2021

Consent for Emergency Treatment: Demographic Variables and Relationship to Patient Comprehension

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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

Objective*:* One of the most important pillars of patient autonomy is informed consent for medical treatment. This study was undertaken to measure patient recall and understanding of consent for treatment among ED patients. ***Methods:*** This prospective survey study was conducted at Miami Valley Hospital, an Urban Level 1 Trauma Center. Trained research assistants obtained verbal consent in private patient treatment rooms. Data were collected from the electronic medical record and from a survey questionnaire. ***Results:*** A total of 293 patients consented to participate (95% participation rate). The majority of participants stated that they had signed a consent document (N = 272; 93%). A minority of patients read the entire document (7%) or read part of the document (11%). Most patients did not read the document (36%) or received only a verbal explanation (45%). Many patients did not recall anything about what they signed (N = 107; 39%). The most frequently recalled elements of consent included consent for treatment (N = 144; 52%), information regarding finances and billing (N = 36; 13%), and privacy rights (N = 12; 4%). Respondents who said they didn't know what they had consented to

were significantly older (median 56 years) than respondents who remembered something from the consent form (median 47; p=0.01). ***Conclusion:*** The majority of ED patients in this study recalled signing a consent document. Most were not aware of elements of the Consent for Treatment document they had signed. **Key Words:** consent for treatment, recall, demographics

Introduction/Literature Review

Patient autonomy is one of the four fundamental principles of ethics in medicine, along with beneficence, non-maleficence, and justice. The process of informed consent includes delivery of relevant information to patients about the proposed intervention and obtaining their consent to proceed. There are many reasons to obtain informed consent such as preventing the patient from having unwanted procedures, protecting autonomous decision making, and having documentation that provides safeguards to ensure these ethical and legal requirements were fulfilled.

Unfortunately, many studies have shown that patient understanding of consent for treatment in medical facilities is not optimal. A study was done on patient views of consent for research during an acute MI and it was found a little over half of the patients remember being asked to participate in the trial.[1,2] Another literature review states that between 21% and 86% of patients were able to recall the potential risks and complications of their medical procedure. [3] A study looking at consent for cardiac procedures revealed use of interactive multimedia or audiovisual presentation over written or verbal consent was shown to increase patient recall and understanding.[5]

There are a few demographic correlations with information recall from the informed consent process. One of the most prevalent correlations in multiple studies is that degree of recall

decreased with older age.[3,6,7] It was also measured that patients with an external locus of control (patients who believed their health was not in their own control) had poorer information recall.[6] There is limited literature published that describes the relationship between gender and degree of recall of consent for treatment which is a relationship we will try to address in this study. This study aimed to bring to light how well consent for treatment is understood in the setting of an Emergency Department and if ethnicity, gender, or age play a factor. It identified patient recall and understanding of the ED Consent for Treatment document and will guide future communication with patients regarding emergency treatment. The topics we asked the patients to recall include consent for treatment, attending physicians, release of medical information, and privacy, photographs/video recording, financial agreement and assignment, cooperation with billing, patient assistance programs, Medicare and personal property, which are all found in the emergency medicine consent for treatment document at MVH.

Hypothesis/Specific Aims/Research Questions

This study was undertaken to measure patient recall and understanding of consent for emergency treatment, among Emergency Department (ED) patients. The main research question is "Is there a difference of understanding of consent by demographic groups such as gender, race, and age?". We will also measure the overall recall for consent for treatment among all demographics.

Methods

Context/Protocol

The data were collected at an Urban Level 1 Trauma Center, the Miami Valley Hospital. This was a cross sectional study. We chose this type of study to get an unbiased and large sample size.

Inclusion criteria included ED patients from March 2018 to December 2018 who consented to participate, spoke English, and were not in acute distress. The sample was a cross sectional convenience sample of consecutive ED patients, when a research assistant was available. Patients who declined to participate, presented with psychiatric complaint, didn't speak English, or were in distress were excluded.

The research assistants went into individual private patient rooms to obtain verbal consent for the study and verbally ask standardized questions from a prewritten questionnaire. These research assistants completed IRB training and project specific training to ensure standardized administration. The questionnaire (Appendix A, Appendix B) includes questions on age, ethnicity, gender, how much of the read consent form they read and what of it they can recall

Data Collection

Data collected included demographic information, including patient gender (male, female), patient ethnicity (African American, Asian, White, Hispanic, Multiracial, or Other), and age. There were also additional data collected on mode of arrival in the ED, chief compliant, and triage level, which will not be analyzed in this study. We categorized responses to "What did you consent to?" under the different topics covered in the consent for treatment document (consent for treatment, attending physicians, release of medical information, and privacy, photographs/video recording, financial agreement and assignment, cooperation with billing, patient assistance programs, Medicare and personal property) and record the number of patients that mention each. The amount of patient recall was grouped by four different responses "yes, I read the entire document", "yes I read part of the document", "no, I did not read the document",

or “no I did not read the document but received a verbal explanation”, in an attempt to quantify the responses in categorical variables.

Data Analysis

Prior to data collection, a power analysis determined that minimum sample size of 197 was required, based on a population of 400, to have confidence interval of 95% and 5% margin of error. This allowed sufficient participants to account for ineligibility, missing data, or those who decline to participate. Data were analyzed using SAS Version 9.4- (Statistical Analysis Software, Copyright © 2002-2017 by SAS Institute, Inc., Cary NC, USA). Because of the qualitative nature of the demographics included in this study, Chi-Square tests or Fisher Exact Tests were used to assess for relatedness between the variables including statistical significance.

Results

Initial data set had 309 participants that were interviewed. 16 of them declined to participate in the study. Thus, the finalized sample size was 293. Table 1 shows the demographics of the participants of this study; two patients were excluded from the study because their questionnaire was not completed entirely.

Table 1 Descriptive Statistics for All Variables

	N (%)	No. missing data or not applicable
No. participants	293	
Age (years, median) [Interquartile Range (IRQ)]	52 [35 – 65]	0
Gender Male Female	 122 (41.6%) 171 (58.4%)	0

Ethnicity African American Asian White Hispanic Multiracial Other	 100 (34.4%) 4 (1.4%) 179 (61.5%) 5 (1.7%) 2 (0.7%) 1 (0.3%)	 2

Among these participants, most individuals reported only receiving a verbal explanation of the consent document (45%) or not reading the document at all (36%) [Table 2]. A minority of patients read the whole document (7%) and a minority of patients reported reading part of the document (11%). 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.

In Table 2, we delineate the associations between age, gender, and race in association with if they read the consent document prior to signing. These demographics correlations, especially with gender and race, are not studied in prior literature, thus important to define in this study. The association with age was tested with a Kruskal Wallis test, while associations with gender and race were tested with Chi Squared or Fisher's Exact test. The only significant difference found was between African Americans and Whites, which will be elaborated more upon in the discussion section.

Table 2 Associations with Reading the Document Prior to Signing*

	N (total)	1. Read all	2. Read parts	3. Did not read	4. Did not read but verbally explained	p-value
Age (years, median) [IQR]	278	44 [34 – 55]	53 [34 – 60]	55 [40 – 68]	49 [32 – 64]	0.13
Male	117	9 (7.7%)	12 (10.3%)	50 (42.7%)	46 (39.3%)	0.25

Female	161	11 (6.8%)	19 (11.8%)	51 (31.7%)	80 (49.7%)	
African American White	95 170	9 (9.5%) 11 (6.5%)	14 (14.7%) 15 (8.8%)	22 (23.2%) 74 (43.5%)	50 (52.6%) 70 (41.2%)	0.01

*N <293 due to missing data.

Table 3A and 3B display the two most common answers when asked for patient recall on which topics they consented to: either "I don't know" or "treatment". For Tables 3A and 3B, 17 patients had missing data on their questionnaires, so were excluded, making the N = 276. Both of these responses are stratified by age, gender, and race. The association with age and recalled what was consented to was tested with Mann Whitney Wilcoxon test, while associations with gender and race were tested with Chi squared or Fisher's Exact test. Fewer patients recalled information about finances and billing (N=36, 12%), patient rights (N=9, 3%), and privacy rights (N=12, 4%). No patients (N = 0; 0%) recalled information regarding physician information, personal property, or photography.

Table 3

3A – Don't Know

	N	Remembered a Category*	Said "Don't Know"	p-value
Age (years, median) [IQR]	276	47 [33 – 62]	56 [39 – 69]	0.01
Male Female	115 161	67 (58.3%) 102 (63.4%)	48 (41.7%) 59 (36.7%)	0.39
African American White	95 168	65 (68.4%) 93 (55.4%)	30 (31.6%) 75 (44.6%)	0.04

*Categories from Consent for Treatment Document including consent for treatment, attending physicians, release of medical information, and privacy, photographs/video recording, financial agreement and assignment, cooperation with billing, patient assistance programs, Medicare and personal property

3B – Treatment

	n	Not Treatment*	Recalled Treatment	p-value
Age (years, median) [IQR]	276	54.5 [38 – 68]	48 [32.5 – 61.5]	0.02
Male Female	115 161	57 (49.6%) 75 (46.6%)	58 (50.4%) 86 (53.4%)	0.63
African American White	95 168	37 (39.0%) 90 (53.6%)	58 (61.0%) 78 (46.4%)	0.02

*Did not recall consenting to treatment

Respondents who said they didn't know what they had consented to were significantly older (median 56 years) than respondents who recalled one of the categories (consent for treatment, attending physicians, release of medical information, and privacy, photographs/video recording, financial agreement and assignment, cooperation with billing, patient assistance programs, Medicare and personal property) from the consent form (median 47) (p=0.01, Table 3A). Respondents who said they recalled consenting to treatment, which is found under the "Recalled Treatment" column were significantly younger (median 48 years) than respondents who didn't (54.5 years) (p=0.02, Table 3B). A higher percentage of White (44.6%) respondents said "don't know" compared to African Americans (31.6%) (p=0.04, Table 3A). A higher percentage of African American (61.0%) respondents recalled consenting to treatment compared to Whites (46.4%) (p=0.02, Table 3B).

Discussion

Informed consent is a crucial element of patient autonomy and independence. We undertook this study in hopes to quantify this relationship between consent for treatment and patients as well as identify any significant difference among different demographics. We found

that a majority of patients either did not read the consent for treatment form or rather had it verbally explained to them. Nearly 80% of the patients either did not recall what they were consenting to when they signed the Consent for Treatment form or recalled solely consenting to treatment.

We did not identify any significant differences among males and females. There was a significant difference in age between patients who remembered something and patients who couldn't recall anything; the latter group was significantly older. As mentioned before, this supports the previous literature between the relationship of recall and older age.[3,6,7] Also of note is that African Americans more often recalled something from the document, while White patients did not, which also correlates with the fact that Whites were more likely not to read the document prior to signing. This correlation has not been previously identified in the published literature. This begs the question: why is it that African Americans are more likely to read and recall items from the consent for treatment document? Potential explanations include less trust in the healthcare system, or attempting to overcome a misplaced stereotype. This relationship between informed consent and race is complex and unstudied, so it is difficult to give a conclusive reasoning behind this correlation.

There are a few limitations of this study. All of the subjects were taken from one hospital and only in an emergency department setting, and the urgency of the setting may have affected the results. Results were dependent on the veracity of subject responses. There was very limited racial diversity with nearly 96% of the population pool being either African American or White. Lastly, most of the patients were over the age of 50 years old with no patients under the age of 30.

Conclusions

In conclusion, though many patients recalled a consent form was signed, a majority of patients did not read the form and could not recall what they had consented to. This might indicate trust in ED providers, miscommunication between staff and patients, or decreased healthy literacy among the general population. Despite the reasoning, this issue undermines the idea of patient autonomy and needs to be improved among our nation's healthcare facilities.

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***

2. Was the document paper or electronic?
   ___Paper ___Electronic

3. If Yes, did you read the document prior to signing?
   ___Yes, I read the entire document
   ___Yes, I read part of the document
   ___No, I did not read the document
   ___No, I did not read the document but I received a verbal explanation

4. How long was the description of what you consented to?

5. If Yes, What did you consent to? Please list everything you remember.

6. Do you have any comments about the process for obtaining consent for treatment in the Emergency Department ? (ER)

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