**Title: The ethics of psychiatry care and research in resource-poor settings: The case of a psychiatric research trial including chained mentally ill participants in a prayer camp in Ghana**

**Authors: Albert Coleman**

**Review comments**

**Reviewer 1**

The randomised trial “Joining psychiatric care and faith healing in a prayer camp in Ghana: A randomised trial” (Ofori-Atta et al 2018) raises many ethical questions. Some of these have been addressed in the accompanying commentaries in the same issue of the journal (Patel V and Bhui K, 2018; Hughes, JC 2018) and are also discussed in the article by Coleman.

The following suggestions will improve the paper:

The ethical issues can be divided into two categories:

1. Ethical issues associated with standard psychiatric treatment of people with severe mental illness
2. Ethical issues particular to the study

Ethical issues associated with standard psychiatric treatment of people with severe mental illness

1. *Informed consent to treatment:*

Respect for individual autonomy demands that informed consent is obtained from people prior to treatment. However, the principle of beneficence in context of severe mental illness is used to argue for the taking over of decision making in people when they lack the mental capacity to make informed choices. Informed consent by the person’s relatives is often used as an option in low-income and middle-income countries while the state or their representatives take over decision making for legal involuntary hospitalizations. Such takeover of decision making by the treating team can result in the use of psychotropic medication and which may be associated with coercion.

1. *Use of physical restraints and seclusion in psychiatric practice:*

While the use of restraints and seclusion is often associated with coercion, they are employed in people with severe mental illness only when the risk of harm to self or to others is considered high. However, such measures are temporary, time-limited, require special procedures to activate and are usually used along with psychotropic medication proven to be efficacious and effective in treating severe mental illness.

Nevertheless, the right to informed consent (and respect for the individuals autonomy) reverts to the individual as soon as the person is a judged to have mental capacity to make informed choices.

Ethical issues particular to the study

1. *Randomised trials and clinical equipoise:*

Randomised trials are done in clinical medicine only when there is clinical equipoise (i.e. when one has no good basis for a choice between two or more treatment options.) However, there is substantial evidence to support the use of antipsychotic medication in people with psychosis. Antipsychotics are superior to placebo/no treatment. Antipsychotic medication in people with schizophrenia has been shown to be efficacious and effective across populations, cultures and regions. On the other hand, there is no current evidence that chaining per se has therapeutic benefit. Consequently, conducting a randomized trial in such a context, with the use of antipsychotic medications only in one arm of the trial, raises ethical questions.

1. *Epistemic and pragmatic values:*

While the study aimed at knowledge acquisition and scientific development (epistemic and pragmatic objectives), which are value investment and commitments, its methodology did not specifically match its stated objectives. If the aim of the investigation was to study the impact of psychotropic medication on chaining, the authors should have employed scales to assess agitation/violence/risk of violence (common indicators for harm to self or to others) rather than the BPRS, which focuses on psychopathology. Statistically significant differences between the two groups on measures of safety but not on time spent in chains would suggest that the basis of chaining in the prayer camp was not related to safety issues. On the other hand, the absence of statistically significant difference on these measures would suggest the lack of efficacy of antipsychotic medication on agitation and violence and hence on the practice of chaining. The study did not address these specific questions.

1. *Value entailments, implied or assumed:*

Value entailments are implied or assumed in individual and global worldviews. These include neurobiological reductionism with its political and economic pressures. The sole use of psychotropic medication as treatment for severe mental illness supports the narrow biological framework of mental illness rather than psychiatry’s biopsychosocial model.

1. *Consequences of association with the practice of chaining:*

While it is common for people with mental illness to seek treatment from psychiatric hospitals and from traditional and faith healers in sequence and in combination, the agencies, which provide such resources, are not co-located. Co-location of psychiatric treatment in the context of gross violations of human rights within the prayer camp raises ethical concerns.

While cultural imperialism may be a contested notion, the fact that Ghana is a signatory to the United Nations Conventions on Rights of People with Disabilities implies that chaining is a cruel and inhuman way to treat people. The association of psychiatric services within prayer camps, without questioning issues related to human rights, legitimises cruel and degrading measures employed in such settings. These need to be discussed.

Organising the paper under such heads will add clarity.

**Reviewer 2**

1. I am unable to see the arguments being made in the paper.

2. The ethical issues are very very superficially discussed. There is no mention of the Convention on Rights of Persons with Disabilities for example, which is a major omission. The author also demonstrates a very poor understanding of patients' rights and the need for protection of these rights. There is nothing at all in the paper about the effect that this practice can have about chaining.

3. The ethical issues around consent for the particular study are not discussed.

4. Not once in the paper does the author actually decry the chaining practice.