

## Web Appendix I

Piloting a sexually transmitted infections (STIs) preventive intervention among children in the southern United States involved a range of ethical challenges. In this section, we highlight the ethical issues faced and how we addressed each.

### STIs and minors

Florida state law defines the age of consent for sex as 16 years (Florida Statutes Section 39.201 and 800.04). Thus, while the school enrolled girls ages 12 to 17 years, and was interested in teaching all ages about STI prevention, we limited our study to 16- to 17-year-olds. The Florida state law also requires reporting and investigation of 16- to 17-year-olds reporting having sex with someone 24 years or older. Thus, we tailored the response options to our question about the age of the partner to “What was the age difference between you and {Insert made up partner name} when you had sex?” so we could not isolate partners of illegal ages. The most extreme category, 5 or more years, included legal and illegal partners:  $\geq 21$  years old and  $\leq 12$  years old. Furthermore, in the consent and assent, we informed parents and participants that study and school staff have legal obligations to report any sex between a 16- to 17-year-old and someone  $< 16$  years or  $\geq 24$  years.

We took three steps to minimize the risk of girls becoming upset when completing a behavioral survey about sexual, alcohol, and drug use beliefs and behaviours. First, we created the survey with progressive questions about sexual experience. Girls who had never had sex skipped the sexual activity questions. Only girls who had sex in the past month received all the questions. Second, girls were instructed to skip any questions they wished. Third, in addition to the school's available counsellors, we provided girls phone access to a licensed clinical

psychologist who has worked extensively with high-risk adolescent populations regarding sexual behavior and substance use. In our pilot study, however, the school did not report unusual counselling needed following the survey and our psychologist did not receive any calls.

Finally, we applied for and acquired a Certificate of Confidentiality from the United States National Institutes of Health.<sup>1</sup> In accordance with Section 301 (d) of the Public Health Service U.S.C. Section 241(d), the certificate provides special protection to subjects enrolled in research collecting identifiable and potentially sensitive information. Specifically, the certificate protected the research team from being forced to disclose identifiable sensitive information via subpoenas for example. We informed parents and adolescents of this additional protection during the consent process. As of December 31, 2016, all research funded by the United States National Institutes of Health that is collecting identifiable, sensitive information will automatically be issued a Certificate of Confidentiality. Research funded by other entities can apply for a Certificate of Confidentiality.

### **Sexual partnership issues**

To prevent defensiveness among girls or labeling of individuals, we carefully crafted our intervention materials to focus on characteristics rather than individuals. For example, the first intervention session introduces girls to the relevant partner characteristics with a board game that includes fictional partners. We primarily encouraged girls to modify the timing of sexual activities rather than the individual partner. For example, a partner's risk was reduced with more time since their most recent partner and if they were not using alcohol or drugs in the two hours before sex. Especially with partners who had more risk characteristics, the intervention presented strategies to negotiate condom use. Evidence suggests, however, that some partners may become

violent when girls are more assertive about using a condom.<sup>2</sup> To help girls with potential partner violence, triggered by our suggestions of condom negotiation or not, we included a session on sexual assault warning signs and resources.

## References:

1. U.S. Department of Health & Human Services Office of Extramural Research, National Institutes of Health Certificates of Confidentiality Kiosk: Background Information. September 29, 2017; Retrieved October, 23 2018.  
<https://www.ncbi.nlm.nih.gov/pubmed/>.
2. Mittal M, Senn TE, Carey MP. Fear of violent consequences and condom use among women attending an STD clinic. *Women Health*. 2013;53(8):795-807.