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The growing complexity of medical care and practice has increasingly brought a number of otherwise independent disciplines into closer working relationships for purposes of mutual education and problem solving. This process is prominently visible in the ways law, ethics, and psychiatry intersect around patient care in the general medical and hospital setting. This special section will publish informative and provocative articles which address these vital matters.

Ethical Considerations in Research Participation Among Acutely Injured Trauma Survivors: An Empirical Investigation

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Abstract: *Posttraumatic behavioral and emotional disturbances occur frequently among physically injured trauma survivors. Despite increasing investigative interest in the evaluation and treatment of psychological distress in acutely injured patients, few studies have assessed ethical considerations surrounding research participation. The authors empirically investigated ethical considerations in research participation among 117 physically injured, hospitalized, motor vehicle accident and assault survivors. Immediately following a 1-hour research interview, participants responded to 10 questions assessing the experience of research participation. The majority of study subjects found participating in the protocol a positive experience. Most of the hospitalized patients reported that they experienced control over initiation and discontinuation of the protocol and that they derived benefit from their research participation. A minority of participants reported that they experienced unwanted thoughts and unanticipated upset during the protocol and that they felt they could not refuse participation. However, over 95% of patients reported that the benefits of protocol participation outweighed the costs and that in retrospect they would again agree to participate. These results suggest that while a minority of participants may have difficulties with specific aspects of protocol enrollment, overall research participation is well tolerated by the majority of acutely injured, hospitalized, trauma survivors.* © 2000 Elsevier Science Inc.

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Introduction

In 1985 and 1992 over 2 million Americans were hospitalized after traumatic physical injury [1,2]. Physically injured trauma survivors may be at high risk for developing posttraumatic behavioral and emotional disturbances [3–6]. Though high quality medical interventions are routinely implemented for physically injured patients, an understanding of the optimal evaluation and treatment protocols for patients suffering posttraumatic distress in these settings is still developing [7].

This increased investigative interest in the evaluation and treatment of acutely injured trauma survivors comes at a time when ethical concerns surrounding research participation by patients suffering psychological disturbance are rising [8–10]. It has been suggested that research with trauma victims requires an increased attention to ethical considerations beyond the standard guidelines for conducting research with human participants [11]; these concerns are heightened among acutely injured patients for several reasons. Acutely injured patients often surrender control over emergency care decisions and frequently undergo treatment procedures about which they may have minimal awareness or understanding; traumatically injured patients may therefore come to passively accept loss of autonomy as an unavoidable circumstance of their hospitalization. Also, the traumatic injury and subsequent medical procedures induce

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psychological distress which could be exacerbated by research participation.

Thus, the processes of care surrounding traumatic physical injury raise a series of concerns regarding the autonomy and well-being of potential research participants [12]. First, does participation in research that elicits memories of the traumatic event and evaluates posttraumatic symptom levels adversely impact the participant by exacerbating psychological distress? Second, do participants feel a sense of control over the process of participation? That is, do they feel they are able to refuse or discontinue participation? Third, with regard to the process of informed consent, are injured trauma survivors able to accurately predict levels of distress prior to engaging in research protocols? In retrospect would they again agree to participate? Last, beyond the potential threats to participant well-being and autonomy posed by investigative protocols, are there potential benefits of patient participation in trauma research?

Recent commentary has suggested that questions about reactions to participation in studies of traumatic stress should be submitted to empirical investigation [12,13]. Empirical investigation of ethical considerations in trauma research is needed in order to inform decision making by Institutional Review Boards and investigators regarding the potential risks and benefits of particular study designs [14]. Our literature review, however, revealed no studies that directly assessed acutely injured patients' experiences with trauma-focused research participation. Two investigations [14,15] assessed subjective distress and satisfaction with research participation among adult female HMO subscribers asked to answer questions regarding the long-term effects of prior sexual and physical victimization. These studies reported that, generally, questions were well-tolerated. Higher levels of posttraumatic stress symptoms were associated with greater subjective distress while completing the questionnaire; however, higher levels of posttraumatic symptoms were not associated with increased global dissatisfaction with participation.

The goal of this investigation was to empirically evaluate ethical considerations in research participation among acutely injured, hospitalized trauma survivors. Our primary aim was to directly assess a broad profile of reactions to research participation including the extent to which participants experienced immediate unanticipated and/or adverse responses, the degree to which participants experienced control over protocol enrollment and discontinuation, participants' understanding of the process of informed consent, and participants' experiences of benefits from protocol enrollment. As suggested by prior research with female HMO subscribers, we hypothesized that the majority of participants would endorse positive experiences with research participation, but that subgroups of patients might express dissatisfaction with aspects of the experience. Thus, we were also interested in identifying demographic, injury, and symptomatic characteristics of participants who endorsed negative experiences with the protocol.

Method

Study Site and Participants

The UC Davis Medical Center is the only Level I trauma center in inland Northern California; it provides care to the population of patients who reside in Sacramento County and to the residents of 22 other inland Northern California counties. Between 2500 and 3000 physically injured trauma victims are admitted to the trauma surgery service each year. Approximately 70% of those admitted are victims of motor vehicle accidents and violent assaults.

Participants approached for inclusion in the study were motor vehicle accident and assault survivors between the ages of 14 and 65 who were English speaking, and had sustained mild-to-moderate physical injury. Participants who had sustained severe head, spinal cord, or other injuries (Maximum Abbreviated Injury Scale scores (AIS) $\geq$ 5) [16], were excluded from the protocol. All participants approached for the study were hospitalized for at least 1 day but not more than 9 days.

One hundred and seventeen participants were recruited into the protocol. Patient ages ranged from 14 to 61 with a mean of 33 years of age and a standard deviation of 12 years; 10 participants were between 14 and 18 years old. Approximately one-third of participants were female; approximately two-thirds were admitted to the hospital as a sequelae of motor vehicle accidents, and one-third after violent assaults. Participants were from diverse racial backgrounds including white (N = 57, 48%), African American (N = 20, 17%), American Indian (N = 13, 11%), Hispanic (N = 8, 7%), Asian (N = 4, 4%), and other (N = 15, 13%) backgrounds. Approximately one-third of participants reported that they lived alone. Over 50% of participants had yearly incomes of $15,000 or less

and 39% had educational experience beyond high school.

Participant Recruitment and the Process of Informed Consent

All informed consent procedures were approved by the UC Davis Institutional Review Board prior to the study. After a surgical chart review assessing inclusion criteria, eligible patients were approached on the surgery ward by a research associate. Research associates gave each hospitalized patient a brief verbal overview of the protocol and asked participants whether or not they would be interested in hearing a more detailed description of the study. If a subject decided to listen to more details of the protocol the research associate gave a copy of the consent form to the subject and read aloud the entire form, allowing participants to ask questions or voice concerns. The following general principles of informed consent were outlined in the consent form [17]: 1) voluntary participation, 2) the right to refuse or withdraw from the protocol at any point in time, 3) that participation, refusal, or withdrawal from the protocol would in no way impact the participants' ongoing medical care, 4) a description of the risks and benefits of participation, including the statement that the study entailed a risk that the subject may find some of the questions distressing, 5) the nature and extent of confidentiality, 6) identification of whom to contact for problems that occurred in the course of the research protocol, 7) a discussion of payment for the protocol that included notification that as participants they would receive a $10 reimbursement immediately following the ward interview, and 8) that the subject would receive a copy of the consent form as well as a copy of the experimental subjects bill of rights. For participants under the age of 18, adolescent assent and parental consent were obtained.

Procedure

After obtaining informed consent, study participants were administered a 1-hour interview. Initial attempts to administer self-report checklists met with feasibility problems, because many hospitalized trauma survivors had difficulties with mobility, vision, and the use of extremities. Therefore, the research team constructed large print cards outlining the responses for each scale. Cards were visually presented to patients and scale items were simultaneously read aloud by the research associate. The interview included questions regarding subject demographic characteristics, prior traumatic history, psychological symptoms, alcohol and drug use, physical health and functional status, utilization of medical services, and satisfaction with care. Immediately following completion of the interview, patients were asked to respond to 10 additional interview questions assessing their reactions to research participation.

Interview Items

Ethical Considerations in Research Participation. Ethical concerns were assessed with 10 items from the Reactions to Research Participation Questionnaire (RRPQ) (unpublished data). The RRPQ is a 60-item scale designed to evaluate participants' reactions to specific aspects of research participation. It has been found to have good internal consistency and split-half reliability [18]. Research participants are asked to indicate their degree of agreement with the RRPQ items on a 5-point Likert scale with anchors "False," "Mostly False," "Uncertain," "Mostly True," and "True."

We limited our selection to 10 items in order to decrease response burden in these acutely injured, hospitalized patients. Our item selection followed methods described by prior studies in the emerging area of empirical investigation of ethical considerations among research participants [14,19]. At the time of protocol implementation, our review revealed no validated brief instruments designed to assess reactions to research participation among traumatically injured patients. Thus, 10 RRPQ items with face validity for the ethical considerations we wished to evaluate were selected (see Table 1). Two items were selected to assess whether participation in acute trauma research resulted in immediate unanticipated and/or adverse responses (Table 1, questions 1 and 2). Two items were selected to assess participants' retrospective "cost-benefit" [14] assessment of protocol enrollment (Table 1, questions 3 and 4). Three items assessed the patient's experience of control over initiation and discontinuation of protocol enrollment (Table 1, questions 5–7). A single item was included to directly assess the participant's understanding of the consent form (Table 1, question 8). Last, the participant's global satisfaction with and perceived benefit from research participation was assessed (Table 1, questions 9 and 10).

Table 1. Likert Scale responses (N = 112) to questions regarding ethical considerations in research participation

Question	False N (%)	Mostly False N (%)	Uncertain N (%)	Mostly True N (%)	True N (%)
1) "The research made me think about things I didn't want to think about."	58 (52)	8 (7)	10 (9)	18 (16)	18 (16)
2) "Participating upset me more than I expected."	87 (78)	8 (7)	4 (4)	6 (5)	7 (6)
3) "Had I known in advance what participating would be like for me I still would have agreed."	1 (1)	1 (1)	3 (3)	7 (6)	100 (89)
4) "Participating in this project was worth it, despite any inconvenience I experienced."	2 (2)	0 (0)	8 (7)	11 (10)	91 (81)
5) "I felt like I couldn't say "no" to participating."	85 (75)	2 (2)	4 (4)	5 (5)	16 (14)
6) "I felt free to skip questions and/or parts of the study."[a]	5 (5)	1 (1)	5 (5)	9 (8)	91 (81)
7) "I felt I could stop at any time."	2 (2)	1 (1)	3 (3)	9 (8)	97 (86)
8) "I understood the consent form."	2 (2)	0 (0)	4 (4)	6 (5)	100 (89)
9) "I gained something positive from participating."	4 (4)	2 (2)	17 (15)	16 (14)	73 (65)
10) "Volunteering made me feel good about myself."	4 (3)	1 (1)	16 (14)	13 (12)	78 (70)

[a] One subject did not respond to this item

Posttraumatic Stress Symptoms. Levels of posttraumatic stress disorder (PTSD) symptoms were assessed using the civilian version of the Post-Traumatic Stress Disorder Checklist (PCL-C; [20]). The PCL-C is a 17-item self-report measure that elicits responses for each of the DSM-IV symptoms used in diagnosing PTSD. Weathers et al. [20] found good test-retest reliability (0.96) for the measure. In a study of motor vehicle accident and assault survivors, Blanchard et al. [21] reported a correlation of 0.93 between PCL total score and the Clinician-Administered PTSD Scale [22] total score. The instrument has been used in an interview format with medically ill breast cancer patients [23]. In the current study, responses were anchored in time to the traumatic event that brought participants to the hospital; for each item participants were asked to rate, "How bothered you have been by these experiences since your injury?" Responses to each of the 17 items were recorded on a scale from (1) "not at all" to (5) "extremely."

Depressive Symptoms. We used the Center for Epidemiological Studies Depression Scale (CES-D) [24], a 20-item self-report instrument to measure levels of depressive symptoms. The CES-D has been used extensively to evaluate depressive symptoms in patient populations presenting for care outside of the mental health specialty sector. Response format is a 4-point scale (0–3) used to indicate frequency of experiencing symptoms in the past week; responses range from "rarely or none of the time" (less than 1 day) to "most or all of the time" (5–7 days). For purposes of the study, patients were asked to indicate "How often you have felt this way since the event that brought you to the hospital?" The measure has good internal consistency and convergent validity [24]. The CES-D has been used in an interview format among hospitalized stroke survivors [25].

Peritraumatic Dissociative Symptoms. The Peritraumatic Dissociative Experiences Questionnaire (PDEQ) [26] measures dissociative experiences at the time of the traumatic event. We used the 8-item interview version of the instrument that includes experiences of change in sense of time, feelings of unreality, and feelings of disorientation. Across several studies, the measure has been demonstrated to be internally consistent and evidence

supports its convergent, discriminant, and predictive validity [3,27].

Traumatic Life Events. We used a modified version of the traumatic event inventory that accompanies the Composite International Diagnostic Interview (CIDI)-PTSD module as developed for the National Comorbidity Survey (NCS) [28]. Participants are asked if any of 12 events (i.e., combat, life-threatening accident, natural disaster, witnessing injury, rape, molestation, physical assault, physical abuse, child neglect, threatened with a weapon, held captive or kidnapped, or great shock) have ever happened to them. Yes or No responses to each event are recorded by the interviewer. We modified the inventory by asking "For each event, please tell me if it has happened to you before the event in which you were injured."

Alcohol and Drug Use. Two questions from the drug and alcohol use module of the Addiction Severity Index (ASI) [29] were used to assess the number of days in the past month that participants had used alcohol or illicit drugs.

Data Analyses

Because negatively affected participants may have dropped out of the investigation prior to completion, we first tracked subject flow through the protocol and compared the demographic and injury characteristics of those participants who completed the protocol with those who refused or interrupted their participation. Next, among those participants who completed the protocol we ascertained the frequency distributions of responses for the 10 RRPQ items.

We were also interested in assessing symptomatic, demographic, and injury characteristics that identified substantial subgroups of participants who responded negatively to research participation. However, for 7 of the 10 RRPQ items, participants with negative reactions to participation constituted 7% or less of the sample. We therefore undertook bivariate analyses only for the three RRPQ items in which greater than 10% of participants endorsed responses indicative of negative reactions to research participation. We divided participants into negative vs positive response groups. Examination of the raw data for continuous variables revealed distributions approximating normality; therefore, *t*-tests were used to compare the means of the groups on the PCL-C, CES-D, PDEQ, NCS traumatic events inventory, ASI items, and age. We used the χ^2 statistic to compare the groups along the following dichotomized injury and demographic characteristics: motor vehicle accident vs assault mechanism of injury, gender, education greater than, less than, or equal to high school, white/other vs minority (i.e., African American, American Indian, Asian, Hispanic) racial status, living alone vs living with others, and income greater than, less than, or equal to $15,000/year. When expected counts fell below five subjects in any one cell, Fisher's exact test was used. The SPSS statistical package release 8.0 was used for the data analyses [30].

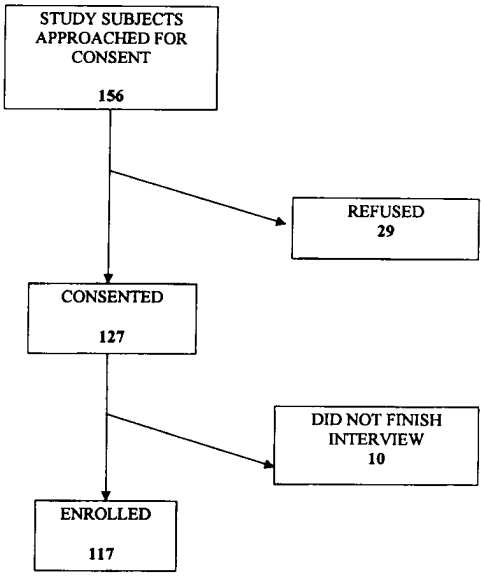

Figure 1. Subject flow through protocol.

Results

Of the 156 patients approached on the surgical ward for participation in the study, 127 signed consent forms and began the structured interview (Figure 1). Among the 29 participants who refused participation, 11 declined because physical injuries prevented participation, 3 reported not being interested, 1 was discharged before questions could be administered, 1 was participating in another study, 1 reported that the hour interview would be too long, and 12 had unknown reasons for refusing. Ten of the 127 patients who signed the consent form did not finish the interview. Two patients stopped

the interview during its administration and eight participants had the interview interrupted by procedures or discharge. Participants who did not enroll or complete the interview (N = 39) did not differ from completers (N = 117) with regard to age [(t(df = 154) = 0.99, p = 0.33), gender (χ^2(df = 1) = 0.45, p = 0.49)], and assault vs motor vehicle accident injury status [χ^2(df = 1) = 0.04, p = 0.84].

Of the 117 enrolled participants, 112 completed the 10 RRPQ items (Table 1). For 9 of the 10 items, over 75% of subjects endorsed responses indicative of positive experiences with the protocol.

The two RRPQ questions that assessed whether participation in acute trauma research resulted in unanticipated and/or adverse responses were among the items for which participants most frequently endorsed negative reactions (Table 1). Thirty-two percent (N = 36) of participants endorsed the "Mostly True" or "True" responses to the statement, "The research made me think about things I didn't want to think about," and 12% endorsed the "True" or "Mostly True" responses to the statement, "Participating upset me more than I expected."

In contrast, few participants endorsed negative responses to RRPQ items that assessed the retrospective cost-benefit of protocol participation (Table 1). Only two participants responded "Mostly False" or "False" in response to the statement, "Had I known in advance what participating would be like for me I still would have agreed." Likewise, only two participants endorsed "False" in response to the statement, "Participating in this project was worth it, despite any inconvenience I experienced."

Twenty-one participants (19%) answered "Mostly True" or "True" to the statement, "I felt I couldn't say "no" to participating. Few participants, however, responded negatively to other questions assessing perceived control over research participation. Three participants endorsed "Mostly False or False" responses to the statement "I felt I could stop anytime," and six participants endorsed "Mostly False" or "False" responses to the statement, "I felt free to skip questions and/or parts of the study." Over 90% of participants reported that they understood the consent form.

The majority of participants reported that they derived benefit from their research participation (Table 1). Approximately 80% responded "Mostly True" or "True" to the statements "I gained something positive from participating" and "Volunteering made me feel good about myself." Although few participants responded negatively to these items, approximately 15% endorsed "Uncertain" responses to these two statements.

Participants who responded "Mostly True" or "True" to the question "The research made me think about things I didn't want to think about," were significantly more likely to have higher PTSD and depressive symptom levels (Table 2). Participants who endorsed negative responses to this item were significantly more likely to be older than those who endorsed positive responses. In order to assess whether there was a unique association between symptomatic patients and negative research experiences we controlled for the effect of age with partial correlations. In these analyses the associations between PTSD (r = 0.30, $p < 0.01$) and depressive (r = 0.27, $p < 0.01$) symptoms and negative responses on the RRPQ item remained significant.

Participants with higher PTSD symptom levels and who were hospitalized after physical assaults were more likely to endorse "True" or "Mostly True" responses to the statement "I felt I couldn't say 'no' to participating" (Table 2). Older participants and participants with greater physical injury severity were significantly more likely to respond "True" or "Mostly True" to the statement, "Participating upset me more than I expected." There were no statistically significant differences between negative and positive responders on any of the RRPQ items with regard to peritraumatic dissociative symptoms, lifetime trauma, alcohol or drug use past 30 days, gender, race, living alone, or income.

Discussion

To our knowledge this is the first investigation to empirically assess ethical considerations in research participation among acutely injured trauma survivors. We found that over 75% of respondents derived some benefit from participating in the research protocol. Over 70% experienced control over their ability to initiate or discontinue protocol participation. Also, the observation that at least 17 hospitalized patients were able to either decline participation or stop the interview once it had started is further evidence of the ability of participants to autonomously choose to engage in protocol participation.

As hypothesized, subgroups of participants reported negative reactions to protocol participation. Over 30% of subjects reported that they had unwanted thoughts as a result of research participation, 12% reported unanticipated emotional upset,

Table 2. Symptomatic, demographic, and injury characteristics of participants with negative and positive reactions to research participation

	Unwanted thoughts			Couldn't Say 'No' to participating			Unexpected Upset		
	True[a] (N = 36)	False[b] (N = 66)		True[a] (N = 21)	False[b] (N = 87)		True[a] (N = 13)	False[b] (N = 95)	
Variable	Mean (SD)	Mean (SD)	t (df = 100)	Mean (SD)	Mean (SD)	t (df = 106)	Mean (SD)	Mean (SD)	t (df = 106)
Posttraumatic stress symptoms (PCL-C)	44.7 (12.1)	35.4 (13.6)	3.4[c]	43.7 (17.0)	36.9 (12.7)	2.1[d]	44.0 (16.5)	37.7 (13.7)	1.4
Depressive symptoms (CES-D)	29.7 (8.9)	23.1 (12.0)	2.9[c]	25.6 (11.6)	25.4 (11.3)	0.1	28.8 (11.1)	25.2 (11.2)	1.2
Dissociative symptoms (PDEQ)	1.8 (0.6)	1.9 (0.7)	−0.5	1.9 (0.7)	1.9 (0.7)	−0.3	2.0 (0.9)	1.9 (0.6)	0.8
Alcohol use, days past 30 (ASI)	5.8 (8.6)	6.1 (8.6)	−0.2	8.6 (10.8)	5.4 (8.2)	1.5	3.0 (4.9)	6.4 (9.2)	−1.2
Drug use, days past 30 (ASI)	5.0 (10.6)	6.8 (11.5)	−0.7	7.0 (12.2)	6.0 (11.2)	0.3	3.5 (9.0)	6.5 (11.5)	−0.9
Lifetime traumas (NCS)	4.6 (2.4)	4.4 (2.6)	0.3	5.1 (2.5)	4.3 (2.5)	1.2	4.5 (2.5)	4.8 (2.3)	0.6
Injury severity (AIS)	2.1 (1.0)	2.3 (0.9)	1.4	2.3 (0.9)	2.3 (0.9)	0.3	2.8 (0.7)	2.2 (1.0)	2.3[d]
Age (years)	36.7 (11.8)	31.5 (10.9)	2.2[d]	38.3 (10.3)	32.9 (12.0)	1.9	39.9 (13.3)	32.7 (11.5)	2.2[d]
Variable	N	N	χ^2 (df = 1)	N	N	χ^2 (df = 1)	N	N	χ^2 (df = 1)/ FET[c]
Assault	14	24	0.1	12	26	5.5[d]	5	32	n.s.[c]
Motor vehicle accident	24	42		9	61		8	63	
Female	16	21	1.6	5	34	1.7	4	36	n.s.[c]
Male	20	45		16	53		9	59	
Education ≤ high school	22	40	0.0	14	50	0.5	7	57	0.2
Education > high school	14	25		7	36		6	37	
White/Other	23	40	0.1	13	54	0.0	8	59	n.s.[c]
Minority	13	26		8	32		5	35	
Living alone	13	18	0.4	6	26	0.0	7	26	n.s.[c]
Living with others	23	48		15	61		6	69	
Income ≤ $15,000/year	17	33	0.1	9	45	0.3	6	50	0.5
Income > $15,000/year	16	30		10	38		7	39	

PCL-C = Posttraumatic Stress Disorder Checklist; CES-D = Center for Epidemiological Studies Scale; PDEQ = Peritraumatic Dissociative Experiences Questionnaire; ASI = Addiction Severity Index; NCS = National Comorbidity Survey; AIS = Abbreviated Injury Scale Score

[a] "True" and "Mostly True" Responses = Participants with Negative Responses to Protocol Participation

[b] "False" and "Mostly False" Responders = Participants with Positive Responses to Protocol Participation

[c] (FET) Fisher's Exact Test result

[d] $p < 0.05$

[e] $p < 0.01$

and 19% felt they could not decline protocol enrollment. However, over 95% of patients reported that the benefits of protocol participation outweighed the costs and that in retrospect they would again agree to participate. These results suggest that while a minority of participants may have difficulties with specific aspects of protocol enrollment, overall, research participation is well tolerated and may actually benefit the majority of physically injured trauma survivors.

Our results are consistent with the limited previous empirical work examining reactions to participation in trauma-focused research. As part of their study of the long-term effects of prior sexual and physical victimization, Newman et al. [14] and Walker et al. [15] included a 3-item version of the RRPQ that assessed unanticipated upset, retrospective cost-benefit, and perceived benefit from participating. The 3 RRPQ items were administered in both a questionnaire to 1174 participants and as an interview to a subsample of 252 women. Seventy-seven percent of women in the Newman et al. and Walker et al. study who completed the questionnaire and 97% of women interviewed reported no regrets over research participation (compared with 94% in the current investigation). Ten percent of women completing the questionnaire and 19% completing the interview reported unexpected upset. On both the questionnaire and interview, participants with higher levels of PTSD symptoms endorsed greater unexpected upset than those with lower PTSD symptom levels. Thus, in both the current investigation and the study reported by Newman et al. [14] the majority of respondents endorsed positive experiences with trauma-focused protocol participation. Subgroups of patients with higher levels of posttraumatic psychological distress endorsed unwanted thoughts, unexpected upset, or difficulty refusing protocol participation. Despite these negative experiences with protocol participation, the majority of subjects in both investigations reported that they would agree again to participate.

Interestingly, though 86% of female HMO subscribers in the interview sample reported deriving some benefit from research participation, only 23% of women completing questionnaires reported some perceived benefit (compared with 91% of participants in the current investigation). This suggests that participants in trauma-focused research may be more likely to perceive benefits from participation when administered interviews rather than questionnaires.

One difference that did emerge between the two investigations was in the association between histories of prior trauma and negative reactions to protocol participation. Though Newman et al. and Walker et al. reported that individuals with histories of maltreatment were more likely to underestimate their level of upset from research participation, we found no association between the number of prior lifetime traumatic events and negative experiences with the protocol.

Within our study, we identified several participant characteristics that inconsistently predicted negative experiences with protocol participation. For instance, older enrolled subjects were more likely to experience unwanted thoughts and difficulty declining protocol entry. Age, however, did not predict which subjects initially refused or discontinued protocol participation. Given that it may be difficult to consistently identify participant characteristics across studies that predict negative experiences with protocol participation, we suggest that investigators conduct ongoing individualized assessments of patient well-being and perceived control throughout trauma-focused protocol enrollment. Beyond the administration of standardized items, future investigations may want to employ open-ended interview questions that elicit more comprehensive assessments of protocol experiences for particularly disaffected individuals such as study dropouts.

There are a number of important considerations in interpreting the results of this investigation. We assessed immediate responses to research participation among hospitalized trauma survivors. It is possible that participants' responses are colored by a positive "institutional transference" that they experience during the acute hospitalization. Negative reactions to research participation may emerge only with time. Future investigations of ethical considerations among acutely injured trauma survivors may want to employ follow-up procedures beyond the inpatient hospitalization, that assess lasting negative reactions to research participation [14]. Also, given the relatively small sample and the few negative responders, we may not have had adequate power to identify many of the individual characteristics that predict negative experiences with protocol participation. Finally, as with prior investigation in this area, we only measured unexpected distress and cannot comment on the absolute level of distress experienced by protocol participants [14].

Beyond these considerations, the information de-

rived from this investigation can aid the decision making of clinical researchers and Internal Review Board members assessing ethical concerns in research participation among acutely injured trauma survivors. Specifically, the results of this investigation support the ongoing implementation of acute phase evaluation and treatment protocols for physically injured trauma survivors. More broadly, the investigation adds to the growing empirical literature on ethical considerations in the conduct of psychiatric research.

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