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Methodological and Ethical Issues in Early Intervention Research

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Despite widespread recognition among researchers and clinicians that trauma can result in profound psychological and emotional distress for a small but substantial proportion of victims, and despite the intuitive appeal of providing mental health services soon after traumatic exposure in order to prevent chronic psychopathology, we continue to be faced with the uncomfortable fact that, at present, a compelling evidentiary base in support of such services is lacking. Although some promising early interventions for trauma have recently been developed (e.g., Foa, Hearst-Ikeda, & Perry, 1995; Bryant, Harvey, Dang, Sackville, & Basten, 1998), their clinical utility with varied trauma populations and their applicability to diverse posttraumatic contexts (e.g., incidents of mass violence) remain to be empirically investigated in controlled clinical trials. Arguably, psychological debriefing (PD) generally, and critical incident stress debriefing (CISD) specifically are presently the "standard of

treatment" in the immediate aftermath of trauma as evidenced by their ubiquitous application. CISD is used throughout the world following disasters, incidents of mass violence, transportation accidents, and so forth. This is due, in part, to the fact that the American Red Cross mandates the use of CISD as formal policy (American Red Cross, 1998). Unfortunately, although these forms of intervention are widely disseminated and implemented as a result of their intuitive appeal, coupled with the supportive conclusions of several uncontrolled investigations attesting to their efficacy, recent comprehensive reviews of controlled investigations of debriefing-based interventions have concluded that in terms of reducing the prevalence or incidence of posttraumatic stress disorder and other problems implicated by trauma, these "treatments" are seemingly inert (Litz, Gray, Bryant, & Adler, 2002; Rose, Bisson, & Wesseley, 2001).

There is an understandable humanitarian desire to help those who are suddenly confronted with unimaginable pain and distress in the wake of a horrific traumatic event. Unfortunately, well-intentioned but ineffective interventions have been developed, widely disseminated, and implemented, as our efforts to help have greatly outpaced our knowledge of what is needed and what is actually effective. To prevent the emergence and persistence of unhelpful interventions, it is not only necessary to develop truly beneficial interventions but to subject these interventions to rigorous empirical scrutiny. Failure to do so may paradoxically increase the likelihood that victims' posttraumatic distress will persist as they may be less likely to seek out alternative interventions, and clinicians may be less likely to pursue alternate treatment avenues, believing that the "standard of care" is more effective than it actually is.

Accordingly, the primary goal of this chapter is to delineate standards of evidence for deeming an early posttraumatic intervention to be effective. These standards are not meant to restrict pilot work and initial treatment-development research, but they should be met or approximated prior to widespread adoption of an intervention by major federal agencies and disaster relief organizations. Improvements in experimental design and greater attention to methodology of early trauma intervention studies will no doubt result in the development of optimal interventions for at-risk victims and will enhance the quality of services proffered in the early posttraumatic environment. In this chapter, we also outline practical and ethical issues that necessarily threaten the internal validity of early intervention studies. We argue for the necessity of randomized clinical trials (RCTs)—even in the early intervention context, and we describe methodological considerations and imperatives for this line of inquiry.

PRACTICAL AND ETHICAL BARRIERS TO CONDUCTING SOUND EARLY INTERVENTION RESEARCH

The most defensible statement that may be made about the efficacy of early intervention for trauma is that, at present, there exists no empirically validated form of treatment that can be recommended as a standard therapeutic response to meet the needs of victims of diverse traumas. Although trauma-specific interventions have yielded promising results in preliminary empirical investigations, it is unclear whether these results would hold in larger samples or in other posttraumatic contexts. The limitations of the existing evidentiary base may not be attributed to lack of innovation or effort. Rather, there are significant complications and barriers to conducting rigorous investigations in a typically chaotic posttraumatic environment. Such barriers certainly present a formidable challenge to early intervention researchers, but we contend that such challenges are not necessarily insurmountable. Indeed, the very future of early intervention rests on researchers' collective capacity to overcome the challenges inherent in this type of research.

Certainly, one of the most common practical barriers to conducting methodologically sound early intervention research pertains to access to, and continued contact with, trauma victims. Given the inordinate distress that most trauma victims experience acutely, they are often unwilling or unable to discuss their experiences or emotional state. In the context of large-scale technological or natural disasters or mass violence, many survivors may flee the area and seek refuge with relatives or friends. Thus, available samples may not always be representative.

One of the more prevalent difficulties experienced by those who do report chronic distress is posttraumatic stress disorder (PTSD). Because a hallmark feature of PTSD is marked avoidance of reminders of the traumatic event (including discussions of the trauma; American Psychiatric Association, 1994), those who are most distressed may avoid contact with mental health clinicians and researchers. Participating in a longitudinal study of PTSD symptom course necessarily involves continued revisiting of a painful memory—a process that the most distressed survivors may seek to avoid. The difficulty of accessing victims of a large-scale trauma and studying that sample longitudinally is perhaps best evidenced by a comprehensive review of postdisaster research studies published between 1981 and 2001, in which Norris and colleagues (Norris, Friedman, Watson, et al., 2002; Norris, Friedman, & Watson, 2002) found that two-thirds of these studies involved a single postdisaster assessment. The practical barriers to conducting longitudinal investigations of victims' response to intervention are compounded in instances of large-scale

disasters such as the terrorist attacks of 9-11-01. Not only does the sheer number of victims make it difficult to access and track a large representative sample of the afflicted population, but the fact that many are forced to flee their homes and neighborhoods makes follow-up contact inordinately difficult.

There are also a number of ethical issues in the context of the immediate posttraumatic treatment environment which have yet to be satisfactorily addressed. The lack of consensus among trauma researchers on these issues is one of the primary factors contributing to the present state of early intervention research. One such issue is whether trauma victims are capable of providing fully informed consent in the immediate aftermath of trauma. Informed consent is an obvious mandatory prerequisite to participating in a clinical trial of an early intervention for trauma. The fact that this remains an open empirical question has disturbing implications for investigations of treatments delivered early after exposure to a traumatic event (e.g., debriefing-based interventions).

Although we are unaware of any empirical investigations documenting difficulties with the informed consent process immediately after a traumatic event, it seems reasonable to suppose that victims may be too overwhelmed, distraught, or impressionable in the early stages following traumatic exposure to fully process or comprehend information provided about the risks and benefits of the investigation or the requirements of their participation. Indeed, a diagnosis of acute stress disorder cannot be given within the first 2 days of traumatic exposure (American Psychiatric Association, 1994) in recognition of the fact that most individuals experience pronounced emotional distress and shock during the period immediately following the traumatic event—even those who will not experience more enduring difficulties.

Because trauma typically involves legitimate life threat and/or actual or threatened serious injury, the stress reaction involves the mobilization of physiological and psychological resources to respond to such threat. Accordingly, in addition to understandable deleterious psychological consequences (e.g., dread, horror, and intense helplessness), higher circulating levels of epinephrine and cortisol can act in concert with emotional distress to impair coping, attention, and information-processing capacities (e.g., Christianson, 1992; Eysenck & Calvo, 1992). For these reasons, we have argued in this volume (Litz & Gray, Chapter 5) and elsewhere (Litz et al., 2002) that it is difficult to defend initiating formal complex or demanding psychological interventions during the *immediate impact phase*—the initial 48 hours after the trauma. Though restrictions within the 48-hour period may seem rather arbitrary, and tremendous individual variability will mean that exceptions to this rule will abound, it does afford a degree of protection from well-intentioned, but perhaps ill-timed, treatment efforts. A period of quiescence will allow the initial shock of

trauma to wane and will increase the likelihood that victims are able to fully process the information presented. Presumably, this reasoning would hold true for the informed consent process as well. Subsequent empirical inquiry may ultimately alter this time frame, but, at present, it would seem prudent to refrain from providing formal emotionally and cognitively complex and demanding treatment or obtaining informed consent for such procedures within the first few days following traumatic exposure.

Additional ethical considerations relevant to early intervention research include concerns about the random assignment of participants to treatment conditions when one condition is expected to promote better posttraumatic adjustment and whether it is ethical to randomly assign recent trauma victims to no-treatment or to nonspecific factors/placebo control conditions.

It is helpful to consider both of these issues with reference to the concept of "clinical equipoise" (Freedman, 1987). Ethical clinical research requires a state of equipoise or genuine uncertainty concerning the relative merits of interventions being evaluated. Specifically, if one intervention is known to be superior to another, equipoise has been violated and it is unethical, in the context of an RCT, to assign participants to the inferior treatment. Similarly, if, during the course of an investigation, it becomes abundantly clear that the merits of one arm of a clinical trial (i.e., one of the treatments) far outweigh those of the other arm(s), it is incumbent upon investigators to terminate the investigation and recommend the more effective treatment to all study participants (Freedman, 1987). One of the most famous instances of the premature termination of an investigation due to the clear superiority of one arm of a clinical trial was the investigation by the Steering Committee of the Physicians' Health Study Research Group (1988) which established that regular aspirin intake significantly reduces the risk of heart attack. Despite the minuscule effect size, the aspirin component of the larger-scale investigation was terminated due to the clinical significance of the findings, and all study participants were informed of the benefits of taking aspirin every other day. This investigation used a sample of several thousand participants; thus investigators were able to discern highly significant findings in the middle of the investigation. Typically, the superiority of one intervention relative to others will not be evident until the conclusion of the study.

Some investigators have misconstrued the concept of clinical equipoise and have applied it, not at the level of the scientific community but at the level of the individual experimenter. This means that if an investigator believes—even in the absence of compelling data—that one intervention is likely to be superior, then equipoise is disturbed and the trial cannot ethically continue (Enkin, 2000). Freedman (1987) refers to this as "theoretical equipoise" as opposed to clinical equipoise and notes that it is "conceptually odd and ethically

irrelevant" (p. 143) because it is subject to the idiosyncrasies of the investigator and mandates that a trial be discontinued whenever the investigator perceives a slight superiority of one treatment over another—regardless of whether such a difference actually exists. Any bias or hunch would be grounds for discontinuing an investigation. Thus, the very reason for a clinical trial—substantive disagreement among a community of clinicians and scholars—takes a back seat to the subjective intuition of a single individual. Only a controlled clinical trial is capable of resolving legitimate disagreement of the clinical community. Intuition and hunches can only serve to perpetuate confusion and, in the absence of compelling data, can never resolve pressing clinical dilemmas. A controlled clinical trial should be conducted even if the experimenter believes in the superiority of one of the interventions relative to the alternatives, provided that other learned colleagues are in disagreement (Weijer, Shapiro, & Glass, 2000). Freedman (1987) points out that "persons are licensed . . . after they demonstrate the acquisition of professionally validated knowledge, not after they reveal a superior capacity for guessing" (p. 144).

Disagreement among the professional community most certainly exists regarding the appropriate early intervention (if any) for trauma victims. Given that the standard of treatment (i.e., variants of PD) has been shown to be inert in a number of controlled clinical trials (Litz et al., 2002; Mayou, Ehlers, & Hobbs, 2000; Rose, Brewin, Andrews, & Kirk, 1999; Rose et al., 2001) a state of clinical equipoise unequivocally exists. A failure to conduct controlled RCTs with promising, innovative treatments is arguably more unethical than conducting such investigations. It is clear that a small but significant proportion of trauma survivors develop chronic psychopathology (e.g., Breslau et al., 1998; Kessler, Sonnega, Bromet, & Nelson, 1995). At present, however, intervention options seem to consist of employing traditional but ineffective treatments (i.e., debriefing) or waiting for chronic pathology to develop before implementing valid treatments. This approach is unacceptable. Brief, multisession, early interventions have been developed and appear to hold great promise but await evaluation in the context of RCTs before they can be routinely recommended. Researchers bear the ethical responsibility of developing and implementing valid treatments. However, one could argue that ineffective early interventions have been allowed to take root precisely because the field has relied on the subjective intuition of well-intentioned clinicians rather than insisting on empirically rigorous trials.

Regarding the use of nonspecific factors/placebo control conditions in early intervention research, it is difficult to appreciate ethical objections which may be tendered given that the present standard treatment is, if anything, inert—and some have contended that it may be detrimental (Bisson, Jenkins, Alexander, & Bannister, 1997). The principle of clinical equipoise implies that

placebos are unacceptable in any situation in which validated effective treatment exists (Young, Annable, & Stat, 2002). Early intervention for trauma clearly does not meet this criterion. There appears to be increasing convergence among the research community on this point, as the Declaration of Helsinki, the World Medical Association Council, the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council, and the U.S. Food and Drug Administration all condone the use of placebos in instances in which no standard treatment exists that has been shown to be more effective than no treatment (Young et al., 2002). In sum, given the status of the present evidentiary base for early trauma interventions, it is not only permissible to use RCTs to test promising new interventions for trauma victims and to employ placebo/nonspecific factors control conditions, but it is arguably unethical to fail to do so as this will likely perpetuate our present state of futility in attempting to alleviate the suffering of the recently traumatized.

EVALUATION AND ASSESSMENT: IDENTIFYING THOSE LIKELY TO BENEFIT FROM EARLY INTERVENTION

As noted elsewhere in this volume, early intervention for all trauma victims is ill advised, given that the vast majority will return to baseline levels of functioning in the absence of treatment. Efforts to provide universal early intervention will necessarily involve a considerable waste of resources (this is especially true in the context of mass violence or large-scale disaster), thereby decreasing the likelihood that the most needy individuals will receive necessary services. From a methodological standpoint, attempting to intervene with any and all trauma victims without regard to differences in risk for developing sustained distress increases the likelihood of falsely identifying cases of pathology when they do not exist (Type II error). Specifically, if all trauma victims are randomly assigned to various treatment conditions of a clinical trial, all conditions will invariably be associated with large decrements in average symptom levels over time because the vast majority of trauma survivors experience pronounced, but relatively transient, distress following traumatic exposure. Thus, because inert conditions will be characterized by tremendous spontaneous symptom remission, it will be difficult to document the incremental validity of truly effective treatments because 90% of participants in both active and inert conditions will return to baseline levels of function. In contrast, if clinical trials target individuals who exhibit some degree of risk for developing chronic posttraumatic difficulties, it will be easier to document the efficacy of truly helpful treatments because symptom reduction will be unique to those condi-

tions and ineffective treatments will be exposed. For far too long, inert treatments have been touted as necessary interventions because evidence for their efficacy has capitalized on inevitable symptom remission. However, the true measure of early intervention effectiveness is documented symptom improvement among those who are likely to experience persistent distress in the absence of treatment.

ATTENTION TO RISK AND RESILIENCY FACTORS

King, Vogt, and King (Chapter 3, this volume) extensively review risk factors and risk mechanisms that are known to predict sustained posttraumatic distress. Researchers and clinicians alike should attend to these factors carefully in making decisions about appropriate candidates for early intervention. This will allow the ethical, practical, and methodological problems noted previously to be avoided. Investigations designed with attention to, and consideration of, risk factors will also shed light on the complex interplay between and among risk mechanisms in producing or increasing pathology. As noted by Norris, Friedman, and Watson (2002), with respect to pre-, peri-, and posttraumatic risk factors, "despite some synergism, we now must think of them as additive and propose that an individual's risk will increase along with the number of risk factors present and decrease along with the number of protective factors present" (p. 247). Such is the present understanding of how risk mechanisms may operate; only investigations designed to explicitly test alternative mediational models of risk and resiliency will allow for more sophisticated prediction of chronic posttraumatic distress. Readers are encouraged to refer to King et al. (Chapter 3, this volume) for a thoughtful delineation of methodological and statistical considerations specific to evaluating risk and resiliency factors in traumatic stress research. As these researchers note, risk factors are often identified in specific contexts or with specific trauma populations and may depend on the admixture of variables studied. Researchers and clinicians alike should exercise caution when using specific risk and resiliency factors in identifying candidates for early intervention. Although we lack a detailed understanding of the synergy between and among various risk factors at the present time, we know that some are generally more potent than others. Norris, Friedman, and Watson's (2002) assertion that we must, at present, treat risk factors as additive does not preclude prioritizing them as a function of potency. Regardless, attention to needs assessment and severity of distress will be a significant advance in early trauma intervention efforts. Assessing these factors is essential in conserving resources, ensuring treatment for truly needy individuals, and differentiating effective from ineffective interventions.

RANDOMIZED CLINICAL TRIALS AND TIMING OF EARLY INTERVENTIONS

As noted previously, we have little definitive information about what interventions (if any) are helpful in the wake of trauma. Only methodologically rigorous clinical trials will be able to answer this question as well as the even more basic question of whether formal interventions within the first few weeks following traumatic exposure should be attempted at all. Although randomized allocation of participants to treatments is difficult following trauma (especially large-scale disasters), it is essential in answering these questions. Given that we have no firm basis for advocating any particular form of intervention, it is also an ethical imperative to employ RCTs to work toward discontinuing the routine administration of interventions proven to be ineffective and providing forms of treatment that have long-term beneficial impact.

In addition to the obvious question of whether early intervention should be provided (as evidenced by lower incidence rates and/or severity of psychopathology), there is the important question of the optimal time frame for intervening. This is an open empirical question that must be answered to ensure proper posttraumatic care. We argue that formal interventions should not be provided during the immediate impact phase, but it is unclear whether there is an optimal time frame for intervening after this initial 48-hour period. Although there are no compelling data addressing this question, it is interesting to note that interventions that are provided within hours or a few days of trauma (i.e., debriefing-based interventions) have not been shown to be especially helpful (Litz et al., 2002), whereas a couple of early interventions that have yielded positive outcomes were implemented an average of 10 or more days after the trauma occurred (Bryant et al., 1998; Foa et al., 1995). We propose that RCTs explicitly designed to answer the question of the best timing for an intervention should be conducted. In the context of mass violence and large-scale disasters, clinical resources are scarce; thus it is most often impossible to provide assistance to all who may need it in a timely fashion. In these instances, wait lists are invariably implemented. It would be just as easy to randomly assign participants to treatment waves such that the effects of the same intervention provided at different time points could be determined empirically.

Clearly, some individuals will be more distressed than others (and therefore more in need of professional assistance); thus it may seem intuitively obvious to triage victims in the event of limited clinical resources and to provide services to the most distressed individuals first. This ethical consideration would obviously disallow a randomized trial of intervention timing. We argue, however, that this "intuitively obvious" solution may not be appropriate, as this scenario is more complex than meets the eye. Specifically, this solution relies

on the implicit assumption that the earlier intervention is provided, the less likely it is that chronic posttraumatic difficulties will ensue. Although RCTs of intervention timing have yet to be conducted, existing data are more consistent with the possibility that intervention is more helpful after some (unspecified) delay (as discussed earlier). These interventions differ from traditional, immediately delivered treatments on a number of dimensions, so their therapeutic effects cannot be fully attributed to their timing. Still, adopting a symptom-severity triage approach may seem to be the ethical high road, but this strategy begs the question of optimal timing and, if anything, is contrary to extant research findings. Only RCTs of interval timing can answer the question of *when* to intervene in addition to how to intervene after a trauma.

STANDARDIZED TREATMENT PROTOCOLS AND TREATMENT FIDELITY

Improvements in posttraumatic care are contingent upon explicit, detailed descriptions of interventions offered. The more detailed intervention descriptions are, the easier it will be for the scientific community to discern critical components and parametric features (e.g., timing and duration) which differentiate helpful from unhelpful interventions. To this end, we recommend that treatment innovators develop and disseminate detailed treatment manuals which fully delineate their interventions. It is insufficient to simply note that an intervention employed cognitive restructuring, *in vivo* exposure, or imaginal exposure, for instance. An apparently ineffective intervention may indeed be due to the inclusion of inappropriate or inert components. But it is often the case that effective treatment components are poorly timed or administered for an insufficient duration. It has been suggested, for instance, that debriefing-based interventions use a degree of exposure therapy but that the exposure is hasty and incomplete, which has the effect of exacerbating distress rather than abating it (Bisson, McFarlane, & Rose, 2000). Detailed depictions of the parameters of an intervention, rather than a brief listing of treatment components, permit early intervention researchers to revise potentially helpful interventions rather than summarily concluding that a treatment does not work.

Detailed manualized interventions also allow researchers to ascertain whether the intervention was administered properly. Routine assessments of treatment fidelity allow researchers to decide whether ineffectual treatments are indeed inert—or whether apparent treatment failures are attributable to poor implementation or administration of theoretically sound treatments. Similarly, evidence of high treatment integrity increases one's confidence in the outcome of a clinical trial. Unfortunately, even when detailed accounts of an intervention are provided in the literature, mention of manipulation checks

or evaluation of treatment integrity is almost invariably absent. As noted by Kazdin (1998), assessment of treatment fidelity ensures that treatment conditions are distinct. For example, assume that trauma victims who have been deemed especially likely to develop chronic posttraumatic difficulties are randomly assigned to an early intervention which is anticipated to be quite beneficial (e.g., five sessions of cognitive-behavioral therapy), to a placebo/nonspecific factors, control condition (also five sessions) or to a no-treatment control condition. Assume also that at the end of the clinical trial, both active treatment conditions resulted in a 50% reduction in symptom severity relative to no-treatment control participants. In this situation, it would be tempting to conclude that the five sessions of cognitive-behavioral therapy (CBT; hypothesized to be especially helpful) promoted positive posttraumatic adjustment but not to a greater extent than nonspecific therapeutic factors such as basic empathy and support. That is, the unique components of the CBT intervention such as imaginal and *in vivo* exposure are not associated with incremental treatment gains above and beyond nonspecific therapeutic factors. Although this conclusion may be accurate, it is possible that the "nonspecific factors" condition included an exposure component. An evaluation of the integrity of the nonspecific factors condition may reveal that participants in that condition spent a good deal of time talking about the traumatic event in detail. In such a scenario, the condition would arguably be a variant of exposure rather than a proxy for professional therapeutic support. Without evaluating the fidelity with which all conditions were administered, one might hastily conclude that a truly helpful intervention is not particularly useful. The critical importance of developing and implementing effective treatments that can ameliorate the severe emotional distress that often accompanies trauma mandates that the scientific community provide more detailed accounts of early interventions and, more important, that we attend to, and document, the fidelity with which our interventions are delivered.

EVALUATION OF MULTIPLE OUTCOMES BY MULTIPLE INFORMANTS

Perhaps understandably, trauma researchers and responders have focused their efforts on the study and treatment of PTSD following traumatic events. However, this focus should not prevent researchers from attending to other forms of emotional and behavior distress. Norris, Friedman, Watson, et al. (2002) review varied and diverse difficulties that have been extensively documented in the wake of trauma. These difficulties include specific psychological problems (PTSD, major depressive disorder, panic disorder, and generalized anxiety disorder), nonspecific emotional distress, health problems, alcohol

and substance abuse and dependency, occupational and financial stress, impairments of social supports and interpersonal relationships, and age-specific problems (e.g., temper tantrums, incontinence, and hyperactivity in children). Evaluating and documenting more diverse outcomes will allow investigators to determine the breadth of impact of their interventions and will also allow interventions with fairly specific effects to be modified in order to target more varied forms of psychopathology. For instance, it may become apparent that an explicit focus on maladaptive coping strategies (substance abuse) needs to be incorporated depending on the documented prevalence of this problem in specific populations and contexts. Although the immediate posttraumatic environment may not allow for comprehensive assessment of all possible difficulties, investigators can use the literature to inform the selection of outcome domains to be examined (e.g., complicated grief reactions in incidents of mass violence).

In addition to evaluating diverse outcome domains, investigators should, to the extent possible, use multiple informants in assessing treatment response. In addition to self-report measures (which is often the only means used to evaluate treatment response), investigators should consider using structured clinical interviews and, if possible, the reports or ratings of significant others. Clearly, if structured clinical interviews are employed, they should be conducted by individuals who are unaware of the participants' treatment condition status. Finally, instead of the traditional exclusive focus on differences between treatment conditions at the end of treatment, greater attention should be paid to the rate of recovery promoted by alternative interventions (Kenardy et al., 1996). That is, two seemingly equivalent interventions (as evidenced by end-state symptom levels) may, in fact, be quite different in terms of how precipitous the decrease of symptoms is in each condition. An intervention that achieves improvement more quickly is arguably a superior intervention, all other things being equal.

TIMING AND DURATION OF EVALUATIONS

It goes without saying that it is difficult to determine the impact of an intervention if measures of emotional and behavioral functioning are not administered prior to beginning treatment. Unfortunately, a surprising number of published reports attesting to the efficacy of a trauma intervention have relied exclusively on posttreatment evaluations, preventing definitive statements regarding the magnitude of symptom change. Precious few data are available to illuminate the persistence of treatment gains following effective interventions. Although it is often quite difficult to track trauma victims longitudinally, ef-

forts to do so will afford information about the maintenance of treatment gains and may also provide information about benefits of treatment which are not immediately apparent. For instance, marital or occupational problems may increase significantly after a period of relative quiescence. One's spouse or employer may be understanding or especially accommodating of problems within the first few months of a traumatic event—but may be less accommodating thereafter. Conceivably, alterations in marital or employment status may not become known until well after a traumatic event. In such a scenario, the full benefit of a therapeutic intervention relative to a no-treatment or a nonspecific-factors control condition may go undetected if the participants are only followed for a few months after the traumatic event.

Finally, with respect to the timing of evaluations, periodic measurement of functioning and distress during the intervention period may be illuminating. Although this may not be appropriate or feasible for all or even most early intervention studies, periodic evaluation of functioning during treatment may help to elucidate which elements of multicomponent treatment packages are associated with greater improvements and may also help to identify possible process variables which are instrumental in promoting positive posttraumatic adjustment. There exists, for instance, a great deal of speculation that emotion-focused traumatic processing too soon after traumatic exposure may exacerbate rather than alleviate posttraumatic distress (Bisson et al., 2000). This may certainly be the case, but at present, there are no compelling data to substantiate or disconfirm this possibility. Associations between postintervention symptom status and peri-intervention negative affect and arousal would be required to empirically evaluate this possibility.

GREATER ATTENTION TO INDIVIDUAL DIFFERENCES

Given the limitations of our current knowledge about early intervention for trauma, it is not especially surprising that clinical trials to date have focused primarily on group-based outcomes. That is, interventions have been applied in a one-size-fits-all fashion, and investigators have understandably concerned themselves with the question whether the active treatment condition exhibits superior outcomes when compared to the group(s) not receiving the favored intervention. Clearly, individuals differ in their needs following trauma, their capacities to use formal interventions and informal supports effectively, their inclinations to discuss the trauma and associated difficulties with others, and so forth. As we have noted elsewhere (Litz et al., 2002), some individuals may benefit greatly from sharing their harrowing experience with supportive others whereas others may prefer to work out problems on their own and may

therefore perceive encouragements to share their experiences as impositions. Conclusions about intervention effectiveness based on group-based statistics necessarily obscure individual differences in symptom course and do not speak to individual difference variables which are associated with differential outcomes. Accordingly, the inclusion of measures which may mediate responses to intervention (personality measures, coping indices, etc.) will enhance our ability to apply interventions selectively and appropriately and will allow clinicians to "troubleshoot" problems along the way by identifying individuals who are unlikely to benefit from standard interventions by tracking process variables known to be predictive of deleterious outcomes. Collecting data on individual differences and process variables will improve our understanding of the synergy between and among the resiliency and vulnerability factors reviewed above.

ATTENTION TO TRAUMA-SPECIFIC CHARACTERISTICS

When investigating and attempting to alleviate posttraumatic distress, it is necessary to consider issues unique to particular trauma types and contexts that may affect symptom expression and treatment.

Terrorism and Mass Violence

A recent review comparing the psychological impact of natural and man-made disasters found that intentional mass violence was the most distressing type of disaster (Norris, Friedman, Watson, et al., 2002). The specification of traumatic exposure includes the possibility of witnessing an event, a dead body, or body parts (American Psychiatric Association, 2000). Without the specification of in-person observation, the question of the extent to which witnessing events via live television coverage or video replay may result in significant posttraumatic distress arises. Schlenger et al. (2002) found that during the second month following the terrorist attacks of 9-11-01, the amount of television coverage watched and the number of different kinds of events that respondents reported seeing on television (live coverage of the planes as they impacted the buildings, people jumping or falling from the World Trade Center [WTC], people running to escape the buildings, replayed footage, etc.) were both significantly related to the prevalence of probable PTSD.

Moreover, one's proximity to a natural or technological disaster or mass violence event may have implications for mental health outcomes. Schlenger et al. (2002) also found the prevalence of probable PTSD was significantly related to the individual's geographic proximity to the WTC site on 9-11. Studies in-

vestigating the relationship between proximity to an incident of mass violence and subsequent distress have not produced uniform findings. For instance, although the prevalence rate in the Washington, DC area was slightly higher than the national prevalence rate, it was not statistically significant (Schlenger et al., 2002). Considering the incongruous findings, early intervention research in the context of mass violence should include information regarding both direct (e.g., first-person observation) and indirect (e.g., media coverage) exposure to the potentially traumatic event and, if applicable, should determine victims' relative proximity to the disaster epicenter. This variable may be important because it serves as a proxy for legitimate life threat or endangerment.

Compensation and Symptom Exaggeration

When the mental health and legal arenas coincide, research and anecdotal evidence illustrate the demand characteristics inherent in litigation and attest to the possibility of malingering. It has been suggested that as many as 20–30% of personal injury plaintiffs could be considered possible malingerers (Lees-Haley, 1997). Are PTSD symptoms exaggerated or falsely reported in an effort to establish grounds for a personal injury claim? Ehlers and Mayou (1998) assessed PTSD diagnosis and litigation status for individuals who had been involved in motor vehicle accidents (MVA). At 1-year post-MVA, 28.9% of those whose claims had not been settled reported symptoms that met criteria for PTSD. Those who had not filed a claim, had dropped a claim, or whose claim had been settled had a 10.4% PTSD incidence rate. This is not to say that all claimants embellish their symptoms. When an individual's primary goal is to alleviate his or her PTSD symptoms, malingering has been found to be less frequent (Kuch, Cox, & Evans, 1996). However, an individual's worker's compensation claim, Veterans Affairs benefits, or personal injury lawsuit may affect the severity and persistence of his or her reported symptomatology. To more accurately assess the veracity of symptom reporting, and to eliminate the possibility of responding biases affecting outcomes, researchers should consider assessing litigation status or compensations seeking as part of their protocol.

Symptom Minimization

It has been suggested that in some contexts, individuals may minimize symptom severity or be reluctant to endorse symptoms. Military personnel may prefer not to report symptoms while continuing to serve in the military (e.g., Wolfe, Erickson, Sharkansky, King, & King, 1999). Emergency service personnel (e.g., firefighters and police officers) may fear being viewed as "unfit" or having their duties restricted. Some trauma survivors may fear they will be

stigmatized for seeking psychological services (Yehuda, 2002). As with screening for litigation, researchers should be aware of the impact that specific contexts or populations may have on veracity of reported distress.

Sexual Assault

Resick and Schnicke (1996) discuss the necessity of assessing for, and addressing, issues of trust and intimacy for survivors of sexual assault. Self-distrust may be manifest in thoughts of self-blame, second-guessing of choices, or difficulty with everyday decisions. Other people are often presumed untrustworthy. Family and friends may unwittingly reinforce this presumption through their own reactions. Sexual assault survivors may also avoid emotional intimacy with friends and family in an effort to avoid possible rejection or blame, thus depriving themselves of social support. Physical intimacy is rife with reminders of the assault, may trigger intense fear or flashbacks, and is, therefore, often avoided. Intimate relationships may suffer, further isolating the individual. In addition, the sexual assault survivor may not have any positive intimate experiences with which to counter the traumatic experience of the assault. The seemingly protective measures taken in an effort to avoid intimacy or violations of trust may ultimately be counterproductive during PTSD intervention. As such, early interventions for sexual assault need to be designed with these issues in mind. Moreover, explicit assessment of social support utilization may be more important in this particular posttraumatic context.

OVERVIEW OF RESEARCH "BEST PRACTICE" RECOMMENDATIONS

In this chapter, we have reviewed the ideal characteristics of early trauma intervention investigations. We recognize that no single study will likely adhere to all these recommendations because the early posttraumatic environment is fraught with a number of practical barriers. Optimal methods are, in many instances, simply impossible to employ due to practical and ethical issues and resource limitations. As a community of clinical scientists, however, we can collectively overcome the limitations of any single investigation by attending to and improving existing limitations of the literature in this area. Thus, although it may be impossible to implement all the suggestions advanced in this chapter in a single clinical trial, multiple clinical trials should be able to compensate for the methodological deficiencies of any particular trial. Moreover, single clinical trials will be particularly compelling to the extent that they are able to incorporate several of these features.

1. *RCTs must be employed to evaluate the efficacy of early interventions.* Because the present "standard of treatment" appears not to be superior to receiving no intervention whatsoever (Rose et al., 2001; Litz et al., 2002), there seems to be no ethical risk in using no-treatment control conditions and/or nonspecific-factor control groups. A state of clinical equipoise certainly exists, as we presently have no form of early posttraumatic intervention which has been shown, in the context of rigorous clinical trials, to be superior to receiving no treatment and which has been shown to be broadly applicable to varied posttraumatic populations and contexts. Although promising interventions are being developed, only large-scale RCTs using appropriate control conditions will determine whether they are superior to inefficacious debriefing-based interventions that have been the treatment standard to date.

2. *Researchers should seek to identify and treat only those individuals who bear some known risk for developing chronic posttraumatic difficulties.* As reviewed earlier, intervening only with individuals likely to develop chronic distress represents a judicious use of limited clinical resources. In addition, from a methodological standpoint, focusing our efforts on those who are unlikely to exhibit spontaneous symptom remission makes it easier to detect genuine treatment effects—effects which may be masked if treatment is supplied to all victims, as the vast majority of participants in all experimental conditions will experience pronounced symptom decreases in the months following traumatic exposure.

3. *Randomly assignment to varied timings of intervention will elucidate the optimal time frame for treating at-risk trauma victims.* Despite a great deal of speculation about the merits or dangers of providing formalized intervention at certain time points shortly after traumatic exposure, there are no compelling data that speak to the issue of timing. Promising interventions have been delivered approximately 1½ weeks after traumatic exposure and ineffective treatments are often provided within hours of the event. Yet these various interventions differ in a number of ways; thus differential efficacy cannot be fully attributed to differences in timing. This issue must be empirically evaluated in the context of subsequent clinical trials.

4. *Researchers should use detailed, manualized treatment protocols and should evaluate the fidelity with which interventions are implemented.* Dissemination, implementation, and evaluation of effective interventions require that other clinicians and research teams can replicate newly developed treatments. The mere listing of treatment components does not allow for advancement of the science. Moreover, hasty conclusions regarding treatment efficacy may be prevented to the extent that treatment integrity is formally evaluated.

5. *Researchers should evaluate multiple outcome and process variables and*

individual difference variables across diverse domains and should attempt to use multiple informants. Researchers are advised not only to include measures that assess diverse forms of emotional distress but also to include measures of functional impairment and relationship difficulties. Moreover, inclusion of measures of treatment process variables and individual difference measures will illuminate differential responses to (overall) effective interventions, which will allow clinicians to begin tailoring treatments to individuals based on unique constellations of risk and resiliency factors. Using multiple informants, rather than relying exclusively on self-report measures, will shed light on the strength and generality of reported treatment gains and will reduce the threat of expectancy effects and demand characteristics.

6. *Evaluations should be made frequently before, during, and after treatment.* The inclusion of a pretreatment evaluation is absolutely necessary if any firm conclusions about treatment efficacy are to be made. Longitudinal evaluation of functioning (i.e., well after the termination of treatment) will allow for the assessment of the persistence of treatment gains and will also allow researchers and clinicians to detect posttraumatic difficulties which may emerge well after traumatic exposure. In addition, evaluations during the course of treatment will allow researchers to empirically evaluate potentially important process variables of existing early interventions (e.g., premature emotion-focused processing of trauma as an indicator of deleterious outcomes).

7. *Finally, researchers should be mindful of unique characteristics of different trauma populations and contexts and should resist the temptation to apply effective interventions to different trauma populations without regard to necessary modifications.* Early intervention researchers should develop interventions geared to specific trauma contexts. Existing early interventions are often applied without regard for unique needs of different trauma populations and have not been shown to be especially helpful.

In summary, efforts to treat trauma victims soon after exposure have been largely ineffective. A sober examination of methodological and ethical issues germane to early intervention research reveals that attention to methodological rigor exposes seductive but inert treatments and will stimulate further efforts to develop more fruitful interventions. Waiting for chronic pathology to develop is counterintuitive, and innovated researchers are beginning to modify empirically validated treatment components for use in acute trauma intervention contexts. We are encouraged by recent early intervention innovations which will likely supplant traditional debriefing-based interventions. But we are more encouraged by the ever-increasing quality of early intervention research designs. Attention to the considerations and recommendations outlined in this chapter will allow us to better serve at-risk trauma victims and

will ensure that our interventions continue to grow and evolve in order to meet the needs of traumatized populations.

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