The Role of the research nurse:

INTRODUCTION:

Currently research is not part of the nursing curriculum but is being introduced in the form of assignments in varies subjects. Nurses therefore has a very basic idea of what research entails, but there is still a huge gap as to research training in the nursing curriculum. For this reason appropriate training in roles and responsibilities and the different research guidelines are essential for any nurse that enters the area of research. The reasons for nurses making the switch from clinical service to research are varied. It may range from a desire to work better hours, earn a better salary, or seek new opportunities and challenges. Many nurses however, choose research out of curiosity to explore a new aspect of nursing and to further their career.

Clinical research is a team effort. Health care providers of all cadres are needed to ensure the success of any research study. All categories of nurses are increasingly employed into research driven organisations and are an integral part of these multi-disciplinary teams. They have a critical role in recruitment, management and follow-up of participants.

In this article I would like to explore the role of nurses in clinical TB Research and would like to give a personal perspective of my day to day experiences of the role of the research nurse.

Nurses working in clinical research have a specialist focus, they are responsible for the preparation of the site including procurement of supplies and equipment; recruiting and appointing of staff; training of staff; implementation of the study protocol; collection of the data; quality assurance and control as data integrity is of utmost importance for the value of the results of the research and most importantly providing quality care to participants. Experience has shown that not including nurses may harm clinical studies due to poor recruitment; management and follow-up.

Research outcomes depend on the accuracy of data, therefore a focus on detail and the ability to record data meticulously are essential personality traits for research staff. Nurses that enter this field should remember that the care requirements of study participants may differ considerably from those in standard care.

The work of a nurse in research is interesting, varied and full of challenges. In clinical research teams nurses provide clinical expertise, continuity of care and are advocates for the participant and the community. In addition nurses are increasingly managing clinical studies from conception of the protocol to the presentation of the data at a public forum. Once trained, they can also take responsibility for writing protocols and communication with funders, research ethics committees and participants. Therefore apart from the clinical acumen and continued patient care and advocacy, research nurses require an understanding of the research process and terminology, which includes special knowledge of the data collection and study management processes that are part of all clinical trials. They also need to be able to work within a multidisciplinary team with cadres with different skill levels.

Roles and responsibilities of a research Nurse:

File Preparation – put all the documentation needed to complete a study visit in a file prior to the participant’s arrival at the clinic, etc.
Recruitment – this is a process that starts off with identifying where one will find the appropriate subjects, informing the site staff of what the study entails and what patient population is required for the study and then approaching the potential study participants of the study.

Patient preparation – ensure the participant understand what the procedures he/she will have for the visit/s.

Case report form entry – This gets done when all the relevant information is documented in specific forms as requested by the sponsor.

Education – ongoing education is given to the participants regarding the study; medication; possible side-effects of medication; laboratory results etc.

Counselling – this gets done at three sessions prior to the start of ARV’s or one at the start of other medication. The research nurse continues with noting of adherence of medication as well as follow-up visits. Compliance is vital as it will impact on the outcome of the research results.

Informed Consent – this is a process that starts at the first contact with the participant and ends at the end of the study.

**Major roles and responsibilities:**

Quality management – to ensure good data integrity.

Submissions – relevant documentation to all regulatory bodies.

Coordination of research team.

Meetings

Managing operating procedures- see that all procedures are done according to good clinical practice guidelines for research teams.

Regulatory – write reports as requested monthly; six monthly; annually.

Monitoring – prepare files, site for auditing and monitoring.

Training – arrange training for staff and keep record of all training updates on all staff members.

Orientation of new staff.

**Clinical Nurse Practice:**

Nurse in clinical research should also remain registered with national nursing bodies and cannot practice outside the scope of their registration.

In this role nurses need to familiarize themselves with the clinical aspects of the disease as well as the protocol-specific aspects of clinical care. These research nurses are at the frontline of care and often form the interface between the study and the participants, the community and the broader health service. Clinical acumen and patient management skills are an essential skills set. For instance where research includes diagnosis and management of childhood TB, skills such as performing induced sputa or gastric aspirates are essential. Nurses may need to acquire knowledge at a steep learning curve. As a research nurse you also learned to read up a lot; attend workshops, courses and
TB clinical forums to empower you with as much as possible knowledge to give advice to the people who need it.

**Good clinical practice:**

All research staff are trained in the so-called principles of “Good Clinical Practice”. These courses put the research nurse in the local and international frame as well as outline the rights of the participant and the duties of the study staff. The critical issues are respect for the patient’s autonomy, non-maleficence, beneficience and justice. The process of informed consent and ensuring the patient’s anonymity and rights are essential.

**New Ideas may come from Research Nurses**

Often nurses working in the research setting develop a research question they would like to answer, requiring skills to develop a protocol with data collection and analysis plans outlined. It is a daunting task for the uninitiated for instance when the research needs financial support and skills for grants applications are needed.

**Conclusion**

Nurses are increasingly involved in research both as clinical staff and as research investigators. This is a very interesting and challenging field and offers lots of opportunities for growth.