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Informed Consent: An Ethical Issue in Conducting Research with Male Partner Violent Offenders

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Abstract

Ethical codes help guide the methods of research that involve samples gathered from “at-risk” populations. The current paper reviews general as well as specific ethical principles related to gathering informed consent from partner violent offenders mandated to outpatient treatment, a group that may be at increased risk of unintentional coercion in behavioral sciences research due to court-mandates that require outpatient treatment without the ethical protections imbued upon prison populations. Recommendations are advanced to improve the process of informed consent within this special population and data supporting the utility of the recommendations in a sample 70 partner violent offenders are provided. Data demonstrate that participants were capable of comprehending all essential elements of consent.

Keywords

partner violence; informed consent; court-ordered outpatient treatment

Psychological research often utilizes participants who have been deemed vulnerable due to the nature of their referral or significant physical, mental or psychological impairment. Guidelines exist to protect these individuals throughout the course of their research involvement, including the initial steps of gaining informed consent (American Psychological Association [APA], 2010). Few efforts have been undertaken to assess the effectiveness of consent procedures to meet the basic goal of assuring or verifying patient comprehension to enter into a clear research agreement. Obtaining informed consent from perpetrators of intimate partner violence (IPV) who have been mandated to treatment

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through criminal diversion courts represents one of the many gray areas in an ethical debate about the utility and necessity of gathering informed consent from vulnerable populations. Research is needed to assess whether or not IPV offenders mandated to treatment understand their rights as research participants and perceive their participation as both voluntary and lacking coercion.

In the current paper, we begin with a brief description of consent as well as a review of the ethical progression that resulted in our current standards of obtaining informed consent from research participants. We then discuss the development of IPV as an active area of research and clinical practice as it relates to the criminalization of partner violent acts. After a brief description of general and IPV-specific informed consent research, we describe and evaluate a rigorous informed consent procedure using a sample of court mandated IPV offenders. Finally, we advance 7 recommendations to enhance the process of obtaining valid informed consent in mandated outpatient populations prior to discussing implications for treatment and research.

Background

The distinction between assent and consent has been well established. *Assent* refers to the agreement of an individual to participate in research and must exceed an absence of resistance or objection to participate (US Department of Health and Human Services, 1983). *Informed consent* represents a legal document that, when signed, legally indicates but does not ensure that pertinent information about the study was adequately absorbed by the participant (Syse, 2002). *Valid informed consent* describes a process in which the participant is capable of fully comprehending the presented information and appreciating his or her decision to consent to participating in the course of research (Syse, 2002). All consent requires assent; not all assent implies consent.

While the medical and behavioral sciences strive to improve the human condition, they share a distant history of disturbing research practices. Over the past seventy years, the medical establishment has made advances in assuring the protection of human subjects' mental and physical safety during research studies, an idea now commonly referred to as *respect for persons*. A requirement for the voluntary participation of subjects was included among the earliest regulations set forth by the Nuremberg Code (Washington, DC: US Government Printing Office, 1949). The importance of knowledgeable consent was upheld in the original and each revised draft of the Declaration of Helsinki (World Medical Association, 2000). It was shortly thereafter that the National Institutes of Health (NIH) responded to the publication of a review that examined 50 unethical research studies (Beecher, 1966) by announcing the creation of a set of requirements that would have to be met before a research study could receive approval. This directly resulted in the formation of Institutional Review Boards (IRBs) in the United States to oversee the ethical conduct of researchers who worked with human and non-human subjects. The notion of informed consent became more elaborate over time and was expanded upon to include the three elements of information, comprehension, and voluntariness as well as an introduction of both risks and benefits to subjects by the time of the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

The APA issued the first Ethical Standards of Psychologists text in 1953 (APA, 1953), shortly after the publication of the Nuremberg Code, in an effort to provide an ethical standard governing each professional service performed by Ph.D. level psychologists. The APA has revised this code 9 times as ethical dilemmas in the field have evolved. The Ethical Principles of Psychologists and Code of Conduct document was published on December 1, 1992 and represented a more comprehensive and inclusive set of guidelines than had previously existed (APA, 1992). This document was amended in 2010 (APA, 2010). The APA has established a number of ethical standards to guide the use of human participants in psychological research and states in standard 8, section 2 that

“When obtaining informed consent as required in Standard 3.10, Informed Consent, psychologists inform participants about (1) the purpose of the research, expected duration, and procedures; (2) their right to decline to participate and to withdraw from the research once participation has begun; (3) the foreseeable consequences of declining or withdrawing; (4) reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects; (5) any prospective research benefits; (6) limits of confidentiality; (7) incentives for participation; and (8) whom to contact for questions about the research and research participants' rights. They provide opportunity for the prospective participants to ask questions and receive answers” (p. 12).

The APA ethics code continues on to describe ethical issues as they relate to specific circumstances of informed consent, including treatment research, working with subordinate or vulnerable participants, the use of deception, offering incentives, and general circumstances that would allow for researchers to forego informed consent (APA, 2010). More recently, the American Psychiatric Association published a task force report detailing 12 recommendations for ethical research that also recognized the importance of obtaining informed consent (American Psychiatric Association's Task Force on Research Ethics, 2006).

Beyond the need to conform to organizational guidelines, researchers gather informed consent for a wide variety of reasons. First, as history demonstrates, the protection of each participant's human rights and personal safety must be of primary importance. Similarly, each participant's autonomy must be respected. In the area of criminal diversion, an informed participant understands that participation is not necessary to receive services or avoid additional punitive action. Second, the public must feel that researchers can be trusted. Without public trust, it would not be possible to recruit participants in any practical manner. Third, informed consent protects researchers and institutions from legal consequences. Finally, participant miscomprehension has the potential to introduce unanticipated variability and spurious effects into a study. For each of these reasons, the development of methods to optimize a potential participant's understanding of the procedures to which they may consent would be of great benefit to both the field of social science research as well as those responsible for conducting it.

It is rarely the case that the behavioral sciences implement procedures that may result in immediate, serious, and long-term changes to physical health but researchers in this area often work with protected or at risk populations, including juveniles, elderly or demented

individuals, and those with severe mental illness. Regarding populations for whom legal pressure may conceivably influence the decision to participate in research, the Nuremburg Code clearly states that participation must be voluntary and free of forceful or deceitful influence. Inmates and those involved in the criminal justice system have demonstrated an increased susceptibility to the influence of requests made by those in authority, calling into question both their comprehension of rights as research participants and the degree to which their participation in research is truly voluntary (Koocher & Keith-Spiegel, 1998).

Under Federal guidelines, incarcerated persons are considered a vulnerable population and protected by various guidelines. Specifically, IRBs are required to give extra scrutiny to selection, risks, and benefits of research that proposes the use of prisoners and one member of the prison IRB must represent the vulnerable population (i.e., must be a prisoner) (Parvizi, Chakravarty, Og, & Rodriguez-Paez, 2008). Further, federal regulations specify that the prisoner be clearly informed that parole boards and other legal entities are forbidden from considering participation or refusal to participate in deciding upon recommendations. Additional limitations are imposed on the type of research that can be conducted with prisoner populations, primarily focusing on population specific research and individual benefits. These amended guidelines do not extend to those in criminal diversion, such as the majority of partner violence perpetrators (Babcock, Green, & Robie, 2004). Thus, consent procedures and documents for IPV offender research are not scrutinized by a prison-specific IRB, nor are special considerations enacted to respect autonomy and ensure the greatest likelihood of fully voluntary participation among court-mandated outpatient treatment seekers.

Mandated IPV Offenders

The field of intimate partner violence has grown considerably over the past 40 years. IPV was first formally recognized as a social problem in the United States in 1972 with the onset of the Shelter Movement for female victims of domestic violence; victims programs numbered in the hundreds by the late 1970's (Schechter, 1982). Theories explaining the perpetration of male-to-female IPV followed (Dobash & Dobash, 1979) and IPV perpetration became the subject of serious academic research (Straus, Hamby, Boney-McCoy, & Sugarman, 1996) resulting in considerable epidemiological, naturalistic, and experimental research (Stith, Green, Smith, & Ward, 2008).

Although IPV was considered socially undesirable prior to 1994, the Violence Against Women Act (VAWA) criminalized acts of aggressive behavior perpetrated against female partners under federal law. Perpetrators faced criminal charges and began to interface with the legal system. Since the passage of VAWA into law, most states have accepted mandatory arrest policies which call for officers who have probable cause to believe that domestic violence has occurred to detain the perpetrator (Peterson, 2008). Convicted IPV offenders are typically mandated to attend one of many theoretically and practically heterogeneous outpatient treatment facilities collectively referred to as batterer's intervention programs (BIP) for 12–52 weekly sessions of psychoeducational material and cognitive-behavioral therapy (Austin & Dankwort, 1999).

Despite representing the standard of care for IPV perpetrators in the United States, few BIPs are supported by empirical research (Dutton & Corvo, 2007). Further, empirical studies of BIPs on outcome variables reveal, at best, small reductions in IPV recidivism (Babcock, Green, & Robie, 2004). In order to advance more effective intervention strategies for mandated offenders, researchers have begun systematically evaluating experimental treatments compared to ineffective standard regimens (Easton, Mandel, Hunkele, Nich, Roundsaville, & Carroll, 2007). The need to conduct research in this population is clear, however ethical codes regulating the conduct of research with at risk populations do not apply to those court-mandated to outpatient treatment. Thus, the risk of unintentional ethical violations are particularly prominent in working with court-mandated IPV and substance abuse offenders.

IPV Offenders as an At-Risk Population

We assert that IPV offenders may constitute a particularly vulnerable group as evidenced by multiple factors that may place them at increased risk for consenting to participate in research without adequate competency or autonomy. First, when participants are recruited into a study at probation or a treatment site, it is possible that they may perceive research participation as required or beneficial in some way, thus detracting from the voluntary nature of participation. Applebaum, Roth, and Lidz referred to this phenomenon in medical research as the Therapeutic Misconception (Appelbaum, Roth, & Lidz, 1982). According to this misconception, participants involved in medical research continued to report that research involvement would be of direct benefit to their medical condition despite being informed that others in the future may benefit but that participants themselves would not. As the standard of practice involves mandating offenders to a batterer intervention program (BIP) for rehabilitation rather than punishment (i.e. prison time or community service), the majority of BIP clients and potential participants are in attendance to fulfill a court mandate (Babcock, Green, & Robie, 2004; Peterson, 2008).

Second, IPV offenders present with disproportionately higher rates of cognitive and substance-related impairment. Specifically, aggressive individuals show deficits in prefrontal cortical functioning as evidenced by neuropsychological tests of inhibitory control, working memory, and attention (Blair, 2001; Dolan & Park, 2002). Further, research suggests substantial comorbidity between IPV and substance use as nearly half of all substance abuse clients also report IPV perpetration within the past year (e.g., Chermack, Fuller & Blow, 2000; Leonard, 2005). Meta-analyses have demonstrated a strong association between IPV perpetration and various substances of abuse. IPV and illicit drug use were found to share a medium overall effect size ($d=.65$, 95% CI=.58-.73) across 5 studies totaling 4,496 male offenders (Stith et al., 2003). Small but significant effect sizes between IPV and alcohol ($d=.23$ CI= .21-.24; Foran & O'Leary, 2008) as well as cannabis ($d=.35$, 95% CI=.25-.44; Moore et al., 2008) use among males have been established, suggesting that IPV perpetrators are more likely than non-violent males to use alcohol and cannabis. Research has demonstrated that substance abuse, and alcohol abuse in particular, is associated with various cognitive deficits and neuropsychological impairments, such as poor executive functioning, limited working memory capabilities, cognitive rigidity, as well as poor attention and concentration (Easton, Sacco, Neavins, Wupperman, & George, 2008;

Portnoff, 1982). Easton and colleagues (2008) compared the neuropsychological functioning of alcohol dependent offenders with and without recent IPV perpetration to a group of smoking controls on a battery including the Wisconsin Card Sorting Task, the Continuous Performance Test, the California Verbal Learning Test, Digit Span, the Iowa Gambling Test, the Trail Making Test, and the Stroop Color Word Test. The authors concluded that the IPV group demonstrated more impulse control and executive functioning impairment, relative to the control group, than the alcohol dependent group without an IPV history (Easton et al., 2008).

Thus, IPV offenders diverted to treatment by court order may perceive participation in research as equally mandatory or may be cognitively compromised while giving informed consent. It is particularly important to generate and routinely evaluate standardized, broadly applicable guidelines to improve the likelihood that participants will comprehend the essential elements of consent in order to protect against unintentional coercion.

Evaluations of Informed Consent

To date, few investigations have specifically focused upon evaluating the effectiveness of informed consent with court mandated, treatment seeking participants. Recently, Rounsaville and colleagues (2008) collected the responses of 130 probation referred marijuana dependent participants to a brief, four-item informed consent quiz to globally assess the degree to which the sample group understood the most essential elements of their rights and the research following a standard informed consent procedure. The standard informed consent procedure proved to be insufficient as nearly half of the sample incorrectly responded to one or more of the questions immediately after reading along with a consent form while a trained research assistant detailed specific information about the study, participant rights, and expectations. Twenty-four of the participants (18.5%) did not respond correctly to a question designed to assess the voluntary nature of participation and 33 (25.4%) failed to understand the study's treatment options. Despite the growing literature, there have been no investigations into informed consent with IPV participants. The current descriptive study represents an initial attempt to introduce and evaluate a rigorous method for gathering informed consent from a unique IPV participant population.

Evaluation of an Informed Consent Procedure

Participants

Seventy court-mandated male perpetrators of IPV completed the informed consent process outlined above as part of a randomized control trial designed to evaluate the efficacy of an integrated CBT treatment for IPV perpetrators with substance use diagnoses compared to a 12-step facilitation program to reduce IPV recidivism and substance use. Participants were relatively high functioning individuals determined by the courts to have problematic alcohol or cannabis use in addition to current IPV charges. All participants denied serious mental illness and the abuse of stimulants as well as opiates. Participants were, on average 39.71 (SD = 8.64 years) years old, high school graduates (76.80%), and self identified as European American (45.70%), African American (35.70%), Latino/a (14.5%), or multi-racial (1.4%). Forty percent of males reported that they had either separated or divorced

from their partner. Alcohol use (79.50%) and illicit drugs use (62.86%) was commonly reported during the study period.

Procedure

Participants completed the Mini Mental Status Exam, a 30-item measure commonly used to detect the presence of cognitive impairment during a brief triage appointment. Eligible participants were invited to return for an intake session and were provided a paper copy of the 9 page consent form for personal review prior to their return. Participants were advised to review the consent via telephone the day before their scheduled session. At the intake session, participants were given a new copy of the consent form documents. Researchers verbally reviewed the consent form while the participant read along for the first 20 minutes of the session. Active involvement was fostered through prompts to read one sentence in each section, reframe or summarize each section after review, and respond to an open ended question about each section. Following the review, participants were actively encouraged to ask questions. The few participants who posed questions received both a verbal response and direction to the relevant section of the consent form. All participants signed a consent form and were instructed to retain a copy for their own records.

Results

Participants responded to an 11-item informed consent quiz (ICQ)¹ in order to assess their comprehension of key informed consent elements and to help solidify an accurate understanding of the nature of their participation.² Although the standard multiple choice presentation is advisable, questions were presented in the true/false format for reasons of 1) rapid assessment, 2) fostering clarity on behalf of the participants about critical consent issues, and 3) compliance with the APA mandate of using reasonable and appropriate language to obtain informed consent. The quiz took between 2 and 5 minutes to complete. Research staff reviewed each incorrect response with the participant, again using verbal and written modalities, to correct errors and confirm comprehension before continuing the intake.

Participants scored expectedly high on the ICQ ($M=10.91$, $SD = 0.28$) on the 11 item quiz (99% out of 100%). The variance in the sample was low (0.08) with 63 participants (91%) responding accurately to all items and only 7 (9%) answering 10 of the 11 items correctly on the first attempt. Accuracy was considerably higher than other evaluations of consent described in the literature (Bergler, Pennington, Metcalfe, & Freis, 1980; Rounsaville et al., 2008; Wirshing, Wirshing, Marder, Liberman, & Mintz, 1998). All responses were reviewed and the 7 participants with an incorrect response completed the ICQ after a 10 minute break to achieve perfect scores.

¹Each ICQ item was drawn directly from the crucial elements engendered by the basic concept of informed consent as defined by the American Psychological Association, the American Psychiatric Association, and federal regulations. The quiz consisted of items related to voluntary involvement (2), confidentiality (2), understanding of available treatments (3), rights and compensation (3), and validity to assess effortful responding (1).

²Following the generation of items, the ICQ was sent to a multidisciplinary group of experienced IPV clinicians and researchers in the areas of social work, psychology, psychiatry, and addictions counseling for content validation. Each collaborator agreed that the elements of informed consent were represented by the questions that appeared on the ICQ and provided suggestions that helped to shape the measure's format and syntax into the current form. All items were worded differently from the consent materials to prevent high scores from rote memorization rather than comprehension.

Recommendations

Given the nature of mandated samples as well as the results of the rigorous informed consent procedure described above, we advance the following procedural recommendations to assure participant comprehension of informed consent in treatment research with mandated IPV offenders. Further, the current informed consent recommendations acknowledge each of the component steps suggested by Lavori and colleagues to improve upon the process of informed consent (Lavori, Sugarman, Hays, & Feussner, 1999). Lavori recommended that researchers establish competence, convey all of the relevant study information, determine understanding of the information, confirm that the prospective participant is capable of making a voluntary decision to participate, and obtain a signature from the participant to signify formal consent.

Recommendation 1. Assess basic competence and impairment through the administration of brief screening and self-report measures.

Recommendation 2. Provide an advanced copy of the detailed informed consent documents to prospective participants via e-mail, mailing, or paper copy provided following an initial interview whenever possible. Encourage prospective participants to read the material and return with questions.

Recommendation 3. Provide participants with a new copy of informed consent materials at the time of scheduled completion. Allow ample time to verbally review the material with the participant, making the process interactive through the use of visual images as appropriate.

Recommendation 4. Engage the participant throughout the consent process. Alternate reading with the participant, have the participant summarize sections, and encourage questions during the process. Study personnel should integrate motivational enhancement techniques throughout the informed consent process, such as asking open-ended questions and expressing empathy. Participants should be prompted to ask questions through a compassionate statement articulated to validate the difficulty of materials and normalize the need for clarification (e.g. "This is a lot of information being given to you during a stressful time. What questions do you have?") rather than, "Do you understand?").

Recommendation 5. Evaluate comprehension using a simple, rapid written or verbal assessment. Word assessment items differently from the consent materials to prevent high scoring through rote memorization rather than comprehension. This step not only provides the researcher an ideal opportunity to solidify key concepts of informed consent but also allows participants to convey deficits in understanding without the need to ask questions directly. Address key areas of misunderstanding detected during the evaluation of comprehension in a non-confrontational manner. Readminister the evaluation or verbally confirm comprehension as necessary.

Recommendation 6. Complete informed consent materials when the participant fully understands his or her rights as a research participant.

Recommendation 7. Analyze participant responses to the evaluation of comprehension and adapt the informed consent procedures to address systematic deficits throughout the recruitment period.

Discussion

Unlike prison samples, IPV offenders court ordered to outpatient treatment may constitute a vulnerable group but receive no special protections. Safeguards to protect against unintentional coercion and to ensure truly voluntary participation may be required. Researchers must practice increased caution due to the nature of the interactions that IPV offenders share with mental health providers and the potential for perceived benefits or consequences of compliance that should not ethically exist. Results of the simple ICQ indicated that, with comprehensive procedures, the current sample of IPV offenders determined to be of sufficient cognitive capacity to provide consent were highly capable of comprehending written and verbal consent information. Thus, the procedure proved effective at communicating the key concepts of voluntary participation, confidentiality, study procedures, participant rights, and compensation. Result further demonstrated the viability of conducting a rigorous informed consent procedure and eliciting appropriate participant involvement in a clinical setting.

Therapeutic and procedural misconceptions, the latter of which include uncorrected false assumptions about a research project (Fisher, 2006), must be explored more fully in the area of forensic psychological research to determine the degree to which participants falsely believe that their activities may influence their legal or psychiatric standing (Applebaum et al., 1982). In the forensic context, participants could believe that cooperation may reduce or that refusal may increase negative legal consequences through a form of procedural misconception. Participants may also perceive that cooperation with research could result in medical or therapeutic benefits above and beyond treatment as usual, a form of therapeutic misconception. As participants may process and recall elements of informed consent without necessarily believing them (e.g., The researcher might say that refusal won't affect my legal status but what would my probation officer think if I refuse?), we recommend that future attempts to devise a consent quiz in social science research include an assessment of subjective endorsement of misconceptions.

Limitations

The current findings should be interpreted within the context of several limitations. First, the absence of control groups makes it difficult to determine the efficacy of individual steps in the consent process detailed above. We recommend that the current procedure should represent a starting point which future research can alter to optimize the ratio between training burden and participant comprehension. Similarly and although results suggest that the current consent procedure produced superior scores relative to standard procedures used in other court-mandated samples (e.g., Rounsaville et al., 2008), the absence of a control group also precludes us from concluding that the current procedure was superior to standard consent procedures in this sample of IPV offenders. Second, inclusion criteria may have limited the external validity of the current results. Specifically, participants with severe

mental illness and those who reported abusing stimulants or opiates were excluded from participation. We recommend that additional time and care be devoted to ensuring comprehension among special needs samples, though researchers and clinicians working with perpetrators should be aware that further research is needed to determine the applicability of the current informed consent procedure to more seriously impaired or dependent IPV offenders.

Conclusions

In summary, further consideration should be given to categorizing mandated outpatient offenders as an “at risk” population to ensure that research protocols mandate participant safety and autonomy. In the absence of such mandatory research guidelines, we recommend that investigators independently opt to complete enhanced consent procedures with outpatient offenders. The administration of measures to assess a client’s comprehension of informed consent is now highly recommended for most populations (Hyder & Wali, 2006). We fully support and expand upon the recommendations of previous researchers to improve the informed consent procedure (Flory & Emanuel, 2004). Future research should investigate the possibility of retaining high comprehension while limiting the burden of the consent process on both subjects and study personnel.

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