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An Unexplored Ethical Issue in Clinical Research: Disclosure of Individual Findings in the *Creando Posibilidades* [Creating Possibilities] Study

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Abstract: Individual disclosure refers to the presumptive ethical responsibility of an investigator to communicate to a study participant information that was collected as a part of a research study protocol and is specific to the individual. Currently, there are no federal regulatory guidelines specifying the conditions and management of disclosure of health-related individual-specific information. In this report, the authors discuss the challenges associated with individual disclosure in the context of a longitudinal descriptive study. Arguments favoring disclosure and those challenging disclosure as a general ethical duty are presented. Finally, strategies for addressing individual disclosure are discussed using a research exemplar in which risk behaviors related to health outcomes were measured. © 2013 Wiley Periodicals, Inc. Res Nurs Health 36:311–319, 2013

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Disclosure of individual findings is a challenging ethical issue in the design and implementation of clinical research. Individual findings include information about a research participant discovered during the course of a research project, which would likely, if disclosed to the participant, make a difference to that participant's ability to plan for his or her well-being. In contrast to aggregate findings for which there are clearer ethical mandates regarding communication both to study participants and the scientific community (Fernandez, Kodish, & Weijer, 2003), obligations regarding the communication of individual-specific findings to study participants remain controversial and unclear. Currently few laws or guidelines are

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available to support decisions about individual disclosure, and across institutional review boards little consensus exists (Gordon, 2009; Miller, Christensen, Giacomini, & Robert, 2008; Stein, 2009). Consequently, investigators are unlikely to consider this important issue in planning their studies, and well-thought-out plans for managing potentially critical clinical information within the context of a complex study protocol may be lacking.

Clinical research studies often include the collection of data that may reveal an undiagnosed health problem or a potentially alterable profile that confers increased risk for disease or disability. *Creando Posibilidades* [Creating Possibilities] was a study of determinants of disordered eating (DE) behaviors in a sample of young adult Mexican-American women, in which ecological momentary assessment (EMA) was used to measure eight DE behaviors. A detailed review of the behavioral patterns recorded during the EMA, when integrated with the attitudinal measures, might have been used to identify women meeting diagnostic criteria for an eating disorder. As the investigators proceeded with design and implementation of *Creando Posibilidades*, our research team considered the obligation to review each participant's data to determine if signs and symptoms of an eating disorder were present, and if so, whether the participant should be informed, and when and how. The overall purpose of this paper is to discuss the issue of individual disclosure and to describe how these questions were addressed within the context of this community-based 12-month longitudinal study. Basic issues that should be considered regarding individual disclosure during the planning stages of health-related risk behavior studies also are discussed.

Disclosure of individual results refers to the presumptive ethical responsibility of an investigator to communicate to the study participant information specific to the individual that was collected as part of the research study protocol (Shalowitz & Miller, 2005). Disclosure is predicated upon the principles of ethical research that include respect for persons and avoidance of harms. Individual disclosure extends the more broadly accepted ethical duty of group disclosure (Miller et al., 2008). The issue of individual disclosure emerged earlier in this decade as a pressing and contentious issue in the context of genetic research. Genetic findings have the potential to influence reproductive decisions, lifestyle choices, health behaviors, family relationships, and employment opportunities and benefits, as well as attitudes and behaviors toward specific groups. Within this context, ethicists began to examine and debate study participants' "right to know." Although the issue of individual disclosure was initiated in the area of genetic research, there is growing consensus that it is relevant across many domains of biomedical research (Miller et al., 2008).

The issue of disclosure of findings to individuals is compounded by the complexity of legal and ethical responsibilities that confront investigators, and it varies within the context of the study and the nature of study participants. For example, state laws generally require disclosure of confidential information without a client's consent when there is reason to believe that a client poses a serious, imminent, and foreseeable threat to an identifiable third party, such as when a police officer requests confidential information about a client. In this case, the investigator must consider legal guidelines pertaining to the disclosure of confidential information to a law enforcement official without a client's consent.

The Study

Creando Posibilidades was a two-site study approved by the Institutional Review Boards (IRBs) of both universities. The purpose was to examine the trajectory of DE behaviors of college-enrolled Latinas (Mexican-American/MA) over a 1-year period, with measurements occurring at 3-month intervals, to ascertain patterns of risk behaviors over time and to explore the causal relationship between self-cognitions (self-schemas) and DE behaviors. The pattern of associations among DE and alcohol and tobacco use also were explored. Three specific aims were addressed to test the proposed relationships between self-schemas and the risk behaviors in MA young adult women: (1) examine the pattern of associations among DE behaviors and alcohol and tobacco use; (2) examine the role of the organizational properties of self-schemas in predicting the availability of a fat body-weight self-schema and the severity of DE behaviors; and (3) examine the association between sociocultural factors and the organizational properties of the self-schema.

Inclusion criteria for the sample were: (1) (self-identified) Mexican-American women between 18 and 35 years, (2) freshman, sophomore, or junior (not senior or in final year of

study based on credit status) level student at community, junior, or 4-year college, and (3) English speaking. Exclusion criteria included: current treatment for DE or substance abuse/dependence disorders. Two factors underpinned the selection of participant characteristics: (1) literature suggests that rates of DE and tobacco and heavy alcohol use are higher in MA compared to other groups of Hispanic women (Bachman, Wallace, & O'Malley, 1991; National Institute on Alcohol Abuse and Alcoholism, 2004; National Women's Information Center, 2003; Swaim & Wayman, 2004; Vega, Sribney, & Achara-Abrahams, 2003), and (2) the transition and adjustment to college presents vulnerabilities to engaging in risk behaviors, such as DE and tobacco and alcohol use (Brewer, 1994; Nielsen & Ford, 2001; Wechsler, Rigotti, Gledhill-Hoyt, & Lee, 1998; White, Pandina, & Chen, 2002).

Individual disclosure obligations emerged for the eating disorder symptom data. In clinical practice, eating disorder diagnoses are based on self-reported behavioral patterns, attitudes towards body weight and shape, and objective body weight measurement. In this study, a 12-month longitudinal design was used with measurement of eight DE behaviors (binge-eating, self-induced vomiting, laxative, diuretic, or diet pill use, excessive exercise, food restricting, fasting, alcohol and tobacco use) every 3 months for a total of five 14-day periods using EMA methodology. With this measurement approach, participants recorded their behaviors as they occurred on a PDA (handheld computer) and were asked to transfer their data weekly to a secure website. Participants were weighed at the beginning of each data collection period, and paper and pencil questionnaires were administered to measure attitudinal symptoms of the eating disorders. Symptoms of depression and anxiety disorders were measured once at baseline.

During the EMA data collection periods, participants were asked to carry with them at all times a project-provided PDA and to record all instances of the target behaviors, with the exception of food restricting and fasting, which were measured once a day. A PDA software program developed for the project began with a list of the target risk behaviors. Once a participant endorsed a behavior, a series of follow-up questions was presented that allowed discrimination of clinically significant levels of the behaviors. For example, the binge-eating algorithm included questions to verify that the episode met DSM-IV criteria for binge episode (i.e., objectively large quantity of food ingested within a 2-hour period accompanied by subjective feelings of being out of control). At the end of each day, participants reported food restricting and fasting over the last 24-hour period. The Eating Disorder Inventory (EDI) (Garner, 1991), a measure of the attitudinal symptoms of eating disorders, was administered at each EMA data collection point along with a measurement of objective body weight. The EDI scale includes 64 items that generate eight subscale scores, which are computed by summing scores across all items in the subscale. Criterion-related and concurrent validity of the subscales have been shown with clinical and non-clinical samples (Garner, 1991). Internal consistency of the subscales, using Cronbach's alpha, examined in samples of Hispanic young females ranged between .84 and .93 (Joiner & Kashubeck, 1996).

Together, this set of data held the potential for identification of women who were suspected of meeting diagnostic criteria for anorexia nervosa, bulimia nervosa, and eating disorders not otherwise specified. Thus, one issue of disclosure within the protocol was whether there was an obligation to inform participants of the potential diagnosis and its health consequences.

Support for Individual Disclosure

Arguments favoring individual disclosure of results are largely founded on the ethical principles of respect and beneficence. Respect refers to treatment of individuals as autonomous agents, capable of making decisions about personal goals and acting in accordance with those decisions (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education, and Welfare [NCPHS], 1979). The principle of respect has been used to support the argument for disclosure in two ways. In the first case, the focus is on the individual as an autonomous agent with the capability and right to seek information. According to this perspective, participants should be informed that the data collection procedures will result in the availability of individual-specific information and given the opportunity to decide whether or not to seek it (Shalowitz & Miller, 2005). If the individual seeks information, it should be provided along with a clear explanation about the certainty and clinical utility of the information.

The principle of respect also is used as the foundation for the argument that participants

should be given individual results when the information could empower proactive lifestyle changes in behavior (Dressler, 2009). According to the Belmont Report, the principle of beneficence is a subset of respect, including two general rules viewed as complementary expressions of the principle of respect: ''do no harm'' and ''maximize possible benefits and minimize possible harms'' (NCPHS, 1979). Some ethicists have argued that providing participants with individual results is an obligation grounded in the principle of beneficence, when information provides evidence of immediate risk, and interventions to manage or treat the threat are available (Dressler, 2009; Ravitsky & Wilfond, 2006). For example, findings revealing a genetic vulnerability to lung cancer hold strong potential for empowering the individual's decision-making related to tobacco use. The failure to provide individual information collected as part of the study protocol has the potential to harm the individual when awareness of the problem could lead to specific risk reduction behaviors, and effective treatment to assist with smoking cessation is available.

Against Individual Disclosure

Arguments against disclosure span a diverse range of issues including investigator role clarity, the ethical principle of beneficence in relation to characteristics of the research findings, and resource utilization. Perhaps the broadest argument against individual disclosure is referred to in the ethics literature as ''therapeutic misconception,'' the potential confusion in the participant's understanding of the goals of research and role of the investigator in relation to these goals. More specifically, therapeutic misconception occurs when the research participant does not distinguish between the clinical research and ordinary treatment and attributes therapeutic intent to research procedures (Lidz & Appelbaum, 2002).

The principle of beneficence and its component rule to ''do no harm'' also have been used to ground the argument against individual disclosure. This argument focuses on issues related to the validity of the study findings, that is, the quality and quantity of the evidence (Ravitsky & Wilfond, 2006). For example, if a study's aim is to develop a diagnostic test, are results of the test sufficiently reliable to support disclosure to the participants? If not, how many replications are necessary before the test can be considered sufficiently reliable to warrant disclosure? Similar questions also can be raised in regard to studies addressing causality. Is it possible that the findings can be due to chance, biases, or confounding? What is the point at which there is sufficient confidence about the results? In these uncertain circumstances, harm is a possible outcome of both positive and negative results (Dressler, 2009). With positive results, perhaps indicating the presence of a vulnerability to disease, inaccurate results may cause needless stress and anxiety. In contrast, a false negative result may lead to false reassurance and inaction when prevention or early detection is possible.

Several issues further confuse the picture, one addressing the influence of individual disclosure on study outcomes and risk/benefits assessment. Meltzer (2006) argued that because the outcome of a study cannot be known before the study is completed, it is impossible to weigh whether participants will benefit by gaining potentially useful results. Further, he argued that even if the information is available, it is unknowable whether the participants will perceive access to this information as a risk or benefit. In addition to complicating the risk/benefits assessment, under the conditions of individual disclosure, investigators may be more susceptible to overstating the benefits of enrollment to potential participants.

Another argument against individual disclosure also focuses on the overall goals of research but extends the discussion to the issue of utilization of resources. Ethically sound disclosure of individual findings requires that the information not only has validity but that appropriate supports are available to assist the participant with issues related to the disclosure.

One issue that has emerged in this discussion is whether the quality control standards that guide laboratory testing for clinical use also should be implemented in the research context. The Clinical Laboratory Improvement Act of 1988 (Centers for Disease Control, 1988) stipulates that laboratory studies, to be used in the diagnosis and treatment of humans, must be completed in a CLIA-compliant laboratory. Because laboratory studies often are done by research groups in their own laboratories, questions have been raised about the obligation to have the tests redone in a CLIA-compliant laboratory to ensure analytic validity before disclosing results to the individual participant (Shalowitz & Miller, 2005). In this case, the

burden of cost becomes a key issue in the debate (Meltzer, 2006).

Similarly, counseling may be appropriate to assist the individual in making the decision about receiving research findings, particularly in the area of genetics research, but again questions emerge about the use of research resources to cover the cost of individual-based services. Finally, disclosure of findings raises issues of patient education and counseling needs at the time of disclosure, the provision of treatment referrals, and ultimately, responsibility to cover the costs of subsequent care. In all cases, decisions about the appropriate utilization of resources are multidimensional and complex.

At the center of the issue of disclosure is the fundamental difference between research and practice, somewhat narrowly outlined in the Belmont Report (NCPHS, 1979). Research is defined as a set of activities designed to achieve scientific objectives and contribute generalizable knowledge. From this viewpoint, the primary obligation of the researcher is to conduct good science and contribute knowledge to the general population (Belsky & Richardson, 2004; Meltzer, 2006; Morreim, 2005). In contrast, the focus of practice is on the health and well-being of a particular individual. Practice provides diagnosis and treatment that are specifically designed to meet the needs of individuals. For the practitioner, the primary obligation is to act in the best interest of the specific patient.

The demarcation of the issue of respect for persons between investigators and clinicians may become muddy because research involving human subjects, regardless of its scientific aims, must still ensure beneficence and justice. Research using human participants is directed at providing a good for humans, and not just knowledge for knowledge's sake. Further, the sharp differentiation between research and practice emphasized in the disclosure literature creates dissonance for investigators in practice disciplines. Grace (2009) argued that the obligation of research extends beyond the focus on generalizable knowledge for societal good. According to this view, the individual is the essential component of society. Therefore, contributions to the general good cannot occur without attention to the needs and good of the individual. The rightful emphasis on individual good as the single pathway to societal good that underlies the ethics of research in practice disciplines increases the complexity of the investigator's decision-making related to individual disclosure.

In summary, conflicts stem from the fiduciary (trust) relationship between clinician and patient, the potential conflation of roles between investigator and clinician, protection of the aims of the research project in the context of addressing the individual's rights and needs, and the utilization of resources to both achieve the study aims and address the needs of the individual participant. These are examples of the complex and compelling tensions that must be considered as the investigator addresses the issue of individual disclosure.

Creando Posibilidades: Considerations for Individual Disclosure

In implementing *Creando Posibilidades*, we attempted to resolve questions regarding the risks, benefits, and obligations to participants related to individual disclosure by addressing the issue collaboratively with co-investigators across the two study sites, emphasizing mindful planning and collaboration with the IRBs prior to the launching of the study protocol. The process of deciding whether to identify women at risk for meeting diagnostic criteria for eating disorders did not follow a linear path but rather was modified over the study design period by conferencing and seeking recommendations from the IRBs.

The EMA data presented a special case for disclosure in that they provided an unusually specific account of patterns of risk behaviors. Unlike many measures of eating disorder symptomatology that have limited diagnostic utility, the EMA records provided detailed information about specific behaviors and the patterns of behaviors over time. For example, laxative use is considered a purging behavior only when it is taken for the purposes of ''getting rid of'' ingested food as a means to lose weight or prevent weight gain. Similarly, an episode of eating is considered an objective binge episode only when: (1) the quantity of food ingested was larger than most others would eat in similar circumstances, (2) it occurred within a 2-hour interval, and (3) it was accompanied by feelings of being out of control. These specific attributes were queried in *Creando* each time a target behavior was recorded. Further, the EMA data captured the weekly frequencies of behaviors, information which can be used to establish an eating disorder diagnosis.

There were several additional reasons why disclosure was an important issue for this study.

First, despite the fact that women know they are engaging in these behaviors, women often do not know the physical health consequences of DE behaviors (Le Grange, Swanson, Crow, & Merikangas, 2012). Further, recent studies have shown convincingly that sub-threshold levels of DE behaviors, patterns of behaviors at lower severity than required for the diagnosis, have significant, if not equal, physical and mental health consequences (Patton, Coffey, Carlin, Sanci, & Sawyer, 2008). Finally, the eating disorders, including anorexia nervosa, bulimia nervosa, and eating disorders not otherwise specified, are most easily and successfully treated at the early stages of the illness before the behaviors have consolidated into a stable syndrome (Treasure & Russell, 2011). From this perspective, disclosure of individual information for women with signs of an eating disorder may empower them to seek treatment and make health-directed behavior change.

Identification of Potentially Meaningful Information

Once study measures and procedures were identified during the research planning stage, the first issue addressed was the potential clinical utility of the data at the individual level. Currently no specific guidelines exist for determining ''direct clinical utility'' within clinical and behavioral research [see Miller et al. (2008) for a referenced discussion]. However, Sharp and Orr (2004) suggested that clinical utility could profitably be defined as information related to a life-threatening condition or signs and symptoms of potentially treatable disorders. This definition enables distinction between measures designed to detect clinical conditions (e.g., Structured Clinical Interview for DSM-IV, Beck Depression Inventory [BDI], blood pressure) and other measures designed to tap constructs with less direct clinical significance (e.g., Positive and Negative Affect State Measure—PANAS; Measure of Hostility).

In addition to determining whether measures hold potential for generating clinically important information for individual participants, decisions regarding the threshold point for disclosure must be made prior to the start of a study (Sharp & Orr, 2004). Clinical standards and empirical evidence supporting sensitivity and specificity of a measure for a defined population can be used as guidelines when establishing a reporting threshold. For example, study results suggest that a score of 4 or higher on the Beck Depression Inventory for Primary Care has 97% sensitivity and 99% specificity for identifying adult outpatients with and without a current major depressive disorder (Steer, Cavalieri, Leonard, & Beck, 1999).

For *Creando Posibilidades*, issues of sensitivity and specificity were not applicable to the EMA data, and threshold points not easily determined for the EDI. Although alcohol intake was assessed, the issue of individual disclosure was not addressed relative to at-risk levels of alcohol use behaviors. One reason that this issue was not raised by the research team or the IRBs was that amount of alcohol intake does not provide diagnostic information about DSM-IV alcohol abuse or dependence diagnoses. However, recent evidence of the sensitivity and specificity of a single alcohol screening question and the effectiveness of brief interventions (McCance-Katz & Satterfield, 2012) point to the need for future researchers who collect alcohol intake data to address the issue of disclosure.

Plans for Monitoring Data

Research data collection activities often are handled by auxiliary research staff, and very frequently the principal investigator is not involved in monitoring the data as they are collected. Therefore, specific plans for *Creando Possbilidades* were developed to identify who would be responsible for monitoring the clinically relevant measures to identify individuals who scored above the threshold for disclosure. Furthermore, specific plans for the timeline and management of the information were determined. For paper-and-pencil questionnaires like the BDI, responsibility for computing the score and the timeline for doing so were clearly specified. Each data collector would be required to compute the scale score immediately after conclusion of the data collection session. Scores over the reported threshold would trigger communication with the principal investigator so that plans for disclosure to the participant could be arranged.

Plans for Disclosing Information to Individual Participants

An important point of team consensus was that if implemented, individual disclosure should be addressed in the informed consent process

(Dressler, 2009; Shalowitz & Miller, 2005). A detailed description of the information and the circumstance that would trigger disclosure was articulated in the informed consent form. Additional planning identified the research staff person who would be responsible for disclosing information to the study participant. Details such as the qualifications and/or training required for persons assuming this responsibility and the format of the disclosure meeting were specified. Although it was decided that the principal investigator would assume primary responsibility, issues such as the importance of an established relationship were discussed to determine whether other research staff, such as the data collector, might be more appropriate to assume the responsibility.

Timing of Disclosure

The timing of the disclosure required consideration of both the nature of the health information and the implications for the study protocol. Information that has immediate and life-threatening consequences for the individual, such as suicide intent, was judged clearly to take precedence over all other concerns. However, discussion about the timing of disclosure of other non-life threatening information considered the implications for the study protocol and the investigator's obligation to conduct scientifically sound research that contributes generalizable knowledge.

In this study, EMA data were collected at five points during the 12-month protocol, including baseline, 3, 6, 9, and 12 months. Although early treatment-seeking would improve the participant's likelihood of recovery, disclosure during the protocol held strong potential for biasing the data, thereby compromising the ethical obligation to utilize funding resources to achieve the stated scientific objectives. For example, discussing alarming behavior patterns with the participant during the study protocol would create the possibilities that the participant would not be comfortable continuing to report behaviors during subsequent measurement periods, or that the feedback would lead to a project-induced decision to seek treatment, which would likely alter the natural course of behaviors.

Use of Study Resources

Another important factor influencing the decision regarding individual disclosure was the feasibility and costs associated with monitoring participant data for signs of an eating disorder. The target sample for this study was 540 women, with data collection coordinated at two research sites. At each EMA data collection point, participants were asked to download their data from the PDA to a secure website at least once weekly during each 14-day recording episode. Identification of cases with a potential eating disorder would require an ongoing detailed review and evaluation of these EMA data and their synthesis with other measures of eating disorder attitudes, including the EDI. In the end, the use of resources to engage in clinical diagnostic activities was deemed incongruent with the explicit study purpose to investigate the role of properties of knowledge structures related to the self (e.g., self-schemas) in predicting risk behavior trajectories over a 12-month period. While we could not separate the obligations of "do no harm" and "promote the good" from their congruent obligations in both practice and research, we did evaluate whether the focus of the research (study purpose) might be diluted or not achieved if the care obligations subsequent to follow-up diagnostic procedures became a study activity.

Contract With Participants

A final issue we considered was the context of the research study and the participants' expectations about participation and desire for individual specific feedback. For this study, women were recruited from their college settings based on ethnic background, age, and enrollment in school, and all data collection activities were completed at the participant's campus. The informed consent clearly stated that the purpose of the study was to learn about factors that contribute to health risk behaviors, and the specific behaviors measured were clearly specified and defined. However, study participants were not recruited for health problems, nor were they recruited from a health care site. Therefore, participants did not enter into a relationship with the research team in the context of seeking health care services or in response to a perceived health care need. Rather, participants contacted the research team in response to advertisements seeking participants for a research study that would include monetary remuneration for participation. Prior to enrollment, the investigators did not discuss with the participants their personal preferences for receiving

individualized health-related information that was collected as part of participation in this study. Within this context, it was unlikely that the participant was seeking or expecting personalized information about her health status as an outcome of participation.

Thus, although the initial plans and consent process included a plan for disclosing to participants if they were at risk, after team discussion regarding the nature of study data, the relative risk of disclosure related to participant health and continuation in the study, and recommendations from our IRB, the team chose not to disclose data assessments of at-risk behaviors for eating disorders. Instead, the IRBs recommended that the last data collection session of the study include the provision of information about eating disorder symptoms and treatment options. At the final debriefing session, each participant was given a description of the signs and symptoms of the eating disorders and a list of potential treatment options, both verbally and in writing. The protocol required that the research assistant verbally provide information about the symptoms of anorexia nervosa, bulimia nervosa, and binge eating disorder, along with a brief summary of the potential health consequences of these behaviors. This information also was given to each participant in a written pamphlet along with a list of treatment centers in the area.

Summary and Conclusions

The *Creando Posibilidades* study provides an example of the array of complexities that can emerge within a clinical study when considering disclosure of individual results, and how these considerations may be mutable during project implementation. Although the fundamental value of caring that underlies health-related disciplines may lead clinical investigators to automatically conclude that disclosure is an obvious and nondebatable obligation, the arguments supporting and challenging disclosure point to the complexities involved. Clinical investigators, like all scientists, have critical obligations to generate knowledge that will contribute to the general good as well as address the needs and good of the individual. Furthermore, investigators cannot assume that disclosure is the desired choice for study participants or that disclosure itself has no risks. Mindful consideration of the nature of information that will be collected, on-going discourse about the pros and cons of disclosure within the research team, and initial discussion and continuing review with the appropriate regulatory body are essential aspects of study planning for all health-related research that involves human subjects.

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