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Research Recruitment of Adult Survivors of Neonatal Infections: Is There a Role for Parental Consent?

Ann J. Melvin

University of Washington

Kathleen M. Mohan

University of Washington

Anna Wald

University of Washington

Kathryn Porter

Seattle Children's Research Institute

Benjamin S. Wilfond

Seattle Children's Research Institute

Abstract

Research on competent adult subjects does not require the consent of anyone beyond that of the adult subject. This case is complicated, however, because the targeted subjects were initially enrolled by their parents in a neonatal study and because the focus of the study, genital herpes simplex virus (HSV), carries significant stigma in the community. In considering the ethical issue of directly approaching the young adults for participation in this research, there are three key themes that need to be evaluated and considered: 1) the importance of the research for anticipatory guidance about the long-term impact of neonatal HSV; 2) the concerns of parents in disclosing the diagnosis; and 3) the interests of affected teens/young adults and their future partners.

First, knowledge about the long-term effects of neonatal HSV infection is very limited. Follow-up for neonatal HSV has been limited to early childhood in the majority of studies (Kimberlin 2011; Whitley 1991). Apart from one small study involving children up to age 15 (Malm 1991), sparse data exist to inform families of the long-term clinical and psychosocial consequences of neonatal HSV infection. For example, while clinicians know that many children have periodic skin outbreaks of HSV that can continue for years (Malm 1991; Kimberlin 2011), they do not know if infection with HSV at birth will result in genital or oral recurrences or asymptomatic shedding of the virus later in life. Therefore, researchers do not know if these individuals are at risk of passing the virus on to their sexual partners. This is particularly relevant to children who have survived neonatal herpes unscathed and thus would expect to have normal sexual activity during adulthood. The proposed research would address the questions parents of children with neonatal HSV have about the long-term

prognosis for their children and the risk of future genital shedding of HSV, for which there are no data on which to base an answer.

Second, the initial parental response to the proposed research demonstrates reluctance to either enroll their teen or now-adult children in this new research study or to pass the information about the study to them. Only the parents themselves can articulate their precise concerns, but it is possible to speculate about reasons for this reluctance. There is significant shame and stigma associated with HSV related to sexual behavior (Newton 2008; Bickford 2007) and a parent might be uncomfortable sharing this sensitive and personal information with their child. Telling their child about the neonatal HSV infection exposes the mother's HSV status, something that many parents would prefer not to share. This might stem from shame or even play into an issue of authority—it may be harder to maintain authority as a parent tries to instill values of safe sex or abstinence if the mother must also admit that she has a sexually transmitted infection (STI). Additionally, there may be parental guilt, knowing that the child acquired the infection from the mother. It could also be argued, however, that parental authority could be strengthened when speaking from an honest position of experience and lived consequences.

Finally, teens and young adults have a right to the health history contained in their medical record, which would contain documentation of a neonatal HSV infection. Thus this information could be considered to be theirs already. They might want to know that they carry the virus, whether for their own health reasons or to protect their sexual partners. Their HSV infection might be detected later on during requested STI screening, or even at the time of a woman's pregnancy, but could be wrongly attributed to the person's, or their partner's, sexual behavior. The challenge is how to balance a young adult's direct interest in the information and the previously stated concerns of the parents, in the context of research that will benefit future parents and children in this community. One unique aspect of the research context is that the investigator's original relationship is with the parents. Examination of two somewhat comparable research areas that might provide some guidance into this situation are genetic diseases and human immunodeficiency virus (HIV), although these comparisons also highlight the unique aspects of this HSV research dilemma.

In genetics research, it is common practice to prioritize the interests of the person with whom researchers have a relationship. With hereditary genetic conditions, family members of an individual found to carry a specific genetic condition may benefit from knowing this information. However, because of concerns about respect and privacy, researchers typically do not inform a family member of their risk if the research subject is not willing to share the information (Shah 2013). The researchers, however, may try to persuade the participant to share this information with family members who might be affected. In the current situation, there is a triadic relationship involving the child, the parent(s), and the researcher. Parents and researchers have an aligned obligation to consider the child's interests, but the actual interactive relationship is between the parents and the researchers, and this also must be acknowledged and respected.

In the HIV context, infected children are likely receiving lifelong treatment and the potential risk for transmission to future sexual partners is well established. There is a strong case for

eventual disclosure to the adolescent who will need to manage the therapy for his or her HIV infection, even if some of the issues of parental discomfort are the same. In contrast, HSV infection may remain asymptomatic and never require treatment. Additionally, the risk of transmission to a sexual partner from an individual infected with HSV as a neonate is unknown. This is a large part of why a standard of routine disclosure for HSV has not emerged.

The examples of genetics and HIV suggest a challenging tension that may be mitigated by additional empirical data about the reasons for parental reluctance to disclose HSV information to their affected children. Further conversations with the parents of these young adults, possibly through focus groups or in one-on-one meetings, may be useful. Perhaps if parents understood the potential outcomes of the research, they would be more willing to encourage participation. Researchers could develop several research outcome scenarios and ask parents to share their opinions on participation after considering potential outcomes. Furthermore, in discussing concerns or potential harms, ideas may be developed to better support parents and reduce identified harms or risks.

Through interviews and discussion, parental concerns could be identified. Would parents consider allowing the researchers to follow up directly with the young adults? Would parents feel differently if they were given the opportunity to understand the importance of the research and be provided with counseling or tools to talk to their teen or adult children about the neonatal infection? While such data will not be fully dispositive to resolve the ethical tension, better understanding of the nature and intensity of parental concerns could allow researchers to develop materials that directly address those concerns and an ethically justified plan allowing for successful recruitment.

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