



ETHICAL PERSPECTIVE ON MALARIA RESEARCH FOR AFRICA

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INTRODUCTION

- Malaria is Public Health Enemy No.1
- Malaria: Africa's silent Tsunami
- Malaria is the Greatest shackle to Africa's Socioeconomic Development
- "The malaria epidemic is like loading seven Boeing 747, with children each day, then deliberately crashing them in Mt. Kilimanjaro"
- Historical havoc 400x > 9/11 on New York City
- Population suffering from malaria @ year greater than population of USA, Canada, and Mexico combined.



INTRODUCTION (2)

MALARIA REMAINS A MERE STATISTIC

- Kills, maims and impoverishes poor communities.
- Kills voiceless infants, young children, young pregnant women
- Effects worse in rural areas: *access to health care* ltd.
- Traditions make at risk groups more vulnerable
- Research participants most vulnerable among vulnerables.



WHY RESEARCH (1)

- Failure of safest and most affordable antimalarials.
- Reliance on one antimalarial, CQ.
- Abandoning vector control even where promising.
- Abandoning vc even where successful.
Pretext: perceived insecticide resistance, unsustainable!
- Asia and Latin America continued vc, see difference!!



WHY RESEARCH (2)

- To sharpen existing blunt antimalarial tools.
- Discover → Develop → Deploy new antimalarial tools.
- New discoveries, genomic revolution to reveal leads to new tools.
- Bridge the 10/90 gap.
- Research must answer to the health needs of study populations.



WHY CONCERN?

- All Clinical and Field Studies involve humans.
- Historically researchers abused research participants.
- Need to protect research participants.

Vulnerability from:

- ignorance
- poverty rampant
- human rights abuses rife
- health systems are weak and poorly managed
- research systems are poor.



INFORMED CONSENT

- Who are most affected?
<5s, pregnant women.
- Can these give genuine informed consent?
- Proxy consent by parent/guardian.
- Position of girl child worse.
- Autonomy to young pregnant women?



CONSENT IN AFRICAN SETTINGS*

Western culture: emphasize INDIVIDUAL

African cultures: SOCIAL AGENT

.: In Africa: consult family members

: consult communities

: community assent/permission

- Consent as a process
- Verbal consent (no-signature)

*CIOMS 2002, EGE 2003, NCB 2002



STANDARD OF CARE

- Is it universal?
- Area differences in antimal. drug susceptibility, which is the standard?
- Many MoH policies make ITNs standard of care. Will ERC/IRBs demand ITNs?
- Who should provide the care?
:Sponsor, researcher, MoH, local govt?



SOME DILEMMAS RE STANDARD OF CARE

Who should provide non-routine care:

- HIV sero+ at baseline?
- Seroconvert (HIV+) during trial?
- when to provide ARTs?
- how long to provide ARTs?
- for other ailments?
- for chronic diseases?



BENEFITS vs RISKS

What are the risks inherent in:

- Novel vaccine formulations?
- Novel adjuvants?
- Age de-escalation?
- Transmission blocking vaccines?
- Trials in countries of origin?
- Bioprospecting/MTA?



MOSQUITO INTERVENTION AND EPIDEMIOLOGICAL STUDIES(1)

- 1991 CIOMS International Guidelines for Ethical Review of Epidemiological Studies vs frequent clinical trials updates
- Mosquito collection on human bait.
- Community Assent.
- Individual Consent.
- Household Entomological Studies need individual and family consent
- Community wide vector interventions need individual and community consent.



MOSQUITO INTERVENTION AND EPIDEMIOLOGICAL STUDIES (2)

STANDARD OR CARE:

Provide best available intervention.

What was best available intervention during 1980s?

Was IRS compared with ITNs?

ITN scaling up relying only on pyrethroids!!



MOSQUITO INTERVENTION AND EPIDEMIOLOGICAL STUDIES (3)

RISKS vs BENEFITS

- Larviciding and environmental pollution.
- GM mosquitoes transfer transgene to non-targets?
- ITN trials in rural areas, but initially benefits urban!
- Rumors on releases decrease consent and cohort!
- “Management of Adverse Event” if release goes wary!
- Failure to provide successful product: rebound effect!



WHEN RESEARCH /TRIAL IS OVER (1)

- Malaria still remains.
- Research results compel health authorities to act.
- Access to successful product limited.
- Who makes product available?
- How long, how far?



WHEN RESEARCH/TRIAL IS OVER (2)

- Making Successful Product available: PPP
- Link bilateral research sponsors with bilateral donors e.g.
 - NIH-USAID
 - NWO-DGIS
 - MRC-DIFID
 - IDRC-CIDA
 - DG-Research-DG-Dev
- Mobilize philanthropy and private funding



WHEN RESEARCH/TRIAL IS OVER (3)

What is owed to sponsor – clear

What is owed to PI not so clear

What is owed to:

co-investigators, other researchers,
assistants, host study institutions, study
communities??



WHEN RESEARCH /TRIAL IS OVER (4)

Is completing research a means to an end?

(publications, promotions, accolades, greener pastures).

What happens to junior workers?

Authorship, international interviews

Information dissemination: many targets

Data ownership.



ETHICAL REVIEW

Ethical review new to many African inst.

Some questions/problems:

- Primacy of host country vs sponsor country ER.
- Separation of scientific from ER.
- If host country research participants are very vulnerable shouldn't ER be more stringent?
- Who should fund institutional ER?
- Oversight is weak.

Guidance inconsistent.



THE WAY FORWARD

- Increase protection of study participants by improving ethics review.
- Include African voice in dev. guidelines.
- Experience with new formulations limited, therefore weigh risks vs benefits.
- Ensure appropriate trial designs, informed consent, standard of care.
- Promote PPP
- Ensure post trial obligations



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