What can we learn from innovative ways of monitoring health research?

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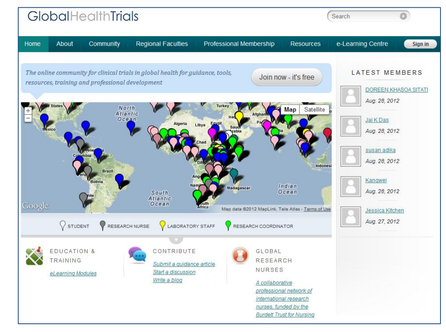
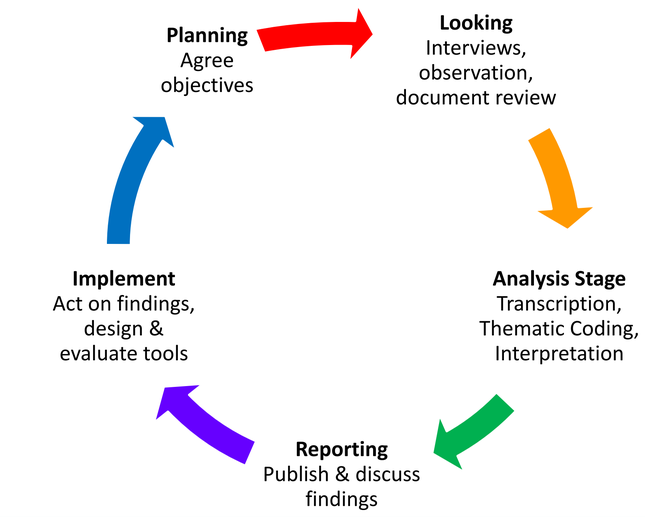


Introduction & Aim

Innovative schemes for monitoring health research are being developed by the Mahidol Oxford Research Unit in Thailand (MORU) and by the East African Consortium for Clinical Research (EACCR). The goals are to develop pragmatic, cost-efficient models tailored to the context and risk posed by different research designs. This participatory evaluation aims to determine the value of these schemes, identify challenges, and develop tools to measure performance.

The quest for alternative models of quality management (QM) and monitoring is part of the drive for a more pragmatic, sensible and cost efficient application of guidelines and regulations in biomedical research [1 2]. It is argued that the well-intended values and principles of 'Good Clinical Practice' (ICH-GCP) [3] have become hampered by bureaucracy and misapplication [4 5]. An associated 'tick box' mentality is considered to divert attention away from key questions about the ethical process, participant safety, study endpoints and data validity. The development of alternative models is viewed as a way of establishing a counter argument and directing attention back to these questions.

Participatory Action Research



EACCR Scheme

- EACCR is an EDCPT funded network of excellence with the aim of increasing research capacity in the East African region
- Since 2010 EACCR has been piloting a reciprocal monitoring scheme to establish a pool of monitors who can undertake cross-site monitoring

Key Characteristics

- Two coordinators based in Kenya and Uganda provide oversight and logistical support
- Partner institutes nominate research staff for monitors training (currently 22 active)
- Experienced monitors are paired with less experienced monitors for mentoring
- Scheme coordinators consult with investigators to identify trials for monitoring
- Monitoring pairs are allocated trials taking place at partner institutes
- After an introduction visit the pairs develop a monitoring plan, conduct a series of site visits and compile reports for the investigators and scheme coordinators

MORU Scheme

- MORU is a collaboration between Mahidol University and the University of Oxford and its main offices are located in Bangkok
- MORU has study sites in Thailand and other parts of developing world across Asia and Africa
- MORU established a Clinical Trials Support Group (CTSG) in 2008

Key Characteristics

- CTSG is embedded within MORU which promotes communication and transparency
- CTSG includes experienced clinical trial coordinators, data managers and statisticians
- Members of CTSG provide assistance in planning, managing and monitoring research activities to ensure compliance with ethical and regulatory requirements
- CTSG monitors focus on findings which will impact key trial outcomes and actively involve sites in problem solving

Core Findings

Monitoring Approach

- Value of a *'non-threatening'* and *'shared learning'* monitoring style which increases capacity '*…because it's a sort of co-operative monitoring and not hostile, you're much more likely to get problems sorted out rather than hidden.' (MORU investigator)*
- Value of *'observing research in action'*-focussing on the process not just the paperwork
- Prioritise errors which could affect the primary study outcomes & participants' safety

Relationships

- The positioning of CTSG '*…creates the sense that monitoring is not policing but it is adding to the quality of this trial with a constant feedback loop.' (MORU investigator)*
- Constructive interactions allay fears and help investigators appreciate *'that monitoring is something very essential and very important for all the studies' (EACCR Investigator)*
- Value of 'local' monitors who know the culture & context and understood certain limitations

Challenges

- EACCR**:** Investigators value input of peer researchers but are concerned about confidentiality and some question the mandate and authority of the EACCR scheme
- EACCR**:** Sustainability; funding, focus of service, infrastructure and human resource management
- MORU**:** Balancing a heavy work load, covering costs , and incorporating an external perspective

Credibility

- Professional expertise of the monitors: MORU monitors have worked with other monitoring organisations and EACCR monitors are experienced researchers and clinicians
- Detailed monitoring plans & reports and involvement in protocol development for MORU
- EACCR scheme promoting exchange of expertise and strengthening QM across the network
- Schemes valued as a means of professional development and exchange

Conclusions

The MORU & EACCR schemes represent viable alternatives for monitoring health research and their value needs to be recognised and developed.

- ✓ **They focus on research conduct and prioritise key outcomes and participants' safety**
- ✓ **They demonstrate the value of co-operative interactions between researchers & monitors**
- ✓ **They utilize existing scientific and monitoring expertise to build capacity and increase the quality of research**

References

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