



The role of the clinical trial nurse in Italy

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A B S T R A C T

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Purpose: To assess the role of the Clinical Trials Nurse (CTN) and to evaluate the quality of the job performed by Clinical Trials Nurses (CTNs) in Italy.

Methods: The study design was descriptive. The sample included 30 CTNs in Italy who were involved in conducting clinical trials in the last years. Respondents completed the Italian Clinical Trials Nursing Questionnaire (CTNQ) developed to measure frequency and importance of clinical trials nursing activities. Data analyses included descriptive statistics, Student's *t*-test and Chi-Square test.

Results: Thirty out of 34 CTNs consented to participate. Respondents were more involved in the experimental drug management, in the protocol implementation and, partially, in the informed consent process. CTNs have a marginal position with respect to the protocol assessment and planning, subject recruitment, data management. CTNs reported high rates for the importance evaluation. Number of years in the nursing role was significantly associated with data management related activities ($p = 0.016$). Items with minor response rate differences between frequency and importance were not statistically significant (p values ranging from 0.087 to 0.911). The CTNs reported to be autonomous and competent; however, they lack and/or do not perform some nursing-related responsibilities and/or activities.

Conclusions: Although CTNs are not involved in all of the activities listed on the CTNQ, most of them are fully aware to be a key member of research teams. Overall, the Italian CTN role is mostly practical task-oriented and focuses little on data management and organizational activities.

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Introduction

Clinical trial is one of the final steps of a long and careful research process. According to the National Cancer Institute (NCI), clinical studies are carried out on cancer patients to investigate whether new promising approaches to prevent, diagnose or treat cancer are both safe and effective (NCI, 2008). As cancer has become a major concern worldwide, oncology is now one of the most investigated medical fields.

In Italy the number of clinical trials has increased considerably over the last six years; and data from the National Monitoring Centre on Clinical Trials of Drugs (Osservatorio Nazionale sulla Sperimentazione Clinica dei Medicinali [OsSC]) report that 4465 clinical trials were registered between 2004 and 2009 (OsSC, 2010). It is worth mentioning that whereas, phase III trials have progressively decreased since 2005, falling below 40% in 2009, phase I and

II studies rose to 43.5% of the total number of registered studies in the same year. Most of such studies were multi-centered (80%), international (74.3%) and/or sponsored by pharmaceutical companies (63.5%). In Italy, as in the rest of the world, oncology is nowadays the most investigated therapeutic branch (29.4%) (OsSC, 2010); indeed, it was estimated that in 2008 approximately 250,000 Italians were diagnosed with cancer and that in 2006, 122,000 people died of cancer (AIRTUM Working Group, 2009).

Clinical research is a long and complex process involving large numbers of patients in a wide variety of clinical settings, and anecdotal evidence suggests that Clinical Trials Nurses (CTNs) are paramount both in giving optimal care to patients and their families, and in successfully designing, implementing, and evaluating clinical trials (Jenkins and Hubbard, 1991).

Although the role of CTNs has not as yet been greatly looked into in Italy, literature from the UK and the USA offers considerable insight into their position and many authors (Hubbard, 1982; White-Hershey and Nevidjon, 1990; Eaton and Pratt, 1990; Cassidy and MacFarlane, 1991; McEvoy et al., 1991; Wheeler, 1991; Arrigo et al., 1994; Berry et al., 1996; Di Giulio et al., 1996; Rosse and Krebs,

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1999; Coulson and Phelan, 2000; Ocker and Plank, 2000; Barrett, 2002; Carlson et al., 2005) and organizations of oncology professionals such as the Oncology Nursing Society (ONS) (Klimaszewski et al., 2008) have reported on how the role of CTNs has developed to include and integrate organizational, clinical and ethical responsibilities.

Regarding ethical responsibilities, Davis et al. (2002) identified three different CTN advocacy roles and described the commitment required by each: in order to address and balance the rights of the patients, to ensure the protection of research subjects, and to guarantee the quality of clinical studies. As a direct result of both educational and certification programmes in the research area, Deininger (2008) describes how CTNs have both the knowledge and the skills required in supporting and monitoring both the integrity of studies and the safety of patients.

Unlike other European and American countries, where the role of the CTN is well acknowledged, in Italy this specific nursing role is relatively new and has only just begun to develop and to spread into the area of clinical research in oncology (Bryce, 2008). The overall purpose of this survey was to delineate the role of the CTN in Italy, with a two-fold focus on (1) role assessment and (2) quality of job performance.

Methods

A nationwide survey for Italy was carried out among oncology CTNs with the aim of validating the national version of the Clinical Trials Nursing Questionnaire (CTNQ). Italian CTNQ validation results, including tests of validity and reliability, are reported elsewhere (Catania et al., 2008) and described briefly in the Instrument section below. For the current study, gathered information was further analyzed in a specific attempt to delineate the role of the CTN in Italy.

Sample

The study sample comprised oncology CTNs working at cancer hospitals located in northern, central and southern Italy.

All 34 CTNs listed in the Libro Bianco dell'Oncologia Italiana (Associazione Italiana Oncologia Medica (AIOM, 2004) - an ongoing

census compiled by the National Association of Medical Oncology (Associazione Italiana di Oncologia Medica [AIOM]) regarding Italian cancer centres - were duly contacted.

Instrument

The instrument used in this study was the validated Italian version of the CTNQ (Catania et al., 2008) originally developed by Ehrenberger and Lillington in 2004 (Ehrenberger and Lillington, 2004) to measure frequency and importance of clinical trials nursing activities. For the Italian validation of the CTNQ, a total of 30 CTNs were recruited from different areas in Italy. Linguistic and content validation were accomplished through a forward translation, a backward translation, and a review by experts in clinical trial nursing. An analysis of the internal consistency showed a Cronbach α coefficient of 0.98 on the frequency scale and 0.96 on the importance scale. A comparison of the test-retest reliability was conducted within a 2-week interval on a sample of 10 CTNs out of the 30 recruited participants, and an overall κ coefficient of 0.98 was obtained on the frequency scale while 0.99 was obtained on the importance scale (Catania et al., 2008). The Italian CTNQ is structured into five areas divided into a total of 12 sections featuring 149 items in total (Table 1). In order to define (1) the frequency with which CTNs perform each activity and (2) the importance of each activity for the safety and effectiveness of nursing practice, the items listed in sections 1–8 are scored by respondents through reference to two separate five-point Likert-style rating scales. Section 9 assesses the level of perception of the professional nursing role, as respondents choose one out of six agreement/disagreement options. Sections 10, 11, and 12 investigate nursing role, organizational characteristics and demographics, respectively (Table 1).

Procedure

A description of the study, and instructions for completing the study questionnaire were emailed to potential participants.

Out-going e-mails clearly stated that, by returning a completed questionnaire, respondents were consenting to the survey.

Table 1
Structure of the Italian CTNQ.

Area	Topic	Section (n° of item)	Content	Score
1	Clinical research activities/responsibilities	1 (15)	Protocol Assessment	Frequency Scale: –0 (never, not part of my role) –1 (once or twice) –2 (occasionally, as needed) –3 (repeatedly) –4 (extremely frequently) Importance Scale: –0 (not important) –1 (somewhat important) –2 (important) –3 (moderately important) –4 (very important)
		2 (14)	Protocol Planning	
		3 (13)	Subject Recruitment	
		4 (14)	Informed Consent Process	
		5 (10)	Investigational Product	
		6 (23)	Implementation/Evaluation	
		7 (18)	Data Management	
		8 (10)	Nursing Role Performance	
2	Professional Perception	9 (10)	Nursing Role Perception	– Strongly Agree – Agree – Strongly Disagree – Disagree – Undecided – Not Applicable Not Applicable
3	Nursing Role Characteristics	10 (11)	Highest degree completed; Years of experience; Certification.	Not Applicable
4	Organizational Characteristics	11 (8)	Primary work setting; Assigned position title; Opportunity for advancement.	Not Applicable
5	Demographic Information	12 (3)	Gender, Age, Geographic Region	Not Applicable

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