

PUBLIC SUBMISSION

As of: 3/24/21 5:41 PM
Received: February 20, 2021
Status: Posted
Posted: February 24, 2021
Tracking No. kle-e7dv-revq
Comments Due: February 22, 2021
Submission Type: Web

Docket: CDC-2020-0110

The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs) 0920-20AC NEW NCHHSTP.

Comment On: CDC-2020-0110-0001

The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs) 2020-28113

Document: CDC-2020-0110-0003

Comment from McCulloch-Hutton, Avery

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General Comment

This study should absolutely be implemented. According to the CDC “An estimated 770,000 people have died from AIDS-related illnesses since the start of the epidemic.” This is an absolutely devastating statistic that will only worsen if action is not taken. Although testing and treatment has improved in recent years, it is the responsibility of public health officials to continue to refine such technology. The proposed study would allow for a scientific comparison of standard HIV-tests with nucleic acid tests. The findings of this study would help determine exactly how effective NAT tests are in ensuring HIV is detected and treated early. This would help people access treatment as soon as possible (if they are HIV positive) or help them to implement preventative measures (if they are HIV negative and at risk). This not only has the benefit of ensuring the health of the individual but also of preventing new cases of HIV/AIDS. This study will help the CDC to prevent and control the spread of HIV which is a serious threat to global health.

The estimates of time seem reasonable when compared to other public health studies. The method for collecting data is in accordance with the scientific method. It will include results of both HIV-negative and HIV-positive people, it will compare the accuracy of different tests, and it will also take into account how accessible this technology will be. The study has beneficence in mind and does not pose any imminent risk to the safety of the participants. As long as informed consent and the right to end participation are provided then this study is in accordance with ethics as outlined by the National Institutes of Health. All of these factors are important in obtaining objective data to determine whether the new technology should be expanded, improved, or more widely used. It is also worth noting that this is in

compliance with the FAR part 25 document as the CDC is neither a foreign NGO, nor violating any terms of the policy such as “perform[ing] or actively promot[ing] abortion as a method of family planning”.

It is important to consider how this study can be made more accessible and convenient for participants. This issue is sensitive as it deals with sexual health, so appropriate confidentiality is essential as is respect for participants. Some respondents may be more comfortable if they can submit data remotely (online, by phone, etc.) It is also important to consider that we are in the midst of another pandemic. This may make travel very dangerous or inconvenient for some people, especially those with a compromised immune system. Therefore it is instrumental to ensure that options for remotely submitting data are available. Some options for data collection may be online forms which can be filled out by the participants and their healthcare provider (if necessary). Given the sensitive nature of this topic and current public health concerns it is instrumental to work with study participants and health care providers to find innovative ways to make testing available and data collection feasible.

The cost of this study seems to be completely appropriate. The time required is reasonable and necessary to collect viable data. It is also important to consider the value of this study. The current COVID-19 pandemic is especially dangerous for people who have HIV/AIDS. Right now expanding the ability to detect, manage, and prevent HIV infections is more important than ever. This is an imperative public health incentive that should absolutely be pursued at the costs outlined in the summary of the policy.

Sources:

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