**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.**

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**Abstract:**

A publication in the January 2018 British Journal of Psychiatry (BJP) detailed a clinical trial on persons

with mental illness (PWMI) some who were in chains in a prayer camp setting in Ghana. The camp’s

advertised mission statement was to “set free those held captive by satan....through its ministry of

fasting and prayer”. This article considers the potential ethical problems raised by the clinical trial on

chained PWMI against the background of Ghanaian ethnic-anthropologic beliefs.

Of importance is that the article highlights specifically two significant ethical issues: firstly that

associated with standard psychiatric practice in the treatment of persons with severe mental illness

(specifically the issue of informed consent and the use of physical restraint and seclusion in

psychiatric practice); and secondly issues specific to the study under discussion (specifically issues

of study methodology and the principle of equipoise, biological determinism as against the

multifactorial paradigm of mental illness/practice, implied or assumed; misalignment between the

research methodology, results and underlying aim of the study, bordering on epistemology and

pragmatism/values, and finally the association of the trial researchers with the practice of chaining).

The article in highlighting the ethical issues raised by the clinical trial in question attempts to

suggest what (and how) Ghanaian healthcare professionals (HCPs), policymakers and the national

government can do to institute workable, enforceable measures towards ending the practice of

chaining PWMI in Ghana.

**Keywords:** Chained mentally ill patients, Ghana prayer camps, randomized medication trial,

ethical ramifications.

**1. Introduction:**

An article was published in the British Journal of Psychiatry (BJP) in January 2018 detailing the

conduct of a clinical research trial comparing anti-psychotic medication response in mentally ill

participants along with prayer intervention, in contrast to mentally ill participants having only prayer

intervention in a prayer camp in Ghana (1). The study or trial participants of persons with mental

illness (PWMI) in this instance included a number of chained PWMI, a situation that raised issues of

the ethical concern in two commentary articles in the same issue of the BJP (2) (3).The article as

published in describing the trial site, a prayer camp said among others that the camp mission

statement was to *“set free those held captive by satan....through its ministry of fasting and prayer”*

(1). This particular study was duly registered with study # NCT02593734 on the registry of clinical

trials in the United States of America ([www.clinical](http://www.clinical) trials.gov). Granted the article was of interesting

reading, my post-reading thoughts were as follows; (a) the normative ethical problems the study

raised, (b) the scientific validity/utility of the trial against the background knowledge of the

effectiveness of antipsychotic medication, as well as the well documented intertwined problems of

chained PWMI in prayer camps and ethnoanthropological beliefs of disease causation prevalent in

Ghana, and (c) considering the study population and setting, the research ethics challenges of

obtaining valid informed consent from the participants.

When it comes to clinical research in resource-poor countries including sub-Saharan Africa (SSA)

countries, various challenging factors have been identified from the field of research ethics including

but not limited to the issue of research participants informed consent (4) (5).Ghana is no exception

to some of these research ethics challenges (6) (7). In this particular article by Ofori-Atta et al (1) I

will focus primarily on the study setting and method considering the context of psychiatric care and

research on PWMI in SSA country settings (and especially Ghana), and its ethical implications.

**Mental healthcare/policy, illness causation, PWMI and prayer camps: The Ghana situation.**

Going back from the early documented history of the evolution of mental health/psychiatric

practice in Ghana from the mid-1800 (8) (9) and the coming into law on 2nd March 2012 of the

Ghana mental health act, [Act 846]/ (MHA 846) (10) with the subsequent setting up and

inauguration on the 19th of November, 2013 of the Ghana mental health authority; Ghana hopefully

is moving towards bringing mental health practice (and hopefully the plight of PWMI), in line with

mental health practice norms of developed/high-income countries (11). Unfortunately though as at

the time of writing the dream of attaining such a mental healthcare status in Ghana despite the

passage of MHA 846, is more of a dream in the pipeline waiting on the legislative instrument that

will inject financial muscle to back up the act and activities under the act (12).This leaves the Ghana

Mental Health Authority in the position of a lame authority at this time. The current situation is

compounded by donor financial assistance for country mental health activities being curtailed,

resulting in instances of non-admission of PWMI in need of psychiatric admission, premature

discharge of admitted PWMI from the few existing psychiatric inpatient hospitals, chronic shortages

of psychotropic medications to treat psychiatric in/outpatients, pay disputes with strike threats by

aggrieved mental healthcare professionals (MHPs) etc (13).

Adding to the quagmire of a poorly resourced mental health authority overseeing and supervising

mental healthcare provision and hence the optimum well being of PWMI is the pervasive problem

of the Ghanaian perception of locus of control/cause of mental illness. The pervasive thinking as to

the cause of illness and more so mental illness continues to be pre-occupied with spiritual causes,

witchcraft or curses (14) (15); with the urge amongst families of PWMI to consult on a good number

of instances spiritualists, traditional healers, witch doctors etc, rather than primarily with allopathic

mental healthcare professionals. Numerous studies back this ethnic-anthropological hypothesis up,

even in current times (14) (15).Against this ethnic-anthropological belief/hypothesis of causation of

mental illness has thrived the still existing practice of “prayer/healing camps” role in the community

“management” of PWMI (including instances of chaining of PWMI in some of these camps); about

which a number of articles have been written (16a-16b) (17) (18).

Severely mentally ill patients constitute a vulnerable group by reason of stigmatization associated

with the illness (19), and in some cases as a consequence of their secondary and temporary (or in

some cases enduring) diminished mental capacity to make informed decisions (20). In the situation

PWMI find themselves in then persons working with them as healthcare professionals (HCP),

informal carers, friends etc need to protect the best interests of PWMI while they remain impaired,

in order that they are not taking advantage of. This is a duty of care obligation for HCP, especially

for mental health professionals (MHP) this should be a prima facie duty.

**2. Ethical considerations emerging from the clinical trial under discussion.**

The construct and implementation of this particular trial under discussion (1) raises some ethical

issues that could be broadly highlighted in three parts as follows:

(i) **Fundamental normative ethics concerns.**

Contemporary life including biomedical activities is influenced by societal moral norms. More so for

biomedical activities are influenced by research ethics norms; especially post the second world war

(21). In general normative ethic terms, the clinical trial under discussion raises in the context of

Kantian (deontological) ethics HCPs’ duty to manage PWMI as equals within the moral kingdom in so

far as there is no conflicting other obligation(22). On a consequential/utilitarian level HCP in all

ways, possible should contribute towards PWMI “maximizing their happiness” (23)or promotion of

their value as a consequence of the care they give to PWMI.

Under a virtue/care ethics paradigm, HCPs’ are supposed to ensure that PWMI incapacitated by

their illness be cared for and protected in order that they do not “fall through the web of

vulnerability” (24). Using a dignity and rights paradigm, PWMI need not lose their dignity as their

personhood is not diminished as a consequence of mental illness and their human rights need to

be protected as human persons (25) (26). Without doubt considering the four principles paradigm

(27) PWMI should have their autonomy respected (including within a legal framework), they need to

be protected from harm (beneficence) and not be subjected to harm (malfeasance), and they should

be treated in a just manner. In considering these normative ethical theories/paradigms within a

therapeutic setting though, one should as always in medical ethics take into consideration the care

context. Surely in the face of most normative moral considerations chained PWMI in prayer camps

as in this example of the mentioned study (1)are being deprived of their personhood and moral

attributes. In relation to research ethics again one needs to consider the specific issues/problems in

relation to research in developing or poorly resourced settings and be mindful of guidelines

pertaining to the conduct (or means) of trials without sacrificing participants to satisfy the goal or

ends of the trial (28).

Otherwise put in the case of the chained PWMI in a prayer camp in Ghana (1)considering the

pervasive ethnoanthropological basisof stigmatization, the medication trial was not necessarily the

intervention needed to free the chained PWMI. A similar thought was raised by one of the

commentators regarding the trial article (3). Additionally in case of trials involving participants some

of who may lack capacity as was the case of this trial article (1)specific attention needs to be

paid to some core principals of research with such subjects who may lack capacity(29).

(ii) **Ethical issues specific to the psychiatric management of patients suffering from**

**severe mental disorder.**

- [a] **Informed consent.**

In general informed consent obtained from patients by HCW prior to initiating treatment is done on

the ethical principles of respect for the autonomy of the person(s), (this more so in most countries

with developed economies), beneficence and non–Malfeasance (27). When it comes to LMIC

especially sub-Saharan settings the relatives of Patients (as in some instances of the study under

discussion) may be asked to consent on behalf of the PWMI where the particular individual is deemed

not able to consent. Not only that but in practice, there are cases even where patients who otherwise,

are deemed to have the ability to give an informed opinion and deemed to have capacity but are

illiterate, sometimes have their relatives either intervening to give consent on behalf of them, or

relatives being asked by HCW to do so (first-hand experience). Other times relatives are allowed to

confer and then give consent on behalf of a patient. These instances are accepted in some

SSA settings under the “communitarian” principle of community life (30) (31). In this study under

discussion, for example, PWMI who were illiterates had an HCP translating the consent form.

This potentially could result in inter and intra translation relay/perception issues, as to the quality of

the patient’s understanding of the inherent value of the given consent. Additionally, in some other

cases, relatives were asked for consent on behalf of some of the patients considered otherwise unable

to give consent. The issues raised in relation to consent in this particular study could lead to coercion

by relatives and or HCW and possible corruption of the informed consent process or a possible breach

of the rights of PWMI, more so considering what is already known about the issue of informed

consent in patients who lack capacity to give informed consent (20). Of additional concern especially

for clinical trial design in SSA settings, and worth considering for future trials involving PWMI is the

findings from previous trials in SSA not involving PWMI was the findings that even in those cohorts,

there were some observed difficulties in the perception/understanding and expectations they

participated in (32)(33).

[b] **Use of physical restraints (including chaining) and seclusion in psychiatric**

**management of severely disturbed PWMI.**

Granted in contemporary psychiatric practice in cases of severely disturbed (and disruptive) PWMI

restrain (and in some cases seclusion) is used in a time-limited manner following guidelines of

professional and regulatory bodies, even this practice is frowned on even by some mental health,

human rights, and legal professionals (34-35). The instances of non-time limited, non-evidenced

based, and non-regulated practice of chaining some PWMI (sometimes with no history/evidence of

disruptive/aggressive behaviours) in prayer camp settings in Ghana (and other LMIC), as was the

case in some of the trial participants in this particular study trial goes against the dignity and rights of

these PWMI and human rights (including the specific rights of persons with disability) [PWD]

conventions of the United Nations (36).

iii. **Ethical problems specific to the study under discussion.**

**-**[a] **Study methodology and the principle of equipoise.**

The procedural practice in randomized clinical trials involves the use in one trial arm of

product/substance with evidentiary/potential therapeutic value juxtaposed against another

trial arm usually a placebo. Where a trial compares two products therapeutic products in

a randomized trial there is a supposition of the principle of equipoise (37). In the trial under

discussion, the two trial arms compared were an arm with some of the chained participants being

administered in addition, psychotropic medications, juxtaposed with the other arm (also with some

participants chained) not receiving psychotropic medication. The ethical problem despite the trial

premise of acquisition of knowledge on therapeutic benefits is that whereas psychotropic medication

have the evidence-based information of therapeutic efficacy in most cases of use (38), the practice

of chaining has no such evidence base or therapeutic efficacy; (albeit its use to constrain or “tame” an

alleged self-destructive /disruptive behaviour which is a more physical/mechanical measure to

manage the PWMI or the milieu). The trial construct thus does not satisfy the research notion of

equipoise in this instance and hence does not respect/comply with the science and ethics of clinic trial

comparator studies. More so as the trial results demonstrated that even in the case of participants in

the psychotropic arm, treatment with psychotropic medication did not show any statistical value

where freeing from chains was concerned. This could be interpreted as the use of psychotropic

medications in this instance not being efficacious in the management of the PWMI under the

described conditions.

-[b] **Biological reductionism/determinism as against the biopsychosocial paradigm of mental**

**health practice: Implied or assumed views/values.**

This trial with the use of psychotropic medication in the hope of effecting the unchaining of chained

PWMI, from its results, shows how the trial team’s supposition played right into the

“biological/neurobiological” paradigm of the possible aetiology of mental illnessdespite criticism of

this paradigm[and hence its management primarily with psychotropic medications (39). This despite

contemporary thinking about the biopsychosocial (40) and or multifactorial causes of mental

illness (41).This probably stems from underlying issues of value entailment either by way of

assumption or inclination as to the causality of mental illness. Hence the trial team in the design of

their trial may not have considered the other variables (including socio-anthropological factors), often

associated with Ghana prayer camps (14)(15)(16)(17)(18).

-[c] **Misalignment between research methodology, results and underlying aim of the**

**study. Issues of epistemic and pragmatism views/values.**

Considering the aim of the trial researchers and the outcome of the results of the study There

appears to be a misalignment in the quest to hopefully acquire new knowledge towards informing

mental health care/practitioners/researchers for current and future activities. The trial researchers

granted from the aim of the study were trying to demonstrate that psychotropic medication

administered to chained PWMI in a prayer camp could get a result in the chained PWMI getting

better, and hopefully leading to them being unchained, used as a measure of effectiveness the BPRS

(brief psychiatric rating scale), an instrument that measures the presence of disease/psychopathology

instead of using an instrument measuring the degree of illness/symptoms (pre and post-treatment) like

the global assessment of symptoms scale (GAS) or other measures of agitation/violence risk

assessment either of the structural clinical judgement type like the “historical, clinical, management

20 or HCR-20”, or the actuarial instrument type like the “classification of violence risk or COVR”;

and similarly for the patients suspected or diagnosed with dementia, the use of neuropsychiatric

inventory scale for example. Being that the results of the study did not show any statistical difference

between patients in the trial arm with psychotropic treatment and those in the arm without treatment,

and being that the obtained results did not influence unchaining of the PWMI either on medication or

without, it follows to infer that the administered psychotropic medication lacked clinical efficacy on

the symptoms exhibited by the PWMI, and additionally on the practice of chaining.

-[d] **Impact of trial researchers association with the practice of chaining.**

Granted there is the historical antecedent of chaining of PWMI from as far back as the

seventh/eight centuries, prior to the discovery of efficacious psychotropic medications/antipsychotics

(42), chaining just a containment measure has no place in contemporary psychiatric/mental health

practice, especially in countries with developed economies. As stated earlier under the use of

restraints/seclusion in contemporary mental health practice on the basis of evidence, regulatory

guidelines and it's even though it is strictly time-limited, this practice has its strong critics from

different professionals including human rights advocates and HCP (34)(35).The type of chaining of

PWMI pervasive in prayer camps in Ghana and some other LMIC settings, with which the trial

researchers by way of their study got associated with is unacceptable, goes against the principle of

human dignity, and an affront on human personhood. Apart from its being an infringement on the

PWMI human rights, specifically for the PWMI who are considered persons with disability, they are

supposed to be protected under the United Nations convention for persons with disability (PWD)

(36). It is regretful that in this time of the upcoming tenth anniversary of the PWD convention such

practices still occur in some parts of the world, more so including the association of some

researchers/MHP with such practice settings. MHP should not associate with such practices or

practice sites except solely for the purpose of unchaining the PWMI and re-directing them to

specialist treatment sites, as was done once last year in Ghana (43). Chaining of PWMI is unethical

in all shape and form, and should not be entertained under the guise of “cultural relativism” as some

may argue, more so as the argument of cultural relativity does not deny universalism of fundamental

ethical norms (44).

**3. Discussion**

The challenges of psychiatric care of PWMI in resource-poor SSA countries are well documented

(45) The challenges facing mental health care delivery in Ghana a country in SSA is no exception to

those of other SSA countries (12) (13). When it comes to psychiatric research in resource-poor

countries (including Ghana) there are challenges as identified earlier on (4) (6) (7). That said the trial

as written about in the article (1) probably should not have been conceptualized/executed as is for

the following reasons: (a) there is ample scientific evidence to date that demonstrates that

psychotropic medications at the appropriate doses in large part lead to amelioration of symptoms in

PWMI in general (36), this is supported by epidemiologic data from resource-poor settings too (46).

(b)The issue of chaining of some PWMI in Ghana has been going on for some time and have been

written about prior to the said trial (15) (17) (18).(c) PWMI get sent to some of the prayer camps

and get chained not because psychotropic medications do not work pharmacodynamically but rather

for other reasons, principal among them being: (i) ethnic-anthropological based reasons (14) (15)

(17) (18) (ii) stigmatization leading to some PWMI being disowned by families (47); (d) hitherto

poorly administered national mental health policies/programmes, with an apparent national lack of

will/interest (12) (13) (arising from stigmatization?) and other non-enumerated causes besides

availability/access to psychotropic medications. It is, therefore, refreshing that one of the

commentaries in the BJP of January 2018 on the published article, raised the point that helping

PWMI (especially chained PWMI) is not all about medication only (3). Against the background of the

immediate causes alluded to, a qualitative outcome driven research by MHP, not on PWMI (chained

or unchained, but rather cohorts from the general population or targeted cohorts of families with

PWMI, prayer camp operators etc need to be done towards extracting their views as to what rather

could be done for PMWI instead of being their being sent to prayer camps.

These qualitative research activities if done in my view will enable MHP/ HCP to fully appreciate and

understand the cognitive themed basis of the population beliefs in order to better inform

evidence driven community belief reduction/ablative interventions, rather than quantitative

outcome based research on PWMI, which rather may place the dignity and rights of PWMI under

threat.

In the specific situation of some chained PWMI within prayer camp settings in Ghana, granted

the practice has been written about (including documentaries) no real sustained targeted

enforcement of the safeguards or laws barring such practices since the passage of the Ghana mental

health law beyond the occasional verbal outbursts by some MHP, for all sort of reasons (11) (12)

(13). This in my view, unfortunately, demonstrates a lack of national will in general on advancing the

national mental health policy level even with the passage of a mental health act (12). As a Ghanaian

born psychiatrist and bioethicist with working experience in both higher income and lower and

middle-income countries (LMIC), this research paper (1)sets off alarm bells for me in terms of

psychiatric care and mental health ethics.

**4. Conclusion:**

Psychotropic medications including anti-psychotics have already been proven to be efficacious in

patients with psychosis and psychotic-like illnesses (38), as opposed to prayer only intervention. In

addition, there is evidence of the utility and therapeutic efficiency of psychotropic medication when

used in resource-poor countries (46).PWMI, especially in SSA countries including Ghana constitutes

a vulnerable group due to among other things stigmatization (47). Considering in some cases their

impaired ability to give informed consent and their vulnerability (20) (24) MHP/HCP including

mental health and researchers, should in their interaction with PWMI ensure that the

PWMI best interest is paramount when they are accessing service or being made research subjects.

A parallel can be drawn in this case from the international convention provisions on the

responsibility to protect (R2P) paradigm, on the role of the international community’s duty to

intervene in individual sovereign states when the particular state fails to protect a minority within

the particular state from internal acts of extreme pervasive aggression (48). This parallel duty of care

in line with the R2P paradigm calls on MHPs’/HCPs to have a responsibility to protect the PWMI

under their care or as research subjects and is well along the care ethic paradigm of protecting

PWMI from falling through the web of vulnerability (24).

On a governmental level/policy level where the practice of chaining PWMI in various settings in

Ghana is concerned, the government owes PWMI the governance duty of care and R2P through

strictly enforcing (in a sustained manner) enacted legislation so that this abhorrent practice is

minimised/eradicated for good while ensuring appropriate basic care for PWMI. Other national-

level measures should include the necessary national /governance political will manifested through

appropriate sustained and targeted financing of mental health programmes, including mental health

prevention, promotion, and education, as a sustained national campaign against the

practice of chaining in any form. The Ghana media can help with sustained awareness campaign

against the practice of chaining PWMI as well as (NGOs), churches (contemporary and “traditional “)

traditional chiefs and village elders. In short, all hands should be mobilized to end the unethical and

inhumane practice of unchaining of PWMI and prohibition of the practice. Additionally, Ghanaian

MHP at all levels should inculcate in their local practice universally accepted ethical and human

rights-based norms in managing PWMI.

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None to declare.

**Authorship declaration:**

The author is accountable for all aspects of the work in ensuring that questions related to the

accuracy or integrity of any part of the work is appropriately investigated and resolved.

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