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The conundrum of clinical trials and standard of care in sub-Saharan Africa – the research nurse perspective

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Abstract

Background: Nurses form a very important part of the health workforce in sub-Saharan Africa. Research nurses are critical to the implementation of clinical trials. The duties and responsibilities of a research nurse are complex and continue to evolve as new practices and guidelines are formulated.

Aims: In this paper, we have highlighted the major contributions of research nurses in HIV clinical trials in sub-Saharan Africa from the unique perspective of Ugandan nurses.

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Methods: The requirements and challenges of two multi-site, randomised cryptococcal meningitis clinical trials in Uganda were assessed from the perspective of research nurses conducting complex research in resource-limited settings.
Results: Over the course of 8 years, approximately 1739 participants were screened and 934 people were enrolled into the two trials. The nurses found that patient education and engagement were among the most important predictors of success in minimising loss to follow-up.
Conclusions: Research nurses played a key role in communicating clinical research goals to patients, obtaining informed consent, minimising loss to follow-up, and ensuring that research practices are translated and implemented into standard of care. However, there remains a need to integrate the same level of care provided in clinical research studies to non-study patients.

Keywords
clinical research, cryptococcal infection, research nurse, standard-of-care, sub-Saharan Africa

Introduction

Nursing encompasses the prevention of illness, alleviation of suffering, and protection, promotion and restoration of health in the care of individuals, families, groups and communities (American Nurses Association, 2001). In sub-Saharan Africa, clinical nurses comprise a very important part of the health workforce, and are possibly the group of health workers most affected in terms of the numbers required to correct the deficit (Munjanja et al., 2005). However, migration to developed countries appears to have impacted the state of nursing practice in sub-Saharan Africa negatively (Dovlo, 2007). Furthermore, due to the increased number of research and clinical trials being conducted in resource-limited settings, there is a need for more nurses with advanced training to coordinate and implement research studies.

In addition to the routine care that nurses provide, a research nurse must perform essential research-related duties, ranging from ensuring the study's regulatory compliance and adequate documentation, to coordinating and administering study protocols on behalf of their sponsor (National Institutes of Health (NIH), 2009). At a minimum, a research nurse is a registered nurse (RN) with at least 1 year of experience as a nurse in a clinical setting. These nurses must be trained in Good Clinical Practices (GCP) and protection of human subjects, as well as have a thorough knowledge of the study protocol and operating procedures. The nurse must also be familiar with both international and local guidelines and regulations, and maintain annual credentialling in order to be able to perform their duties. Collectively, their responsibility is to ensure that the rights and well-being of the research participants are protected, while balancing the needs and requirements to complete a study in a specific timeframe, within a specific budget. In sub-Saharan Africa, these challenges can be exacerbated when working in an overburdened healthcare system with patients who are very poor and transient. It is essential for the research nurse to effectively engage the prospective study participants and provide a fair and balanced description of the research study as well as the risks and benefits of the study, while avoiding coercive language.

In this paper, we describe the experiences of, and lessons learned from, research nurses working on two prospective multi-site randomised clinical trials managing patients co-infected with HIV and cryptococcal meningitis in sub-Saharan Africa. We seek to

highlight and discuss the complex roles and challenges of research nurses in research in Uganda, and the requirements needed to be successful in this environment.

Method

We assessed our experiences during two longitudinal cohort studies at the Infectious Diseases Institute in Kampala, Uganda. In both cohorts, all research participants or their surrogates provided written informed consent. Ethical approval was obtained from the Uganda National Council of Science and Technology (UNCST), Mulago Hospital Research and Ethics Committee, and the University of Minnesota. During both studies, approximately 1739 patients consented and were screened for meningitis; 934 patients were ultimately enrolled into the trials. Each trial documented loss to follow-up among enrolled patients.

The first cohort was the Cryptococcal Optimal ART Timing (COAT) research study. COAT was a randomised multi-centre clinical trial conducted in Uganda at Mulago National Hospital, Mbarara Regional Referral Hospital and Cape Town in South Africa between 2010 and 2012 (Boulware et al., 2014). This trial was a treatment strategy trial focusing on determining the optimal time to initiate anti-retroviral therapy (ART) in HIV patients with cryptococcal meningitis (CM) against standard of care. The results from this trial showed that early initiation of ART following CM is detrimental, and led to the current World Health Organisation (WHO) recommendation that patients should start ART at 4–6 weeks following diagnosis as well as treatment of CM (Govender et al., 2013). This study included 46 weeks of follow-up.

The second cohort was the Adjunctive Sertraline for the Treatment of HIV-Associated Cryptococcal Meningitis (ASTRO-CM) Clinical Trial (ClincalTrials.gov: NCT01802385). ASTRO-CM was a randomised multi-centre clinical trial conducted in Uganda at Mulago National Hospital and Mbarara hospital between 2013 and 2017 (Rhein et al., 2016). This study investigated the effectiveness of adjunctive sertraline therapy on fungal clearance and survival in HIV patients co-infected with CM. The ASTRO-CM study included 18 weeks of follow-up time.

Using our experience implementing these studies as context, three areas of focus are described in terms of key additional requirements needed to perform the duties of a research nurse: proper training in research ethics, including consent and participant engagement; detailed documentation of clinical work; and translating research into practice. We discuss these three areas in detail in the results and discussion below.

Results and discussion

Competency of research nurses in delivering clinical trials in sub-Saharan Africa

All nurses were qualified and registered/licensed with the Uganda nurses and midwifery council. The nurses involved in the trials went through a vigorous selection process. On-job training occurred through protocol training before the start of the trials. Nurses had weekly continuous medical education (CME) on nursing care, case presentations and other related topics. In addition, regular refresher courses were given to nurses in standard operating procedures, infection control, and management of HIV and cryptococcal patients, highlighting the current updates or advances in the field. Training in GCP was mandatory and renewed every 2 years, according to the International Conference on Harmonisation (ICH). The nurses were also mentored by a group of physicians from the University of Minnesota and Makerere University.

Mentorship for the research nurses was integrated into the clinical trial experience. Weekly meetings at which the team discussed clinical care of patients, sub-projects and manuscripts in preparation were a vital part of the mentorship process. The research nurses were challenged to think through how best to share the important and unique aspects of their work. Writing was encouraged by discussing ideas, and setting aside time to write was given priority once the clinical research work slowed down.

Translating clinical research findings into practice

Research nurses can play a vital role not only in educating patients, but also in educating the larger hospital community. This can have a significant impact beyond the specific research study. Research nurses can use the lessons learned during the study to assist with improving care on the hospital wards. One example of this is the challenging issue of lumbar punctures (LPs) in an African setting. LPs are an important part of diagnosing and managing the complications of meningitis. In Uganda and other African settings, many myths surround LPs despite their diagnostic and therapeutic importance, resulting in a refusal rate of up to 25% (Kambugu et al., 2008; Ling and Boey, 2000; Rolfes et al., 2014; Thakur et al., 2015). The majority of patients and/or their caregivers believe that LPs increase a patient's chances of dying prematurely. Both clinical trials involved regular LPs performed to diagnose CM. These were performed at days 0, 3, 7, 10 and 14 of treatment and as clinically indicated to control intra-cranial pressures. We found the myths to be a major challenge at the beginning (pilot phase) of the first study (COAT) in 2010. This delayed diagnosis and prolonged the screening consent process longer than we anticipated, with an approximately 31% refusal rate (Boulware et al., 2014).

We created educational materials and developed a plan to continuously educate patients and caregivers/relatives of the patients about the importance of the regular LPs. In 2015, the study nurses collaborated with a film student to create a short movie about the importance of LPs in diagnosing meningitis (https://www.youtube.com/watch?v=222eM9s7xq0). This 20-minute film was shown to patients in order to increase awareness of the procedure and remove the stigma. In addition, groups were formed to discuss all myths surrounding LPs in the African setting, and families were encouraged to speak to others who had undergone the procedure and ask questions. This was a continuous process similar to the informed consent process. In the long run, those patients and/or caregivers who understood what we taught them could sometimes help us explain to other new potential study participants, sharing with them their own experience. We took this teaching a step further to the health workers (intern doctors, nurses) by engaging them during CME sessions and one-on-one discussions at different sites. In addition, we designed posters that provided information in strategic locations on the wards. All these efforts helped to the increase acceptance of LPs and the enrolment rate, reducing refusal to less than 1%.

In addition to LPs, regular blood draws up to three times weekly for monitoring liver and kidney function for early detection of drug toxicity, especially due to amphotericin B, ART and other concomitant medications, were performed as part of the trial protocols. Additional blood draws were performed for research purposes. The regular multiple blood draws were viewed negatively by patients and caregivers, such that at times they would decline these procedures. It was the role of the research nurse to educate the participants and caregivers about the necessity of regular multiple bloods draws

performed in the research setting to monitor drug toxicity and treatment response. This was a continuous process similar to the informed consent process.

Patients in these trials were also on multiple concomitant medications to manage HIV, CM and other opportunist infections. The research nurses educated the patients and their caregivers about the administered drugs and their side effects to ensure medication adherence. Direct observation of therapy was done by the nurses as well as proper recording on the patients' charts. Pill counts were also done by the research nurses to ensure adherence. For unconscious patients, a nasal gastric (NG) tube was inserted in order not to miss any medication. Medication adherence counselling was continuous and, in some cases, the research nurses provided food for patients who were financially unstable. This may not be the case in the clinical setting.

Obtaining informed consent

The informed consent process is one of the most critical parts of research involving human subjects. It involves providing information and evaluating the participants' understanding and willingness to participate in the research study and does not simply terminate at signing a form. For conscious patients with suspected meningitis, the informed consent process was conducted in the presence of at least one relative/caregiver, highlighting the study objectives, procedures, potential risks and benefits, and their alternatives to participation. The research nurse had to translate complex medical/research topics and information in a simple way and language that patients and caregivers understood. This was a key ongoing role for the research nurse. It was even more pertinent since we were working with international partners. Most importantly, we emphasised the importance of serial LPs and blood draws in the study protocol, including discussion on all known myths about them. In this process, the nurses also had to encourage participants to disclose their HIV status to their caretakers, which was a particularly difficult task, given that some participants were unable to consent for themselves and yet had been newly diagnosed as HIV-positive with AIDS-related opportunistic infections.

To compound the enormity of these tasks, there was a significant proportion (29%) of admitted potential participants who were either confused, disoriented or in a comatose state. These were very challenging participants but could not be excluded based on their altered mentation. In such scenarios, surrogate consent was obtained from the legal representative or next of kin (International Conference on Harmonisation Good Clinical Practice (ICH-GCP), 2017). However, as soon as the patient regained consciousness, we requested consent from the patient himself or herself again. For both scenarios, we tried to assess the level of comprehension of the patient and caregiver after reviewing the consent form. We used the following set of simple questions;

- What conditions are we treating?
- Are you aware that you are going to participate in a research study?
- How long are you going to participate in the study?
- Do you have any questions concerning consent for participation?

As research nurses, we are typically the first healthcare staff who patients and their families encounter, therefore proper training in ethics and patient engagement is as essential as a knowledge of the study protocol. A positive interaction leads to an open discussion about the study requirements, and it allows the consenting process to be educational and interactive, thereby minimising confusion on the part of the participant.

Minimising loss to follow-up

Loss to follow-up compromises the quality of data generated from clinical studies, especially in resource-limited settings. A system needs to be put in place to encourage participants to return for their outpatient study visits and track those who seem to be lost to follow-up. In the studies discussed here, during the informed consent process the nurses ensured that they explained to the participants how often they had to return to the clinic for a specified period of the research. We reimbursed transport costs since many participants were residing in rural areas and were referred to the national referral hospital only for the diagnosis and treatment of meningitis. Participants were asked to provide more than one telephone contact, including contacts of at least two other close relatives through whom we could easily reach the participant. The nurses continuously called participants to remind them of their clinic visits at least a day before the visit. Participants were counselled continuously about the importance of keeping appointments on top of the regular drug adherence counselling. Current addresses were registered to perform home visits in case a participant missed a visit and did not return a call. Due to these skills and our diligent work with follow-up visits, we were able to have a $<3\%$ loss to follow-up across all trials. Participants were given the phone numbers for the study doctor and nurse so they could contact them if they felt ill. Due to the support developed, they generally always contacted the research nurse.

Ensuring that research practices are translated and implemented into standard of care

Clinical and translational research is done to gather evidence that can guide policies and patient care. The research nurses in these cohorts were at the forefront of making sure that research is implemented at the clinical level. In the 7 years during which these clinical trials were performed on the infectious diseases ward, the research nurses taught medical students, residents and other nurses how to manage and take care of patients with CM. They taught them about cryptococcal antigen screening, performing LPs, Amphotericin B administration, electrolyte supplementations and fluid hydration. We also taught other healthcare personnel how to manage phlebitis, a common adverse event caused by Amphotericin B deoxycholate intravenous administration. Since participants were receiving multiple concomitant medications as part of standard care, working with the patients to manage their pill burden, was an important aspect of their care, requiring counselling for patients and developing a plan to administer the drugs in divided doses as scheduled. However, in our normal HIV standard clinical setting, all the above procedures are rarely performed. This is attributed mainly to a disparity in human resources for health, given a setting with a large burden of disease and many patients. There is also a limited supply of equipment, sundries and other medical supplies. These are usually available in research/clinical trial settings as a result of research funding.

The disparity gap between research and routine hospital care

While clinical trials are essential to answering important medical questions and improving healthcare, they also highlight the fact that disease does not exist in a silo, particularly in our setting where we are working with vulnerable and low-income populations. We faced many other social issues that affect a person's ability to have a good outcome post-study: lack of social support, loss of a job, or other attendant health issues that are often outside the scope

of a particular research study. Furthermore, while our study patients were able to receive more focused attention from the research team, there were many other severely ill people on the ward (ineligible for our studies) who needed medical attention. The nurses in the studies described here faced these obstacles over the years doing research in vulnerable populations, seeking healthcare for a complicated disease in an already overburdened healthcare system.

Given this reality, research nurses working in resource-limited settings must often assist ward nurses with non-study patients and relieve some of the burden of a busy ward. They must also forge a productive relationship with families of participants to develop plans of care post-discharge. While these duties are not directly within the scope of the research study, they are crucial to a well-run research study.

Evolving roles of research nurses in HIV care and research in sub-Saharan Africa

Clinical trials have been the cornerstone of improving outcomes for HIV-infected individuals with CM. The in-hospital mortality rate for CM have declined from >50% to 25% (Kambugu et al., 2008). Research nurses are critical to the implementation of these clinical trials. However, over the years their responsibilities have evolved drastically, and we highlight from these two cohorts the modifications in the roles played by the research nurse in clinical trials.

The research nurses played a pivotal role in the process of informed consent for LPs, in study participation and in ensuring adherence to human subject protection was adhered to. The nurses were involved in implementing strategies to minimise loss to follow-up of participants during the trials.

Since these were cohorts enrolling participants with suspected meningitis, the nurses had an extra role of performing the neurocognitive or neuropsychological assessments. This is a complex procedure aimed at evaluating the cognitive status using a specific battery of tests to determine performance in specific neurologic domains, namely memory, attention, problem solving, language, visuospatial, processing speed motor, and emotion (Snyder et al., 2011). The evaluation takes approximately 1 hour and requires a private quiet room.

The nurses also had a role of collecting primary data from the participants and recording it in the case report forms (CRFs) and blood report form (BRF). In our setting, the manual recording was accompanied by scanning of the CRFs via data fax into the trial data base. The weekly quality control (QC) reports were reviewed and errors corrected by the nurses to ensure completeness and collection of high-quality data.

Dispensing the many investigational and routine drugs in the study setting was the duty of the research nurses. The concomitant medications in these studies were many, to manage HIV, CM, other opportunist infections and electrolyte supplementation. These included fluconazole, cotrimoxazole, paracetamol, potassium chloride, amphotericin B deoxycholate and sometimes tuberculosis drugs. The nurses had to develop a dosage routine unique to each participant by giving divided doses and at different times to reduce pill burden. The nurses had to make an inventory to account for all study drugs in addition to other related study supplies.

One outstanding role that the nurses played during these trials was the continuous health education to both the participants and their caregivers/relatives. This involved ART-adherence counselling, especially among participants with concerns about the pill burden and myths about ART. Other socio-economic issues unique to each participant were discussed and resolved by nurses. Some issues were related to the study but the majority

were not. At times, a home visit by the nurse would occur for serious issues. For patients with other co-infections such as tuberculosis, it was the duty of the nurses to educate the participants and their caregivers on how to prevent infecting other household members.

Limitations to the study

The reflections and discussion presented in this paper is based on our experiences in Kampala and Cape Town during two longitudinal multisite HIV trials. The experiences may not be applicable in all sub-Saharan African countries due to variations in local guidelines and socio-economic factors.

Conclusion

The responsibilities of research nurses have evolved drastically in sub-Saharan Africa. More research nurses are needed in sub-Saharan Africa to provide primary care and teach the next generation of nurses; however, more important is the need to invest in the healthcare system in order to transfer the same level of care, to a reasonable extent, that prevails in clinical research studies to the usual clinical care provided in the facilities where patients are managed.

Key points for policy, practice and/or research

Research nurses are key in:

- Ensuring that research ethics, informed consent and participant engagement are implemented in the trial;
- translating clinical research goals to patients in a simple lay man's language;
- ensuring that research practices are translated and implemented into standard of care.

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Ethical consideration

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Joshua Rhein has a broad background in global health and infectious diseases, with specific focus on CNS infections in resource-limited areas. His specific expertise is on cryptococcal meningitis and other AIDS-related opportunistic infections, as well as HIV immune reconstitution inflammatory syndrome (IRIS). His current research is focused on improving the clinical outcomes of HIV-infected persons with cryptococcal meningitis, a globally neglected disease which is the second most common AIDS-defining opportunistic infection in Sub-Saharan Africa. Dr. Rhein has been a co-investigator on several large, guideline-informing clinical trials on HIV-associated meningitis. He has played central roles in these projects including protocol development, study administration (budgets, staffing, research protections), building collaborations with international partners, and engaging in the scientific process through presenting at international conferences and producing several peer-reviewed publications from each of these projects.

David R Boulware is a distinguished Associate Professor in Infectious Diseases at the University of Minnesota with formal training in clinical trials, public health, and tropical medicine. He combines his clinical research with nested basic science investigations into disease pathogenesis to conduct translational research. His primary research interests are in meningitis in resource-limited areas including diagnosis, prevention, treatment, and quality improvement initiatives incorporating cost-effectiveness analyses in order to translate knowledge into improved care. Dr. Boulware's current research is focused on improving the clinical outcomes of adult meningitis in Africa. He has had an active research partnership in Uganda since 2005. Through leading his team, Dr. Boulware has had the opportunity to enthusiastically mentor numerous U.S. and African trainees. Within clinical research studies, He has consistently promoted opportunities for U.S. and African scientists to develop sub-projects, learn new skills, present at conferences, and write first-author manuscripts. Dr. Boulware is an enthusiastic mentor who has led the Univ. of Minnesota T32 program for adult infectious disease physicians since 2015. He would be happy to serve as an advisory committee for the pre-doctoral virology T32 training program.

David B Meya is an Associate Professor in the School of Medicine at the College of Health Sciences, Makerere University, and he is an adjunct Associate Professor at the University of Minnesota. He has participated in clinical research pertaining to CNS infections and complications, with a focus on HIV Immune Reconstitution Inflammatory syndrome. He has led epidemiological and translational research studies as well as randomized clinical trials in Uganda in collaboration with colleagues from the University of Minnesota. He has been the PI and Co-PI on many clinical research grants funded, amongst others, by NIH, CDC, and the MRC. He also has a specific interest in public health interventions to prevent meningitis at population level, and have advocated for cryptococcal antigen (CrAg) screening as a strategy to reduce deaths and hospitalizations from cryptococcal meningitis. He is currently leading efforts to initiate implementation of the national CrAg screening program in collaboration with the Ministry of Health, Clinton Health Access Initiative (CHAI), the Central Public Health Laboratories and U.S. CDC.