UNMET NEED FOR HIV SCREENING AMONG ADOLESCENTS WITH PELVIC INFLAMMATORY DISEASE
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Purpose: Adolescents and young adults account for approximately 26% of all new HIV infections. The Centers for Disease Control and Prevention [CDC] recommends routine HIV screening in all health care settings, particularly when patients are diagnosed with another sexually transmitted infection (STI). Adolescents and young adults with pelvic inflammatory disease (PID) represent a unique and vulnerable group of women at risk for HIV who should be routinely screened as a part of PID care. As care of the adolescent PID patient as shifted to outpatient settings with limited capacity for HIV counseling and testing (CTS), there may be missed opportunities for screening. The goal of this project is to examine changes in the frequency of HIV screening as a result of nursing case management intervention embedded in a large randomized controlled clinical trial and to determine unmet need for HIV screening among adolescents and young adults with pelvic inflammatory disease (PID).

Methods: We utilized an interrupted time series design to evaluate the baseline pre-/post-intervention HIV screening practices for patients enrolled in the Technology Enhanced Community Health Nursing (TECH-N) trial, a large randomized controlled clinical trial evaluating the effectiveness of a combined text-messaging and community health nursing intervention to improve adherence and reduce STI re-acquisition among women seeking acute and emergency care in an urban, largely minority, low-income, and high STI/HIV prevalent community. Midway through data collection, TECH-N partnered with recruitment sites [an academic pediatric and adolescent medicine practice [PP] and pediatric [PED] and adult [AED] emergency departments] to collect blood samples for related research and encouraged HIV screening consistent with the CDC guidelines. In the post-intervention period, TECH-N provided nurse case management services including HIV results follow up, community outreach services, and linkages to HIV care for positives. 128 charts were identified for review. Participants who were HIV positive [N=2] or recently screened [N=1] at baseline were excluded from the analysis, leaving a total of 125 participants in the analytic sample. Data were evaluated using bivariate analyses [chi-square analyses].

Results: Most participants were African American [93.6 %] and 70.1% had public insurance. Most patients [71.1%] also received care in the PED compared with the AED [22.4%] and PP [6.4%]. Overall, 32.4% of all participants were offered HIV screening at baseline and 49.1% in the post intervention period. Documentation indicated that 1.6% of patients offered testing refused. There were no HIV positive results requiring linkages to care services. Overall, HIV screening significantly improved in the AED [46.9% versus 66%, p=0.036] during the post intervention period, but no significant improvement was seen in the PP or PED.

Conclusions: Despite the CDC recommendation for HIV screening at the time of STI diagnosis and the
added clinical infrastructure afforded by the TECH-N trial, adolescent and young adult women with PID continue to have unmet need for HIV screening in this setting. Funding and workflow strategies to support HIV CTS in acute and emergency care settings for patients diagnosed with complicated STIs are warranted

Sources of Support: 5R01NR013507-03, PI: Trent, M, CDC-5U50MN000025-04 5R01NR013507-03 5R01NR013507-03

45.

THE EFFECT OF HORMONAL ADD-BACK THERAPY IN ADOLESCENTS TREATED WITH A GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST FOR ENDOMETRIOSIS: A RANDOMIZED TRIAL
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Purpose: Endometriosis is a debilitating disease complicated by pain, bleeding, limitation of activities, and poor social function. Gonadotropin releasing hormone agonists (GnRHa) are utilized for patients who have failed primary treatments, but their long-term use is associated with deleterious effects on bone mineralization. Adults lose 5%-8% of spinal BMD after only 3-6 months of GnRHa use. “Add-back therapy” is a promising adjunct to treatment for bone loss prevention, but has never been studied in adolescents. Given that adolescence is the critical time for attainment of peak bone mass, these patients are at high risk for the negative effects of GnRHa. We sought to determine whether an add-back regimen of norethindrone acetate or norethindrone acetate + conjugated equine estrogens (CEE) is superior to maintain bone mineral density (BMD) and skeletal strength in adolescents with endometriosis treated with a GnRHa.

Methods: Fifty-one adolescents (age 17.9 ± 1.7 years) who were initiating therapy with depot leuprolide for endometriosis received a random, double-blind assignment to add-back therapy with either norethindrone acetate (5 mg/d) + placebo or norethindrone acetate (5 mg/d) + CEE (0.625 mg/d) for 12 months. Anthropometrics, quality of life measures, and serum bone turnover markers (bone-specific alkaline phosphatase [BSAP], C-telopeptides [CTx]) were collected at 0, 3, 6, and 12 months. Body composition, bone mineral content (BMC), and areal BMD were obtained by dual-energy X-ray absorptiometry (DXA) every 6 mo. Volumetric BMD at the tibia and radius were measured by peripheral quantitative CT (pQCT) at 0, 6, and 12 months. Intention-to-treat comparison of outcomes in the 2 trial arms was conducted by repeated-measures analysis.

Results: Thirty-three adolescents completed the trial. Participants had normal DXA measures at baseline. Over the 12-month study, total body BMD and BMC increased in the norethindrone + CEE group (BMC baseline 2018.8 ± 181.2 g vs. 12-mo 2069.8 ± 204.2 g, p<0.001), while remaining unchanged in the norethindrone + placebo group (BMC baseline 2021.5 ± 218.8 g vs. 12-mo 2001.8 ± 208.4, p=0.06). Lean mass similarly increased in the norethindrone + CEE group only (+1368.7 g at 12-mo, p=0.006). During the same time, serum BSAP increased in those receiving CEE only (p=0.04); CTx did not change over the 12 months. No differences were seen across the trial at the hip or lumbar spine by DXA,
in pQCT measures, or in other anthropometrics (weight, fat mass). Quality of life measures improved in both groups. No significant adverse events occurred during the trial.

**Conclusions:** Both hormonal add-back regimens successfully preserved bone health and improved quality of life for adolescents with endometriosis during 12 months of treatment with a GnRHa. However, combination norethindrone + CEE appears to be more effective for increasing aBMC and lean mass than norethindrone monotherapy. These effects may be mediated by higher rates of bone formation, as reflected by increased serum BSAP. No significant side effects of either regimen were observed over one year of treatment.

**Sources of Support:** McCarthy Family Foundation. Thrasher New Investigator Award. BCH CTSU.

### 46.

**EFFECTS OF A RANDOMIZED HEALTH CARE TRANSITION CARE COORDINATION INTERVENTION ON PERCEPTION OF CHRONIC ILLNESS CARE AND TRANSITION READINESS**

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**Purpose:** Care coordination has been reported to be effective in facilitating health care transition (HCT) from pediatric to adult care. No studies have examined the effects of HCT care coordination compared to a robust control group in real time. In this study we report longitudinal perception of chronic illness care and transition readiness data from a randomized HCT care coordination intervention trial for youth with special health care needs.

**Methods:** 210 participants ages 16-22 years old (mean age 18.9 +/-1.7 years) were enrolled in a randomized controlled HCT care coordination intervention and were recruited from a large urban academic adolescent health clinic located in a pediatric tertiary referral health system. Following enrollment and baseline data collection, 105 participants were randomized to the HCT care coordination intervention group, and the other 105 were randomized to the control group. All participants were interviewed at 0, 6 and 12 months completing the Patient Assessment of Care for Chronic Conditions (PACIC) which assesses five domains (patient activation, delivery system design, decision support, goal setting, problem solving, and follow-up/coodination), the Client Perceptions of Coordination Questionnaire (CPCQ) assessing perception of patient-centered care and care coordination, and a self-rating on a scale of 1-10 how ready they feel to transfer to adult care. We compared responses in intervention and control participants using contingency table analyses and relied on chi square tests to identify differences that were unlikely to have occurred by chance.

**Results:** At baseline there were no statistical differences in PACIC, CPCQ or readiness scores when comparing the intervention to control group. At 6 months, no differences were observed in the PACIC scores, while intervention participants rated quality of chronic illness care higher (p=0.065) and reported less conflicting advice from providers (p=0.018) than the control group. At 12 month follow-up there were significant differences seen in the PACIC as patient activation (p=0.015), goal setting (p=0.034), problem solving (p=0.009) and coordination/follow-up (p=0.016) all rated statistically significantly higher...
in the intervention than control group. At 12 months, intervention participants reported more often receiving the services they thought they needed \(p=0.03\), were less confused about the role of providers \(p=0.012\) and reported more frequent discussions with providers about future care \(p=0.05\) than control participants. There were no differences in self-rating of transition readiness between the two groups throughout the study period.

**Conclusions:** This HCT care coordination intervention improved many aspects of quality of chronic illness care for participants. Self-assessment of readiness was not impacted by this intervention. Future studies need to assess medical outcome and cost data to see if these perceptions of improved quality of care translate to better HCT outcomes.

**Sources of Support:** This study is supported by grant R40MC23627 awarded to Lisa Tuchman from the Maternal and Child Health Research Program, Maternal and Child Health Bureau (Title V, Social Security Act), Health Resources and Services Administration, Department of Health and Human Services.

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47.

**URBAN MINORITY YOUTH PARTICIPATION IN CLINICAL RESEARCH: TESTING THE DESIGN OF THE TECH-N TRIAL:**

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**Purpose:** Pelvic inflammatory disease (PID) disproportionately affects young women and can negatively influence reproductive health trajectories. Low-income, minority adolescents are particularly vulnerable as they often receive inadequate treatment, fail to return for follow-up evaluations, and have high recurrence of sexually transmitted infections (STIs). Few RCTs have focused on strategies to improve outpatient adherence and/or reduce the reproductive morbidity in this population as they are often viewed as non-ideal RCT candidates. Further, delivery of community based and in-home sexual health interventions have not been well described in the literature. The objective of this study is to describe the preliminary effectiveness of recruitment and retention strategies being employed in a novel clinical trial designed to test a technology-enhanced community-health nursing (TECH-N) intervention among low income, minority adolescents with PID.

**Methods:** Young women aged 13-25 were recruited during acute PID visits in pediatric, adolescent medicine clinics, and emergency departments (ED) to participate in this IRB-approved trial. Participants completed an audio-computerized self-interview (ACASI), provided vaginal and serum specimens, and were randomized to standard treatment or the intervention. Intervention participants received daily text messaging support for 30 days and a community health nurse interventionist performed a clinical follow-up assessment in the patient’s home within 5 days after the diagnostic visit in which the Sister-to-Sister Teen program was embedded. Cell phones were provided as needed. All staff were trained in cultural competent research engagement, STI/PID care, all aspects of the trial design. All patients received a full course of medications and completed research visits at 2 weeks (adherence), 1 month (STI testing/ACASI), and 3 months (STI testing/ACASI) by an outreach worker. Exploratory analyses using
descriptive statistics, chi-square and t-tests were conducted to examine recruitment, retention, and follow-up data.

**Results:** In the first 18 months, 150 patients were eligible (70%) and 127 (85%) of eligible patients were enrolled. Most participants were low-income (Medicaid), African American, and resided in female-headed households with maternal education level as high school or less. Most (83%) were recruited in ED settings (54% Pediatric ED, 26% Adult ED, 20% Acute Care Pediatric or Adolescent Clinic) and there was no difference in enrollment assignment using the randomization sequence. Only 10% of intervention patients required a study cell phone to participate in the intervention. All intervention participants received welcome text and had the series of text sent. Ninety-two percent of individuals assigned to the TECH-N intervention completed the nursing visits. The mean number of days to complete nurse visit was 2.2 days. Almost all participants completed their 2-week, 1-month, and 3-month visits [92%, 94% and 92%, respectively]. Mean number of days to complete the 2-week research visit was 1.1 [SD 0.55] days.

**Conclusions:** Preliminary data from the TECH-N study demonstrates that low-income, minority urban adolescents can effectively be recruited and retained from acute visits to participate in clinical trials if culturally sensitive, invested, persistent, and non-judgmental recruitment staff and outreach supports are in place. In-home sexual health and clinical interventions appear to be both feasible and acceptable in this population.

**Sources of Support:** National Institute of Nursing Research 5R01NR013507 (PI: Trent)

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**48.**

**ADULT IDENTITY MENTORING 4 TEEN MOMS (AIM4TM): ADAPTING AN EVIDENCE-BASED PREGNANCY PREVENTION PROGRAM (PROJECT AIM) TO REDUCE RAPID REPEAT PREGNANCIES AND IMPROVE OUTCOMES FOR ADOLESCENT MOTHERS**

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**Purpose:** Three in ten young women have a birth before the age of 20, and one in five of those women will go on to have a subsequent birth while still in their teens. Teen mothers who have repeat births are less likely to receive prenatal care, complete school, work or maintain economic self-sufficiency, and have children who are ready for school; they are also more likely to experience preterm delivery, receive federal benefits, and have children with emotional and behavioral problems. AIM 4 Teen Moms is an adaptation of an innovative evidence based intervention to lower sexual risk among youth in poverty. This adaptation addresses the risk of rapid repeat births by providing targeted interventions to at-risk teen mothers in their homes. This program seeks to increase long-term contraceptive use and delay rapid repeat pregnancies among teens in areas with high rates of teen and repeat pregnancy. AIM 4 Teen Moms is a nine-session program that targets new teen mothers in the Los Angeles County, California. Seven of the sessions are delivered one-on-one in the homes of program participants AIM for
Teen Moms is based on the Theory of Possible Selves, AIM4TM engages parenting teen mothers in planning for the future around a desired occupational goal (i.e. a positive possible future self).

**Methods:** A total of 949 participants took part in the AIM 4 Teen Moms (AIM4TM) program. 475 participants were part of the control group and 474 were in the treatment group that received the AIM4TM program. There were a total of 15 cohorts that went through the program since October 2011. 304 participants completed 5 out of 8 sessions and 281 participants completed 6 out of 8 sessions.

**Results:** Those who were part of the treatment group were asked at the end of the program their overall thoughts on AIM4TM. Eighty-four percent strongly agreed that participating in AIM4TM was worthwhile and that the AIM4TM materials were helpful to them. Participants were also asked questions in regards to birth control. Eighty-nine percent reported that they were to have sexual intercourse in the next year they would be more likely (or much more likely) to use some form of birth control with 67% saying they would be much more likely to use a condom and 56% to much more likely consider using either the shot (Depo Provera), an IUD (Mirena or Paragard), or an implant (Implanon). Finally, 67% said that they were much more likely to ask their partner to be a part in their birth control decisions.

**Conclusions:** Preliminary analyses supports that AIM4TM is a well received and feasible alternative to existing programs to reduce rapid repeat pregnancies among adolescent mothers. Data analysis from the RCT is ongoing. By fostering a positive vision of the future, AIM4TM encourages the formation of adult identities that benefit from family planning behaviors to protects against a rapid repeat pregnancy. AIM4TM addresses both personal barriers to contraception use and promotes problem-focused coping and achievement motivation.

**Sources of Support:** Office of Adolescent Health; PRIES

49.

**ADOLESCENT WILLINGNESS TO PARTICIPATE IN REPRODUCTIVE HEALTH CLINICAL TRIALS**

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**Purpose:** The development of new biomedical options for the prevention of sexually transmitted infections (STIs) will require clinical trials with adolescent participation. This study evaluated the association of demographics, sexual experience, family characteristics, and perceptions of clinical trial privacy on adolescents' willingness to participate (WTP) in a hypothetical trial evaluating topical microbicide safety.

**Methods:** Adolescents (n = 300), ages 14 to 17 years, were recruited with their parents to enroll in a study regarding WTP in a hypothetical topical microbicide safety trial. Adolescents were interviewed about demographics (age, gender, Hispanic ethnicity), sexual experience, family characteristics (selected scales of the family environment scale (FES) and three parental monitoring scales), previous participation in a research study, and beliefs about parental involvement during clinical trial participation. Adolescents were presented a hypothetical trial similar to typical Phase 1 studies, and
were asked if they would agree to participate if offered participation today (a 6 point Likert scale was divided into agree versus disagree for analytical purposes). Age was categorized into 14-15 versus 16-17 years. Sexual experience was divided into no experience beyond a romantic partner and/or kissing versus reports of touching genitals, oral/anal/penile-vaginal intercourse. Chi square analyses or logistic regressions were used to evaluate whether individual or groups of variables were associated with WTP. Significant variables were placed in a common model.

Results: The characteristics of participants was as follows: 62% female, 75% Hispanic, 55% 16-17 years, 65% no sexual experience beyond a romantic partner and/or kissing. Fifty-nine percent reported some level of likelihood of participating in the clinical trial. Typically, these trials are not offered to anyone who is not sexually experienced; however, 103 of 194 (53%) sexually inexperienced adolescents agreed to participate. In individual/group models, significant predictors of WTP were age ($p = 0.02$), sexual experience ($p < 0.01$), indirect monitoring ($p < 0.01$), and parental involvement during clinical trial participation ($p = 0.03$). Adolescents who were older, had more sexual experience, who had less indirect monitoring, and wanted less parental involvement during research participation were more likely to agree to participate. Gender, Hispanic ethnicity, selected FES scale scores, direct monitoring, direct monitoring with peers, and previous research experience were not associated with WTP. When sexual experience was left out of the common model, only indirect monitoring stayed in the model ($p < 0.01$).

Conclusions: As might be expected, adolescents with greater sexual experience were more likely to agree to be in a study involving placing a product in the vagina or on the penis; however, many adolescents who had not experienced penile-vaginal sex were still willing to participate. Other associations suggested that willingness to participate is not associated with demographics but rather with evidence of increased autonomy (less indirect monitoring, beliefs in less parental involvement in the study) or a possible surrogate for autonomy (age). Understanding how to engage a full range of adolescents in reproductive health trials will enhance the development of products that can be used safely and effectively among all adolescents.

Sources of Support: NIH R01HD067287

50.

THE EFFECTIVENESS OF THE MINDFUL AWARENESS AND RESILIENCE SKILLS FOR ADOLESCENTS (MARS-A) INTERVENTION ON ADOLESCENT MENTAL HEALTH: A PILOT CLINICAL TRIAL
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Purpose: Adolescents with psychological distress, chronic illness, and/or chronic pain experience critical challenges in their mental health and development, coping, and transition to adulthood. A large body of evidence supports the benefits of mindfulness-based interventions for adults in coping with a wide range of stressors, including chronic pain and illness, depression, and anxiety. The empirical literature on clinical mindfulness-based interventions for adolescents is still in its infancy. The purpose of this pilot
study is to develop and examine the effectiveness of a novel mindfulness-based intervention on adolescent mental health.

**Methods:** A novel mindfulness-based intervention, MARS-A, was developed by two experienced clinicians (Adolescent Medicine specialist and Child and Adolescent Psychiatrist), who also have significant personal mindfulness practice experience. MARS-A is an 8-week referral-based outpatient program for adolescents age 14 to 19 with psychological distress (depression or anxiety symptoms), with or without co-occurring chronic illness and/or chronic pain. The developers adapted elements from existing evidence-based mindfulness-based interventions for adults, and also integrated elements of their personal mindfulness practices and clinical practice with adolescents. Data were collected pre and post intervention from participants in the MARS-A intervention (n=31, 71% female, ages 14 to 17 years). A survey at baseline and immediately after the intervention assessed psychological distress (Kessler-10), stress (Perceived Stress Scale), depressive symptoms (Center for Epidemiological Studies-Depression), and functioning in daily and physical activities (Functional Disability Index). Thirteen cases had some incomplete data. Tests of missingness revealed data were missing at random and therefore could be handled by imputing information using an Expectation-Maximization (EM) algorithm. Analyses involved paired t-tests with bootstrapping to compare mean scores pre and post intervention. Effect size was calculated using Morris and DeShon’s (2002) equation 8 to correct for dependence among means.

**Results:** Perceived Stress scores declined (t[30]=3.07, p=.01, d=.55) from pre to post-test (3.63 to 3.22) as did Kessler-10 scores (t[30]=2.08, p=.05, d=.37) (T1=2.92, T2=2.64) and depressive symptoms (t[30]=2.08, p=.05, d=.37) (T1=2.43, T2=2.21). Daily and physical activities, as measured by the Functional Disability Index, changed in the predicted directions but results were not statistically significant. The effect sizes for Perceived Stress, Kessler-10, and CES-D scores (d ranging from 0.37 to 0.56) are noteworthy.

**Conclusions:** This study is one of the first trials of a mindfulness-based clinical intervention for adolescents. Results of this study suggest that MARS-A is a promising intervention for a heterogeneous clinical population of adolescents with anxiety and depressive symptoms. Participants reported lower perceived stress, psychological distress, and depression symptoms. The magnitude of changes suggests clinically significant benefit. Adolescents’ life functioning showed a non-significant trend towards improvement, and the study may have been limited by power to detect statistically significant improvements. This was an uncontrolled pilot study, so definitive conclusions cannot yet be drawn. Further research (including randomized controlled trials, and qualitative research to examine adolescents’ perception of the intervention) is warranted.

**Sources of Support:** Children’s and Women’s Mental Health Programs, British Columbia Mental Health & Addictions Services
51.

JUST TRAC IT!: ASSESSING A MOBILE-HEALTH (MHEALTH) INTERVENTION FOR YOUTH WITH CHRONIC
HEALTH CONDITIONS AND/OR DISABILITIES (CHC/DS) TO ENCOURAGE ENGAGEMENT AND READINESS
BEHAVIORS FOR TRANSITION
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Purpose: The purpose of this study was to determine whether using a mobile-health (mhealth)
intervention, promoted as Just TRAC It! would improve youth engagement, self management and
transition readiness. Background: A developmentally-appropriate approach is required for youth with
chronic health conditions and/or disabilities (CHC/Ds) to prepare them and for self-management skills
expected in the adult health care system. A major component of healthcare reform centers on the use
of technology to empower youth in their healthcare decisions. The project leveraged the recent
phenomenon that most youth own cell phones, and that various existing functions could be used for
entering health information. The study sought to determine if encouraging youth 14-18 years of age
with a CHC/Ds, to use the functions on their own personal phones was a feasible activity and to
determine if having this easily retrievable personal data in their phones would be used when they were
required to make health decisions and manage health care. The recommendation was “When you come
to the clinic, turn your phone on”, as a counter to the usual mantra, “Turn your phone off”.

Methods: In this pilot study (n=30) the Just Trac it! intervention was introduced to youth aged 14-18
years prior to a subspecialty clinical visit (rheumatology, neurology). After consenting, research students
taught the youth patients to input personal health information into their phone’s existing functions
(using the Notes, Contacts and Calendar applications in their phones). Further, a promotional flyer given
to the youth, outlines information about the intervention to encourage future use of phone features for
their own healthcare management. At one-month and four-months after the intervention youth were
sent a follow-up online survey that evaluated the usefulness (measured by usability, impact on health
care visit, and knowledge translation) of the intervention

Results: One hundred percent of the youth approached participated in the intervention. With a 50%
response rate to the questionnaire, 71% indicated that they will “Always” or “Sometimes” use ‘Just
TRAC it’ to bring question(s) to their medical visits. 22% indicated that they had the opportunity to use
one of the three phone’s applications for healthcare purposes during the follow-up period. Less than
half the youth (47%) indicated they would use the phone to track their appointments. One youth
commented that the work of loading the information into her phone improved her health literacy.

Conclusions: The Just TRAC it! intervention was co-designed by youth who live daily with a CHC/D. To
date, the concept has well received by youth, families and care providers. The intervention is free and
easy to implement and was highlighted as a creative technology solution for health care at the Fall 2013
Canadian Association for Pediatric Health Centres annual conference This intervention can be linked to
the self-management skills required for readiness to transfer to adult health care services.

Sources of Support: unfunded