Adolescents & Microbicide Trials: Challenges and opportunities for their participation in HIV clinical research

Looking Back to Look Forward
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Joy Noel Baumgartner, PhD, MSSW
Overview of research

- **Background:** Adolescents and young women are disproportionately affected by HIV yet underrepresented in HIV prevention clinical trials. Their exclusion from trials may hinder access to new prevention technologies, once available.

- **Study objective:** to identify opportunities and barriers to adolescents’ participation in HIV prevention trials

- **Approach:**
  - Study site: Dar es Salaam, Tanzania
  - Phase 1: Repeated in-depth interviews with young women, aged 15-21, drawn from different contexts (married, single in-school/out-of-school, engaged in sex work)
  - Phase 2: Six-month, prospective mock clinical trial (MCT) with 135 young women, aged 15-21
Main findings

- Adolescents (15-17) had similar HIV risk profiles as young women (18-21)
- Relatively high pregnancy rates in MCT (10%), no HIV incidence, but moderate rates of RTI/STIs and HIV+ diagnoses (5) at baseline screening
- Overall, retention challenging – but not different between age groups
- High interest in new HIV prevention products, no clear preference for pills vs. gel
- Relatively good comprehension of consent information
Lessons learned from conducting research with young people

• Recruitment and retention in cohort studies
  – Age verification and consent (16+ did not need parental consent; but needed to use a few options for verifying age)
  – Community-based inf sessions and facilitating group recruitment and transport aided recruitment
  – Retention barriers included keeping in touch (using family or friend’s cell phones), mobile population, and motivation for follow-up visits—getting to clinic even if contacted (“I’m on my way!”)

• Issues relate to clinical research
  – Lack of experience with clinical/gynecological exams – It’s scary!
  – However, participants liked regular HIV and pregnancy testing—speaks to their need to know their health status
Involving youth in the research continuum

• Youth Advisory Group (YAG) helpful throughout the study
  – Recruitment (where to find potential participants)
  – Retention (facilitating group follow-up visits)
  – Reviewing study promotional materials, study instruments

• Trained YAG on research literacy, regularly updated on study, inputs along the way, YAG involved over 5 years, invaluable!
Lessons learned for future programming and research

• Clinic study site considered a model youth-friendly services (YFS) site but it needed ongoing YFS training, support, supervision; cannot assume YFS standards upheld at clinics over time without sustained (human/financial) resources

• Adolescents – and their mothers – need better, more positive information on contraception. (Moms seemed to have more positive attitudes towards talking about HIV prevention than contraception with their daughters. Talking about contraception connoted encouraging sex.)

• Adolescents need greater access to clinic-based services, including HIV testing and contraception – of which they have limited information; need FP integrated into STI services which youth appear to access more frequently. However, if adolescents not accessing clinics, how else to get contraceptive services to them?
Wicked question

• Recent HIV prevention trials have found that younger, single women (18-24) had higher HIV incidence levels, but also lower adherence to products. Their trial inclusion challenges our ability to test the effectiveness of these products.

• Should we just exclude younger women such as adolescents from prevention trials – until we have been able to evaluate efficacy of products?
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