CASE STUDY

The ethics of psychiatric care and research in resource-poor settings: The case of a research trial in a prayer camp in Ghana

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Abstract

A communication in the January 2018 issue of the British Journal of Psychiatry detailed a clinical trial on persons with mental illness (PWMI), some of whom 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 ethnoanthropological beliefs.

It highlights two significant categories of ethical issues: first, those 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 second, issues pertaining 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 the underlying aim of the study, bordering on epistemology and pragmatism/values; and finally, the association of the trial researchers with the practice of chaining).

This article, in highlighting the ethical issues raised by the clinical trial in question, attempts to suggest what Ghanaian healthcare professionals, policymakers, and the national government can do (and how) to institute workable, enforceable measures towards ending the practice of chaining PWMI in Ghana.

Introduction

An article was published in the *British Journal of Psychiatry (BJP)* in January 2018, detailing the conduct of a clinical research trial comparing antipsychotic medication response in conjunction with prayer intervention for mentally ill participants with prayer intervention alone, in a prayer camp in Ghana (1).

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The study or trial participants—persons with mental illness (PWMI)—in this instance included a number of chained PWMI, a situation that drew ethical concern in two commentary articles in the same issue (2,3). The article, in describing the trial site—the prayer camp—reported that the camp mission statement was to "set free those held captive by Satan" through its "ministry of fasting and prayer."¹

When it comes to clinical research in resource-poor countries, including sub-Saharan African (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 my critique of 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 of and research on PWMI in SSA countries (and especially in Ghana) and the associated ethical implications.

Mental healthcare/policy, illness causation, PWMI, and prayer camps: The Ghanaian situation

Going back from the early documented history of the evolution of mental health / psychiatric practice in Ghana from the mid-1800s (8,9), the coming into law on March 2, 2012 of the Ghana Mental Health Act (MHA 846) (10), and the subsequent setting up and inauguration on November 19, 2013 of the Ghana Mental Health Authority, Ghana seems to be 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, it rather appears, as of this writing, that the dream of attaining such a mental healthcare state in Ghana despite the passage of MHA 846—is more of a dream in limbo, 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 a fairly titular authority at present. 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).

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Adding to the guagmire of a poorly resourced mental health authority overseeing and supervising provision of care, and thus affecting the optimum wellbeing of PWMI, is the pervasive Ghanaian perception of the locus of control/cause of mental illness. The overarching belief as to the cause of illness-and more so, mental illness-continues to centre around spirits, witchcraft, or curses (14,15). The tendency amongst families of PWMI generally is to consult spiritualists, traditional healers, witch doctors etc, rather than allopathic MHPs. Numerous studies back this ethnoanthropological hypothesis, even in current times (14,15). Against this supposed cause of mental illness has prevailed the practice of "prayer/healing camps" playing a 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 (16-19).

Severely mentally ill patients constitute a vulnerable group by virtue of the stigma associated with this type of illness (20), and in some cases, as a consequence of their secondary and temporary—or sometimes, enduring—diminished mental capacity to make informed decisions (21). In these situations, it becomes the responsibility of the persons working with them as healthcare professionals (HCPs), informal carers, friends, etc to protect their best interests while they remain impaired, in order that they are not taken advantage of. This is a duty of care obligation for HCPs, and this should be a prima facie duty for MHPs especially.

Ethical considerations emerging from the clinical trial under discussion

The construct and implementation of the particular trial under discussion raises some ethical issues that could broadly be categorised into three parts as follows:

Fundamental normative ethics concerns

Contemporary life, including biomedical science, is influenced by societal moral norms. Biomedical activities are influenced by norms around research ethics, especially after the Second World War (22). In generic, normative ethics terms, the clinical trial under discussion raises—in the context of Kantian (deontological) ethics—HCP duty to manage PWMI as equals within the moral kingdom, in so far as there is no conflicting other obligation (23). On a consequential/utilitarian level, HCPs should contribute, in all ways possible, towards PWMI, "maximising their happiness" (24) or promoting 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 are cared for and protected so that they do not "fall through the web of vulnerability" (25).

Using a dignity and rights paradigm, PWMI need not lose their dignity as their personhood is not diminished as a consequence of mental illness; their human rights need to be protected as human persons (26,27). Without doubt, considering the four-principles paradigm (28), PWMI should have their autonomy respected (including within a legal framework). They need to be protected from harm

(beneficence) and must not be subjected to harm (nonmalfeasance), 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, the chained PWMI in prayer camps in this study are being deprived of their personhood and moral attributes. In relation to research ethics, one needs to consider the specific issues/ problems of 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 (29).

Otherwise put, in the case of the chained PWMI in the prayer camp in Ghana, considering the pervasive ethnoanthropological basis of stigmatisation, 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 who may lack capacity—as was the case in the concerned trial—specific attention needs to be paid to some core principles of research as suggested by some authors (30).

Ethics issues specific to the psychiatric management of patients suffering from severe mental disorders

Informed consent

In general, informed consent obtained from patients by HCP prior to initiating treatment is done on the ethical principles of respect for the autonomy of the person(s) (this is more so in most countries with developed economies), beneficence, and non-malfeasance (28). When it comes to low- and middleincome countries (LMICs), especially in sub-Saharan settings, the relatives of patients (as also in some instances, in the study under discussion) may be asked to consent on behalf of the individual where the individual is deemed unable to consent. In practice, there are additionally cases in which patients otherwise capable of forming an informed opinion who are illiterate, sometimes have their relatives either intervene to give consent on their behalf or cases of relatives being asked by HCPs to do so (first-hand experience). At 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 (31,32). In this study under discussion, for example, PWMI who were illiterate had an HCP translating the consent form.

This could potentially result in inter- and intra-translation relay/perception issues, that may impact the patient's comprehension of the task at hand. 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 HCPs 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 it (21). Of additional concern, especially for clinical trial design in SSA settings and worth considering for future trials involving PWMI, are the findings from previous trials in SSA countries not involving PWMI; even in those cohorts, there were some observed difficulties in the perception/understanding and expectations of the participants as to the meaning of the consent they gave for participating in the trials (33,34).

Use of physical restraints (including chaining) and seclusion in psychiatric management of severely disturbed PWMI

While granting that in cases of severely disturbed (and disruptive) PWMI in contemporary psychiatric practice, restraint (and in some cases, seclusion) may be used in a timelimited manner following the guidelines of professional and regulatory bodies, even this practice is frowned upon by some mental health, human rights, and legal professionals (35,36). The instances of non-time limited, non-evidence based, and unregulated practice of chaining some PWMI (sometimes with no history/evidence of disruptive/aggressive behaviours) in prayer camp settings in Ghana (and other LMICs), as with some of the trial participants in this particular study trial, go against the dignity and rights of these PWMI and human rights (including the specific rights of persons with disabilities [PWD]) conventions of the United Nations (37).

Ethical problems specific to the study under discussion

Study methodology and the principle of equipoise

Randomised clinical trials involve the use of a product/ substance with evidentiary/potential therapeutic value in one trial arm juxtaposed against another trial arm with, usually, a placebo. Where a randomised trial compares two potentially therapeutic products, there is a supposition of the principle of equipoise (38). In the trial under discussion, the two trial arms compared were: one arm with some of the chained participants being administered (in addition to "prayer intervention") psychotropic medications; and 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 has evidenced therapeutic efficacy in most cases of use (39), the practice of chaining has no such evidence base or therapeutic efficacy (despite its use to constrain or "tame" alleged self-destructive / disruptive behaviour). 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, 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.

Biological reductionism/determinism as against the biopsychosocial paradigm of mental health practice.

In using psychotropic medication in the hope of effecting the unchaining of chained PWMI, the study team reinforced the "biological/neurobiological" paradigm of the possible aetiology of mental illness despite criticism of this paradigm (40) and contemporary thinking about the biopsychosocial (41) and or multifactorial causes of mental illness (42). This act 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 socioanthropological factors) often associated with Ghana prayer camps (14-19).

Misalignment between research methodology, results, and underlying aim of the study

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 healthcare/practitioners/researchers for current and future activities. The trial researchers, from the aim of the study, were trying to demonstrate that psychotropic medication administered to chained PWMI in a prayer camp could result in the chained PWMI getting better and hopefully lead to their being unchained. As a measure of effectiveness, they used the Brief Psychiatric Rating Scale (BPRS), an instrument that measures the presence of disease/ psychopathology. Instead, they could have used an instrument measuring the degree of illness/symptoms (before and after treatment) such as the Global Assessment of Symptoms scale (GAS) or other measures of agitation/violence risk assessment either of the structural clinical judgement type (such as the Historical Clinical Risk Management 20 [HCR-20]), or the actuarial instrument type (such as the Classification of Violence Risk [COVR]), or for patients suspected or diagnosed with dementia, the neuropsychiatric inventory scale, for example.

Since 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 since the obtained results did not influence unchaining of the PWMI either on medication or without, it follows that the administered psychotropic medication lacked clinical efficacy on the symptoms exhibited by the PWMI and additionally on the practice of chaining.

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/eighth centuries, prior to the discovery of efficacious psychotropic medication/antipsychotics (43). However, chaining just as a containment measure has no place in contemporary psychiatric/mental health practice, especially in countries with developed economies. As stated earlier, the use of restraints/seclusion in contemporary mental

health practice on the basis of evidence, even if strictly following regulatory guidelines and in strictly time-limited fashion, has strong critics among different professionals, including human rights advocates and HCP (35,36).

The type of chaining of PWMI pervasive in prayer camps in Ghana and some other LMIC settings, with which the trial researchers became associated by way of their study, is unacceptable. It goes against the principle of human dignity and is an affront to human personhood. Apart from that, it is an infringement of the human rights of PWMI, specifically for PWMI who are considered PWD and are protected under the United Nations Convention on the Rights of Persons with Disabilities (CRPD) (37). It is regrettable that since the coming into force of the CRPD such practices still occur in some parts of the world, more so when researchers/MHPs are found to be associated with such practice settings.

MHPs should not associate with such practices or practice sites except solely for the purpose of unchaining the PWMI and redirecting them to specialist treatment sites, as was done once last year in Ghana (44). Chaining of PWMI is unethical in all shapes and forms 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 (45).

Discussion

The challenges of psychiatric care of PWMI in resource-poor SSA countries are well documented (46), The challenges facing mental healthcare delivery in Ghana, an SSA country, are no different from those in other SSA countries (12,13). When it comes to psychiatric research in resource-poor countries (including Ghana) there are challenges, as identified earlier on. That said, the trial under discussion probably should not have been conceptualised/executed as is, for the following reasons:

- (a) There is ample scientific evidence to date that demonstrates that psychotropic medication in the appropriate doses, in large part, leads to amelioration of symptoms in PWMI in general (37). This is supported by epidemiological data from resource-poor settings as well (47).
- (b) Chaining of some PWMI in Ghana has been going on for some time and has been written about prior to the said trial (15,18,19).
- (c) PWMI are sent to prayer camps and chained not because psychotropic medications do not work pharmacodynamically but rather for other reasons, principal among them being ethnoanthropological reasons (14,15,18,19) and stigma, leading to some PWMI being disowned by their families (48).
- (d) Hitherto, national mental health policies/programmes have been poorly administered. This has been attributed to an apparent national lack of will/interest (12,13) (possibly arising from stigma?) as well as other non-enumerated

causes besides the availability/access to psychotropic medications.

It is, therefore, refreshing that one of the commentaries in the BJP issue of January 2018, commenting on the published article, raised the point that helping PWMI (especially chained PWMI) is not all about medication alone (3). Against the background of the immediate causes alluded to, qualitative outcome-driven research by MHP, (not on PWMI, chained or unchained, but rather on cohorts from the general population or targeted cohorts of families with PWMI, prayer camp operators, etc) needs to be done in order to extract their views about what could be done for PMWI instead of their being sent to prayer camps.

These qualitative research activities, in my view, would enable MHPs/HCPs to fully appreciate and understand the underlying assumptions 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 (and featured in documentaries). However, there is no real, sustained, targeted enforcement of the safeguards or laws barring such practices since the passage of Ghana's MHA 846, beyond the occasional verbal outbursts by some MHPs (11-13). In my view, this 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).

One can draw a parallel in this case from the United Nations 2005 "World summit outcome document A/RES/60/1 international commitment provisions on the responsibility to protect (R2P) paradigm". This document spells out 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 (49). This parallel duty of care in line with the R2P paradigm calls on MHPs/HCPs to recognise their 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 (25).

On a governmental level/policy level, with respect to the practice of chaining PWMI in various settings in Ghana, 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 as well as non-profit organisations, churches (contemporary and "traditional"), traditional chiefs, and village elders can help with a sustained awareness campaign against the practice of chaining PWMI.

Conclusions

As a Ghana-born psychiatrist and bioethicist with working experience in both high-income countries and LMICs, reportage of this trial sets off alarm bells for me in terms of psychiatric care and mental health ethics.

Psychotropic medications, including anti-psychotics, have already been proven to be efficacious in patients with psychosis and psychosis-like illnesses, as opposed to prayeronly intervention. In addition, there is evidence of the utility and therapeutic efficiency of psychotropic medication when used in resource-poor countries. PWMI, especially in SSA countries, including Ghana, constitute a vulnerable group due to stigma, among other things. Considering the vulnerability and impaired ability of PWMI to give informed consent in some cases, MHPs/HCPs and mental health researchers should in their interaction with PWMI ensure that the best interests of PWMI are prioritised when they are accessing a service or being made research subjects.

In short, all hands should be mobilised to end the unethical and inhumane practice of unchaining of PWMI and enforcing prohibition of the practice. Additionally, Ghanaian MHPs at all levels should inculcate in their local practice universally accepted ethical and human rights-based norms in managing PWMI. These actions including the appropriate government policies taking together will satisfy the "R2P responsibilities" of MHP/HCP, responsible national agencies and the Ghana government in ensuring PWMI are protected from abuse, whilst ensuring that the practice of chaining PWMI in general is eventually eliminated.

Conflicts of Interest

None to declare.

Note

This particular study was duly registered (No. NCT02593734) in the registry of clinical trials hosted by the National Library of Medicine at www.ClinicalTrials.gov. While the article made for 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 the ethnoanthropological beliefs about disease causation prevalent in Ghana, and finally, (c) considering the study population and setting, the research ethics challenges of obtaining valid informed consent from the participants.

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