Introduction to Revision

The central critique of our first proposal was the absence of a coherent theoretical framework. This absence was reflected in questions about measurement and analysis. In addition, there were smaller points about attrition estimates and clarifications. Although the study design and general aims remain unchanged, this revision reflects sweeping changes in the theoretical framework and subsequent measurement and analysis. These changes enable us to present a study design that will not only provide valuable information about infertility helpseeking and infertility outcomes, but will enable an unusually comprehensive examination of the central ideas of helpseeking theories.

Drawing from general theories of helpseeking, we have developed an integrated theoretical framework for infertility helpseeking. This theoretical framework (illustrated in Figure 1, page 37) draws attention to the cognitive processes that intervene between biomedical cues and treatment seeking and to the factors that moderate these cognitive processes. In this model, perception of biomedical cues and cognitive appraisals of possible responses to these symptoms are key determinants of helpseeking. The model also specifies the extent to which these processes are modified by individual, social, and temporal cues that are specific to infertility (e.g., intensity of childbearing desires, demands for children by spouse and parents, awareness of biological clock) as well as classic enabling and predisposing conditions that are thought to predict general help seeking, such as education, income, health, and having a doctor. We extend our theoretical perspective to include outcomes of helpseeking, both behavioral and psychosocial.

This new theoretical framework led us to re-examine the measures we proposed earlier. Although many of the measures remain the same, they have been re-organized under the central concepts of the theory. This re-organization made it clear that some central concepts had not been measured adequately in the original proposal. In particular, the revision reflects stronger measurement of perception of a fertility problems and cognitive appraisals and the addition of measures of temporal perspectives.

Although some members of the research team have extensive experience working with help seekers, neither the team members’ experience nor the literature provide much guidance on developing appropriate measures of self perception or cognitive appraisal for infertility. As the critique suggested, we have built a preliminary focus group process into this revision. These focus groups of non-treatment seekers who meet a medical definition of infertility should provide useful insight into cognitive processes that intervene between biomedical cues and treatment seeking. In addition, the revision includes a process of cognitive interviewing before the study is fielded. In this process, a relatively small group (2 dozen) respondents are given the interview in the laboratory rather than via telephone and debriefed extensively about the meanings they attached to the questions. These two new processes should ensure that the final instrument reflects not only a thorough grounding in theory and prior research, but also in the experiences of those experiencing infertility.

As noted by the reviewers, our original submission focused on race/ethnic disparities, but it had little to say about social class disparities. Our new theoretical framework explicitly includes social class indicators. Our null hypothesis is that social class as well as race/ethnic disparities in help seeking are explained through intervening variables such as individual and social cues and predisposing and enabling factors.

The integrated theoretical model provides a strong framework for our analysis plan. As a result, the comprehensive but fragmented analysis plan proposed in the first submission has been extensively reworked. The new proposed analyses reflect a systematic approach to the key theoretical issues. The three detailed analysis plans have been reworked and situated theoretically.

In addition to problems attributable to absence of an integrated theoretical framework, the critique also raised a variety of more technical issues.

Critique 1 wondered why we used a 15% attrition rate between waves. We have gone back to the drawing board on this, and we now use a 25% attrition rate and cite the research that supports this figure.

The same reviewer asked us to include state laws in the analysis. Geocoding of state of residence and linkage to state laws regarding insurance coverage for infertility treatment is now included.
Critique 1 asked whether we would have enough cases for the proposed analysis of how involvement with nonbiological children (step, adopted, foster) would modify the effects of infertility. Pilot data show that 15% have stepchildren and 18% have experience with fostering (largely informal). Percentages are higher for women with biomedical fertility barriers. Because we anticipate wave 1 interviews with 3,500 women with biomedical barriers, we should have adequate power for these analyses. Sample size estimates are provided in more detail than the previous submission in the section on power analysis.

Critique 2 questioned a unitary measure of social support. The revised measurement section (as well as Figure 1) make it clear that we assess two types of social support. General social support, which is viewed as one of a broad group of enabling conditions, and infertility-specific support. The latter, included under Social Cues, differentiates between support from partner, from family, and from friends.

Critique 3 and Critique 4 ask about the rationale for the initial age range of 25-50. Careful analysis of the pilot data convinces us that this is a valid critique. Although many women in the age group of 46-50 had infertility experiences, this experience was largely in the distant past and none of these women intended to have additional children. Inclusion of this group is largely of historical interest, and it does not contribute to the focus of the prospective design, i.e., to follow women who intend additional children. As a result, the design has been changed to include only women 25-45. Reducing the age range will require a little more screening (reducing the likelihood of an appropriate respondent from 35 to 29% of households), however the younger age range means that the same number of interviews produces a larger sample of women who intend more children. The larger base sample balances the higher attrition estimate used in the resubmission so that number of reinterviews and total costs have changed little.

Critique 3 also raises the issue of whether a $2 incentive is adequate to raise cooperation rates. In the resubmission, we cite research that demonstrates that a token incentive is sufficient to raise cooperation rates, even among affluent research populations (such as physicians). We will continue to follow research coming out in this area to monitor changes in this conclusion.

Critique 4 raises the question of whether we have too broad a conception of infertility. The key point of entry into our model, as with most helpseeking models, is the experience of symptoms, in this case of infertility. We also allow entry into the helpseeking process of women who are circumstantially childless (no male partner). In addition, we explicitly compare psychosocial outcomes across a continuum of childlessness, from more to less voluntary. Reviewer 4 asked whether the helpseeking model was relevant to these groups and whether such a broad perspective might not dilute the focus. The helpseeking model is clearly relevant to the circumstantially childless. Studies suggest that 1/3 of the women seeking donor insemination are unmarried, and many who seek adoption are unmarried. The processes whereby unmarried women evaluate their circumstances and choose to seek or not seek medical and other remedies provide a broad test of the general helpseeking model in a situation where neither the symptoms nor the remedies are exclusively medical. Childless women are included as a comparison group. Without their inclusion, we run the risk of attributing consequences to infertility that are more properly attributed to childlessness. We believe that the inclusiveness of our design enables us to provide a comprehensive test of helpseeking theories and enables us to untangle the consequences of biomedical infertility compared to other causes of childlessness.

The study design in this resubmission remains virtually unchanged. As a result of reducing the upper age limit from 50 to 45 and increasing our estimate of attrition between waves from 15% to 25%, however, all of the numbers listed in the study design and power analysis are slightly different. Because of higher attrition, we now estimate we will need 5,774 complete interviews at time 1 instead of 5,000. At time 2, however, the number of completed interviews expected changes only from 2,708 to 2,791. We have rewritten the descriptions of the reinterview process and power analysis to make them clearer.

Throughout the Research Plan, revisions are presented in Times New Roman and original material is presented in Arial.

1. Research Plan

A. SPECIFIC AIMS.

Extended education and delayed marriage have transformed the critical issues in studying American fertility from an exclusive focus on preventing unwanted pregnancy to enabling pregnancy in women over 30. Approximately 20% of
American women aged 35-39 in 1995 were childless, but only half of them expected to stay that way. Less than a third of the women who were childless at ages 30-34 expected to remain that way. These estimates from the 1995 National Survey of Family Growth (NSFG) suggest that many women remain confident of their ability to have children at ages during which their risk of infertility is rising sharply (Dunson et al. 2002). The importance of this dilemma is reflected in NICHD’s Strategic Plan, from Cells to Selves, and in growing popular concern (e.g., Hewlett 2002).

Data from the 1995 NSFG indicate that fewer than half of women with fertility impairments seek medical help (Chandra & Stephen 1998), yet most prior work on infertility focuses only on those who have sought help. No prospective studies have examined responses to infertility among a general sample experiencing infertility.

The proposed cross-sectional and prospective study of a large random sample of American women will allow us to answer many questions that have been impossible to address using the NSFG, the best source of information previously available. The proposed study begins with a cross-sectional study of women with an over-sample of women of color. This cross-sectional study includes interviews with partners (male or female, married or cohabiting). Three years after the initial cross-section, we will reinterview all women (and their partners) who desire children in the future, childless women, and a random sample of others.

In demography, infertility is absence of biological children; in medicine, infertility is subfecundity, specifically failure to conceive after 12 months of unprotected intercourse. Our primary focus is on what we call biomedical fertility barriers. These barriers include subfecundity, but also repeated miscarriages, health conditions that preclude childbearing, and sterilization regret. All of these barriers may result in blocked childbearing or affect psychosocial wellbeing. In addition, we consider infertility due to absence of a male partner, so that we can differentiate between the consequences of biomedical infertility and circumstantial infertility.

The proposed study has four aims.

1. Test a general model of medical helpseeking applied to infertility. In addition to providing a novel and unusually thorough test of the general model, we document the pathways to treatment and the routes and obstacles that take women out of treatment.

   We use an integrated model of helpseeking to assess how individual, social, and temporal cues and enabling and predisposing conditions predict pathways for infertility helpseeking. We consider the extent to which these factors as well as race/ethnicity and social class track women away from helpseeking. Our cross-sectional study design includes those who have not recognized their infertility, those in various stages of considering options and responses, those who have and have not sought medical help, and those who use only spiritual, educational, and social resources to cope with infertility. The prospective design follow women who have experienced infertility and those who experience fertility impairments for the first time between waves. The results will provide a comprehensive test of a general helpseeking theory and provide insight into infertility consequences and helpseeking.

2. Identify the consequences of infertility for individual psychosocial outcomes, identities, and social relationships.

   We expand the analysis of infertility sequelae in several ways. First, our sample is more inclusive. We include those who do not seek treatment, allowing examination of consequences of infertility among those who do and do not seek treatment. We also include those who are childless by choice or circumstance. This allows us to examine whether outcomes attributed to biomedical infertility are similar to those due to other sources of childlessness. Second, our study includes a prospective design. This will allow analysis of changes in outcomes and of the extent to which the identification of and response to fecundity impairments (including successful and unsuccessful treatment and adoption) modify psychosocial outcomes, identities, and social relationships. In addition, the prospective design will allow us to examine a feedback process in which psychosocial responses to infertility affect on-going cognitive and behavioral responses.

3. Assess prevalence of concerns about the ethics of assisted reproductive technologies, including the extent to which ethical concerns act as barriers to treatment.

4. Provide a public use data set for researchers who are interested in issues of fertility, infertility, helpseeking, and well-being among adults.
B. BACKGROUND AND SIGNIFICANCE

We briefly review research on prevalence of fecundity impairment, treatment seeking for biomedical fertility barriers, and outcomes of infertility before describing the conceptual framework that underlies the proposed study.

PREVALENCE OF FERTILITY BARRIERS. Data from the 1995 NSFG suggest that 10% of non-surgically sterile American women of reproductive age currently experience “impaired fecundity” (Chandra & Stephen 1998), a twenty percent increase since 1988. The 10% figure is based on a markedly conservative measurement of infertility. The cornerstone of this measure is inability to conceive after three years of unprotected intercourse (Chandra & Stephen 1998), yet the common medical definition considers women to be infertile if they have not conceived after one year of unprotected intercourse. Because it measures only current infertility, the 10% estimate also excludes younger women who have never had unprotected intercourse and have therefore never tested their fertility.

Using a lifetime prevalence measure, studies in England suggest that 25% of women have experienced subfecundity, i.e., had difficulty conceiving at some point in their lives. Our pilot data show that 35% of American women 25-50 have experienced subfecundity. Although these figures may strike the reader as exceptionally high, they are close to what NSFG data imply. If 15% of American women 15-44 have ever sought help for infertility and less than half of those with current infertility have ever sought help (both figures from NSFG), we can extrapolate that at least 30% of ever-married U.S. women aged 15-44 have experienced subfecundity.

Disparities. Subfecundity varies only modestly by socioeconomic status. NSFG data show that women with high school educations are slightly more likely to meet the medical criterion for infertility (one year of unprotected intercourse without conception) than women with college degrees (8% versus 6%). Black and Hispanic women are substantially more likely than white women to meet this infertility criterion (10% and 14% compared to 6% for non-Hispanic white women), but there is little racial difference in a broader measure of fecundity impairment (Abma et al. 1997). In general, disadvantaged groups’ higher risk of poor health outcomes is counterbalanced by lower risk of infertility because of earlier childbearing.

TREATMENT AND TREATMENT SEEKING. Reproductive science and technology provide a growing array of remedies for those who face impaired fecundity, sterilization regret, and male partner absence. Demands for these expensive infertility treatments will pose a challenge to calls for cost containment of public and private health care costs. In addition to these societal costs, individuals face financial, physical, and social-psychological costs that restrict help seeking.

Of the women identified as fecundity impaired in the 1995 NSFG, 43% had ever sought infertility services, an increase from 38% in 1982. As the level of treatment rises, from advice to tests to minor corrective surgeries to artificial insemination to in-vitro fertilization (IVF), smaller numbers are involved (Abma et al. 1997). From studies of clinic populations, we know that treatment seekers are disproportionately white, well-off, married, and insured. These findings suggest that economic barriers are critical, but no studies have used a general model of helpseeking to situate these differentials in a broad theory of health beliefs and health behavior.

Another important issue is the role of gatekeeping, when treatment providers deny services to some treatment seekers because of characteristics presumed to be associated with low parenting quality or low likelihood of success (Gerrity 2001). Insurance companies (including Medicaid) may also act as gatekeepers by paying for some diagnoses but not others. In early 2003, only 3 states required that insurance companies cover costs of infertility treatment.

Disparities. Although disparities in fecundity impairment are modest, disparities in treatment seeking are substantial. Black and Hispanic women are significantly less likely to seek medical services for fecundity impairments than non-Hispanic whites (31 and 35% v. 48%). Gaps are also large by social class indicators. For example, 56% of college graduates with fecundity impairments have sought help compared to 41% of those with less education and 47% of those with private health insurance had sought help compared to 28% without (Stephen & Chandra 2000). These gaps grow as the level of service rises from advice to surgery to artificial reproductive technologies (ART).

CONSEQUENCES OF INFERTILITY & INFERTILITY TREATMENT. Research on the social-psychological consequences of infertility provides mixed results. Health care providers report high levels of anxiety and distress among patients being treated for
infertility (Downey and McKinney 1992; Domar et al. 1993; Mahlstedt 1994). Qualitative studies of infertile couples produce poignant accounts of grief and loss, in which people question their faith, the meaning of life, their marriages, and their doctors (Greil 1991). Quantitative studies, especially those with a control group, find weaker negative associations. About half find a connection between infertility and measures such as anxiety and distress (Dunkel-Schetter & Lobel 1991). Infertility appears to be associated with varying degrees of distress and worry but not with clinical levels of depression or anxiety. These effects are stronger for women than men (Abbey et al. 1991).

Studies based on clinic samples confound the consequences of infertility and infertility treatment. Using the 1995 NSFG, however, King (2003) reports that levels of anxiety are higher among those with impaired fecundity regardless of whether they are seeking treatment. She was unable to assess consequences of impaired fecundity for outcomes such as marital quality, distress, and life satisfaction. Another weakness of prior work is the absence of prospective studies. Without a panel design, it is impossible to examine plausible reciprocal relationships between variables such as distress and relationship quality and treatment seeking.

AN INTEGRATED MODEL FOR UNDERSTANDING RESPONSES TO INFERTILITY.
Our goal is to understand the pathways that lead toward or away from treatment for infertility and the consequences of these pathways for psychosocial wellbeing. We draw hypotheses from theories of helpseeking, identity, and stress. The conceptual model guiding this analysis is shown in Figure 1, adapted from models presented by Andersen (1968), Becker (1974), House (2002), Pescosolido and Boyer (1998), and Shaw (1999).

Figure 1 emphasizes that each step of the process from the experience of biological cues to cognitive and behavioral responses to psychosocial responses is problematic. Major explanatory concepts are grouped within the categories of social, individual, and temporal cues, enabling conditions, and predisposing conditions. Our null hypothesis is that background variables, race/ethnicity, socioeconomic status, age, gender, parity, and relationship status, work through these explanatory variables. To make the figure manageable, these variables are grouped in larger boxes called Key Explanatory Variables and Background Variables. We do not include arrows for all of the modifying hypotheses, but the variables most central in each situation are indicated in the discussion.

For most, the entrance into fertility problem solving begins with biomedical cues of infertility, failure to conceive after a number of months of unprotected intercourse. As Anderson (1968) suggests, self diagnosis – or perceiving these cues as a signal of infertility – is a key step in helpseeking, and one that is far from automatic. Zola (1973) points out that symptoms are ubiquitous in social life and that the social construction of illness is mediated by social triggers, such as perceived interference with personal and social relationships and sanctions from significant others. In a similar vein, Mechanic (1968) argues that helpseeking will be influenced by the perceptual salience of deviant signs and symptoms, the extent to which symptoms disrupt activities of daily life, and competing possible responses to symptoms. Self diagnosis is particularly problematic for infertility, which is often heralded, not by the development of undesired symptoms, but by the absence of change. We hypothesize that the likelihood that this absence will be perceived as a signal of infertility depends on individual, social, and temporal cues (such as the immediacy and strength of fertility plans, perceived stigma of infertility, messages from partners, and temporal perspective).

Our pilot study confirms that the single most important predictor of helpseeking among the subfertile is self-identification as someone with a fertility problem. This suggests that perception of fertility problems is a critical factor for understanding infertility pathways. Once fertility is perceived as a problem, the individual may progress to consideration of alternative solutions. These cognitive responses include assessment of the need for treatment (i.e., how likely it is that the situation will resolve itself), perception of options (childlessness, medical help, self care, and
Figure 1 Conceptual Framework: Infertility Pathways and Outcomes

Key Explanatory Concepts and Variables

**Biomedical cues of fecundity impairment**
- Perception of a biomedical fertility problem (self-identification)

**Circumstantial childlessness**

**Background variables**
- Racial ethnic identification
- Mothertongue
- Gender
- Age
- Parity
- Socioeconomic status
- Relationship status

**Social cues**
- Perceived pressure for children
- Perceived stigma of infertility
- Network member’s experiences
- Social support for treatment
- State laws

**Individual Cues**
- Identity salience
- Valued goals
- Value of children
- Religiosity
- Fertility intentions & ideals

**Temporal Cues**
- Time perspective
- Life course

**Enabling Conditions**
- Resources
- Availability of treatment
- Social support

**Predisposing conditions**
- Health
- Attitudes/ knowledge about ART
- Medical locus of control
- Self-esteem
- Just world beliefs

**Cognitive Responses**
- Assess the need for, barriers to, and benefits of behavioral responses
- Identity work

**Behavioral Responses**
- Health care utilization
- Self-care
- Non-medical help seeking
- Alternative parenting routes

**Behavioral outcomes**
- Birth of a child
- Adoption
- Gate-keeper rejection

**Psycho-Social Outcomes**
- General distress
- Substance abuse
- Life satisfaction
- Marital (union) quality
- Satisfaction with social relationships
- Infertility-specific distress
- Childless-specific distress

New cycle over time.
adoption), perception of the benefits and barriers of various options, and identity responses such as a transition to non-parenthood (Matthews and Matthews 1986). This “cognitive processing” (Shaw 1999) is critical in all theories of helpseeking and is affected not only by biomedical cues but directly and indirectly by predisposing conditions (health beliefs, health, knowledge and attitudes about reproductive technology), enabling conditions (resources, availability of treatment), and individual and social cues. We expect these variables to have a direct effect on cognitive appraisal of the need for helpseeking (to some extent, independent of biological cues), but also that cognitive responses will depend on (be modified by) these key explanatory factors. For example, individuals who perceive a fertility problem will be more likely to process this information cognitively if they perceive a short time horizon, believe in the efficacy of medical treatment, have parents impatient to be grandparents, and so on. Assessments of the time dimension are critical in all illness appraisals (Shaw 1999), but they should be particularly important in judging whether infertility requires action.

The central assumption for theories of illness behavior and helpseeking is that moving from symptoms to medical treatment is not automatic. Such models in the social and behavioral sciences downplay the role of physical symptoms in comparison to cognitive appraisal and predisposing and enabling conditions. In the study of infertility, we take this one step further to include another source of entry into the helpseeking model, i.e., circumstantial infertility. Women who face childlessness because they do not have a male partner or have a sterilized partner may perceive this as a problem and process the various responses open to them, including donor insemination, adoption, and so on. These women are a growing proportion of the population seeking donor insemination (Jacob 1999). Inclusion of women who enter the process via social rather than biomedical cues enables us to assess more fully the role of biomedical cues in the helpseeking process.

Reproductive science and technology provide a growing array of remedies for those who face impaired fecundity or circumstantial infertility. In addition, fertility problems admit solutions other than the biological achievement of pregnancy. These alternative responses may be pursued simultaneously or sequentially. For example, some may pursue adoption only after they have exhausted treatment options while others pursue both courses. Our model hypothesizes that on-going cognitive appraisals of the need for, success of, and barriers to treatment and adoption are the primary determinants of moving on to behavioral responses. In addition to responding to cognitive appraisals, behavioral responses are directly affected by enabling conditions such as income, health insurance, and availability of treatment, and by predisposing conditions, such as knowledge of and attitudes toward reproductive technology. Both medical treatment and adoption are affected by partner and family support, temporal issues, and individual characteristics such as strength of fertility desires and life goals. We hypothesize that these factors will affect behavioral responses directly and will also modify the effect of cognitive responses. For example, individuals, who perceive the need for and benefit of fertility treatment will be more likely to act on these appraisals if, for example, they have private health insurance.

We know most infertile women do not seek treatment to resolve impaired infecundity (Chandra and Stephen 1998) and that treatment seeking is linked to race/ethnicity and social class indicators. Prior studies have been unable to assess whether such patterns of helpseeking are due directly to resources or whether they can be explained by differentials in perceiving a problem, cognitive appraisals of the alternatives, predisposing conditions (e.g., knowledge and attitudes toward reproductive technology), or social and individual cues. For example, Black and Hispanic women’s lower use of infertility treatment may be due to a cultural aversion to technological solutions to a holistic health problem, greater aversion to infertility labels and treatments, distrust of a medical establishment that has victimized minorities in the past, or to other factors. Molock (1999) suggests that childless African Americans are more able than other groups to resolve infertility through formal or informal adoption and more likely to seek spiritual solutions. Our framework will test the hypothesis that observed patterns by race/ethnicity and social class are mediated by these key explanatory factors. We will also, however, examine whether variables in the model operate with more or less strength among these critical population groups.

Behavioral responses may or may not lead to desired outcomes. Although the likelihood of conception following infertility treatment depends on many factors including age and type of treatment, overall perhaps somewhere between one half and three quarters of women who seek medical help for infertility are able to conceive a child (Mosher & Pratt, 1990). Likewise, many who start the process of adoption do not end up with a child. In our model, the likelihood of successful outcomes depends directly on behavioral responses but also on other key variables such as resources, support from family and friends, and intensity of desire for children.

**Psychosocial outcomes** of infertility and infertility pathways include general psychological distress, infertility-specific stress, childless-specific distress, quality of marital relations, life satisfaction, and satisfaction with social relationships. These outcomes are
affected by cognitive and behavioral responses to infertility, by background variables, and by factors included in our model as key explanatory variables.

Stress occurs when people experience events or circumstances, called stressors, with which they do not believe they have sufficient resources to cope (Pearlin, et al., 1981). According to Aneshensel (1992), stressors need not be events but can also be “non-events” or failures to achieve life goals. According to Burke (1991), such identity disruptions will result in higher levels of distress when the interruption is repeated or severe, when the identity in question highly salient, and when the interrupted identity is one to which the individual is highly committed. The Identity-Relevant Stress perspective suggests that, whether barriers to fertility are bio-medical or circumstantial, fertility problems will lead to distress, especially when parenthood is a central identity (Thoits 1991, 1999).

Little is known about psychosocial outcomes for those who do not perceive a problem or those who decide not to pursue treatment. Although King’s study (2003) suggests that the consequences of fertility impairment are not dependent on treatment, she was unable to address perceptions and cognitive appraisals that intervene between biomedical cues and treatment seeking. Our pilot data suggest infertility is distressing for those who remain childless regardless of treatment, but that women who eventually have children suffered no long-term distress. Similarly, Greil (1991) found that infertile couples who adopted were just as satisfied with their lives as those who had biological children. There are many decision points in the helpseeking process and, even among those with biomedical barriers, there are degrees of choice. The proposed study will allow analysis of how these choices, e.g., treatment, a carefully considered decision not to seek treatment, or failure to recognize biological cues, affect psychosocial outcomes.

We expect that psychosocial outcomes will be worse for those who place more value on children. Because individuals with at least one child have already attained parenthood, we expect that primary infertility (i.e., infertility among the nulliparous) will create more negative outcomes than secondary infertility (i.e., for those who are already parents). Outcomes should be more positive among those with weaker childbearing intentions, less pressure from others for children, and stronger salience of non-family roles.

The literature on mental health shows that race and ethnicity, gender, age, socioeconomic status, and relationship status all exert a strong direct influence on measures of psychological well-being (Ross & Mirowsky 1989). We hypothesize that these variables will have a direct effect on psychosocial outcomes as well as operating indirectly through the other variables in our model. Suggestions about how the effects of infertility may vary by race/ethnicity and social class are largely speculative. It has been suggested that stress may be higher for African American and Latina women because of a stronger value for children (Phipps 1998). On the other hand, minority women may have more contact with nieces and nephews (Mollock 1999). In regard to social class, Scritchfield (1995) has argued that infertility is more likely to be perceived as a crisis by middle-class, well-educated women who are used to having their plans fall into place. The basic premise of stress theories (e.g., Pearl et al. 1981), however, is that coping resources such as education and income ameliorate the effect of stressors. We examine whether the effect of infertility on psychosocial wellbeing depends on race/ethnicity and social class and, if so, whether these effects are explained by factors such as educational and financial resources, social and individual cues, or predisposing conditions such as health and attitudes toward ART.

Most studies report that women experience greater levels of infertility-related distress than men (Abbey et al. 1991; Greil 1993). In addition to the biological dimensions of infertility that differ for men and women (for example, regardless who is identified as the primary source of the infertility, wives are more likely to undergo treatment), this difference is generally attributed to a higher value of parenthood for women than men. No prior studies have tested whether such variables do in fact explain observed gender differences. We examine whether gender differences are attributable to individual factors (such as value of children and intensity of childbearing desires), social cues, or predisposing conditions (such as knowledge of and attitudes toward reproductve technology). Because the social meaning of motherhood as a valued social status may be more important for women who do not have alternate avenues for a valued social status (Rothman 1989; Lorber 1994), we also test whether factors such as marital status, work involvement, and contact with children explain gender differences.

RECI PROCAL INFLUENCES. Helpseeking pathways are complex and dynamic (Pescosolido, 1992). People do not form an identity as infertile once and for all. Nor do they opt for only one behavioral response and stick with it. Rather, infertile couples are constantly weighing their options, rethinking their identities, and making new plans (Daly 1988). During this process, distress levels and relationship satisfaction may well have an impact on infertility decision making. Only through a prospective, longitudinal analysis can the dynamic nature of fertility problem solving be investigated successfully. The longitudinal component of our design will allow
us to investigate the extent to which psychosocial wellbeing, including general distress, life satisfaction, and relationship quality, affects cognitive and behavioral responses to infertility.

A key component of the identity-relevant stress perspective is the reflexive component of identity.Thoits (1994, 1999) argues that individuals are not merely victims of stress, but that they take actions to protect themselves from challenges to their identity, including changing their identity salience hierarchy to match what they can realistically attain. In this case, we expect individuals who face barriers to parenthood to reduce their commitment to a parental identity and elevate the importance of other identities. Matthews and Matthews (1986) introduced the concept of “transition to non-parenthood.” Their formulation addressed individuals with insoluble infertility problems who admit defeat, but our model suggests that this transition can occur at earlier stages. That is, the transition to non-parenthood may be a cognitive response that precludes help seeking. The longitudinal component will enable us to examine this identity work by observing consequences of behavioral responses and outcomes for identity reformulation.

INFERTILITY HELP-SEEKING AS A DYADIC PROCESS. Biomedical infertility is more likely to be experienced by married couples, in part because marriage is a social trigger for normative childbearing. Unlike other health conditions addressed by helpseeking models (e.g., urinary incontinence or mental health), infertility is a uniquely dyadic experience. Not only do timing and frequency of intercourse require both partners, but behavioral responses such as adoption or treatment seeking are generally not attempted unless both partners agree (Daly 1988). The dyadic nature of infertility helpseeking is both a complicating factor and an opportunity. Pescosolido’s (1992) help-seeking framework emphasizes the critical importance of social relationship and networks on helpseeking, suggesting that social ties will affect identity and information available and thus affect cognitive processes of diagnosis and cost/benefit assessment. The most critical social network member in infertility helpseeking is likely to be the partner. Qualitative research on adoption and treatment seeking suggests that reaching agreement is often a long process, where his enthusiasm is thwarted by her uncertainty and then her certainty is cancelled by his ambivalence (Daly 1988; Pasch et al. 2002). Analysis of this dyadic process will bear on general models of helpseeking as well as specific pathways to infertility treatment and the consequences of infertility and infertility treatment.

C. PRELIMINARY STUDIES.

PILOT STUDY. Using seed money from the University of Nebraska, all of the co-investigators were involved in designing a pilot study of infertility in 2002. In that study, 580 women ages 25 to 50 were selected by random digit dialing in the North Central region and interviewed by telephone. The pilot study was conducted by the Bureau of Sociological Research at the University of Nebraska-Lincoln. The pilot project included an experiment with response rates among those without pre-notification letters, with pre-notification letters, and with pre-notification letters with a $2 incentive. It included an oversample of telephone numbers in census tracts with more than 40% minority population to evaluate methods to increase minority representation in the sample. The questionnaire remains a work in progress, but results of the pilot project provide valuable information about infertility pathways, a pretest of the questionnaire, and provide firm data about costs, response rates, incidence, and sampling design. (Frequency distributions of items in the pilot study are included in Appendix B.)

All of the investigators have been involved in analysis of the pilot data. Our analyses have focused on four areas so far: 1) incidence of fertility barriers; 2) the association between perceived infertility and help seeking; 3) the relationship between infertility and psychological distress; and 4) attitudes towards the ethics of infertility treatment.

Nearly one third (35%) of our sample of women 25-50 had experienced subfecundity (a delay of at least one year in conceiving among those having unprotected intercourse). This is comparable to that identified in British studies (Greenhill & Vessey, 1990; Page 1989). Of these women, 29% had sought medical tests and treatment. A full 8% of our total sample reported seeking medical help for the conception of at least one of their pregnancies. Racial differences in subfecundity were small, but nonHispanic white women were significantly more likely to have treatment than African American women or Latinas.

The pilot study show that 46% of our sample had experienced biomedical fertility barriers. In addition to the subfecund (35%), 5% of the sample reported two or more miscarriages and 6% had other fertility problems (sterilization regret and health problems that precluded pregnancy). Finding that nearly half of women experience biomedical barriers to desired fertility is striking. A preliminary report of these data was given at the 2002 Conference on Socio-Medical Perspectives on Childlessness in Goa, India in 2002.
A critical finding from the pilot study is that only one-third of the women who met the medical criterion for subfecundity thought of themselves as having had fertility problems. As in Daly’s (1988) report from a small qualitative study, a debriefing session with interviewers revealed that many subfecund women were offended by questions about fertility problems, asserting that this did not apply to them. These findings highlight the central role of perception. In our pilot study, it is the step in the helpseeking process that culls two-thirds of those experiencing subfecundity out of the help-seeking process. Because prior studies of clinic samples of helpseekers provide no data on this critical step, the pilot study provided vital information about the need to conceptualize and measure perception more thoroughly and to assess the stigma associated with infertility. Johnson will present these results at the PAA meetings in May 2003.
The pilot data allow us to make a preliminary examination of the relationship between subfecundity and psychological distress. In a paper now under review, we test hypotheses drawn from Identity Relevant Stress theories. We find only a modest main effect of subfecundity on distress (p < .10), an effect that is not mediated or moderated by role accumulation or resources. They key finding is that subfecundity has a statistically significant and substantively important relationship (effect size of .75) to distress among those who do not have children (step, adopted, or biological). Although the power of the pilot data is inadequate to examine this carefully, analysis suggests that infertility attributed to ill health and sterilization regret rather than subfecundity has a strong relationship to distress.

Analysis of the ethics of ART shows that experience with infertility did not significantly impact women’s perceptions of the ethics of ART. Rather, beliefs about the ethics of these procedures were significantly driven by religiosity, educational attainment, age, and the acceptance of non-biological versus biological children in their families. Younger infertile women appeared more accepting of these procedures than older infertile women, suggesting a cohort difference in ethical perceptions that needs to be confirmed with a larger sample.

PRELIMINARY STUDIES FOR LYNN WHITE (Principal Investigator).
Dr. White’s research has focused on how children affect parents’ lives, in particular how presence of children, whose children (his/hers/ours), and children's wellbeing affect outcomes such as parents' life satisfaction and marital quality. Trained in demography at the University of Washington and a demography instructor, she is knowledgeable about fertility determinants as well as family relationships. She has extensive experience working with the analysis of complex data sets, most recently the National Survey of Families and Households, that require addressing issues of sample weighting, design effects, and panel designs. She and McQuillan have completed a research project (under review) that uses panel data from the National Survey of Families and Households to evaluate the consequences of abandoned fertility plans for distress. The fixed-effects pooled time series analysis demonstrates that those who abandoned fertility plans, especially women and those with ill health, showed increased levels of distress between waves.

PRELIMINARY STUDIES FOR DR. JOHNSON (Co-Investigator)
Dr. Johnson has had extensive NIMH funding. He has been the principle methodologist and study designer for the Booth et al. 6-wave study of family relationships. He is currently director of the Survey Research Center at Penn State and he is former director of the Bureau of Sociological Research at Nebraska. He was also PI on funded research analyzing helpseeking for depression and alcohol use disorders. The research design ensured that persons who had specific disorders (such as major depression and alcohol dependency/abuse) but had not sought help through formal sources were included in the study. In addition to extensive work in mental health, he has published research on methodologies related to the proposed study, e.g., design effects (Johnson & Elliott, 1998), panel analysis (Johnson, 1995), and untangling the roles of crisis and self selection in panel studies of distress (Johnson & Wu, 2002). With Scheuble, he has completed two pilot projects concerning ethics of infertility.

PRELIMINARY STUDIES FOR DR. McQUILLAN (Co-Investigator)
Dr. McQuillan has focused primarily on quantitative analysis of 9-wave survey data to examine gender, chronic illness, and emotional distress. In addition to quantitative research in the mental health consequences of chronic disease (e.g. Fifield et al 2001), her work on gender issues (McQuillan and Ferree 1997) has prepared her for focusing on the gendered basis of many behaviors, attitudes, and expectations related to infertility and their consequences for well-being. She has methodological skills essential to analyzing longitudinal survey data and couple-level data and was invited to give a workshop on multi-level modeling at the 2001 meetings of the National Council on Family Relations.

PRELIMINARY STUDIES FOR DR. JACOB (Co-Investigator)
Dr. Jacob is Professor of Psychiatry and OBGYN at the University of Connecticut School of Medicine, where she screens and counsels patients and screens gamete donors. She has reported research on lesbian couples as donor insemination recipients (Jacob, Klock et al. 1999), single and married recipients of donor insemination (Klock, Jacob et al. 1996), and gender differences and coping among donor recipients. She has 17 years of clinical and research experience in the area of coping with chronic pain, which is psychologically very similar to coping with infertility. Her clinical and research experience related to medical treatment of infertility will bring expertise in infertility to the project and ensure that results are made available to the medical community as well as the social science community.

PRELIMINARY STUDIES FOR DR. GREIL (Co-Investigator)
Dr. Greil is Professor of Sociology and Health Policy at Alfred University. His work focuses on medical decision-making regarding infertility, sex and intimacy among infertile couples, how infertility differs for men and women, the theodicies that infertile women and men develop to answer the question "Why me?", the conception of the stigma of infertility as a type of chronic illness and disability, and adoption and the politics of parenting. Dr. Greil's critical review of the literature on infertility and psychological distress guided the current research project, which is designed to address many of the shortcomings he recognized in research on the social and emotional dimensions of living with infertility. He is currently conducting quantitative research on the interplay between medical, psychological, and social variables among infertile couples.

PRELIMINARY STUDIES FOR DR. NAOMI LACY (CO-Investigator)

Dr. Lacy is an Assistant Professor of Family Medicine at the University of Nebraska-Medical Center. Her research focuses on helpseeking and interaction between doctors and patients. In particular, she has focused on patients' use of the internet for information and how bringing this information into the clinic setting affects patient pathways and doctor-patient relationships.

PRELIMINARY STUDIES FOR DR. LAURIE SCHEUBLE (Co-Investigator).

Dr. Scheuble is currently a lecturer at Penn State University. She has worked on two research projects involving attitudes toward infertility in collaboration with Johnson. "Determinants of attitudes toward infertility and infertility treatments," analysis of data from a statewide sample of 1800 Nebraskans, was presented at the 2001 American Sociological Association meetings, and "Determinants of infertility attitudes, options, and expectations among college students" was presented at the 2002 Midwest Sociological Society Meetings. Both papers are in preparation for submission.

D. RESEARCH DESIGN AND METHODS

SAMPLING STRATEGY.

INITIAL CROSS-SECTION. We seek to interview a national probability sample of women between the ages of 25 and 45 that is large enough to allow us to examine those with biomedical barriers who do and do not seek treatment and to compare women with biomedical barriers to those who are childless by choice or circumstance. We omit women younger than 25 because NSFG data show that they represent only 3% of those with infertility experience. Although the pilot study included women 46-50, analyses of our data suggest that only a tiny fraction have recent infertility experiences and none intend additional children. Thus, we focus our cross-sectional sample on the age range most likely to experience infertility.

Because we want enough cases to undertake specific analyses of African American and Latina women, our design includes an over-sample from Census tracts with more than 40% minorities and a Spanish-language interview. Estimates from the pilot project suggest that these tracts produce a sample that is 60% minority. Our overall goal is a sample that is 25% African American and 15% Latina. Interviews will be available in Spanish.

The sample will be representative of all adults living in households with a telephone in the contiguous United States. The sample will be a random-digit dialing (RDD) sample and will be generated using the Genesys® sampling system. Because of falling response rates in survey research, our sample design includes a pre-notification letter with a $2 incentive for all telephone numbers with address matches. An experiment to test the efficacy of a pre-notification letter with no incentive and a pre-notification letter with a $2 incentive was built into our pilot project. In the North Central region, Genesys had address matches for 38% of the random numbers and 60% of the probable households. Pilot data suggest we can expect a 70% cooperation rate in matched households with the pre-notification letter and $2, a rate substantially higher than we would expect in matched households without a letter (42%) or in matched households with a letter but no incentive (58%). Prior research demonstrates that a token payment, even $1, is more important than the size of the payment in raising response rates (Singer et al. 1999), however we will monitor this research.

We will interview a sample from the population of all women age 25-45 living in households with telephones in the contiguous United States. A short screening interview will determine the presence of any eligible women in the household, and one will be chosen at random if more than one is present. Estimates from the pilot suggest that 29% of likely households include a woman 25-45. Some categories of women are of interest largely as controls, and questions in the early part of the interview will identify them. We will give the full interview to a randomly selected 1/4th of mothers...
who desire no more children and have not experienced bio-medical fertility barriers. When we want to present estimates representative of all women age 25-45, we will weight back to proportionality. Power analysis (detailed below) suggests that we need full interviews with 5,774 women.

PARTNER INTERVIEWS. The main sample will be of women (all marital statuses). Many of the pathways and issues with which we are concerned can be affected by the woman's partner: whether he/she wants children, is willing to pursue treatment, or has children by prior unions. Because previous studies only provide data on individuals who have sought treatment, we do not know the extent to which couple disagreement retards treatment seeking. Because prior research indicates that couple disagreement on childbearing intentions retards childbearing (Thomson 1997) and because of a theoretical commitment to the "linked lives" tenets of life course theory, we intend to interview partners as well. Percent with partners varies by parity and fertility status, but pilot data suggest that, overall, 75% will have partners. (We include cohabiting partners of either gender, but we suspect we will not get sufficient numbers to be able to make generalizations about lesbians. In the pilot project, only 2 respondents reported a female partner.) Because male response rates are lower than female, we anticipate completing interviews with only 80% of the partners. Partner interviews will be virtually identical to those for the main respondent, eliminating only the detailed questions on treatments and modifying the questions about childbearing history.

REINTERVIEW. Three years after the initial cross-sectional survey, we will seek to reinterview approximately two thirds of the women. We will include all women who desire additional children and all childless women (groups which overlap extensively), but we will only interview a fraction of women who have children and intend no more: 1/5th of women with infertility experience and 1/10th of those without (respectively 26 and 30% of the pilot study). Following the entire group that desires children in the future will produce a diverse panel, including not only new cases of infertility among those with no prior biomedical barriers but also follow ups of the large group of women who want additional children despite having already experienced biomedical barriers. We will reinterview the partners for those in same union and new partners for those in different unions. Based on experiences of the 2-wave National Survey of Families and Households and the 6-wave Marital Instability Over the Life Course study (Booth & Johnson 1985; Booth et al. 2001), we anticipate 25 percent attrition between waves. Overall, we anticipate completed reinterviews with 2,791 respondents.

The research team has extensive experience in tracking respondents over long periods of time, and we have a set of tested procedures necessary to track respondents between waves. These include collection of information about respondent and close family members at the time of the initial interview and periodic mailings to track address changes and maintain interest.

SAMPLE SIZE: POWER ANALYSIS

This is a complex study with many different research questions to be examined in different but linked samples so a basic power analysis is impractical. Our strategy instead is to estimate the sample size required for the smallest groups that are key to our research aims. One such analysis focuses on those who have had no prior biomedical barriers and intend to have children, comparing changes in distress between waves for those whose fertility intentions are met without problem and those whose fertility intentions are thwarted by biomedical barriers. To do this, we need a sufficient number of fertile women who actually try to have children over the 3 years between the waves.

Estimates for this power analysis were based on simulations making use of panel data from the Helpseeking Study (Ortega, Johnson et al. 1994) which measured depression at two time points. We generated estimates with estimated effect sizes to determine the sample size necessary to test the difference in depression change between women who tried to have a child and had infertility problems compared to those who tried and did not. Our simulations and subsequent power estimates with PASS 6.0 suggest that a sample size of 250 would be necessary to detect as statistically significant (alpha = .05, power = .80) an effect size of 1/4 of a standard deviation unit in a regression model of change in depression.

Although adequate to compare changes in distress for those who do and do not develop fertility problems, a sample of 250 would yield only a small number of women who newly experience infertility. Over 3 years, we expect 42.5% of intenders to have had a child within 12 months of trying, 7.5% to have had a child but with delay or help, and another 7.5% to have tried unsuccessfully to have a child. These estimates rest on two assumptions. First, NSFH panels show that 50% of women age 25-45 who intend more
children will actually have a child in a 3 year period. Second, from NSFG, we estimate that 15% will experience biomedical barriers, only half of which will preclude childbearing within 3 years. Based on these estimates, in a sample of 250 only 38 (15%) of the women will experience biomedical barriers over the 3 year period. Although these women will be combined with those who already have had (whether they perceive it or not) the experience of infertility to examine longitudinal progress along the entire helpseeking continuum, the new infertility group needs to be larger in order to examine differentials in helpseeking. An exact power calculation for this group would be difficult as they would be combined with other groups in different ways in different data analyses. Our judgment is that minimum number of women experiencing biomedical barriers for the first time by the second wave should be approximately 150. Analysis of the pilot study suggests that effect sizes are large enough to yield adequate power (.80 at the .05 level) for a sample of this size. To obtain the 150, we would need to interview 1,000 women in wave 2 who had fertility intentions and no biomedical barriers at wave 1. As we expect a 25% attrition between the waves, we would need to interview 1,333 (1000/(1-.25)) women in this group in wave 1.

In the pilot study, 17.9% of women 25-45 have no prior fertility problems and intend to have children. For this group to equal 1,333 at time 1, we will need to conduct interviews with 7,450 women 25-44 (1,333/.179 = 7,450). By omitting a full interview at time 1 with 3/4 of a large group (30% of the pilot sample) in which we have less interest (mothers who desire no more children and have not had infertility problems), the number of full interviews we need at time 1 is reduced to 5,774

The table below summarizes the sampling process overall and by substantive groups of interest, including whether they experience biomedical barriers (BMB). Estimates are based on the distribution in the pilot study. The actual numbers obtained may differ somewhat as these estimates are subject to sampling error and are based on a Midwest rather than national sample. They are, however, the best estimates we have of the sample sizes.

<table>
<thead>
<tr>
<th>Substantive Group</th>
<th>First Wave</th>
<th>Second Wave</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percent in pilot</td>
<td>Wome n in study</td>
</tr>
<tr>
<td>No BMB, intend (all parities)</td>
<td>18%</td>
<td>1,341</td>
</tr>
<tr>
<td>No BMB, kids, not intend</td>
<td>30%</td>
<td>2,323</td>
</tr>
<tr>
<td>No BMB, no kids, not intend</td>
<td>5%</td>
<td>372</td>
</tr>
<tr>
<td>BMB, No kids</td>
<td>7%</td>
<td>522</td>
</tr>
<tr>
<td>BMB, kids, not intend</td>
<td>26%</td>
<td>1,937</td>
</tr>
<tr>
<td>BMB, kids, intend</td>
<td>14%</td>
<td>1,043</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>7,450</td>
</tr>
</tbody>
</table>

a A random 25% of women in the screen will get the full interview.
b A random 25% of partners will be interviewed (from pilot, 80% this group expected to have partners).
c A random 10% of the women will be reinterviewed in wave 2.
d A random 20% of the women will be reinterviewed in wave 2.
e Attrition between waves is estimated at 25%.

Sample size will vary depending on the specific group appropriate to each research question and on whether it is a cross-sectional or change analysis. In the first wave, we estimate 3,502 will have experienced a biomedical barrier, of which 1,287 will have partner data. Thus, the cross-sectional analysis of help-seeking among those with biomedical barriers will be adequate to explore differential effects and pathways. Analysis of the effects of infertility on psychosocial outcomes and of ethical concerns would use the full sample of 5,774 respondents. In the panel analysis, we should have a sample of 1,464 women with prior biomedical barriers and 150
women with new biomedical barriers. The sample of couples with biomedical barriers should total 1,059. These groups are of sufficient size to have adequate power (.80) for most small to moderate effect sizes at the .05 level and also large enough to enable examination of differentials by race/ethnicity and other background variables.

To make full use of available data and minimize power loss from missing data, we will use missing data imputation techniques. The EM method in the SPSS missing data module will be used for most analyses with checks of final models with multiple imputation methods in the SAS MI procedures. For structural equation models, full information maximum likelihood methods (e.g., in Amos) will be used.

FOCUS GROUPS. Greil and Jacob have extensive experience interviewing treatment seekers, but neither the literature nor the research team’s prior experiences provide a solid empirical footing for developing measures of self diagnosis and cognitive appraisal tailored for people experiencing infertility. As a result, our study design includes focus group research prior to the development of the formal instrument. Three focus groups with 8 to 12 participants each will be formed prior to creating the final interview schedule. The participants will be recruited with a short screener telephone interview to identify women in the 25-45 age range who have experienced infertility problems but have not sought treatment. They will be recruited in Nebraska (2) and Pennsylvania (1). Each participant will be paid $25. The focus groups will be administered by trained staff at the Bureau of Sociological Research in Lincoln and the Survey Research Center in Pennsylvania. Transcripts will be analyzed by the research team to guide our refinement of the survey and the interpretation of the quantitative results.

MEASUREMENT

The interview schedule we used in the pilot study is attached as Appendix B. This should be regarded as a draft of the interview schedule that will be used in the proposed study. We will change the instrument based on an additional year of reading and research, the revised theoretical framework, results of the pilot study, focus group interviews, and cognitive interviewing before fielding the full study. Nevertheless, the pilot study provides important information about instrumentation. In the interview itself, items are randomized within scales for order of administration.

BIOMEDICAL INFERTILITY

Measures of biomedical infertility draw from NSFG. On the pilot study, these appear in the pregnancy history (Q8C.2a) and in Qs 15-24. We do not get as much detail as NSFG about impaired fecundity (e.g., about peri-menopause) or surgical sterilizations, and more of our questions are open-ended probes rather than a series of direct questions (e.g., about surgical sterilizations or treatments). We assess whether barriers keep people from having children they would like or whether these problems occurred after fertility objectives had been reached (e.g., Q20a). We will add a yes/no question using the format, “Have you ever been treated for any of the following” that lists fecundity-threatening STDs as well as some less threatening conditions. Questions about timing allow us to distinguish primary and secondary subfertility.

CIRCUMSTANTIAL CHILDLESSNESS

Q45 is a single-item indicator that asks childless women to choose which of 3 scenarios best explains the process through which they arrived at being childless. Together with information on childbearing intentions and a series about reasons for childlessness (Q42), we can create a typology of childlessness.

PERCEPTION OF A BIOMEDICAL FERTILITY PROBLEM

We asked a single question about self-identification (Q. 25) in the pilot study. Because the pilot study and theory highlight the importance of self-identification in helpseeking, we will develop a reliable scale to measure perception following focus group research. We anticipate developing a 5-8 item scale that includes statements in a SA/SD format such as: I worried that I might have a problem conceiving. It was important for me to get pregnant right away. I was always really disappointed when I had a period. I wasn’t really paying attention to how long it took.

COGNITIVE RESPONSES TO INFERTILITY

Although there is no generic set of measures for this critical dimension of the helpseeking model, scales have been devised for specific diagnoses or treatments (O’Conner & Capelli 1999). We intend to modify existing scales (e.g., Bradley 1994) that will
provides multiple items in a SA/SD format to measure standard elements of the helpseeking model. Our effort is complicated by the fact that appraisals of other solutions besides medical treatment need to be considered for infertility.

**Treatments.** R’s assessment of the need for treatment will include questions about the likelihood that the problem will solve itself and that the situation is serious enough to justify treatment seeking. R’s assessment of benefits of treatment will assess R’s beliefs about whether effective treatment is available and appropriate for her situation. R’s assessment of treatment barriers will tap worries about money, partner’s support, family and community support, eligibility for treatment, and about treatment itself. Note that these are worries about obstacles and not the obstacles themselves. The pilot included some of these issues in a 10-item scale (Q32a-j), alpha = .70, drawn primarily from Greil’s (1997) research. The scale must be reframed in the questionnaire so that it bears on deciding to pursue treatment as well as how much treatment to pursue.

**Adoption.** The pilot study included questions about adoption (Q11), but these will be reframed and augmented so that they parallel the assessments of medical treatment options.

**Identity work** will be assessed by questions reflecting R’s reassessments of identity. Three items on the pilot (Q36h,s,p) ask whether R was relieved to have the decision taken out of her hands, whether this was a sign she should do something else with her life, and this would give her an opportunity to do other things (alpha = .67). The scale will be augmented with additional items to tap transition to nonparenthood.

**Behavioral responses to infertility**

**Health care utilization.** Medical visits, tests, and treatments, is measured using a combination of closed- and open-ended questions (Qs 26-30) that tap timing, outcomes, and satisfaction. Q31f explicitly asks about non-conventional treatments. More detail about timing will be added.

**Non-medical helpseeking** includes support groups and psychological and pastoral counseling to cope with infertility. These were addressed in the pilot (Qs33d-f).

**Self-care** includes individual research and attempts to conceive without formal medical intervention. Information seeking is covered in Qs33-35. We will add questions on non-medical behavioral responses, such as timing intercourse, smoking cessation, and so on.

**Alternative parenting routes** are assessed through a series of questions about adoption, fostering, and informal fostering (Qs. 9-14), about stepchildren and spouse’s children from prior marriage (Q53), and closeness to children of friends and sibs (Qs 48,49,51).

**Behavioral outcomes**

These include birth of a child, adoption, and gatekeeper rejection.

**Psychosocial outcomes.**

**General distress** is measured by the 20-item CES-D scale (Q. 54). This widely-used measure (Hann et al, 1999) is not a diagnostic instrument, but it is easy to administer, has been translated into Spanish, has excellent measurement properties (alpha = .87 in the pilot test), and is appropriate for a study in which pathways is a central focus. We include single-item indicators regarding treatment for anxiety, depression or other psychiatric disorders (Qs. 55, 56).

**Substance abuse** is assessed by 4 items (Qs. 57-60) about drugs and alcohol. Because of gender differences in the expression of mental health problems (Anschensel, 1992), we considered it important to include substance abuse as well as depressive symptoms. Life satisfaction is measured by a 4-item scale (Qs 7a-c,d,f) that has desirable psychometric properties across a variety of age groups (Diener & Diener 1995). We also include the standard single-item indicator of life satisfaction. In the pilot test, the combined scale had an alpha reliability of .75.

**Marital (union) quality** (Qs. 71-77) is measured through a 7-item problems scale (alpha = .77), an 8-item happiness scale (alpha = .86), a 4-item instability scale (alpha = .49), and a single item measuring conflict. These scales are widely used and their measurement properties have been extensively validated (Johnson, 1995). Subsidiary questions here and in the infertility battery (e.g., Q36f) inquire whether reported marital instability is related to impaired fecundity.

**Satisfaction with social relationships** is a 4-item scale from the National Survey of Women (Tanfer, 1991). Previous empirical work shows that people experiencing fecundity impairments may feel alienated from social life (Miall, 1989; Greil, 1991), and DeBoer (2001) found that infertile women scored significantly lower on this scale. In the pilot study, it had an alpha = .64.

**Infertility-specific distress** is a 23-item scale (Q36) including items drawn from Hjelmstedt et al.’s Infertility Reaction Scale (1999), Greil’s qualitative work, and Jacob’s clinical experience. In the pilot data, the scale had an alpha = .92, but factor analysis suggests it may reflect multiple dimensions of stress.
Childlessness-specific distress is measured by two scales that allow comparison between childless Rs with and without infertility. Social concerns about childlessness is a 10-item scale drawn from Newton et al. (1999) that assesses childless Rs’ comfort in social relationships. It is included as Q37a-j for childless people with fecundity impairments (alpha = .88) and as Q43a-j for childless individuals without fecundity impairments (alpha = .83). Internal childlessness stress is 4 items (Q44c,d,g,j) drawn from the Infertility-specific distress scale. On the pilot study, the alpha was .57 (n = 44). Cognitive interviewing will be used to improve the scale prior to implementation.

SOCIAL CUES
Perceived pressure for children was not measured fully on the pilot (Qs 2h and 2i). We will add questions about perceived expectations of partner, parents, and social network.
Network members’ experiences asks whether others in one’s network have sought medical treatment for infertility (Q31c).
Social support for treatment (Qs 31a-b) asks about perceived support from partner, family, and friends. The partner interview will provide direct evidence about partner’s actual support.
Perceived infertility stigma will be measured by a short scale asked of all respondents. It will include 4-5 questions from the infertility distress scale reframed as hypotheticals (I would feel like a failure as a man/woman if I was infertile; I would feel embarrassed to admit I was infertile).
State laws regarding health insurance coverage will be linked to each case via their area code. Date of mandatory coverage will be included.

INDIVIDUAL CUES
Valued goals are measured using a set of 4 items taken from the NLSY. These items (Q1) have been used by Clarksberg et al. (1995) to discriminate among those who marry rather than cohabit. They are treated as single-item indicators rather than a scale.
Value of children is assessed by a 9-item scale (Q2) that draws 3 items from Andrews et al.’s (1991) scale, Rejecting a Childfree Lifestyle, supplemented with 6 items designed to assess the importance of biological parenthood for happiness and identity. Pilot data show the scale is multi-dimensional, with the strongest being an identity factor (alpha = .64).
Identity salience will be assessed by a short scale tapping R’s commitment to normative identities such as career, spouse, parent on a 7-point scale. This technique yields results similar to more complex rating techniques (Simon 1992).
Religiosity is measured by a 3-item scale (Qs 83-88), alpha = .77 on the pilot study. In addition, we assess religious affiliation for respondent and partner.
Fertility intentions and ideals are measured using questions modified from NSFH (Qs 38-41).

TEMPORAL CUES
Time perspective will be assessed by a short scale assessing future/present time orientation (drawn from Gonzalez and Zimbardo, 1985) and by a scale yet to be developed that assesses sense of urgency specific to fertility.
Life course measures will assess career, educational, and marital/union trajectories.

ENABLING CONDITIONS
Resources include family and personal income, economic hardship, and current health insurance. (Qs 89-92). Insurance coverage was assessed inadequately in the pilot test. We asked about extent of fertility payments for tests and treatments (Q28c, Q29d), but we failed to ask whether insurance would have paid for tests and treatment and whether level of insurance coverage affected help seeking. We will add additional questions on the proposed project.
Availability of treatment was not assessed on the pilot. We will ask about perceived availability of treatment plus we will use zip codes to code individuals by geographical location.
Social support is an 8-item social support scale (Q. 46) drawn from a 20-item scale designed by the Canadian Community Health Survey to tap medically-relevant social support. The single-factor scale has an alpha reliability of .93 on the pilot test

PREDISPOSING CONDITIONS
Health is assessed by the standard single-item indictor (Q 78) plus two questions about limitations in ADLs and about chronic health problems (Qs 79-80).
Attitudes about ethics of ART is a scale (Q. 62) assesses R’s concern with five levels of ART (alpha = .89 in the pilot study) and two questions (Q63) about ethical concerns about multiple births.
Knowledge of ART was not assessed on the pilot. We will add questions asking R’s familiarity with these techniques and whether R knows individuals with this experience.

Medical locus of control is a uni-dimensional 5-item sub-scale of internal medical locus of control (Q.7h-l) based on the work of Wallston et al. (1978). The scale is designed to assess the degree to which health issues are within one’s control. In the pilot study, alpha = .69.

Self esteem is a 3-item scale drawn from the classic Rosenberg scale. The 3 items (Q64) have an alpha reliability = .77 on the pilot test.

Just world scale is 3 items (Q7.b,g,e) taken from Ritter that are designed to tap whether respondents believe that people get what they deserve (alpha = .54)

BACKGROUND VARIABLES

Race and ethnic identification are assessed separately as per NIH policy. Mother-tongue is also measured to identify recent immigrant groups. Gender, age, and parity will be measured.

Socioeconomic status is assessed by education and occupation for respondent and partner (Q 3,4,6).

Relationship status assesses current marital status, whether cohabiting, and dating status among those not in residential union.

RESEARCH QUESTIONS

Our research plan calls for a prospective study in which we interview a cross-section of women (and their partners) and then reinterview two thirds of them again three years later. Some of the central research questions of this project can be answered fully only with the prospective data, but important information will be available from the initial cross-section. We anticipate it will require two dozen research papers to answer our major research questions fully, a task for which our group of 7 investigators is adequate. Because space prohibits detailed description of each of these research projects, we provide a brief list of the major research questions separately for the cross-sectional and the panel analysis and then describe in some detail three papers that are central and yet illustrate different analysis issues. Gender and race/ethnicity issues will infuse all of the analyses, however we propose major papers that focus explicitly on these issues.

QUESTIONS TO BE ADDRESSED BY THE CROSS-SECTIONAL DATA:

Aim 1: Test a general helpseeking model

Analysis 1. Examine predictors of perception of a fertility problem, examining the effect of social, individual, and temporal cues on likelihood that one will recognize the symptoms of infertility.

Analysis 2. Provide a test of the general helpseeking model applied to infertility, by examining perceptual and cognitive pathways that lead toward and away from helpseeking (medical treatment and/or adoption) and the extent to which these care explained by enabling and predisposing conditions and by social, individual, and temporal cues.

Analysis 3. Examine racial and social class disparities in helpseeking, testing whether observed differences are explained by intervening processes in the helpseeking model (likelihood of perceiving the symptoms and cognitive responses) or by enabling and predisposing conditions.

Analysis 4. Using couple data for those with biomedical barriers, assess the relative contributions of husbands and wives to helpseeking.

Analysis 5. Compare helpseeking processes for those with biomedical fertility barriers and those with circumstantial barriers.

Analysis 6. Assess the place of self care and individual research in the process of help-seeking.

Aim 2: Identify consequences of infertility

Analysis 7. Using a sample of all women, examine the effect of infertility (biomedical and other) on general distress, life satisfaction, quality of relationship with partner, and satisfaction with social relationships.

Analysis 8. Focusing only on women who experience biomedical barriers, assess effects of intervening variables in the helpseeking process on general psychosocial responses and infertility-specific distress.

Analysis 9. Using couple data for those with biomedical barriers, assess the gendered nature of infertility stress and the extent of cross-over between partners.
Analysis 10. Using only childless women, compare general psychosocial responses and childlessness-specific distress among those with and without biomedical barriers.

Analysis 11. Identify the extent of involvement with non-biological children (adopted, foster, step, informal fostering, family) and examine the role of relationships with non-biological children for resolving infertility distress.

Aim 3: Assess ethical concerns about ART

Analysis 12. Analyze disparities in and determinants of ethical concerns about ART.

QUESTIONS TO BE ADDRESSED WITH THE PROSPECTIVE DATA:

The field work on the second wave of this study will be completed only 9 months before the end of the 5-year funding period proposed here. A competing continuation grant will be submitted to fund expeditious analysis of the prospective data.

Aim 1: Test a general helpseeking model

Analysis 13. Examine predictors of perceived infertility problems among those with biomedical barriers, both prior and new. Similar to Analysis 1 with the cross-sectional data, the prospective data will allow us to use time 1 measures of goals, identities, and so on to predict changes in perception.

Analysis 14. Provide a prospective test of the helpseeking model among those with bio-medical barriers, both prior and new. Although similar to Analysis 2 using the cross-sectional data, the prospective data will allow us to examine feedback loops in which distress and wellbeing at time 1 affect helpseeking between waves.

Analysis 15. Using couple data for those with biomedical barriers, examine a dyadic model of helpseeking over time.

Analysis 16. Examine disparities in responses to infertility, in particular assessing the effects of race and class (including education, income, and insurance) on seeking treatment, treatment experiences, and infertility resolutions.

Aim 2: Identify consequences of infertility

Analysis 17. Among those who intend children and had no biomedical barriers at time 1, assess changes in psychosocial wellbeing associated with biomedical barriers, changed perceptions, cognitive responses, behavioral responses, and behavioral outcomes.

Analysis 18. Using all those with biomedical barriers (new and continuing), assess the relationship between changed perceptions, cognitive responses, and behavioral responses to psychosocial outcomes.


Analysis 20. Examine life course changes following identification of fertility problems. The prospective study will allow us to examine changes in life goals, identities, and interactions with children between time 1 and time 2 that are associated with infertility or infertility treatment.

Aim 3: Assess ethical concerns about ART

Analysis 21. Describe changes in attitudes toward ethics of ART, both among the general population and among those who newly face a need for them.

TIMETABLE

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<th>Year</th>
<th>Preparatory work</th>
<th>Complete field work</th>
<th>Field women’s survey</th>
<th>Field partner’s survey</th>
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<td>Analysis 2. General helpseeking model</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Analysis 3: Race and class disparities</td>
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EXAMPLES OF DETAILED PROJECTS

We provide detailed descriptions of three research papers, each of which illustrates unique research strategies. We provide two examples for analyses from the cross-sectional data, one which uses only women respondents and one which makes use of couple data. The third example shows a change analysis from the panel data.

ANALYSIS 1: PERCEPTION OF SUBFECUNDITY

This paper will focus on predicting the circumstances in which women who meet criteria for subfecundity (one year of unprotected intercourse without conception) perceive themselves to have a problem. Aside from our pilot data, no research has addressed perception of infertility. We rely on the prior research on health beliefs to frame our analysis.

The sample for this analysis is restricted to those who meet the criterion for subfecundity (approximately 75% of all those with biomedical barriers). We anticipate a sample of 2,626 women for this analysis. Perception of infertility is assessed with a multiple-item scale forming a continuous variable, with a high score indicating greater awareness. The basic predictors in the model are age, parity, race/ethnicity, socioeconomic status, and relationship status, and the theoretical issues to be addressed are the extent to which the effects of these background factors are mediated or modified by variables in the theoretical model. OLS regression is a suitable technique for assessing interaction effects using a continuous dependent variable. We will consider effects statistically significant if they meet the p < .05 level.

In step 1 of the analysis, perception of subfecundity will be regressed on the background variables. Because so many of the central hypotheses involve interaction effects, age and socio-economic status indicators will be mean centered. The other variables will be added in blocks, testing first to see whether, say, Social Cues, explain observed effects of parity, age, and ethnic identification on perception of subfecundity. The next step will be to create multiplicative variables (e.g., age x perceived pressure to have children) to
see whether the effects of perceived pressure depend on age. As this research is in some ways exploratory, the major blocks of explanatory variables will be analyzed separately. We anticipate that enabling and predisposing conditions have stronger effects on actual helpseeking than on perception of a problem, and our analysis will bear on this hypothesis.

After this exploration, however, we will want to combine all variables to assess the overall model. In classic health beliefs models, enabling and predisposing conditions occur later in the causal chain than individual measures of social, individual, and temporal cues (Anderson, 1968). Thus, our strategy in evaluating the entire model will be to enter measures of social, individual, and temporal cues found significant in the exploratory analysis and then ask whether addition of enabling or predisposing conditions adds significantly to explained variance or helps explain (intervenes between) prior variables in the model.

**ANALYSIS 4: HELPSEEKING AS A COUPLE PHENOMENON.**

Even though biomedical barriers often characterizes couples more than individuals, we know little about the relative influence of spouses on the decision to seek medical help for infertility.

If data from both partners is incorporated simultaneously in ordinary least squares analysis regression, the analysis violates the assumption of independence. If partners are analyzed separately, we lose the "coupleness" of the experience and fail to take advantage of the data. We will exploit the "coupleness" of the data using the structural equation approach suggested by Thompson and Williams (1982). This approach corrects for the lack of independence by measuring and correlating the errors of partner’s responses. We will organize the data so that each partner response adds a variable. Partner responses to the same questions will be modeled simultaneously. We anticipate a sample of approximately 1,300 couples with biomedical barriers for this analysis.

Structural equation models provide a useful way to assess the degree to which medical helpseeking is a couple or an individual process for those in unions. Figure 2 shows the general structural model we will use, but with only a subset of the relevant variables for ease of presentation. Because of sample limitations, we limit this example to heterosexual couples.
The first part of this analysis involves the measurement model (not pictured in figure 2). A central question is the degree that the latent variables reflect each partner or the couple as a unit. We will compare the fit of a single couple latent variable to two separate latent variables, one for each partner. If two is better than one, there is evidence that these concepts are more individual than couple phenomena. Figure 2 shows separate partner latent variables. Because partner reports are not independent, we will correlate the errors between partners for corresponding items. Once we establish a measurement model with a good fit to the data, we will conduct the structural analysis. The resulting model will be what Kline (1987) calls a “hybrid model”. Because the outcome variable is dichotomous (health care utilization), we will use the Mplus software to estimate this model (Muthén and Muthén 2001).

The second part of the analysis addresses several important questions. For example, we will evaluate the direct and indirect effects of a perceived problem on health care utilization through important mediating variables such as perceptions of barriers and perceptions of benefits of health care for infertility. We will compare the relative influence of partner assessments by using equality constraints on the path parameters. If the paths from the same variables for different partners are constrained to be equal and the fit of the model does not change, then the exogenous variables have similar influences on perceptions or help seeking. This suggests that gender does not influence these relationships. If one partner’s path is significantly larger than the other partner’s, then there is asymmetrical influence. If both partners’ exogenous variables are equally associated with the outcomes, then there is joint influence. We will evaluate direct and indirect cross partner influence with the paths from each partner to the other partner’s assessments. As portrayed in Figure 1, perceptions of barriers and benefits of health care should be important mediating variables for health care utilization.

The third part of the analysis allows us to assess the moderating effect of key explanatory variables such as wife’s age, couple resources, or the availability of treatment. One way to do this in structural equation modeling is to use multiple group comparisons. For example, we can split the sample in to younger and older women, and compare models with the coefficients between both groups constrained to be equal compared to models without equality constraints. If the fit of the model does not change significantly (using a chi-square test for the difference), then we conclude that the associations operate the same way among both groups. Our sample size of 1,300 is adequate for this analysis.

We will compare women with partner information to women in unions but missing partner information to assess possible bias in this sample and limit our generalizations accordingly.

ANALYSIS 17: CHANGES IN PSYCHOSOCIAL WELLBEING

An important research question that has not been answered in previous studies is whether characteristics of women such as general distress, life satisfaction, and identity salience affect their response to infertility. The analysis discussed here will focus on the women who had not experienced any fertility problems in the first wave and compare those who did and did not experience fertility barriers between the two waves of data. The sample for this analysis is those women who had not experienced infertility problems in wave 1 and desired more children. We anticipate a sample size of 1,000 women interviewed in both waves, of which 15% will newly experience infertility.

The analysis method will be fixed effects pooled time-series regression analysis (Allison, 1994; Johnson, 1995). This method estimates within-individual effects, and thus controls for between individual differences, both measured and unmeasured. The data set is stacked so each wave is a separate record and individual records are linked by an identification number. The Xtreg procedure in Stata will be used for the analysis. We illustrate this approach by examining how infertility may affect depressive symptoms. Depressive Symptoms (DS) are measured at time 1 and 2. We code a set of dummy variables indicating changes between the waves. Included are a dummy for whether they experienced infertility (I) and for whether they experienced a live birth (B). The fixed effect estimators for the dummy variables estimate the within individual change in marital happiness due to experiencing the event. Subsidiary analyses can refine these analyses by breaking the infertile into those who sought testing and those who managed to have a live birth compared to those who did neither. Interaction terms by individual characteristics (such as race/ethnicity, education) can be included to test if the amount of individual change differed significantly between groups. The same logic can be used to examine other outcome variables. When the outcome variables are binary a logistic fixed effect estimator (Xtlogit in Stata) will be used.

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1.1 HUMAN SUBJECTS RESEARCH

1. Risks to Subjects

Subject Population. The respondents in this survey will be non-institutionalized women ages 25-45 and their partners. Each will participate in a telephone interview averaging approximately 35 minutes in length.

The survey data will be collected in a computer-assisted telephone interview that begins with a screen of adults ages 19 and older who reside in a household with a telephone in the contiguous U.S. The surveys will be conducted from the premises of the Bureau of Sociological Research at University of Nebraska-Lincoln and at the Survey Research Center at Penn State University. The sample is selected through telephone numbers generated randomly by Genesys© sampling system. We will send a pre-notification letter including $2 to households whose telephone numbers are sampled and for whom addresses can be obtained. In central office codes where census data show that 40% or more of the population is minority, we will draw twice as many random numbers.

After reaching a household member age 19 or older, Screen 1 asks whether there are any women ages 25-45 in the household. If no, the interview terminates. This woman (or, if more than one woman 25-45, a randomly chosen woman) becomes the respondent. Approximately 10 minutes into the interview, we will terminate interviews with 22% of the sample (i.e., 3/4 of those who have children and have no desire to have future births and have no biomedical fertility barrier). We will make a separate call to interview partners of women in unions (married or cohabiting, female as well as male partners).

The research plan calls for re-interviewing about two-thirds of these women and their partners three years later. Thus sufficient personal information will be gathered to enable tracking: full names and current address of respondent and partner, names, addresses, and telephone numbers of a parent and a sibling of the respondent.

Risks to subjects. The chief risk to subjects would be embarrassment in the situation where his or her responses become publicly known. It is possible that some respondents will experience psychological discomfort in responding to questions about infertility. With adequate protection for confidentiality and careful instrument construction (detailed below), we believe both risks are minimal.

2. Adequacy of protection against risks

Informed Consent. Because this is a telephone survey, consent to interview will be secured verbally. For a survey with minimal risk, we treat consent as implicit in the respondent’s willingness to continue with the interview. When an adult (age 19 or older) household member is reached, they will receive a very brief description of the study and be told that we are interviewing women between the ages of 25-45. If the household does not contain any women in this age range, the survey will end. When the selected woman is on the telephone, the purpose and sponsor of the study will be provided in more detail, as is an assurance of confidentiality, and a statement regarding the use of the data. The interviewer will record the woman’s name on a separate sheet, along with the date consent was granted and will provide his/her own signature as an assurance that the information is true and accurate.

All households for which an address match is available will receive a pre-notification letter describing the study and its sponsors and providing telephone numbers and a web link if they want additional information.

Protection against risk.

EXPOSURE. We take great care to eliminate the possibility that an individual’s responses might be exposed. Arrangements to protect the rights of individuals who choose to take part in the study are extensive and occur at many points throughout the project. Efforts begin with the employment and training of interviewers. Each interviewer is carefully screened and trained before beginning work on the project. An important part of the training is teaching interviewers to protect the rights of the respondents and to impress them with the importance of confidentiality. It is made clear to them that any indication that they have discussed information given in confidence with other than project staff or otherwise violating the rights of the respondents are grounds for immediate dismissal. Many of the interviewers have extensive

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experience in similar surveys. Interviewers are not permitted to interview respondents if they are acquainted with them, either directly or indirectly through mutual acquaintances.

The respondents’ names and telephone numbers will be kept separate from the data that are collected. Only an identification number serves to link the records to the individuals. The list linking numbers and names is kept in a locked file cabinet, accessible only to the investigators. The list is seen only by the investigators and the staff members of the two survey organizations who will assist in keeping the list up to date. The history of the Bureau in protecting the rights of respondents is excellent. The Bureau has conducted hundreds of surveys over the last 35 years, and, as far as we know, no respondent’s confidence has ever been violated. The respondents will be assured that their names will only be used for the purpose stated, and they will not be released for any other purpose.

No response can be identified with a particular individual or small geographical area in any reporting of the research results. The central office codes in the telephone number will be used to code state, region, metropolitan/nonmetropolitan designation, and distance to a major metro area before being stripped from the data. No other geographical identifiers will be included in the investigator’s or the public use data set.

EMBARRASSMENT. We will attempt to minimize potential distress that the questions may cause in several ways. First, interviewers are trained to maintain a neutral, non-judgmental tone, always being supportive of the respondents’ thoughtful consideration of the questions, but never responding either positively or negatively to the content of the questions. Second, questions about sex and infertility are framed in clinical fashion, and we rely heavily on questions used successfully for the last 50 years in the National Survey of Family Growth conducted by the National Institutes of Child Health and Human Development for question wording. Third, respondents are informed that, if they believe any question is too sensitive, they do not have to answer the item. Fourth, interviewers are instructed to ask the respondent to call us back for further assistance or to offer that one of the senior project staff can call them at another time if they seem distressed or request contact with a mental health or fertility treatment agency. We have fliers from two national infertility support groups that we can send to respondents who want additional information. Our web site provides links to medical and social support resources. In our previous experiences, even when asking sensitive questions, well under one percent of respondents have needed such assistance. We believe that the risk presented by asking such questions is minimal.

3. Benefits to subjects

No subject benefits are associated with this research. Because the risks to subjects are minimal and the interview questions concern issues of central importance to the people being interviewed, especially the approximately 50% of the sample that has experienced infertility, we believe that the time subjects contribute to this research is not burdensome. Some evidence suggests that opportunities to talk about emotionally distressing events such as miscarriages, even during a phone survey, can be therapeutic (Neugebauer et al. 1992). We will establish a project website through which interested subjects can monitor research reports developed from the study. Interviewers will be prepared to provide an 800-number for an infertility crisis line and to mail respondents a brochure from a national infertility support group.

4. Importance of the knowledge to be gained

The proposed study will provide a comprehensive test of the helpseeking model and specific information about barriers to childbearing (bio-medical and situational), pathways through which individuals cope with these barriers, obstacles to treatment, and outcomes of biomedical and other barriers to fertility and will identify disparities in barriers, pathways, obstacles, and outcomes. Because prior studies have been limited largely to clinic populations, these data on a national sample provide the first opportunity to sort out the effects of treatment and treatment failures from the effects of infertility and to assess the cognitive processes involved in helpseeking. This study will provide useful information for scholars seeking to understand fertility and infertility as well as policy makers concerned with access to infertility services.

5. Collaborating Site
The Survey Research Center at The Pennsylvania State University will conduct half of the interviews. Its OHRP assurance number is M1145. A written assurance from that site of points 1-4 above will be filed at the University of Nebraska-Lincoln.

Women and Minorities Inclusion

All of the primary respondents will be women. We propose a study design that includes an over-sample of census tracts with more than 40% minority population and a questionnaire in Spanish for Spanish-speaking households. With a national sample and a Spanish interview, we anticipate a sample that is 60% non-Hispanic white, 25% African American, and 15% Latina. Our pilot study demonstrates that targeting the 40% minority Census tracts is an effective means to oversample minorities.

Exclusion of Children

The respondents in this study will be 25 years of age or older. We exclude not only children, but also females ages 21-24. Although young women do bear children, they are at low risk of experiencing fertility impairments, and the cost of identifying the small number of adolescents and young women with fertility impairments would be prohibitive. Although the helpseeking processes we seek to identify may depend on age, preliminary analysis suggests that the critical age difference is under or over 30.

Data Sharing Plan

Two years after the completion of each wave of data, we will make our data accessible to other scholars by filing the data and the methodology report with the ICPSR and with the Population Research Institute at Penn State University. Before being filed, the data will be stripped of all identifying information, including telephone numbers, area codes, census tracts, names, and tracking information.

References


