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Standard HIPAA Authorization Forms Decreased Response Rates for a Multi-site Pragmatic Trial

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ABSTRACT

BACKGROUND: The Health Insurance Portability and Accountability Act (HIPAA) aims to safeguard patient information; however, complex legal language may lead to confusion and mistrust, and hinder enrollment in clinical trials.

OBJECTIVE: To evaluate the effect of a standard HIPAA authorization included in mailed survey packets on study enrollment for a multi-site pragmatic trial.

DESIGN: This study is nested within an advance care planning pragmatic trial at 50 primary care clinics across three University of California (UC) Health Systems.

PARTICIPANTS: We included English and Spanish-speaking seriously ill patients.

INTERVENTIONS: One third of eligible patients received and 2/3 did not receive the HIPAA authorization in their enrollment packet.

MAIN MEASURES: We compared enrollment rates at 3 months and assessed the readability, understandability, and actionability of the standard HIPAA form using the Federal Plain Language Guidelines Checklist for Plain Language, the Automatic Readability Checker consensus calculator (grade 8 is the average reading level for US adults), and the Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P, 0–100%, 70% considered the minimum).

KEY RESULTS: Of 4632 eligible patients (mean age 71, 48% women, 11% Spanish-speaking, 40% racial/ethnic minority); 1543 received a mailed enrollment packet with a HIPAA form and 3089 did not. Patients mailed the HIPAA form were less likely to enroll (10.2% vs. 14.8%, $p<0.001$). The standard HIPAA form scored at the 12th grade reading level, had a PEMAT-P Understandability score of 42%, had an Actionability score of 40%, and only met 50% of Federal Plain Language Guideline Checklist items.

CONCLUSIONS: The inclusion of a standard HIPAA authorization in mailed enrollment packets for a large pragmatic trial led to lower rates of study enrollment. This study informs how HIPAA authorization forms should be redesigned to be more accessible to patients to prevent unnecessary barriers to research enrollment.

KEY WORDS: health literacy

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INTRODUCTION

The Health Insurance Portability and Accountability Act (HIPAA) protects patients by setting limits on who can view and receive personal health information (PHI). HIPAA requires adherence to institutional regulations and standardized forms include complex legal language that can be confusing and concerning to potential research subjects, similar to informed consent.[1–5] For example, HIPAA authorization includes language about several entities who can view someone's PHI (e.g., the study sponsor) and financial records, which may introduce privacy concerns and mistrust. These concerns along with literacy barriers may affect recruitment and enrollment into research studies where HIPAA form completion is required.[6–8]

Interactive interventions for informed consent, such as teach-back, have been shown to increase patient comprehension.[9] However, for pragmatic trials, intensive teach-back approaches for consent and HIPAA are infeasible. While many institutions allow informed consent forms to be modified to simplify their language, HIPAA language is often mandated and unmodifiable. Institutions may also be unable to permit the exclusion of unnecessary information on a HIPAA authorization that is not needed in individual studies (e.g., financial information).

Small studies with historical controls and one randomized study in which investigators were allowed to shorten the HIPAA form showed that inclusion of a HIPAA form decreased study enrollment,[6–8] but little is known about how standardized HIPAA forms affect enrollment for large pragmatic trials. As part of a large, pragmatic trial of primary care patients with serious illness in the University of California

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(UC) healthcare system designed to test scalable advance care planning (ACP) interventions, we invited a subset of patients to complete questionnaires through mailed enrollment packets. Through input from an engaged Community Advisory Group (CAG) of patients and caregivers, we were able to modify the informed consent form to a 5th grade reading level. However, we were unable to modify the HIPAA authorization and the CAG expressed concern that the standard HIPAA form would inhibit study enrollment. For example, the CAG identified the following sentences as potentially instilling fear: "Once your health information is released by (name of health system) it may not be protected by the privacy laws and may be shared with others" and "Information includes information in your medical records, financial records, and other information that can identify you."

Therefore, we evaluated the effect of including, versus not including, a standard HIPAA authorization in mailed enrollment packets on study enrollment among primary care patients with serious illness. We also compared the readability, understandability, and actionability of the standard HIPAA form with health literacy guidelines for patient-facing materials and provide suggestions for change.

METHODS

The UC Health Care Planning Study is a large pragmatic trial that enrolled English or Spanish speaking seriously ill primary care patients from 50 primary care clinics at 3 UC health systems. Primary care patients were 18 years or older with at least two primary care clinic visits in the past year and serious illness identified using an automated algorithm.[10] In addition to the larger population cohort that were eligible to receive an ACP intervention at time of study initiation through the electronic health record if they did not have ACP in the last 3 years, this study enrolled a "research cohort" for collection of detailed survey and medical record information. This paper focuses on the initial enrollment effort to recruit the "research cohort" subset of seriously ill patients at the beginning of the UC Health Care Planning Study (prior to the initiation of the trial) and whether the HIPAA authorization form affected enrollment rate within 3 months of enrollment packet mailing. The UC Health Care Planning study was approved by a UC Central IRB for all institutions (trial registration: UC Health Care Planning Study; NCT04012749; https://clinicaltrials.gov/study/NCT04012749) and we obtained a HIPAA waiver for most aspects of the study except we required a signed HIPAA form to conduct detailed medical record review.[10,11]

An amendment to the IRB was approved to allow us to use two different approaches to collecting HIPAA authorization: 1/3 received the HIPAA form within the enrollment packet and 2/3 did not include the HIPAA authorization with a plan to collect it at a later time. We randomly assigned which patients would receive HIPAA in the mailed packet and which would not and compared response rates after 3 months to inform our approach to ongoing recruitment.

Patient Population Seriously ill patients who were eligible to receive an ACP intervention in the UC Health Care Planning Study were mailed an enrollment packet to enter the "research cohort" prior to initiation of the trial.[10] Patients were removed for ineligibility by their primary care clinician due to moderate-to-severe cognitive impairment or severe mental health disorder.

Enrollment Process The enrollment packet was co-developed with the CAG. The packet was sent via mail and included an introductory letter that indicated a $30 incentive for study participation, a self-addressed, stamped return envelope, and two copies of an easy-to-read consent form written at a 5th grade reading level. The consent form was co-developed with the CAG and, if signed, provided consent to complete the baseline questionnaire (included in the enrollment packet) and to receive additional surveys at 12 and 24 months. To obtain permission for our team to access PHI from their medical record, a HIPAA authorization was also required. The standard HIPAA form was a three-page HIPAA form that used standardized, unmodifiable legal language. We were not able to specify the limited parts of the medical record we would be accessing or to decrease the literacy level of the form. Our protocol allowed for up to three telephone recruitment calls in addition to the mailings.[11]

HIPAA Form Included or Not Included in Mailed Enrollment Packets The CAG was concerned about the non-modifiable HIPAA form language and initially did not want any enrollment packets to be sent with HIPAA authorizations. To test whether the standard HIPAA forms would be associated with enrollment, we collaborated with the CAG to send them to 1/3 of the eligible cohort. We received approval by the IRB in an amendment to use two approaches for the initial mailing of the enrollment packet: a randomized sort of the mailing list was created within each health system and 1/3 of eligible patients received two copies of the HIPAA authorization in the enrollment packet and 2/3 included no HIPAA form. Packets including the HIPAA form also contained an easy-to-read (5th grade reading level) one-page explanation, co-created with the CAG, that described why a HIPAA form was needed and what our study team would be doing or not doing with the information. For example, we clarified that we would not share their data with anyone outside of the study and that we only needed to access the medical record to review ACP information. For patients who did not receive the HIPAA form in their mailed enrollment packet and who signed the consent form and completed the questionnaire, we modified research staff telephone follow-up scripts that were approved by the IRB that included education about and

assistance with the HIPAA form if needed. There were no other changes to the research protocol and both groups were able to receive up to three telephone calls for recruitment.

Data and Outcomes The primary outcome was the proportion of patients who enrolled in the research cohort 3 months after the first wave of mailing the enrollment packet. We also report data on demographics, language spoken, and a social vulnerability index[12,13] (SVI: 0–1 values, with higher values indicating increased vulnerability) among patients who were mailed the first wave of the survey. Among patients who returned the survey, we also report their highest education attainment and confidence filling out forms (i.e., self-reported health literacy) and whether they received a recruitment phone call.

We also assessed the readability, understandability, and actionability of the HIPAA form using three main methods: (1) the Federal Plain Language Guidelines Checklist for Plain Language (a 14-item guide for writing in accordance with Federal Plain Language Guidelines, as designated by the Federal Plain Writing Act of 2010);[14] (2) the Automatic Readability Checker consensus calculator which provides readability statistics such as grade level equivalent, number of complex words, number of words per sentence, and number of syllables per word using six formulas (i.e., the Flesch-Kincaid Grade Level; Flesch Reading Ease; Gunning FOG Formula; SMOG Index; Coleman-Liau Index; the Automated Readability Index) with a target mean reading level of US adults (8th grade) or below);[15–20] and (3) the Agency for Healthcare Research and Quality Patient Education Materials Assessment Tool for Printable Materials (PEMAT).[19] PEMAT is a structured assessment tool to evaluate written materials. PEMAT scores range from 0 to 100%, and scores below 70% in any category are considered not to meet health literacy principles.

Analysis We used descriptive statistics to describe the cohort and study outcomes, and chi-square and *t*-tests to assess the relationship of outcomes and patient characteristics. We also assessed the HIPAA form for readability, understandability, and actionability by reviewing the form against all aforementioned literacy indices.[16–18] Finally, we rated the HIPAA form according to understandability and actionability standards using the PEMAT.[19] Based on assessment findings and literature review, we identified best practices to simplify the HIPAA authorization for research participants.

RESULTS

Of 4632 enrollment packets mailed during the first wave, 1543 (33.3%) were randomized to contain a HIPAA form and 3089 (66.7%) were not. Patients were on average 71.3 years old, 51.9% were male, 10.6% Spanish-speaking, 51.5% White, 19.5% Hispanic, 12.0% Asian, 8.8% Black, and 8.2% Other. There were no significant differences in demographic characteristics between the two randomized groups (Table 1). Only 19.5% of patients who completed the baseline survey received phone calls to encourage

Table 1 Surveys Sent

	Surveys sent with HIPAA form ($n=1543$)	Surveys sent without HIPAA form ($n=3089$)	*p*-value
Social vulnerability index, mean			
Overall	0.39	0.39	0.97
Socioeconomic	0.37	0.37	0.88
Household composition	0.37	0.37	0.81
Minority and language	0.43	0.43	0.91
Housing and transportation	0.48	0.48	0.95
Age, mean	71.50	71.23	0.55
Gender, n (%)			
Male	796 (51.6)	1608 (52.1)	0.82
Female	745 (48.3)	1481 (47.9)	
Non-binary	1 (0.1)	0 (0.0)	
Race/ethnicity, n (%)			
White	778 (50.4)	1606 (52.0)	0.10
Hispanic	313 (20.3)	591 (19.1)	
Asian	207 (13.4)	350 (11.3)	
Black	134 (8.7)	273 (8.8)	
Other	111 (7.2)	269 (8.7)	
Language, n (%)			
English	1283 (83.1)	2602 (84.2)	0.14
Spanish	161 (10.4)	332 (10.7)	
Other	99 (6.4)	155 (5.0)	

recruitment within 3 months after the initial packet mailing and there was no difference between groups (Table 2).

Patients randomized to receive the HIPAA form in their mailed enrollment packet were less likely to enroll in the study within 3 months of mailing compared to participants whose packet did not include a HIPAA form (158 (10.2%) vs. 457 (14.8%), $p \leq 0.001$) (Table 2). Of the 158 patients who received the HIPAA form and enrolled in the study, 22 (13.9%) only signed the consent form and did not mail back a HIPAA form. Nine patients who did not receive a HIPAA form in their mailed enrollment packet subsequently completed the HIPAA form during telephone follow-up.

Patients who enrolled in the study and whose mailed enrollment packets included a HIPAA form were on average 3 years older than patients who enrolled in the study and whose mailed packets did not include a HIPAA authorization (Table 3). No other demographic variables were associated with enrollment, including language, education, and self-reported health literacy.

Readability, understandability, and actionability analysis revealed that the HIPAA form did not meet the standards for accessibility (Table 4). The Automatic Readability Checker scored the HIPAA form at a 12th grade readability. This was largely due to the high number (17%) of complex words (i.e., three or more syllables, and average sentence length of 18.6 words per sentence). The PEMAT Understandability score was 42% and the Actionability score was 40%, well below the 70% threshold in each category. The form only complied with 50%, or seven of the 14 items on the Federal Plain Language Guidelines Checklist for writing in plain language. Based on literature review, suggestions to improve readability are to target the form to the 8th grade reading level or below. To improve understandability, recommendations are to use common, everyday language and the active voice, reduce sentence length, put important information first, and use call out boxes for key points. Suggestions to improve actionability include consolidating choices and organizing information into explicit actionable steps (Table 4).

DISCUSSION

In this large pragmatic population-based clinical trial across the UC system, the inclusion of a standard HIPAA form led to decreased enrollment. The readability assessment demonstrated that the HIPAA form did not meet evidence-based standards for readability, understandability, or actionability.

The decreased baseline enrollment rates from mailing standard HIPAA forms had consequences for our study procedures. Based on study findings of decreased enrollment and the CAG's concerns about the difficult-to-read, legal HIPAA language, the CAG recommended that HIPAA forms should not be included in any subsequent recruitment mailings. To achieve our research cohort recruitment targets, a second mailing was required (note that it was initiated after the 3-month follow-up for the study presented in this paper). Based on the findings reported here and CAG recommendations, we did not include the HIPAA form in those mailings and employed more intensive telephone follow-up. Thus, to succeed in recruitment and to be able to review study participants' medical records, the team needed to conduct resource intensive follow-up phone calls to verbally describe the HIPAA form and explain to patients the purpose and limits of medical record review in order to obtain HIPAA authorization.

Similar to prior informed consent studies, this study demonstrates that the complex, legalistic, and required high-literacy language used in HIPAA authorizations for research may be a barrier to recruitment and enrollment in clinical trials.[9,21–24] The high literacy level of standard research forms may also affect informed consent, study understanding, and trust, as has been shown in other literacy studies.[22,25–29] We hypothesize, based on the feedback from our CAG, that an easy-to-read form would have had a positive impact on enrollment; future studies should test this hypothesis.[20] Prior non-pragmatic studies using historical controls or a shortened version of a HIPAA form showed similar decreases in study enrollment due to the HIPAA authorization requirement.[6–8] Although the absolute difference in study enrollment between the two groups in the current study was only 5%, for large pragmatic trials, this can extrapolate to many

Table 2 Enrollment Rates and Procedures within 3 Months

	Surveys sent With HIPAA form ($n = 1543$) *n* (%)	**Surveys sent Without HIPAA form ($n = 3089$)** *n* (%)	***p*-value**
Completed survey	158 (10.2)	457 (14.8)	<0.01
Completed baseline HIPAA	136 (86.1)	9 (2.0)	<0.01
Received 0 phone calls	128 (81.0)	359 (78.6)	0.59
Received 1 phone calls	11 (7.0)	41 (9.0)	0.54
Received 2 or 3 phone calls	17 (10.8)	51 (11.2)	0.99
Opted out	125 (8.1)	218 (7.1)	0.22
Deceased within 3 months	190 (12.3)	398 (12.9)	0.61

Table 3 Surveys Completed within 3 Months (Bivariate Analysis)

	Surveys completed with HIPAA form ($n=158$)	Surveys completed without HIPAA form ($n=457$)	p-value
Social vulnerability index, mean			
Overall	0.34	0.37	0.20
Socioeconomic	0.32	0.35	0.34
Household composition	0.34	0.37	0.27
Minority and language	0.42	0.43	0.78
Housing and transportation	0.43	0.47	0.11
Age, mean	71.37	67.87	0.01
Gender, n (%)			
Male	82 (51.9)	228 (49.9)	0.68
Female	75 (47.5)	229 (50.1)	
Non-binary	1 (0.6)	0 (0.0)	
Race/ethnicity, n (%)			
White	86 (54.4)	280 (61.3)	0.12
Hispanic	31 (19.6)	85 (18.6)	
Asian	22 (13.9)	35 (7.7)	
Black	13 (8.2)	30 (6.6)	
Other	6 (3.8)	27 (5.9)	
Language, n (%)			
English	139 (88.0)	410 (89.7)	0.56
Spanish	15 (9.5)	41 (9.0)	
Other	4 (2.5)	6 (1.3)	
Highest education, n (%)			
Less than high school or GED	11 (7.2)	37 (8.2)	0.53
High school graduate	23 (15.0)	65 (14.4)	
Some college or 2-year degree	43 (28.1)	154 (34.1)	
4-year college graduate	28 (18.3)	83 (18.4)	
Graduate degree or more	48 (31.4)	113 (25.0)	
Confidence in filling out forms, n (%)			
Not at all	7 (4.5)	24 (5.3)	0.30
A little bit	10 (6.4)	14 (3.1)	
Somewhat	15 (9.6)	38 (8.4)	
Quite a bit	39 (24.8)	97 (21.6)	
Extremely	86 (54.8)	277 (61.6)	

unenrolled potential participants and additional recruitment efforts for study teams.

The study standard HIPAA form was written at a 12th grade level, well beyond the average reading level of US adults (8th grade).[30,31] Many IRBs allow investigators the opportunity to adjust the literacy level of informed consent forms to the 5th grade level and adjust formatting for readability. These changes have been shown to improve informed consent.[22] However, HIPAA language is often mandated and non-editable, as was the case in this study. To foster health equity and participant trust, we could consider a path forward for easily understandable HIPAA forms. With the growth of implementation science and pragmatic, system-wide research approaches, it is important that the materials are written at an appropriate literacy level with appropriate formatting (e.g., large font, white space) to allow patients to make informed decisions. Table 4 provides actionable suggestions that could help bridge this gap, such as including only data that are necessary (e.g., chart review for one piece of data in one area of the medical record, rather than all aspects of the record or financial information), and increasing the use of plain language, blank or white space, large font (e.g., 14-pont), and clear calls to action.

The IRB at University of Arkansas for Medical Sciences (UAMS) recently approved and made available a simplified HIPAA research authorization form template, building on momentum from recent efforts to implement Common Rule changes[32] designed to improve understandability and actionability of informed consents.[33] The update was led by the UAMS Center for Health Literacy, whose efforts focused on lowering the reading demand to less than grade 7 and addressing issues related to understandability (such as defining or replacing jargon, using bullets/sub-bullets, and organizing content with helpful headers). This form could serve as a guiding example. Future studies should explore if a readable, understandable, and actionable HIPAA form improves recruitment and enrollment rates in pragmatic and non-pragmatic studies and increases patient comfort in participating in research.

The strengths of this study are the inclusion of patients from three UC medical centers and the involvement of an active CAG. However, this study is limited in that it only

Table 4 Suggestions to Improve HIPAA Form Literacy Domains

Literacy domain	HIPAA Form	Suggestions
Readability[15,21]		
	Grade level 12 • Percent complex words: 17%	Grade level 8 or below • Reduce percent of complex words
Understandability[15,21]		
Word choice	• High percent complex words • Uses excess words • Duplication (sections A and D) • Uses abbreviations ("CRO" and "N/A")	• Use common, everyday language • Omit excess words to reduce document length • Avoid abbreviations
Active voice	25% of the sentences are written in passive voice	Use active voice • Makes it clear who is supposed to do what • Eliminates ambiguity about responsibilities
Organization	Lacks concise summary • Details about information that will be shared scattered throughout (sections B, C, G) • Lacks sign/no sign scenario language Content overload—reader must read through all possible sharing options	Put the most important information at the beginning and include background information (when necessary) toward the end • Start by stating purpose and the bottom line • Arrange content in a logical order
Section and sentence length	The following key sections are too lengthy: • Section A. What is the purpose of this form? • Section I. Can I cancel my permission?	• Reduce sentence length • Chunk content into shorter sections
Layout and design	• Key study details (title, PI name, sponsor) are not well differentiated from main content • Section I. Can I cancel my permission? Presents a series of options in prose form, requiring the audience to read (vs. skim) • Uses all sans serif fonts when document is presented in print format	Use call out box to draw attention to key points for easy reference Use bulleted lists to: • Help readers skim and scan • Make it easy to identify all steps in a process Use sans serif for headings, serif font for body text when document is presented in print format
Actionability[21]		
Uses visual aids	Initial spaces are located at the end of sentences making them difficult to spot	Use visual aids to make it easier to act on the instructions • Align initial spaces along the left margin • Make initial spaces or check boxes bold
Provides simple instructions	Spreads action items (check boxes and initial sections) throughout the document	Consolidate choices and organize information into manageable, explicit steps

took place in California with one HIPAA form using a Central-IRB mechanism and may not be generalizable for other HIPAA forms or IRBs. We also did not control for unmeasured confounders; however, there were no statistically significant differences in the two groups after randomization based on the variables we were able to measure. It is also unclear whether our efforts to include an easy-to-read (5th grade level) one-page explanation about the HIPAA form led to more people signing the form or fewer people signing and returning the form due to the stark difference between the easy-to-read cover letter and the standard form and/or due to privacy concerns. We also do not have data from patients about the effects of the HIPAA language on their mistrust or their decision not to enroll in the study.

Inclusion of a HIPAA authorization in mailed enrollment packets for a large pragmatic trial led to lower rates of study enrollment compared to not including this form. HIPAA authorizations should be redesigned to be more accessible for patients of all literacy levels to prevent unnecessary mistrust and barriers to research enrollment.

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