EXECUTIVE SUMMARY: The role of a Clinical Research Nurse (CRN) cannot be underrated at all levels of research. A nurse is almost a general fitter in research work. CRN possess multiple skills that are highly respected by fellow healthcare professionals. They develop skills associated with essential patient care. This works to the advantage of the nurse as CRN is intellectually demanding and this encourages personal development and a desire for more knowledge at the same time it contributes to scientific knowledge at a big picture.

Alongside nursing care, a CRN gains analytical skills such as quantitative and qualitative data collection and analysis. Teaching is fundamental to the smooth running of research studies; as such CRN works as a nurse educator. CRNs help coordination between nursing, medicine and science in their role as managers. They have specialist knowledge of research methodologies, and the provision of support and education for multidisciplinary staff, this assists in closing the historical hierarchical gap between nursing and medicine. [1]

ACRONYMS

AHI Acute HIV Infection

CHA V I Centre for Acute HIV Vaccine Immunology

CRN Clinical Research Nurse

HPTN HIV Prevention Trial Networks (feasibility and acceptability of behavioural interventional counselling study among acute HIV infected people)

MP3 Methods for Prevention Packages Program (acute HIV infection: Key link to HIV transmission prevention study among acute HIV infected people)

MHRA Regulatory Agency

STI Sexually Transmitted Infections

PPRB Pharmacy and Poisons Regulatory Boards
1. **Research activities of a CRN**: The first stage of a clinical trial or indeed any research study is protocol development. There is usually a team involved in developing the protocol but it is really very important that research nurses be included at this stage as they know patients and care pathway better being front liners in clinical care. Approvals by Ethics Committees and other regulatory bodies are required before any study can begin recruiting patients. Some research nurses have the responsibility of completing these application forms and submitting them to the appropriate authorities for review and approval. I have done these in the depression study I conducted.

When approvals come, sensitizations talks of the study to prospective clients, consenting process to the willing participant, clinical protocol specific procedure such as randomization to study arms, specimen collection, clinical care provision and education on adherence to study visits and/or study interventions if any are done by a CRN. I have done all the above in all the 12 studies I have worked.

**Operation research/Monitoring and evaluation**: I have once planned and conducted operational research within the Centre for Acute HIV Vaccine Immunology (CHAVI) study. In this study we used to conduct mass screening whereby every eligible person coming for Sexually Transmitted Infections (STI) care was screened into the study. This was costly and time consuming as we needed to screen thousands of participants in order to identify an Acutely HIV infected (AHI) individuals. I did monitoring and evaluation of the trends in the identified AHI participants. We found that there were certain clinical characteristics and STI syndromes which yielded more AHI patients. This helped the team to work on AHI algorithm score which led us from shifting from mass screening to targeted screening using the AHI algorithms eventually this contributed to the cutting down of costs.

2. **CRN as a nurse educator**: This is done at all stages of research. Education can be in a form of sensitization talks to prospective clients, communities and stakeholder as well as team members. I have done this during preparatory studies of acute HIV infection, Methods for Prevention Packages Program (MP3) studies. Nurse educator role is also an on-going process whenever there is a change in protocol versions. Being placed in a referral Hospital surrounded by health training institution, has given me an opportunity as a CRN to orient and supervise students allocated to the STI clinic. I also work as Continuous Professional Development coordinator for my department where I budget source out trainers and train fellow staff on important topics. This contributes to nursing/medical education thereby improving skills and knowledge of health professionals.

3. **CRN as a Manager**: At research nurse team leader level I have managed staff and resources. I have worked with different cadres of clinical staff of different discipline; doctors clinical officer, nurses, counsellors and support staff who need collaboration, coordination, supervision, leadership, conflict resolution and performance appraisal. I have lead and supervised most study teams.

On resource management a nurse must have financial budgeting and resource management skills for the day to day running of the clinic. I was once assigned to a
section of procurement and ordering of pharmaceutical equipment and resources. This assignment required me to work on daily stock cards for monitoring of monthly consumptions which helped in planning the monthly supplies. In Cryptococcal Meningitis study I took charge of budgeting, ordering and dispensing stipends which required me to acquire and use financial management and budgeting skills.

4. **CRN and the role of generating scientific knowledge for evidence based clinical care**: Nurses contribute a lot in scientific knowledge through collection of credible data and quality control and assurance by checking correctness, completeness and consistency of data. For quantitative data I was assigned as a QA/QC nurse checking data for CHAVI study before faxing and entry. I have also worked in behavioural qualitative studies as an interviewer where tasks of data collection through in-depth interviews recording, translation and transcription. By the end of the transcription data has also to be verified by a senior nurse or a social scientist. I also have done quite a lot of verification of transcripts in HPTN 062, CHAVI 011, MP3 studies under University of North Carolina Malawi Project.

It feels good for a nurse to contribute to science and clinical care whenever a research is done and evidence has been generated to improve patients care. CRNs in their quest to improve on their skills, they also learn research methodologies; they design, conduct and publish their research findings in peer reviewed journals. This contributes to the body of knowledge globally as nowadays we live in a global village. I have also done this in one of the research work I did for my masters’ degree. This same research work has generated more knowledge in the area of depression among HIV infected people receiving care at an ART clinic. This is an under researched area in my country as such the research institution I am working with has planned and is applying for a grant for a large scale depression study among people living with HIV. This has given me job satisfaction as a CRN, a rare opportunity in research unlike clinical care where you evaluate impact there and then when you provide care and service to a patient and you see them getting well after a few days. The impact of the research that I designed, conducted and am working on a manuscript has made me and my institution proud of the contribution of CRNs.

5. **CRN as a clinical care, advocacy and referral system provider**: clinical research is inevitable of clinical care and other support systems. I once worked in Cryptococcal meningitis study which dealt with very ill admitted patients with Cryptococcal meningitis. I also worked in a fertility intensions study among HIV positive women. This included providing services like STI syndromic management, provision of family planning methods and cancer screening and treatment. Those needing more care and services outside our research environment were advocated and referred for such services. I worked in a survey on prevalence of depression amongst HIV positive people at an ART clinic where I screened the patients for depression and suicide among other things. Identified cases were referred to a psychiatric nurse/clinician for continuity of care. For any potential participant with issues and problems that needs other people’s expertise, I have often times as a CRN done the advocacy and referrals.
6. **CRN as a nurse counsellor**: I have worked in research studies involving infectious diseases like STIS and acute HIV infection. There is much counselling sessions going on with individuals, their partners and couples and I had to take the counselling responsibilities and supervision of behavioural intervention counsellors in addition to the general research work.

To conclude it all, a CRNs cut across in clinical research settings. Clinical research Nursing empowers a nurse to work autonomously within a team, hence providing job satisfaction as it offers an element of happiness as you roll your sleeves up and give it your best in your work, it also provides the CRN good sense of Ethics in their actions and finally it gives the nurse an opportunity to be part of change and generation of evidence based clinical care and that is what I am today through the 11 years of working as a CRN at different levels and assignments. I am proud to be a CRN.

References: