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Randomized Trial Showed an “Embedded” Survey Strategy Optimized Authorization Rates Compared to Two “After Survey” Strategies in Veterans with PTSD

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Abstract

Objectives: To test methods to optimize mail survey response and authorization rates (i.e., allowing one’s survey to be linked to medical records) when the survey is sensitive and the targeted population has a mental disorder.

Study Design and Setting: Randomized controlled trial of 1,099 veterans treated for posttraumatic stress disorder (PTSD) at a Midwestern VA Medical Center. Subjects were randomized to one of three groups: 1) Health Insurance Portability and Accountability Act (HIPAA) authorization form embedded in the survey (checking “yes” for consent), 2) HIPAA form requiring signature for consent sent after the survey, or 3) HIPAA form requiring a signature and social security number for consent sent after the survey.

Results: The “embedded” strategy yielded the lowest survey response rate (67.5%) but highest authorization rate (59.1%). Requiring respondents’ signature and social security number after the survey was returned generated the highest survey response rate (74.2%) but lowest authorization rate (48.7%). However, the response rate difference was not statistically significant. Reported emotional upset was low (1.5%) and primarily directed to the survey, not the HIPAA form. Older age and greater trustfulness were associated with higher authorization rates.

Conclusion: Even with our most optimized strategy, authorization rates were disappointingly low.

Keywords

Authorization; Health Insurance Portability and Accountability Act; HIPAA; Randomized trial; Patient surveys; Posttraumatic stress disorder

1. INTRODUCTION

Meeting the health care needs of the approximately 1.5 million veterans affected by posttraumatic stress disorder (PTSD), particularly those returning from deployments to Iraq

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and Afghanistan, is a national and Department of Veterans Affairs (VA) priority. However, to address this priority, researchers, clinicians, and policy makers must first understand these veterans' symptom severity, related concerns, and current health care utilization patterns. Mailed surveys can efficiently obtain individual-level information about symptoms and concerns from large numbers of people, but are notoriously inaccurate for relaying patterns of health care utilization [1]. Conversely, administrative data are well-suited for identifying health care utilization patterns, but tend to be incomplete in terms of individual-level diagnoses, symptoms, and concerns [2]. Combining the two should lead to better ascertainment of veterans' health care needs, concerns, and utilization patterns.

Unfortunately, obtaining the consent needed to link survey responses to participants' medical records requires much time and effort [3–7] and may be even more difficult when targeting a population with mental illness. For example, veterans and soldiers frequently describe PTSD as something “weak” people get. Many resist the diagnosis and find it stigmatizing [8]. They may therefore be reluctant to disclose such symptoms to others, and they may carry especial concerns about their medical information's confidentiality [9, 10]. Hypervigilance and anxiety, two cardinal PTSD symptoms, likely impede the development of trusting relationships (e.g., [10]), which could cause some sufferers to question researchers' motives when asked for medical record access. Others might opt out of surveys that ask about trauma-related symptoms for fear of intensifying those very symptoms.

Aspects of the Health Insurance Portability and Accountability Act (HIPAA) authorization form might further inhibit some PTSD sufferers' willingness to return surveys or to release their medical records. Many institutions' HIPAA forms require research participants' signatures and social security numbers, which have been shown to suppress consent rates even in general populations [11]. For example, Beebe et al. [12] obtained 220 ultimately unusable telephone interviews because interviewees did not return their HIPAA authorization forms, and Singer [13] showed that requiring signatures on informed consent documents suppressed interview response rates by 8 full percentage points—not because respondents refused the interview, but because they didn't want to sign.

Because many Human Studies committees are reluctant to grant HIPAA waivers of authorization, researchers have begun investigating strategies to optimize survey return and authorization rates (“authorization rate” is the percentage of subjects who allow their survey responses and medical records to be linked). Previously, we found that embedding HIPAA authorization forms with a mailed survey resulted in response rates comparable to when we mailed the forms after the survey [14]. The “embedded” approach also yielded a more representative sample of consenters than the “after survey” approach. Importantly, although not the study's main focus, veterans with PTSD were twice as likely to release their medical records using the “embedded” approach compared to the “after survey” approach (68% v. 34%, respectively). However, we targeted a relatively well-educated, retired population and addressed a pro-social behavior (getting screened for colorectal cancer). While promising, it was unclear whether our findings would pertain to a survey focusing on mental health.

In the present study, we tested three different strategies' effect on survey response and authorization rates in a population of veterans with PTSD. The survey explicitly assessed

PTSD symptoms. As previously, we examined the HTPAA form's timing (embedding it and sending it with the survey or sending it separately after the survey). However, we also manipulated the form itself, so that veterans who received a HIPAA form after returning the main survey were randomized to provide their signature alone or their signature and social security number both. In the "embedded" arm, signing the form or supplying a social security number would have clearly linked individuals to potentially sensitive information, so we did not request either.

We hypothesized that survey response rate would be highest when the HIPAA form was sent after the survey's return, but authorization rate would be highest when the HTPAA form was embedded in the survey, and authorization rate would be lowest when the HIPAA form required both a signature and social security number. Since the survey topic was sensitive and these manipulations varied in intrusiveness, we anticipated that emotional upset would be highest among veterans randomized to receive a HIPAA form requesting both their signature and social security number. We also expected greater symptom severity and higher distrust to be associated with lower authorization rates regardless of strategy, and that distrust's effects on authorization would be greatest among veterans required to provide a social security number.

2. METHODS

2.1 Assignment

2.1.1 Population and setting—Subjects were all 1,099 patients enrolled in the Minneapolis VA Medical Center's Posttraumatic Stress Recovery Clinics who did not receive medical care from the first author.

2.1.2 Study Design—This was a randomized controlled trial designed to assess survey response and authorization rates. We were allowed to manipulate the HIPAA authorization form only because we did not actually access veterans' medical records. HIPAA documents require specific, meaningful descriptions of the personal health information to be gathered, who will access the information, how it will be used, the date authorization expires, and the participant/legal representative's signature, plus date of signature [15]. However, many institutions, including VA medical facilities, also require participants' social security numbers. Because we were making a one-time request for health information, our form did not specifically list an expiration date. We also did not ask participants to date their signature, which was an oversight. Subjects were randomized to one of three strategies:

Strategy 1 ("embedded"): 367 subjects received a one-page HIPAA authorization form requesting permission to link their survey responses to their medical records. The form was embedded into the next-to-last page of the main survey and complied with core HIPAA requirements, as described above, except that it did not include a signature or date line. Instead, checking a "yes" or "no" box signified whether we had authorization.

Strategy 2 ("after survey, signature only"): 367 subjects received the main survey without an embedded request. Once they returned their main survey, we mailed a separate

HIPAA authorization form. Respondents' signified their authorization to link survey and medical information by checking a "yes" box and signing the form.

Strategy 3 ("after survey, signature plus SSN"): 365 subjects received the main survey without an embedded request. After they returned their main survey, we mailed a separate HIPAA authorization form. Respondents signified their authorization by checking a "yes" box, signing the form, *and* providing their social security number (SSN).

- Except for the authorization request embedded in Strategy 1, main surveys were identical. We used the same wording and font for all 3 HIPAA authorization forms. However, to improve readability, Strategies 2 and 3 HIPAA forms had more highlighting and covered two pages. Lines were also provided for participants' signature and social security number.

2.2 Protocol

Subjects were mailed an 8-page questionnaire ("main survey"). We included a \$2 cash incentive and cover letter that described the study's risks and benefits and emphasized the voluntary nature of subjects' participation. The survey's return signified veterans' consent to participate. At two-week intervals, non-respondents were mailed a postcard-reminder and two more surveys.

Veterans randomized to Strategies 2 and 3 received an additional \$2 incentive and cover letter requesting they complete and return their HIPAA form. Those who didn't return a form received a post-card reminder and two additional forms at two-week intervals.

2.2.1 Main Outcome Variables—Main outcome variables were *main survey response rate*, *authorization rate*, and *rate of emotional upset*. We calculated the main survey response rate by dividing the number of returned surveys by the number of veterans randomized to each strategy. Authorization rate was calculated by dividing the number of veterans who provided all the required information for authorization (e.g., for Strategy 3, checked the "yes" box, signed their name, and provided their SSN) by the total number of veterans randomized to that strategy. Rate of emotional upset was calculated by dividing the number of all veterans who spontaneously reported emotional upset to the survey by the total number of veterans randomized. To identify cases of emotional upset, we used Halek et al.'s [16] methods to qualitatively evaluate the content of veterans' telephone calls, letters, and written comments. Questionable cases of upset were adjudicated by consensus of the study team.

2.2.3 Correlates of Response and Authorization Rates—Respondents' *sociodemographic characteristics* were ascertained using single-item survey questions. *PTSD symptoms* were assessed using the Penn Inventory for PTSD ("Penn Inventory") [17]. We created a single-survey item that followed the Penn Inventory's format to assess *distrust*. Accordingly, respondents were asked to pick the one sentence that best described their past-week's feelings. Response options were: 0 ("I believe most people can be trusted"), 1 ("Outside of friends and family, only a few people can be trusted"), 2 ("The only people I can trust are really close friends and family"), or 3 ("I cannot trust anyone").

2.3 Analysis

We used intention-to-treat analysis. Cross-strategy differences and characteristics of authorizing *v.* non-authorizing veterans were compared using Yates' continuity-corrected χ^2 or Student's *t* tests. We used univariate analysis of variance to examine potential strategy-by-respondent characteristic interactions on authorization rates.

2.4 Masking, Disclosures, and Ethical Approval

Data collectors and analysts were aware of study group assignment. The Minneapolis VA Medical Center's Subcommittee for Human Studies approved the study's protocol.

3. RESULTS

3.1 Main Outcomes

Overall, 71.2% of veterans returned surveys, 53.3% authorized linking their surveys and medical records, and 1.5% spontaneously reported emotional upset to the survey. Outcomes across the three strategies were not significantly different (Table 1). However, the authorization rate for the "embedded" strategy was significantly higher when compared to the two "after" strategies ($p < .001$). Pairwise-comparisons indicated that authorization rates in the embedded strategy were significantly higher relative to the "after survey, signature plus SSN" strategy ($p = .006$). Emotional upset ranged from 0.5% to 1.9% across strategies, and pairwise-comparisons identified no significant between-strategy differences. Of the 17 veterans who reported emotional upset, 16 conveyed upset to the main survey and just 1, to the HIPAA form.

3.3 Correlates of Response and Authorization Rates

Respondent characteristics, including PTSD symptom severity and distrustfulness, did not significantly differ by strategy (Table 2). The 17 veterans who spontaneously reported emotional upset were less likely than other veterans to return a main survey (41.2% *v.* 71.7%, $p = 0.001$), but there was no interaction between response rate, emotional upset, and strategy ($p = 0.09$). Table 3 indicates that, when combining respondents across all three strategies, authorizers tended to be older and more trustful than non-authorizers. Although emotional upset was low in both groups, authorizers were almost 8 times less likely than non-authorizers to have spontaneously reported emotional upset to the survey. Interactions between strategy, respondent characteristics, and authorization rates were not statistically significant.

4. DISCUSSION

In this sample of veterans with PTSD, an embedded HIPAA authorization form yielded significantly higher authorization rates than two "after survey" strategies. The embedded form, however, was associated with a non-significant reduction in survey response rate. Regardless of strategy, spontaneously reported upset to the survey was low.

Prior research evaluating HIPAA-type authorization forms and mailed survey responses has been mixed. Two studies identified essentially no effect [14, 18], while a third showed that a

HIPAA form mailed with the survey reduced response rates fifteen full percentage points compared to when it was mailed afterwards [7]. A fourth study using mixed mail- and telephone-modes showed a similar 15 percentage-point reduction when using a HIPAA form versus omitting it altogether [12]. Our findings were somewhat intermediate between these, with the embedded HIPAA form reducing response rates by up to six full percentage points compared to when it was sent after the survey. Although potentially clinically important, the difference was not statistically significant.

Unexpectedly, severer PTSD symptoms were not associated with lower authorization rates. Furthermore, despite targeting veterans with PTSD, our authorization rate was similar to that reported for more general patient samples and for some national probability samples. In all such studies, however, authorization rates have been disappointingly low, ranging from approximately 26% [7, 19, 20] to about 50%–60% [6, 11, 14, 20]. While low authorization rates do not necessarily result in biased samples, risks for bias do increase as participation rates decrease [21], and most prior studies have identified important differences between authorizers and non-authorizers. For example, as in the present study, authorizers tend to be significantly older than non-authorizers [6, 11, 14, 22].

Although Damschroder et al. [9, pg. 223] recently concluded that trust was the “most powerful determinant” of how much control patients wanted over their medical records, previous research has not directly investigated the impact of distrust on authorization rates. Per our expectations, higher distrust was associated with lower authorization rates. Whether because of distrust or for other reasons, the impulse of people with potentially stigmatizing conditions to protect their health information is understandable. Yet population-based research—as opposed to research limited to authorizing participants—has been identified as one of the “most effective tools to battle against ... stigma associated with psychiatric disorders and treatment” [23, pg. 1731]. As Simon et al. [23] note, population-based studies using large administrative data have been critical in identifying best-practices gaps in depression treatment and in describing the impact of restricting insurance coverage for mental health on clinical outcomes. However, when access to such databases becomes biased according to a characteristic that is also associated with study outcomes, findings are likely to be flawed and even misleading. By denying medical records access to researchers, some disadvantaged groups may undermine their own advocacy.

Based on Singer’s [13] findings that signature-requests function much like a sensitive question in suppressing research participation, we expected our request for social security numbers to be particularly intrusive and sensitive. However, authorization rates were only minimally suppressed in the “signature plus SSN” group relative to veterans randomized to the “signature only” group. Nor did distrust interact with the social security number requirement to suppress authorization rates, though each was independently predictive. Compared to civilians, veterans may be relatively inured to disclosing their social security numbers to VA personnel since social security numbers are routinely used for dispensing VA benefits, collecting payments, and tracking medical information. For some veterans, asking for a social security number may actually have legitimized our request to access their medical information. It would be interesting, therefore, to see if our findings generalize to civilian samples.

Although reporting emotional upset substantially reduced veterans' odds of authorizing access to their medical records, overall, emotional upset to the survey appeared to be very low. This corresponds with other research showing that surveys asking about trauma or trauma-related symptoms are well tolerated [24]. Despite more opportunities to be upset in the two "after survey" strategies compared to the embedded strategy, emotional upset was not significantly increased in those arms, and only one participant expressed upset to the "after" HIPAA form.

This study had several strengths, including its randomized, controlled design. However, it was limited to a single VA medical facility and may not generalize to other institutions, civilians, or individuals with other mental disorders. Reasons underlying the embedded strategy's higher authorization rate cannot be definitively determined since it could be related to increased convenience or to the fact that we did not ask participants for their signatures or social security numbers. To maximize the HIPAA form's return in the two "after survey" arms, we sent veterans a more attractively formatted HIPAA form, cover letters to specifically promote its return, and more money. Without these enhancements, authorization rates in the two "after survey" arms would probably have been even lower, and the observed difference between them and the "embedded" strategy, more striking.

The study also relied on research participants' initiative to convey their feelings of upset and hence probably underestimated the actual rate. Unmeasured confounders could have been conflated with variables that were measured. For example, the aversive homecoming experiences reported by some Vietnam-era veterans [25] could persistently affect their trustfulness of others. Understanding the correlates of distrust and other influences on authorization will be needed if we are to effectively counter authorization bias in research.

Ethical questions related to HIPAA also need exploring. For example, should anyone—even those willing to open their medical data—undertake the inconvenience of completing forms and answering questions if scientifically defensible conclusions cannot be drawn from their responses? Since "after survey" strategies elicit surveys from non-authorizers as well as authorizers, are such strategies appropriate when only linked surveys are usable? The signature requirement and some institutions' extra requirement to collect social security numbers for HIPAA forms may pose additional barriers to maximizing authorization rates [11], yet provide patients with no more practical control over their medical records than checking an "I do/do not allow access to my medical records" box does (cf., [13]). Nor do signatures protect participants against fraud, since few researchers have the wherewithal to verify returned signatures' validity.

Despite limitations, we believe this is the first randomized, controlled study to specifically target a population with mental illness and assess survey methods to increase their participation in linked survey-medical records research. Having extended the literature, we also highlight the need for more investigation. Mailed surveys' ease of administration, relatively low costs, and broad scope make them far too attractive to abandon. Nor is it clear that other, more expensive data collection methods, such as direct, in-person recruitment, would bypass the problem of biased sampling (e.g., [4]).

Because representative sampling is key to generating accurate scientific conclusions and because it is arguably unfair to ask participants to engage in research that will not generate accurate conclusions, full HIPAA waivers of authorization may be appropriate for selected studies, particularly if they involve underserved or disadvantaged populations. Studies granted such waivers must submit to vigorous Human Studies oversight, however. Until representative research participation among the mentally ill can be assured, we risk drawing flawed conclusions from those who do participate.

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What is New?

- **Key Findings:** In this population, a sensitive survey topic and Health Insurance Portability and Accountability Act (HIPAA) authorization form were well tolerated. However, even with our most optimized strategy, authorization rates were disappointingly low. Correlates of authorizing linkage between surveys and medical records were older age and being more trustful. PTSD symptom severity was not a correlate. Eliminating the HIPAA form's signature and social security requirement increased authorization rates without compromising patients' control over their medical records.
- **Unique contributions:** To our knowledge, this is the first randomized trial to test strategies to optimize response and authorization rates in people with a mental disorder. It is also the first randomized trial to examine how modifying the HIPAA form influences authorization rates.
- **Implications:** Care must be taken so that flawed conclusions are not drawn from inadvertently biased samples, particularly when studying hard-to-recruit and disadvantaged populations, such as those with mental disorders.

Table 1.

Response Rates, Authorization Rates, and Rates of Emotional Upset by Strategy

	HIPAA Form "Embedded" in Main Survey		HIPAA Form Mailed "After" Main Survey was Returned		p-value
	Strategy 1 HIPAA Form Required Checked "Yes" Box N = 367	Strategy 2 HIPAA Form Required Signature Only N = 367	Strategy 3 HIPAA Form Required Signature plus SSN N = 365		
Main Survey Response Rate, % (N)	67.5 (248)	71.9 (264)	74.2 (271)		0.13
HIPAA Form Return Rate, % (N)	NA	60.4 (222)	60.3 (220)		0.44
Authorization rate, % (N)	59.1 (217)	52.3 (192)	48.7 (178)		0.46
Rate of Emotional Upset, % (N)	0.5 (2)	1.9 (7)	1.9 (8)		0.11

Note: The denominator for all strategy-specific rates is the total number of subjects randomized to that strategy. The strategy-specific numerator used to calculate authorization rates was determined by counting the number of veterans within each strategy who completed all the elements required by their HIPAA form (i.e., in Strategy 1, checked "yes;" in Strategy 2, checked "yes;" and provided the needed signature; and in Strategy 3, checked "yes," signed the form, and provided their social security number).

SSN = Social Security Number. HIPAA = Health Insurance Portability and Accountability Act. NA = Not applicable.

Table 2.

Respondent Characteristics by Strategy

	HIPAA Form “Embedded” in Main Survey			HIPAA Form Mailed “After” Main Survey was Returned	
	Strategy 1 HIPAA Form Required “Yes” Box N = 248	Strategy 2 HIPAA Form Required Signature Only N = 264	Strategy 3 HIPAA Form Required Signature plus SSN N = 271	p-value	
Age, <i>mean (SD)</i>	56.1 (10.1)	54.6 (8.8)	56.2 (9.9)	0.11	
Gender, % <i>male</i>	95.1	91.7	91.9	0.24	
Education, <i>median response</i>	Some college	Some college	Some college	0.46	
Married, % <i>yes</i>	55.7	51.4	54.3	0.66	
Employed, % <i>yes</i>	22.9	23.3	26.1	0.76	
PTSD Symptom Severity ^a , <i>mean (SD)</i>	41.3 (14.0)	41.9 (13.7)	42.4 (14.8)	0.71	
Distressfulness ^b , <i>mean (SD)</i>	1.6 (1.0)	1.6 (1.0)	1.6 (1.0)	0.92	

HIPAA = Health Insurance Portability and Accountability Act. SSN = Social Security Number.

^aHigher scores indicate severer PTSD symptoms.^bHigher scores indicate more distrust.

Table 3.

Respondent Characteristics by Whether They Authorized Linkage Between Survey and Medical Records

	Authorized Linkage n = 587	Did Not Authorize Linkage n = 196	p-value
Age, <i>mean (SD)</i>	56.1 (9.7)	54.4 (9.3)	0.04
Gender, % <i>male</i>	92.3	94.3	0.43
Education, <i>median response</i>	Some college	Some college	0.98
Married, % <i>yes</i>	52.3	53.6	0.82
Employed, % <i>yes</i>	24.9	21.6	0.42
PTSD Symptom Severity ^a , <i>mean (SD)</i>	41.4(13.7)	43.4(15.3)	0.09
Distrustful ness, <i>mean (SD)</i> ^b	1.5 (1.0)	1.7 (0.9)	0.03
Emotional upset, % <i>upset</i>	0.3	2.6	0.02

^a Higher scores indicate severer PTSD symptoms.^b Higher scores indicate more distrust