

## **Proposed Measures and Variables:**

### **Primary Behavioral Outcome**

*The Primary Outcome* is the proportion of vaginal and anal condom protected sex acts in the 30 days prior to the ACASI assessment. This measure is defined as the number of protected vaginal and anal sex acts divided by the total number of vaginal and anal sex acts during the 30 days prior to ACASI assessment. This is one of the most commonly used measures to assess outcome efficacy in HIV prevention trials.

*Other Self-Reported Sexual Behaviors* to be assessed include the number of unprotected vaginal and anal sex acts during the three months prior to assessment and whether condoms were used at the last sexual intercourse prior to assessment. The ACASI interview will also assess other self-reported sexual behaviors. Information will be elicited on: the number of different sexual partners, the types of partners (primary, casual, new), the frequency of oral, anal and vaginal sex, use of alcohol and other drugs prior to sexual intercourse, STD and pregnancy history, and partners' risk status (i.e. sexual partner has other female partners).

A widely recognized problem is that participants' reports of their sexual practices might be unintentionally or intentionally inaccurate. We will take several steps to increase the validity of self-report measures. To reduce memory problems, we will ask the participants to recall the sexual behavior over a relatively brief period (i.e. during the past 30 days, during the past 3 months and at last sexual intercourse). It would be more difficult for participants to recall accurately behavior that occurred 6 months prior to the assessment. We will give participants a calendar on which the relevant dates are clearly marked, which will make salient to them the dates that are included when we ask them to recall their sexual behavior. To reduce the likelihood of demand being induced by giving their responses to the same person from whom they received the SiHLE intervention their health educators will not be involved in any way in the data collection. Instead, specially trained Assessment Assistants, blind to adolescents' group assignment, will collect the data. The use of ACASI has also been demonstrated to increase respondents' willingness to provide frank responses to sensitive questions about their sexual behavior. Participants will also complete a standard measure of social desirability bias (Crowne-Marlowe Scale of Social Desirability<sup>92</sup>), which will allow us to examine statistically whether apparent intervention effects can be explained by such bias.

### **Moderators**

*Sociodemographic data* We will collect information about the adolescent's age, current living arrangement, education and relationship length.

*Parental Monitoring:* In a study with African-American female adolescents, we examined the effects of parental monitoring on adolescents' sexual risk behaviors and STD outcomes. In logistic regression analyses, controlling for observed covariates, adolescents perceiving less parental monitoring were more likely to test positive for an STD (OR=1.7; p=.01), report not using a condom at last sexual intercourse (OR=1.7; p=.01), have multiple sexual partners in the past six months (OR=2.0; p=.05), have risky sex partners (OR=1.5; p=.06), have a new sex partner in the past 30 days (OR=3.0; p=.02), and not use any contraception during the last sexual intercourse episodes (OR=1.9; p=.05).<sup>65</sup> Subsequently, we conducted a prospective analyses on the same cohort and observed similar findings,<sup>66,67</sup> confirming the importance of parental monitoring as a potential moderator of sexual risk behavior.<sup>68</sup>

*Parental Communication about Sex:* In the SiHLE study, less frequent communication with parents was associated with: never using condoms in the past month (OR = 1.6), during the last 5 sexual episodes (OR = 1.7), and at last intercourse (OR = 1.7). Less communication was also associated with less communication between adolescents and their sex partners (OR = 3.3) and lower self-efficacy to negotiate safer sex (OR = 1.8).<sup>69</sup> These findings highlight the

importance of including this measure in the proposed study. This 5-item scale had an alpha of .88.

*Relationship satisfaction* will be assessed with the Dyadic Adjustment Scale,<sup>70</sup> a 31-item measure that assesses how the adolescent relates to their partner with respect to finances, time spent together, relational factors, and intimacy. Used in other studies of young African-American women, the scale has excellent internal consistency.

*Partner related variables* such as age of sexual partners, and economic dependency on sexual partners will also be assessed. Our research, as well as the work of others, has demonstrated that young females who are more economically dependent on their sexual partners and females with older partners are less likely to use condoms.<sup>71</sup>

*History of abuse* will be assessed using the Revised Conflict Tactics Scale (CTS).<sup>72</sup> The CTS is 19-item measure with five subscales, including psychological aggression, negotiation, physical assault, and injury. This scale assesses participants' history of abuse during the past 90 days. Drs. Wingood and DiClemente have published several studies illustrating the adverse impact of having a physically abusive dating partner or a physical abusive sexual partner on African-American female adolescents' HIV sexual risk behavior.<sup>73,74</sup>

*Psychological distress* will be assessed by using a brief version of the Center for Epidemiologic Studies-Depression Scale (CES-D).<sup>75</sup> This scale was designed and validated for minority women and contains 7-items, each rated on a four-point scale according to how frequently symptoms were experienced during the previous week. Although the CES-D was not designed for clinical diagnosis, it is a useful indicator of psychological distress. The CES-D has been successfully used in studies examining depression as a mediator of risky sexual behavior among African-American women.<sup>76</sup> Moreover, in the SiHLE study, the brief CES-D was prospectively predictive of higher sexual risk behaviors and pregnancy among African-American female adolescents (internal consistency was 0.84).<sup>77</sup>

### **Theoretically-Important Psychosocial Mediators of HIV-preventive Sexual Behavior**

*HIV Prevention knowledge* will be measured using a scale developed in our ongoing research with African-American female adolescents. The scale has 23-items and uses a True-False-DK format for each item. Combining all correct responses creates a composite HIV knowledge score. The internal consistency of the scale is 0.86.

*Condom Expectancies* have been associated with safer sex behaviors among inner-city minority adolescents.<sup>78-81</sup> To assess adolescents' expectancies about condoms, we will use a modified version<sup>82</sup> of the Condom Attitude Scale developed by Sacco and his colleagues.<sup>83</sup> St. Lawrence and her colleagues,<sup>82</sup> in an extensive re-evaluation of the Sacco scale, re-calibrated the scale for administration to low literate teens as well as reduced the number of scale items. The internal consistency of the total scale, in the SiHLE trial with African-American adolescents, was 0.83.

*Condom Use Self-Efficacy* is a theoretically and empirically critical construct associated with condom use. A Condom Use Efficacy Scale was developed by the PI and Co-PI to measure self-reported ability to use condoms effectively among African-American adolescents and young adult women. The scale has 11 items, each measured using a 5-point Likert format. The scale has an internal consistency for young women of  $\alpha=0.84$ .<sup>84</sup> Used in the original SiHLE study with African-American female adolescents, the scale had a internal consistency of 0.88.

*Communication Self-Efficacy* has been repeatedly demonstrated to be associated with more frequent condom use among a variety of young adult populations and African-American females,<sup>85,86</sup> minority adolescents in high-risk environments<sup>87,88</sup> and young adult women.<sup>89</sup> A scale assessing African-American female adolescents' self-efficacy to communicate with sex partners was developed by the PI and Co-PI. This 7-item scale uses a binary response format and demonstrated satisfactory internal consistency in the SiHLE study ( $\alpha = 0.82$ ).

*Frequency of Communication with Male Sex Partners* has been identified as a determinant of HIV-preventive behavior.<sup>90,91</sup> The Partner Communication Scale assesses the frequency with which sexual topics, particularly condom use, are discussed with different types of sex partners (steady, new). This scale was used in the SiHLE study and demonstrated satisfactory internal consistency for new partners (0.80) and steady partners (0.82).

*Interpersonal Power Scale* has been developed by our research team, is designed to assess power imbalances in relationships; a central construct in the Theory of Gender and Power. Used in the SiHLE study of African-American female adolescents this scale had an alpha of 0.72.

*Peer Normative Influences* assesses perceptions of reference-group norms with respect to participating in low and high risk sexual behaviors. Scale items were originally developed by Catania<sup>91</sup> and were subsequently modified by our research team to be suitable for young African-American women. Used in the SiHLE study its alpha was 0.86.

*Social desirability bias* is important to assess since self-report data for sensitive topics may increase the likelihood that adolescents will answer questions in the manner they perceive these questions should be answered. The proposed study assesses this bias using the Crowne-Marlowe Inventory.<sup>92</sup> This measure will be administered as a check on socially desirable response bias with scale scores being covaried in the analysis. The scale consists of True-False statements concerning personal attitudes and traits. A adolescent's score consists of her total socially desirable responses. Internal consistency has been reported at .88 with test-retest reliability of .89. Concurrent validity has been demonstrated with significant correlations with the Lie scale and the Validity scale of the MMPI.

### **Collecting data for the cost-effectiveness analysis.**

Direct costs to be measured will include: resource use, personnel, equipment, supplies, allocation of administrative staff, postage and phone use, rental of space, advertising costs and division of space and supplies. Costs will be divided into recruitment versus intervention costs and protocol-driven versus standard of practice costs. One advantage of collecting cost data as part of a research project

is that financial records tend to be more accurate and detailed. To distinguish between research-driven and actual program costs, interviews will be conducted with the Principal Investigator and the Project Director at baseline and at 6-, 12-, and 18-months follow-up. Indirect costs incurred by adolescents will include: time spent participating in the study (i.e. completing ACASI interviews, attending the SiHLE HIV intervention group sessions); any loss of income that may have resulted from their participation, and travel costs. Intangible costs such as pain and suffering will not be measured. If a delivered service or input does not have a separate unit cost, then modeling will be used to construct an appropriate unit cost. Estimated or modeled costs for donated resources will also be measured. The actual service use of study subjects will be evaluated to estimate the costs associated with patterns of service use. Health service utilization will be collected from the adolescents' self-reports as assessed via the ACASI interview. Project implementation costs will be obtained by staff time logs, project expense records, and staff interviews.