Patient Attitudes Regarding Consent for Emergency Department Computed Tomographies

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Introduction: Little is known about patient attitudes towards informed consent for computed tomography (CT) in the emergency department (ED). We set out to determine ED patient attitudes about providing informed consent for CTs.

Methods: In this cross-sectional questionnaire-based survey study, we evaluated a convenience sample of patients' attitudes about providing informed consent for having a CT at 2 institutional sites. Historically, at our institutional network, patients received a CT at approximately 25% of their ED visits. The survey consisted of 17 "yes/no" or multiple-choice questions. The primary outcome question was "which type of informed consent do you feel is appropriate for a CT in the Emergency Department?"

Results: We analyzed 300 survey responses, which represented a 90% return rate of surveys distributed. Seventy-seven percent thought they should give their consent prior to receiving a CT, and 95% were either comfortable or very comfortable with their physician making the decision regarding whether they needed a CT. Forty percent of the patients felt that a general consent was appropriate before receiving a CT in the ED, while 34% thought a verbal consent was appropriate and 15% percent thought a written consent was appropriate. Seventy-two percent of the ED patients didn't expect to receive a CT during their ED visit and 30% of the ED patients had previously provided consent prior to receiving a CT.

Conclusion: Most patients feel comfortable letting the doctor make the decision regarding the need for a CT. Most ED patients feel informed consent should occur before receiving a CT but only a minority feel the consent should be written and specific to the test. [West J Emerg Med. 2014;15(1):14–19.]

INTRODUCTION

From 1995 to 2007, the number of emergency department (ED) visits that included a computerized tomography (CT) examination increased from 2.7 million to 16.2 million, and the percentage of visits associated with CT increased from 2.8% to 13.9%.[1] With this increase in the number of scans and the associated radiation doses from these commonly performed diagnostic examinations, concern regarding radiation exposure has increased.[2] Problems from dye allergies, renal failure, expense, length of ED stay, and the burden of false positives are other associated risks.[3-7] At a time when the federal government is encouraging physicians to reduce unnecessary tests[8], and with physicians' and laypersons' increasing awareness regarding the radiation risks associated with CT, it is unclear what patient's attitudes are regarding a formal patient consent process for CTs ordered from the ED. It is reported that only 15% of academic medical centers inform patients about possible radiation risks and 9% about alternatives to CT.[9] Additionally, the existing

literature does not reflect the current attitudes of emergency patients regarding this important issue.

Patients can give informed consent for CTs in different ways. A common process is the general consent in which a patient signs to request treatment before their ED visit. Physicians and patients operate on the presumption that it includes any CTs that might be recommended. If during the course of treatment a patient tells the healthcare provider that they agree to have the CT this would be considered verbal consent. Patients might be required to sign a form right before they have the CT. This is a written consent specific to the CT. We set out to assess patient expectations about CTs in the ED and attitudes about which type of informed consent they felt was most appropriate. Secondarily we set out to determine if demographic factors correlated with the perception of appropriate consent.

METHODS

We obtained expedited Institutional Review Board approval for this cross-sectional, questionnaire-based survey study. The survey was developed and refined by the study team and piloted with 50 surveys distributed over a 2-month period in 2010. We used these pilot surveys to power the study; they were not used in the final data analysis. Subject criticisms and common concerns from this pilot were used to further revise and contribute to the survey validation. Analysis of the pilot data led to adding a second site for data collection to increase the yield and shorten the data collection period as well as potentially expand the diversity of our population cohort. The pilot data also led to powering the sample size to 300 responses (alpha=0.05; power of 0.80) to discriminate a difference of 5 percentage points between responses on the primary outcome question (#12) on the survey.

Surveys were distributed over an 11-month period in 2010 by approaching a convenience sample of patients during weekday hours (8:30AM–4:00PM) at 2 of our institutional sites. The first, a tertiary, suburban, Level 1 trauma center, has a yearly census of 74,000 patients, while the second, an urban freestanding ED has a yearly census of 33,205. Historically, this urban second site has demographically had more diversity in patient ethnicity and educational level. Previously, in this same fiscal year at these sites, patients received a CT at approximately 25% of their ED visits. Our primary outcome measure was to determine if ED patients feel informed consent is required for CTs ordered from the ED. Our secondary outcome measure was to determine how much a patient trusts the doctor to make the decision for them about whether they need a CT.

A research team member gave the paper survey to the patient to complete. If the patient was not able to make medical decisions themselves (for example, children), their surrogate (for example, parent) was given the survey. The survey instructed surrogates to choose the answer that reflected their demographics and opinions (not the patient's). Surrogates were allowed to participate as appropriate because the study team felt their involvement was representative of the common clinical scenario in which a family member provides consent. Team members included research assistants (no volunteers), coordinators, and physicians (EM residents and attendings). The survey was administered to subjects in the treatment bay. Inclusion criteria included any ED patient (or their surrogate), without regard to acuity or chief complaint, who agreed to participate and was able to understand and respond to the survey questions in English. No incentives were provided to subjects for participation.

The survey instrument stated that participation was voluntary and anonymous. The study team member was aware of the study's purpose, but no patient education about the risks of CT was provided or questions answered in this regard by survey administrators. A brief definition for each of the different types of consent was imbedded in the survey. The survey consisted of 17 "yes/no" or multiple-choice questions, 5 of which were demographic questions (Appendix).

We computed frequencies of responses for each question. This was followed by a series of cross-tabulations and logistic regressions that examined the potential relationships between selected socio-demographic factors (age, gender, race/ethnicity, language, educational level, and the relationship between the respondent and the patient seen during that visit) and questions relating to the use of informed consent for CT administration. We used Chi-square and students t-test to determine significance and unless otherwise noted, all comparisons were statistically significant at $\geq$0.05. We used SPSS version 18 (IBM Corporation, Armonk, NY) for analysis.

RESULTS

We analyzed 300 surveys, 90% of surveys distributed. For demographics of survey respondents, see Table 1. Forty-five percent of the ED patients were age $\geq$50 and 55% were female. Eighty percent of the ED respondents were white and 84% were non-Hispanic. Forty-five percent of these respondents had at least some college education. Ninety percent primarily spoke English, and 9% primarily spoke Spanish. Seventy-one percent of the responses to the survey were from the patient themselves, while a parent or guardian of the patient provided 11% of the responses. A son or daughter responded 7% of the time, other relative, 9%, or a friend, 2% of the time.

Survey response rates are shown in Table 2. Seventy-two percent of the ED patients did not expect to receive a CT during their ED visit that day. Thirty percent of the ED patients had provided consent prior to receiving a CT in the past. Seventy-seven percent of the ED patients thought they should give their consent prior to receiving a CT. Ninety-five percent of the ED patients also responded they were either comfortable or very comfortable with their physician making the decision regarding whether they needed a CT. Prior to CT in the ED, 40% of patients reported that general consent was sufficient, while 34% required verbal and 14% written.

We correlated age, race/ethnicity, education level and

patient relationship to the respondent with the patient's expectation of a CT during their ED visit. Surrogates for minors were less likely than other adults to expect a CT during the ED visit (4% versus 33%, 34%, 29% and 25%, respectively according to age category, p<0.001).

Hispanics were somewhat less likely than non-Hispanics to expect a CT (20% versus 29%, p<0.01). Persons of other races were less likely than whites or African Americans to expect a CT (15% versus 30% and 26%, respectively, p<0.01). The parent/guardian of the patient or the son/daughter of the patient also were less likely than the patient to expect a CT during the ED visit (11% versus 26%, p<0.001).

Perspectives on the necessity of informed consent are in Table 3. Age, race/ethnicity, language and patient relationship were also correlated with the patient's perceptions of informed consent. Surrogates of persons under age 18 were less likely than other adults to indicate that patients should give their informed consent prior to CT (60% versus 84%, 82%, 77%, 73% and 79%, respectively according to age category, p<0.01). Whites were less likely than African Americans or other ethnicities to indicate that patients should give their informed consent (74% versus 87% and 91%, respectively, p<0.01). Hispanics were more likely than non-Hispanics to indicate that patients should give their informed consent (87% versus 75%, p<0.01). The parent/guardian of the patient was less likely than the son/daughter of the patient, some other relative, or a friend of the patient to indicate that patients should give informed consent (57% versus 73%, 88%, 75% and 81%, respectively according to relationship category, p<0.01).

Race was correlated with the degree of comfort patients felt with the physician making the decision regarding whether a CT should be administered during an ED visit. Whites were more likely than African Americans to indicate that they feel comfortable with the physician making the decision (95% versus 87%, p<0.01), while Hispanics had a similar comfort level as whites. Adjusting for socio-demographic factors, educational level was also correlated with the patient's comfort with the physician making the decision regarding the administration of a CT. Persons with 9-11 years of schooling or with some college education were more likely than others to feel comfortable with the physician making the decision (p<0.01).

Lastly, race/ethnicity and language were correlated with the type of consent the patient felt was appropriate for having a CT. Whites were less likely than African Americans to feel that a written consent was needed for a CT (15% versus 26%, respectively, p<0.01).

Table 1. Demographics of survey respondents

	Percent (95% CI)	N
Patient's age		
<18	8 (05-11)	24
18-29 years	18 (14-22)	54
30-39 years	13 (09-17)	39
40 to 49 years	16 (12-20)	48
50 to 59 years	14 (10-18)	42
60+ years	31 (26-37)	93
Gender		
Female	55 (50-60)	165
Male	45 (40-50)	135
Hispanic/Latino		
Yes	16 (12-20)	48
No	84 (74-84)	252
Not sure		
Race		
White	80 (75-84)	240
Black or African-American	8 (05-11)	24
Other	12 (08-16)	36
What language do you speak most often?		
English	90 (87-94)	270
Spanish	9 (05-13)	27
Other	1 (00-02)	3
Relationship to the patient		
Parent/Guardian	11 (07-15)	33
Son/Daughter	7 (03-11)	21
Other relative	9 (05-13)	27
Friend	2 (00-04)	6
Self	71 (66-76)	213
Highest grade of schooling completed		
Grades K-8	3 (02-06)	9
Grades 9-11	12 (08-16)	36
GED/12 years	37 (32-42)	111
Some college	26 (21-31)	78
4 years of college or more	19 (15-23)	57
Pregnant		
Yes	7 (05-09)	21
No	93 (90-97)	279
ESI		
1	0	0
2	34 (29-40)	102
3	49 (44-54)	147
4	15 (11-19)	45
5	2 (00-04)	6
N		300

CI, confidence interval

DISCUSSION

Little is known about emergency patients' feelings concerning CTs and the need for informed consent. This study sought to evaluate current attitudes of patients regarding the appropriateness of and/or need for informed consent for CTs in the ED. The majority were either comfortable or very comfortable with the physician making the decision regarding whether they needed a CT. Of those, whites and Hispanics were more likely than African Americans to indicate feeling comfortable with the physician making the decision regarding whether they need a CT during their ED visit. This is similar to prior studies that have shown ethnic variations and disparity in trust levels of physicians.[10,11]

Table 2. Patient survey responses.

	Percent (95% CI)
What is your chief complaint?	
Abdominal pain	21 (17-25)
Injury (trauma)	12 (08-16)
Fever	2 (02-04)
Headache	4 (02-06)
Other	62 (56-67)
Do you expect to receive a CT on today's visit?	
Yes	28 (23-33)
No	72 (67-77)
Do you think patients should give their informed consent before they get a CT in the ED?	
Yes	77 (72-82)
No	23 (18-29)
How much do you trust the doctor to make the decisions for you about whether you need a CT?	
Very comfortable	59 (54-65)
Comfortable	35 (30-41)
Uncomfortable	5 (02-09)
Very uncomfortable	1 (00-02)
What type of informed consent do you feel is appropriate for a CT in the ED?	
General consent	40 (35-46)
Verbal consent	34 (29-40)
Written consent	15 (11-19)
I don't think the patient's consent is necessary	11 (07-15)
Have you ever given consent prior to a CT?	
Yes	37 (32-42)
No	44 (39-49)
Don't know	19 (15-23)
Which type of informed consent did you give?	
General consent	32 (27-38)
Verbal consent	41 (36-47)
Written consent	15 (11-19)
I did not given informed consent	12 (08-15)
For your most recent CT, to whom did you give your informed consent?	
Physician	48 (43-53)
Nurse	12 (08-15)
CT technologist	9 (06-13)
I did not give informed consent	12 (08-15)
I gave informed consent, but don't know to whom	19 (15-23)
Have you or anyone you know ever had a problem that was caused by having a CT?	
Yes	5 (03-07)
No	95 (92-98)
What was the problem caused by having a CT?	
Allergic reaction to the CT dye	38 (33-44)
Kidney failure	4 (02-06)
Local skin irritation	15 (11-19)
Other	42 (37-48)
N	300

CI, confidence interval;
ED, emergency department;
CT, computed tomography

Table 3. "Patients should give their informed consent" by selected demographic characteristics.

	Yes (95% CI)	No (95% CI)	p
Patient's Age			
<18	60 (55-66)	40 (35-46)	
18-29 years	84 (80-89)	16 (12-20)	
30-39 years	82 (78-87)	18 (14-22)	0.262
40 to 49 years	77 (72-82)	23 (17-28)	
50 to 59 years	73 (68-78)	27 (22-33)	
60+ years	79 (74-83)	21 (17-26)	
Gender			
Female	78 (73-82)	21 (17-26)	0.632
Male	76 (71-81)	24 (19-30)	
Hispanic/Latino			
Yes	87 (83-91)	13 (10-17)	0.001
No	75 (70-80)	25 (20-31)	
Race			
White	74 (69-79)	26 (21-32)	
Black or African-American	87 (83-91)	13 (10-17)	0.038
Other	91 (88-95)	9 (06-13)	
What language do you speak most often?			
English	76 (71-81)	24 (19-30)	
Spanish	93 (90-97)	7 (04-11)	0.08
Other	50 (45-55)	50 (45-55)	
Relationship to the patient			
Parent/Guardian	57 (62-63)	43 (38-49)	
Son/Daughter	73 (68-78)	27 (22-33)	
Other relative	88 (84-92)	12 (09-16)	0.04
Friend	75 (70-80)	25 (20-31)	
Self	81 (77-86)	19 (15-23)	
Highest grade of schooling completed			
Grades K-8	80 (76-85)	20 (16-25)	
Grades 9-11	74 (69-79)	26 (21-32)	
GED/12 years	76 (71-81)	24 (19-30)	0.945
Some college	80 (76-85)	20 (16-25)	
4 years of college or more	79 (74-84)	21 (17-26)	
N	230	68	

The majority of the patients surveyed in our study thought consent should occur before a CT. Of those, the majority stated a general consent, such as that signed by the patient at the beginning of the visit for all treatments, was acceptable. Approximately one third surveyed felt a more specific verbal consent should occur before receiving a CT. African Americans were more likely to feel a written consent was appropriate.

Although layperson-accessible media supports the increased awareness of radiation exposure from CT, it is perceived to be emphasized without including the other, equally problematic potential adverse events associated with CTs, including allergic reaction to the CT dye, kidney failure and local skin irritation at the intravenous site. Our study supported this, as 95% of those surveyed had not had

or known anyone to have had a problem caused by having a CT. Of the small subset that did, the majority reported the problem to be allergic reaction to the CT dye. Of note, adverse outcomes are distinctly different between CT with and without contrast and were not evaluated separately in our study design.

Approximately 25% of patients in the ED received CT during the fiscal year in which the surveys were distributed. Interestingly, 28% of the respondents answered that they expected to receive CT during his/her ED visit. Men and women showed no difference in expectations in regard to receiving a CT . In contrast, Hispanics were less likely to expect to receive a CT than Whites or African-Americans. More importantly, 72% of those participating in this study did not expect to receive a CT. When these patients signed their registration and general consent to treat paperwork, they signed it, not expecting to receive a CT.

Some ethicists might argue this refutes the ability for our generalized consent to be used as implied consent for CT studies. Further detailed exploration of how this expectation plays into attitudes could be considered.

Past literature regarding consent reported that the majority of CT informed consent was obtained by a CT technologist.[9] In contrast, our study revealed almost half (48%) of patients recalled being consented by a physician before getting a CT in the ED. Only 9% reported getting consent from a CT technologist. Future cost analysis projections should include the variations in outcome potentials when responsibility for consent is ascribed to differing personnel.

The authors intend these findings to be a catalyst for discussion about the need and specific type of informed consent that should be provided as standard of care for patients receiving a CT in the ED. This is a complex topic and involves risk to the patient, to the institution and even prevailing legal precedent. There is a marked difference in the sheer practicality of having general consent for treatment encompass permission for CT versus a specific unique consent forms for all CTs in the ED. Factored into the discussion must be surrogate opinions, and the necessity of their verbal or written specific consent for those who are vulnerable by age, dementia, or critical illness. Policy makers must consider the burden in an emergency setting of mandating specific written consent and balance this with the potential benefits.

Future studies may want to compare and contrast the attitudes between providers and patients about informed consent for CTs in the ED, as well as actual cost benefit analysis associated with different formats of consent.

LIMITATIONS

Several limitations deserve discussion. This study was performed at a single healthcare network in Pennsylvania and thus may not be geographically generalizable. Potential sampling bias may have been introduced by surveying a convenience sample of patients only during regular weekday hours. While the response rate was high, it is unknown what differences exist between those who responded to the survey and those who did not. It should also be considered that there was no verification of patient's responses to prior CT questions (potential recall bias) or pre-assessment of the patient's knowledge of the dangers of CT. Although the survey instrument defined the different types of consent there was no verification that the patients knew the difference between the various types of consent. Furthermore, there was a broad nature of chief complaints with "other" being the most commonly (62%) captured. This limited information on chief complaint may have impacted the patients' perceptions that they would not receive a CT. Additionally, potential social desirability bias may have influenced some survey responses.

Either the patient or guardian needed to read and understand English at approximately the eighth grade level to read the survey. This may limit the external validity of the study, especially if more urban settings are included in future studies, as a larger variety of ethnicities and educational levels generally reside in large urban areas.

CONCLUSION

A minority of patients expect to get a CT during their ED visit. Most patients feel comfortable letting the doctor make the decision regarding the need for a CT. Most ED patients feel informed consent should occur before receiving a CT, but only a minority feel the consent should be written and specific to the test.

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