Nurses’ roles in clinical research in developing countries: experiences from Ethiopia

The nursing profession in Ethiopia has seen a remarkable transformation in the past two decades. During this period the need for pre-service educational preparation of nurses for diverse responsibilities beyond the ‘bedside’ was recognized. Among others, the launch of generic degree programs and master’s level training in the various universities in the country has undoubtedly contributed to develop these graduates’ skills in the scientific research methods. In Ethiopia, it could be boldly argued that nurses’ career in research, for various reasons, rarely follows an orderly progression from graduate to post-graduate training. Once obtaining their first degrees only a few pursue their master’s education in the nursing profession and many more join other fields of studies. Other factors such as existing top-down hierarchical relations with other disciplines and apparently few (if any) role models and senior mentors who can spur the young into research also appear to hamper research progress in nursing. However, research skills they’ve acquired through their university education, has contributed to nurses (those who ‘chose’ to remain in the profession as well as those who left) capacity to consume research findings in their profession. In addition, with little or no experience in clinical trials, minimal further relevant training; we’re able to witness what nurses can contribute to research and more specifically to clinical research. This article describes roles nurses played in a facility-based, multi-center randomized controlled trial (RCT) to test the non-inferiority of short-term (7 day) urethral catheterization compared to longer-term (14 day) Urethral catheterization in terms of predicting fistula repair breakdown in Eight African countries.

Obstetric fistula, a result of prolonged, obstructed labour leaves women incontinent, ashamed and often isolated from their communities. It is a debilitating condition affecting approximately 2 million girls across Africa and Asia. Obstetric fistulas predominantly happen when women do not have access to quality emergency obstetric care services. There are numerous challenges associated with providing fistula repair services in developing countries like Ethiopia. These include scarcity of available and motivated medical doctors and surgeons with specialized skills, operating rooms, medical equipment, drugs and funding from local or international donors to support both surgical repair and the all important post-operative care. In 2012-13, in collaboration with Engender Health and United State Agency for International Development
(USAID), the World Health Organization (WHO) coordinated a multicenter trial to examine whether short-term (7 day) catheterization is not inferior to longer-term (14 day) catheterization in terms of fistula repair breakdown on 524 women measured three months following surgery in eight African countries: the Republic of the Congo, Ethiopia, Guinea, Kenya, Nigeria, Niger, Sierra Leone and Uganda. The study concluded that the short term catheterization is accepted as equal treatment outcome as the long term catheterization for fistula repair surgery. Presently in the process of publication, is believed to improve the care of fistula patients in the future.

The study site selected in Ethiopia was Gondar University Hospital, located 748 kilometers north of the capital Addis Ababa. This 200-bed public teaching hospital mostly serves around 4 million rural communities and the poor in the region. The fistula unit is equipped with two operating theaters and 65 beds. Previously, very few small scale clinical trials have been conducted by academicians and other health professionals in the university hospital.

A registered nurse based at Gondar University Hospital served as Research Assistant (RA) in the implementation of what can be considered a larger scale multi-center study. In this position, the RA was responsible for overseeing day-to-day on-site study activities. This included ensuring smooth implementation of the study and safety of study participants as well as checking accuracy and completeness of the data. Follow-up of study participants includes scheduling and contacting participants to remind them of their upcoming follow-up visits; tracing participants who do not return for their scheduled follow-up visit, and distributing transport reimbursements and gifts. Furthermore, the RA was responsible obtaining local regulatory approvals and amendments, eligibility checks, internal monitoring, quality control and responding to queries from WHO data management team.

On the other hand, 10 female nurses also participated as data collectors and clinicians providing care for study subjects. These nurses are middle level professionals with diploma and degree level qualification. Their primary responsibilities include: carrying out a dye test, checking the status of repairs three months after surgery introducing intermittent catheters to subjects who develop urinary retention as well as self-reported urinary incontinence. Training was provided for these nurses before the actual study started. Standardizing and maintain procedures as per the standard operating procedures developed for the study including use of antibiotics (deciding the use of antibiotics in discussion with the RA and physicians) and anti-helminthics, bed rest
versus ambulation, catheter management (e.g. fixation, clearing blockages), sexual activity instructions, perineal and vaginal hygiene, type and timing of bladder training (pelvic floor exercises) and documenting outcomes of procedures.

Nurses played a very crucial role towards the accurate measurement of scientific objectives of the study in a consistent and reliable manner. The quality with which they discharged their responsibilities, collected data and documented procedures was later commended as having greatly contributed to avoid potential confounding in the study. As part of the routine clinical care team which consists of medical doctors, surgeons, anesthetists, physiotherapists and gynecologists, nurses remained the closest in caring to fistula patients, observing and recording individual clinical progresses; standing out not only as the pillars for but also setting good example as to what properly trained and motivated nurses with limited expertise in clinical trials can accomplish.

In closing, the nursing syllabus in Ethiopia is limited in clinical research, there’s a considerable lack of practical experience in clinical trials, as clinical trials in Ethiopia can generally be considered to be in its embryonic stages as well as perceptions that it is ‘too complex’ and a domain only for doctors or other highly trained professionals, have all contributed to the status quo nurses formally occupy in the clinical research arena. Experiences from our study show the pivotal roles nurses can play as part of a research team even in settings where clinical studies are rare. If there is any lesson to be drawn from this, it may be that where there is a considerable scarcity of skilled and motivated doctors and surgeons; clinical trial skills and knowledge as well as chronic shortage of international funding for clinical trials nurses with minimal relevant training can be motivated to be critical members of a clinical research team.