed using SAS Version 9.4- (Statistical Analysis Software, Copyright © 2002-2017 by SAS Institute, Inc., Cary NC, USA).

Results

A total of 293 patients consented to participate (95% participation rate). Most individuals reported only receiving a verbal explanation of the consent document (45%) or not reading the document at all (36%). A minority of patients read the whole document (7%) and a subset of patients reported reading part of the document (11%) (Figure 1). About half of the patients recalled consenting to treatment (N=144, 49%) and over one third of patients could not recall anything that they consented to during the consent process. Fewer patients recalled information about finances and billing (N=36, 12%), patient rights (N=9, 3%), and privacy rights (N=12, 4%). No patients recalled information regarding physician information, personal property, or photography (Figure 2).

Figure 1

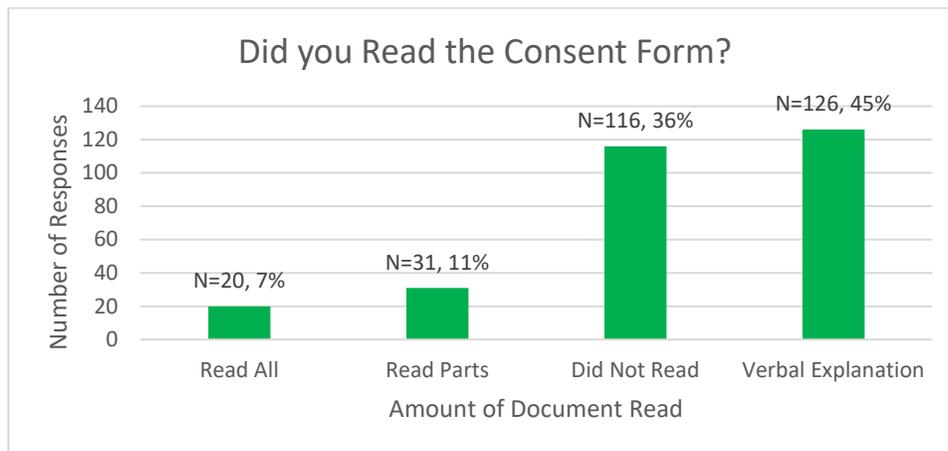
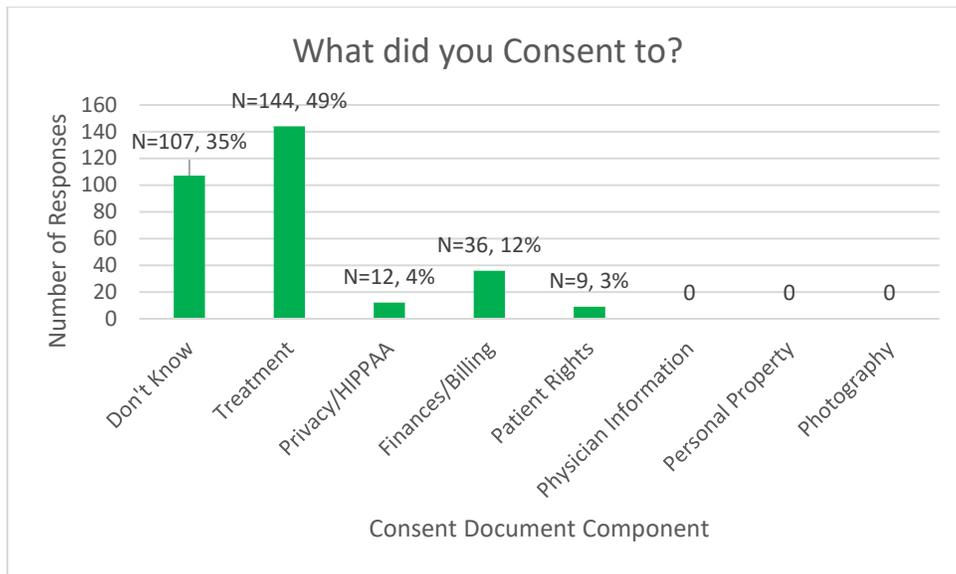


Figure 2



Discussion

Informed consent is an important ethical and legal component of medical care. In this study, we found participants often recalled signing a consent document, but most were unable to recall major components of the document. In addition, many did not even read part the document prior to signing (36%). These results demonstrate poor understanding of the informed consent document. This is consistent with prior studies performed in areas outside of emergency medicine that have also demonstrated poor comprehension of the informed consent process.²⁻⁵

The average adult in the United States reads at an eighth grade level.^{13,14} However, the readability of some informed consent documents has been examined and found to be near that of upper-undergraduate or graduate level.¹⁵ Thus, future efforts may be directed at improving patient understanding through improving readability of informed consent documents.

It is also known that health literacy is a challenge among emergency department patients.¹² Without adequate health literacy, achieving patient understanding remains problematic. To address this, some have also looked to improve comprehension by utilizing multimedia in the consent process.^{9-11, 16-17}

This study does have potential limitations. A convenience sample was utilized which does not account for reasons some participants chose to participate versus others declining participation. In addition, the data of this study were obtained from one hospital and does not take into account how other institutions' policies and procedures for obtaining consent may impact patient comprehension.

In conclusion, these results demonstrate poor patient understanding of the informed consent process in emergency medicine. Future work may look at how documents can be simplified and health literacy can be maximized to obtain better patient comprehension. These issues remain

crucial to achieve patient autonomy and uphold the obligation of care providers to obtain informed consent from their patients.

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Appendix A

Data Collection Form

STUDY ID _____

Day of the week:

____(1) Sun ____ (2) Mon

____(3) Tues ____ (4) Wed

(5) Thurs (6) Fri
 (7) Sat

Patient age (years) _____ (if 90 or older, enter "90")

Patient gender
 (1) Male
 (2) Female

Patient ethnicity
 (1) African American
 (2) Asian
 (3) White
 (4) Hispanic
 (5) Multiracial
 (6) Other _____

Mode of Arrival in ED
 (1) Walk-In
 (2) Ambulance

ED Chief Complaint _____

Triage level 1 2 3 4 5

Appendix B
Patient Survey

STUDY ID _____

Good morning/afternoon/evening.

My name is _____. I am a medical student research assistant.

We are doing a brief research study about Emergency Department treatment.

We would like to ask you some brief questions to help us understand your consent for treatment.

Your participation is voluntary and your health information will be kept confidential.

Participating will not affect your medical care at all. We expect that the study will take about 5 minutes of your time. Are you willing to participate?

Thank you in advance for your time.

Yes *No*

1. Did you sign a document to consent to treatment today in the Emergency Department (ER)?

Yes *No*

