PARENTAL NOTIFICATION FOLLOWING DIAGNOSIS OF PID IN URBAN ADOLESCENT YOUNG ADULTS
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Purpose: Urban adolescent and young adult women often require adult support for successful self-management of reproductive health conditions throughout their transition to adulthood. Although confidentiality is an important feature of adolescent and young adult clinical service delivery, successful PID outpatient adherence involves a complicated set of behaviors; prior research from our team demonstrates that the majority of urban young women engage parents around reproductive health decisions. Our data also demonstrates that parental knowledge of PID is the factor clinical providers are least likely to consider in making clinical dispositions for complicated sexually transmitted infections such as pelvic inflammatory disease (PID) care. The purpose of this research is to determine the factors associated with adolescent initiated parental notification and parental engagement in young women diagnosed with PID.

Methods: Preliminary data were analyzed from 115 participants from an IRB approved, single-blind randomized control trial (RCT) designed to evaluate a community health nursing (CHN) intervention with daily text messaging communication for improved self-management adherence and short-term reduction in adverse outcomes after PID. Participants were recruited in outpatient clinics and emergency departments of a large urban academic center and completed a baseline audio-computerized assisted self-interview through which participants provided data on demographics, reproductive and sexual history, and perceived social supports using the Social Provision Questionnaire (Cutrona & Russell, 1984). Participants also completed a 2-week interview during which they were asked about parental notification and engagement (parental assistance with care) during the 14 day PID treatment period. Logistic regression analysis were used to evaluate relationships between age and parental notification. Given RCT design and nature of the intervention, group status was evaluated as a potential cofounder/effect modifier in the analyses.

Results: Most participants were African American (92%), Medicaid insured (84%), resided in single female headed households (75%) with highest parental education of high school or less (80%). Mean age was 18.3 (+/- 2.1). Sixty-eight percent of participants informed a parent of their PID diagnosis and of that group, 49% reported receiving supportive care in the form of medication reminders, advice or comfort. Neither age (adolescent vs. young adult, p=.701) nor group assignment (CHN intervention vs. control, p=.499) was associated with parental notification. Of the 6 Social Provision sub-scales, the nurturance sub-scale was significantly associated with parental notification. Participants who reported a high sense of responsibility for the wellbeing of others were 25% less likely to notify a parent about their diagnosis [OR 0.75 (95% CI: 0.60, 0.95; p=0.01)] controlling for participants’ age.

Conclusions: The majority of urban young women with PID notify parents regarding their PID diagnosis and almost half of these patients report receipt of support during the treatment window. Young women who perceive greater responsibility to nurture others are more likely to take on self-management alone. While autonomy is a critical milestone for transition to young adulthood, this data suggests that support
from a caring adult is important for most young women. Future research is warranted to determine if nurturance also predicts better self-management or greater need for clinical support.

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**ADOLESCENT SELF-CONSENT FOR BIOMEDICAL HIV PREVENTION RESEARCH: IMPLICATIONS FOR PROTOCOL APPROVAL AND IMPLEMENTATION**

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**Purpose:** The Adolescent Medicine Trials Network [ATN] Protocol 113 is an open-label, multi-site demonstration project and phase II safety study of HIV pre-exposure prophylaxis, using daily doses of an oral anti-retroviral combination drug, with 15-17 year old young men who have sex with men in the U.S. Due to concerns about parental consent, in terms of harm to adolescents that could arise when sexual minority status and risk behaviors were disclosed to parents, the protocol required adolescent self-consent. Pursuant to federal regulations governing drug trials, parental consent is not required if adolescents are entitled to consent on their own behalf under state law to the healthcare or treatment being studied. The purpose of this ATN 113 sub-study was to examine factors related to the process by which Institutional Review Boards (IRBs) and research personnel made decisions regarding whether to approve and implement the protocol, with emphasis on the issue of adolescent consent with high-risk minor participants.

**Methods:** Qualitative descriptive methods were used. The study population included 17 research personnel at 13 ATN sites considering implementation of ATN 113. Data collection methodologies included semi-structured interviews and the receipt of IRB-related correspondence and documents generated during the review process. Low-inference content analysis, using a case-ordered meta-matrix, was utilized to organize, code, and summarize the data.

**Results:** Of 13 ATN sites in 12 states, seven received IRB approval for ATN 113, three were denied approval after full IRB review and three received no formal IRB disposition. Five main categories of factors related to the protocol approval and implementation process were identified. The personal perspectives category included research personnel concerns related to the responsibility they felt as providers and the fears they had as parents. The preparation and decision to submit category included descriptions of existing IRB relationships and advance preparation for formal IRB submission, and decisions about whether and how to proceed with submission. The formal IRB review process category included specific concerns expressed by IRBs during the formal review process (primarily the informed consent process, but also the balance of risks and benefits, the need for additional protections and institutional liability) and the response of research personnel. The final IRB disposition category
comprised justifications for final IRB decisions (most of which focused on legal interpretation regarding state adolescent consent laws) and the outcome assessment category included reflections on final IRB disposition and implementation decisions. An additional category related to advice for researchers seeking to enroll high-risk minors in future biomedical prevention trials also emerged, including reflections on the importance of persistence and collaboration.

**Conclusions:** This study represents a first look at the institutional acceptability and feasibility of allowing high-risk minor adolescents to self-consent to participation in biomedical prevention trials. The results illustrate the complexity of the legal, ethical and practical factors that researchers and IRB members must consider in determining whether to implement such trials, and also highlight the need for more well-articulated standards for adolescent participation.

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**HPV VACCINE RISK PERCEPTIONS AND SUBSEQUENT SEXUAL BEHAVIORS AND SEXUALLY TRANSMITTED INFECTIONS AMONG ADOLESCENT GIRLS**

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**Purpose:** Human papillomavirus (HPV) vaccine uptake remains low. One reason for suboptimal uptake may be parental and clinician concerns that some vaccinated girls may perceive less risk of sexually transmitted infections (STIs) other than HPV after vaccination and thus engage in riskier sexual behaviors. Our aims were to examine the relationship between HPV vaccine-related risk perceptions and subsequent sexual behaviors over 30 months following vaccination.

**Methods:** Participants included 112 sexually experienced girls aged 13-21 years recruited for a longitudinal study who completed >=2 of 4 follow-up visits (2, 6, 18, 30 months). At each visit, surveys assessed HPV vaccine-related risk perceptions (perceived risk of STIs other than HPV, perceived need for safer sexual behaviors) and sexual behaviors. Gonorrhea, chlamydia, and trichomonas testing was done at 6, 18, and 30 months. Primary outcomes were: 1) condom use at last intercourse with main male partner (“condom use”); 2) laboratory diagnosis of gonorrhea, chlamydia, and/or trichomonas at any visit (“positive STI testing”); 3) number of sexual partners since last study visit (“sexual partners”). Primary predictors included perceived risk of STIs other than HPV and perceived need for safer sexual behaviors, each measured with a 5-item scale. Mean scale scores were dichotomized into top tertile vs. lower tertiles (higher score indicates less perceived risk of STI and need for safer sexual behaviors). Covariates included demographics, substance use, HPV/HPV vaccine knowledge, history of HPV or other STI, and maternal and clinician factors at baseline. Associations between risk perceptions and sexual behaviors/STI outcomes were examined using generalized linear mixed models. Predictors that were associated with outcomes at p<0.10 in bivariate analyses were included in multivariable mixed models. Variables with p<0.05 were retained in the final model.

**Results:** Mean age was 17.9 years (SD 2.2); 88% were Black. At baseline, 72% had had more than one
Most girls perceived themselves to be at risk of STIs other than HPV (mean scale score 3.8; SD 2.0), and the vast majority perceived a need for safer sexual behaviors (mean scale score 1.8; SD 1.8). Final multivariable analyses demonstrated that risk perceptions were not independently associated with any outcome. Factors associated with outcomes were as follows: 1) no history of HPV/other STI (p=0.001), maternal communication about the HPV vaccine (p=0.02), and having health insurance (p=0.03) were associated with condom use; 2) greater number of sexual partners since last study visit was associated with positive STI testing (p<0.001); and 3) older age (p=0.03) and smoking in the last month (p<0.001) were associated with greater number of sexual partners.

**Conclusions:** Most girls perceived that they were at risk for STIs other than HPV and that safer sexual behaviors were important. HPV vaccine-related risk perceptions were not associated with condom use, positive STI testing, or number of partners. These findings provide further support that HPV vaccination is unlikely to lead to riskier sexual behaviors.

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**DISSEMINATION STRATEGIES TO PROMOTE HPV VACCINATION AMONG PRETEEN BOYS: EMBRACING THE TRANSITION TO ADOLESCENCE THROUGH THREE-WAY CONVERSATIONS AMONG PROVIDER, PARENT AND PRETEEN**

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**Purpose:** Purpose: Adoption of vaccination against human papillomavirus (HPV) has been slow in the US. Routine HPV vaccination of 11-12 year old boys was recommended by CDC in late 2011, five years after the recommendation for routine vaccination was issued for girls. We developed and evaluated a social marketing intervention with parents and healthcare providers to stimulate adoption of this vaccine for preteen boys. Our aim was to facilitate conversations among providers, parents and preteens about vaccine protection against a sexually transmitted infection.

**Methods:** Methods: Our intervention promoted HPV vaccine with both parents of preteen boys and health providers in 13 south central NC counties, July-September, 2012. The ‘Protect Him’ campaign included distribution of posters and brochures (English and Spanish) to county health departments (n=13) plus 184 providers, two radio PSAs, a one hour online training for providers and a website. The main messages were: (1) HPV is a common sexually transmitted infection and causes disease, (2) HPV vaccine protects against infection and disease from genital warts and certain cancers; (3) HPV vaccine is recommended for boys at ages 11-12. To assess changes in awareness, knowledge, attitudes, beliefs and vaccination actions, we evaluated the campaign using: 1) two independent, cross-sectional telephone surveys of parents with 9-13 year old boys (pre n=516, post n=455); 2) pre- and post-intervention
surveys with enrolled providers; and 3) NC Immunization Registry (NCIR) data to compare vaccination rates in the 13 intervention vs. 14 control counties.

**Results:** Results: Post intervention, providers reported increased likelihood of discussing (p=.03), recommending (p=.004) and vaccinating (p<.0001) 11-12 year old boys against HPV. Parents with campaign recall (62%; n=284) were more likely to have heard of the HPV virus and vaccine (adjusted OR=5.44 and 9.70 respectively, p<.0001). A Cox proportional hazards model for the NCIR data showed an intervention effect (HR=1.34, p=.0024), as the probability of vaccination increased by 34% in the intervention counties relative to control counties during the three months of the intervention.

**Conclusions:** Conclusions: This focused, time-limited, low intensity dissemination intervention boosted preteen HPV vaccination. Multiple evaluation strategies provide insight into intervention impact and potential explanatory mechanisms.

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**CAMP INSIDE OUT: A NOVEL APPROACH TO HIV/STI AND PREGNANCY PREVENTION IN FOSTER YOUTH**

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**Purpose:** Due to past maltreatment experiences and disrupted caregiver relationships, adolescents in foster care are at disproportionately high risk of sexually transmitted infections such as Human Immunodeficiency Virus (HIV/STI) compared with peers. Prior research suggests that effective intervention strategies for foster youth need to address 4 key factors: 1) broad-based interpersonal difficulties with emotion regulation, impulse control, and assertive communication skills, 2) delinquent behaviors resultant from past trauma and impacts on sexual behaviors, 3) maladaptive norms and attitudes regarding HIV/STI/pregnancy risks, and 4) poor condom negotiation skills.

**Methods:** To fill these needs, we developed Camp Inside Out. We used prior qualitative and quantitative research on mechanisms of HIV/STI risk to develop an innovative intervention for youth in foster care, and pilot test it for feasibility and acceptability. Camp Inside Out is a 5-day curriculum delivered in the context of an overnight camp which contains HIV/STI/pregnancy preventive curriculum and content from Dialectical Behavioral Therapy (DBT), a therapeutic program targeting emotion regulation and interpersonal skills demonstrated to reduce delinquent behaviors in traumatized populations. The camp format was chosen to address retention issues anticipated by caseworkers, and because camp itself provides an in vivo “milieu” of activities (e.g., campfires, challenge course) in which interpersonal skills can be practiced. We conducted an initial pilot with 8 youth in 2013; a second pilot was conducted with 13 additional youth in 2014. We collected data on intervention feasibility and acceptability and
generated basic descriptive statistics evaluating HIV/STI knowledge, psychological determinants of HIV/STI/pregnancy risk, behaviors, and emotion regulation skills at baseline, 1 month, and 4 months after the intervention.

**Results:** In 2013, 100% of youth received the full dose of curriculum and participated in baseline and 1 month surveys; 88% participated in a 4 month survey. We received high satisfaction ratings, with 88% of youth indicating that they would refer a friend and 100% of social workers indicating satisfaction with both the recruitment process and camp itself. Qualitative feedback also suggested high acceptability, e.g.: “I really miss you guys, that was the highlight of my summer” (female participant); “I learned all about relationships and sexual health” (male participant); “He seems more excited about his future [since camp]” (social worker). Pre-posttest descriptive statistics suggested that baseline ratings of HIV/STI/pregnancy related knowledge improved moderately after the intervention (mean proportion of items correct = 29%, 38%, and 36% at the baseline, 1 month and 4 months). Attitudes, norms, and self-efficacy improved at 1 month; effects attenuated for norms and self-efficacy at 4 months. We also found an increase in positive coping skills and a decrease in dysfunctional coping strategies at the 1 month follow up point; the improvement in dysfunctional coping strategies again waned by 4 months. Two of four female participants reported having long-acting birth control devices placed by the 1 month interview.

**Conclusions:** Camp Inside Out appears to be a feasible and acceptable strategy to reduce HIV/STI/pregnancy risk in foster youth. Additional data is needed to determine intervention effects on sexual risk behaviors.

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**A VIDEOGAME INCREASES HIV RISK-RELATED KNOWLEDGE IN ADOLESCENTS**

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**Purpose:** Nearly 40% and 45% of new HIV infections in the U.S. and globally, respectively, are in adolescents/young adults. Videogames are ubiquitous, foster skill development translating into improved health outcomes, and have the potential to dramatically reduce risk behaviors in youth. Behavior change videogames collect in-game data about the players’ knowledge and skills, how they change in response to gameplay, and how they correlate with out-of-game data collected. PlayForward: Elm City Stories is an iPad-based videogame designed to increase HIV risk knowledge and decrease risk behaviors. The purpose of this study was to assess: (a) if PlayForward impacted on HIV risk knowledge and (b) how in-game knowledge data correlated with data collected through standardized assessments.

**Methods:** As part of a large RCT to evaluate PlayForward, HIV risk-related knowledge data was collected through standardized assessments at baseline, 6 weeks (following gameplay), and 3 months. Software-generated logs of player activity were collected through the iPad, measuring exposure to specific intervention components. Coupled with standardized assessments, the data were analyzed for markers of gains in HIV risk-related knowledge. iPad software data were analyzed using the R statistical
computing software package.

**Results:** One hundred and ninety-eight adolescents have been enrolled in the RCT; 55% boys, mean age is 13 years; 161 have completed 6 weeks of gameplay; 125 have completed 3-month follow-up assessments. There were no significant baseline between-groups differences on a 22-item assessment of HIV risk-related knowledge. After six weeks of gameplay, the intervention group had higher knowledge scores (mean=15 (S.D.=4.8)) than the control group (mean=12.5 (S.D.=4.5); p<0.001) at six weeks and at three months (mean=14.4, S.D.=5.5 vs. mean=12.5, S.D.=4.7; p=0.04). Analysis of 1,289,903 events in log files revealed that the number of game levels completed was positively correlated with knowledge gains measured at 6 weeks (r=0.32; p<0.005) and at three months (r=0.42; p<0.001).

**Conclusions:** These findings demonstrate that (a) PlayForward increases HIV risk-related knowledge among adolescents and (b) exposure to videogame content is highly correlated with knowledge as assessed by standardized tools used outside of gameplay. These methods are a new and exciting way to capture evidence for real-world knowledge acquisition.

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