



The smiles, trials and tribulations of caregivers

Dr Harry Moultrie

MBBCh, MSc Epi

Director of ECHO

Harriet Shezi Children's Clinic

Co-Principal Investigator

IMPAACT Site 8051

harrym@witsecho.org.za



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“Implications of trials for caregivers” (in Africa)



Caregivers on Trial?

Caregiver:

- makes decisions about trial enrollment;
- transports subject to study visits;
- stores and administers study medications;
- responsibility of adherence;
- monitors for adverse events; and
- reports those events to investigators.

Child:

- Swallows medication;
- Exposed to risks;
- Physically examined; and
- Experiences discomfort of having blood taken.

Lingler J et al. Caregivers as subjects of clinical drug trials. 2006. Medscape



Heart to HAART

- Funding to treat 10 children with HAART for 3 years in 2003. Obtained a guarantee from a private funder to cover years 2 and 3 if there was still no public sector access to ARVs
- 670 children attending the clinic
- Observational cohort study
- Who?
- Impact on caregivers?





The Smiles

- Often better than standard of care for the child (Gastrostomy)
- Transport money and stipends (a source of income)
- Better care for the caregiver
 - Monitor CD4 counts and ensure access HAART when needed
 - PMTCT and pregnancy care
 - But not always...
- Shorter queues
- Relationships - children and caregivers are known by name
- “A support network – seen place of safety in crisis”
- Someone to ask for advice (which cellphone company?)
- “Enables clinician to be humane because of limited numbers”
- Countless acts kindness: Food parcels, employment



The Trials...

- High burden on frequent visits particularly for the caregivers of children who experience AEs
- Higher burden of adherence
- Pressure to disclose
- Inadvertent disclosure and loss of privacy
- Greater scrutiny and loss of autonomy



Three case studies of tribulations

Tribulations: “distress or suffering resulting from persecution or oppression”

- Jerry
- Lerato
- Kgotso



Jerry

- 8 year old boy participating in an IMPAACT PK study since 2007. Stable and well on HAART.
- Cared for by mother who has part-time work. Live in an informal structure, with electricity, access to a stand pipe but no flush toilet. Father's vital status unknown.



At Jerry's routine clinical visit last week...

- Observations complete
- Mom not looking well. Sister noticed a “peri-oral rash”. Reviewed Mom’s CD4 count. Asked about rash – “Someone hit me”.
- Completed study visit and went to pharmacy
- Jerry well know to pharmacist. Usually a happy, smiling child.



Reflections...

It was a routine visit, and we were not told of the rape easily. We were not as much a support system as we like to think, not enough to allow her to overcome the shame of rape, to seek help for herself and her child. As a result of her child participating in a clinical trial she was pressured into disclosing the rape.



Lerato

10 year old girl with superb response to study medication

- Losing a little weight over last few months
- Many referrals to social workers for a grant but without success
- Child was left with our pharmacist while mom went to the adult clinic. At the end of a long day with the child, the pharmacist hugged the child. The child then burst into tears and disclosed out of desperation that the family were starving and had in fact been deported from South Africa.



Reflections...

It took a hug

Trial staff seen as part of authority structures. Mom was concerned about her source of income and that we would deport her.

She would not return to Lesotho as could not easily access HAART there, despite the fact that she in Lesotho she could obtain food security.

Study related compensation having an impact on decisions regarding best interest of child



Kgotso

4 year old girl. Lives with mother but Granny was the caregiver and attended most clinical trial visits. Mother does not accompany Kgotso because she had previously seen neighbours in the clinic.

Granny did NOT like blood draws.

Kgotso developed a grade 2 - 3 AE which equired multiple repeat blood draws. Granny (after talking to the mom by phone) withdrew consent.



Reflections...

The emotional trauma of caregivers does not receive sufficient attention. Ambiguity and conflicting emotions is common: “I am really grateful, but also too frightened for the sedation”. Cases of children having psychotic reactions – highly disturbing to care-givers.

“In contrast to motivations involving self-interest and altruism toward future generations, which have been previously linked to health research participation decisions, AD caregivers interact with investigators within an intensely focused context of altruism toward kin.”

Conclusions?

- Caregivers are on trial. Should they give consent for their own participation as human subjects?
- The reimbursement for transport materially informs decision making regarding the best interests of the child. This raises significant ethical issues.
- We overestimate the benefits to caregivers of the relationships developed.
- The emotional burden of caregivers participating in clinical trials is higher than I had thought and needs to be addressed through formal debriefing.



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- The children
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HAART works!

Before



6 months after



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