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The ethics of HIV cure clinical research among acutely infected adults: points for consideration

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Background: Individuals with acute HIV infection are increasingly targeted for participation in HIV cure clinical trials around the world. However, acute HIV infection may be a socially and emotionally tumultuous period, presenting special challenges when involving individuals in HIV cure research. The purpose of this study was to better understand the experiences of acutely infected individuals (AIs) in order to inform HIV cure research.

Methods: We examined the social hallmarks of acute HIV infection and explored ethical challenges in HIV clinical research in order to offer points to consider when developing guidelines for conducting HIV cure research. A comprehensive review of literature concerning experiences during acute infection and the ethics of clinical research within HIV treatment, prevention, and cure-related studies was conducted. Efforts were made to identify specific areas of concern for research involving AIs.

Results: We found that experiences during acute HIV infection may include confusion, guilt, anger, uncertainty, and/or other feelings that may complicate participation in clinical research. We identified four ethical domains of potential concern related to AIs:

- (1) Identifying and building research cohorts;
- (2) Recruitment and voluntary informed consent (including therapeutic misconception);
- (3) Retention in clinical research;
- (4) Concurrent/post-intervention care and researcher responsibilities.

Existing HIV research ethics guidelines focus on chronic rather than acute infections. We provide ethical points for consideration concerning each of these domains related to research with AIs.

Conclusions: Significant gaps in current knowledge exist concerning the recruitment and retention of AIs to HIV cure-related clinical trials, and necessitate further research. Our study suggests that the social context and personal dimensions of acute HIV infection introduce special ethical concerns that should be addressed during research design and ethical approval. The points of consideration identified may provide an initial foundation for ethical guidelines focused on research with AIs.