

Adolescents in HIV Vaccine Research

Anticipating IRB Review of Inclusion of Adolescents in HIV Vaccine Trials in the United States

**Kevin Fisher, JD MS
Senior Policy Advisor
AIDS Vaccine Advocacy Coalition
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Missing adolescents in US HIV vaccine trials

- Thirty different HIV vaccine trials currently in clinical trials worldwide, but no cohort of adolescents.
- A Phase I trial of the Merck Ad5 vaccine in South Africa with a small adolescent cohort is under consideration.
- Discussion has begun with recent guidance by FDA and NIAID on adolescent trials.
- Yet no US adolescent cohort planned.

Regulatory challenges

- Institutional Review Board (IRB) approval is required of all HHS funded, or FDA approved vaccines.
- Children are provided special protection under the federal law.
- If a study involves more than “minimal risk,” then it can only be approved if it provides a direct benefit to the child (Sec. 405), or
- If a study does not provide a direct benefit then it must be approved by a special committee and the Secretary of HHS (Sec. 407).

Could an adolescent trial be approved under Sec. 405?

- Approval under Section 407 imposes higher approval burden.
 - Study more likely delayed/denied.
 - New conditions imposed.
 - Different consent requirements.
 - Stigma of finding of no “benefit” to child.

- But Section 405 permits approval only if the prospect of direct benefit outweighs the risk.

Survey of pediatric bioethicists (n=9)

- Risk of adverse events appeared low.
- The possibility of disinhibition to risky sexual behavior was identified as a significant risk.
- The potential for societal harm from vaccine-induced HIV seropositivity was the most significant risk that experts identified.
- Finally, the vulnerability of testing upon adolescents at risk of HIV, who might not have a strong support system, was identified as a significant issue.

Reducing risk to adolescents to support Sec 405 approval

Survey participants recommended:

1. Expanded counseling to reduce the risk of disinhibition;
2. improved testing procedures or vaccine selection to reduce the risk of vaccine-induced seropositivity;
3. limiting the age of adolescents in the study to 14 years of age and older;
4. institution of consent monitoring procedures; and
5. exclusion of adolescents with low parental involvement and support.