Collecting Biological Measures for Research With Children and Adolescents

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Health professionals, particularly nurses, have long understood the link between psychosocial, environmental, and behavioral factors and health outcomes. Biologic responses can be measured via biologic markers (biomarkers), defined as characteristics of an individual that indicate normal or abnormal biological functioning (Puntmann, 2009). Examples of biomarkers include weight, hemoglobin, metabolites, and cortisol levels. Biomarkers can be used as surrogate measures to assess the health status of an individual in clinical settings (Goldman, Becker, Jones, Clements, & Leeder, 2011) and are particularly useful in biobehavioral research. Biomarkers also provide insight into the molecular and/or cellular process that links an exposure or behavior and a particular health outcome (National Institute of Environmental Health Sciences, 2015).

As the field of biobehavioral research has grown, so has the application of biomarkers to child and adolescent health. However, working with these populations can present unique challenges when collecting biologic measures. Ethically, concerns exist about the consent and assent process, the protection of biologic samples and data, and the handling of results that may or may not have clinical significance (Ries, LeGrandeur, & Caulfield, 2010). Developmentally, children and adolescents understand and interpret the collection of biologic samples differently than do adults, which may require some further considerations. Additionally,

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children and adolescents are physically growing and changing rapidly. Certain biomarkers and methodologies that are readily utilized in the adult population may not directly apply to children and adolescents or will require adaptations in data collection and interpretation (Goldman et al., 2011).

In this article, we will discuss the challenges and strategies used for collecting biologic measures from children and adolescents for the purposes of health-focused biobehavioral research. What follows is a general discussion of ethical, developmental, and physiologic considerations that should be deliberated when collecting and interpreting biologic measures in children and adolescents.

ETHICAL CONSIDERATIONS

Ethical considerations concerning the collection of biologic measures in children and adolescents include obtaining consent/assent, ensuring the protection of samples and data, and the handling of results that may have clinical relevance. Children and adolescents are considered a vulnerable population (Broome, Richards, & Hall, 2001). It is generally agreed that this population lacks the capacity to provide fully informed consent for participation in research; therefore, consent is obtained from the parents or caregivers. Children ages 7 years and older prefer to be informed about basic study procedures (Unguru, Sill, & Kamani, 2010) and are able to provide verbal assent, defined as the child verbally agreeing to participate in a research study (Roth-Cline & Nelson, 2013). For assent to be obtained, a child or adolescent should understand why he or she is being asked to participate in the study and how the experience will unfold. The investigator should verify that the individual understands and ask if he or she agrees to participate in the study. If a child or adolescent does not provide assent even after obtaining parental consent, then he or she should not be enrolled in the study.

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Obtaining assent may be more challenging when more invasive measures are required to obtain a biologic sample. Children and adolescents may be less likely to assent to a blood draw as opposed to answering questions about stress in their daily lives. In addition to discussing how biologic measures will be obtained, it is helpful to discuss what actions will be taken to decrease any pain or discomfort during and after data collection. Every effort should be made to use the least invasive means possible when collecting biologic samples. Many biomarkers such as cortisol can be reliably obtained via saliva versus serum (Salimetrics, 2015).

For preschool children and younger, obtaining assent formally is not required. Developmentally, these children are unable to understand the procedures involved in obtaining measures. However, obtaining valid biologic samples generally requires some level of participation on the part of the child. For example, to obtain a valid blood pressure, the young child should be awake and calm. Given this necessity, and the fact that young children should not be required to participate in a study that causes them undue harm, when they protest and cannot be consoled by usual methods, data collection for that particular biologic measure should cease. The measure can be attempted again later during the same data collection period, if appropriate. Many young children will participate in a calmer manner on the second attempt, likely as a result of familiarization (Cohen, 2004). Additionally, caregivers are a valuable resource to researchers. Because young children often rely on their caregivers for consolation, ideally they should be present during data collection.

The protection of samples and data is an important ethical consideration, especially in cases in which information concerning genetic data is gathered or in the cases in which biobanks are being utilized. A biobank is a repository for human biologic material and clinical data garnered from that material (Sanner, Yu, Udtha, & Williams, 2013). De-identification of samples and data is a standard per the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulatory requirements (U.S. Department of Health and Human Services & National Institutes of Health, 2004). Information regarding storage and access of data should be clearly reviewed in the consent form. When this material is gathered for long-term use, it is also important to consider the need for a re-consent process once a child or adolescent reaches the age of consent (Sanner et al., 2013).

Finally, it is important to consider how the results of biologic sampling will be handled, especially those that have clinical relevance. Harris and colleagues (2012) conducted focus groups with parents of developmentally disabled children enrolled in a genomic research repository study and noted that the majority wished to receive all individual research results even though the results may not be diagnostic in nature. Holm and colleagues (2014) discussed guidelines for returning potentially sensitive biologic research results that included allowing the caregiver and participant (when developmentally appropriate) to indicate preferences for receiving results. Additionally, this team recognized the potential for harm when returning