

Do Characteristics of Consent Forms Affect the Response Rate?

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Abstract

Researchers are required to obtain authorization from patients to gain access to protected health information for research purposes under the HIPAA Privacy Rule. Obtaining signed approval from individual patients can be difficult because: 1) the forms are idiosyncratic by hospital, 2) the forms are long, and 3) the forms are often written in legal language. We are interested in learning how the characteristics of the form affect the likelihood that a patient will sign it.

This paper reports on a recent telephone survey of previously hospitalized patients in which respondents were asked if they would be willing to allow researchers to review their medical records to get more complete information about their hospital stay. The study included patients from 16 Massachusetts hospitals. Nine hospitals required the use of own distinct forms, while the other 7 were variations of basically the same form. Those respondents who agreed over the phone to be mailed authorization forms were sent a copy of their hospital's form and were asked to return it. The goal of this paper is to learn if selected characteristics of the consent form, rather than some patient or hospital characteristics, are associated with the rates at which signed consent forms are returned. Forms varied with respect to characteristics such as length, complexity of the form, distinctness of the institution's name on the form, confidential information requested (SSN), witness to signature required, expiration date, and whether an extra copy of the consent form was included for patients' records. The analysis focuses on whether or not these characteristics relate to the likelihood that a signed form will be returned.

Keywords: consent forms, HIPAA, Health Protected Information, response rate

1. Introduction

By the HIPAA Privacy Rule, the national standard for protecting patients' medical records and other personal health information, an authorization form is required "for uses and disclosures of protected health

information not otherwise allowed by the Rule"¹. According to the Rule, researchers are also required to obtain the authorization from patients to gain access to protected health information for research purposes. Obtaining signed approval from individual patients can be difficult because: 1) the forms are idiosyncratic by hospital, 2) the forms are long, and 3) the forms are often written in legal language. So although obtaining signed authorization forms may help protect hospitals, it is often challenging for researchers collecting the forms.

While the effects of confidentiality assurance and informed consent on response rate have been a subject of research (Singer, Von Thurn, and Miller, 1995; Singer, 1978), no work has been done on consent form characteristics and how they affect the response rate. An unpublished internal methodological report that Center for Survey Research prepared for the NICCQ² study is the only analysis we found where the issue of complexity of consent form and rate of returning the forms was considered.³ That report showed that respondents who had to sign comparatively complex forms were significantly less likely to return a completed form than those who had the generic consent form. Although there was no difference in explicit refusal, 15% of those with complex form vs. 9% of those with the generic type did not return a consent form.

In recent years concerns about the impact of the HIPAA privacy rule on research (Armstrong et al. 2005) and about increased unwillingness of respondents to provide Social Security Number to researchers (Bates, 2005; Lewis, 2005; Marshall, 2004; Singer, 2003; Tucker, 1999 in Bates, 2005) have become of interest of social research. A study by Armstrong et al. confirmed that the impact of the HIPAA is significant, as consent for follow-up interviews declined from 96.4% in the pre-HIPAA period to 34.0% in post-HIPAA period. The study which tested four alternatives to asking for SSN for data linkage found that respondents were more likely to refuse when asked for the full SSN (60%), even more likely when given an explanation for the request (74%), less likely to refuse when given an alternative to only provide the last four digits of SSN (48%), and the least likely when asked directly to

give objections to data linkage without being asked for any part of SSN (37%) (Bates, 2005).

The lack of research about form characteristics, the findings that show that requiring respondents to sign consent forms or to provide SSN reduce response rates, and the fact that, according to the HIPAA, researchers are required to obtain signed authorization form to access patients' medical records, suggest the need for analyzing the characteristics of consent forms and their impact on survey response.

2. Methodology

This paper reports on a subset of the sample of previously hospitalized patients who participated in a recent telephone Survey on Patients' Hospital Experiences. The study was sponsored by the Massachusetts Department of Public Health and funded by the U.S. Agency for Healthcare Research and Quality. A team of researchers from Massachusetts General Hospital, the Harvard School of Public Health and the Center for Survey Research at the University of Massachusetts Boston worked on the study. Most of the interviewing was conducted between January and August 2004. The study included patients from 16 Massachusetts hospitals hospitalized between April 1, 2003 and October 1, 2003.

For the purpose of the telephone survey, a two-stage probability sample was drawn, first selecting hospitals and then selecting patients within the selected hospitals. The final number of cases fielded for this study was 5859. The final eligible sample was 4222⁴. A total of 2597 (61.5%) completed an interview.

Only respondents who completed the phone interview (n=2597) were asked if they would be willing to allow researchers to get some additional information from their medical records about their hospitalization, and only those respondents who agreed over the phone to be mailed authorization forms (n=2030) are included in the analysis. After receiving the form, about 80 cases called to refuse or sent in the blank forms. Others, of course, "refused" by simply not returning the form. The respondents who neither refused nor returned signed authorization forms were sent one re-mail. Mailing materials included: a letter, a fact sheet, an instruction sheet indicating fields to fill out, an authorization form with highlighted fields that needed to be filled out, a copy of the authorization form (when required), and a business reply envelope.

Name, address, and DOB (when needed) were pre-filled form records to minimize the effort on respondents' part.

Nine hospitals required the use of their own distinct forms, which they designed themselves, while the other seven were variations on a single form and were quite similar to one another. Five forms came from the hospitals that were part of one big hospital system, and those forms were very similar, with the name of the hospital system written in the heading, and the name of the hospital written in the introductory sentence. Some forms came from hospital systems, but had the hospital name in the heading, not the name of the system. And finally, some hospitals, that were not part of any system, had entirely unique forms. We received 1021 signed forms (50.3% of all sent forms)⁵.

The goal of this paper is to learn whether selected characteristics of the consent form, rather than patient or hospital characteristics, are associated with the rates at which signed consent forms are returned. Forms varied with respect to characteristics such as:

- number of pages,
- number of fields to fill out,
- confidential information requested (SSN),
- witness signature required,
- expiration date,
- whether a copy of the authorization form was included for patients' records.
- complexity of the form,
- distinctness of the institution's name on the form,

In terms of length, eight forms had 2 pages, six forms had 1 page, and two forms had 3 pages. The number of fields that needed to be filled out by respondents varied from 2 to 5 fields. Most of the forms (13) did not require social security number, but 3 did. Also, most of the forms (12) did not require a witness signature but 4 did. As for the expiration date, most forms (12) said that form expired at "the end of the study", 2 forms had "6 months", and 2 had no expiration date, even though the privacy rule (<http://www.hhs.gov/ocr/hipaa>) states that an expiration date is required for all authorization forms used for research purposes. When requested by hospitals, an extra copy of the authorization was included for the patients' records (6 out of 16 forms).

In order to measure the complexity of the form and the distinctness of the institution's name on the form, we decided to ask three coders to independently rate

each form as if they had received it in the mail. Along with each form we included a letter and a fact sheet. For the complexity coders were asked: “Please rate how easy to complete this form appears” (easy, medium, and hard). For the distinctness they were asked: “On this form, is the name of the hospital clearly identified” (yes, no). The modal value was used when rating complexity and the distinctness of the forms. As a result 10 forms were coded as easy, 4 as medium, and 2 as hard to complete. For 13 forms coders thought that the name of the hospital was clearly identified and for 3 that it was not clearly identified.

3. Findings

The dependent variable in this analysis is the rate at which authorization forms were completed and returned. The effects of the following characteristics of the consent form were examined: number of pages, number of fields to fill out, Social Security Number requested, witness signature required, rated complexity, distinctness of the institution’s name, expiration date, and whether a copy was provided for respondent’s records or not. In addition, two respondents’ characteristics were used as independent variables – gender and age.

Number of pages, number of fields to fill out, SSN requested, rated complexity, distinctness of the institution name, and expiration date all had some effect on the response rate, and were in the direction we expected. The first table shows the relationship between the number of pages and whether authorization form was received or not.

Table1: Crosstabulation of Number of Pages by Result of Authorization Form Collection

Number of pages (# of forms)	Result of Authorization Form Collection		Total (N)
	Received	Not Received	
1 (n=6)	51.7%	48.3%	100.0% (871)
2 (n=8)	50.4%	49.6%	100.0% (969)
3 (n=2)	43.7%	56.3%	100.0% (190)
Total	50.3% (1021)	49.7% (1009)	100.0% (2030)

Chi-square=3.977, df=2, p=.137 (2-tailed)

From Table 1 we can see that as the numbers of pages increase the response rate decreases. As expected the lowest return rate is when the forms that were 3 pages long (43.7%) and the highest when the forms were one page long (51.7%). Although the

relationship is not statistically significant, it is close to being significant one-tailed (p value is .068 1-tailed) as we expected that response rate would only decrease with an increase in the number of pages, not vice versa.

The increase in the number of fields to complete did not decrease the response rate, except for the forms that had 5 fields (41.7 % return rate compared to 48.6%, 51.2%, and 53.3% for 2, 3 and 4 fields respectively). One could ask if there is a certain point when it becomes too cumbersome for respondents (e.g. five fields). However, the data show that percentage distributions vary between different groups, and that this relationship is statistically significant with p value less than <.01.

Requesting the respondent’s social security number seems to be the factor that determines the return rate the most: the return rate was 41.7% when SSN was requested and 52% when it was not requested (p=.001 2-tailed). In times of the growing fear of identity theft, giving away a social security number to a third party may be making people uncomfortable.

The complexity of the form is another characteristic that can affect the return rate. The harder the form, the lower the return rate. For the forms that were coded *easy*, the return rate was 51.8%; for those that were coded *medium* it was 49.0%, and for the *hard* ones the return rate was 43.7% (p=.037 2-tailed)⁶.

Having the name of the institution clearly visible also had a significant positive effect on the response rate, whereas requiring a witness to the respondent’s signature had no effect on the response rate. Providing a copy of the authorization form for patients’ records had a negative effect on the response rate. This effect was in opposite direction from what was expected.

Table2: Return rate depending on the presence or absence of different form characteristics

Characteristic (# of forms)	Presence of the characteristic	
	Yes	Not
SSN requested (3/16)**	41.7% (141)	52.0% (880)
Hospital name distinct (13/16)*	51.3% (904)	43.7% (117)
Witness signature required (4/16)	50.9% (377)	50.0% (644)
Copy provided (6/16)*	46.4% (243)	51.7% (778)

* p<.05. ** p<.01. *** p<.001 (2-tailed).

Under the HIPAA Privacy Rule an authorization form must specify an expiration date (<http://www.hhs.gov/ocr/hipaa>), and since the forms we used differed in that respect, we wanted to see what effect different expiration dates have on the return rate.

Table 3: Crosstabulation of Expiration Date by Result of Authorization Form Collection

Expiration Date (# of forms)	Result of Authorization Form Collection		Total (N)
	Received	Not Received	
No expiration date (2)	43.7%	56.3%	100.0% (190)
End of the study (12)	48.8%	51.2%	100.0% (1395)
6 months (2)	57.8%	42.2%	100.0% (445)
Total	50.3% (1021)	49.7% (1009)	100.0% (2030)

Chi-square=14.441, df=2, p<.01 (2-tailed)

From the Table 3 we see that there is a relationship between different expiration dates and the rate at which authorization forms are returned. The people were the most likely to return the signed form if it expired at the definite period of time (6 months), less likely if the expiration date was ambiguous (“the end of the study”), and the least likely to return the form if there was no expiration date. These data suggest that having expiration date can help researchers when collecting authorization forms to obtain better return rate.

In addition to form characteristics, we wanted to see what effects the respondents’ characteristics have on return rate. We looked at gender and age⁷. Our data showed that men were more likely than women to complete the authorization forms (54.0% vs. 47.3%, p<.01), and that respondents under 50 years of age were significantly less likely to complete and return the signed form than those who were older (Table 4).

Table 4: Crosstabulation of Age by Result of Authorization Form Collection

Age	Result of Authorization Form Collection		Total (N)
	Received	Not Received	
18-49	37.1%	62.9%	100.0% (520)
50-64	53.0%	47.0%	100.0% (542)
65-74	57.3%	42.7%	100.0% (457)
75 or older	54.6%	45.4%	100.0% (511)
Total	50.3% (1021)	49.7% (1009)	100.0% (2030)

Chi-square=50.497, df=3, p<.001 (2-tailed)

Since we saw that most of the form characteristics have some effect on the return rate, we wanted to see which form characteristics when put together have the biggest effect on the outcome (return rate). The regression analysis was conducted to include the simultaneous effects of multiple independent variables.

Table 5: Multiple Regression of Simultaneous Effects of the Various Form Characteristics on the Return Rate^a

	B
Constant	1.807***
Number of pages	-.042
Number of fields	-.010
SSN required	-.190**
Witness required	.036
Copy provided	.003
Rated complexity	.015
Hospital name distinct	.092*
Expiration date	-.034
R	.115
R squared	.013
(N)	(2030)

* p<.05, ** p<.01, *** p<.001

^a Coding: Form return rate 1=received, 2=not received; Number of pages 1-3; Number of fields 2-5; SSN required 1=yes, 2=no; Witness required 1=yes, 2=no; Copy provided 1=yes, 2=no; Rated complexity 1=easy, 2 medium, 3=hard; Hospital name distinct 1=yes, 2=no; Expiration date 1=the end of the study, 2=6 months, 3=no expiration date.

The analysis showed that requesting Social Security Number and not having the hospital name distinct both had significant effects on the return rate when put together with other form characteristics.

4. Conclusion

The format of the consent form matters. Some form characteristics matter more than others, but requesting SSN had the single worst effect on the return rate among the variables examined. Fear of identify theft, personal policy not to disclose SSN, and media messages discouraging practice of giving out SSN are the top three reasons for refusing to provide SSN (Lewis, 2005 in Bates, 2005). Requesting the SSN mainly serves the purpose of an additional verification that the correct medical records are being accessed, and since this process of authentication can also be accomplished by using date of birth, it would be desirable, from the researchers’ perspective, to use the latter and omit requesting SSN.

Distinctness of the institution's name is the second most important form characteristic. When a hospital joins a hospital system and the name changes, a person may not recognize or feel certain that the form is coming from the hospital he or she was in. Obtaining a signed authorization form for research purposes then becomes a challenge. Having the hospital name clearly visible, preferably at the head of the form, can help assure that the patients recognize where the form is coming from, and therefore increase likelihood that a signed form would be returned.

Obtaining signed authorization forms may help protect hospitals, but it may become a barrier for researchers collecting the forms and it creates a potential for lower response rate. However, we can say that forms that are shorter, with less burden on those who need to fill them out, without requesting the confidential information such as Social Security Number, forms that clearly identify the hospital that they belong to, and that have specified expiration date, should have better chances to be completed and returned than those that do not satisfy these criteria. Nevertheless, we need further research to test and to help understand the effects of the form characteristics on response rates.

References

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¹ "An authorization is a detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual" (<http://www.hhs.gov/ocr/hipaa>).

² The National Initiative on Cancer Care Quality

³ Note that the NICCQ study was a mail study where consent forms were sent along with the self-administered surveys, whereas in our study interviews were first conducted over the phone and at the end of the interview respondents were asked if they would be willing to allow researchers to review their medical records. Also NICCQ study used the combination of distinct hospitals' forms and a generic form, whereas in our study all the forms came from the participating hospitals.

⁴ About a third of the ineligible cases were deceased, another third were too ill to do the interview, and the rest of the cases we couldn't interview because they were either in nursing homes, didn't speak English, or were not selected properly by hospitals that provided samples to fit our eligibility criteria.

⁵ The overall return rate for NICCQ study was 85%; however a portion of the interviews were completed over the phone and the consent forms needed to be mailed back. Only 45.4% of those (98/216) eventually sent in a completed consent form.

⁶ The NICCQ study considered a form to be "complex" if it required more than one signature, a witness, initials on the bottom of each page, or some a combination of these things. Those respondents who had to sign the complex forms were significantly less likely to return a completed form than those who had the generic consent form (although there was no difference in explicit refusal 15% of those with complex form vs. 9% of those with the generic type did not return a form).

⁷ Unfortunately we didn't collect information on education in our survey, which is a misfortune since the one work that discusses the effects of understanding the consent forms on research looks into educational level of participants (Flory, Emanuel, 2004).