

Clinical Research Nurse involvement to foster a community based transcultural research in RODAM European study

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Abstract. *Background and aim of the work:* The Clinical Research Nurse (CRN) can be considered the fulcrum of clinical studies, being a vital link between patient, principal investigator, study sponsor and administrative staff. The clinical research's way is still long and the contribution that CRNs can provide is crucial. In Italy, a CRN was employed in the study: Research on Obesity & Type 2 Diabetes among African Migrants (RODAM). The aim of the paper is to explore and describe the experience of this involvement. *Methods:* The CRN managed the project in order to gain a complete collaboration from the Ghanaian population. From the first contact, the CRN decided to adopt a transcultural approach with the aim to create a relationship of understanding, mutual trust respect for each other's cultural diversity. The CRN also used organizational, technical and linguistic skills. *Results:* The day-to-day trial management from CRN included the following activities: obtaining local Ethics Committee study approval; recruiting the study staff; planning the study activities; identifying potential study participants; collaborating with the mediators; managing contacts with other RODAM centers; conducting a follow-up of patients. The most important results of CRN involvement have been the empowerment of Ghanaian community and the effective healthcare promotion. *Conclusions:* The project encouraged the Ghanaian community to increase their healthcare awareness and encouraged the Ghanaian population to create new strategies to face the hard health challenges. The CRN is the most versatile and appropriate health professional to deal the entire study.

Key words: clinical research nurse, transcultural nursing, relational and communication skills, Ghanaian community

Background and aim of the work

In 2007 the United Kingdom Clinical Research Collaboration (UKCRC) asserted that Clinical Research Nursing combines the more familiar nursing responsibilities of holistic patient care with the world of clinical research protocols, governance and management (1). The Clinical Research Nurse (CRN) is employed principally to undertake research within the clinical environment. CRNs are highly skilled registered nurses who usually possess at least twelve months post-registration general nursing experience. They

work as members of multidisciplinary study teams that can consist of physicians, pharmacists and staff from other disciplines who have a specific interest in the clinical study, and they are integral to the successful application of research to nursing practice (2). Nursing as a profession tends to focus on care giving, the nature of compassion, and the importance of dignity and respect in the relationship with patients, on the contrary nursing is less often considered in terms of its knowledge base and the research evidence on which practice is based. However, already Florence Nightingale (the nurse who set up the first training school

for nurses more than 150 years ago) emphasized the necessity for nurse education and research to produce a body of knowledge that would underpin nursing as an autonomous profession. Therefore, to fully achieve these ideals, the nurse ‘at the bedside’ must incorporate knowledge and understanding generated by research into their practice. This is not to suggest that all nurses must carry out research, but that all nurses must be “research minded” (3). It is important that nurses question the knowledge and rationale on which they base their practice and, by doing so, seek to develop ways to improve care and patient outcomes (4).

The role of the CRN, within the clinical trials, is complex, multifaceted, requiring leadership and organizational skills (5). It comprises several sub-roles ranging from understanding of the research process and adherence to research-specific legislation and guidelines to coordinate day-to-day trial management, to provide care and support to research participants, to ensure effective communication and negotiation with members of the multidisciplinary clinical team, to obtain ethical and local approval through the relationships with all departments involved with the trial (6). For these reasons, CRN could be considered the fulcrum of clinical trials, being a vital link between patient, principal investigator, study sponsor and administrative staff (7). In the last five years, the CRN’s role has evolved and it has become clearer. The UK government and NHS trusts began to realize the importance of such nursing role. In fact, the latest achievement was the creation of clinical academic research careers (8-10) and programs for graduate nurses, such as the Masters of Nursing in Clinical Research at the University of Edinburgh (started in 2014). It incorporates research practice into the program of study; it aims to encourage nurses to become involved in research earlier in their career and to develop their own research ideas from nursing practice and pre-registration learning (4). The role of the CRN is diverse, rewarding and challenging. It is necessary to view research as being integral to patient care and it adds to the body of nursing knowledge contributing to evidence-based care and improved patient outcomes, so nurses should be encouraged and supported to consider a career in nursing research. The clinical research’s way is still long and the contribution that CRNs can provide is crucial.

A CRN was employed in the Research on Obesity & Type 2 Diabetes among African Migrants (RODAM) study. RODAM is an European Commission project of the Seventh Framework Programme (FP-7) which fund eight partners from four European countries (the Netherlands, Germany, UK and Italy) and one African country (urban and rural Ghana), addressing studies in obesity and type 2 diabetes mellitus (T2DM) in migrant Ghanaians. The main aim of the RODAM study is to understand the reasons for the high prevalence of T2DM and obesity in African migrants by studying the complex interplay between environment (e.g. lifestyle), biochemistry and (epi)genetics and to identify specific risk factors within these broad categories to guide intervention programs and provide a basis for improving diagnosis and treatment.

Undoubtedly, obesity and T2DM can be considered as an epidemic threat to the European and world population (11). The prevalence of obesity has risen up to three-fold in the last two decades. In 27 member states of the European Union (EU) approximately 60% of adults and over 20% of school-age children are overweight or obese. This equates to around 260 million adults and over 12 million children being either overweight or obese, and numbers are increasing fast (12).

For T2DM, there are now estimated about 31 million people living with the condition aged between 20 to 79 in the EU alone (13). This signifies an average EU prevalence rate of 8.6% of the adult population – up from 7.6% in 2003 – a figure which is expected to grow to over 10% by 2025 (13). The rising prevalence of T2DM and obesity has huge consequences both in terms of health care cost and human suffering (14).

Ethnic minority and migrant populations in Europe have been disproportionately affected by both obesity and T2DM compared with the host European populations (15) and this in turn contributes to a widening of health inequalities. The prevalence of adult T2DM, for example, is about three to five times greater compared with the European people (16). They also develop T2DM at a younger age; and they have higher morbidity and mortality from T2DM and related complications such as cardiovascular disease (CVD) than European populations (17). The reasons for these inequalities are only poorly understood, but may in-

volve genetic predisposition (thrifty genotype), migration-related changes in lifestyle and diet (westernization), as well as peculiarities in perceptions and practices (18). Migration from Sub-Saharan Africa (SSA) to Europe is accelerating in the last decades. In 2006, 1.8 million people from outside the EU relocated in the EU; 16% came from Africa. Today, an estimated two to three million migrants from SSA reside in EU countries (19). Contrasting the increasing number of SSA migrants in Europe, the health status and needs of these specific populations remain largely unexamined, and have only insufficiently been integrated into national plans, policies and strategies (20). With increasing migrant populations in Europe, who are also disproportionately affected by obesity and T2DM, it is necessary to address these health problems head on.

Aims

The aim of the present paper is to explore and describe the experience of CRN involvement in the Italian RODAM study site.

Method

Transcultural approach

During the Italian sample recruitment, a CRN was involved. She organized the project in order to gain a complete collaboration from the Ghanaian population. In this way they will be able to achieve a real awareness of the study aims and to disseminate the health information, learned during the project, to their community. For this reason, the CRN's role did not include only the organization of the activities but also an important task of healthcare promotion among the Ghanaian community. From the first contact with the community, the CRN decided to adopt a transcultural approach with the aim to create a relationship of understanding, mutual trust and respect for each other's cultural diversity. Keeping in mind that RODAM project is focused on educational and screening activities within the Ghanaian migrant community, the CRN realized that the Italian National Health System was un-appropriate for the following reasons: National

Health System is highly standardized, it has been designed for homologated users and it mainly focus to diagnose and treat diseases. In this setting, users are forced to observe strict rules fixed by the organization. This type of offering health and social services is not sensitive to the holistic dimension of the person with his feelings of anguish and hope, and with his vision of the world (21). In particular when offered to foreign users this model of health care appear very complex with little flexibility and capacity to give answers to the complexity of the health demand requested by a "different" cultural background (22). For this reason, the RODAM Italian team did not choose the hospital as the place where to offer the project, but they preferred a friendlier environment: the Ghanaian churches. The best places where Ghanaian tradition and culture can be expressed. In this setting the CRN aim was to create a *human care* health model where individuals and not procedures, nor protocols, nor health techniques are at the center of the organization in respect of the needs, the desires, and the values of the beneficiaries. According to Bertolini (23) transcultural health promotion is a process that enables immigrants to gain greater control of their health and improve it, always in accordance with their needs and their values. For this reason, the CRN focused the attention to the conceptualization of *primary prevention* program, something to be addressed to healthy population with the purpose of preventing diseases, removing risk factors and improving the quality of life. The RODAM team fulfilled it through a plenary speech, through fielding the questions and through providing Ghanaians some brochures containing the general information about the diseases and about the project.

Intercultural mediators

Getting in deep touch with such different culture like Ghanaian was not an easy task, so the CRN realized that she needed someone who could help RODAM team in this purpose. She decided to collaborate with intercultural mediators. Intercultural mediation, therefore, is not intended to describe the cultural differences but rather to support and facilitate the relationship between people, especially when this occurs in the field of health. The mediator facilitates the

meeting by bringing out and valuing different points of view. The choice of intercultural mediators was not an easy task. The CRN had to take in consideration not only linguistic issues (not all Ghanaians speak English, especially those from small towns and villages where they speak local dialects), but also the fact that intercultural mediators had to be familiar with the community and could help CRN putting herself in contact with the community in the most productive and positive way as possible. In fact, the role of intercultural mediators goes beyond the problem of linguistic barrier but rather of educating to deal, in a creative way, with the typical and inevitable misunderstandings of intercultural encounter. The CRN selected two young university students, children of couples Ghanaian immigrants who arrived in Italy over twenty years ago. They represented the bridge necessary for proper execution of the project since they were members of the Ghanaian community and spoke correctly both Italian and English - in addition to their dialect - and they were interested in the project, because they saw it as an opportunity to promote health care in their community. The mediators supported the health care RODAM team's work in every phase of the project, helping them in understanding the better way to provide a culturally sensitive education.

Linguistic skills

The communication with the Ghanaian community was one of the most important aspect of the RODAM study and the CRN needed linguistic skills for effective communication with them. A language-appropriate care is often the first and most critical intervention implemented to improve the migrants' experience in the health care system. Research shows that language barriers have a negative effect on access to care and prevention services, adherence to treatment plans, timely follow-up, and appropriate use of emergency departments (20). The RODAM mediators were essentials for the team, because the risk to create prejudices, due to misunderstanding, was very high. Anyway, RODAM team tried to get in touch directly with the community as much possible. They were not able to speak Ghanaian's dialects, but they were able to speak English, the official language of Ghana. Not all

Ghanaians spoke English as their mother language but all of them spoke it enough to understand the team. In this way, RODAM team tried to convey the message that they were really interested in the Ghanaian population and in their health. CRN noticed that, speaking directly with Ghanaians, the team could better understand how participants were feeling during the physical examination (planned in the RODAM study), or if they were showing doubts for some questions or some steps of the physical examination.

Results

The Clinical Research Nurse task was to conduct the day-to-day trial management, ensuring that every part of the RODAM study was conducted according to Good Clinical Practice.

The day-to-day trial management included the following activities:

- (1) Obtaining local Ethics Committee study approval.
- (2) Recruiting the study staff.
- (3) Planning the study activities.
- (4) Identifying potential study participants.
- (5) Collaborating with the mediators.
- (6) Managing contacts with other RODAM centers.
- (7) Conducting a follow-up of patients.

- 1) The CRN role included the control of the study ethics, the presentation of the study to the Ethics Committee and the archive of the study approval.
- 2) The CRN is the person in charge of the study, so she analyzed the professional skills necessary for the study management. She then contacted different health professionals into a multidisciplinary team. She chose a dietitian, a medical fellow of specialization course in hygiene, a medical fellow of specialization course infectious disease, a bio-technologist and a social worker. These health professionals and students were chosen for their different expertise, necessary for the correct performance of the study. They were interest in transcultural medi-

cine, especially in working in a project with a foreign community in their town. The level of enthusiasm and motivation of the team was always very high.

- 3) Before starting the study, the RODAM staff met all together few times in order to share and discuss procedures, decide the start date, identify each member role, and discuss the general organization. The CRN also invited the Ghanaian community leader to attend these meetings: in those occasions, the CRN explained to him the project, the clinical importance of the study and the need for his collaboration. In fact, gaining approval among Ghanaian community leaders, both in Europe and in Ghana, is a highly desirable since this is an important aspect of the Ghanaian cultural tradition. Gaining the collaboration from the leaders means gaining the collaboration from all community. After the starting of the activities the team had periodically a meeting in which they talked about the faced problems, they proposed new ideas for working better and they talked about new communities to be contacted to introduce RODAM study.
- 4) It was a CRN's responsibility to enroll participants onto the research study. First at all, she needed to identify potential study participants, because RODAM study had strict inclusion criteria that had to be respected. CRN went to the communities and she presented personally the project to all the people and she talked about the health care promotion to everybody. Then she invited people respecting the inclusion criteria, to join the project. For all other people she suggested that, even if they could not join the study, they should have a medical examination by their general practitioner, if it was a long time since they did not have it. Moreover, she gave to everybody (not only to study participants) the brochure with the information about obesity, diabetes and cardiovascular diseases. The most important thing she always highlighted the participants, was the fact that she will act as *advocate* for them during all the study time. Meaning that she would always protect their values, their privacy and their choices. These things are part of a CRN's professional responsibility and it is her task to ensure them.
- 5) It has already been explained the importance of working in a transcultural project with mediators. They were useful not only for creating a productive relationship between RODAM team and the participants, and for ensuring a good number of participants, but also for solving most of the problems the team faced. They help RODAM team in logistic problems, for example they found appropriate places where to conduct the project when the churches weren't available or didn't have enough space, but especially they helped participants in understanding the project and in supporting them during the study. In fact, mediators help the participants in filling out the questionnaires, in promoting focus group to talk about the project and to motivate them during all the time of the study.
- 6) RODAM is a multicenter project including the Netherlands, the UK, Germany, Ghana and Italy. A task of the CRN was to take contact with other centers of the same project, in order to be sure to work in the same way in all phases of the study. This is crucial because a lot of researchers work in a multicenter project and the risk of making mistakes, if someone does not follow the procedures correctly, is high. For this reason, it was necessary to take always in contact with other centers and to share with them the Italian team's work. Having a standardized way in performing the project was the most important issue in a multicenter project.
- 7) One of the tasks of a research nurse was to conduct, in those communities the team finished the project, a follow-up of the participants, in order to understand their perceptions about the care they received and about their current health status. This is important because the knowledge of their perceptions makes us understand if our health prevention program was effective, and if people really increased their awareness. During an interview, our Ghanaian mediators told to

CRN that their people do not trust much the Italian National Health System, because they felt misunderstood. Often they do not receive enough explanations and health professional talk with a specific medical language, showing that they do not want to create a relationship with them, and they are often in a hurry, without the time to understand what they are thinking and feeling. Ghanaians were very shy and closed, they spend time just with people from their community and if one person told to the others that he/she was treated badly in the hospital, nobody trusts anymore in health system. For these reason, they prefer to find home solution for their sicknesses or to ask only to Ghanaian health professionals. RODAM staff tried to deliver a culturally tailored health care activity, it means that they worked always taking into account their own cultural backgrounds, biases, and professional cultural norms and incorporating relevant knowledge and interpersonal skills related to the care of patients from different cultural backgrounds (24). In fact, the RODAM team always asked clarifications and explanations to mediators. The team listened to them and did what they suggested to do. During the health promotion activities RODAM staff always tried to explain the concepts, making examples from Ghanaians daily life, from their life style. For example, when the team talked about right and wrong eating habits they took into account only food Ghanaians usually eat. During the physical examination, they used all the precautions necessary, for example they knew the importance of performing women's examinations only by female staff. Even when the CRN explained them their examination results she always took into account what participants think, believe and know about obesity and diabetes, so she always remembered that these pathologies are perceived in a really different way by Italians. Moreover, even the linguistic choices, adopted by the CRN, led to good results; in fact, the mediators told that their community felt in a very positive way the choice to speak in Eng-

lish and told that this choice fostered the great participation in the study.

The result of RODAM team actions and of CRN health care promotion led to a community empowerment. Community empowerment refers to the process by which people gain control over the factors and decisions that shape their lives. It is the process by which they increase their assets and attributes and build capacities to gain access, partners, networks and/or a voice, in order to gain control (25). The person re-gains responsibility in the protection of his/her health. In this way the community is restituted in its dignity and ability to be aware and promote lifestyles. Community empowerment refers to the process of enabling communities to increase control over their lives. "Enabling" implies that people cannot "be empowered" by others. In the health care relationship, it means that people become protagonists in operating choices and they are their own assets (26).

This is what happened in Ghanaian community during the course of RODAM. The community made a gradual improvement in becoming aware about the health topics such as obesity and diabetes, and then developed their own strategies to prevent and control them. At the beginning the general reaction to the project was wary and after the correct information about these issues some individuals became interested and, subsequently, they convinced the community to participate or at least to talk about the RODAM issues all together. After the end of the project, the community was more aware and so they considered it appropriate to talk about it with other Ghanaian communities, which contacted us to get more information and to take part in the project. Interestingly many participants, or their relatives, after taking part of the project, went to their doctor for a medical checkup or asking for nutritional and physical therapy support. Small but important signs of community empowerment!

By way of information, we report that 118 Ghanaian migrants (72 males and 46 females) were recruited in the Italian sample. Median age was 41 years. In 63% participants migration time was after 1/1/2000. Prevalence of co-morbidities were: Obesity 23%, Hypertension 36%, Diabetes 7%, peripheral vascular disease 29%, Proteinuria 5%, Multimorbidity 45%. Independent predictors for multimorbidity were: male gender

(OR=0.3, CI: 0.13-0.67), age >55 years (OR=8.55, CI: 1.53-59.05) after correction for age group categories and migration time.

Discussion and conclusion

In RODAM study, the CRN role was crucial. The RODAM team would never gain a wide participation or an effective health care promotion if CRN did not act with those strategies. It was essential to operate with a transcultural approach; it was essential to choose and entrust mediators. It was essential to involve the community leaders and the second generation of migrants in order to help the team to better understand how to deal with Ghanaian community. It was essential that CRN had linguistic, technical and organizational skills, in order to manage the trial in several perspectives. The RODAM team also learned that Italians cannot think that the health needs of a foreign community, different for language and culture, are the same as ours. The Italian today's society needs cultural competent health services, where the health professionals are able to communicate not only in Italian language, where the intercultural mediators are always present, and where the individual is not isolated from his cultural and social context. The migrants health is still a difficult objective, given the difficult social situation that involves them; and the social obstacles they are experiencing now (real or perceived discrimination, lack of Italian language knowledge, lack of integration with Italians etc.) could become health obstacles. The RODAM experience showed that the second generation of migrants could be a source to prevent this from happening. The methodology used in RODAM project leads the team to state that the collaboration with the mediators of second generation was really effective and that without their support, collaboration and trust RODAM study would not obtain the same results.

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