International Multi-Site and Multi-disciplinary Studies

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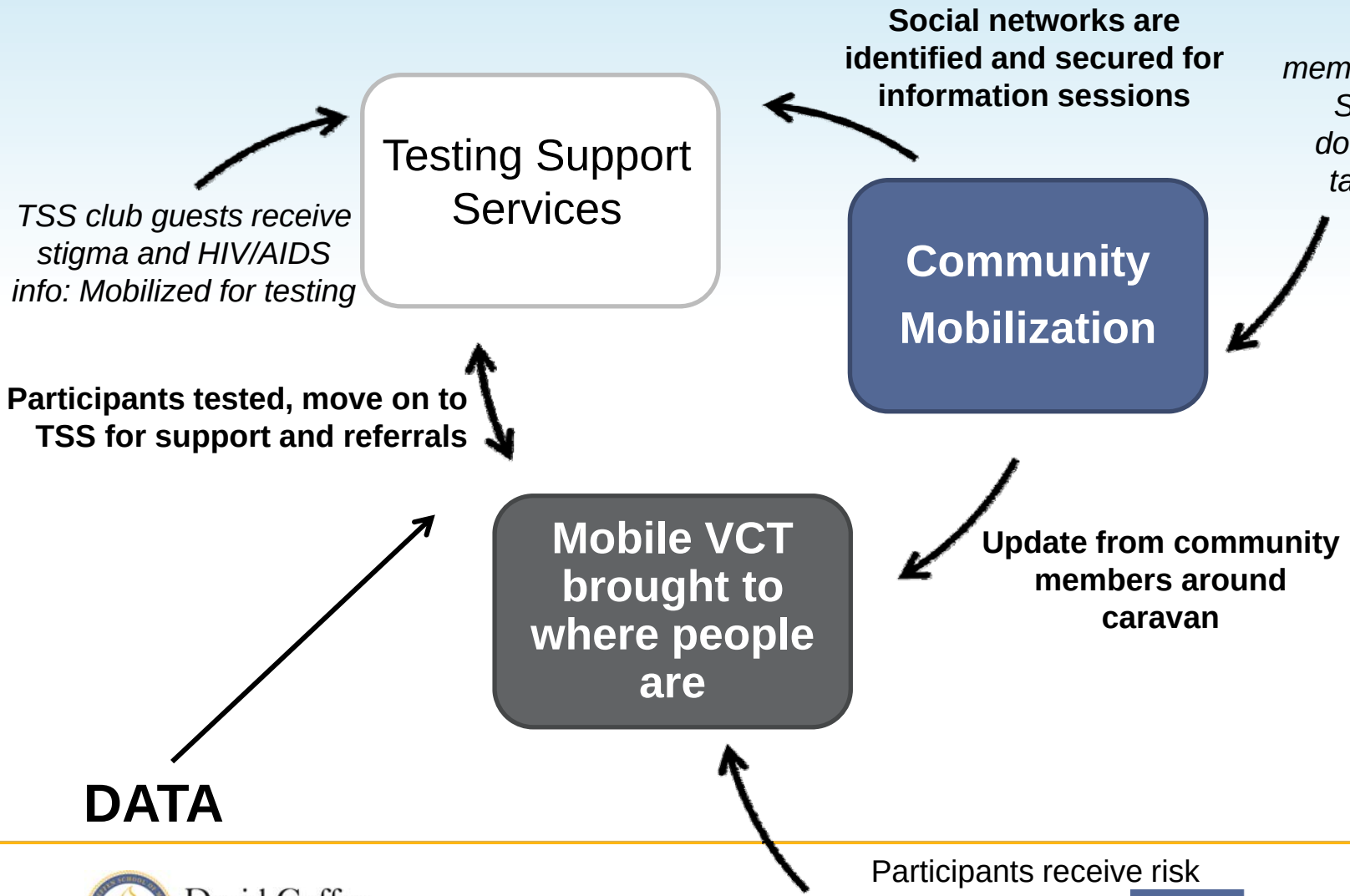
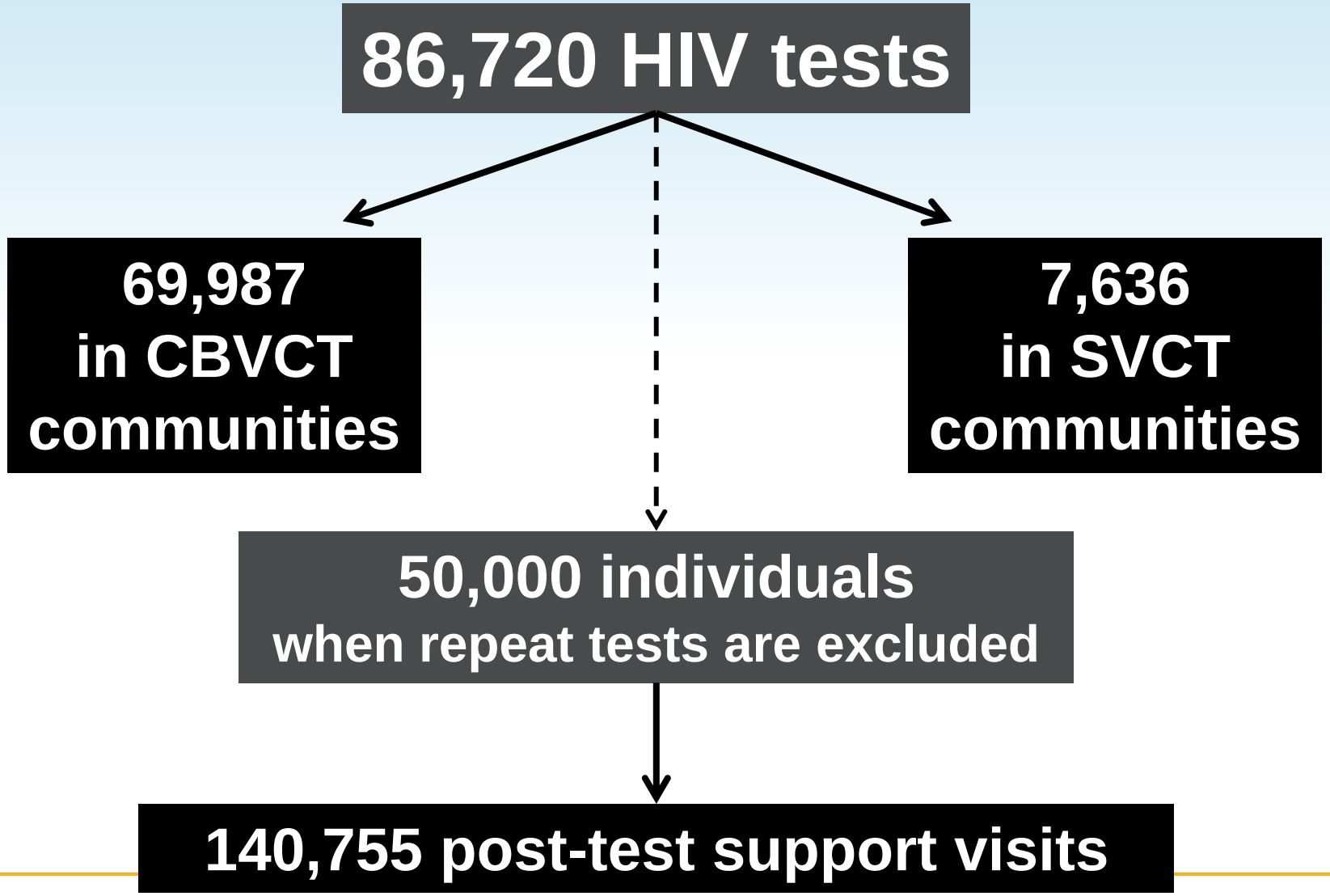
NIMH PROJECT ACCEPT (HPTN 043) STUDY SITES

THE COMPLETE INTERVENTION PACKAGE FOR COMMUNITY BASED VCT (CBVCT)



ALL OF THIS RESULTED IN:



Sweat et al. Lancet ID. 2011

Issues

- International research not addressed in Common Rule proposed changes; implications are vast and in some ways similar to other issues addressed in this panel
  - Remember Nuremberg and Guatemala syphilis experiments
  - Paternalism
  - Less stringent regulation and legislation
  - Failure to obtain informed consent or to ensure that indviduals are consenting for themselves
  - Lack of strict ethical oversight
  - Lack of concerns for confidentiality and privacy
  - Cost of regulatory oversight

Issues

- Blending of behavioral, social, and biomedical research in many venues; not recognized in proposed new regulations
- If you want American money, then you have to follow American standards
  - Is this paternalism?
  - A good export?
  - Should foreign regulatory bodies be required to have FWA or should an equivalent be accepted?
  - Do the proposed changes have the same implications in the US as they might in a foreign country?
  - Is minimal risk the same here as elsewhere?

Issues

- Processes for strengthening local oversight should be taken into consideration as Common Rule changes are enacted
  - This may include, but not be restricted to, the levels of expertise needed; the requirement for community input; classes of participants requiring special protections; documentation, audit, and enforcement
  - Should the Common Rule be silent on training issues—for investigators and teams, for members and staff of the IRB?

Changes and Proposed Alternatives

- Would apply to funding from all Federal Agencies and clinical studies seeking FDA approval
- Should they apply to studies funded entirely by other countries, multi-lateral agencies, or philanthropies?
- Adverse event reporting systems, even for social and behavioral studies, should be designed to address issues arising in international studies and should be multi-national
- Enhanced and simplified consent procedures would be useful and important; written consent not necessarily useful or central to international research

Changes and Proposed Alternatives

Changes and Proposed Alternatives

- One IRB for multi-country studies?
- A series of regional IRBs?
- Who determines what is acceptable in a given country or region?
- Which IRB takes precedence: The US IRB or the local IRB?
- How can local IRBs be held to standards of efficiency and timeliness of approval?
- Is minimal risk the same in all locations?
  - Childhood physical abuse ~ 4 to 30%; sexual abuse ~2 to 5%
  - Could reporting this abuse be greater than minimal risk?
- Could multi-site IRBs have membership from all countries involved?

Issues

- Should US guidance be harmonized with international guidance and regulations? Should HHS be working actively with WHO, the EU, and other multinational bodies to harmonize recommendations and regulations?
- Who determines minimal risk and expedited status? The US or the local IRB?
- Would elimination of administrative review lead to harm and possibly ‘cutting corners?’
- Would the extension of exempt studies and those not requiring annual review lead to lax oversight in international studies?

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