Advocates’ Perspectives on Next-Generation HIV Prevention Trial Design

BACKGROUND

HIV incidence is declining globally, but not nearly at the pace or scale embedded in the UNAIDS Fast Track targets. Many populations and geographies remain underserved, and there is urgency to both deliver existing treatment and prevention methods and simultaneously develop new options.

Researchers developing new biomedical prevention options, such as vaccines, antibodies and long-acting PrEP, need to design efficacy trials in this context of declining incidence and expanded access to daily oral PrEP, which can have implications on sample size, statistical analysis, trial duration and cost.

As various novel trial designs are discussed and deliberated, the necessity for meaningful community and advocacy engagement has been emphasized.

DESCRIPTION

In September 2019, AVAC convened a group of global advocates to build capacity around next-generation HIV prevention trial design and forge initial engagement between advocates and key research stakeholders, including statisticians, trialists, ethicists, and regulators, around emerging questions and challenges.

Objectives included:

➢ Establishing a cadre of advocates skilled to engage in discussions and decisions with researchers, regulators, and funders;
➢ Identifying opportunities for further engagement of advocates around protocol-specific and broader product development issues;
➢ Developing mechanisms and tools for ongoing capacity building and engagement.

Following this convening, advocates participated in key discussions around product development and clinical trial guidance, e.g., efficacy trial protocol deliberations and a UNAIDS consultation on ethical considerations for next-generation HIV prevention trials.

EVOLUTION OF HIV PREVENTION TRIAL DESIGN

Graphics from slides presented at Sept 2019 convening

Standard of prevention, pre-PrEP/ART

Evolution preventing trials:

PrEP as active comparator

Evolution preventing trials:

PrEP as part of standard prevention package

Evolution preventing trials:

Trials among those who have tried PrEP but it is not for them

Evolution preventing trials:

Hypothetical comparisons

LESSONS LEARNED

Participants developed a statement outlining their perspectives, asserting that:

➢ Efficacy trials will require a new level of cohesion between the trial context, evolving prevention standards and program implementation.
➢ The gold standard of randomized, placebo-controlled trials should continue to be used where possible. Rationale for alternative, innovative designs need to be clearly articulated and carefully navigated with communities and advocates.
➢ Negotiated post-trial access plans should be in place in advance of trial launch.
➢ There is an urgency for better cohesion between ethics guidance at normative, national, and institutional levels around the practical conduct of next-generation trials.
➢ Robust Good Participatory Practice as a part of innovative trials will help accelerate translation of research results into real world outcomes and public health impact.

CONCLUSIONS AND RECOMMENDATIONS

A cadre of well-versed, committed advocates stands ready to partner with product developers, researchers, ethicists, regulators and funders to navigate discussions and necessary solutions around next-generation prevention trial designs.

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