



EVALUATION OF CULTURAL COMPETENCY IN AN AFRICAN SETTING: LESSONS LEARNED FOR TRIAL REPORTING STANDARDS

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BACKGROUND: CULTURAL COMPETENCY

- Cultural competence is a broad term used in trial design and conduct
- CC refers to the consideration of the cultural and linguistic diversity of a targeted populations
- By not considering relevant cultural, ethnic and diversity parameters during trial protocol development and trial conduct – recruitment, intervention development and delivery, adherence, and retention, might be negatively impacted and potentially reduce the overall internal validity of a study
- Lack of reporting of these parameters can further hamper the successful implementation of effective interventions post trial due to an inability for the reader to assess external validity (generalizability)

BACKGROUND: GIBBS FRAMEWORK (2007)

Gibbs Framework Scoring	Reason
0	Culturally blind which describes methodological approaches underpinned by the belief that neither colour nor culture influence behaviour and that all people are the same
1	Culturally pre-competent describing approaches recognising that the dominant race or culture of a country is not universally applicable but fails to fully attend to cultural differences
2	Cultural competent describing approaches recognising the cultural diversity of the intended population
NM	Not Mentioned – if there was no reporting or no information provided relating to cultural competency considered

BACKGROUND: GRIPP-2 (SF)

No	GRIPP-2SF Domain	GRIPP-2 questions
1	Aim	Is the aim of PPI reported in the study?
2	Methods	Is there a clear description of the methods used for PPI in the study?
3	Study results	Outcomes: Were the results of PPI in the study, including both positive and negative outcomes, reported?
4	Discussion and Conclusions	Outcomes: Did the investigators comment on the extent to which PPI influenced the study overall? Did they describe positive and negative effects?
5	Reflections/critical perspective	Did the investigators comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience?

PPI=patient and public involvement

- GRIPP2-Long Form and GRIPP2-Short Form are guidelines for the reporting of PPI in research
- The GRIPP-2(SF) is an abbreviated five-item checklist targeted to clinical trial reports

AIM

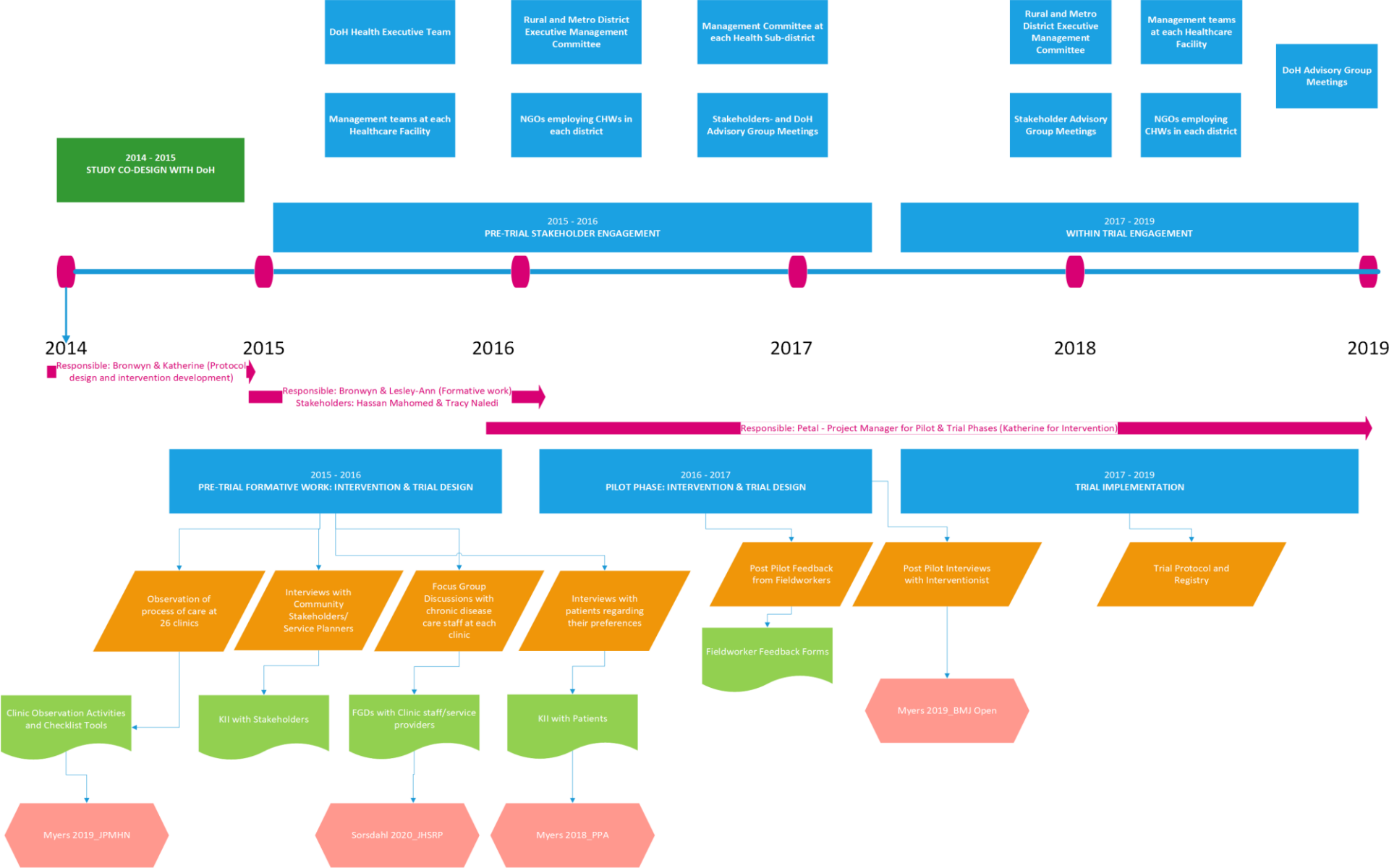
- Study evaluating *utility* and *comparability* between the Gibbs and GRIPP-2 tools to measure cultural competency when applied in a complex trial conducted within an African setting, i.e. Project MIND



METHODS (1)

- Secondary data analysis:
 - 1) identified and collated all relevant publications, source and procedural data related to the trial
 - 2) prepared a trial process diagram specific to Project Mind with the responsible investigator linked to each stage*

* As an additional component of the study, we explored the use of MS Visio to assist with integrating data sources into one shared environment, for easier accessibility of data sources and enhancing our ability to conceptualize all the stages of the Project MIND trial



METHODS (2)

STEP 1:

- Two independent investigators applied and scored both Gibbs and GRIPP-2(SF) tools to the four published manuscripts arising from the trial
- Prepared a decision-making matrix to identify where no judgement could be made due to inadequate reporting, or where scores were '0' or '1'

STEP 2:

- Third investigator independently and systematically scrutinised all procedural and source data to establish whether cultural competency had been met
- Consensus for final score reached between discussion of all investigators

FINDINGS: APPLICATION IN PROJECT MIND

	Gibbs Domain	Gibbs score following publication analysis	Additional source or procedural data analysis	Gibbs final Score
1	Forming partnerships	2	Not required	2
2	Defining research questions	1	No	1
3	Identifying data sources and target populations	2	Not required	2
4	Appointing staff	1	Yes	2
5	Recruitment of sample	2	Not required	2
6	Data collection	2	Not required	2
7	Development of intervention	1	Yes	1
8	Analysis/evaluation	2	Not required	2
9	Reporting/disseminating findings	2	Not required	2

FINDINGS: APPLICATION IN PROJECT MIND

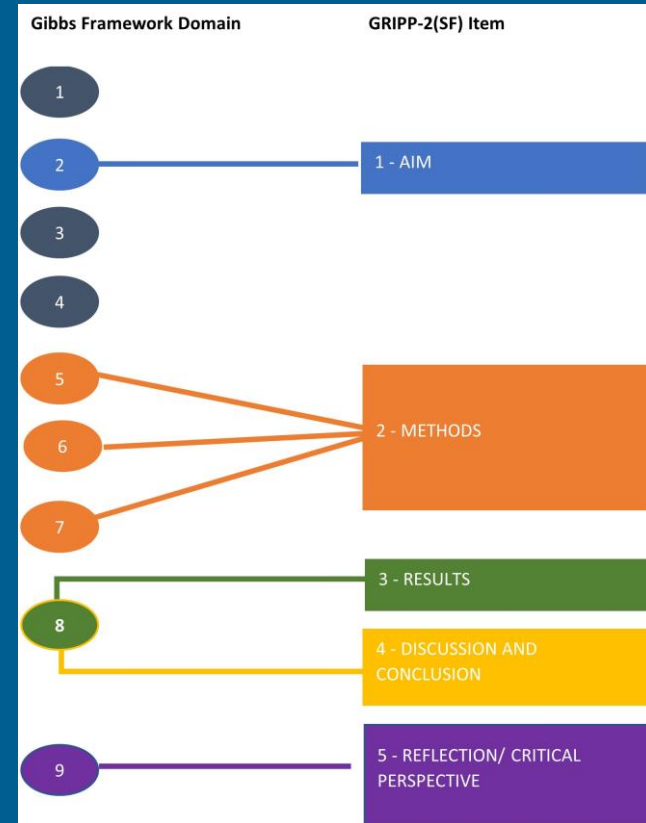
- The application of the Gibbs Framework indicated that the Project MIND trial was highly culturally competent, fully meeting all but two of the nine Gibbs criteria
- The Gibbs Framework revealed that the trial research question was not driven by the articulated needs of patients (question 2), and neither were patients, caregivers and clinical providers involved in the development of the intervention (question 7)

FINDINGS: UTILITY OF GIBBS FRAMEWORK

- The Gibbs Framework includes:
 - evaluation of partnerships forged before the start of the trial
 - assessment of the awareness of the investigators' cultural framework and its influence on their research approach
- Self-reflection of a researcher's own cultural bias:
 - is a key research attribute but is rarely considered in the conduct or reporting of a clinical trial
 - important for trialists working in countries and cultural settings different from their own
 - failure to consider the lens of the trialist, how it may differ to those of the trial participants and trial clinical staff, may *impact successful recruitment, participation, and ultimately the robustness of findings if attrition is high*
- Challenges in coding and operationalizing the guidance due to lack of definitions, glossary and examples

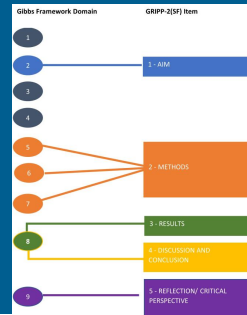
FINDINGS

COMPARABILITY BETWEEN THE GIBBS FRAMEWORK AND GRIPP-2 (SF)



COMPARABILITY BETWEEN THE GIBBS FRAMEWORK AND GRIPP-2 (SF)

- **Gibbs framework** can be used to guide all stages of framing the trial research question, protocol development and final analysis before and during trial conduct with reference to cultural competency
- **GRIPP-2 (SF)** more applicable when reporting PPI retrospectively and as a quality assurance step in the writing up of PPI in trial publications and reports



CONCLUSIONS (1)

- We operationalized secondary data analytical methods in the application of the Gibbs Framework to a LMIC trial which was judged to be culturally competent in seven of nine domains
- We recommend that an updated version of the Gibbs Framework tool consider inclusion of a user glossary and worked examples
- Consideration should be given to whether “cultural competency” as a term is fit for purpose (othering)

CONCLUSIONS (2)

- Further evaluation of the Gibbs Framework may take the form of retrospective application to completed trials or prospective application in planned and ongoing trials while monitoring the utility of its use
- Comprehensive evaluation of the trial's cultural competency required scrutiny of both published manuscripts and source and procedural data, suggesting that there is a gap in current trial reporting standards with respect to cultural competence

KEY MESSAGE

- Identification of the key components of the Gibbs Framework to incorporate into the current CONSORT Statement and SPIRIT Statement which guide reporting standards for trial conduct and protocol development respectively, will clearly require further interrogation, development, and collaboration among trialists.
- However, we believe the Gibbs Framework is a reasonable starting point.

ANY QUESTION OR COMMENTS?



