

Ethics case study

Group Work report back

Catherine Slack

ADVAC 2014

'Other' recommendations

- ✓ Require DSMB [1,4,6] with community representation [1]
- ✓ Ensure SAE monitoring [1] detail safety monitoring [4]
- Revisit exclusion criteria (HIV-infected) [6]
- Consider multiple opportunities to enrol [6]
- Ensure confidentiality [4,6]
- Reconsider schedule of visits (condense) [6]
- Provide more detail about blood sampling [6]
- Do better planning for drop-outs [4]
- Ensure registration with clinical trials registry [6]

2

'Other' / placebo

- Ensure placebo-recipients have additional proven vaccine pneumococcal [3,4] meningitis [2]
- Beware un-blinding [2]
- Ensure intervention arm get proven vaccine post-trial [2, 4]

3

Engagement recommendations

- Engage fathers [1,6]
- Engage care-providers [1; 2] to ensure treatment sustained post-trial [1], to ensure routine services are not undermined [2]
- Engage community leaders to communicate using scripts [1]
- Engage local representatives as translators [6]
- Prepare clear messages in local language [1,6] – ph1/ph2 results
- Allow for discussion/ Q and A [1]
- Develop engagement plan/ 'report' and provide to IRB [5]

4

Consent recommendations

- Train staff [2, 4, 6] incl to assess understanding in conversations [2]
- Be sensitive to language [6]
- ✓ Pilot consent form with local representatives [2]
- ✓ Prepare additional brief sheet [3]
- ✓ Simplify the consent [6]
- ✓ Develop additional materials – video [6]
- Confirm consent [3]
- Assess understanding [1,6]
- Document understanding [4]
- Pilot assessment of understanding in small sub-study [1]
- Ensure re-review by IRB [4,6] after community inputs [4]
- Describe consent strategies in more detail [4], 'rewrite' [5]

5

Prevention recommendations

- For participants
 - Provide bed-nets [5,6]
 - Provide counselling/ education on bed-nets
 - By sponsor [3]
 - By site staff – study nurses [1]
 - By site staff but separate those advocating for bed-nets from other functions [4]
 - By third party [3]
 - Inform about approach in consent form [1]
 - Monitor uptake of bed-nets [1, 6]
 - By blinded investigator in sample home visits [2], home visits [6]
 - Analyse bed-net uptake as a confounder [2]
- For broader community
 - Ensure access to bed-nets and education (incl. Ps) [2]
 - Ensure regular spraying (incl. Ps) [2]
 - Monitor and record spraying [6]
 - Agree with case approach (incl. donor -provided ITNs to community) [4]

6

Care recommendations

For participants

- Ensure ACTs for malaria [2, 3, 4, 5,6]
- Ensure 'standard of care' treatment is received for malaria [1]
- Ensure transport of sick infants to clinics [3]
- Consider vitamin supplementation [5]
- Ensure referral for care of other illnesses [2]
- Treat anaemia [2]

For non-participants

- Screen-outs : Treat some conditions (anaemia) [2] Refer to local facilities [4];
- Families of Ps : Ensure ACTs [4]
- Broader community –
 - Ensure ACTs, supportive Rx [2] monitor resistance [2]
 - Ensure improvements in care [2]
 - Reflect investments/capacity building (e.g. cold chain) in the protocol [5]
 - Ensure full standards for vaccine delivery including cold chain [6]

7

Ancillary care [Belsky and Richardson, 2004]

- Consider various factors
 - Gratitude - uncompensated risks and burdens?
 - Engagement - length and intensity of interaction?
- Implement responses for medical needs proportional to contribution and engagement
- Suggests different responses may be implemented for different classes of persons with whom researchers interact
 - Volunteers (but not enrolled)
 - Participants
- Provides for 'differential treatment' in non-arbitrary way

8

Payment recommendations

- Agree with proposed approach: expenses and time/inconv [6]
- Amend proposed approach
 - Ensure payment for expenses only (travel expenses) [50% of 2]
 - Consider payment for time [50% of 2, 1] but justify in local wages [1]
 - Agree that payment can involve money but specify in local currency [4]
 - Consider in-kind payments (e.g. ^{Donor}Tobacco) versus money [1,3]
- Get community input on proposed payment approach [4]

9

Closing remarks

- Consulting community:
 - Cannot proceed in a moral vacuum
 - Should be preceded by reasoning based on norms
 - Data doesn't automatically make right
 - Morally relevant not morally definitive
 - May help to apply norms more sensitively
- Opens door to inter-site differences
 - Resolve
 - Defend
 - Assess

10
