

HIV Rates Are Increasing in Gay/Bisexual Teens

IRB Barriers to Research Must Be Resolved to Bend the Curve

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Federal regulations (45 CFR 46) created IRBs to protect the rights and welfare of human research participants. Like overprotective parents whose short-term precautions have the unintended long-term consequence of depriving their children of the opportunity to develop skills necessary to be independent adults, IRBs are complicit in the creation of health inequities when their disapproval of studies systematically prevent some communities from having the opportunity to receive the benefits of research. When health inequities are produced, even in part, by scientific inequities created through a system chartered to protect human well-being, the imbalance must be called to account. Against the backdrop of recent developments in proposed revision to the Common Rule that governs IRB policies and new scientific opportunities to create an HIV/AIDS-free generation, this article recounts how the highest-risk group in the U.S. has been too often left behind, and the role IRBs have played in enacting these disparities.

The recently updated National HIV/AIDS Strategy for the U.S. set a goal to reduce the number of new HIV infections by 25% by 2020.¹ In recent years, rates of HIV diagnoses have remained stable—but this hides the fact that rates are declining in some populations and increasing in others.² For years, rates of HIV infections have been increasing among adolescents—increases that have been driven by male-to-male sexual transmission that represented 80% of diagnoses among those aged 13–24 years in 2013.² Adolescent men who have sex with men (AMSM) of color are disproportionately infected.²

In the 15 years since the first large-scale surveillance projects among AMSM documented very high HIV

prevalence,³ one might have expected for AMSM to be a priority population for HIV prevention research. However, our review of the 93 HIV risk reduction programs in CDC's *Compendium of Evidence-Based Interventions for HIV Prevention*⁴ identified only four that were evaluated with samples that were mostly or exclusively young MSM aged older than 18 years (i.e., CLEAR and Together Learning Choices for young people living with HIV; Mpowerment and Young Men's Health Project for young MSM who are HIV-negative) and none that were evaluated primarily or exclusively with MSM under age 18 years. Critical advances in HIV prevention among AMSM have been impeded by the failure of IRBs to apply federal regulations permitting adolescents to self-consent to research without parental involvement. This failure is abetted by the policy issue of statutory silence on the extension of mature minor laws from health care to research,⁵ as well as by false assumptions regarding parental rights and youth decision-making capacity.⁶

Science is the engine for evidence-based HIV prevention programs. Given National HIV/AIDS Strategy recommendations for providing HIV risk populations access to effective prevention, such as pre-exposure prophylaxis (PrEP), the relative dearth of studies on the efficacy of PrEP and other behavioral and combination strategies for AMSM under age 18 years is disturbing.⁷ Differences in neurobehavioral, psychosocial, and familial characteristics between adolescents and adults mean that prevention strategies tested on older MSM may be ineffective (e.g., poor adherence) or iatrogenic (e.g., sexual disinhibition) in younger populations.⁸ It is anticipated that more jurisdictions will follow New York State's blueprint to end AIDS by 2020,⁹ which permits youth to receive PrEP or non-occupational post-exposure prophylaxis without parental consent when a provider determines they have the capacity to give informed consent. In this likely future, a lack of scientifically informed and adolescent-appropriate approaches to implement HIV prevention strategies will become increasingly problematic.

Ethics studies of biomedical and behavioral HIV prevention research show that AMSM whose parents

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are unaware or reject their sexual orientation will refuse to participate if guardian permission is required.^{10,11} This reluctance exists even in youth who are “out” to parents, and even many parents who do not explicitly reject their child’s sexual orientation enforce a “code of silence” on discussions of sexual orientation and sexual health.¹¹ As a result, the minority of AMSM who are willing to participate in studies requiring parental permission are unrepresentative of the larger population, thereby skewing study findings in ways that can lead to poorly conceived interventions or misapplication of prevention resources.¹²

Although there is great variation, all U.S. jurisdictions have some form of laws permitting minors to obtain HIV testing and other sexual health services without parental involvement.⁶ Consistent with these laws, federal regulations for the protection of human research participants from the Office of Human Research Protections (OHRP) and the U.S. Food and Drug Administration classify minors as “adults” if they have attained their state-defined legal age for consent to treatment or procedures involved in a research study (§§45CFR46.402(a), 21CFR50.55).⁵ After consultation with the Food and Drug Administration and OHRP, this approach was applied in the NIH Adolescent Trials Network adolescent MSM PrEP trial (ATN113).¹³ However, some sites were unable to participate because their IRBs required guardian permission, arguing that because their state laws did not include language specific to research or HIV prevention services (i.e., program to reduce HIV risk as opposed to testing or care), youth under age 18 years must be considered “children.”^{5,13} Such IRB decisions are not unique to the Adolescent Trials Network and have been applied in other studies of HIV among AMSM.^{10,12}

In states in which adolescents do not have legal self-consent rights to HIV-prevention services, and therefore would be classified as “children,” OHRP regulations still permit IRBs to waive the requirement for guardian permission when it is not a reasonable requirement to protect the subjects, provided an appropriate mechanism for protecting the “child” is substituted (§46.408c). The prototypical example provided in OHRP regulations for when parental permission is not a reasonable requirement is the case of neglected or abused children; federal advisory committees to OHRP have specifically recommended that studies involving high school-aged AMSM who may not have revealed their identity to their parents be accepted as studies that offer “a credible argument that serious physical, social or psychological harm may come to child subjects if parents/guardians are informed about the reason for the study.”¹⁴ To date, however, many risk-averse IRBs refuse to grant such

waivers for research on AMSM,¹⁰ thereby contributing to the continued lack of age-appropriate evidence-based interventions.

It is the authors’ belief that failure to apply policies allowing adolescent self-consent to HIV research largely flow from two widely held misconceptions. First, is the prioritizing of “parental rights” over the health rights of the child. This concern often manifests in the form of concerns about depriving parents of a moral right to control the activities of their children. It may also arise from a legal perspective that a fundamental liberty interest of natural parents in the care, custody, and management of their child is protected under the law.⁵ In both state mature minor laws and across a variety of constitutional cases, courts have recognized that parental rights to make medical decisions for their children can be superseded when they jeopardize a child’s health or are fundamentally in conflict with children’s right to bodily integrity.⁶ Perhaps most importantly, the language of “parental rights” does not appear anywhere in federal regulations governing the conduct of research; rather, guardian permission is conceived as a primary means of protecting the rights and welfare of child participants and not the guardian’s rights. When parental involvement is inadequate or harmful, IRBs are justified under OHRP regulations, and ethically obligated, to waive the guardian permission requirement as it does not serve its intended protective role.

Second, the belief that by mid-adolescence youth cannot provide informed, rational, and voluntary consent is another specious argument spurred by misapplication of some research on adolescent brain development (e.g., impulse control) while ignoring other findings (e.g., superior rate of learning). Such reductionist conclusions ignore the large body of empirical data indicating that youth as young as age 14 years can make research consent decisions at adult levels when information is presented at an age-appropriate level and in contexts in which stress is minimized.¹⁵ In fact, research has demonstrated that lesbian, gay, bisexual, and transgender youth aged 14–17 years demonstrate adequate understanding of the rationale for and voluntary nature of participation in PrEP adherence trials, including a rational weighing of risks and benefits.¹¹

Preventing research that will create and evaluate interventions to help turn the tide of the growing HIV epidemic among AMSM is inconsistent with the core ethical principal of justice.¹⁶ Several policy initiatives can help. First, OHRP and the Food and Drug Administration can increase efforts to educate IRBs on their responsibility to appropriately classify youth under age 18 years as adults when research involves biomedical and behavioral health interventions for which their

jurisdiction permits self-consent and clarify that parental “rights” do not supersede the rights of sexual minority and other youth to fair access to research essential to the development of evidence-based interventions. Similarly, OHRP can add physical abuse, stigmatization, and parental rejection to its example of harms to minor research participants that it interprets as “reasonable” requirements for guardian waiver. Second, both agencies should encourage IRBs to become more familiar with, and require investigator protocols to include, up-to-date contextually appropriate data on the ability of youth to independently consent and how to best fit consent procedures to the decisional needs of adolescents, including the appropriate use of participant advocates.

Protecting the rights and welfare of AMSM requires applying empirical data on participant consent strengths and vulnerabilities to design procedures that reflect a “fit” between youth characteristics and the unique demands of the research context.¹⁷ Ethics research in the form of qualitative interviews and quantitative surveys that elicit youth and parent perspectives and experiments that compare the effectiveness of different procedures can help empirically identify consent techniques that maximize youth understanding of procedures and minimize potential risks. In the absence of such empirical data, IRB decisions denying AMSM the right to self-consent to HIV prevention research will continue to be based on untested opinions about youth’s consent abilities, naïve assumptions that guardian permission is always in a child’s best interest, personal or institutional biases, or anecdotal evidence.

IRB barriers to self-consent deprive AMSM of their right to participate in trials that will protect them from receiving developmentally untested, inappropriate, and unsafe interventions and is a clear case of scientific inequity driving health inequities.¹² It is also an instance of losing sight of the forest for the trees. Study-by-study IRBs have sought to minimize risk to the institution and to AMSM participants by disapproving waivers of parental permission; in doing so, those individual decisions add up to a systemic injustice. The goals of the National HIV/AIDS Strategy to reduce new HIV infections will not be met if evidence-based prevention approaches are not delivered to this leading edge of the epidemic. Science is needed to develop these approaches. To clear the road for such research does not require large-scale changes in regulations or laws—rather, those in place need to be clarified and used appropriately.

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