Evidence For Action on HIV treatment and care systems

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Case Study
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Improving children's access to research participation in poorly resourced communities

Summary

The experience of the ARROW trial highlights the importance of dialogue and communication between researchers and ethics bodies to ensure that children participate in research that will contribute to an improvement in their care while their safety and rights are protected. The Zimbabwean researchers' relationship with care-givers was strengthened when those who were guardians of orphaned children were given permission to act as "legally authorized representatives" and provide informed consent for their participation in ARROW. Forty percent (40%) of the children enrolled in ARROW in Zimbabwe have lost one or both parents and live with relatives. Engagement of care-givers who are part of the community has the potential to pave the way for translation of the ARROW research findings into practice.

Description of the ARROW study

The ARROW study is an open label randomised trial whose main objectives are to evaluate two strategic approaches to managing ART in HIV-infected African children in Uganda and Zimbabwe. Enrolment was open to HIV infected children aged between 3 months and 17 years who satisfied the eligibility criteria. Built within the eligibility criteria was the fact that the children should have an adult carer who was either participating in the DART trial at the time, was on ART, was HIV positive but not yet needing ART but with access to a treatment programme or was HIV negative. The 4 sites enrolled 1207 children over a period of 15 months but experienced slow initial recruitment at some sites due to consenting issues. The IRB in Zimbabwe adopted the CIOMS guideline 14 which provides guidance for research involving children. One of the statements is that "consent should be sought from a parent or legal representative for a child to be involved in research". It became obvious that a significant number of potential participants had lost one or both parents and lived with relatives who had not gone through the formal adoption process to satisfy the term 'legal representative'. The researchers engaged the child protection agencies to find ways of legalising the adoption. Apart from being a lengthy and costly process, it was discovered that legal adoption was not the cultural norm in the indigenous Zimbabwean culture as children belonged to the communities. The Institutional Review Board (IRB) was informed of the situation and after some discussions accepted that the child's guardian could stand in as the legal representative once the researchers were satisfied that he/she was fully aware of the high level of commitment required to study procedures.

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What is the potential impact of this?

ARROW is the first large paediatric clinical trial in Zimbabwe and the engagement of the research community with the national ethics body has opened the way for future research involving children. Communication between researchers and the ethics committee resulted in a change in the requirements of legal guardianship for orphaned children. HIV-infected orphaned children (40% of total enrolled in Harare) have been enrolled in the ARROW trial and the child's guardian was recognized as the legal representative for consenting

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purposes. Biomedical research in humans is governed by international codes and regulations derived from the three basic principles of respect for persons (autonomy), beneficence and justice. Children are considered a vulnerable group in research and it is the responsibility of ethics bodies to protect research participants. Protection should however not limit access to participation.

How is this research novel?

Children are considered vulnerable subjects by research regulators and this has limited their involvement in participating in clinical trials that will contribute not only to the body of scientific knowledge but to treatment policy and practice. It has been said that children are not small adults and this is correct in research as well: findings in adults are not always transferrable to children by virtue of physiological differences.

Who has been involved?

The ARROW trial is a collaboration between:

- University of Zimbabwe, Harare, Zimbabwe
- Joint Clinical Research Centre, Kampala, Uganda
- The Paediatric Infectious Diseases Clinic (PIDC), Kampala, Uganda
- MRC/Uganda Virus Research Institute Programme on AIDS, Entebbe, Uganda
- MRC Clinical Trials Unit, London UK

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Recommendations

- **Researchers should familiarise themselves with local ethics requirements for research that involves children.**
- **The ethical guidelines should be regularly reviewed so that children including vulnerable groups are not denied the opportunity to participate in studies.**
- **Research involving children by its very nature involves adult care-givers from whom we expect adherence to study procedures. It is therefore important that researchers and ethics bodies make them equal partners in research.**

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About Evidence for Action

Evidence for Action is an international research consortium with partners in India, Malawi, Uganda, UK and Zambia, examining issues surrounding HIV treatment and care systems.

The research is organised in four key themes:

1. What "package" of HIV treatment and care services should be provided in different settings?
2. What delivery systems should be used in different contexts?
3. How best should HIV treatment and care be integrated into existing health and social systems?
4. How can new knowledge related to the first three questions be rapidly translated into improved policy and programming?

Partners:

International HIV/AIDS Alliance, UK

Lighthouse Trust, Malawi

London School of Hygiene and Tropical Medicine, UK

Medical Research Council Uganda Research Unit on AIDS, Uganda

Medical Research Council Clinical Trials Unit / University College London, UK

National AIDS Research Institute, India

ZAMBART, Zambia

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