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Editorial

The Pandemic from COVID 19: a Lesson that we must not forget

Leopoldo Sarli
Department of Medicine and Surgery, University of Parma, Italy

This issue of the Acta Biomedica for Health Professions magazine was prepared during the lockdown, imposed by the Italian government, for the containment of COVID 19.

This acute syndrome was initially thought to concern only the respiratory system and for this reason it has been defined as SARS CoV-2. To date, however, we know that COVID 19 affects numerous areas of the body (1,2). In Italy, the first western country where the infection manifested itself in the form of an epidemic, we listened to health bulletins that resembled war bulletins, which reported on thousands of people affected by the virus and hundreds of dead people.

We therefore witnessed the organizational upheaval of our hospitals, the transformation of operating theaters into resuscitation rooms, the reopening of wards closed for some time because they were obsolete and even the construction, in a few days, of entire hospitals. We had to wear masks and we witnessed scenarios that, during our life, we had never seen, such as, for example, rows of military trucks carrying coffins.

We have witnessed, and some of us have experienced it in the front line, a sudden and violent catastrophe that many have called a "Tsunami".

We have often heard that many things will change in the near future, precisely because the experience we have lived has constituted a "lesson" that has taught us many things that we had not considered and that we should take into account.

Our editorial staff worked from home, read and selected scientific articles thus allowing the publishing of this issue. At first, it seemed to us that the articles that had been sent to us dealt with outdated topics and with scientific discussions contextualized in another "epoch", but then we understood that it was not so. Reading those articles, during the pandemic, forced us to re-contextualize the scientific discussion, instinctively led us to immerse the contents of what had been written before the appearance of COVID 19 in a "present" different from "before". In other words, it forced us to make comparisons and reflections, imagining a different "after", during which those topics took into account what the pandemic was showing us.

Within this perspective, the article by Dionisi et al. "**The application of the Theory of Planned Behavior to prevent medication errors: a scoping review**" becomes extremely current. This contribution deals with the prevention of errors in healthcare, through the application of the Theory of Planned Behavior. It emerges that an individual's behavior is often dictated by the motivation to please others' expectations and their approval. This willingness to please sometimes constitutes a barrier to action. On the contrary, the barrier to action is sometimes overcome if the individual perceives that he/she can also face difficult tasks because he/she is convinced he/she can do it (self-efficacy).

These beliefs can be the result of mistakes that could be prevented. How can we not think, reading this article, about the action of colleagues who, despite the risks caused by inevitable mistakes, have faced a situation never experienced before, without the possibility of applying the Theory of Planned Behavior. How can we not think of the slogan that has been written everywhere, even on the personal safety devices (PPE) of health professionals: "everything will be fine". Many and perhaps too many, professionals of the Italian health system, such as nurses, doctors, socio-health workers, have lost their lives in the exercise of their profession, to perform their duty, that is to save human lives, and for this they have been defined heroes.

The contributions of Marcotullio et al. "**NANDA-I, NIC, and NOC taxonomies, patients' satisfaction, and nurses' perception of the work environment: an Italian cross-sectional pilot study**" and that of Bonetti et al. "**Nurses' interventions to promote cancer patient engagement and related outcomes: a systematic review and meta-analysis protocol**", read in light of recent events, stimulate reflections on how difficult collaboration with patients, and therefore the therapeutic contract, becomes when emergency situations explode and of generalized panic, which force politics to overshadow some fundamental human rights, to guarantee the primary right to individual and collective health.

The difficulty in relating to the patient during the emergency (3) emerged clearly in cases where the need for social distancing reduced the professional-patient and professional-relative communication to short telephone interviews, even in the case in which they had to communicate bad news to families. And this difficulty emerged even more in cases where the health care worker had to communicate with the patient by wearing individual safety devices (PPE), completely altering the possibilities of mutual use of sight, touch, hearing, smell, which contribute significantly to communication. The pandemic has taught us that communication between health professionals, belonging to any professional category, and with patients or relatives is crucial in the perception of the quality of the services provided and, sometimes, also in the determination of the outcomes.

The article by Gallazzi et al. "**The Medical Emergency Team in Italy**" and Lupo et al. "**The use of an automatic defibrillator by non-sanitary personal in sport areas: an Observational Study**" lead us to reflect on another important lesson, given to us by the experience of the pandemic, which concerns the utility, I dare say the indispensability, of the inter-professionalism in modern healthcare (4).

The PPE did not allow us to distinguish the professional category to which the members of the professional teams belonged, who worked in the reanimations trying to save the most severe COVID patients. What we all perceived is that, never as in this circumstance, professional groups acted as a team, made available and shared their professionalism to allow the team to function at its best. This is because they helped each other and comforted each other. To their work, that of the volunteers was also added, "ordinary people", who helped, as far as possible, to ensure that the patients reached those specialized teams.

This magazine has always dealt with the issue of inter-professionalism and interdisciplinarity which allow each professional to make his/her skills available and guarantee the assisted person to be able to benefit from all scientific, medical, psychological, communicative and logistical resources, indispensable for modern and quality healthcare. The medical-scientific knowledge must therefore be accompanied by what we call "Medical Humanities", which allow the "care management" of the assisted person.

It is precisely on the theme of "care" that Bertuol et al. focus on in their articles: "**The process of developing the Professional Identity of the Case Care Manager: A Grounded Theory**", Artioli et al. "**The impact of a" narrative interview "intervention in oncology. A study protocol for a feasibility study**" and, in the pediatrician field, Strini et al. "**Transition of care in pediatric oncohematology: a systematic literature review**". Also this topic, inserted in the context in which we have lived these last months, takes on particular importance. The infection of the new coronavirus has in fact highlighted the limitations of a national health system, considered an excellence all over the world, above all for the fact that it can be reached almost free of charge by the whole population and for having as reference points for acute care, hospitals of the highest scientific and technological level.

The limitations that have emerged concern the territorial health organization, which has significantly reduced in recent years, with repeated cuts in money and personnel with less efficient assistance for vulnerable people and often affected by multiple chronic diseases. The Italian regions in which primary health care managed by the territorial structures had obtained more funding and fewer staff cuts responded better and faster to the spread of the infection. Nations such as China (Hong Kong) and South Korea which, after previous episodes of serious epidemic, such as the SARS of 2003, brought health care to workplaces and living places of the population, have addressed this new pandemic in a much more effective and less disastrous way in terms of loss of life.

This observation constitutes a further lesson provided by COVID-19, namely that the future of the health organization of western countries cannot neglect the strengthening of territorial assistance systems, paying more attention to the assistance of the family and the community (5). The measurement of the risk of chronic diseases and the risk of contagion will therefore favor prevention. An example of the effectiveness of these principles is reported in the article by Guasconi et al. "**Use of traffic crash as a risk assessment scale in hospitalized seniors: a perspective observational study**" and in the article by Miraglia et al. "**Italian pilot version of DEMOQL-PROXY. Content and Face validity: a methodological bridge for a future Italian validation** ".

Since its foundation, this magazine gives space to contributions that emerge from the project work carried out by the students of all the masters organized by the work group with the aim of revitalizing the attention to scientific research of professionals in the health professions, but also with the aim of using the collaboration of the students to collect suggestions for the qualitative improvement of the training offer.

The contributions of Gemellaro et al. "**Evaluation of midwifery students' satisfaction with regards to clinical internship**", by Cosentino et al. "**The VaRP Project: qualitative evaluation of the training effectiveness of post-graduate specialization courses for health professionals**", and Rubbi et al. "**Effectiveness of a video lesson for the correct use in an emergency of the automated external defibrillator (AED)",** are an example of the attention paid to measuring the quality of the training offer.

This attention is even greater today. The closure of the university environments, which became necessary to contain the spreading of the pandemic, forced the study courses that wanted to continue the training course to convert traditional teaching into presence in distance learning (6). This change required an adaptation by both teachers and learners, who in many cases had never previously used digital platforms for teaching, but at the same time allowed students and teachers, often in collaboration with each other, to significantly accelerate the processes of change in the educational organization which involve the use of information technology, the object of experimentation and evaluation analysis for several years already.

The article by Marra et al. "**Third mission and relationship system with local communities: experience at the Nursing Study course University of Parma**", written before the pandemic arrived in Italy, focuses on the role of the third mission of the university health departments. This role, the advantages of which had already been highlighted in the article, was, in this case too, exalted by the events linked to COVID 19. Universities and research centers all over the world began to collaborate assiduously to join forces, in the attempt to find therapeutic solutions or vaccines to counter COVID-19 infection as quickly as possible.

Historic and inevitable competitiveness seems to have been put aside, in order to work in the service of citizens. This service perspective has also found impetus in international cooperation, for the exchange of experiences and information.

In the days in which this magazine issue is about to be published, the health situation in Italy has significantly improved. As a consequence of the progressively comforting data, which are provided by the Istituto Superiore di Sanità (National Health Institute), many restrictions have been abolished and social distancing has been reduced. However, we must not forget that many outbreaks of infection are still active in many regions of the world and that the infection can recur. It will therefore be very useful for everyone to take advantage of the lessons that this exceptional event has provided to the whole community of health workers and professionals.

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The medical emergency team in Italy: an overview of in-hospital emergencies response

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Abstract. *Background and aim*: Medical Emergency Team (MET), implemented in many hospitals worldwide, aims to improve the safety of in-hospital patients whose condition is deteriorating. This study describes MET presence and organization in the Italian National Healthcare System Hospitals. *Methods*: A national survey with an online questionnaire was performed. The questionnaire, created ad hoc, was sent by e-mail to the nursing coordinators and MET referents of the Hospitals affiliated to the Italian National Healthcare System with an Anesthesia and Intensive Care service. *Results*: One hundred-ninety-seven hospitals were interviewed (36.2% of the whole national network). A dedicated MET, composed at least by an intensivist and a nurse, was present only in 118 cases (59.9%). The team was composed by a non-dedicated staff (67.8% of doctors, 69.5% of nurses) and a minimum shared standard of education for the nurse component was absent. One third of the estimated hospitals did not use a warning score for emergency call activation. *Discussion and conclusion:* This survey showed a heterogenous and often lacking organization of in-hospital emergency management in Italy. MET system needs to be implemented in terms of presence in the Italian hospitals, and standardized for personnel structure and training, and equipment availability. A broader study is necessary to compare our data with those of other European Countries to better identify the specific areas which need to be improved more promptly. (www.actabiomedica.it)

Key words: In-hospital emergency, Rapid Response System, Medical Emergency Team, Nurse, Survey

Introduction

The absence of an organized system able to face in-hospital emergencies outside the intensive care unit (ICU) or emergency room (ER) may result in a high risk of potentially preventable life-threatening injuries to patients, with an increased rate of death or unfavorable outcomes (1, 2).

One of the nurse's main working tasks is the vital signs monitoring, which is essential for the timely detection of patients' clinical deterioration (3-6). It has been reported that patients start to deteriorate several hours, i.e. 6.5 hours in median, before the occurrence of an unexpected life-threatening acute event or a cardiac arrest (7).

A rapid response system (RRS) is defined as "a whole system for providing a safety net for patients who suddenly become critically ill and have a mismatch of needs and resources" (8). There are four components of a RRS: an afferent limb, which identifies the deteriorating patient and escalates care, an efferent limb or the responding team, a process improvement arm, and a governance/administrative structure (8).

In 2006, an International Consensus Conference (9) proposed standardized definitions and suggested RRS as a model of rational approach for in-hospital emergencies. RRS refers to the whole system of rapid response, which may consist either of a medical-nursing team or medical emergency team (MET), with high skills in resuscitation and care of critical patients, or of a first intervention team composed of a critical care nurse and defined as rapid response team (RRT), with subsequent medical intervention if needed (8, 10). The composition of these teams is tailored to the Institution's goals and resources, the team's aims, and the severity of illness in the patients it would assess. Thus, a great heterogeneity is present among hospitals (11).

A RRS able to early recognize vital signs alteration and to perform appropriate interventions is therefore crucial for patients' clinical outcomes (12). For these reasons, it is considered an important part of the chain of prevention for in-hospital emergencies (13). In the majority of the studies, the introduction of a RRS resulted in an overall reduced rate of unexpected cardiac arrest outside ICU, unscheduled critical care admissions and hospital mortality, although these findings remain controversial (12, 14-20).

METs are rapidly gaining acceptance in the United States, Australia and Europe and several international guidelines and recommendations have been developed (21, 22). In Italy, guidelines on the implementation of MET have been issued jointly by SIAARTI (Italian Society of Anesthesia Analgesia Reanimation and Intensive Care) and IRC (Italian Resuscitation Council) in 2007. The purpose of SIAARTI-IRC recommendations was to delineate a shared program for a gradual improvement of multidisciplinary and multi-professional response systems for intra-hospital emergencies (23). Despite all these efforts, no data are currently available from the literature about the actual organization and implementation of METs in Italian hospitals.

Aim

Aim of this study was to describe MET implementation in the Italian National Healthcare System Hospitals, focusing on activity, organization, composition and education of the team members.

Methods

Study design

A survey was conducted using an online questionnaire Google Docs (Copyrigth 2018. Google LCC, Mountain View, California) from 27th of July 2018 to 10th of January 2019. The coordinating center was the General ICU of Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico of Milan – University of Milan.

Instrument

The survey consisted of a questionnaire created ad hoc and composed of 7 questions if MET was not present in the hospital or of 24 questions if MET was present exploring: the participating hospitals characteristics (9 questions), MET organization (6 questions), activation (5 questions) and equipment (4 questions). The complete questionnaire can be found in Table 1.

Participating centers

Inclusion criteria were affiliation to Italian National Healthcare System and presence of an Anesthesia and Intensive Care service. In Italy, an official list of these hospitals is not available, so a thorough research on the Internet and on GiViTI (Italian Group for assessment of intervention in ICU) (24) and Intensiva 2.0 (25) websites was performed. GiViTI is an ICU group born with an epidemiologic mission while Intensiva 2.0 promotes the humanization of the care in ICU. ICU nurse coordinators and MET referents were invited to participate to the survey, both via direct email invitation and through the Italian Critical Care Nurses Association (ANIARTI) digital media (website, Facebook, Twitter) and on Nurse24.it®, nursing focused website.

Data analysis

Data analysis was performed on aggregated form with a descriptive statistic approach, using Microsoft Excel (Copyrigth 2018 Microsoft Corporation, Redmond, Washington). Stata 13.1 (StataCorp, College

Table 1. The questionnaire

1) Select your Region:
   - Name of your Region
2) Select your hospital:
   - Name of your hospital
3) Type of hospital:
   - Not university hospital
   - University hospital
4) Number of hospital beds:
   - Number of beds
5) In your hospital is there a doctor for the management of the in-hospital emergency?
   - Yes
   - No
6) Do you have an emergency team whose minimum composition is an intensivist doctor and a nurse?
   - Yes
   - No
7) If present, do you consider this emergency team useful?
   - Yes
   - No
8) If not present, do you believe that this emergency team should be necessary?
   - Yes
   - No
9) How long has the emergency team been present?
   - Number of years
10) When is the emergency team on?
   - Monday – Friday H12 diurnal
   - Monday – Friday H12 nocturnal
   - Monday – Friday H24
   - Monday – Sunday H12 diurnal
   - Monday – Sunday H12 nocturnal
   - Monday – Sunday H24
   - Saturday – Sunday H12 diurnal
   - Saturday – Sunday H12 nocturnal
   - Saturday – Sunday H24
11) When the emergency team is off, who carries on its functions?
   - The emergency team is always on
   - An intensivist doctor
   - A doctor
12) Which are the nurses' emergency team shifts?
   - Shift morning/afternoon/night
   - Shift H12 diurnal/nocturnal
13) What are the educational courses needed to be an emergency team nurse?
   - Years of working experience in critical care area
   - Course BLSD/PBLSD
   - Course ALS/ACLS
   - Course ATLS/ATCN
   - Course managed by the local hospital
   - None particular criteria
14) In which situations is the emergency team nurse involved?
   - Emergency situations
   - Execution of planned invasive maneuvers
   - For consulting

15) What wards do the emergency team nurses come from?
  - Intensive care unit
  - Emergency room
  - Other critical areas (high intensity of care wards of medicine or surgery)
  - From any wards, no particular criteria

16) Is the emergency team staff dedicated to this service or do they carry out other activities at the same time during the shift?
  - Intensivist doctor dedicated
  - Intensivist doctor not dedicated
  - Nurse dedicated
  - Nurse not dedicated

17) Where is the emergency team waiting for activation?
  - Intensive care unit
  - Emergency room
  - A dedicated room in the hospital

18) What warning score are used in the wards?
  - None
  - Single parameters systems – MET (Medical Emergency Team)
  - Multiple parameter systems – PART (Patient At Risk Team)
  - Aggregated scores systems – MEWS (Modified Early Warning Score)
  - Other systems

19) How is the emergency team alerted?
  - Any telephone
  - A dedicated telephone
  - Radio
  - Intercom
  - Beeper

20) Is every hospital ward equipped with a cart for emergencies?
  - Yes
  - No

21) What kind of devices has the emergency team available?
  - Monitor defibrillator
  - Bag with drugs
  - Infusion pumps
  - Oxygen tank
  - Suction unit
  - Ultrasound
  - Automated CPR device

22) Who check the emergency team devices?
  - Intensivist doctor
  - Nurse
  - Healthcare assistant

23) When are the emergency team devices checked?
  - At the beginning of every shift
  - Weekly
  - Monthly

24) How are nursing activities shared between the ward and the emergency team nurse?
  - The emergency team nurse replaces the ward nurse
  - The emergency team nurse and the ward nurse cooperate sharing their roles independently
  - The emergency team nurse and the ward nurse cooperate sharing their roles according to hospital procedures

25) Does the emergency team nurse record the nursing activities he/she carried out?
  - No
  - Yes, in the ward medical record which asked for the emergency team intervention
  - Yes, in a specific emergency team medical record

Station, TX, USA) was used for chi square test to evaluate relationships between categorical variables.

Ethical considerations

The study protocol was approved by the Internal Review Board of the Foundation IRCCS Ca' Granda Ospedale Maggiore Policlinico of Milan – University of Milan (12/5/2018). The survey was conducted on a voluntary basis and on anonymous form. The only available reference was the name of the Hospital, in order to perform a regional analysis and to exclude duplicate answers.

Results

Five-hundred and forty-four hospitals met the inclusion criteria and were invited to participate. During the study period, 246 questionnaires were completed. After duplicate answer exclusion, a total of 197 questionnaires from 544 hospitals (36.2%) were included in the analysis. The characteristics of the participating hospitals are reported in Table 2.

Of the 197 participating hospitals, 121 (61.4%) were from Northern regions, 37 (18.8%) from Central regions and 39 (19.8%) from Southern ones. The regional distribution of participating hospitals is showed in Table 3.

Table 2. Characteristics of the 197 participating hospitals

Italian Regions:	
north	121 (61.4%)
center	37 (18.8%)
south	39 (19.8%)
Type of hospital:	
not university hospital	156 (79.2%)
university hospital	41 (20.8%)
Number of beds:	
≤ 500	143 (72.6%)
501 – 999	32 (16.2%)
≥ 1000	22 (11.2%)
Presence of MET:	
yes	118 (59.9%)
no	79 (40.1%)

The majority of questionnaires (143; 72.6%) came from small hospitals (≤ 500 beds), while medium and high-volume hospitals were less represented in the survey: 32 (16.2%) had between 500 and 999 beds, and 22 (11.2%) more than 1000 beds.

In all (100%) participating hospitals an emergency service was present, but a MET composed of at least a nurse and an anesthesiologist was present only in 118 cases (59.9%), with a higher percentage in Norther regions (66.1%) compared to Central and Southern regions (48.7% and 51.3% respectively). A MET service was present in 143 (72.6%) hospitals with less than 500 beds. MET was also more present in non-university hospitals (61.5%) compare to university hospitals (53.7%) ($p = 0.3596$).

In the majority of cases (61; 51.7%) MET was only recently implemented (≤ 10 years), while some hospitals had a longer experience: 40 (33.9%) between 10 and 20 years, and 17 (14.4%) more than 20 years.

Table 3. Regional distribution of participating hospitals

Italian Regions	Number of interviewed hospitals	Number (%) of replying hospitals
Abruzzo	11	2 (18.2)
Basilicata	8	2 (25.0)
Calabria	16	2 (12.5)
Campania	47	4 (8.5)
Emilia Romagna	43	10 (23.3)
Friuli Venezia Giulia	11	5 (45.5)
Lazio	29	12 (41.4)
Liguria	17	5 (29.4)
Lombardia	88	57 (64.8)
Marche	13	2 (15.4)
Molise	6	1 (16.7)
Piemonte	40	17 (42.5)
Puglia	42	11 (26.2)
Sardegna	23	3 (13.0)
Sicilia	43	4 (9.3)
Toscana	39	12 (30.8)
Trentino Alto Adige	14	4 (28.6)
Umbria	10	4 (40.0)
Valle d'Aosta	1	1 (100.0)
Veneto	43	12 (27.9)
Total	544	197 (36.2)

Almost all (91.1%) respondents working in hospitals without MET reported that the implementation of this service in their structure would be necessary and who had MET considered it useful (99.2%).

MET service was active on a 24/7 basis in 84.8% of hospitals. In the other cases (15.2%), an anesthesiologist managed emergency calls during the hours when MET was not active (mostly night hours and weekends). MET organization is reported in Table 4.

Table 4. MET organization

When the emergency team is on:	
always (7d/week)	100 (84.8%)
only diurnal (7d/week)	5 (4.3%)
only nocturnal (7d/week)	2 (1.7%)
always on working day (5d/week)	3 (2.5%)
diurnal only on working days (5d/week)	3 (2.5%)
nocturnal only on working days (5d/week)	2 (1.7%)
only on holydays	3 (2.5%)
MET nurses' shifts:	
morning-afternoon-night	100 (84.7%)
h12 diurnal-nocturnal	18 (15.3%)
MET nurse's educational courses:	
years of working experience in critical care area	83 (70.3%)
BLSD/PBLSD course	74 (62.7%)
ALS/ACLS course	41 (34.7%)
ATLS/ATCN course	9 (7.6%)
course managed by the local hospital	25 (21.2%)
none particular criteria	12 (10.2%)
Situations in which the MET nurse is involved:	
emergency situations	118 (100.0%)
execution of planned invasive maneuvers	30 (25.4%)
for consulting	26 (22.0%)
Wards the MET nurses come from:	
intensive care unit	98 (83.1%)
emergency room	25 (21.2%)
high intensity of care wards of medicine or surgery	15 (12.7%)
from any ward	4 (3.4%)
MET staff dedicated to this service or not:	
intensivist doctor dedicated	38 (32.2%)
intensivist doctor not dedicated	80 (67.8%)
nurse dedicated	36 (30.5%)
nurse not dedicated	82 (69.5%)

In all participating hospitals, MET was composed by an anesthesiologist and a nurse. In most cases MET nurses worked in ICU (98 hospitals, 83.0%) or ER (25 hospitals, 21.2%). The MET nurses' emergency training and education was extremely variable among the centers. In 83 hospitals (70.3%) the major selection criteria was the years of working experience in ICU/ER. Basic life support - Pediatric Basic Life Support (BLSD - PBLSD) and advanced life support (ALS or ACLS) training were mandatory in 62.7% and 34.8% of cases, respectively. An in-hospital MET training course was activated in 21.2% of cases, while in a minority of hospitals (12, 10.2%) there were no specific selection criteria for MET nurses.

MET nurses were involved in all emergency calls and in many hospitals they were also involved in some elective situations, such as execution of scheduled invasive maneuvers (25.4%) or non-urgent consultations (22.0%).

MET was composed by a dedicated anesthesiologist in 32.2% of hospitals and by a dedicated nurse in 30.5% of hospitals. In the other cases, MET staff was employed in other hospital activities during the regular working shift. The MET organization with non-dedicated staff was more evident in non-university hospitals (77.1%) compare to university hospitals (45.5%) ($p = 0.0031$).

In most cases, MET staff remained in ICU (102, 86.4%) or ER (20, 17.0%) waiting for activation. One hundred and three (87%) hospitals had a dedicated number for MET activation.

MET activation was triggered by patient physical status deterioration, detected through validated single or multiple parameter scoring systems (MET, PART, MEWS, NEWS or other) in 77 hospitals (65.2%), while in the remaining 41 hospitals (34.8%) ward staff requested MET intervention on the basis of a subjective evaluation of the patient's conditions. MET activation is described in Table 5.

In most participating hospitals (113, 95.8%) an emergency cart was present in every ward, while in the others (5, 4.2%) MET carried all emergency devices.

In most cases routinely emergency device control was performed by nurses (114, 96.6%), and in some cases by anesthesiologists (10, 8.5%) or healthcare assistants (4, 3.4%).

Table 5. MET activation

Where the MET waits for activation:	
intensive care unit	102 (86.4%)
emergency room	20 (16.9%)
a dedicated room in the hospital	6 (5.1%)
Warning score used in the wards:	
none	41 (34.7%)
MET (Medical Emergency Team)	35 (29.7%)
PART (Patient At Risk Team)	2 (1.7%)
MEWS (Modified Early Warning Score)	27 (22.9%)
other systems	13 (11.0%)
MET modalities of activation:	
any telephone	21 (17.8%)
a dedicated telephone	94 (79.7%)
intercom	1 (0.8%)
beeper	9 (7.6%)
How nursing activities are shared between ward and MET nurse:	
MET nurse replaces ward nurse	28 (23.7%)
MET nurse and ward nurse cooperate sharing their roles independently	39 (33.1%)
MET nurse and ward nurse cooperate sharing their roles according to hospital procedures	51 (43.2%)
MET nurse recorded nursing activities:	
no	27 (22.9%)
yes, in the ward medical record which asked for the intervention	34 (28.8%)
yes, in a specific MET medical record	57 (48.3%)

A check list of available emergency devices and materials was performed daily in 90 hospitals (76.3%), on a weekly basis in 25 hospitals (21.2%) and monthly in 19 hospitals (16.1%). MET equipment is described in Table 6.

The collaboration between MET and ward nursing staff during an emergency call varied among participating hospitals: in 51 hospitals (48.3%) individual roles were formally established by internal procedures, in 39 hospitals (33.1%) individual roles were not formally established, while in 28 hospitals (23.7%) MET nurse usually replaced ward staff. MET nurse activities performed during an emergency call were documented on a dedicated form in 57 hospitals (48.3%), and in activating ward medical records in 34 hospitals (28.8%). Conversely, in 27 hospitals (22.9%) there was no formal documentation of MET nurse activity.

Table 6. MET equipment

Presence of a cart to deal emergencies in each hospital ward:	
yes	113 (95.8%)
no	5 (4.2%)
MET equipment available:	
monitor defibrillator	85 (72.0%)
bag with drugs	114 (96.6%)
infusion pumps	34 (28.8%)
oxygen tank	59 (50.0%)
suction unit	56 (47.5%)
ultrasound	15 (12.7%)
automated CPR device	10 (8.5%)
Who checks the MET equipment:	
intensivist doctor	10 (8.5%)
nurse	114 (96.6%)
healthcare assistant	4 (3.4%)
When the MET devices are checked:	
at the beginning of every shift	90 (76.3%)
weekly	25 (21.2%)
monthly	19 (16.1%)

Discussion and Conclusions

This is the first survey on MET implementation in Italian hospitals, including also data on nursing staff. The survey had a response rate of 36% (197 questionnaires from 544 invited hospitals). Most questionnaires came from Northern regions (61.4%), reflecting the higher number of Hospitals present in those regions. Small volume hospitals (< 500 beds) were the most represented in the survey (72.6% of responding hospitals), being also the most common healthcare facilities in Italy. MET was more commonly implemented in small volume hospitals (72.6%) than in medium and high-volume hospitals. We have hypothesized that in large hospitals, with multiple specialist ICUs and Anesthesia services, it was more likely that in-hospital emergencies could be handled by more than one response system and not by a unique official team. This consideration could be particularly true in pavilion hospitals than in block hospitals in which it was easier to reach the patients. Moreover, in university hospitals the emergency team often consisted of an anesthesiologist (consultant) and an Anesthesia and Intensive Care fellow (resident), who replaced the nurse. In some cases, however, the emergency call was handled only by an anesthesiologist.

It was important to highlight that almost all survey respondents, working in facilities without a dedicated MET believed that its implementation would be essential to improve the management of in-hospital emergencies. This meant that probably healthcare professionals judged alternative systems of management of in-hospital emergencies inadequate.

In most cases MET was active on a 24/7 basis. However, there were hospitals where this service was not always available, particularly during night hours and weekends, when hospital ward staff is usually reduced and patients are more at risk.

According to our survey, in the majority of cases MET had been implemented for less than 10 years. It was also important to note that, while the specialization in Anesthesia and Intensive Care was mandatory for MET medical staff, no minimum shared standards of education and training for the nursing component of the team were required. Indeed, based on the results of our survey, advanced life support training (ALS/ACLS) was mandatory only in a minority of hospitals (34.8%), and basic life support training (BLS/BLSD) was not formally required in over a third (37.3%) of participating hospitals. These data were in contrast with American Heart Association and European Resuscitation Council guidelines that recommend basic life support principles as fundaments of early emergency management and supported their diffusion through the whole population (26, 27).

Only in about one third of the cases MET was composed of dedicated personnel. In the remaining cases (the majority), it was made up of personnel actually working in the ICU (or ER), who left the ICU to manage in-hospital emergencies. This lack of personnel weighed on the intensive departments, which were already burdened with a high workload and might lead to an increased risk of complications for critically ill patients (28).

An even more worrisome finding was that in some hospitals a dedicated telephone number for MET activation was lacking, leading to a less prompt activation of the emergency team (29,30). This delay could increase hospital mortality and morbidity (31).

Parameter scoring systems were widely recognized as excellent tools for early detection of patients at increased risk of death or complications (32-35). However, they were routinely used only in 65% of Hospitals with a MET service. Subjective patients' assessment by healthcare professionals was associated with a greater number of unnecessary or late MET activations.

Limits

The main limitation of this study is the relatively limited sample size, since approximately 36% of the hospitals meeting the inclusion criteria actually responded to the survey. However, this response rate is in line with the average values reported in the literature for this type of survey. Second, our survey was specifically targeted to the hospitals in which MET has already been implemented but it didn't explore other kind of intra-hospital emergency management systems, which may be equally effective. Finally, we didn't consider pediatric in-hospital emergency systems. However, dedicated pediatric ICUs are present only in few hospitals, and, in most cases, the same MET manages both adult and pediatric emergencies. Third, the study was a purely descriptive investigation. Indeed, new studies are needed to better analyze variables that may affect the MET implementation, and to describe outcome differences in the hospitals where MET is present compared to those in which it is absent.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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The process of developing the Professional Identity of the Nurse Case Care Manager: a Grounded Theory study

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Abstract. *Background and purpose.* The Nurse Case Care Manager (NCCM) is still an emerging figure in the Italian healthcare context. The knowledge of the dynamics inherent in the process of identity development shows how they can be decisive for the affirmation and recognition of this new role. The aim of the study was therefore to analyse the psychosocial processes of developing the identity of the NCCM for a better understanding of the variables that influence its development. *Methods.* A qualitative study with Grounded Theory method was conducted. From December 2018 to January 2019, 20 semi-structured interviews were given to the NCCM of the Emilia Romagna Region and the Lombardy Region. The analysis of the material has led to a structuring of the theoretical model on the processes of development of professional identity. *Results.* Two main conditions have been identified: that of the "LOST CASE CARE MANAGER" and that of the "CASE CARE MANAGER DIRECTOR". This process requires time, perseverance, courage and personal skills. Two transversal background concepts have been identified, namely "available space" and "relationship with the family". *Conclusion.* The process of developing the NCCM's professional identity encounters several obstacles. Among these, in particular a lack of recognition by operators highlighting the need for greater organizational clarity in the context in which the professional operates, in order to facilitate the inclusion of the NCCM clarifying skills and effectiveness profile. (www.actabiomedica.it)

Keywords: professional identity, influence factors, professional competences, culture evolution, Case Manager, nurse, development, Grounded Theory, case management, care management

Introduction

Nurse Case Care Manager (NCCM)

The decentralization of treatment, the increase of the complexity of the cases and available services has led to the birth of the Case Management model in 1960 (1). A scoping review in 2016 examined in particular the definition, the theoretical bases, the components and the interventions of the Case Manager (CM) (1). It has emerged that the significant variability of terminology, the gap in a common understanding of the definition of Case Management model, and the varied contexts in which a professional person works with several resources and in different communities have gone ahead with the development of models varied for competences and task, penalizing a study of effectiveness.

In short, it emerges that the model of Case Management deals with short-medium-long term assistance, the participation of the community and the support of a person with different health conditions in various welfare settings.

Two in particular are the dimensions that identify the process of CM's work: the management dimension, where the object is organization, human resources and welfare dimension, where the focus of intervention is the patients' care needs (2). Consequently there is a superimposition between the role of Case Management and the one of Care Management. Depending on the National reality in which their work is done, they take on a different taxonomy, even if, in fact, both of them are connected with the same model. In our context they go by the name of Case Care Managers (CCM).

The professional identity of the Nurse Case Care Manager (NCCM)

Some ambiguities of the role noticed in literature reflect the need to define the professional identity of such a figure. Their identity in itself includes a series of aspects that can be significant for their professional recognition, for the attainment of the outcome and job satisfaction (2,3,4,5). The professional identity is a complex concept, it is dynamic with various characteristic levels. The "self-concept" (6), in particular, can be understood as the way in which a person thinks of oneself and, in this specific case, for nurses, it concerns the knowledge and beliefs related to their role, behaviour and values defining their jobs. Nurses build up their own self-concept, perceiving in their job, which are the values and the reference culture both in the specific context of their welfare setting and in the more general one of the nurse as a member of a category of the nursing profession (7,8). The self-concept is therefore closely related to the concept of the self-professional (9). In this aspect several authors agree on the fact that the inner image of the professional is contradictory with the public one which is often distorted and stereotyped: it is depicted as subordinate to the medical profession, with little chance of career, causing dissatisfaction about their role, negatively influencing the internal recognition (9,10). Professional identity and self-concept may undergo changes due to interactions with colleagues, other health staff and patients (9). The identity construction, in fact, includes the sense of belonging to a group and the interpersonal relationships (11). Smith, in a revision of the literature, shows what the psychosocial factors involved in the transition from nurse to CM are (12): motivation, expectations, work satisfaction, but also the main sources of stress that originate from the fact of not feeling prepared to cope with the critical issue related to the role. The study also emphasizes that the inadequate training is a factor negatively associated to the definition process of the CM's professional identity, who feels responsibility without power. This aspect has been pointed out even in other researches on Case Management (1,10,13).

Aims

The aim of this study is to analyse the psychosocial processes of the development of a professional identity who carries out the job as Nurse Case Care Manager (NCCM) in a hospital facility and/or on the territory, in the context of the National Health System. In particular, the NCCM's perceptions have been studied in depth regarding their role and the importance they give to their activity and the relationship system.

Method and procedure

Study design

It is an exploratory study that adopts a qualitative research strategy on the method of the Grounded Theory (GT).

The GT is a research method that originates from the field of sociological research inspired by the so called "interpretative paradigm" (14,15). It seemed to be the most appropriate methodology for this study under discussion for the setting-up of a theoretical model regarding the psychosocial process that verifies in the construction of the NCCM's identity process.

Participants and setting

The analysis unit of this research project is the nurse working as Case Care Manager or Case Care Manager, both in hospital and national territorial contexts. The participants were through a sampling of suitability.

In the course of the research, the initial avalanche sampling was adopted, so as to recruit further participants from the first NCCMs involved. According to the data analysis the theoretical sampling followed until the achievement of the conceptual density (16). In line with the principles of the methodology Grounded Theory, the sample was not pre-arranged numerically (17, 18).

The settings in which the research was done were hospital services/wards and the territorial services where the roles of Case, Case Care Manager in Emilia Romagna and Lombardy are done.

Inclusion criteria

Nurses working as Case or Case Care Manager, who gave their consent to participate in the research, have taken part in the study.

Study population: sample recruitment

The people in charge of the structures involved have been informed personally by the research team concerning the aims of the study and the type of required collaboration. The Italian Association Case Manager has spread the request for taking part in the research through the Association's internet site. Some NCCMs were recruited during the Master's at the University of Parma in "Case Care Management in hospital and on the territory for the health professions". The professional people eligible for the protocol were contacted and informed via e-mail directly by the research team. Date and place for data research were shared through e-mail or phone contact.

Instrument

The selected means was a semi-structured fact-finding interview, with the main aim of collecting data. It is led by an interviewer who uses the outline of a survey with a series of questions asked of all the people interviewed without needing a set order, leaving space for any further information (19, 20). The interviews were conducted by two researchers who had proper training on the matter. An observer was present who took notes of the observations which emerged during the interview.

In the course of this study interviews lasted between 30 and 50 minutes and were audio-recorded. All the people interviewed were asked if they would participate in a second meeting. The setting where the interview took place was a private place chosen by the participant.

The interview was built up by the team on the basis of the aims of the research (see table 1), since they wanted to inquire into the field of competences, the perception of the role on behalf of the NCCMs and the other professional people who collaborated the interfering factors and favouring the transition of the role and finally the field of the expectations.

Analysis and data encoding

Coherent with the methodological approach of GT, the research team analysed the data, at the same time as their collection. The construction of a theory rooted in data or of a theoretical model is possible thanks to the construction of conceptual categories. This analytic process consists of three phases: an initial coding through the use of codes or labels, a focusing coding that group the labels in conceptual categories and a theoretical coding with the construction of the model (16, 21).

Table 1. Semi-structured interview grid

Opening question: used to open free communication and report on the skills of the new role	Do you feel you could talk about a significant episode of your new professional activity?
	Could you tell us what skills are required in performing the functions of Case/Care Manager compared to when you were a nurse?
In-depth questions: to understand the process and the main changes	What is your perception of the role and, in your opinion, what is the perception of the others?
	What influenced the role shift? Are there any factors that have hindered or facilitated the change?
	Can you tell us about a meaningful episode?
Closing question: has functions to express expectations and requests	What are your expectations for this profession?
	Would you like to add something you think is important that you didn't say before?
	Thank you for your availability

Ethical considerations

Before starting the interview the participants were asked to sign an informed consent including an advisory note that clarified how the survey was a voluntary participation, with the possibility to withdraw at any time, and the note specified precisely the information on the study carried out.

The participants were informed they could modify or eliminate the collected data if and whenever they wanted. The document also declared that the interview would have been audio-recorded and the collected data would have been disclosed in strictly anonymous form. The starting of the survey was subordinated to the opinion of the Ethical Committee of the Area Vasta Emilia Nord. The CE expressed a positive opinion on 09/10/2018 (protocol N. 2018/0112764).

Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

Results

Twenty professional people took part in the research, their average age was between 45 and 75 with a standard deviation of 5.51. 95% were women. As reported in table 2, it can be deducted that 20% of the participants is attending a Training Master's in Case Care Management, 60% has already obtained it and the remaining 20% never got it. The total years of service as a nurse is 21.3 years, while the average number of years of service as a Nurse Case Care Manager is 3.37. The NCCMs work in different contexts.

The first phase of the collection, analysis and data codification was carried out during 8 interviews, decoding parts of tests considered important with labels deriving from the results of reflections prompted by the analysis. In the first phase 223 strings of interest were identified. Labels were made from the strings and then grouped in categories. The second phase of data collection provided a theoretical sampling of 12 NCCMs, in order to diversify the experiential sources as much as possible. With a further 331 strings of interest a saturation of the categories was reached. Each category had a precise definition so as to represent all the observed concepts.

The formulation of concepts happened through the creation of a conceptual map, to organize more abstract ideas. Starting from the elaborate concepts, the connections emerging among them were identified up to the theoretical modelling (Table 3).

The theoretical model (Figure 1) is characterized by two main conditions: condition 1, the one of "Lost Case Care Manager" that is the initial phase of the process, and a final condition, the one of "Case Care Manager Director", reached through an intermediate phase of the process. Two background concepts transversal to the entire process also emerged: the "available space" and the "relationship with the family". The first concerns a further consequence of lack of company directives, the

Table 2. Socioeconomic characteristics of participants (N= 20)

Age	Gender	Total length of service	Length of service in the role of Case or Case-Care Manager and department	Master's degree
49	F	28	5, Residential Home	Yes
47	F	26	2, Infectious Deseases	In progress
41	F	18	3, Surgery	In progress
43	F	24	2 years 6 months, Residential Home	In progress
40	F	18	1, Neurosurgery	In progress
44	F	25	10, Breast Unit	Yes
49	F	30	1, HNS	No
33	M	11	5, Oncology	Yes
44	F	15	Medical Area	Yes
40	F	15	5, Oncology Medicine	Yes
45	F	18	2, Vascular Medicine	Yes
42	F	12	5, Long-therm care	Yes
47	F	25	1, HNS	No
57	F	34	3, Medical Area	No
45	F	23	8, Hospice	No
45	F	23	2, Surgery	Yes
45	F	26	3, Long-therm care	Yes
40	F	18	2, HNS	Yes
31	F	8	1, HNS	Yes
48	F	29	3, HNS	Yes

Table 3. Identification and definition of conditions

CONDITION	*CONCEPTS*	*EXCERPTS*
LOST CASE CARE MANAGER	Unclear role	*"my perception of the role is quite confused...I feel a bit as if I am in a centrifuge"*
	War climate	*"we nurses.. do not help ourselves... We fight against one another"*
	Enemy nurse	*"you will realize over time, and it is sad, that the worst enemy of the nurse, is the nurse himself/herself"*
	Fractional vision	*"the putting together of my patients' fragmented stories."*
CASE CARE MANAGER DIRECTOR	Acting as the glue	*"you also have to... keep directing a lot of things"*
	Feeling different	*"that patient said, that nurse over there... really makes the difference in this ward."*
	Satisfaction	*"I think it is a key role… he/she acts as glue that keeps everything together"*
	Acquired recognition	*"[...] It is a question of trust gained because in the end I bring you the result"*
BACKGROUND CONCEPTS		***EXCERPTS***
RELATIONSHIP WITH THE FAMILY		*"it is a satisfaction to see people who recognize you as the person who helped them overcome a difficult moment."*
AVAILABLE SPACE		*"We act within a framework so… very wide... on a very fragile track... Yes, references are still a little scarce"*

available space, at initially experienced as a negative factor: *"we act within a framework so… very wide... on a very fragile track... Yes, references are still a little scarce"* [C 3-8; I 7; S 31] and subsequently it turns into autonomy. The second concerns the **relationship with the family.** Immediately this is a motivating force for the NCCMs, that stimulates them to go on with their work, and the appreciation recognized by patients and their families evolves in a fulfilling relationship, as shown below: *"it is a satisfaction to see people who recognize you as the person who helped them overcome a difficult moment"* [C 1-10; I 6; S 18].

Lost Case Care Manager

The NCCMs, in the initial phase of their identity path, experience a state of confusion that make them feel **Lost**: "*there is a lot of space that leaves you a little un-*

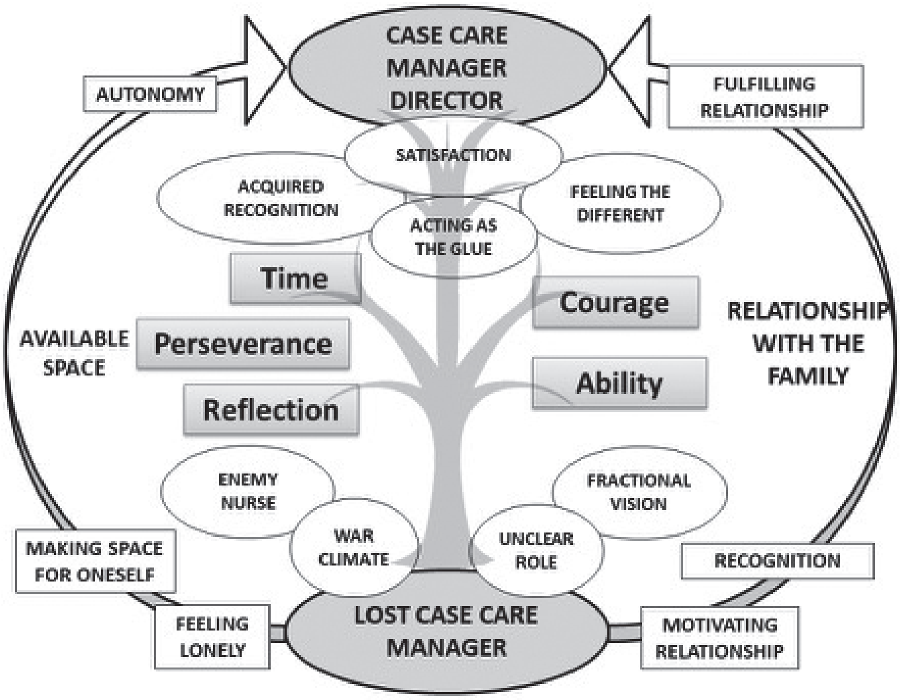

Figure 1. Representation of the theoretical model

comfortable at the beginning" [C 3; I 1; S 4], *"my perception of the role is quite confused... I feel as if I am in a centrifuge"* [C 3; I 20; S 93]. Defining concepts are showing which contribute to the lack of company directives, that creates the state of confusion in the professional. The **unclear role** negatively influences not only the perception nurses have of themselves, but also the one of their colleagues and of the whole team: *"there is no precise definition inside the various Companies.", "you are made do something different and maybe it is not clear to the group what you are going to do."* [C 8-3; I 3; S 8]. This is one of the reasons why **a climate of war** is established, that obstructs the initial phases of the process in which the professional figure is that of an **enemy nurse**: the colleagues themselves seem to be less inclined to the change and to the acceptance of the new role: *"you will realize over time, and it is sad, that the worst enemy of the nurse, is the nurse himself/herself"* [C 8; I 2; S 1], *"we nurses … do not help ourselves. We fight against one another"* [C 8; I 8; S 17].

Another concept identified in the NCCM's competences is "*the putting together of my patients' fragmented stories."* [C 2; I 2; S 1]. It is about a new required competence compared to the previous work as nurse, which represents, in its initial phases, a big effort to change course and that is evident in the concept of a **fractional vision**.

Transition process

To identify the entire identity formation process there were 5 concepts that allowed the evolution of the professional until the final condition. The first is the concept of **time**, which takes on several nuances. Time is necessary in order for changes to take place: *"I want to give myself time to... know how to wait too"* [C 3-6; I 13; S 58] it is the privileged means that the NCCM use to be able to express themselves in their new working role as professional, far away from the fast "pace" of the ward nurse: *"I am lucky I can dedicate time, all the necessary time to a fact-finding interview..."* [C 4-9; I 15; S 69] and finally as I expected *"I hope the CMs... make things clear, as to the ones who can develop their profession over time and integrate with one another.* [C 6; I 4; S 7].

Perseverance and **courage** are other two relevant concepts which emerged from the analysis, personal characteristics common to the interviewers, necessary to support the most difficult phases of the process and to overcome barriers and obstacles: *"I have started to take my own space, to elbow my way through, put my foot down and say: "that's enough!" I must do that and I will. Do you agree or not? It is not my problem!"* [C 7; I 2; S 6], *"i.e., someone thought I was crazy, after working all day you stay longer, work more hours for what…?"* [C 7; I 6; S 23], *"well, I think being more courageous is difficult while training, but I think courage is a gift a NCCM must have"* [C 7; I 1; S 1].

Another concept is represented by the **skills** that include the "technical" abilities belonging to this role (organizational, managerial, relational, financial, all part of health education), and the ones concerning the personal sphere (communication and human skills together with empathy, flexibility and ability to mediate). These skills can be interpreted as the result of the intersection between formation and experience. Finally **personal reflection**, which means thinking carefully and scrupulously, which allows the professional the possibility to look ahead: *"we have more possibilities to be able to look even further"* [C 3; I 19; S 92].

Case Care Manager Director

The intersection of the above listed factors leads to the achievement of the second condition, the final one, where the NCCMs mature their own abilities and competences, as much as to recognise and be recognised as course **Director**: *"a more articulated solution is required, maybe the NCCM has a wider vision and is able to put together the interventions of various professionals and … more areas of a person's life"* [C 2-3; I 1; S 1], *"you must also... take other factors into consideration"* [C 2; I 13; S 21], *"this role is positive and I experience it, as the most important potentiality in a nurse"* [C 3; I 12; S 52]. The NCCMs feel the **glue** as they create networks, join and catalyse the path of a cure *"I think it is a key role… he/she acts as glue that keeps everything together"* [C 2; I 13; S 19]. The NCCMs who were interviewed feel the need to do something different that would help to gain excellent results and they say they **feel different** from the others: *"training that really helped me a lot and amplified the skills I already had"* [C 4; I 10; S 44], *"..that patient said: that nurse over there... really makes the difference in this ward"* [C 10; I 16; S 31].

The concept of **satisfaction** for the NCCMs derives, in the last phase, from the work done, from the aims reached, from the feeling of being efficient in their work, resolving the conflict. This brings us to the final concept which is the **required recognition**, not only by the patient or the family, but also by the team which perceives the NCCM as a point of reference, with a special role in course management, as shown in the following: *"[..] it is a question of trust gained because in the end I bring you the result"* [C 1; I 12; S 39], *"now there is no longer this friction, on the contrary I think I am a support to them even if the colleagues are always the same"* [C 1; I 15; S 47].

Discussion

Most of the theories that form the model of this study are supported by previous literature. Grounded Theory research has allowed to develop a model that attempts to describe the process of developing identity of the nursing professional who is to play the role of NCCM: the director of change.

Ambiguity of the role is a concept that has emerged in our model. According to the analyses carried out, the health authority was unclear about the competence profile of the NCCM. In the literature, several authors have described this phenomenon (8, 9, 19, 21-24) and it has been highlighted that clarity in the role is necessary to reduce the risk of overlapping skills between professionals, since it is in the duplication of functions and roles that the peculiar effectiveness of one specific professional figure vanishes and the consequent acceptance by the other within the pre-existing system (25).

This may also be due to the semantic confusion of the interventions of the NCCM, the lack of a definition of the model as introduced (1), and the resistance to change, a common component of the group which adversely affects the process of identity formation (26).

The nurse who becomes NCCM immediately changes work context is no longer mainly part of the nursing team, but acts as a link with other professionals. The study shows that in the initial phase of the process, the relationship with fellow nurses becomes an obstacle to identity formation. In the literature it has also been noted that nurses indicate in particular the conflict dimension as a potential problem in the work environment (27).

At the beginning, fundamental aspects of the role that the NCCM plays in the nursing nucleus enter into crisis: relational, communication, teamwork, trust, coordination, preventing integration and collaboration. From the analysis of the research, however, the NCCM is well integrated in the inter-professional team and in the literature it is highlighted that this is a fundamental feature to obtain comprehensive care and respond to the complexity of health care, objective of the Case Care Management model (2).

The relationship with the family is an emerging concept that plays an important role in the transition process being studied. When they played the role of nurses, the NCCMs interviewed claim that they did not have complete information about the patient, to have access to a fragmented and focused story on the problem of the moment. Subsequently, from NCCMs, they find themselves "putting together the pieces" of the care path and communicating with the family in a more constant way.

Family members, like the patient, do not recognize the figure of the NCCM in the organizational structure but this does not hinder the consolidation of a relationship of trust. The NCCM is recognized as a point of reference, of listening, of help and with the passage of time the relationship becomes rewarding for the professional. The link between the coordination of home actions and the care process offers the NCCM the opportunity to reconnect with care and, as a result, contributes to increasing satisfaction levels and reducing stress at work (2).

As other authors have previously analysed (5), experience as a nurse in our model is essential, reported by the interviewees as a determining factor to perform at best their function. As we have seen, the NCCMs are associated with different types of cases, instruments and timing. The experience allows them to develop skills about the reference setting.

Training is also an essential element. Franco & Tavares noted that nurses holding a Master's degree or Specialization Diploma are more competent in their profession (27), which is important to feel effective. Training in the specific managerial context is perceived as a fundamental need for some Case Care Managers (28).

The sample of our research in possession or in the course of a specific training, stated that it was useful to provide a background of skills, although the professional figure and the profile of skills were not always clarified. Training influences the development of identity not only in the transmission of content and skills that define the role, but also in the way in which it lets perceive "who" should be the NCCM.

The NCCMs interviewed focus on their personal and relational skills such as communication, empathy, courage, mediation and flexibility. The latter is a key element for nurses to be effective, not only for their patients but also for other healthcare professionals (29). For Rocco et al. (27), courage is recognized as a means to overcome difficulties and is mentioned in several interviews of our research.

Depending on the stage the NCCM is going through, confidence in the role is also a determining factor. The lack of initial clarity creates a state of confusion in the professionals that, over time, evolves on the basis of the results obtained, despite the unfavourable environment, with a problem-oriented coping strategy that allows them to face a challenge through his own resources (22). Trust in the role allows the NCCMs to persevere in a first phase of isolation and lack of recognition, thus drawing on personal skills, as well as their own skills. Finally, it is time that mitigates the difficulties and that allows to metabolize the change.

The process leads to the conclusion that the NCCMs are "different", finally seeing themselves recognized in the role and feeling satisfied with their work. The NCCMs in this final stage of the process feel satisfied not only with what is recognized from the outside (by family members, patients, the team, colleagues) but also by how they see themselves: they perceive that they are directors of the path of care.

Conclusion

From this study emerge a variety of factors determining the identity construction "in transition". The NCCMs interviewed built their identity step by step, developing autonomy and building welfare networks. They have encountered several difficulties, probably due to the novelty of this position within the health services and the process of integration still in place. When NCCMs take leadership positions in care management, through integration and collaborative relationships with healthcare professionals and patients, they enable timely, safe, continuous and personalised care (2). Taking into account the importance of the management function of the NCCM, it is necessary that training mitigates the gap between theory and practice, emphasizing the importance of the study of the components of Case and Care Management (2,27).

Finally, Health Companies should allow the inclusion of the professional figure with greater clarity and managing the frictions that have been verified in the research.

Relevance to the practice

The identification of how the change takes place, at a personal and social level, ensures that the professional identity of the NCCM is enriched with new content, raising awareness of the importance of an integration of this figure within the different settings. The new aspect that we dispose allows the NCCMs to better understand the factors that hinder and favour the development of identity, increasing the awareness and the evolution of their role. The benefit will be not only the work performance but also interpersonal relationships and the sense of belonging to the group. The hope is that it will be useful to the NCCM to heal the sometimes distorted image present in collective thought.

Limits

The study imitators mainly concern the exploratory research method used: the reported data cannot be generalized and can concern only the context studied, even if the recruited professionals belong to different Italian realities and regions. Further qualitative and quantitative research will be needed, which in addition could focus on the perception of the role attributed by the whole multi-branch team to the NCCMs and the change undergone after their integration.

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Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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The application of the Theory of Planned Behaviour to prevent medication errors: a scoping review

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Abstract. *Background and aim of the work:* A safer drug therapy is a relevant aspect of nursing care and an essential component of the clinical governance function. Nurses are key players in the identification and prevention of medication errors that could occur in the drug management process. In the literature there is a particular interest to environmental and organizational factors, while, as we know, the subjective components are little considered. In psychology, the theory that prefers individual factor, at the expense of the environmental one, is Theory of Planned Behavior (TPB), although it has been little applied in the health field. The aim is to search the existing literature on the medication errors and the TPB to predict the intentions that foreshadow risk behaviours of nursing interns. *Methods:* This scoping review is grounded by Arksey and O'Malley's framework. *Results:* Attitude is the most determining predictor of intention. For many students reporting an error would lead to a loss of trust in the nursing profession and this could prevent the report. Nevertheless, some of them affirmed to be positively judged when they did it. It was then observed that a better education on safety raised the level of self-confidence and the sense of responsibility of the students, making them more inclined to the drug therapy management.*Conclusions:* The Theory of planned behaviour is essential to forerun the behavioural intention of students on the pharmacological safety and the collaborative practice through predictive factors, as attitude, subjective norms and perceived behavioural control. (www.actabiomedica.it)

Key words: medication errors, medicine error, medicament error, drug error, near miss, theory of planned behaviour

Introduction

As highlighted in the available literature, there is a certain relation between medication errors and potential life risk (1). According to the Joint Commission International (2) the occurrence of damages caused by medication errors is higher than any other kind of error. Medication errors are more frequent in hospital settings, especially in ICUs and Emergency Departments (3), and may deeply affect both patients' health and healthcare expenditure, as they often imply the hospitalization of the patient or a longer hospital stay due to the deterioration in his clinical conditions.

Nurses play a key role in the therapy administration phase and they are accountant for the error prevention (4-6). The error prevention activity accounts for 40% of the clinical and nursing tasks (7,8). Nurses are key players in the identification and prevention of errors that could occur in the drug management process.

The drug therapy management represents a crucial moment in the nursing practice. The therapy management goes beyond the mere drug administration to patients: it is indeed, a longer process that requires high-level competences, solid theoretical knowledge and practical skills, and it is more and more complex and more often autonomously managed by the nursing staff (9). Thus, the occurrence of medication errors in one of the drug management phases is far than rare.

Errors may occur in every phase of the drug management, nevertheless, the available literature shows that there is a higher incidence of errors in the administration phase (10-12).

The main causes of these occurrences can be attributed to a scarce organization (i.e. inadequate communication, lack of standardized procedures or inaccurate draft of the documentation) or personal deficit (i.e. poor knowledge, attitude and behaviours) (13-15). But if we consider the University Hospitals, the phenomenon of drug errors occurrence must be analysed taking into consideration the presence of nursing students. Students become co-leading figures in the drug therapy management during their internship activities and according to their level of study. It is plausible to think that the possibility of making a mistake or a near miss increases in these contests.

It is necessary to specify the intentions of the workers and the purpose of their intervention to understand if a particular occurrence should be considered an error or not.

The systematic review of the errors is indispensable to identify the causes and the circumstances that could lead to an error. The analysis of the error modalities can highlight the reasons why a person does not adopt an ideal behaviour in a specific context. This approach lets it possible to recognize the motivations that ground the wrong choices, which are the subject matter of this study: the awareness of the factors that can lead to the occurrence of an unwanted event will make the event itself predictable and, consequently, avoidable.

In psychology, the Theory of Planned Behaviour (TPB) by Ajzen (16) is the theory that prefers the individual factor to the environmental one.

The TPB results from the modification of a previous theory named "Theory of Reasoned Action" (17). This model aims at explaining the adoption of particular behaviours by the individuals, and it is based on three predictive factors:

1. Intention to behaviour: reason, development of conscious plans, decisions and self-instructions implemented to adopt a specific behaviour (18). The intention to behaviour is determined by the attitude toward behaviour and the subjective norms.
2. Attitude toward behaviour: attitude to perform or not a behaviour on the basis of the personal judgment regarding the behaviour itself (18). Attitude is a function of the behavioural beliefs, which represent the perceived consequences or the characteristics associated to the behaviour taken into consideration. In line with this conceptualization, consequences are made of the combination of the perception of the probability that the adoption of a behaviour could lead to a specific result and its evaluation.
3. Subjective norms: influence of other people's opinions on the behaviour of an individual (18). It refers to the beliefs of other people or groups of people whose attitudes toward a behaviour are important to the individual. This variable is highly representative of the social influence, which individuals perceive with regard to the eventual adoption of a behaviour. Nevertheless, at practical level, the Theory of Reason Action developed only a limited success in the prediction of intentions (19). The limitation of the Theory of Reasoned Action is that it explains only voluntary behaviours, which require capability, sources and opportunities. If these are not easily accessible, the explanation of the behaviour cannot fall under the domain of application of the Theory of Reason Action, as it would predict it in an inadequate and incomplete way (20).

For this reason, the Theory of Reasoned Action was developed further to include the perceived behavioural control (16)and apply the Theory to behaviours, which differ from the voluntary ones. Some explicit considerations on the perceived control on the adoption of a behaviour were elaborated. Due to the addition of the perceived behavioural control as intention-predictive variable, the model was renamed Theory of Planned Behaviour (17).

The TPB has been largely applied to the Social Psychology and the Health Psychology fields to analyse the factors that determine the adoption of different risk behaviours with prevention and health promotion purposes (21). However, this theory could be applicated to the health field.

The purpose of this paper is to search the available literature on the prevention of the medication errors and evaluate the application of the TPB to predict the intentions that forerun risk behaviours of nursing students and hypothesize its use with a preventive purpose.

Materials and Methods

The method employed to carry out this scoping review is grounded on the framework developed by Arksey and O'Malley (22), which consists of 5 primary phases: 1. Definition of the research question, 2. Identification of the pertinent studies; 3. Selection of the studies, 4. Data classification, 5. Comparison, summary and presentation of the results. The sixth optional phase of consultation was not performed (see Supplementary File 1).

Definition of the research question

"What is available in literature on the TPB and its application in the prevention of medication errors of nursing students?"

Identification of the pertinent studies

To answer the research question we took into consideration two fundamental concepts: *medication error* and the *theory of planned behaviour*.

We identified some key words and MeSH terms for each concept, then they were combined through the Boolean operator "OR" and "AND". The research strategy employed is explained in the Appendix 1. In order to investigate the extension, the range and the kind of the available literature (22-24), the following online databases were searched: CINAHL, PubMed, e Cochraine Library, Scopus. We considered the publications issued in the last decade (2008-2018) in English and/or Italian.

Selection of the studies

The results of the search were imported in the software Zotero® and duplicates were eliminated. The selection of the pertinent studies was carried out based on some criteria, which were defined after a preliminary review of the results of the research.

The studies selected focused on the application of the TPB in the nursing field or in a similar field, with a particular focus on the interns. The evaluation of the quality of the studies was not an eligibility criterion, as it is not contemplated in scoping reviews (22-24). An initial reading of the title and abstracts, if present, allowed the exclusion of non-pertinent studies. Then, we analysed the full texts of the studies that proved to be suitable, or whose nature was in doubt.

Data classification

The reading of the full texts permitted to classify and organize the data in an extraction table (Appendix 2) using the Excel® software. The registered information was: author/s, year of publication, title, purpose of the study, method and results.

Comparison, summary and presentation of the results

Lastly, the classification of the data allowed the elaboration of a report of the facts that emerged from our scoping review. The data elaborated in the model were then analysed on the basis of the research question, using a qualitative analysis of the content.

Results

Three studies out of the 33 references extracted were considered pertinent (Figure 1).

In all the 3 pertinent studies (25-27) it was used the conceptual-theoretical framework of the Theory of Planned Behaviour, even if it was used for different purposes and kind of studies.

The study by Lapkin et al. (25) aimed at investigating the usefulness of a questionnaire based on the TPB to forerun the behavioural intention of students on the pharmacological safety and the collaborative

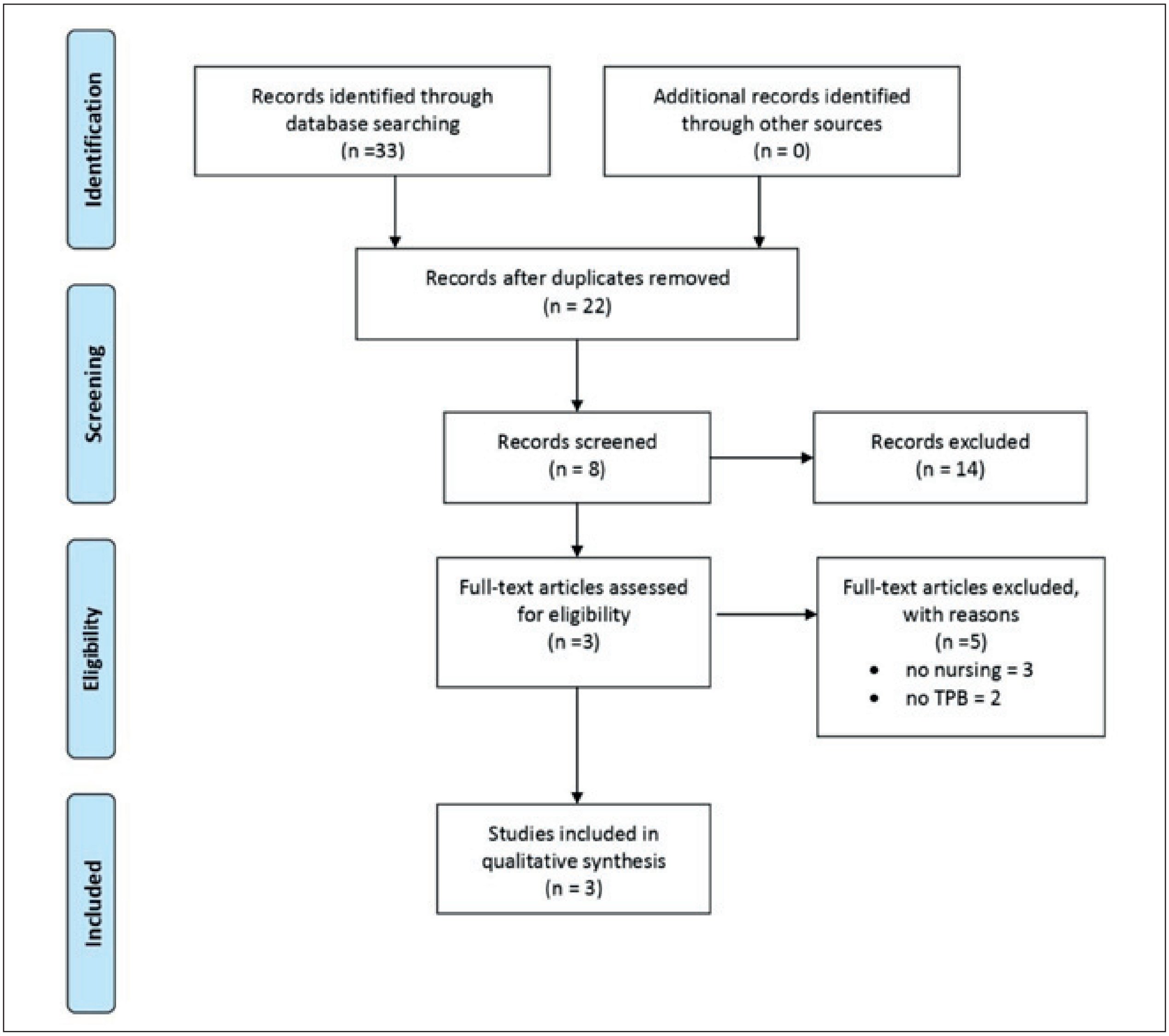

Figure 1. Flowchart

practice through predictive factors, as attitude, subjective norms and perceived behavioural control.

Omura et al. (27) analysed the impact of a multimedia learning resource on the action intention through a questionnaire based on the TPB framework, to foster the pharmacological safety among nurses and nursing students.

The study carried out by Natan et al. (26) aimed at analysing the factors that determine the intention of nursing students to report medication errors, identifying the Theory as a tool to predict the intention to report the errors committed.

Limits of the study

The main limitation of this study is the availability of few studies that support the use of the TPB in the specific field of therapy errors made by nursing students. Author(s) report on results of a scoping review for the purpose of searching the available literature on the prevention of medication errors and evaluate the application of the TPB to predict the intentions that forerun risk behaviours of nursing students, and to then hypothesize its use with a preventive purpose. For this aim, only three sources out of a possible 33 were included for this review. Although there are few sources, only those relevant to the research question have been selected. Moreover, the use of this theory in the health field has been used mainly to investigate the variables that lead to the genesis of medication errors principally in workers (nurses and doctors), to our knowledge there are few studies that interest nursing students. An ad hoc in-depth study is therefore necessary to evaluate the applications of this theory to prevent medication errors at clinical level.

Discussion

This work seeks to assess the effectiveness of the TPB in predicting the intention of adopting or changing some behaviours in the health field, mainly focusing on the pharmacological security. To meet this goal, we carried out a scoping review, through which we investigated the available scientific literature on medication errors and the application of the TPB in this field.

The analysis of the literature highlighted a little availability of specific studies on the application of this theory in the pharmacological error sector. For this reason, it was necessary to take into consideration some studies in which the TPB was applied in fields similar to the one of our interest.

Thanks to the comparison of the employment of the TPB in the different studies, it was then possible to identify some grouping areas of expertise of the selected articles (which correspond to the three constructs of the psychological theory considered) to make the presentation of the main outcomes uniform and structured.

Attitude

Attitude is considered the most important intention predictor of the all elements of the TPB (25). One of the studies included in this scoping review revealed that 78% of nursing students show a strong intention to report pharmacological errors, as they are aware that reporting an error is crucial to avoid the reiteration of that mistake (26).

The intention of reporting an error is associated to the behavioural beliefs and the perceptions of the students of the importance of reporting an error (26). The outcome of the study by Natan et al. (26) does not perfectly match with the study by Omura et al. (27), who administered a questionnaire to evaluate the effects of a multimedia path on the intention of students of reporting a pharmacological error. Actually, in this study the test group registered lower scores relating to the behavioural intentions than the control group (27). The author advanced some motivations to explain this outcome, as follows: the scores of the test group are low because Japanese students have limited experience in administering drugs, as they mainly have an observational knowledge, and this may prevent them from understanding the nursing responsibilities that are at the base of the pharmacological errors (27).

Subjective norms

All the studies included in this scoping review demonstrated the correlation between the subjective norms and the intention of the students to report a pharmacological error, even if some studies focus on the positive effects of this relation, while other focus on the negative ones. This dual point of view of the correlation between subjective norms and error reporting depends on the fact that people tend to perform willingly only those behaviours that the society sees as positive and acceptable (25,26) focused on the negative effects, paying particular attention to the social pressure that, according to the students, tutors and professors may make on those who admitted to make a pharmacological error. Moreover, some students believe that reporting a therapy error may cause a loss of trust of the society in the nursing profession. The concern for the damage to the reputation of the nursing profession could prevent students from reporting the errors they made (26). Even from this point pf view, Natan et al. (26) achieved results that differ from Omura's outcomes: actually, Omura highlighted that, based on the scores of the test group, students believe to be positively judged by professors and nurses when reporting a pharmacological error (27). The results of Lapkin's study (25) led him to an intermediate position between Omura et al. (27) and Natan et al. (26). According to his study, students seem to attach little importance to other people's judgment on the pharmacological error and the professional who made it. This result contrasts with the results achieved by the majority of the studies carried out on this field, as the opinion of the others deeply affects the adoption of a behaviour (25).

Perceived behavioural control

All the studies included in this scoping review highlighted an important correlation between the perceived behavioural control and the intention to report a pharmacological error (consequently to its actual reporting too). Omura et al. (27) observed a significant increase of the perceived behavioural control scores at the end of a multimedia learning path (27). This matches with the results achieved by Lapkin et al. (25), according to whom learning opportunities aimed at enhancing the communication, the team working and the trust in the colleagues make students more competent in the drug therapy and more responsible in case of error reporting (25).

Natan drew a similar inference: he observed that raising students' awareness on the drug administration safety increases their level of self-confidence and their sense of responsibility, making them more inclined to report therapy errors (26). Probably, self- confidence and intention to report a pharmacological error are two variables, which are correlated in a directly proportional way, even if it is necessary to carry out specific studies to confirm this hypothesis. In light of what it was shown up, the perceived behavioural control is a critical factor in the management of pharmacological errors (25). Taking educational actions focused on the cooperation with the group may be a valid intervention in the pharmacological safety area.

Implication for education, nursing practice and health policy

The analysis of the available literature highlighted the usefulness of the TPB in explicating the adoption of some behaviours on the basis of its three main constructs and its successful implementation in some areas of expertise similar to the pharmacological safety field (25-27). Actually, the predictive power and the perceived behavioural control, in relation to the safe management of the therapy, support the application of the theoretical model of the TPB.

The predictive power of the attitude, in particular, is crucial. The analysis of studies carried out in hospital environments and focused on nursing workers highlight this concept. The prevention of medication errors is analysed in relation to the attitude and it highlights that awareness is a decisive factor to reduce the risk of errors (3, 28, 29). The results of the scoping review indicate important inferences to the development and implementation of strategies aimed at improving the pharmacological safety and to the application of the TPB and tools based on it, in order to evaluate the effectiveness of educational interventions. Indeed, it was clear that educational opportunities aimed at promoting communication, team working and trust in the colleagues, help to enhance students' competency in the pharmacological therapy and their sense of responsibility in case of adverse events (27). Given the considerable influence of the subjective norms on the behaviours, it is necessary to raise health and care safety awareness, fostering productive and non-punitive discussions, whose object is to analyse errors, instead of start a "hunt for the guilty party".

Experiences play a key role: it is thanks to them that nurses gained awareness of the importance of complying with the correct behaviours during the whole drug management process, to prevent medication errors (9,30).

Conclusion

In the light of this analysis, we believe it would interesting to examine further this issue, carrying out new studies that focus on the possible effective application of this conceptual model to prevent medication errors made by nursing students and professionals.

The Theory of planned behaviour (TPB) is essential to forerun the behavioural intention of students on the pharmacological safety and the collaborative practice through predictive factors, as attitude, subjective norms and perceived behavioural control. Authors emphasize the importance to an in-depth research to identify appropriate measures to minimize MEs and improve patient safety.

Although the global interest on this topic is still insufficient; modern medicine must be able to respond to the complex health needs of the person however it must do so through a consistent use of resources without jeopardize patient safety (15).

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Study design: SD, EDS, NG, RC, MDM
Data collection: SD, EDS, VF, EC, FDM, RC, NG, MDM
Data analysis: SD, EDS, NG, MDM
Study supervision: SD, MDM
Manuscript writing: SD, EDS, VF, EC, FDM, RC, NG, MDM
Critical revisions for important intellectual content: SD, EDS, VF, EC, FDM, RC, NG, MDM

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Appendix 1

ID	QUERY
#8	Search **((((((medication error[MeSH Terms]) OR medicine error) OR medicament error) OR drug error) OR near miss)) AND theory of planned behaviour**
#7	Search **theory of planned behaviour**
#6	Search **((((medication error[MeSH Terms]) OR medicine error) OR medicament error) OR drug error) OR near miss**
#5	Search **near miss**
#4	Search **drug error**
#3	Search **medicament error**
#2	Search **medicine error**
#1	Search **medication error[MeSH Terms]**

Appendix 2

Authors and years	Title	Aim	Method	Result
Natan M.B., Sharon I., Mahajna M., and Mahajna S., 2017.	Factors affecting nursing students' intention to report medication errors: an application of the theory of planned behaviour	Examine the factors associated with nursing student intentions to report pharmacological errors, using planned behavior theory (TPB).	Cross-sectional study	The results of the study reveal that 78% of students expressed a strong intention to report therapy errors. The behavioral beliefs of the students regarding the reporting of therapeutic errors were associated with their intention to report, in fact more than 70% of the students agreed that the identification of the causes of errors is the responsibility of the coordinating nurse. The behavioral intention, the subjective norms (social pressure) on the part of peers and clinical preceptors, the knowledge of the students about the reporting of therapy error and their perceived behavioral control resulted in correlation with their intention to report.
Omura M., Levett-Jones T., Stone T.E., Maguire J., and Lapkin S., 2015.	Measuring the impact of an interprofessional multimedia learning resource on Japanese nurses and nursing students using the Theory of Planned Behavior Medication Safety Questionnaire	Assess the impact of an interprofessional learning resource on the intentions of nurses and nursing students, with the aim of promoting drug safety.	A quasi-experimental study using the TPB-MSQ questionnaire.	The results emerged from this study show that the variables that influence behavioral intention, ie attitude, perceived behavioral control and subjective norms were higher in nurses after seeing the video. The significantly higher average in the scores of perceived behavioral control and in the subjective norms in the experimental group compared to the control group show: in the first case the participants showed greater self-esteem and therefore awareness of having better skills and security in the implementation of specific behaviors relating to pharmacological safety; in the case of subjective rules, in the same way, the results indicate that the participants believed that they would be judged positively by colleagues for the promotion and safe management of drugs. On the contrary, in the nursing students who saw the multimedia learning resource (the experimental group) the behavioral intention scores were lower than those of the control group, whose motivation could be found in the little clinical experience of drug therapy and in using mainly a type of learning that exploits memorization rather than practical skill.

Authors and years	Title	Aim	Method	Result
Lapkin S., Levett-Jones T., and Gilligan C., 2015.	Using the Theory of Planned Behaviour to examine health professional students' behavioural intentions in relation to medication safety and collaborative practice	The main objective of the study is to evaluate the usefulness of a questionnaire based on the theory of planned behavior (TPB) to predict the behavioral intentions of students in the health professions in relation to drug safety and collaborative practice. Moreover in the study we want to determine the contribution of attitude, subjective norms and perceived behavioral control on the intentions of the students.	Cross-sectional survey based on TPB.	The study reports that attitude, subjective norms and perceived behavioral control represents 46% of the variance in the students' intentions to practice in such a way as to improve the safety of drug therapy. Attitude is generally considered to be the strongest predictor of intention, perceived behavioral control, in the same way, is a critical factor that influences students' intention to exercise in a way that improves drug safety and collaborative practice. Efforts to improve drug safety and collaborative practice should therefore, once you have ensured that health students are provided with educational opportunities that promote teamwork, communication, competence and trust, the elements necessary for the safe management of drugs. The elements of the subjective rules have had a negative effect on the behavioral intention, this result suggests that students seem to value the contribution and perceptions of others on drug safety.

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The impact of a "narrative interview" intervention in oncology. A study protocol for a feasibility study

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Abstract. *Background and aim of the work.* Oncological diagnosis determines a biographical breakdown and requires the person to adapt to the disease. If patients, after diagnosis, ask professionals for 'compassionate care', research on these issues is still underdeveloped. There are currently no studies that use the narrative interview as an intervention tool. The objectives of the study are to evaluate: (1) the feasibility of the narrative interview intervention on cancer patients in the first diagnosis; (2) the impact of the narrative medicine intervention on the patient's self-perception, his psychological distress and adaptation to the disease. *Methods.* It is a mixed-method study, with an intervention (narrative interview) and quantitative evaluation before/after intervention and qualitative evaluation post-intervention (reflective writing). The analysis will use the Psychological Distress Inventory scale for the assessment of psychological distress and the Mini-Mental Adjustment to Cancer Scale for the assessment of disease adaptation. Adult patients, with oncological pathology will be recruited one month after the communication of the diagnosis, regardless of the type of tumor. The Wilcoxon test for paired data will be used to verify pre-post-intervention differences. The 'reflective writings' will be subjected to thematic analysis. *Discussion and conclusion.* The study evaluates the feasibility of the narrative interview intervention as a primary outcome. Secondly, the impact of the intervention is assessed in relation to: a) identification of risk or protective factors on psychological distress and adaptation to the disease; b) re-elaboration of the patient's experiences and experiences related to his/her own illness. (www.actabiomedica.it)

Key words: oncological patient, narrative interview, study protocol, intervention, psychological distress, adjustment to cancer

Background

Narrative Medicine is a clinical-care intervention methodology based on specific communication skills. Interventions that exploit the appreciation and interpretation of a narrative (e.g. poetry, film, storytelling) fall within the sphere of narrative medicine (1). Its use encourages patients to see themselves at the center of their stories and this can help the person in an attempt to find a balance between self-concept, disease and therapeutic treatment (2, 3): people thus, become protagonists of the treatment process (4).

One of the instruments of narrative medicine is the narrative interview that studies phenomena through people's experience. It is not based on a generalized and decontextualized study of a given phenomenon but it analyzes and defines it through the stories of individuals. In the narrative interview, the interviewer asks questions to interpret and understand the participant's words rather than trying to explain or predict them: in fact, those who tell their health and disease history do so to convey a specific perspective of an event (5). Researchers who use this investigation technique tend to let the interviewee guide the content and pace of the interview itself (6). On average, each interview has a total duration of about 60 minutes (7). The narrative interview also allows you to better understand the different problems of assistance for the person and his family (8, 9).

The narrative interview, often used as an educational and sociological methodology (10), was intended by the authors (11, 12) in an innovative way: specifically structured and used by healthcare professionals (suitably trained), aimed at promoting listening active and the empathic relationship that is created between the practitioner and the patient during the interaction and favors ‘compassionate care’ (13). Indeed, ‘compassion’ was born as an empathic response to the suffering of the sick person, as a rational process that pursues the well-being of patients: this should be part of the daily work of health professionals (14). It is therefore essential to give primacy to the patient’s voice, to provide the patient with a relationship of care appropriate to the evolution of their history (15). Active listening participates in eradicating patients from that condition of solitude and suffering that implies disease by allowing them to live with dignity (16). Providing holistic care according to this model will help meet patients’ physical and psychosocial needs (17).

In this perspective, healthcare professionals can help patients make sense of the disease by helping them recognize it as part of their life path and as a challenge to be faced rather than being overwhelmed by it (18). Helping to reflect on the disease can represent a modality of nursing care with a significant wellness potential supported both by narrative theory and by the theoretical and philosophical heritage of nursing care (15).

The need to have explicit conversations with patients on their mental state and understanding of their suffering is highlighted. A patient-centered approach enhances the patient’s conceptualization of their problem and narrative to understand the disease, this can improve the care relationship (19).

It is very important to use effective communication strategies during the interview as they lay the foundations for the creation of a good empathic relationship (20): it is also necessary to find what is important from the patient’s point of view to optimize assistance (21). The narrative interview is curative (18, 22), as it allows you to talk about yourself and the new condition that you are experiencing, recalling its experience and trying to give meaning to the disease (15).

At the time of cancer diagnosis, the communication of bad news represents the fundamental starting point of the individual’s path of illness. The diagnosis of cancer involves a substantial increase in anxiety and this emotional response is mediated by the communication style used by the professional (23). The disease affects not only the body but also the psyche and the whole system of social and family relationships that revolves around the patient (24, 25). Cancer is a disease that often leads to stress, anxiety and potential exhaustion in family members, (26). The individual must learn to live with a chronic disease between the promise of treatment and the threat of disease progression: this produces complex and paradoxical experiences that do not easily adapt to familiar mental patterns (27).

In a narrative perspective, the diagnosis of cancer, in fact, determines a biographical breakdown of one’s life history; In this perspective the communication of bad news to the person requires an adaptation to the disease itself, trying to reconstruct the history of interrupted life that becomes history of the disease.

People who receive a cancer diagnosis and a negative prognosis are significantly more likely to develop psychological distress (28, 29).

The ‘compassionate care’ are required by patients, but research on this is still underdeveloped (13) and patients during the disease course, want to meet the professionals who listen to them showing compassion and competence in dealing with the pain (16).

The scientific literature concerning medicine and the narrative interview turns out to be quite wide thanks to the considerable interest that this narrative tool has aroused in researchers and scholars, however there is no focus on the application of the narrative interview as intended by the authors of this study, or carried out by health professionals, in the post-diagnostic phase and which helps the professional to understand the possible effects of the disease on the person.

This feasibility study aims to assess what impact the narrative interview, carried out by health professionals, could have on the person who has recently received a tumor diagnosis and, in particular, on two outcomes: psychological distress and adaptation to disease.

Aims

The study has the primary objective of evaluating the feasibility of the narrative interview intervention carried out by health professionals on cancer patients in the first diagnosis.

The secondary objective is to evaluate the impact of the narrative intervention on the patient's self-perception, psychological distress and adaptation to the disease.

Method and procedure

Study design

This study is a mixed method study, which provides a quantitative assessment before / after intervention (narrative interview) and a qualitative assessment of post-intervention (reflective writing).

The intervention consists in performing two narrative interviews, after fifteen days of each other.

The qualitative evaluation will be addressed to patients recruited and subjected to a narrative interview and will use the tool of reflective writing, after the first interview (T1) and after the second interview (T2).

The quantitative analysis will use the scale Psychological Distress Inventory (PDI) for the assessment of psychological distress and the Mini-MAC scale for the assessment of adaptation to the disease. The two scales will be administered before (T0) and after the first narrative interview (T1) and will be administered again after the second narrative interview (T2), scheduled two weeks after the first (Table 1).

Study population: sample recruitment

The study population concerns patients in the first cancer diagnosis. Patients with oncologic pathology in first diagnosis will be included, regardless of the type of the tumor and will undergo narrative interview a month before the communication of the diagnosis. This period of time is foreseen in respect of the patient's emotionality.

Inclusion criteria are taken into consideration:

- Speaking well in the Italian language;
- Having expressed willingness to participate in the study and have given written informed consent;
- Cancer patients in the first diagnosis of cancer;
- Be over 18 years old

The experimenters will illustrate the study, explaining the objective that it aims to analyze. Participants will be asked to read the information sheet, sign the consent and be informed explaining the possibility of stopping the trial at any time.

Training of professionals

To conduct a narrative interview, various skills are required that help the professional to create a context of relationship and participation suitable for data collection. For the purpose of the good performance of the interview, in fact, the interviewer should create a climate based on non-judgmental listening and mutual trust. For these reasons, the interviews will have to be conducted by members of the research team who have received special training in this regard. Nursing professionals who attended the I Level Master in "Case / care management in hospital and on the territory for

Table 1. Study design

	Pre-Intervention		**Post-Intervention**		**Post-Intervention**
	T0		**T1**		**T2**
PDI (Psychological Distress Inventory)	X	**Narrative Interview1**	X	**Narrative Interview 2**	X
Mini-MAC (Mini-Mental Adjustment to Cancer)	X		X		X
Reflective writing			X		X

the health professions" received this training during their training course. Before carrying out the interview, researchers will be aware of how to conduct a narrative interview that will help understand the complexity of the person, what moves them, what determines their manifestations, what are their responses to internal and external changes and where it is oriented.Particular attention will be paid to the ability to identify the appropriate setting, the use of effective communication, the use of communication facilitation strategies, the ability to actively listen, the development empathy and the ability to know how to be in a difficult relationship. The preparation of the individual researchers will be integrated with an afternoon of interactive training where the contents learned will be put into practice through role-playing activities and narrative interview simulations.

Variables studied: pre-test

Before the narrative interview, the study participants will complete the following questionnaires validated in Italian for the evaluation of the outcomes parameters: Psychological Distress Inventory (PDI) for the evaluation of psychological distress; Mini-MAC for the assessment of disease adaptation.

The PDI (Psychological Distress Inventory; (30): is a self-administered tool developed by a group of Italian researchers that measures the impact of disease and therapies in terms of psychological distress, in particular adaptation disorders such as reactive anxiety to cancer and its therapies such as inner tension and worry; reactive depression like displeasure, decreased energy, loss of self-esteem and loss of interest and, finally, emotional reactions to changes in body image and disturbances in interpersonal and sexual behaviors. The PDI consists in 13 questions, the answers of which use a 5-point Likert scale for assessing the intensity of distress (from 1 = "not at all" to 5 = "very much"). The PDI has been developed and validated for use in patients with tumor in different stages of disease and uses the 7 days prior to the compilation as time reference. The overall score is calculated by adding the score of single items: a high score indicates a high distress in all items except 2 and 6; in these two items it is necessary to invert the score before being able to sum. The overall score varies from a minimum of 13 points to a maximum of 65 points. The Mini-MAC (Mini-Mental Adjustment to Cancer (31, 32): is a test consisting of 29 items that examine patients' cognitive and behavioral responses to the tumor using a 4-point Likert scale (from 1 = "completely disagree , it is not my case at all "a 4 =" completely agree, it is exactly my case "). The items define 5 types of psychological reactions to the pathology and have been formulated to evaluate the coping style most frequently chosen for tackle the problems and not the quantity of the reaction or the symptoms. The results therefore show which of these styles tend to be most used. The 5 typologies are, specifically, Fatalism (5 items): the idea of the subject is that successes and failures depend on a life plan already set which cannot be escaped; the Combative Spirit (4 items): the individual believes in his own ability to improve the uneasy situation he is experiencing through commitment, the right act attitude and collaboration with healthcare staff; Desperation / Depression (8 items): the subject refuses to evaluate positive alternatives and has an approach towards depressive events; Anxious Concern (8 items): the person experiences emotions such as anger, fear, anxieties tends to agitate himself/herself and makes him/her live the path of treatment with greater concern; Avoidance / Minimization (4 items): the person avoids thinking about disease and treatment, trying as much as possible to distract himself/herself so as not to think about the situation he/she is experiencing.

Intervention

The intervention is based on the administration of two narrative interviews to the participants, the first one month from the diagnosis of the disease and the second with a time interval of two weeks.

Narrative interview: the tool is used by specially trained health professionals and has the purpose of understand how the person experiences the communication of the diagnosis of disease, in particular, in terms of stress and adaptation, using as a tool of 'cure' the relationship between the patient and the health professional, that will analyze the following three topics: the communication of the diagnosis as an element that causes stress, the adaptation of the person to the disease and the impact of the disease on the person's lifestyle history.

The interviewer will be trained to create a positive relationship with the sick person, to use some communication facilitation strategies, to maintain the relationship even in difficult situations (such as the silence or hesitation of the participant) to create an atmosphere of active listening and empathic understanding. The interviewer will also collect some socio-personal data of the participants. In addition, an observer is expected to be present. The observer collects and notes information on the participant's verbal and non-verbal communication and supports the interviewer so that the dialogue remains relevant to the objectives of the meeting and to the stimulus questions proposed. In the context of this study, the interview will have a duration between 30 and 40 minutes and will be audio-recorded.

Two weeks after the first interview will be done the second narrative interview that will be based on the topics of the first one detecting any changes on the main covered topics.

The topic of the first narrative interview is reported in Table 2, the topic of the second narrative interview is reported in Table 3.

Variables studied: post-test

In relation to the quantitative assessment, at the end of the second interview, the participants will be given the same tools as in phase 2.

About the qualitative assessment, to verify the impact of the narrative interview carried out by health professionals on the person who received a diagnosis of cancer and on the two outcomes of psychological distress and adaptation to the disease, the sample will be asked to write a reflective text in which to expose one's emotions and reflections with respect to the narrative interview previously carried out and describe the aspects appreciated and criticized. This will allow to understand the patient's declared perception of a narrative medicine intervention carried out by health professionals, in the first cancer diagnosis. The Reflective Writing is a tool of evaluation of person's life experience (33, 34). Reflective writing promotes the use of critical thinking, meta-cognition (35), self-awareness (36), mental processes that promote flexibility and adaptation (37) allowing individuals to analyze life events and situations of disease (38) in an objective way depending, above all, on those clinical events considered critical or adverse (39). Reflective writing gives concrete meaning to one's inner processes, to one's anxieties and worries that, otherwise, would remain disjointed and worthless (36, 40).

The trace of reflective writing is shown in Table 4.

Data analysis

Statistical analysis

As outcome parameters the scores reported by the participants in the questionnaires of the pre / post narrative interview sessions will be analyzed. The statistical analysis of the data will be descriptive: average, median, minimum, maximum, significant percentiles, central tendency index, standard deviation. Non-parametric analyzes will be performed on the collected data and in particular the Wilcoxon test for paired data to verify the pre-post-intervention differences.

Qualitative analysis

The 'reflective writings' written on paper format then computerized will be subjected to thematic analysis (44). The method requires two researchers to independently analyze the transcripts by repeatedly reading the text, extrapolating the emerging themes, grouping them and / or dividing them into content categories. During the analysis, the researchers verify that, from time to time, the main themes and the categories of content that compose them are consistent with the transcription data, identify significant sentences that condense and represent the meaning of the themes and categories identified. The methodological rigor of the analysis process will be further guaranteed through the supervision of a third researcher outside the study. Once the categories have been extrapolated, any change in meaning (meaning shift) will be highlighted in relation to what the professionals express before and after the training intervention.

Table 2. Trace of conduction of the first narrative interview

The narrative interview, as an intervention tool for patients who have received the diagnosis of oncological disease, includes 3 fundamental sections:

a) The communication of the diagnosis as an element of stress;

b) The adaptation of the person to the disease;

c) The impact of the disease on the person's life and relationships

For each area some example questions are reported.

Introduction to the interview

At this stage it is useful to try to put the interviewee at ease as much as possible, thanking him/her for having accepted the invitation and willingness to provide clarifications.

Examples of questions:

Thanks for being here. Compared to the information you received, is there something that is not clear to you?

Opening question of the interview

For the sick person

Examples of questions:

Do you feel like telling how the disease diagnosis was communicated?

(try to understand where the communication took place, with what style of communication, in what terms, who was present ...)

1. The communication of the diagnosis as stress element

These questions are a guide to starting an interview about communicating the diagnosis of cancer disease.

The questions focus on how the diagnosis relates to distress and personal difficulties.

Examples of questions:

Do you want to tell us what your experiences were when communicating the diagnosis?

(investigate thoughts, emotions, concerns, expectations…)

2. The adaptation of the person to the disease

These questions can help understand how and if the sick person uses internal or external strategies to cope with the disease.

The answers to these questions can help identify coping strategies that could be more or less helpful in the process of adaptation to the disease.

Examples of questions:

Would you like to tell us how your life has changed since the diagnosis?

(attention is paid to highlighting internal and/or external elements that may have been obstacles or favorable to change)

To date, do you want to tell us what you are experiencing?

(we investigate changes in thoughts, emotions, concerns, expectations ...)

3. The impact of the disease on life and relationships

These questions help to understand how and if the person's life changed after the diagnosis and in which crucial domains: physical well-being (symptoms related to pathology and/or therapy), psychological well-being (emotional and cognitive aspects), social well-being (social relationship and emotional life), finally spirituality, religion and personal beliefs.

Examples of questions:

Would you like to tell us how the quality of your life has changed?

(pay attention to physical aspects, aspects related to concerns, social and family relationships, self-image and social role, work…)

Would you like to tell us what possible changes there are in your family and social relationship life?

Final question:

Example:

For today we are almost done, do you think of anything else you would like to add? Would you like to meet us again in 15 days?

Closing of the interview

At this stage the interview ends, thanks and requests for the second interview are available

Example:

Thank you very much for your availability

Now I would close the interview, but I would like to ask you if I can possibly hear you again if, re-reading what we said, there are points to be explored.

So, do I have your availability?

Table 3. Trace of conduction of the second narrative interview

The second narrative interview takes up the tracks of the first interview and includes the same 3 fundamental sections. For each area, also in this case, some example questions are reported.

Introduction to the interview

At this stage it is useful to try to make the interviewee as comfortable as possible, thanking him/her for having accepted the invitation and willingness to provide clarifications.

Examples of questions:

Thanks for being here again. Compared to the information you received in the last interview, is there something that is not clear to you? Can we proceed?

Opening question of the interview

For the sick person

Examples of questions:

Compared to the last time we met, how do you feel today?

1. The communication of the diagnosis as stress element

These questions are a guide to highlight if there have been changes in relation to experiences of distress and personal difficulties related to the communication of the diagnosis.

Example of questions:

To date, compared to the communication of the diagnosis, what are your experiences?

(explore if something has changed from the first to the second interview with respect to thoughts, emotions, concerns, expectations)

2. The adaptation of the person to the disease

These questions can help understand whether the person has changed his internal or external strategies to cope with the disease.

Example of questions:

To date, do you want to tell us how you are facing your illness? Do you feel that your life has changed? If so, in what?

(explore changes in thoughts and emotions, about how to deal with the disease and adaptation to it)

3.The impact of the disease on life and relationships

These questions help to understand how and if the person's life has changed since the last meeting and if there have been changes in the related domains: physical well-being (symptoms related to pathology and / or therapy), psychological well-being (emotional and cognitive aspects), social well-being (social relationships and emotional life), finally spirituality, religion and personal beliefs.

Examples of questions:

In your opinion, what changes have occurred in your life?

(physical aspects, aspects related to concerns, social and family relationships, self-image and social role, work)

What eventual changes did you have in your relationship life (with family, with friends ...)?

Final question:

Example:

We are almost done; do you think of anything else you would like to add?

Closure of the interview

At this stage the interview ends, we thank the participant for participating in the study

Thank you very much for your availability

Table 4. Form for filling in reflective writing

Dear participant, the following questions are intended to understand how you lived the experience of the narrative interview previously carried out. There is no right answer, feel free to express any kind of opinion, emotion and reflection, aspects appreciated or criticized referring to the interview itself. This will make it possible to understand, through your opinion, if a narrative interview intervention proves to be advantageous applied in the present clinical context. Thank you for your cooperation.

1. Would you like to try to describe how you felt during the previous interview?
2. What did the interview stimulate in you?
3. Were there any particular moments that you appreciated, or moments of difficulty or unease?
4. Do you feel any need that could allow you to live this interview better?
5. Is there anything else you want to add and feel that you are reporting?

Ethical considerations

The study will be conducted in accordance with this protocol, any amendments introduced and authorized, the ethical principles of the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm). The participants in the study will be informed in detail by the investigator on the aims and objectives of the study and must sign specific informed consent to the study and to the processing of personal data which will be archived together with the study documentation. The informed consent including the information note clarifies how the study is voluntary, with the possibility of withdrawing at any time, and through the specific information note, the information on the study that will be carried out is complete. Participants can at any time modify or delete the collected data. The document also declares that the interview will be audio-recorded and that the data collected and studied will be disclosed in strictly anonymous form. The study obtained a favorable opinion from the Ethical Committee of Area Vasta Emilia Nord (Protocol N. 2019/0111884).

Discussion

The primary objective will be assessed by trained professionals who carry out their work outside the clinical setting of the study and who will not have contact with the patients involved in the study, to protect the confidentiality of data collection. For the feasibility of the study, the number of patients who, once recruited, offer their consent to participate in the study and the number of patients who, once the informed consent has been signed, will complete the intervention. The study will be considered feasible if ≥50% compliance is found in both cases.

About the evaluation of the secondary objective, the fallout of the intervention will be evaluated on:

- Self-perception by the patient: reflective writing
- Psychological distress: PDI (Psychological Distress Inventory);
- Adaptation to the disease through the identification of the types of psychological reactions to the disease: Mini-MAC (Mini-Mental Adjustment to Cancer).

To date, there are no studies using the narrative interview as an intervention tool on cancer patients on their first diagnosis. For this reason, it was decided to proceed with a feasibility study of the intervention, estimating its effect. This will help to structure a subsequent multicentric study on efficacy assessment. The intervention should act on three elements: a) identify risk factors or protective factors on psychological distress and on settling with the disease, which medicine does not adequately consider; b) taking into consideration the person in a holistic dimension, which focuses not only on the bio-clinical aspects, but also on the psychological, relational, spiritual aspects; c) helping the reworking of their life journey and experiences related to the disease, in which the patient becomes an active part of the treatment process, with repercussions on the therapeutic adherence and on the quality of life of the person. It is therefore hypothesized that the narrative interview intervention will help patients to achieve a greater awareness of the psychological and social aspects, not only of the strictly clinical aspects of the disease, as underlined in the study by Murphy and Coll. (2). In addition, the narrative interview is expected to be helpful to the patients to rework their experiences of life and of the illness, their relationship with family members and health personnel. This intervention would therefore improve compliance and therapeutic adherence linked to the development of the disease (41). The narrative interview should therefore help to increase the understanding of the disease in subjects interviewed, reducing their psychological distress

Previous international studies underline the importance of the narrative interview as a tool to help the patient find a meaning and a personal sense of the disease and to overcome suffering (42). Fortuna (43), in the Italian context, also substantiates the evidence that the narrative helps the patient to feel heard and to participate more actively in their health and in their care process. The expected results are also in line with what Sakalys said (15), that reflexive writing and storytelling help to give meaning to the disease with the aim of supporting the patient in organizing the stories and providing a report that allows the evolution of the disease history. By developing the ability to understand and interpret events, experiences could take on a profound meaning which, once integrated and assimilated, will guide future behaviors (44, 45). The act of transforming thoughts into words creates new ideas, since the memory of experience allows, in addition to the analysis and understanding of it, to be able to alter its original perception, giving rise to new ideas and reflections (46)

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Transition of care in pediatric oncohematology: a systematic literature review

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Abstract. *Background:* The transition of medical care from a pediatric to an adult environment is a psychological change, a new orientation that requires a self-redefinition of the individual, to understand that changes are taking place in his life. Up to 60 percent of pediatric patients who transition to adult services will experience one or more disease or treatment-related complication as they become adults. A nurse who knows how to recognize potential barriers at an early stage can play a pivotal role in the educational plan for the transition process. *Materials and methods:* A literature search was undertaken of PUBMED, CINAHL and The Cochrane Library, with specific inclusion and exclusion criteria, including articles published in the lasts ten years.This literature review has been performed according to the PRISMA statement. *Results:* Using the keywords in different combination 38 articles were found in The Cochrane Library, 5877 in PUBMED, 274 in CINAHL. 88 articles were selected after the abstract screening. 31 after removing the duplicates and reading the full text. *Discussion:* The main themes surrounding transition of care that emerged from the synthesis are the organization of care within common models of transition, innovative clinical approaches to transition, and the experience of patients and caregivers. The transition from pediatric to adult care of cancer or SCD survivors is an emerging topic in pediatric nursing. The organization of care is affected by the lack of clear and well-structured organizational models. Further research is needed to deepen the understanding of some aspects of the transition. (www.actabiomedica.it)

Key words: oncology, sickle cell disease, pediatric, nurse, transition, review, models, organization, care, cancer

Background

The transition of medical care from a pediatric to an adult environment is a psychological change, a new orientation that requires a self-redefinition of the individual, to understand that changes are taking place in his life (1). Transition is defined as a "purposeful, planned process with a goal of providing continuity of care and preparing young adults for greater independence" (2).

Transfer of care from pediatric to adult services may occur between 18 and 21 years of age (3,4). Young adults who make this transition from pediatric oncology are usually long-term survivors, children who have survived cancer and need a follow-up period.

About 90% of young people with chronic health conditions survive and reach adulthood (5), and cancer survivors are a growing population (6). About 75% of survivors say they experience a chronic health condition, more than 40% still have serious health problems and 33% have multiple health problems (7). Many centers don't have a plan to prepare the survivors and their families for a successful transition (6), although a good plan can help young adults maintain optimal health outcomes, promote independence and empower them to manage their own health conditions (1,8).

Up to 60% of pediatric patients who transition to adult services will experience one or more disease or treatment-related complication as they become adults, including endocrine, cardiac, reproductive or psychological side effects, difficulty coping with adverse results of treatment, anxiety about the future, or an altered body image (9).

The same problems are experienced by patients with Sickle Cell Disease (SCD) (10). Almost 95% of patients with SCD live past the age of 18 and therefore require transition to an adult healthcare setting. For these patients, the period between 18 and 22 years of age is associated with an increased risk of mortality and morbidity due to poor adherence to therapy (11,12). As a consequence, pre-transition process measures are an important component of quality care in SCD (10).

Different transition models have been proposed to adapt to this difficult phase: generic models fit the traditional medical training models of pediatric, adolescent, and adult health care providers. In primary care models a family physician, or a primary care physician, is viewed as the care coordinator, and subspecialty consultants are used as needed. Single-site models are similar to generic models; the site of care remains constant as transition occurs from pediatric to adolescent to adult health care (3). Many patients have difficulty coping with this initial phase of the transition process, proved by an increase in access to the first aid, to emergency visits and re-hospitalizations.

Barriers to transition of care are most often classified into one of four groups: patient centered barriers, family centered barriers, pediatric caregiver barriers, and adult caregiver barriers (13,14).

A nurse who knows how to recognize potential barriers at an early stage can play a pivotal role in the educational plan for the transition process: this professional can identify the needs and limits of each young person, and must have a strong cultural background on this aspect (15).

Aim

The present study aims at exploring, through a systematic literature review, the main topics of transition care in the pediatric hemo-oncological and oncological setting, at identifying the strengths and weaknesses of this process, the different organizational phases, the models already tested, and at addressing the experiences lived by the main actors (patient and caregiver).

Materials and Methods

A literature search was undertaken of PUBMED, CINAHL and The Cochrane Library, from March to April 2018.

The following keywords were used in combination to identify relevant publications: transition of care, oncology, cancer. The terms were combined using the Boolean operator AND. Limits for the search were: full text, publications in the last 10 years, articles in English or Italian, and any type of study design.

Inclusion criteria: articles about the transition process between pediatric and adult providers; articles about nursing topics related to the transition process, patient experiences of transition, caregivers experience of transition, facilitators, difficulties and barriers to transition; articles illustrating how handover between healthcare professionals is organized. Both articles exploring the transition process for patients with oncohematological, oncological disorders and sickle cell disease were all included as they share the same clinical environment and healthcare team.

Exclusion criteria: articles about the transition process between adult providers, articles about medical topics such as drug dosage, diagnosis, and costs related to the process, articles about transition processes for patients with a diagnosis other than cancer or sickle cell disease.

This literature review has been performed according to the PRISMA statement (16).

Using the keywords mentioned above, 38 articles were found in The Cochrane Library, but excluded because of lack of relevance. 5877 articles were found in PUBMED and 71 of these were selected, 274 articles were found in CINAHL and 17 of these were selected. A total of 88 articles were selected after the abstract screening. After removing the duplicates, 44 articles were considered.

After the reading of Full Text, 31 articles were selected, because the other fall in the exclusion criteria.

Table 1. Search strings and keywords.

Search number	Found articles	Selected articles	Keywords	Limits	Databases
1	4752	65	Transition of care AND oncology AND cancer	2008-2018, Full text, English and Italian	Pubmed, Cochrane Library
2	3351	42	Transition of care AND oncology	2008-2018, Full text, English and Italian	Pubmed, Cochrane Library
3	4053	46	Transition of care AND cancer	2008-2018, Full text, English and Italian	Pubmed, Cochrane Library
4	3	0	Transition AND cancer AND oncology	2008-2018, Full text, English and Italian	Cochrane Library
5	35	0	Transition AND oncology	2008-2018, Full text, English and Italian	Cochrane Library
6	15	0	Transition AND cancer	2008-2018, Full text, English and Italian	Cochrane Library
7	248	12	Transition of care AND cancer AND oncology	2008-2018, Full text, English and Italian	CINAHL
8	156	4	Transition of care AND cancer	2008-2018, Full text, English and Italian	CINAHL
9	162	8	Transition of care AND oncology	2008-2018, Full text, English and Italian	CINAHL

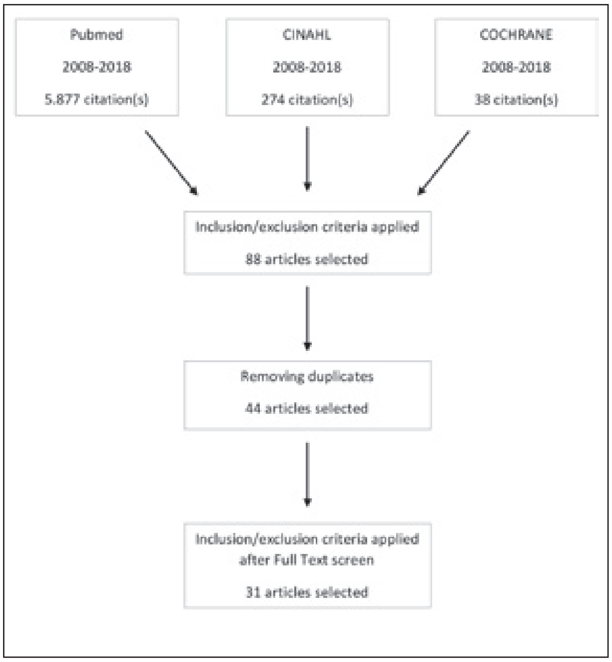

Figure 1. PRISMA Flow Diagram

Of these 6 were reviews of the literature, 1 policy statement, 14 descriptive studies in prospective/retrospective or cross-sectional design, 9 qualitative studies with focus-groups, semi-structured interviews or Delphi studies, 1 qualitative socio-ecological study.

Results

The main themes surrounding transition of care that emerged from the synthesis are the organization of care within common models of transition, innovative clinical approaches to transition, and the lived experience of patients and caregivers.

Organization of care in transition

The definition of transition means the transfer experienced by adolescents and young adults from pediatric to adult care. This transition can be a period of major stress and unfavorable consequences especially for adolescents who have undergone treatment for a serious illness and must move from a sheltered pediatric environment to an independent adult-medicine environment. Adults who transitioned without a concrete plan reported feeling ill-prepared and that their

Table 2. Summary of results

Study Author, Year	Design	Study Aim	Sample, setting	Findings
Freyer et al., 2008	Literature review	To identify specific goals and action items in the following key areas: Models of Transitional Care, Survivor/Family Education, Post-Transitional Care Outcomes, Education of Health Care Professionals, and Health Care Policy and Advocacy.	Not applicable	Deficit in primary care assistance and long-term planning. Some centers use a team with a general adult physician and pediatrician. Pediatric oncologists should develop a plan for patients that accounts for the possible long-term effects that they may experiences as adults. There is a need for increased family education, and additional education for care teams on the transition process.
McPherson et al., 2009	Descriptive cross-sectional study	Primary aim: to describe the preparation and knowledge of adolescents with Sickle Cell Disease during the transition process based on age, sex, degree of severity of the disease. Secondary aim: to identify adolescents' concerns about interfacing with transition process.	69 adolescents with Sickle Cell Disease, 30 females and 39 males, USA- Washington	Older children feel more prepared and have greater levels of knowledge about the process of transition of care. A positive attitude towards this process increases over the years, the difficulty of the process is inversely related to the severity of the disease. An insufficient knowledge and a late introduction to it emerges as the main barriers to the transition process.
Henderson et al., 2010	Literature review	To describe problems and obstacles to the success of transition programs dedicated to child cancer survivors.	Not applicable	Transition programs for child cancer survivors require the input from experts who can act as a bridge between pediatric oncology services and adult primary care services, in order to reduce risks associated with transition. The transition process must take place gradually and can be carried out optimally only by overcoming the concrete problems. The obstacles to the success of transition are put in place by those who should facilitate this process: the health system, the patients and those involved in providing care in the pediatric and adult fields.
Freyer, 2010	Literature review	To explore how the formal transition process can contribute to meeting the medical and psychosocial needs of child cancer survivors who usually have a lack of knowledge on health and health promotion.	Not applicable	Patients who survive childhood cancer are not compliant with the recommended follow-up in adulthood. The systematic transition process is the gold standard, even if there is no model that is ideal or better than others.

Table 2. Summary of results

Study Author, Year	Design	Study Aim	Sample, setting	Findings
Nathan et al., 2011	Literature review	To identify a systematic transition plan that considers diagnosis, initiation of therapy, completion of therapy, entry into long-term follow-up care, transfer from pediatric to adult medical providers, and exit from oncology care providers to primary health care providers.	Not applicable.	An appropriate care plan is essential to transfer the patient from a cancer clinic to the primary care setting. Many patients do not have a primary care provider, so the cancer clinic should help them find one. Some clinics accompany the patient during this phase, others discharge them at the end of the therapy without planning for the transition to the adult clinic.
Sobota et al., 2011	Survey, Descriptive cross-sectional study	To describe how the transition process takes place in pediatric hospitals with Sickle Cell Disease centers (logistic mode, identification of a physician in the adult area, patient preparation, program and transition assessment, demographic aspects).	Directors, or delegates, of 45 pediatric hospitals with Sickle Cell Disease centers. USA- Boston	The transition process is initially discussed when the patient is about 15 years old, and is initiated at around 19. 97% of the centers identify a referring physician in the adult area. Most professionals discuss it with the patient and the family, and prepare a plan that identifies needs. About half of the centers review the program annually, 39% measure patient satisfaction. The main obstacle is finding a referring physician in the adult service.
Schwartz et al., 2011	Qualitative study. Social-ecological model	To create a social-ecological model that describes the patient's preparation for the transition phenomenon.	Adolescent and young adult (AYA) with chronic health conditions, including patients with cancer and survivors.	Model divided into 3 parts (patient, parent, physician) that assesses the degree of preparation for transition by age, knowledge of the disease, and cognitive ability. This model considers the influence of health, culture, sociodemographic factors and health system on the style of coping that the patient and the family may develop. The model aims to be universal, therefore there is a need to validate it in specific populations.
Granek et al., 2012	Qualitative study. Grounded theory.	To identify psychological factors involved in the transition process.	Total: 38 patients. 10 patients still under the care of pediatric services. 28 patients who had undergone transition to adult services: 11 successfully transitioned, 17 failed the transition.	It is very important to take into account the psychological factors involved in the preparation of child cancer survivors who are transitioning to adult services. Identifying and addressing the individual psychological needs of these patients can contribute to a successful transition. Moreover, since the attitude towards one's own health is not always regulated by rationality, but is influenced by emotional drives, focusing on the psychological aspects, can help patients to address themselves in a positive way towards the treatment.

Table 2. Summary of results

Study Author, Year	Design	Study Aim	Sample, setting	Findings
McInally et al., 2012	Literature review	To explore the meaning of effective transition, highlight some of the challenges faced by young people with cancer, identify gaps in the research literature.	Not applicable	The care provided should be appropriate for the young adult; the patient's concerns must be heard by specialists; the transition of care should promote autonomy, independence and responsibility of the young person; the process must be flexible and planned with the family. There is no shared or emerging model to guide the process.
Sadak et al., 2013	Descriptive cross-sectional study	To generate hypotheses of facilitators of the transition process.	129 young adult (> 16 years old) cancer survivors that have not yet "passed" into the adult setting.	Young patients prefer a clinical team with a pediatric specialist and a clinical setting where there is good flexibility in planning the transition process. The possibility of using network to help the process is poorly considered. There is the necessity to clarify meaning of network, if included as a social network or network created by social media.
Schwartz et al., 2013	Qualitative forms: focus group e semi-structured interviews.	Further validation of the Socialecological Model of Adolescent and Young Adult Readiness to transition (SMART) through feedback from stakeholders: child cancer survivors, their parents and caregiver teams.	14 patients who survived childhood cancer. 18 parents. 10 health professionals specialized in the pediatric field.	Progress in the transition process is hampered by the lack of measurement instruments that could identify and improve current practices. SMART is a theoretical model, a comprehensive and empirically appropriate tool for assessing whether a child cancer survivor is ready for the transition process.
Klassen et al., 2014	Interview. Evaluation scales.	To develop and validate instruments that evaluate when a child cancer survivor is ready to transition from pediatric to adult care.	38 child cancer survivors: 10 still managed by pediatric care, 11 successfully transitioned, 17 failed transition process. 331 child cancer survivors, of these 250 completed the questionnaires.	There is limited knowledge about the experience of the transition process for child cancer survivors. Validated assessment tools can be used to investigate obstacles and / or facilitators to the transition process from pediatric to adult care. Creation of three evaluation scales: 1. Cancer Worry Scale 2. Self-management skills scale 3. Expectation scale
Fernandes et al., 2014	Descriptive study.	To determine patient and parent attitudes and perceptions of the education provided during the transition process, and obstacles to transition .	155 patients with various chronic childhood illnesses, aged between 16 and 25.	Most patients and parents say they have received information and training on the health condition. There are significant gaps in the educational process that takes place during the transition.
	Self-assessment survey: 30 multiple choice questions and 1 open-ended question.		104 parents or caregivers.	For example: lack of education regarding unprotected sex, birth control, pregnancy, drug abuse, and lack of job counseling. Some barriers to the transition process have been identified: emotional attachment to the pediatric team, and gaps in the provision of adult care. Most patients feel ready to complete the transition process at the age of 25.

Table 2. Summary of results

Study Author, Year	**Design**	**Study Aim**	**Sample, setting**	**Findings**
Andemariam et al., 2014	Descriptive retrospective study.	To describe risk factors for negative outcomes of the transition process.	47 patients with Sickle Cell Disease between the ages of 16 and 24 who experienced the transition process between 2007 and 2012.	The study shows that a transition with a negative outcome is not related to sex, race, episodes of "acute chest syndrome" or hospitalizations for episodes of vasoc-clusives. There is a correlation with the starting age of the transition (the most favorable outcome for those who start before the age of 21) and with the distance of the adult clinic compared to the pediatric setting.
Bryant et al., 2015	Policy statement	To define the process of preparing pediatric patients with Sickle Cell Disease for the transition of care	Not applicable	It appears necessary to start discussing transition at 12 years old, and start written planning from 14; to get help from organizations in the sector; to include in the plan a multi-professional team, and the family / caregiver; to make sure that parents leave the child alone only a part of the visit from the age of 13, and let completely alone visits from 18 years old. The process ends not in the transition to the adult setting, but when the whole team and the family are sure of the successful outcome of the transition.
Frederick et al., 2016	Qualitative study Focus group	To describe the commonalities and differences between experiences of patients with cancer.	16 patients recruited from a pediatric oncohaematological clinic, aged 21 to 39, who have completed therapy for at least 1 year.	Main themes emerged: education on "self-advocacy", the worry about the future, the role of the family as an obstacle to autonomy, the dependence on parents to book visits and to make health decisions, the expectation of having a close relationship with the doctor, the problem of who to ask for support, the necessity of an individualized plan for the process, different expectations on primary care medical role.
Ganju et al., 2016	Descriptive cross-sectional study.	To evaluate the impact of the previous care, before the transition process, on patient knowledge and awareness of the disease. Identify any demographic or neurocognitive barriers to education.	110 patients enrolled. 93 of these completed the questionnaire.	Participation in patient care program plays an important role in the transmission of information regarding their pathological history and the perception of the risks of future health problems. Care programs for child cancer suvivors must be developed and implemented to fill any gaps in the patients' knowledge of self-management of health.
Svedberg et al., 2016	Cohort observational study. Mixed method.	To explore young adult cancer survivors experiences of support from health services during the transition process.	416 patients diagnosed with acute lymphoblastic leukemia between 1985 and 1997 enrolled in the Swedish Children's Cancer registry. Of these, 144 completed the questionnaire.	Most participants received insufficient physical, mental and social support from health services. During the transition process it is necessary that health services adopt a personalized assistance plan. The approach used must be holistic and must support the patient in managing their life in the best possible way.

Table 2. Summary of results

Study Author, Year	Design	Study Aim	Sample, setting	Findings
Szalda et al., 2016	Descriptive cross-sectional study. Questionnaire.	To describe the patient perceptions of the involvement of adult services during follow up.	80 patients transferred from the Survivorship Cancer program at the Children's Hospital in Philadelphia to the adult-focused follow-up. 99 of these decided to participate in the study; 80 completed the questionnaire.	Young adults cancer survivors report a non-optimal involvement and communication during follow-up meetings for adults with cancer. Patients demonstrate a lack of understanding in the importance of follow-up.
Kenney et al., 2016	Descriptive cross-sectional study. Questionnaire.	To describe the current practices and models of transition process; to describe the perceived obstacles during the transition phase.	1586 medical specialists in pediatric oncohematology, members of the Children's Oncology Group. Of these, 507 replied to the electronic questionnaire. Of these, 347 possessed the eligibility criteria.	Systematic transposition practices do not seem to be widely used by pediatric oncologists. Specialists experience many barriers to the transition of patients to adult care. Medical specialists share the goal of providing patients with a systematic transition education to prepare them to manage their health needs independently.
Bashore et al., 2016	Pilot study	To examine the use of an interactive workbook as an educational method for patients facing the transition.	20 child cancer survivors, between 16 and 21 years old, who have completed therapy two years ago.	Those who are less ready to leave pediatric services are less likely to start the transition process. Patients experienced more anxiety at the start of the study than at the end Those who finished the workbook reported they felt more ready for the transition. The workbook is recognized as an instrument, but more education and knowledge is needed on the process.
Margolis et al, 2017	Descriptive retrospective and cross-sectional staudy	To identify strengths and weaknesses in the management of transition from a pediatric to an adult clinical setting for patients with Chronic Granulomatous Disease	33 patients enrolled from 1 January 2011 to 28 February 2014, aged between 18 and 24.	The authors identified that introducing patients to the adult clinical setting before admission was a facilitator to transition Main barriers identified included a lack of full understanding of the patient's disease and treatment regimen, lack of preparation and planning for the transition process, and missed opportunity for Advance Care Planning.
DiNofia et al, 2017	Descriptive cross-sectional study	To describe the wishes of parents of child cancer survivors in the transition process towards an adult setting.	138 enlisted parents, 123 enrolled, 41 responses collected. Parents of patients > 16 years of age who participated in the 3 years preceding the "LTFU Program at Children's National Medical Center"	Parents want complete involvement in the transition process. They consider it important to promote the independence and responsibility of their children, to be prepared for the transition process, and to maintain a point of contact at pediatric services.

Table 2. Summary of results

Study Author, Year	Design	Study Aim	Sample, setting	Findings
Sadak et al., 2017	Phenomenological qualitative study	To define the characteristics of a positive transition of care from the point of view of the patient's medical team, patient and parents, with semi-structured telephone interview.	29 professionals (10 doctors, 8 experienced nurses, 6 nurses, 2 psychologists, 1 social worker, 1 dietician, 1 administrative) of 3 institutions.	The study identified the following facilitators of transition: good communication between the pediatric and adult teams, multidisciplinary network of specialists, presence of several services within a structure (as happens mostly in Pediatrics), creating the figure of the "Patient navigator" (a bridge between the two settings), hold regular meetings between the pediatric and adult teams. The identified barrier is the lack of a home care team or primary care physician helping this process.
Quillen et al., 2017	Descriptive pilot study.	To identify and describe barriers that young adults encounter during the transition process within 5 years from the end of the pediatric therapeutic path.	48 young adults, aged between 20 and 25, who completed treatment in pediatrics and transitioned to adult services.	Barriers included a knowledge deficit in the transition process among young patients; lack of physicians' knowledge of the long-term effects; poor education on long-term follow-up. It could be useful to have a contact list of adult hospitals to create a transition plan.
Mouw et al., 2017	Qualitative approach: grounded theory. Interview.	To examine existing models of the transition process, emphasizing strengths and weaknesses. To optimize these models in order to maintain a connection with child cancer survivors who go through the transition process.	20 LTF experts (Long term Follow up): doctors, nurses, social workers, educators, psychologists from 10 institutions affiliated to the Pediatric Oncology group.	Most patients who survive childhood cancer develop physical and / or psychosocial sequelae; however, many subjects do not receive adequate long-term follow-up for screening, prevention and treatment of later complications. Patients benefit from transition models in which there is a greater and better connection between patient and specialist.
Nandakumar et al., 2018	Descriptive study: semi-structured telephone interviews	Describe the attitudes and experiences of child cancer survivors and their parents regarding barriers and facilitators to the transition process.	33 subjects interviewed: 18 patients who survived childhood cancer 15 parents of patients who survived childhood cancer	The obstacles to the transition process include: dependence on pediatric health services, low trust in general practitioners, inadequate communication and cognitive difficulties. Facilitators include trust of physicians, good communication, patient independence, and patient age when transition process is commenced.

transition was based on age rather than readiness or needs (17). These adult patients also reported that their follow-up care had declined since the transfer.

In addition, failure of transition and hence of appropriate surveillance for late effects may have potentially important medical consequences (6). Hence, a well-planned transition to adult care allows AYAs (adolescents and young adults) to optimize their health and ability to independently manage their disease and assume adult roles and functioning (5). Thus, transition programs that prepare pediatric patients with SCD for the adult healthcare environment promote self-advocacy and self-management. Model transition programs use interdisciplinary teams to help adolescents develop this independence and knowledge.

While there is a body of literature on Advance Care Planning with AYA, this topic is often overlooked in the literature on transition (18). This is probably due to the vast heterogeneity of situations that may be faced by caregivers dealing with this transition, so that the argument may have been considered as too broad. For instance, the pivotal focus in the transition programs for cancer and sickle cell disease (SCD) – one of the cases studied in this review – has so far been mostly focused on a very specific topic, the optimal age to deal with transition.

Care Transition Models

Several models of care for adult survivors of childhood cancer were identified. According to Freyer et al., some institution-based programs transfer young adult survivors from the pediatric oncology clinic to an adult-oriented Long-Term Follow-Up (LTFU) team within the same medical campus, comprising both primary care physicians (e.g. family medicine or internal medicine) and pediatric oncology clinicians (e.g. physician or mid-level provider) (18). At the time of survivor transition (typically between 18–25 years old), the pediatric oncology team needs to prepare a detailed, comprehensive treatment summary to aid the new physician. This document should include a summary of the cancer diagnosis; prior treatment including significant clinical events; an assessment of current health status including a complete physical examination and list of active health problems and psychosocial issues; and potential late effects (with approximate risk estimate, if possible) that may result from the cancer, its treatment, genetic predispositions and any co-morbid conditions.

Freyer (19) classifies transitional care models under three headings. In the cancer center–based model transitional care is delivered within the same system as treatment was given and involves direct, on-site collaboration of the pediatric oncology team and adult care providers. In the community-based model, transition is located in the office or clinic of the care provider, typically a primary care clinician. With the hybrid model, care is also transferred to the office or clinic of the primary care provider but relies on an ongoing interaction with the cancer treatment center that includes bidirectional updates on patient status, assistance with clinical management, and provision of current survivorship care guidelines. For all three models, the pre-transition phase relies on the pediatric long-term follow-up team (typically a pediatric oncologist, an advanced practice nurse, and a medical social worker).

A similar classification is proposed by Granek (20). In their work, some programs transition to a primary care practitioner, while others offer life-long care in specialized survivor clinics. An intermediate model distinguishes between survivors with high and low levels of morbidity. The former shall be included in specialized survivor programs, while the latter can be addressed to primary care practitioners.

The majority of pediatric cancer centers have a formal survivor program or clinic. The remaining centers do not have a specialized Long-Term Follow-Up (LTFU) program or clinic and provide follow-up to survivors in their acute care oncology clinics. Nathan (21) describes transition models for AYA cancer survivors in Canada. Once survivors reach adulthood, few centers have access to a formal program for adult survivors of childhood cancer, whereas the remaining centers discharge survivors to their primary care physician at some point after the completion of therapy. There are no formal survivor programs for adolescents/young adults who receive their acute cancer care in an adult hospital.

There are five core principles for transition arrangements of childhood cancer survivors to be successful (9):

1. The healthcare setting should be appropriate for the client's age and stage of development.
2. Common concerns associated with young adulthood should be addressed in addition to specialty care.
3. Transition should promote autonomy, personal responsibility and self-reliance in young adults.
4. Transition programmes should be flexible to meet the changing needs of young adults.
5. The designated process should be planned with the young adult and their family.

To describe transition practices and barriers to transfer, Kenney electronically surveyed 374 U.S. Children's Oncology Group members. Personal provision of transition education is delivered by the majority of pediatric oncologists, often with the help of other clinical staff. The majority of pediatric oncologists do not use a formal transition assessment tool such as questionnaire, survey, or checklist to assess their patient's transition readiness (12).

Transition has been studied in depth also for SCD survivors. Andemariam defines the transition period for SCD patients as having three phases: preparatory, transitional, and completion. The preparatory phase is focused on patient education regarding SCD and patient-specific health issues and management (22). It lasts for 6–10 visits done every 4–6 months over a 3-year period. The transitional phase is dedicated to review health summaries, problem lists, and treatment plans with the family and the medical staff. It is focused on empowering the patient and promoting autonomous health management. The completion phase is focused on establishing effective patterns of health care in the adult setting.

Sobota carried out a survey of US pediatric providers and describes transition of SCD patients. Most clinics report having a transition program, although half have been in place for under 2 years (23). There is wide variation in specific transition practices. Close to all centers have an identified accepting adult provider, however, only slightly more than half routinely transfer their patients to an adult hematologist specializing in SCD. Although there has been a recent effort to establish transition programs in pediatric SCD clinics specific practices vary widely. Lack of an accepting adult hematologist with an interest in SCD emerged as a common barrier to transition. One-third of centers allow patients to remain in pediatric care past the cut-off age in cases of cognitive or developmental delay, or needing time to complete a transition program, graduate high school, or find an adult provider.

The majority of the aforementioned studies highlight that the transition age is a main determinant of success or failure of the entire process.

Bashore et al. (1) underlines that the America Academy of Pediatrics (AAP) has established guidelines for clinicians to begin transition as early as 12 years of age, to allow for acquisition of skills necessary for the independence required in adulthood. Not only should the chronological age of the adolescent be considered but also the developmental age of the adolescent.

Andemariam stresses that, in their study, older age at the time of initiation of the modified transition process was associated with poor transition success. The preparatory and transition phases were changed such that both begin at age 16, and the definitive transfer to the adult SCD center is at the age 21. Ideally, patients schedule their first visit to the adult SCD center prior to reaching their 21st birthday, and prior to their last appointment at the pediatric SCD clinic (22).

In all three models proposed in Freyer's classification, the actual transition of care ordinarily takes place when the survivor reaches approximately 18 to 25 years of age and demonstrates transition readiness (19). The transition process needs to be initiated early—it is not too early to begin mentioning transition when the child is initially diagnosed with cancer—beginning at 18 years of age is almost certainly too late.

In another study the majority of respondents transferred childhood cancer survivors to adult care by age 25 years (12). The timing of transfer was most often determined by patients' chronologic age, diagnosis of adult comorbidities, and pregnancy.

According to Bryant et al. (10), a formal discussion about transition and the policy of the practice/institution should begin at age 12 (or when developmentally ready) with both parent and child. All patients should have a written transition plan by age 14. This plan should be developed together with the patient and their family and updated annually.

In a survey of transitioned patients, it has been demonstrated that most participants agreed that the transition should begin in early to mid-adolescence (24). This is needed to optimize education of disease history, current and future survivorship care needs, and medical risk.

In a survey of US pediatric providers, Sobota et al. (23) describes that just over half of the centers are in a system with a required age for transition due to "hospital policy," which ranges from 18–22 years. Transition is first discussed at an mean age of 15.7 years (range 13–18) and transfer occurs at a mean age of 19.6 years (range 18– 25). Age and pregnancy are still the primary factors that determine time of transfer. Pregnancy in adolescents and young adults may not be planned, and therefore, using it as a trigger for transfer is unlikely to allow adequate time for preparation. Using age as a proxy for maturity may be particularly problematic for patients with SCD, who may have neurocognitive delay due to cerebrovascular injury.

According to Quillen (15) pediatric cancer survivors could start transition to adult health care at 21 years of age.

Innovative Approaches to Transitional Care

As underlined by Ganju (25) a transitional clinic for young adult survivors (YAS) of childhood cancer is an evolving model and at present, there is little research evaluating the benefits, implementation, and efficacy of these clinics for pediatric cancer survivors.

Granek stresses that an important implication for practice is to empower teens' sense of identity as a cancer survivor by engaging with their peers and encouraging them to attend cancer-related groups and organizations that provide information and social support for survivors (20). This could be achieved through camps or organizations that involve peers as well as through peer mentor or 'buddy systems' within the health care context.

Freyer (19) propose an interactive online program called Passport for Care, which provides survivors and clinicians with a virtual resource center, where they can enter patient-specific history and receive individualized monitoring recommendations.

A pilot study examined the use of an interactive transition workbook as a method of educating survivors about their medical history, providing necessary information about the transition to adult care, and working with them to establish goals and plans for education and vocational success (1). Having the time to collate this information in an organized manner may have assisted them in processing the transition from pediatrics to adult care in the future.

Klassen et al. (26) developed three scales for childhood cancer survivors that measure concepts identified as barriers and/or facilitators to transitioning successfully to adult-orientated health care. They measure Cancer Worry (about cancer-related issues such relapsing or getting a new type of cancer), self-management skills (investigating skills that adolescents need to acquire to be able to care for their health as adults, such as booking doctor's appointments and filling prescriptions) and expectations (delving into the nature of adult Long Term Follow Upcare, such as expecting to get a reminder call before an appointment).

Sobota, Shah and Mack (27) propose that sending a transfer summary ahead of the first visit in adult care should be part of best practice in transition. According to the results of an expert panel, adult SCD providers would also appreciate direct communication from the pediatric hematologist. Lack of time and reimbursement are often cited as barriers to providing comprehensive transition. To solve this problem, transition advocates have identified billing codes that allow reimbursement for transition activities such as updating a transfer summary (e.g. by billing for "care plan oversight").

A transition model called SMART – Socio-ecological Model of AYA Readiness for Transition was proposed by Schwartz et al. (5). This model of transition extends beyond patient age and patient knowledge and skills by identifying measureable social-ecological components of the transition process and highlighting the potential role of culture and socio-demographics in the transition process, a neglected issue.

Innovative approaches such as peer mentoring programs or web-based interventions may reach more patients compared to the traditional clinic approach (28). Important next steps include further education for patients and adult providers, ensuring adequate transition planning for youth and their families, and research to determine what factors have the most significant impact on transition quality.

The Patient experience

The point of view of YAS is necessary to understand how to achieve a successful transition. To elicit this, patients aged from 16 to 39 years are often asked to complete a questionnaire by e-mail or during their annual survivor clinic visit. The most common questions concern barriers and facilitators to transition, how they received the relevant information, the relationship with their parents, and recommendations for a successful transition. Some studies have investigated gender differences (25,29); the psychological and social aspects of transition (20,21,30,31) and age differences (22,29).

Regarding gender differences, 30 females and 39 males (Median age was 16.7 years) responded to a survey on transition to adult services (29). Female patients reported a higher level of anticipated difficulty than male patients. No significant differences were found between knowledge, thought, interest, and importance of transition. In the study by Ganju et al. (25) men were less likely than women to expect future health risks from their cancer treatment.

Regarding the psychological aspect, severity of disease and a high rate of hospitalization had a negative impact on patients' interest in learning about transition (18,22,29). Using the Childhood Cancer Survivor Study Neurocognitive Questionnaire (CCSS-NCQ), Ganju et al. (25) found that the patients are more likely to assess their health risks based on their current health states, as opposed to the intensity or duration of their treatment. The transitional period often takes place at a critical time during survivors' development into independent young adults. Many survivors view themselves as completely healthy or invincible and they do not recognize their risk of serious cancer-related health problems and do not adhere to recommended cancer-related follow-up care (21). Furthermore, childhood cancer survivors may experience psychological symptoms of depression, anticipatory anxiety prior to the transfer and posttraumatic stress (PTS) which can hinder their engagement with medical care and make the transfer of care to the adult system a difficult emotional process (30,31). In the study by Svedberg et al. on 213 YAS of pediatric cancer, they found that survivors would have appreciated more follow-up information based on their needs and on their psychosocial health (31). The participants reported they had not received the annual follow-up visit to control the risk of late effects of treatment, did not experience sufficient support for: depression, panic disorders, eating disorders, obsessions, hypochondria and did not receive treatment strategies for physical changes.

Patient age was significantly associated with interest in the transition. Older age at the time of initiation of the modified transition process was associated with poor transition success (22) but patients aged 17–20 years demonstrated significantly greater knowledge and interest in transition, greater self-management skills to make their own appointments and call for medication refills than 14–16 years old (10,29). A slightly older age at transfer may improve readiness for transfer but conversations about high-risk behaviors such as alcohol, tobacco, illicit drug use, sexual intercourse, need to begin in early adolescence (32).

In some studies, the relationship and attachment to the family and to the pediatric healthcare providers has been identified as a barrier. Patients recognize the importance of care received from parents and pediatric health care providers but report this has made them less prepared for autonomy in adult life. Therefore, parents still play a significant role in communication with the healthcare services even when the patients become adults (31,32). Dependence on parents or doctors could be necessary to compensate for cognitive difficulties that result from chemotherapy treatments, as these can negatively affect self-management ability (14). Several patients develop their self-management abilities and understand their disease only after transition experience (11,14). Also, pediatric oncologists find it difficult to transfer long-term patients into adult care because of their long-standing relationship with them (14,32).

Patients suggest that awareness of the differences in care between the pediatric world and the adult world could facilitate transition (28). About 63% of adolescents wanted their pediatric doctor to supply specific information about adult hospitals in the area, 59% requested written information about the transition process, 39% requested help in making the first appointment with an adult provider, 33% asked to be connected to someone who had already gone through the transition process (28), 23% requested help in visiting different adult hospitals, and 17% requested group meetings with other patients to discuss transition (29). Other information requests concern specific names of doctors, information on insurance coverage, ease of appointment scheduling and parking/ transportation (29). Good communication was perceived to enable successful transition and was associated with positive transition attitudes. Communication also provided comfort during transition (14). The most important information for patients with SCD, was concern about the modalities of pain management and planning re-entry for transfusions (22).

Key barriers to transition included dependence on pediatric healthcare providers, less confidence in primary care physicians (PCPs), inadequate communication, and cognitive difficulty (14). Less than half of patients (N = 155) and parents (N = 104) reported receiving any education regarding reproductive health (specifically, unprotected intercourse), impact of disease on future offspring, birth control, risk of pregnancy, illicit drug use, and future career (32). Lack of knowledge about the disease and anticipatory guidance about the process were the major barriers in transition (29,33). Nearly a quarter of participants in Margolis' study (33 young adult participants, 19 - 27 years of age), reported that they did not feel included in planning the transfer of care or in the actual transition itself. One AYA said, *"There was no transition. It just kind of happened*" (33). Only in one study, a lower income was a demographic factor that correlates with less knowledge (25). Patients who have experienced a greater number of complications, like acute chest syndrome (ACS) episodes and hospitalization for vaso-occlusive crisis (VOC), are less likely to experience a positive transition (22).

In some cases participants expressed dissatisfaction about losing contact with healthcare services after the age of 18 or after being discharged from the pediatric oncology ward at the end of treatment (31), but the real problem is the perceived negative attitude and lack of trust in new adult care provider (18). Specifically in the Emergency Department and inpatient units, the staff were not well informed about SCD (28) or the PCPs did not demonstrate sufficient cancer-specific knowledge to provide the level of care that pediatric HCPs could (14). In particular, young adults with SCD have the perception that health care professionals in the adult world underestimate the degree of pain experienced (28). Some Adult Patients with SDC have reported "*these physicians did not have enough medical knowledge about sickle cell disease*" (11).

Non-clinical risk factors for unsuccessful transitioning were greater travel distance from the patient's home to the adult SCD center (22), or the inaccessibility of care due to distance (14) transfer to another city (11), and insufficient medical insurance (11,14).

According to the results of this literature review, patients demonstrated high levels of awareness about the importance of transition and showed interest in learning about the process. The transition is a time-consuming process and the goal is to become responsible for oneself (28). Svedberg et al. (31) and Frederick et al. (32) underline the need for a personalized, holistic care plan. Survivors desire a multidisciplinary care team that offers care across multiple specialties and subspecialties but it is unclear which disciplines would be central to the clinical team (34,35). The major barriers in transition included dependence on pediatric HCPs, less confidence in PCPs, inadequate communication, and cognitive difficulty (14). The emotional components such as fear, anxiety, gratitude and gaining perspective acted as both facilitators and barriers to transition in different childhood cancer survivors (20). Improvements in the transition process could be made with more written information about local adult providers and the overall transition process through an appropriate medium "like a website or a booklet" (14,29). In some studies, group meetings and visits to adult hospitals were not highly rated (29), while in the qualitative study of Sobota et al. (28) the young adults with SCD suggested meeting the adult provider prior to transfer. During the transition process, patients also need comfort and support for coping with difficult thoughts and memories of traumatic experiences (31). To increase coping, the figures to be involved are: family, survivors, and adult health staff (1).

The Caregiver Experience

The transition phase should assist parents or caregivers in accepting a new role, as they may no longer be directly responsible for the patients' care. Transition means not only a change in the place of care or a change in the referring physician, but also an increased responsibility for the young adult, who must learn to interface directly with the medical specialist and health services (34). Survivorship care plans are an important method for addressing the challenge of safe and effective transfer of care from cancer center to primary care. These documents should be created by the cancer team and shared with patients, families and primary care providers at the end of treatment (21).

While being the only point of reference in the care path creates a unique bond, at the same time it also creates an important barrier. Young patients identify the longstanding dependence on parents for healthcare management as an important barrier, including their reliance on parents to retain critical health information, coordinate appointments, and engage in critical health decisions (24).

A notable difference between survivor and parent point of view on transition emerges from the study of Frederick et al., where only 43% of survivors reported parental inclusion as "very important" in their decision to transition care compared to 83% of parents (24).

This discrepancy could mean that young adults experience a period of increasing independence.

There is also a subset of childhood cancer survivors that develop an unhealthy dependence on their parents for coordination of their health care.

On the other hand, while there are many possible reasons for this discrepancy between desired parental involvement, this difference in scores emphasizes the fact that all models of transitional care for child cancer survivors must allow adaptation to the new care setting to meet the individual needs of each survivor and his family, including parents

Sadak et al. report that parents feel "*worried because they feel like everyone in pediatrics knows exactly what happened [to their children]*" and may wonder if the team of adult-centered survivors "*really know*" and "*understand consequences of having received the treatments*". It is important for parents to know that "*their child is moving to a team of specialists who focuses specifically on caring for the adult survivor [of child cancer]*" (34). The medical team in the adult area should make caregivers more involved in the care path by showing them the informative and teaching materials that they will give their children.

Fernandes et al. shows that 73% of parents support the allocation of resources and materials for more education and assessment prior to transitioning, and 95% of parents supported the allocation of resources to improve the transfer process of patients from pediatric- to adult- oriented care (32).

DiNofia, Shafer, Steacy, & Sadak showed that 100% of parents believed it was important to promote the independence of survivors. Sometimes, these desires can be conflicted. The achievement of autonomy for adolescents with chronic health conditions is often delayed compared to peers without these conditions (36).

However parents also have the opportunity to be proactively involved in supporting the path of their child towards the independence of healthcare (36).

Some parents suggested strategies that could help alleviate their fears, for example by using the resources of a pediatric provider that could help / mediate part of the transition by working together with adult providers and building patients / parents support groups (32).

These two studies agree that additional studies are needed to determine if parental attitudes about transition of care to adult care settings and their inclusion in the transition process are determinants of successful transfers.

The perceived barriers to transition to adult care included deficits in: disease understanding, medication regimen understanding, knowledge about advance directives, and preparation, planning, and practice related to the transfer in care. In this sense, the participation of caregivers is intended as a facilitator and not a barrier (36).

The good preparation and skill of the adult team to succeed at this stage is fundamental: "*educating the families about the idea of transition and that is beneficial is critical*" (34). This literature review has illustrated that sufficient planning of transition is the main contributor to successful outcomes for survivors.

Discussion

The organization of care is affected by the lack of clear and well-structured organizational models. The first problem that arises is the age of the patient when they start this process. The second is whether the care team is adequate for dealing with the transition and what are the professional figures that shall be involved in the process. The third is the active role given to the family. New innovative models to increase the patient's awareness of this transition have been studied. However, emotional factors such as anxiety and fear are still considered as crucial from the perspective of patients, families, or caregivers. Active involvement of the whole family member is necessary to promote survivor autonomy.

This process has to start at an early age and reach the definitive phase with the full maturity of the young adult.

This review highlights how some non-organizational aspects, mainly related to the sphere of the subject's experience, are essential for the success of the process. In fact, unlike studies that deal only with the issues of therapy, the ultimate goal of the transition is achieved when the patient positively accepts the move into the adult environment and becomes independent and autonomous in dealing with the disease.

The phenomenon of transition faces multiple aspects and includes multiple actors. By dividing the review into these paragraphs, we tried to touch all those fundamental aspects to create a winning treatment plan in the near future.

Conclusion

The transition from pediatric to adult care of cancer or SCD survivors is an emerging topic in pediatric nursing.

This systematic review is the first that includes a review of the transition of care for pediatric patients with cancer or SCD, in all aspects of care.

The review has some limitations: first, it was decided to take into consideration both patients, with oncohematological pathologies and with sickle cell disease, since in most international situations these two groups have in common the same care environment (same hospital unit). However, the two types of patients face different treatments, with treatment paths that can be differently structured, even at the age of taking charge.

Another limitation regards the different types of studies considered to carry out the review: the studies, both quantitative and qualitative, approach the different experiences from different points of view that are sometimes difficult to reconcile. As a result, conflicting results may sometimes emerge.

The strengths concern the originality of the study as the issue of transition, both in the medical and nursing fields, is increasingly prevalent. A review that builds bridges between the different realities can help to create a common care pathway between the two environments.

The review also sought to explore the experiences of both patients and caregivers, considering them both as important and fundamental actors, together with healthcare professionals.

Further research is needed to deepen the understanding of some aspects of the transition care, such as the training provided at university level regarding this process and the possibility of creating an instrument that allows to act as a mediator in the transition process, “like a website or a booklet”.

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Nurses' interventions to promote cancer patient engagement and related outcomes: a systematic review and meta-analysis protocol

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Abstract. *Background and aim of the work.* Due to the ageing of cancer patients, new approaches that require a more active participation in the self-management of cancer treatment at home are needed. Nurses are strategic in improving the patient's engagement capability in this regard. Knowing which interventions are more effective for the promotion of patient engagement could be useful to improve the effectiveness of the care provided. Therefore, this study aims to systematically review nursing interventions or programs that promote patient engagement in oncological nursing care and summarizing the main evidence related to their impact on relevant clinical and psychosocial outcomes. *Method.* This is a systematic review and meta-analysis protocol based on Cochrane Handbook for the systematic review of interventions. We will search the most important electronic databases (PUBMED, CINAHL, EMBASE, SCOPUS, ISI Web of Science, Cochrane library) to find out which patient engagement interventions (active adult patient involvement) are implemented in oncological settings and understand what is the effectiveness of these interventions on the outcomes reported in the literature. The GRADE methodology will be used to synthetize the evidence. If possible, also a meta-analysis will be performed. We registered the study protocol on the PROSPERO database (N° CRD42020146189). *Discussion and Conclusion.* To our knowledge, this is the first systematic review to address this clinical question in the field of oncology. This review will offer health professionals indications on the most frequently adopted patient engagement interventions and verify their clinical effectiveness. Furthermore, any gaps in the scientific literature will be highlighted. (www.actabiomedica.it)

Key words: patient engagement, nurse, oncology, randomized control trials, non-randomized control trials, systematic review

Background and aim of the work

The cancer burden in the forty countries of the European Region is expected to increase from around 3.6 million cases and 1.8 million deaths in 2015 to 4.3 million cases and 2.3 million deaths in 2035, almost entirely due to the ageing and growth of the population (1). Further increases are also likely to occur with the changing prevalence of exposure to "modern" risk factors, especially tobacco, alcohol, unhealthy diet, obesity, and sedentary lifestyles. The changes will not be evenly spread throughout Europe, with variations that depend on the prevalence of risk factors, demographic changes and the level of development of the health service screening and therapeutic options, among other parameters.

In Switzerland, cancer causes 9,000 deaths among men and 7,000 among women every year. In other words, 30% of the total deaths in men and 23% in women are due to cancer. In men, 22% of cancer deaths are due to lung cancer, 15% to prostate cancer, and 10% to colorectal cancer. In women, breast cancer is responsible for 19% of the deaths, lung cancer for 15% and colorectal cancer for 10%. In children, cancer deaths are mostly due to leukaemia and brain tumours(2).

To guarantee health system sustainability there is the need to adopt innovative organizational models and paradigms of care with a renewed focus on the promotion of an effective partnership with patients/consumers (3,4), which is a predictor of patient adherence and compliance to treatment (5–7).

In this regard, patient engagement in cancer care is gaining more and more attention (8,9) and is becoming a requirement for the everyday practices of health care organizations to address the aforementioned challenges (10–13).

Patient engagement has been suggested as a strategy to improve the effectiveness and efficiency of health care systems. The concept of patient engagement was draw up in the USA about a decade ago. This concept was based on the idea that the "individual recipient of care" should be actively engaged across the planning and delivery phases of the health care services. Consequently, patient engagement was soon approved by policy makers and health care managers (14). Therefore, patients not only need to be "put at the centre" of medical actions in terms of consideration of their needs and expectations of care, but should also be seen as a key stakeholder that actively contributes to the successful accomplishment of the health care organization's mission and actions.

Patient engagement involves taking a further step towards a truly interactive partnership between health care recipients and health care providers, where patients are considered as one of the main protagonists of the management of the health care process in which they are directly involved (14).

Finally, patient engagement research has shown the impact of involving people in their healthcare pathway on relevant clinical, psychosocial and economic outcomes (15–18).

According to the First Consensus Conference on Patient Engagement (10,19), health professionals – and in particular nurses – are the key catalysers of a patient engagement revolution, since they are in the frontline with patients in managing the healthcare process (20,21). Putting patients at the centre of the care pathway is a key element of the nurses' professional values and scientific research, therefore nurses play a strategic role in promoting patient engagement (22–24).

However, to the best of our knowledge, no literature reviews have been conducted to date on nurses' interventions aimed at promoting patient engagement in oncology settings. The purpose of this study is to systematically review nursing interventions or programs aimed at promoting patient engagement in cancer nursing care and at mapping the main evidence regarding their impact on relevant clinical and psychosocial outcomes.

Research questions

1. What nursing engagement interventions (active adult patient involvement) have been implemented in oncology settings?
2. What clinical and psychosocial outcomes related to these interventions have been described till now?
3. What is the effectiveness of these interventions on the outcomes considered?

Methods

This is a systematic review protocol and it was drafted according to the Preferred Reporting Items for Systematic Review and meta-analysis protocols (PRISMA-P) check-list (25). We registered the review protocol in the PROSPERO database (Registration number: CRD42020146189).

PICOS

- **P:** Cancer Patients In General (No Specific Diagnosis)
- **I:** Nursing Engagement Interventions
- **C:** Routine Care
- **O:** Improvement of Clinical and Psychosocial Outcomes

- **S:** Randomized Controlled Trials, Quasi Experimental Studies (Non-Randomized Controlled Trials)

Study inclusion and exclusion criteria

All studies considering nursing interventions for the promotion of patient engagement in oncology settings shall be included. To increase the likelihood of retrieving papers related to the research questions, studies reporting concepts similar to patient engagement (i.e. patient empowerment, patient activation, patient involvement, patient participation) shall be included.

We shall try to identify the principal outcomes of patient engagement described in the literature to date, in the field of clinical oncology nursing, to draw a map and evaluate their impact from a clinical and psychosocial point of view.

With regard to the designs of the included studies, since our purpose is to provide an answer to a therapeutic question, we shall include Randomized Controlled Trials. To gain a more comprehensive understanding of what has been studied till now, also non-randomized controlled trials will be included, based on the Cochrane manual for systematic reviews (26).

The type of cancer diagnosis will not be an element of exclusion and all studies involving cancer patients shall be included. We shall include articles written in English, French, Spanish and Italian.

Letters to the editor, case reports, case series, comments and other similar types of papers shall not be included. Also studies involving children will be excluded, given the particular needs of this type of population.

Electronic databases

The following electronic databases will be searched: PUBMED; CINAHL; EMBASE; SCOPUS; ISI Web of Science; Cochrane library.

To retrieve studies not published in peer-reviewed journals and avoid publication bias, also grey literature will be searched through Google Scholar.

Search strategy

The following search terms will be used: ("patient engagement" OR "consumer engagement" OR "patient empowerment" or "consumer empowerment" OR "patient activation" or "consumer activation", OR "patient involvement" or "consumer involvement" OR "patient participation" OR "consumer participation") AND (nurs* OR "oncology nurs*) AND (neoplasm OR tumor OR cancer OR neoplasia OR oncol*).

Where possible, the electronic database Thesaurus and MeSH terms will be used, to refine the string of search terms.

The list of references found in the papers will be uploaded onto Mendeley to remove duplicates. Two researchers will independently search the electronic databases and screen the titles and abstracts. Other studies will be retrieved by scanning the reference lists of the included papers. If necessary, we will contact the authors of a paper to obtain any important missing information.

The review will be conducted on papers published in the last 15 years (2005-2020).

Study selection

The selection of the papers to be included will be performed by two researchers independently, by reading the title and abstracts. To avoid duplication, because of multiple papers derived from the same dataset, articles with the same author name, conducted in the same context and period, will checked.

The papers that meet the inclusion criteria will be evaluated independently by two researchers and the decision to include or exclude a paper will be made jointly following a discussion.

If no agreement is reached, a third researcher will be consulted. The study selection process will be presented using the PRISMA statement flow chart.

Data extraction

The data of the included studies will be extracted by two researchers independently in a systematic way.

The following data will be extracted from the studies: name of the first author and date of publication, country where the study was carried out, objective/research question/hypothesis of the study, method used (specifying the study design, the data collection process, sample size calculation, if it is a blinded study, the process of randomization and recruitment, if the authors performed an Intention-to-treat analysis, description of the experimental intervention, description of the control intervention, description of the outcomes evaluated, main results (both punctual data and the 95% confidence interval of the main outcome will be reported, if these are available in the included studies)), and main conclusions. Data extraction will be summarized in a table.

Quality appraisal of the included studies

The quality of the included studies will be assessed independently by two researchers. In case of disagreement a third researcher will be consulted. For the quality appraisal of the Randomized Controlled Trials, we will use the revised version of the "Cochrane Risk of Bias Tool for Randomized Controlled Trials" (RoB 2.0) (27).

This tool evaluates the range of possible biases of RCTs, such as selection bias, concealment bias, selective reporting, detection bias, and attrition bias. The studies can be classified from high to low risk of bias or uncertain. We will report the quality assessment of the studies in a table to compare all the studies included in the systematic review.

For the Non-Randomized Controlled Trials (NRCTs) we will use the Cochrane tool Risk Of Bias In Non-randomized Studies of Interventions (ROB-INS-I tool) (28).

Statistical analysis

Tables will be created to summarize the data of the included studies and highlight their characteristics in the light of the purpose of this review. Following data extraction, the research team will evaluate the possibility of performing also a meta-analysis. Heterogeneity across studies will be evaluated using Cochran's Q and Higgins's I^2 statistics. A Chi square $< .10$ or an $I^2 > 50\%$ will be classified as a high level of heterogeneity.

Synthesis of the results

An integrated analysis of the included studies will be performed to assess the impact of patient engagement interventions on the outcomes considered, providing, if possible, the confidence interval to estimate the effect size.

Sensitivity analysis

If possible, a sensitivity analysis will be performed to evaluate the influence of each study on the effect of the patient engagement intervention in favouring the outcomes considered, excluding one study at a time to see how the effect changes.

Evidence synthesis

The quality of evidence will be assessed with the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) system (29), which uses a sequential evaluation of the quality of evidence and assesses also the cost-benefit ratio, thus determining the strength of the recommendation.

Validity and reliability

The systematic review will be conducted according to the Cochrane Handbook for Systematic Reviews of Interventions (26). All the steps of the systematic review, such as searching the electronic databases, study selection and appraisal, will be conducted independently by two researchers and a third researcher will be consulted in case of disagreement. The GRADE methodology will be used to synthetize the evidence.

Discussion

This study reports the research protocol of a systematic review aimed at identifying which patient engagement nursing interventions are implemented in oncology settings, as well as what clinical and / or psychosocial outcomes the interventions have produced so far.

Moreover, if the studies meet the criteria of quality and homogeneity, the present revision shall aim to investigate – through a meta-analytical approach – the effectiveness of the patient engagement interventions.

To the best of our knowledge, this is the first systematic review that addressed this clinical question in the field of oncology.

This review will produce indications regarding the most common patient engagement nursing interventions and enable to evaluate their clinical effectiveness. Furthermore, any gaps in the scientific literature will be highlighted.

Limitations

It is very likely that few Randomized Controlled Trials have been conducted to date on this particular research question. Therefore, it is possible that not much evidence will be available.

Conclusion

To ensure the sustainability of health systems it is necessary to adopt innovative organizational care models and paradigms with a renewed focus on the promotion of an effective partnership with patients/consumers. Particularly in oncological settings, new approaches are needed due to the aging of cancer patients, which require a more active participation in their health management, and nurses can play a key role in improving patient engagement capability. Knowing which interventions are more effective in promoting patient engagement could be useful to improve the quality of care.

Ethical considerations

Since this was a systematic review, no formal approval from the ethics committee was required.

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Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Original articles: Health outside the healthcare environment

Effectiveness of a video lesson for the correct use in an emergency of the automated external defibrillator (AED)

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Abstract. *Background and aim of the work:* Every year around 275 thousand people in Europe and 420 thousand in the United States are affected by sudden cardiac arrest. Early electrical defibrillation before the arrival of emergency services can improve survival. Training the population to use the AED is essential. The training method currently in use is the BLSD course, which limits training to a population cohort and may not be enough to meet the requirements of the proposed Law no. 1839/2019. This study aims to verify the effectiveness of an online course that illustrates the practical use of the AED to a population of laypeople. *Methods:* An observational study was conducted to compare a lay population undergoing the view of a video spot and a cohort of people who had participated in BLSD Category A courses. The performances of the two groups were measured immediately after the course and 6 months later. *Results:* Overall, the video lesson reported positive results. Six months later the skills were partially retained. The cohort that followed the video lesson showed significant deterioration in the ability to correctly position the pads and in safety. *Conclusions:* Although improved through significant reinforcements, the video spot represents a valid alternative training method for spreading defibrillation with public access and could facilitate the culture of defibrillation as required by the new Italian law proposal. (www.actabiomedica.it)

Key words: Out-of-hospital cardiac arrest, public access defibrillation (PAD), automated external defibrillator (AED), defibrillation, first responders, lay public, training, outcomes related, safety

Background

An estimated 17.9 million people died from cardiovascular diseases in 2016, representing 31% of all global deaths. Of these deaths, 85% are due to heart attack and stroke (WHO, 2020) (1). In the same year, in Italy were recorded 221,914 deaths (ISTAT, 2019) (2).

Sudden cardiac arrest affects about 420 thousand people in the United States and 275 thousand in Europe annually (3).

Gräsner et al. (4) calculated in Europe an incidence rate of 84 cardiac arrests per 100 thousand inhabitants. Analyzing the primary heart rhythms, a quarter of the victims have initial ventricular fibrillation, which tends to evolve into asystole before extra-hospital rescuers arrive. This because rescue time after 5 - 8 minutes from the event makes the heart rhythm no longer shockable. (5). The presence of an automatic external defibrillator (AED) at the time of collapse could improve the prognosis by restoring a cardiac rhythm compatible with an effective circulation up to 76% of subjects affected by ventricular fibrillation (6).

Recent studies have shown that the use of the AED by unqualified people or with minimal training is safe and effective. Therefore, if a spectator can use an automatic defibrillator, this practice is recommended (7, 8).

In the last ten years, there has been an explosion of defibrillation programs in places with public access (PAD), in fact, even in Italy, the legislator, with its decree, established by law the presence of the AED in places with large numbers of visitors (9).

Yet despite the literature, the recommendations, the regulations, and the increase in the number of AEDs in public places, the portion of patients in cardiac arrest defibrillated before the rescue vehicle arrives, remains significantly low (10). Brooks et al. (11) and Smith et al. (12) have shown that in front of a collapsed person who is not responding, only 1.7-2.1% of viewers look for and use an AED before the ambulance arrives.

Since 2001, in Italy, a precise law grants the use of the semi-automatic defibrillator by non-healthcare personnel with specific training in cardio-pulmonary resuscitation activities (13). This rule does not seem to facilitate the use of the AED, as in the countries where the law allows all citizens to use the AED, their use is about 15-20% higher (8).

However, the Italian law, having requested the presence of the defibrillator in sports centers, highlighted an important first result. In 2015, were 123 the arrests reported in sports facilities with a return to spontaneous circulation for 62% of the victims after using the AED. This shows that the norm works, even if the device used only by specially trained people is not enough to reduce incidence in the general population (14). For this reason, we have made efforts to identify potential obstacles related to the use of AEDs by the lay public. The nature of obstacles turned out to be multifactorial and, among the causes, there is certainly the legal liability (4-38%); other relevant obstacles are the lack of knowledge about how the device works, not feeling comfortable in using it and the fear of causing harm to the victim (12).

A public access defibrillation program (PAD) (15) to be successful requires three requisites: firstly, there must be enough devices in the community; secondly, their position must be known or easily identifiable in an emergency, thirdly the public must have sufficient knowledge and confidence to use them. All these requirements must be met for a bystander to provide effective defibrillation. However, generally, national systems have so far focused on the first of these requirements, therefore greater use of public AEDs will not be achieved until the population has acquired greater knowledge and confidence with them (11).

The current classroom teaching methods, to acquire enough knowledge and confidence for the use of the AED, cannot be easily disclosed to the whole community and can present significant logistical, temporal and financial barriers, especially when it is necessary to form large groups. To cope with these difficulties, the scientific community has proposed alternative training methods for non-experts. Although not yet validated, these new methods present good results in their support (16). Remarkably, the testing of structured courses through video lessons and the use of the web has proven effective even in the physical absence of the instructor (17, 20). Recent studies conducted on school-aged students between 14 and 19 years old have shown a good efficacy of video-based training. This type of population seems to be particularly receptive to training in use the AED through this teaching method (21).

In Italy, a bill proposed at the end of July 2019 called “Progetto Life” provides that it is allowed to be able to use an AED even without specific training.. However, rescuers must follow the instructions given by the 112 emergency center health professionals. (22).

Aim

Assess of level of the learning in the use of the AED, through the viewing of a video spot and the subsequent practice on a static simulator

Research questions

1. In remote training courses, does the lesson through video spots compared to traditional BLSD

courses provide the necessary skills for using the defibrillator?

2. Which skills, acquired through the video lesson and the BLSD courses, remain in the learner after months from the end of the training?

Materials and Methods

Study design and participants

Prospective and retrospective observational studies were conducted in 2019. The research involved the 1st year students of the Degree Course in Nursing at the University of Bologna and a cohort of operators from some metalworking companies in northern Italy. Our convenience sample of 91 lay people, 44 students, and 47 workers never held CPR courses or early defibrillation courses and had no clinical subject knowledge. We divided the sample into two groups according to the training method. The students attended the video lesson, while the workers were trained with the BLSD course certified IRC ©.

The video spot production was carried out by medical instructors and nurses experienced in cardiopulmonary resuscitation and with IRC certification. The video creation took inspiration from three videos found on the web: “How to Use a Defibrillator (AED) - First Aid Training” by St John Ambulance, “Emergency CPR / AED Emergency Response Update” and “HeartStart Field Defibrillator (AED) Video of training “by Philips.

1ª Phase of the study

The prospective study took place in this phase. The students were divided into groups with an instructor and learner ratio of approximately 1: 6. The learners were shown twice, 5 minutes apart, the video in which the use of the AED was explained in 4 minutes. The video instructions included six essential steps: 1. the 112/118 call; 2. switching on the AED; 3. how to uncover the victim’s chest; 4. the positioning of the defibrillator pads; 5. how to comply with the rules for using the AED safely; 6. the delivery of the shock if indicated.

After watching the videos, the students were asked to immediately perform the procedure on the manikin under the supervision of the instructors, who immediately proceeded to evaluate the performance through a specific form that summarized the video steps. As regards the retrospective survey, 47 workers were randomized through the database of BLSD courses carried out in metalworking companies in a province of northern Italy and their performances were obtained from the forms. The BLSD courses had been held a few months earlier by the same instructors

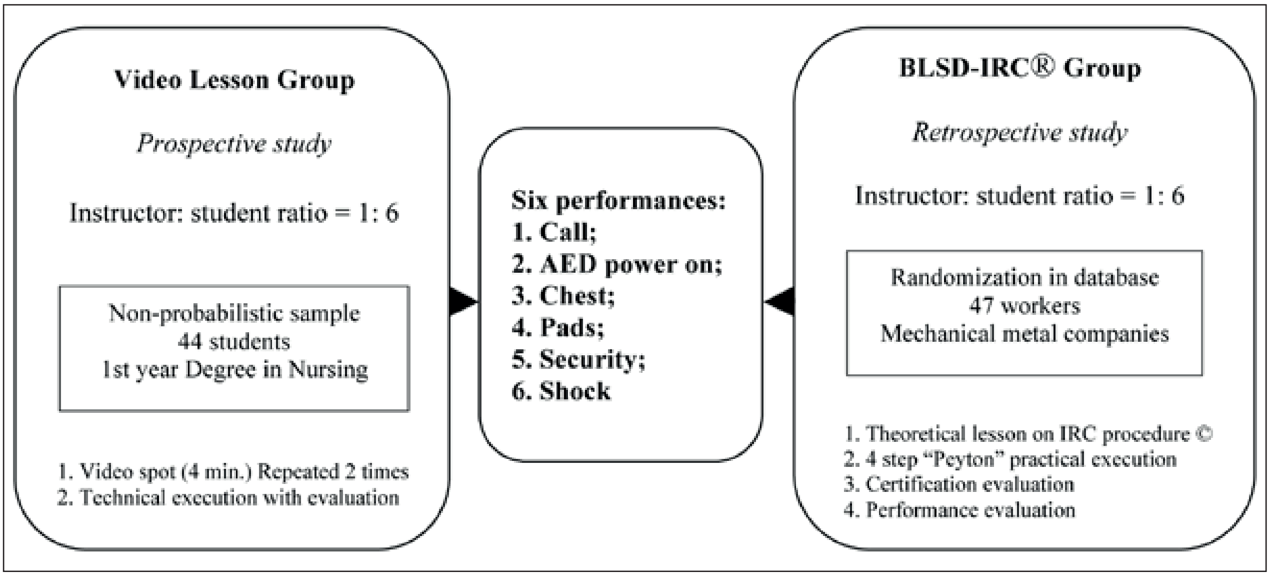


Figure 1. Phase 1 of the study

enrolled for the prospective study with the video lesson (Figure 1).

2ª Phase of the study

After 6 months, 1st year nursing students were recalled. Of these, 34 responded to the invitation, 10 fewer than in the first phase. Without viewing any video or repeating the instructors' instructions, they were asked to repeat the procedure for using the AED on the manikin.

After 6 months, the 47 randomized workers were also asked to use the AED on a manikin without any revision of the IRC © procedures.

The performance of the two groups was assessed by the same instructors, with the same tool used in the first phase.

Ethical considerations

All the sample involved in the study gave their written consent after learning the purpose and method of conducting the research. The anonymity and confidentiality of the participants were guaranteed. The research was authorized by the Bioethics Committee of Bologna University and by the Coordinator of the Degree Course in Nursing in Faenza, Italy.

Statistical analyses

The data were collected through Office Excel; the statistical analysis was conducted with SPSS software, version 26. Descriptive statistics calculations (mean, standard deviation, frequency, percentages) were performed. Significances were analyzed through Pearson's Chi-square.

Results

Nursing students evaluated immediately after the video lesson are 90.9% (n = 40) females, with an average age of 21.32 ± 5.59 and all with a high school diploma without further degrees.

The workers who achieved the BLSD certificate are 95.7% (n = 45) male, with an average age of 38.51 ± 11.69 and all with a high school diploma. Overall, the results of the video lesson are positive. Compared to the performances provided by the BLSD course, which provides for the knowledge of all the passages (100%), the video lesson achieved an average performance percentage of 89.77% ± 15.75. As regards the 6 single performances provided by the video: 79.5% call 112 or 118, 95.5% correctly turn on the AED, 97.7% correctly discover the patient's chest, 81.8% attacks the plates in the correct position, 88.8% follow the safety instructions and 95.5% deliver the shock if required (Graphic 1).

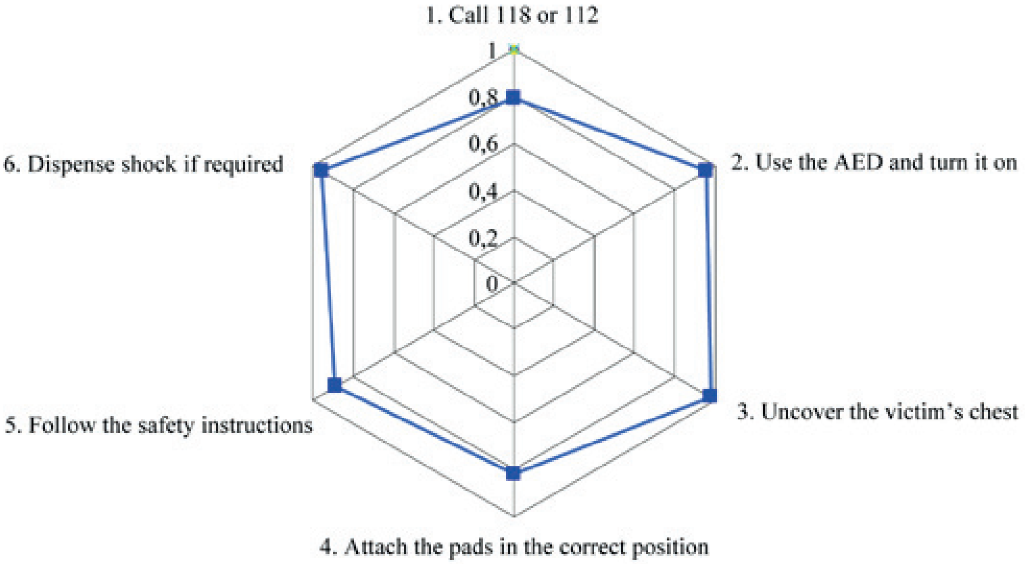
After six months, the average percentage of performance retention is significant for both training modalities (p = < .0001). The BLSD course sustains a performance of 81.21 ± 15.39, with an average difference of 18.79 respect to the certification phase. The video lesson maintains a 63.73 ± 15.05 losing a 26.04. However, both students and workers have maintained positive performances in skills 1, 2 and 3 with a range that varies from 64.7 to 94.1%. Skill 4 suffered a worsening for both groups with an average percentage value of 48.1%, while for performances 5 and 6 there were significant differences. Workers trained with the BLSD responded positively to the "follow instructions safely" ability for 63.8% (n = 30) of the sample, against 2.9% (N = 1) of the student group. In skill 6, although recording a significant difference between the video lesson and the BLSD, the performances remain above 88% (Table 1).

The difference in performance between the video lesson and the BLSD is also highlighted by a significant loss in the performance of the video lesson (activities 4 and 5) in the period immediately after viewing the videos (T0) and its subsequent verification after 6 months (T1) (Table 2).

In graphic 2, after 6 months, there is a good holding of the skills acquired in the video lesson, the curve becomes significantly negative in skills 4 and 5 with a loss of 28.9% in the first and 85.7 in the second.

Discussion

The study, by what has been highlighted in the literature (17-20), shows that a short video lasting some minutes, which illustrates simply the fundamental



Graphic 1. Distribution of students performance in the first phase

Table 1. Performance evaluation after 6 months. Comparison between the two cohorts.

	BLSD Course		Video lesson		Total	
	n = 47		n = 34		N = 81	
Performance	n	%	n	%	N (%)	p
1. Call 118 or 112	35	74.5	22	64.7	57 (70.4)	.342
2. Use the AED and turn it on	47	100	32	94.1	79 (97.5)	.092
3. Uncover the victim's chest	46	97.9	30	88.2	76 (93.8)	.075
4. Attach the pads in the correct position	24	51.1	15	44.1	39 (48.1)	.537
5. Follow the safety instructions	30	63.8	1	2.9	31 (38.3)	.000**
6. Dispense shock if required	47	100	30	88.2	77 (95.1)	.016*

* p = < .05; ** p = < .01

Table 2. Evaluation of students' performance after 6 months from the administration of the video lesson.

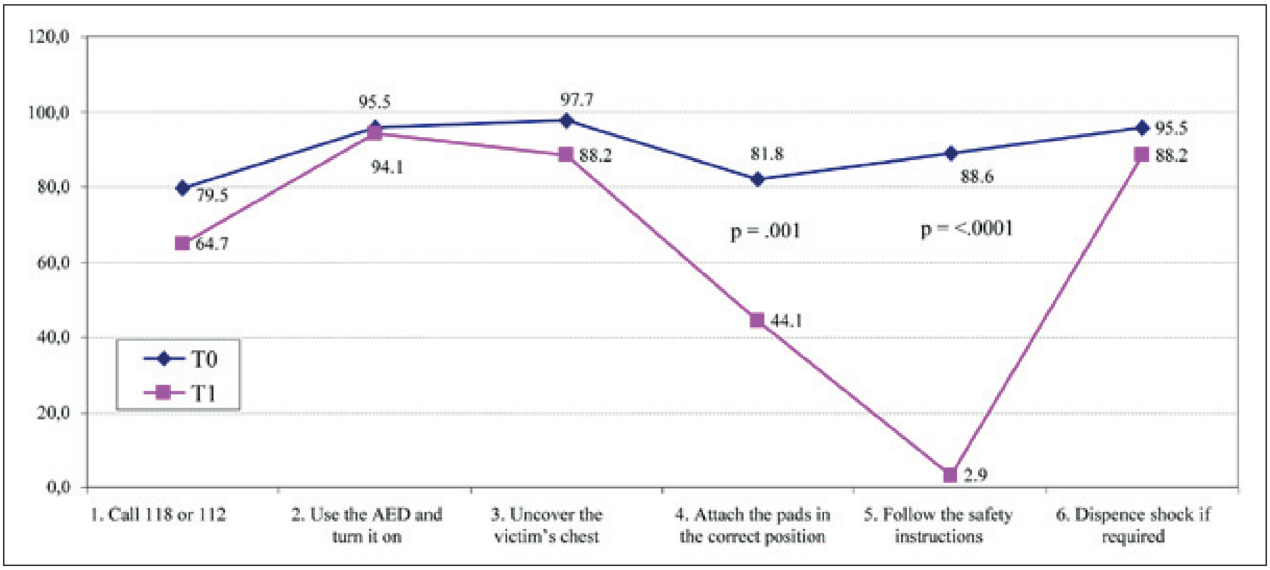
	T0		T1			
	n = 44		n = 34			
Performance	n	%	n	%	Δ	p
n. 1	35	79.5	22	64.7	-14.8	.143
n. 2	42	95.5	32	94.1	-1.4	.791
n. 3	43	97.7	30	88.2	-9.5	.090
n. 4	36	81.8	15	44.1	-37.7	.001**
n. 5	39	88.6	1	2.9	-85.7	.000**
n. 6	42	95.5	30	88.2	-7.3	.235

* p = < .05; ** p = < .01

steps of the use of a semiautomatic defibrillator and which uses an easy to understand language, can be a valid training method for a "non-professional" public of health (layman).

The video allows the desired message to reach many people, especially as regards the youth population (21).

The use of the AED requires specific training and simulation is a tool highly appreciated by learners (23-25), but it is also the method that allows you to prevent accidents and promote safety (26). Simulate the use of the AED through a video lesson could be a valid strategy considering a possible future application of



Graphic 2. Retention of skills with the video lesson at T0 and T1.

the legislative proposal no. 1839 (2019) (22); distance learning could guarantee the minimum skills needed to effectively use the AED (7, 8). The study, however, noted a certain difficulty for the students in maintaining their performances. After 6 months, statistically significant differences were pointed out, especially as regards the safety of the scene, significantly less guaranteed by the students compared to the BLSD sample.

However, even the workers trained through the BLSD course have shown a decrease in performance in the application of adhesive pads on the chest and in the safe execution of the procedure. The skills gaps months after defibrillation courses are confirmed in the literature. Educational reinforcements following certification are recommended to maintain the standards acquired during training (27, 28).

Conclusions

Unlike the BLSD courses that require the physical presence of the students and a certain economic and organizational commitment both in the certification courses and in the retraining, the video lesson can be carried out remotely, at low prices, easily accessible to a large population. A video spot of this kind, related to the law currently under approval, could empower the population. The statements of the video should be passionate and highly engaging on the emotional side, so the main concepts could thus be better retained in the population that receives them (29).

As exemplified by this study, videos need training reinforcement; a simple solution could be to administer them as spots of the Ministry of Health, using both traditional and social information channels; so they could represent a valid tool to spread the culture of defibrillation and encourage citizens to use it effectively, as required by the new Italian law proposal and literature.

The main limitations of the study are the size and characteristics of the sampling. The research takes into consideration a limited sample relating to two cohorts that are not entirely equivalent by age, gender and professionalism: the average age of 20 years, female prevalence, university students for video lessons; an age < 40 years, male prevalence, workers for BLSD courses. To confirm our results further studies with a larger sampling are needed, including subjects randomly assigned to cohorts with comparable age, professionalism and personal characteristics.

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The use of an automatic defibrillator by non-sanitary personal in sport areas: an observational study

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Abstract. *Introduction:* In industrialized countries, sudden cardiac death is a serious public health problem that accounts for about 15% to 20% of all deaths, with an incidence of 0.5 to 3 deaths per 100,000 athletes. In recent years, although both first aid prevention programs and the availability of External Automatic Defibrillator (AED) in public places have increased, few data are available with respect to real knowledge about the use of such devices. The aim of this study is to detect the level of knowledge and skills in the use of automatic external defibrillators among sports and management staff in sports facilities. *Materials and Methods:* A cross-sectional, multicentre study conducted in 16 sports facilities in the Province of Lecce, Italy, and targeted to all the athletic and managerial staff of these sports facilities. Information was obtained through a validated questionnaire consisting of 27 items. *Results:* 339 participants of which 59.3% male (n=201) (average=33.6; SD=13.1). 51.6% (n=175) were informed about the presence of the defibrillator, only 38.1% (n=129) declared to know where it was placed and 43.7% (n=96) considered it to be quite or very accessible. The majority of them (78.8%; n=267) were never involved in a training course and declared limited knowledge about the use of this device. *Conclusions:* Respondents stated that they have poor knowledge and skills in the use of the defibrillator, its operation and maintenance, which could reduce the positive outcomes of early treatment. Further studies should be conducted, although it may be appropriate to implement specific training courses for personnel working in sports centres. (www.actabiomedica.it)

Key words: External Automatic Defibrillator (AED), responsibility, training, athlete, nurse

Introduction

Sudden Cardiac Death (SCD) represents a sudden and unexpected natural death of cardiac etiology (1). Evidence agrees that defibrillation within 3-5 minutes following the onset of cardiac arrest can determine survival in 50-70% of cases (2) and that the spread of semi-automatic defibrillators that can be used by non-healthcare personnel, can triple survival rates beyond hospital settings (3). The study by Kitamura et al. (4) showed that the progressive increase in cardio-respiratory education and training as well as the public availability of semi-automatic defibrillators, has allowed the doubling of survival rates - from 18.2% to 38.5% - in cases of cardiac arrest in public environments. An estimated 30% of cardiac arrests occur in public places (5) with an incidence during sports activity of 0.5-0.6/100,000 per year, corresponding to approximately 1-2% of total cardiac arrests (6, 7). A recent Italian survey on cardiac arrests that occurred in sports facilities revealed that the majority of events affected male amateur athletes (93%) over 35 years of age. In this context, reanimation was effective in 62% of cases when an External Automatic Defibrillator (AED) was used before the arrival of the Emergency Medical Service (EMS) and in 9% of cases when rescue maneuvers began after the arrival of EMS (8). The Ministerial Decree dated 26 June 2017 (9) establishes the obligation for all sports societies, including amateurs, to be equipped with a semi-automatic defibrillator or a more advanced technology defibrillator, also establishing that personnel trained in the use of the device must be present during competitive competitions. This decree supplemented the guidelines on the equipment and the use of semi-automatic defibrillators and any other life-saving devices by associations and amateur sports clubs prescribed by the Ministerial Decree dated 24 April 2013 (10).

Several studies have attempted to deepen the levels of knowledge, skills and attitudes of the general population with respect to the use of AEDs in public places (11–14). Few studies have focused on sport fields (15). In the Italian society, the analysis of the deaths of athletes due to MCI during sports activities allowed to highlight some limitations in the management of rescue, both in terms of organization and training of health and non-healthcare personnel (16). To date, two years after the entry into force of the Ministerial Decree of June 26, 2017 (9), despite the numerous sudden cardiac deaths in amateur and amateur sports, no research has yet been conducted in the Italian context to investigate this issue, to which the outcomes of care seem to be closely related.

Aim of the study

The aim of this study was to determine the level of knowledge and skills on the use of the automatic external defibrillator among the personnel of sports facilities.

Methods

Design and setting. This observational study is cross-sectional and multicentric. The study was conducted in September of 2017, in involved 16 sport centers within the province of Lecce that adhered to it voluntarily. In the month of March in 2017 an email was sent to all sport center, public and private, containing a request to participate in the study. Data collection for the centers that agreed started in April of 2017 until September of 2017. After agreeing on when to compile the surveys, the surveys were distributed among the participants. After collecting informative consent and after an explanation how to complete the survey, a clear explanation was given on how the data would be collected and on the purpose of the study, including how the data and results would be processed. Participants had 20 minutes to compile the self-administrating modules within the supervision of one of the researchers, which provided privacy in the collection of results. The sample included athletes over the age of 18 that practiced sports recreationally or agonistically. The sample wasn't probabilistic and was recruited on the base of it being voluntary and with data collection consent.

Table 1. Sample characteristics

Sample characteristics (n=339).	N. (%)
Age (mean, DS)	**33.56 – 13.06**
Gender	**328 (96.8%)**
Male	201 (61.3)
Female	127 (38.7)
Level of practiced sport	**339 (100.0%)**
Professional	54 (15.9)
Amateur	130 (38.3)
Hobby	155 (45.7)
Types of sports	**260 (76.7%)**
Martial arts	41 (15.8)
Gym/fitness	92 (35.4)
Water sports	35 (13.5)
Other sports (dance, equitation, tennis)	26 (10.0)
Team sports (football, rugby, volleyball)	66 (25.4)
Level of education	**329 (97.1%)**
Primary school	16 (4.9)
Lower secondary school	72 (21.9)
Upper secondary school	178 (54.1)
Degree	63 (19.1)

Instrument. The survey (15) prior authorization received from the author had a linguistic evaluation. It was completed with a process of forward-backward translation as to verify comprehensibility and clarity for the Italian language. The instrument is made up of 30 items divided in two macro-areas. The first section regards availability of a AED device within the sport center, correct maintenance and control of the device and lastly the correct use during training and competitions (items 1-22); the second section is used to analyze and ascertain the capabilities to use the device of athletes and staff in the center by using a Likert scale of 10 points (1-10);(1 = noknowledge,10=veryknowledgeable)(Item 23-27). In the last part of the survey there were two items that would determine perception of athletes towards medical staff within sport centers by using a Likert scale of 5 points (1=very agreeable, 5=not acceptable). Lastly there is a section used to ascertain personal data of the sample (gender, age, level of education, type of sport, level practiced and role within the sport center).

Data analysis. Descriptive testing was conducted on all the qualitative and quantitative variables through the use of Software Statistical Package for Social Science (SPSS) version 17. Continuous variables were synthetized with averages and standard deviation (DS) and categorical variables through frequencies and percentages

Ethical considerations. Data were collected with maximum respect towards privacy and taking care of keeping anonymity of the participants. The surveys were administered only to athletes that accepted to sign the consent form. The full project was presented to the representatives of the centers taken into consideration for the study and the study started only after their consent was obtained. All subjects participating in the study received the information slip and the consent module, which had to be signed.

Results

Socio-demographic characteristics of the sample

A total of 350 questionnaires were distributed and 340 athletes have participated to the study (96.8%); 10

Table 2. Competence, expertise and use of the AED

	N. (%)
Is the AED device available in your club	
Yes	175 (51.6)
No	79 (23.3)
I don't know	83 (24.5)
No answer	2 (0.06)
Does your club have regular checkups for the device?	
Yes	93 (27.4)
No	12 (3.5)
I don't know	81 (23.9)
No answer	153 (45.1)
Is there a member in your club that is responsible for the maintenance of the AED?	
Yes	115 (33.9)
No	10 (2.9)
I don't know	57 (16.8)
No answer	157 (53.7)
Is there a member qualified for the use of the AED in your club during competitions?	
No	5 (1.5)
Yes, only in some	37 (10.9)
Yes in most	31 (9.1)
Yes in all	75 (22.1)
No answer	191 (56.4)
During training sessions is there a member qualified for the use of the AED in your club?	
No	21 (6.2)
Yes, only in some	53 (15.6)
Yes in most	35 (10.3)
Yes in all	58 (17.1)
No answer	172 (50.7)
Do you know were the AED is within your club?	
Yes	129 (38.0)
No	69 (20.4)
No answer	141 (41.6)
How accessible do you think the AED device is during emergencies?	
Very accessible	96 (28.3)
Accessible enough	52 (15.3)
Not very accessible	18 (5.3)
No answer	173 (51.0)
Is the defibrillator locked under key?	
Yes	28 (8.3)
No	144 (42.5)
No answer	167 (49.3)
According to you who can use the external automatic defibrillator?	
No one	3 (0.9)
Every one	29 (8.6)
Only those who have an adequate formation	303 (89.4)
No answer	4 (1.2)

	N. (%)
Have you ever participated in a training course for the use of a defibrillator?	
Yes	65 (19.2)
No	267 (78.8)
No answer	7 (2.1)
How useful do you think a AED is within your club?	
Not useful	1 (0.3)
Not much	4 (1.2)
Enough	28 (8.3)
Important	76 (22.4)
Very important	223 (65.8)
No answer	7 (2.1)

questionnaires have been excluded because the subjects were not athletes. 15.5% (n=54) of the participants practice sport at professional level, 37.2% (n=130) at amateur level and 44.4% (n=155) practice it as a hobby.

Knowledge and skills on the use of the defibrillator

23.3% (n=80) of the respondents reported that they do not have a defibrillator in their centre due to the high cost and the lack of awareness of how important it is to be equipped with it. The provision of this device, in most cases, was achieved through self-financing (25.1%, n=85) or donation (15.1% n=51). Participants indicated a frequency of use in life-threatening situations of 0.6% (n=2), 50.1% stated that they had never used the device and 49.3% refrained from responding. In addition, 78.8% (n= 267) have never participated in a training course, demonstrating a lack of knowledge and skills regarding the correct use and management of the defibrillator. Concerning the placement of the device inside the center, 15.9% (n=54) of the participants believe that AED is quite accessible in case of cardiac arrest, while more than one in two athletes (51.3%) did not provide any statement about it. 8.3% (n=30), reported that the defibrillator is kept under lock and key, only 28.4% of the respondents are aware of the regular technical checks that must be carried out on the device, while almost all respondents (97.4%, n=330) do not know the maintenance schedule of the AED provided in their centre.

Discussion

The main objective of the study was to detect the level of knowledge and skills on the use of the automatic external defibrillator among sports and management staff working in sports centres. The results of this study highlighted the reduced presence of the device inside the participating centers, the lack of knowledge of the athletes with respect to the proper use and management of the AED. The American Heart Association guidelines (17) recommend that the defibrillator should be clearly visible and stored in a locker without a padlock or other security system; this seems to be in line with the results of the study, since less than one in ten (8.6%) said they had to search for the defibrillator, but in contrast to those in the literature, where more than half of these associations choose to keep their defibrillator under lock and key (15). There was a high rate of non-response in items that aimed to probe more technical aspects such as those related to defibrillator maintenance or the presence or absence, during official competitions or training, of personnel trained in the use of the AED. This gap could suggest a lack of awareness from the athletes, which could be answered through targeted strategies, such as the production of information material.

Results suggest that the implementation of the legislation should be accompanied by adequate organization of training and emergency procedures in order to ensure timely and effective intervention in the event of SCD (15). Although there have been significant developments in the technology and distribution of AEDs in recent years, these efforts may prove somewhat unnecessary if devices cannot be located and used in a timely manner when needed and there is no increase in theoretical knowledge and practical skills (13). Studies in literature have shown that the predisposition to form and use the device decreases if there is little consideration of the “sudden cardiac arrest” problem (12) although its use has a positive impact on survival (18, 19). The training of sports center workers to correctly use the AED is an essential requirement to increase the survival rate in case of cardiac arrest; some studies have shown that a high percentage of untrained subjects were not able to use an AED safely, despite following the voice instructions and possibly the instructions given by the emergency system operator (20, 21). According to the current ministerial regulations (9), it is necessary to identify the subjects who, due to availability, temporal presence in the sport facilities and presumed aptitude, appear more suitable to carry out the task of first responder. In addition, the number of subjects to be trained is strictly dependent on the place where the AED is located and the type of organization involved, assuming that a sufficient number of people are trained for each AED.

According to the results of this study, more than half of the participants underlined the lack of adequately trained staff within the centre, and averagely only two members were trained for each participating centre, an aspect that contrasts with the current regulations in force in Italy and with what emerges from the study conducted by Cronin et al. (15), which showed that no less than 10 members were able to use a defibrillator within the centres interviewed. In order to fill this training gap, it could be of fundamental importance to include a suitably trained professional, such as the Nurse, in the centres that practice amateur and competitive sports. The results of the study, suggest that the Nurse could certainly have a key role in training in the field of sports, whose involvement would ensure immediate interventions to reduce the risk of heart death in sports.

Conclusions

Sudden cardiac death and the use of defibrillators is a phenomenon of great social interest; solidarity and sensitivity to this subject should certainly be encouraged through paths of awareness and health education. Awareness-raising on this topic, aimed at making people aware of its dimensions and related issues, can therefore be useful, provided that it takes place through qualified dissemination processes and is placed in a constructive perspective. The results of this study have highlighted a lack of knowledge and skills of athletes on the correct management of the defibrillator and, in general, it emerged an insufficient awareness of the problem within the sports centers involved, in which a defibrillator is not always available. The lack of training could be filled with the contribution of a professional Nurse within the sports centres, a combination that does not exist in the Italian context in amateur and amateur sport where, instead, in other European realities, the Nurse plays a key role in the planning of sports emergencies. Our sample cannot be considered representative of the entire italian sports population.

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NANDA-I, NIC, and NOC taxonomies, patients' satisfaction, and nurses' perception of the work environment: an Italian cross-sectional pilot study

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Abstract. *Background and aim of the work:* Structured nursing care planning, patients' satisfaction with care, nurses' job satisfaction, and the characteristics of the work environment may influence each other and impact on the quality of hospital care. This study aimed at investigating the differences in nurses' perception of the work environment and patients' satisfaction with care, between two groups of hospital wards that used NANDA-I, NIC, and NOC taxonomies or not in the daily practice. *Methods:* A pilot cross-sectional study was conducted involving nurses employed in eight wards of a teaching hospital in central Italy and patients hospitalized in these wards. The 'Nursing Work Index Revised' and the 'Patient Satisfaction Scale' were used to investigate nurses' perception of the work environment and patients' satisfaction with care, respectively. *Results:* Significant better perceptions of both the constructs were highlighted in those wards that used nursing taxonomies. *Conclusions:* The application of a healthcare model based on the nursing process methodology should be empowered in the hospital settings, since it can influence the quality of the environment and patients' satisfaction with care. (www.actabiomedica.it)

Key words: NANDA-I, NIC, and NOC, nursing process, patient satisfaction, standardized nursing terminology, work environment perception

Background

The quality of care and its related factors, despite being an ancient topic (1, 2), is still investigated in the literature (3-6), also given its close relationship with the patient's safety (5, 7). However, considering the multiple factors that define quality of care, its measurement is rather complex, as earlier pointed out in 2006 by the World Health Organization (WHO), which identified six areas that describe more specifically the concept of quality of care: efficacy, efficiency, accessibility, acceptability (patient-centred care), equity, and safety (8). Therefore, several indicators of quality of care are available; they are classifiable as objective, e.g. mortality rate, incidence of failure to rescue, nurse-to-patient ratio (3, 5, 9), and subjective, e.g. both patients' and nurses' satisfaction (3-5). These latter seem to be particularly influenced by the characteristics of the work environment as well as the organizational models adopted in hospital settings (5, 10), such as care planning based on the nursing process, which facilitates a systematic and coherent approach to the needs of patients (11). In the literature, it is acknowledged that the increased utilization of taxonomic classifications supports nursing knowledge (12), also when they are used in an electronic format (13). This can lead to obtain more coherent, complete, and accurate nursing documentation (12) and globally improves the daily care practice, with beneficial effects also on the organizational environment (14). Consequently, care planning based on the nursing process is advantageous for patients who are actively involved in this methodology, which can also improve the continuity of their care from the hospitals to the home settings (15). Therefore, planning and systematically documenting the care process through standardized classifications, such as NANDA-I, NIC, and NOC (NNN) taxonomies, could help to more precisely evaluate nursing-sensitive healthcare outcomes (15) and lay the foundations for more effective control of health facilities' economic performances (16).

Aim of the work

Considering the lack of research on these issues in the Italian context where the utilization of standardized nursing classifications is still limited, the purpose of this study was to investigate the differences between two groups of hospital wards having used NNN taxonomies or not in the daily nursing care practice about: 1) nurses' perception of the work environment and 2) patients' satisfaction with the nursing care received.

Methods

Design

A pilot study with a cross-sectional approach was conducted according to the 'Strengthening the Reporting of Observational Studies in Epidemiology' (STROBE) guidelines (17).

Setting and sample

Eight wards of a teaching hospital in central Italy were included in the study through convenience sampling, involving both wards using NANDA-I, NIC, and NOC in daily care, labelled as 'NNN-Yes', and wards not using them, labelled as 'NNN-No'. In such wards, all employed nurses and patients hospitalized for, at least, 48 hours were asked to take part in the study.

Variables and data collection

Between July and September 2017, nurses' perception of the quality of the work environment and patients' satisfaction with the care received were investigated through the 'Nursing Work Index-Revised' (NWI-R) scale (18) and the 'Patient Satisfaction Scale' (PSS) (19), respectively. Moreover, sociodemographic variables were collected for nurses and patients.

The NWI-R scale was translated and underwent a cross-cultural adaptation process according to Beaton guidelines (20). The questionnaire consists of 15 Likert-type items to which nurses had to express their degree of agreement ranging from 1 (strongly disagree) to 4 (strongly agree). The scale provides information about four dimensions:

- Nurse autonomy, composed of 5 items concerning nurses' perception of their decision-making ability and skills for the care process;
- Nurse control, composed of 7 items investigating the control over the practice setting as perceived by nurses;
- Nurse-physician relationship, composed of 3 items concerning the self-evaluation of nurses' ability to collaborate with doctors;
- Organizational support, composed of 10 out of the 15 items derived from the other three dimensions. This dimension provides information regarding the evaluation of the instruments offered by the healthcare facilities to nurses in support of their professional activity.

The Italian validated PSS consists of 11 Likert-type items (19), as well as the original English version (21), to which patients had to express their level of agreement ranging from 1 (very dissatisfied) to 4 (very satisfied). The scale provides information about three dimensions:

- Satisfaction with technical and scientific needs, composed of 3 items concerning the perception of skills and professionalism of the staff;

- Satisfaction with information needs, composed of 5 items concerning the information received during the hospital admission, recovery, and discharge;
- Satisfaction with interaction and support needs, composed of 3 items concerning the overall perception of the quality of care received.

Ethical considerations

The study was jointly approved by University and Hospital boards where the study was conducted. All the participants were informed about the characteristics and aim of the research and provided their consent to participate. Moreover, data were collected and analyzed anonymously.

Data analysis

Descriptive and inferential statistics were carried out to represent data and test the research hypotheses, respectively. The homogeneity of continuous sociodemographic variables regarding nurses and patients between the two compared ward groups was checked through the t-test for independent samples or the Mann-Whitney U test, depending on the normality of data distribution assessed through the Kolmogorov-Smirnov test. The scores provided by nurses and patients through the Likert-type scales have been coded in dichotomous data, replacing the first and the last two Likert levels with 'negative perception' and 'positive perception', respectively. Hence, some likely differences in the distribution of all the categorical variables between the two groups of wards were checked through the χ^2 test. All the analyses were conducted using the SPSS software, version 19.0 (IBM Corp., Armonk, NY, USA), with an accepted statistical error ≤5%.

Results

Seventy-five nurses with a mean age of 38.2 years (SD 7.3; min 25; max 56), 72.0% of whom were female, and 212 patients with a mean age of 63.2 years (SD 15.9; min 18; max 97), 51.9% of whom were male, were enrolled in the study. The distribution of sociodemographic characteristics between the 'NNN-Yes' and 'NNN-No' ward groups regarding nurses and patients was homogeneous (Table 1).

As shown in Table 2, nurses working in the 'NNN-Yes' wards demonstrated a significantly better perception of the quality of the work environment compared to their colleagues employed in the 'NNN-No' wards for all the dimensions of the NWI-R scale except for the 'Nurse-physician relationship' ($p = 0.651$).

Similarly, patients hospitalized in the 'NNN-Yes' wards showed a significantly better satisfaction with the quality of daily care received compared to those admitted to the 'NNN-No' wards in all the dimensions of the PSS (Table 3).

Discussion

To our knowledge, this is the first Italian study investigating nurses' perceived quality of the work environment and patients' satisfaction with the care received in the hospital wards using NANDA-I, NIC, and NOC taxonomies or not. Results showed that the application of care models based on the nursing process was significantly associated with the perception of beneficial outcomes by nurses and patients, which probably influence each other (5, 9). In fact, the use of NANDA-I, NIC, and NOC taxonomies revealed to be clearly associated with a positive perception by nurses about the nursing care planification and professional independence, which are both specific features of the nursing process (11). According to the literature, a better perception of the quality of the organizational support, as detected in the 'NNN-Yes' ward group, seems to be strongly associated with the quality of nursing care and nurses' job satisfaction (22), confirming the role of the interaction between organizational factors and clinical practice in enhancing a healthy work environment that allows hospitals to provide good quality of care (5, 8, 18).

From the patients' point of view, a better perception of the quality of care in the 'NNN-Yes' ward group was detected in both the interaction with the healthcare workers and the work climate, even if the patients hospitalized in 'NNN-No' wards showed to

Table 1. Sample descriptive analysis. †*t-test for independent samples;* ‡χ^2 *test;* §*Mann-Whitney U test*

		NNN-Yes	NNN-No		*p-value*
Nurses (N=75)	**N**	40	35		
	Age, years				
	Mean (SD)	38.2 (7.1)	38.2 (7.7)		0.975†
	Min-Max	25-51	27-56		-
	Gender, %				
	Females	72.5%	71.4%		0.918‡
	Wards, %				
	Endocrinology	12.5%	*Emergency Medicine*	11.4%	
	Pulmonology	25.0%	*General Medicine*	20.0%	--
	Cardiological Clinic	35.0%	*Thoracic Surgery*	31.4%	--
	Haematological Clinic	27.5%	*General Surgery*	37.1%	--
	Total	100.0%	*Total*	100.0%	--
wPatients (N=212)	**N**	100	112		
	Age, years				
	Mean (SD)	63.2 (15.4)	63.3 (16.4)		0.821§
	Min-Max	20-97	18-90		--
	Gender, %				
	Females	53.5%	43.4%		0.139‡
	Wards, %				
	Endocrinology	24.0%	*Emergency Medicine*	11.6%	--
	Pulmonology	39.0%	*General Medicine*	23.2%	--
	Cardiological Clinic	26.0%	*Thoracic Surgery*	26.8%	--
	Haematological Clinic	11.0%	*General Surgery*	38.4%	--
	Total	100.0%	*Total*	100.0%	--

be quite satisfied with the quality of technical and relational aspects of the care received. Perhaps, this was due both to the influence of the bio-medical model on health perception and management and to the healthcare worker-patient empathy-based relationships. In fact, the biomedical model is still prevalent in guiding health-focused policy choices in the Italian national health service, and empathy is essential in the relationship with patients, independently of the healthcare model used (23).

Table 2. Work environment quality: positive and negative perceptions by nurses in 'NNN-Yes' and 'NNN-No' ward groups

		Positive perception		Negative perception		
	Analysed records	**NNN-Yes**	**NNN-No**	**NNN-Yes**	**NNN-No**	*p-value*
Nurse autonomy (7 items)	375	158 (79.0%)	108 (61.7%)	42 (21.0%)	67 (38.3%)	<0.001
Nurse control (5 items)	525	189 (67.5%)	111 (45.3%)	91 (32.5%)	134 (54.7%)	<0.001
Nurse-physician relationship (3 items)	225	101 (84.2%)	86 (81.9%)	19 (15.8%)	19 (18.1%)	0.651
Organizational support (10 items)	750	300 (75.0%)	203 (58.0%)	100 (25.0%)	147 (42.0%)	<0.001

Table 3. Satisfaction with the care received: positive and negative perceptions by patients in 'NNN-Yes' and 'NNN-No' ward groups

		Positive perception		Negative perception		
	Provided answers/ Analysed records	**NNN-Yes**	**NNN-No**	**NNN-Yes**	**NNN-No**	*p-value*
Satisfaction with the meeting of technical and scientific needs (3 items)	636	291 (98.0%)	322 (95.0%)	6 (2.0%)	17 (5.0%)	0.044
Satisfaction with the meeting of information needs (5 items)	1060	449 (90.7%)	412 (72.9%)	46 (9.3%)	153 (27.1%)	<0.001
Satisfaction with the meeting of interaction and support needs (3 items)	636	291 (98.0%)	319 (94.1%)	6 (2.0%)	20 (5.9%)	0.014
Total	2332	1031 (94.7%)	1053 (84.7%)	58 (5.3%)	190 (15.3%)	<0.001

The interprofessional communication was also perceived as efficient in both the compared groups, meaning that the management of collaborative problems probably does not need a specific methodology, such as the whole nursing process, contrary to what was highlighted by Guadarrama-Ortega and colleagues (13).

Instead, regarding the satisfaction with the fulfilment of the need for information, a larger difference between the two groups of patients was revealed, probably because limited or inadequate time was spent to fulfil these needs in the hospital settings that do not use standardized care processes.

Thereby, the application of the nursing process in the management of healthcare activities highlighted the specificity of the nursing care, which is not mainly focused on facing biological needs but takes into considerable account the psycho-relational aspects of care, favouring a holistic approach toward patients and their families (24-26) and an improvement of economic performances of healthcare facilities (5, 9).

The main limitation of this study was the convenience sample, for which the results should be considered cautiously. In addition, it was not possible to detect any other variable that, given the complexity of the healthcare setting, could have influenced the perception of both nurses and patients. However, we think that the methodology used in this study could be replicated in a broader dimension to keep under control any possible confounding bias.

Conclusion

Overall, the nurses' perception of the quality of the work environment and patients' satisfaction with care revealed to be significantly better in those wards that used NANDA-I, NIC, and NOC taxonomies in daily practice compared to those not using it. The application of a healthcare model based on the nursing process methodology should be empowered in the hospital settings, since it can enhance the quality of the work environment in hospital settings, which would improve patients' satisfaction with the nursing care received. Further studies are necessary to better understand the contribution of structured healthcare models to the improvement of Italian nursing care.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Original articles: Instruments for the healthcare professionals

Use of traffic crash as a risk assessment scale in hospitalized seniors: a perspective observational study

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Abstract. *Background and aim:* According to the World Health Organization (WHO), falls represent the second main cause of accidental and involuntary deaths worldwide, which led to define them as one of the "four giants of the geriatrician" that particularly affect the elderly aged ≥ 65 years. The study's aim is to evaluate whether the Traffic Crash scale is valid in identifying patients at risk of falling by comparing it to the Conley scale currently used. *Methods:* Prospective observational study evaluating the fall risk using TC on a sample of patients aged ≥ 65 years, hospitalized in General Medicine Ward and Gastroenterology, after informed consent and favorable opinion of the AVEN Ethics Committee. The results are compared with those obtained from the Conley scale, and with those obtained from the indications of the Business Operating Instruction. The method of administration occurred concurrently and distinctly on the same patient by two researchers in order to demonstrate the scale inter-rater reliability. *Results:* The final sample was made up of 88 patients. Data shows that 46 out of 55 patients (84%) are medium / high risk for both scales. According to the indications of the Company Operating Instruction, the entire sample is at risk. The inter-rater reliability was confirmed with Cohen's K which is equal to p = 1. *Conclusions:* The TC scale is comparable to Conley scale, for the fall risk identification but specifically the stratification is low-medium-high. Therefore, in future, this will make it possible to implement personalized prevention interventions in care planning. (www.actabiomedica.it)

Key words: Fall risk, Older adults, Tools, Assessment, Hospital, hospitalization, Rating scale, Scale, Score, Fall's Prevention

Background

Falls are defined as "a sudden, unintentional, unexpected downward shift from the orthostatic or seated or clinostatic position" (1). This definition includes patients who fall asleep on the chair while sleeping, patients found lying on the floor and falls despite support (1). They are further classified by Morse by type: 14% accidental, 8% unpredictable physiological and 78% foreseeable physiological which could be identified and therefore prevented (2).

According to the World Health Organization (WHO), falls represent the second main cause of accidental and involuntary deaths worldwide, with an annual global mortality recorded and updated on January 16, 2018 of about 646,000, which led to define them as one of the "four giants of the geriatrician", together with depression, memory deficit and urinary incontinence which particularly affect the elderly aged ≥ 65 years (3).

The cost of these numbers involves the physical, psychological and even economic spheres: already a single first fall can lead to fear of falling again, decrease in safety and progressive loss of autonomy, associated with anxiety and depression. This results in a lower performance of daily activities with an increase in disability and a decrease in the quality of life, in what is defined as "post-fall syndrome" (4), while the direct costs deriving from falls in elderly patients ≥65 years of age they are estimated at $ 19 billion (5).

If the fall causes serious damage or death of the patient, it is a sentinel event and based on their monitoring report by the Ministry of Health in 2015, the patient's fall event represented the highest number of reports and resulted in death in 35.6% of cases, major trauma in 15.9% and surgical reoperation in 10.58% 6). Furthermore, the relationship between the nursing contribution and the patient's results regarding the prevention of falls has been demonstrated (7), considered a Nursing Sensitive Outcome (8).

In order to assess the risk of falling, various scales are present in the literature (9), currently the most used are the Conley scale (10) and the Morse scale (11), but several studies show that these instruments are not completely reliable for prediction of the risk of falling. (12–14) The Australian FROHP scale demonstrated only moderate levels of accuracy in the pilot study (15), the translated and adapted version in Taiwan showed good validity, but was tested on a small sample (16) and in any case not there is a version of the FROHP translated and adapted for the Italian context.

On the basis of the NICE 161 revision (17), the Emilia Romagna region was able to radically change the approach to the evaluation and management of the event that fell from a multifactorial perspective and identified the main risk factors, such as: at least one previous fall in the previous year, fear of falling, environmental barriers, cardiological drugs, drugs with a psychotropic effect but also polypharmacology (at least three active ingredients excluding the two previous categories), in association with an environmental assessment also carried out periodically by designated offices (18).

Currently, the Piacenza Local Health Authority has implemented the regional guidelines (18) and has given instructions to the Operational Units (O.U.) to compile a check list for the identification of risk factors and to carry out an environmental assessment, but too often this is still not done, increasing the risk of missed care. In other cases, the Conley scale is still used, mistakenly considered the gold standard for identifying risk.

To cope with this problem, it was decided to design a new staircase, the "Traffic Crash", built from existing stairs such as Conley (10), Morse (11) and Tinetti (19) and also includes the assessment of risk factors identified by the Emilia-Romagna Region (18), in order to give operators a tool with which they are more accustomed to working, a scale, but more suitable for the purpose than that in use. Furthermore, unlike the other scales, the Traffic Crash, in addition to being a means to more fully identify the risk of falling, the low-medium-high stratification and suggests a behavioral code to be included in the care planning that takes into consideration the indications provided by a review of effective interventions such as additional physiotherapy and educational interventions (20).

Objective

The aim of this study is to evaluate whether the Traffic Crash scale is valid in identifying patients at risk of falling by comparing it to the Conley scale currently in use. In particular, the aim is to verify whether patients identified as "at risk" by the Conley scale are identified as "moderate risk" and "high risk" by the Traffic Crash, the final objective is therefore to verify the non-inferiority of Traffic Crash respect to the Conley scale. In addition, we will check whether the Traffic Crash identifies patients with "moderate risk" and "high risk" patients with the risk factors included in the Business Operating Instruction.

The second goal is to evaluate the inter-rater reliability of the Traffic Crash scale.

Methods

A prospective observational study was conducted, carried out from July 2019 to October 2019, and took into consideration the General Medicine Ward and Gastroenterology O.U. of the Hospital Unit (H.U.) of Piacenza and Internal Medicine of the H.U. Val

Tidone. The sample consists of patients over the age of 65 or older who have been provided with adequate information and have been asked to express their consent to participate in the study. It was chosen to include these O.U. in relation to the number of beds in the various wards, the number of average accesses during the period under consideration and the type of hospitalized patient (mainly elderly and multi-pathological patients; high rate of clinical complexity and non-self-sufficiency). Of the 113 patients who met the study inclusion criteria, 88 (78%) were evaluated while 25 (22%) were excluded, as they did not express consent. The administration of the scale took place concurrently and distinctly on the same patient by two researchers in order to demonstrate the intervalutator stability of the same. Each patient has been associated with a progressive number so as not to report any personal data in the evaluation scales and in the data collection table.

Instruments

The Traffic Crash scale (figure 1) consists of 5 main items that investigate:

History of the fall
Deambulation
Use of drugs that can change your alertness
Gait
Mental state and cognitive impairment, assessed with MMSE (21)

Each item is divided into sub-categories with which a descriptor is associated, each of the descriptors is assigned a score.

The sum of the scores obtained determines the risk of falling which can be attested in:

0 no risk of falling
< 20 Low risk of falling
20 - < 50 Moderate risk of falling
> 50 High risk of falling

Each score also corresponds to a color code, from which derives the name "Traffic Crash" to be affixed to the patient's bed in order to make the risk of falling immediately visible to the operator:

"No risk of falling" and "Low risk of falling" green code
"Moderate risk of falling" yellow code
"High risk of falling" red code

For each level of risk, targeted interventions were devised to prevent the risk of falling (Fig. 1).

The Conley scale is made up of two items:

- Previous falls:
  - fall in the past three months
  - presence of dizziness or lightheadedness
  - loss of urine or feces while going to the bathroom
- Cognitive impairment:
  - impaired gear,
  - motor agitation;
  - deterioration of judgment / lack of sense of danger.

The sum of the scores can result:

- Values between 0 and 1 indicate the low risk of falling.
- Values between 2 and 10 indicate the high risk of falling.

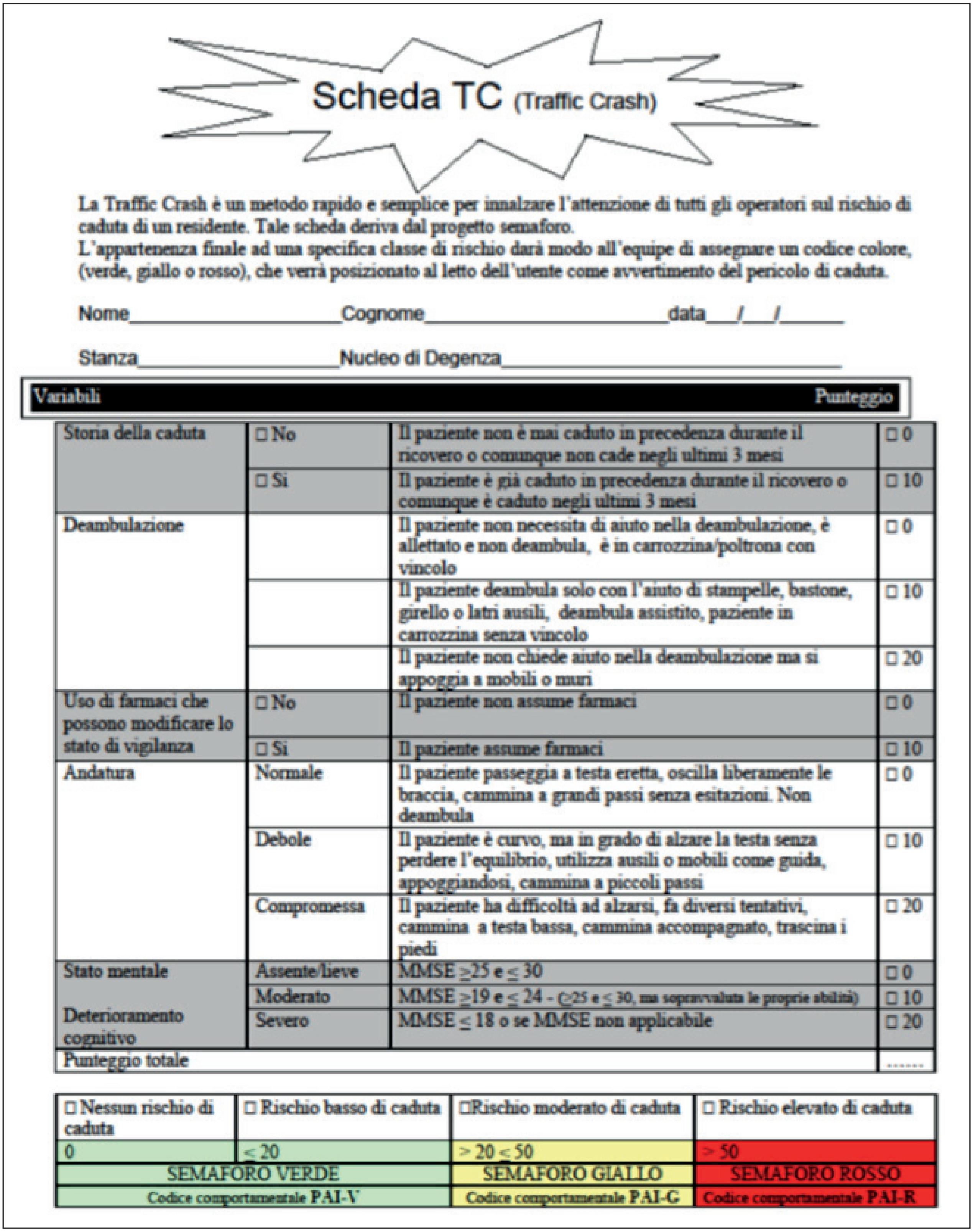
The risk factors identified by the Emilia-Romagna Region and incorporated in the Company Operating Instruction are: at least one previous fall in the previous year; fear of falling; environmental barriers; cardiological drugs; psychotropic drugs; polypharmacology (at least three active ingredients excluding the two previous categories). The assessment of the presence of even one of the following factors is sufficient to consider the patient at risk of falling.

To check:

- Upon patient entry, taking charge (within 24 hours)
- As clinical conditions and therapy vary
- On the occasion of the fall event
- On the occasion of changes in walking
- At regular time intervals in prolonged hospitalizations
- Before a transfer to another Operating Unit or facility and before discharge

Data Analysis

The results of the Traffic Crash scale have been inserted in an Excel table (cf.) and compared both with those obtained from the Conley scale and with those obtained using the indications of the Business Operating Instruction. They have been classified as "low" and "high" risk for the Conley scale and "low", "moderate"



Scheda TC (Traffic Crash)

La Traffic Crash è un metodo rapido e semplice per innalzare l'attenzione di tutti gli operatori sul rischio di caduta di un residente. Tale scheda deriva dal progetto semaforo.

L'appartenenza finale ad una specifica classe di rischio darà modo all'equipe di assegnare un codice colore, (verde, giallo o rosso), che verrà posizionato al letto dell'utente come avvertimento del pericolo di caduta.

Nome____________________Cognome______________________data___/___/______

Stanza____________________Nucleo di Degenza____________________________________

Variabili			Punteggio
Storia della caduta	☐ No	Il paziente non è mai caduto in precedenza durante il ricovero o comunque non cade negli ultimi 3 mesi	☐ 0
	☐ Si	Il paziente è già caduto in precedenza durante il ricovero o comunque è caduto negli ultimi 3 mesi	☐ 10
Deambulazione		Il paziente non necessita di aiuto nella deambulazione, è allettato e non deambula, è in carrozzina/poltrona con vincolo	☐ 0
		Il paziente deambula solo con l'aiuto di stampelle, bastone, girello o latri ausili, deambula assistito, paziente in carrozzina senza vincolo	☐ 10
		Il paziente non chiede aiuto nella deambulazione ma si appoggia a mobili o muri	☐ 20
Uso di farmaci che possono modificare lo stato di vigilanza	☐ No	Il paziente non assume farmaci	☐ 0
	☐ Si	Il paziente assume farmaci	☐ 10
Andatura	Normale	Il paziente passeggia a testa eretta, oscilla liberamente le braccia, cammina a grandi passi senza esitazioni. Non deambula	☐ 0
	Debole	Il paziente è curvo, ma in grado di alzare la testa senza perdere l'equilibrio, utilizza ausili o mobili come guida, appoggiandosi, cammina a piccoli passi	☐ 10
	Compromessa	Il paziente ha difficoltà ad alzarsi, fa diversi tentativi, cammina a testa bassa, cammina accompagnato, trascina i piedi	☐ 20
Stato mentale	Assente/lieve	MMSE $\geq$25 e $\leq$ 30	☐ 0
	Moderato	MMSE $\geq$19 e $\leq$ 24 - ($\geq$25 e $\leq$ 30, ma sopravvaluta le proprie abilità)	☐ 10
Deterioramento cognitivo	Severo	MMSE $\leq$ 18 o se MMSE non applicabile	☐ 20
Punteggio totale			......

☐ Nessun rischio di caduta	☐ Rischio basso di caduta	☐Rischio moderato di caduta	☐ Rischio elevato di caduta
0	$\leq$ 20	> 20 $\leq$ 50	> 50
SEMAFORO VERDE		SEMAFORO GIALLO	SEMAFORO ROSSO
Codice comportamentale **PAI-V**		Codice comportamentale **PAI-G**	Codice comportamentale **PAI-R**

Figure 1. Traffic Crash Scale

and "high" for the Traffic Crash, while for the presence or absence of the risk factors indicated by the Region it has been assigned a "yes" or a "no".

For the analysis of the data, charts were built using Microsoft Excel. Descriptive statistics operations were performed, such as frequencies and percentages, concerning the risk identified in the patients in the four-month period under consideration and inferential statistics operations to assess the intervalutator stability of the Traffic Crash scale by calculating Cohen's Kappa.

Ethical Considerations

The study has been conducted in agreement with the Ethical Principles for Medical Research Involving Human Subjects of the Helsinki Declaration and it has been approved by the International Research Board of the University of Parma.

On 26/07/2019, the Director of UOC Clinical Government approved the authorization for the observational study in question, by protocol no. 2019/0074081.

After obtaining the favorable opinion of the AVEN Ethics Committee and the authorization of the Management all the healthcare setting where the study took place was contacted and was asked for their availability to participate in the research. An explanatory document of the study was sent to the Coordinators of the Operating Units in order to inform them, and to agree on the access times in the structures. All eligible participants were informed of the purpose and characteristics of the study and received a clear informative written document, explaining the design, aims, procedure and ethical considerations of the research. Informed consent was obtained from all participants after a full description of the study. Those who signed the consent have been informed that participation in the study was voluntary and that they could withdraw their consent to participate at any time.

Results

88 patients aged ≥ 65 years admitted to the General Medicine Ward and Gastroenterology of H.U. of Piacenza and General Medicine Ward of the H.U. Val Tidone, in the quarter examined. In reality, the sample should have been 100 patients based on statistical considerations but the time available allowed to include 88 patients; 35 of them were assessed in the General Medicine and 14 in the O.U. of Gastroenterology of H.U. of Piacenza; while 39 in General Medicine of the H.U. Val Tidone (figure 2).

Unlike the Conley scale, the Traffic Crash stratifies the identified risk in low, medium, high. With it, the 88 patients evaluated are arranged on three levels:

33 are low risk; 51 medium risk; 4 high risk.

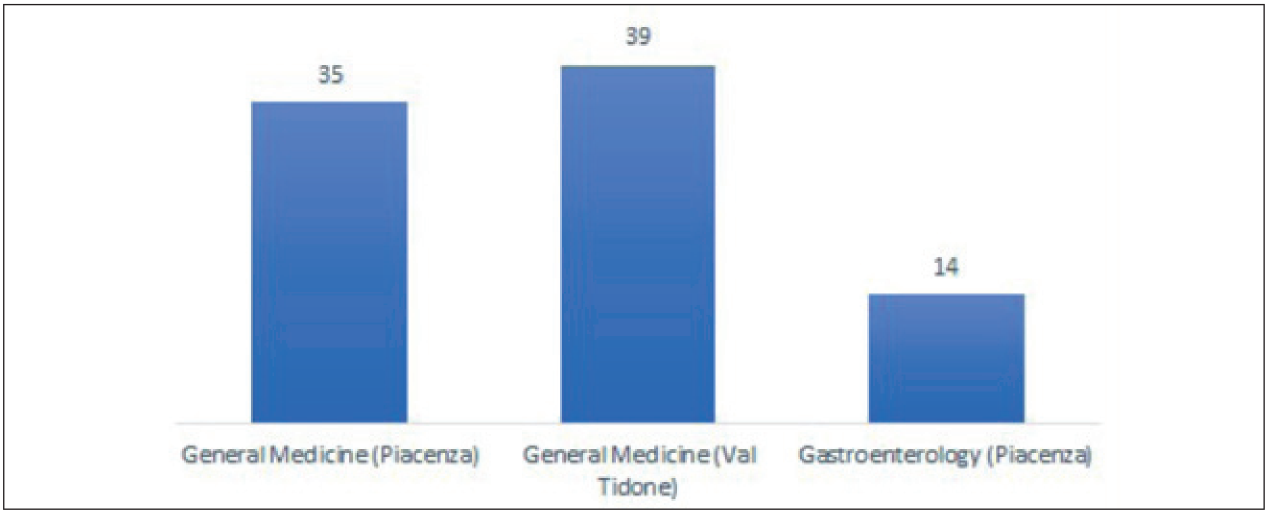


Figure 2. Evaluated Patients

The Conley scale identified at "high" risk 56 (64%) of 88 patients and 32 (36%) not at risk (figure 3).

Instead, Traffic Crash defined 55 (63%) patients at "moderate / high" risk and 33 (37%) at low risk (figure 4). Analysis of the data obtained through the compilation of the Conley scale and the Traffic Crash shows that 46 (84%) patients out of 55 are at moderate / high risk for both scales (42 medium risk, 4 high risk).

Among the objectives of the study was the verification of the inter-rater reliability of the Traffic Crash scale; in order to achieve this, it was completed simultaneously and separately by two operators on the same patient. Stability was verified with Cohen's Kappa which turns out to be p = 1 (figure 5).

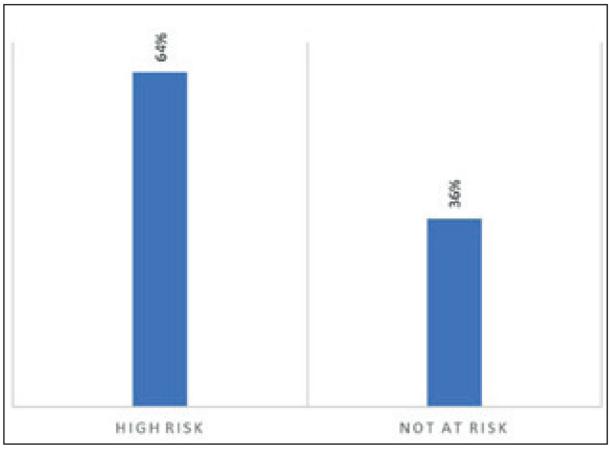


Figure 3. Fall risk using Conley scale

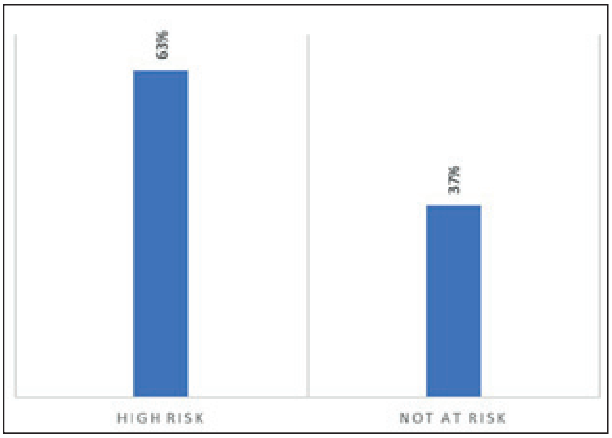


Figure 4. Fall risk using Traffic Crash scale

Discussion

Although the fall event is one of the main outcomes monitored in the companies, the data in the literature show only a rating scale considered effective in preventing risk, the Tw-FRHOP scale (16), which takes into consideration in its items the main factors of fall risk identified by NICE. (17) However, the predictive accuracy of risk was not examined in this study, and the scale was implemented in a single ward with validation related to the criteria, conducted within three days of hospitalization; this was not accompanied by a wide application in all hospital wards or by the registration of subsequent hospitalizations and fall conditions among patients (16).

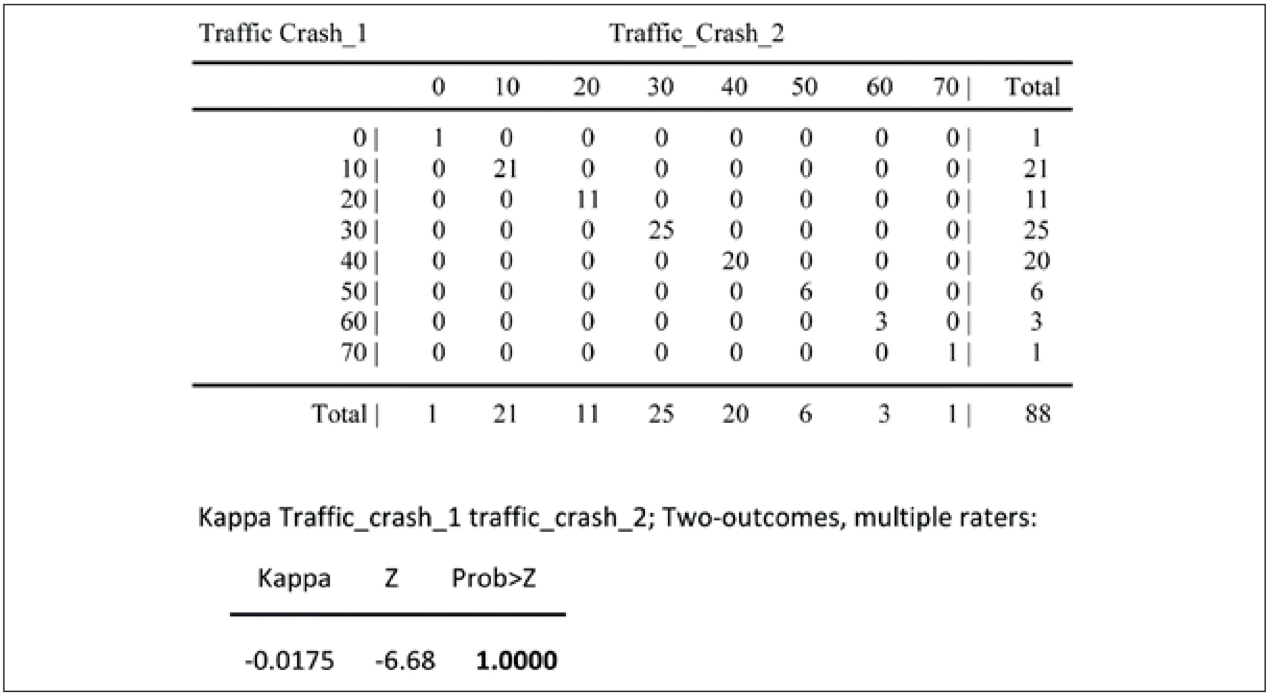
The Emilia Romagna Region has given indications to abandon the use of the scales and to verify the presence or absence of other risk factors (4), but nurses struggle to put the indications into practice given the convenience and immediacy of tools such as scales. Conley, which is the scale used in the Piacenza H.U. does not consider any significant risk factors (13) instead taken into consideration by the Traffic Crash scale.

From the analysis of the data collected during the period under consideration, it emerged clearly that the Traffic Crash scale is superimposable on the Conley for the identification of the fall risk, but specifically the stratification at the bottom, medium, high, while the Conley only in " at risk "or" not at risk ". So it can be said that the Traffic Crash in addition to stratifying also suggests that the zero risk does not exist.

Based on the risk factors indicated in the Company Procedure (18), all patients assessed are at risk of falling, therefore it can be inferred that the latter is overestimated, especially because it is not stratified. In the hospital setting, an overestimation of the risk is acceptable, also taking into account the turnover and the care load of the O.U. but in a residential structure the use of a more specific tool such as the Traffic Crash may be indicated.

The Traffic Crash also provides a series of preventive interventions based on the risk stratification to be implemented also with a view to optimizing resources.

About the reliability, the result was p = 1, the data is commonly considered acceptable for values of p > 0.75, therefore it can be said that the Traffic Crash scale is not operator sensitive.



```
Traffic Crash_1                   Traffic_Crash_2

                  0    10    20    30    40    50    60    70 |  Total

          0 |     1     0     0     0     0     0     0     0 |      1
         10 |     0    21     0     0     0     0     0     0 |     21
         20 |     0     0    11     0     0     0     0     0 |     11
         30 |     0     0     0    25     0     0     0     0 |     25
         40 |     0     0     0     0    20     0     0     0 |     20
         50 |     0     0     0     0     0     6     0     0 |      6
         60 |     0     0     0     0     0     0     3     0 |      3
         70 |     0     0     0     0     0     0     0     1 |      1

      Total |     1    21    11    25    20     6     3     1 |     88


Kappa Traffic_crash_1 traffic_crash_2; Two-outcomes, multiple raters:

    Kappa      Z     Prob>Z

  -0.0175   -6.68    1.0000
```

Figure 5. Cohen's Kappa

Conclusion

The study has some limitations such as the reduced number of subjects sampled compared to the expected and the non-implementation of the foreseen interventions by the scale that can be studied in future works.

The Traffic Crash can be a valid tool for assessing the risk of falling for guests of a residential structure or for patients hospitalized in long-term care with the advantage of also indicating the personalized interventions for prevention to be included in the care planning and make the use of the resources available to the structures.

In the future it would be interesting to study the effectiveness of the scale in question in a residential setting by implementing the planned preventive interventions.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Italian pilot version of DEMOQL-PROXY: Content and Face validity: a methodological bridge for a future Italian validation

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Abstract. *Background and aim of the work*. The assessment of Quality of Life through validated tools allow to improve level of assistance for people suffering from Dementia. To our Knowledge in Italian language seem to be absent a tool to evaluate mild and moderate dementia, consequently underestimating and underrating needs of this specific target. We show an Italian pilot version of the DEMQOL-PROXY (specific for mild and moderate Dementia) testing some psychometric properties as: back-translation, content validity and face validity in Italian language. *Method.* A back-translation by two bilingual authors was presented. Was enrolled an expert panel to test Content Validity composed by eight Medical Doctor and a panel of six participants was recruited to assess Face Validity (three professional caregivers and three family caregivers) related to patients with moderate Dementia (with 10 to 20 MMSE, mild and moderate Dementia). *Results*. Each item has a degree of agreement between experts of more than 70% and the Total CVI score is .90 (90% of agreement). So, in line with these results we can accept the version of items proposed. As regard Face Validity, the items of the instrument seem to be clear, without difficulty and there are no questions consiedered offensive or irritating. *Conclusion*. The Italian version of the DEMQOL-PROXY showed good psychometric properties: its structure and the results it leads to are similar to the original version and to the other translations produced so far. For this reason, we consider this paper as a methodological bridge for a future complete Italian Validation. (www.actabiomedica.it)

Key Words: Quality of Life; Dementia; Content Validity; Face Validity; Back-translation

Introduction

Dementia can be considered one of the major causes of disability and dependency among the elderly around the world, that affects memory, cognitive and behavioural abilities and ultimately interferes with the ability to perform daily activities. Dementia represents substantial human costs for the country, society, family and individuals (1).

Dementia is a domain particularly relevant, for many reasons: (a) entails serious consequences in the affected persons, in the family and in general in the socio-economic context; (b) so far it is not treatable and is recognized by the World Health Organization (WHO) as a public health priority; (c) it affects a growing number of people and represents the first cause of lowering the Quality of Life (QoL) among neurodegenerative disorders and the first cause of institutionalization (2).

The construct of Quality of Life (QoL) has constantly evolved over time, represented by a lot of definitions. In literature, despite we found a lot a consideration about QoL, it's universally recognized that it's a subjective and multidimensional concept, which is not limited to physical contexts, but involves psychic, spiritual and socio-economic spheres and the surrounding environment (3). The QoL has become a fundamental and relevant health indicator; in the next years, the growth and social development policies must be designed with a view of improving and/or maintaining it (4). At the same time, one of the most relevant data of western societies is the aging of population and the consequent spreading of all age-related and loss of autonomy diseases, which is forcing many countries to finding suitable solutions. In the world, there are 46.8 million people suffering from a form of dementia; The WHO estimates that in 2050 it will be three times higher, with 7.7 million new cases per year and a survival from diagnosis of 4-8 years (5). Consideration of QoL in dementia could be directly related to quality care provided, so probably deterioration depends also on the poor quality of care received but improve QoL is a realistic achievable result in people with dementia (6).

The assessment of QoL through reliable and validated tools should represents both the objective and the parameter through which verify the effectiveness and efficiency of assistance.

In the last 20 years in the international context, many tools have been developed to evaluate the QoL in dementia (7).

In Italy, over one million people are affected and 600,000 have Alzheimer's disease: it means that around 400,000 people (the number is expected to grow) (5) are affected by dementia in different forms and severity and we don't have any tools to evaluate the QoL. There are few tools and are not indicated in the less advanced phases of dementia, leaving therefore many people uncovered.

To our knowledge in Italian language, there are only two validated instruments: the QOL-AD scale (8), indicated for people with Alzheimer's disease and the QUALID scale, indicated for people who suffer from severe and/or terminal dementia (9). In Italian language to our knowledge, tool to assess mild and moderate dementia seem to be absent, consequently, underestimating and underrating need of this specific target.

Among the International instruments considered, Smith and collaborators have devised an evaluation scale called Dementia Quality of Life-DEMQOL (10), dedicated from mild to moderate dementia (with 10 to 20 MMSE), whose psychometric properties (reliability and validity) have been re-confirmed in both English and Spanish version (10; 11). This tool has some efforts: firstly, the theoretical framework to which it refers, that includes many different aspects of the holistic conception of person, like personal autonomy, health, well-being, cognitive functioning, social relations and self-image. Secondly for the existence of the Proxy form (DEMQOL-PROXY), that assigns the evaluation of the QoL to the reference caregiver and can be applied in many contexts: specialized medicine wards, hospices, home contexts and long-term care settings. We have selected this scale for the gap in Italian language and for the two reasons aforesaid.

Aim

No Italian version of DEMQOL-PROXY has been validated in Italian language thus far. In line with this gap, we have tested in this paper a pilot version. We show some psychometric properties of the Italian version of the DEMQOL-PROXY: back-translation, content validity and face validity in Italian language, as a methodological bridge for a future complete Italian validation.

Materials and methods

The study was approved by Ethics Committee of the Santa Maria Nuova Hospital of Reggio Emilia (protocol no. 2018/0141634; approved on 19/12/2018). The first step was the back-translation of the DEMQOL-PROXY in Italian. The translation was made by bilingual authors according to existing guidelines (12;13) and back-translations (Table 1) were made to guarantee the maximum adherence to the original version (10). Written informed consent was obtained from subjects after a detailed explanation of the purpose of the study.

We recruited Content Validity Panel of Experts and Face Validity Panel Group, both between January 2019 and February 2019.

To test *Content Validity*, we enrolled an expert panel composed of 8 experts. We have recruited two

Table 1. Original version and Italian translation of the first six items of DEMQOL-Proxy

Question	Original version	Italian version
	In the last week, would you say that your relative has felt:	Nell'ultima settimana, può dirmi quanto il/la suo/a assistito/a si è sentito/a:
1	Cheerful	Allegro/a
2	Worried or anxious	Preoccupato/a o ansioso/a
3	Frustrated	Frustrato/a
4	Full of Energy	Pieno/a di energie
5	Sad	Triste
6	Content	Soddisfatto/a
7	Distressed	Angosciato/a
8	Lively	Vivace
9	Irritable	Irritabile
10	Fed-up	Annoiato/a
11	That he/she has things to look forward to	In grado di guardare avanti
	In the last week, how worried would you say your relative has been about:	Nell'ultima settimana, pensa che il/la suo/a assistito/a si sia preoccupato rispetto a:
12	His/her memory in general	Alla sua memoria in generale
13	Forgetting things that happened a long time ago	Dimenticare cose accadute molto tempo fa
14	Forgetting things that happened recently	Dimenticare cose accadute recentemente
15	Forgetting people's names	Dimenticare il nome di alcune persone
16	Forgetting where he/she is	Dimenticare dove si trova
17	Forgetting what day is it	Dimenticare che giorno è
18	His/her thoughts being muddled	Iniziare ad avere pensieri confusi
19	Difficulty making decisions	Avere difficoltà nel prendere decisioni
20	Making him/herself understood	Farsi capire dagli altri
21	Keeping him/herself clean	Mantenersi pulito/a
22	Keeping him/herself looking nice	Mantenere un aspetto gradevole
23	Getting what he/she wants from the shops	Procurarsi le cose di cui ha bisogno dai negozi
24	Using money to pay for things	Usare i soldi per pagare le cose necessarie
25	Looking after his/her finances	Gestire le sue finanze
26	Things taking longer than they used to	Cose che richiedono più tempo in confronto al passato
27	Getting in touch with people	Mettersi in contatto con altre persone
28	Not having enough company	Non avere abbastanza compagnia
29	Not being able to help other people	Non essere in grado di aiutare altre persone
30	Not playing a useful part in things	Non avere un ruolo importante nelle vicende
31	His/her physical health	La sua salute fisica

Medical Doctor for each domain in which DEMQOL-PROXY can be used:

- Two Medical Doctor working in geriatric ward of Hospital
- Two Medical Doctor working in Hospice
- Two Medical Doctor working in residential structure
- Two Medical Doctor working in Home setting

The methodology for panel of expert's construction enrolled to evaluate content validity was adopted considering literature (14;15;16)

We prepared a questionnaire build *ad hoc* for the Content Panel of Experts. In this questionnaire, we asked to the experts to give a judge on Relevance and

Exhaustively for each items of DEMQOL-PROXY. Quantitatively, experts were required to rate item on a 4-point Likert scale in terms of its relevance to the instruments aim using a specifically designed form: 1=not relevant, 2= relevant with item revision, 3= relevant with minor item revision, 4 = very relevant, experts give also a qualitatively suggestion (Table 2). Then the medium of percentage score was the Content Validity Index (CVI). Content Validity Index consists in the medium percentage of experts' s answers. The acceptability cut-off of CVI is > 70% and in line with this cut-off we have considered no changing in the tool.

To explore *Face validity*, we enrolled 6 participants:

- Three professional-care giver (Medical Doctor and Nurses)
- Three family caregivers

To assess Face Validity, we administered *an ad Hoc grid* to the six experts to rate the 32 items of DEMQOL-PROXY on a two-level point scale (YES/NOT) about: difficulties, clarity, offensiveness. The answer of experts was considered on a qualitative way, to detect any request in line with a changing of the item. For any YES answer expert was required to give explanation.

All participants recruited to test content and face validity, were able to perfectly read and understand Italian and to fill out the questionnaires by themselves. The DEMQOL-PROXY were administered to caregivers during their permanence in structures for visiting their relatives or working.

Statistical analysis

The statistical analysis was performed by using SPSS Version 25,2019. To evaluate Content Validity,

Table 3. Quantification of Item Content Validity on Italian version of DEMQOL-Proxy

Item number of the Italian version of DEMQOL-Proxy	*CVI*	*Action*
1	1.00	*Retain*
2	1.00	*Retain*
3	0.88	*Retain*
4	0.88	*Retain*
5	1.00	*Retain*
6	1.00	*Retain*
7	1.00	*Retain*
8	0.75	*Retain*
9	0.88	*Retain*
10	1.00	*Retain*
11	0.75	*Retain*
12	1.00	*Retain*
13	0.88	*Retain*
14	1.00	*Retain*
15	0.88	*Retain*
16	1.00	*Retain*
17	0.88	*Retain*
18	1.00	*Retain*
19	0.88	*Retain*
20	0.88	*Retain*
21	0.88	*Retain*
22	0.88	*Retain*
23	0.75	*Retain*
24	0.88	*Retain*
25	0.88	*Retain*
26	0.75	*Retain*
27	0.88	*Retain*
28	1.00	*Retain*
29	0.75	*Retain*
30	0.75	*Retain*
31	1.00	*Retain*

CVI, Content Validity Index

Table 2. Example of Content Validity Rating Form for Expert Reviewers

Instruction:

Items listed below were included in the preliminary version of DEMQOL-Proxy. Please review the tool and rate each item for relevance in assessing the Quality of Life in patients with Dementia, using a 4 point Likert Scale (from 1=not relevant to 4=very relevant). Please provide any suggestion or recommendation for necessary item revision or deletion.

In the last week, would you say that _________ (your relative) has felt:	Do you think this item is relevant in the measurement of the Quality of Life in patients with Dementia?				Suggestions and comments
1. Cheerful	1	2	3	4	
2. Worried or anxious	1	2	3	4	

Score 1=not relevant, 2= relevant with item revision, 3= relevant with minor item revision, 4 = very relevant we have performed CVI-*Content Validity Index* (17). Content Validity was carried out using the Scale for CVI-*Content Validity Index* (17), a 4-points Likert Scale which provides for .70 value as acceptability value.

To test Face Validity, we considered answer in a qualitative way, just considered YES answer.

Results

Table 1 shows the Italian version of the DEMQOL-PROXY confronted with the original one in English. Table 3 reports the results for content validity. All the 8 recruited experts completed the grid. The analysis shows that each item has a degree of agreement between experts of more than 70% and specifically the scores obtained from each item are presented below in Table 1. The Total CVI score is 90 (90% of agreement). In addition, it is noted that of the 32 Items 12 obtained a total consensus from all experts. The detection of Content Validity through the administration of the Scale for the CVI provided an adequate degree of agreement between experts to proceed to the subsequent phases expected for pre-validation; furthermore, the fact that most of the items in the questionnaire obtained a total consensus from all the experts represented a very important positive predictive factor. This results did not require changing of the items proposed.

Also for the Face Validity; the 6 participants completed the *ad Hoc grid* but none give YES answer. So, the qualitative results did not require any changing of the instrument. Our results point out that DEMQOL-PROXY seems to be sufficiently understandable and clear in its formulation. In general, the items of the instrument seem to be clear, there is no difficulty in answering questions and there are no questions that are offensive or irritating.

Discussion

We present the back-translation (12,13) and some psychometric features as content validity and face validity (14;15;16) for a pilot Italian version of the DEMQOL-PROXY. Our pilot version must be considered as methodological bridge for a future complete Italian validation. Smith and collaborators, have devised an evaluation scale called DEMQOL-PROXY (10), dedicated from mild to moderate dementia (with 10 to 20 MMSE), another group or researcher (11) have validated also the instrument in Spanish language. The assessment of content validity in our research can be useful to verify thanks to the judgement of the panel of experts if the use of the instrument could be appropriate in Italian Context (14;15;16).

We first produced a back-translation of the DEMQOL-PROXY and then we administered it to the caregivers. Content Validity Index shows that this instrument seems to satisfy the content validity pre-requisite. In our research, the use of DEMQOL-PROXY seems to be appropriate to the Italian context. The total CVI score is .90 and this result points out that, experts evaluate this instrument able to assess in a relevant and exhaustive way the QoL domains for the specific target of people affected by mild or moderate dementia (with 10 to 20 MMSE).

The evaluation of Face Validity confirm that tool was clear, easy to fill and without offensive word. Our results point out that psychometric properties of the Italian pilot version of the DEMQOL-PROXY as back-translation, content validity and face validity in Italian language was verified and allow to consider the Italian version proposed as a valid methodological bridge for a future complete Italian validation.

Conclusions

The DEMQOL-PROXY could be in Italy an important tool dedicated from mild to moderate dementia (with 10 to 20 MMSE), in order to assess the QoL from the caregiver perspective. Our proposed pilot Italian version of the DEMQOL-PROXY showed good psychometric properties: its structure and the results it leads to are similar to the original version (10) and to the other translations produced so far (11). For this reason, we consider that in future it could be useful to implement a complete Italian Validation of this tool. Moreover, it could be relevant to assess in the future this pilot version for: structural validity, convergent and divergent validity.

DEMQOL-PROXY in fact, is a simple and reliable questionnaire which can be completed in a few minutes. Its capacity to explore QoL for patients from mild to moderate dementia is a fundamental characteristic so that caregivers of specialized medicine wards, hospices, home contexts and long-term care settings can understand how to improve patient's experience (18). DEMQOL-PROXY application could be helpful to better manage patients with a level of dementia from mild to moderate (with 10 to 20 MMSE).

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Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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The VaRP Project: qualitative evaluation of the training effectiveness of Post Graduate Specializations for health professionals

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Abstract. *Introduction:* The healthcare professionals' specialized training has a positive impact on professional values, patient's outcome, and promotion of evidence-based practices. To raise the educational standard, the University of Parma has created Post Graduate Specializations which, in addition to learning sector-specific techniques and skills, include the acquisition of soft skills. Aim of the study is investigating the perception of the tutors dedicated to the organization, management, and teaching of the Post Graduate Specializations on the skills gained and the changes achieved in clinical practice, training, and research. *Materials and Methods:* Qualitative research was carried out through a semi-structured interview to 11 tutors who have been coordinating the Post Graduate Specializations. *Results:* The Qualitative analysis developed "thick" descriptions characterized by analytical density and interpretative richness. The emerging thematic nuclei were: General/unpredicted aspects, Professional empowerment, Satisfaction, Professional outcomes, Limits of the Post Graduate Specializations, and Development areas. *Conclusions:* We identified the most effective areas of the Post Graduate Specializations that emerged consistently from the interviews. We hypothesized that the values and mission the Scientific Board, are effectively lived and championed in the everyday activities of the Post Graduate Specializations. Some domains still need to be furtherly developed, as the professional record, the absence of a "follow up" relationship with former students, and the effective management of workload both for students and tutors. The rise of these limits, can be particularly fruitful, as it gives the chance to identify the development trajectory the post-graduate trainings should pursue to raise the standard of excellence. (www.actabiomedica.it)

Keywords: Post Graduate Specialization, Healthcare Professionals, Qualitative Analysis, Inter professionalism, Research literacy

Introduction

The international literature has indicated that the specialized training of healthcare professionals is an important resource for the health system, with a positive impact on professional values, patient's outcome, and on the promotion of evidence-based practices (1–3). At the European Union level, the document "Competences of the Clinical Nurse specialist (CNS): Common plinth of competences for a Common Training Framework of each specialty (4) was created to identify the essential competencies of a nurse specialist, meant as "an advanced practice Nurse prepared in a clinical specialty at the master's, post master's or doctoral level as specialist". These competencies are supposed to involve: the Clinical role, Patient relationship, Patient Teaching/coaching, Mentoring, Research, Organization and management, Communication and teamwork, Ethic and decision making, Leadership / policy making, Prevention.

Moreover, another crucial aspect is represented by soft skills, defined as “socio-emotional intra and interpersonal skills important for personal development, social participation and job success [...]” (5), that can be taught and developed with specialization courses. Soft skills are characterized by being general skills that can be spent in different working contexts which, if possessed and properly used, can contribute both to the achievement of excellent work results and personal development (6).

As from the previous definition, soft skills are considered by literature as a heterogeneous set of transversal skills concerning the capability to adjust to the work environment that healthcare professionals need to develop (7).

Among the main soft skills associated with positive outcomes for both the patient and healthcare professionals, emerges the capability to manage the workload and resilience to burnout mediated by empathy and self-compassion (8), the communication skills, the ability to work in a team, general adaptability, time-management (9,10).

So to raise the educational standard of healthcare professionals, therefore, the University of Parma has created first and second level Post Graduate Specializations that approach specialization with a “collaborative model” (11) which, in addition to learning sector-specific techniques and skills, also includes the acquisition of the soft skills transversal to practice in the socio-health sector. Following what is present in the literature, the Post Graduate Specializations for the health professions, promoted by the University of Parma, active in the years span 2013-2020, share a vision that develops around to the following transversal macro areas:

1. The cultural development of learners through the collaborative creation of research literacy (12–15);
2. The orientation of the learners to the assisted person and his/her family and not only to the clinical case (16,17);
3. The orientation towards the development of competencies through the internship activity (18–20);
4. The focus on communication, relational and teamwork skills (21–27);
5. Inter-professionalism (28–33);
6. Co-creation of the curriculum (34–36);
7. Personalization of the training course (37–39).

Given the salience of short-term and long-term outcomes of post-base training in the health sector, the need for an approach to the training offer that provides for a continuous evaluation of the same becomes evident, to guarantee a high level of “effectiveness” of the training.

The evaluation of post-base specialist training, in the literature, seems to involve different variables such as:

- Learner satisfaction with the content and methods used (40–42).
- Professional record (41,43).
- Perceived levels of effectiveness and preparation in the specialization (43,44)(43).

One approach to evaluate both competences and soft skills, could be through the perception of post graduate trainings Tutors.

As emerged from the study conducted by the Emilia-Romagna Regional Health and Social Agency (45), there are some common identifying functions of the role of the tutor: establishing a relationship climate, organizational and educational conditions that favour learning; encourage the development of meta-skills; adopt the most suitable training methods to guide and support the student’s path; encourage the integration of theoretical and practical knowledge; provide constant feedback.

Aim

This study aims to investigate the perception of the team of expert tutors dedicated to the organization, management, and teaching of the Post Graduate Specializations concerning the skills gained by the learners and the possible changes achieved from the learners in clinical practice, training, and research.

Methods

Research design and context

Qualitative research was carried out through a semi-structured interview.

The Post Graduate Specializations subject to evaluation are:

1. First level (Post - Bachelor degree):
    a. Post Graduate Specialization in Palliative Care and Pain Therapy for Healthcare Professions;
    b. Post Graduate Specialization in Case care management in hospital and on the territory for health professions
    c. Post Graduate Specialization in Intensive Care nursing
    d. Post Graduate Specialization in Interprofessional Management of Chronicity in the Hospital and the Territory
    e. Post Graduate Specialization in Infectious Risk Related to Health Care
    f. Post Graduate Specializations in Integrated Family and Community Assistance
    g. Post Graduate Specializations in Innovative Training Methodologies
2. Second level (Post- Master degree)
    a. Post Graduate Specialization in Innovative Training Methodologies and European Standards.

    These Post Graduate Specializations encompasses three kind of active roles: Didactic tutor, who deals with didactic planning, direct relationship with learners and logistics, organizational and classroom management. Research tutor: who follows the individual groups of students in the research project, with the role of trainer and facilitator. E-learning innovative methodologies tutor: who deals with the research and implementation of multimedia learning and organization systems for learners.

More details on the organizational structure of the Post Graduate Specializations are reported in Table 1.

Sample

The sample consists of 11 tutors (didactic tutors, research tutors, e-learning innovative methodologies tutor), who agreed to participate in the research and gave informed consent. Out of 11 participants, 9 are current or past Didactic Tutors of the specializations, 1 Research Tutor and the e-learning innovative methodologies tutor, the latter being transversal to the different specialization courses.

The average years of experience as a tutor is 2.8 years (Min 1, Max 6)

In the team of 11 Tutors, 6 have the professional qualification of Psychologist or Psychologist / Psychotherapist, 3 of Nurses or Nursing Coordinator, 1 Sociologist.

7 have the title of Ph.D. and 4 Master's Degree.

The totality plays multiple professional roles currently, including freelancers (6), trainers (5), university teachers (2), nurses (2), managers of the Degree Course in Nursing (3).

In total, 7 women and 4 men were interviewed. The description of each participant is in table 1

Instruments

The interviews were conducted and recorded using Skype, the average duration being 30 minutes (Min 13, Max 47, SD: 9,7)

They were subsequently fully transcribed and analysed through the segmentation and identification of meaning units and grouping into descriptive categories.

The semi-structured interview includes 3 sections aimed at exploring 3 themes:

Table 1. Organizational structure of University of Parma Post Graduate Specializations in Health Professions

Scientific Board

President Scientific Coordinator

2 Research Supervisors 1 E-learning innovative methodologies tutor

2 Research Supervisors 1 E-learning innovative methodologies tutor	Case care management in hospital and on the territory for health professions	Intensive Care Nursing	Interprofessional Management of Chronicity in the Hospital and the Territory	Infectious Risk Related to Health Care	Integrated Family and Community Assistance	Innovative Training Methodologies	Innovative Training Methodologies and European Standards
1 didactic tutor	1 didactic tutor	1 didactic tutor	1 didactic tutor	1 didactic tutor	1 didactic tutor	1 didactic tutor	1 didactic tutor
4 research tutor	4 research tutor	6 research tutor	4 research tutor	4 research tutor	4 research tutor	2 research tutor	2 research tutor

Table 2. Participants

Code	Qualification	Specialization	N. of editions	Professional qualification	Study title	Work
01	DT	Palliative care	3	Psyc/PsyT	PhD	PsyT; trainer
02	DT	Intensive care	2	Psyc	PhD	Psyc; Professor; research fellow
03	DT	Infectious risk/ Innovative methodologies	2/1	Nursing coordinator	PhD	Nursing Science Bachelor tutor
04	DT	Palliative care	2	Psyc/PsyT	LM	PsyT;research fellow
05	RMI	All	6	Sociologist	PhD	Research fellow; trainer
06	DT	Infectious risk/intensive care	1/2	Psyc/PsyT	PhD	PsyT; trainer
07	TR	Different	/	Psyc/PsyT	PhD	Psyc; trainer; professor; research fellow
08	DT	Pediatric care	2	Nurse	LM	Nursing Science Bachelor tutor
09	DT	Family community assist/ Innovative Meth/Infective risk	1/1/1	Psyc/PsyT	LM	PsyT; trainer; research fellow
10	DT	Invensive Care	1	Course Manager	PhD	Course Manager
11	DT	Chronic care	4	Nurse	LM	Nurse; Nursing Science Bachelor tutor

DT=Didactic Tutor;RT=Research tutor; EIM=E-learning Innovative Methodologies Tutor; Psyc/PsyT =Psychologist/Psychotherapist

1. **Professional empowerment:** meant as the skills and competencies that students have gained, with attention to educational innovation, project work, research, e-learning platform, program co-construction, soft skills.
2. **Satisfaction:** meant as the actual level of student satisfaction with the classic areas of training such as theory, laboratories, internships, seminars, collaborations with institutions, and for areas of innovation
3. **Professional outcomes**: meant as an opportunity to understand if and in what way the tutors had the opportunity to follow the professional development of the participants and the idea the tutor made of professional development, intended not only as a change/improvement of the working position, but also as development of the thinking ability, ability to socialize the results of one's work also in scientific conferences, or research results through publications, or again, learning of transversal skills such as soft skills.

At the end of the interview, the participant is also invited to add any ideas related to the improvement of the evaluation and the specialization courses themselves.

Results

The interpretative effort has been oriented to the development of "thick" descriptions (46), characterized by analytical density and interpretative richness of the tutors' descriptions. This approach allows this research to get closer to understand and make sense of the teaching-learning practices taken by the Post Graduate specializations currently active in the Department of Medicine and Surgery at the Parma's Major Hospital.

The first reading of the transcripts allowed to access a global idea of their content and the identification of the categories. During the second reading, we built different thematic nuclei made by categories emerged in the first reading through an inductive, open, and generative process and selected the ones relevant for the objectives of the study. The thematic nuclei that have emerged encompass the categories revealed by the interviewed sample. To some extent, all the tutors participating in this study converged to the categories and thematic nuclei that have been defined.

Below are the categories that form each thematic nuclei (Tab. 3).

The thematic nuclei were defined as follows:

Table 3. Categories and thematic units that form up each core of meaning

Thematic nuclei	**Category**
general/unpredicted aspects	Tutor experience
	Student expectations
Professional empowerment	Skills developed by students through the post-graduated training*
Professional outcomes	More effective training instruments*
	Impact in the professional career*
Satisfaction	Methodologies / activities most appreciated by students
	Peculiarities of the post-graduated training
Limits of the specialization courses and Development areas	Criticality / future developments of the post-graduated training

The categories marked with an * belong to the two thematic nuclei on the left

General/unpredicted aspects

The heterogeneity of the groups is an aspect that has an important place for the tutor. The groups are made up of different age students, with different degrees of experience and different work areas. This heterogeneity tends to cause, mainly in the initial period, conflicts and some discomfort in students, who may not find their expectations reflected with the way in which the Post Graduate Specializations are organized.

"…the student is placed in front of a huge challenge... maybe they don't expect to collaborate, to have to participate from the beginning to the end…"

It is difficult for the tutor, but also enriching, to manage or mediate between the characteristics of the students - at a personal level and at the level of specific professional characteristics - and the methodology offered in the specializations. This professional path is enriching not only professionally but also personally. The professionals are relocated because of their relationships with their classmates, their teachers and Post Graduate Specializations' staff, returning to a position of students and peers with their colleagues, a factor that seems to enrich the psychosocial attitude of the group.

"…asking students to enter into relationships with each other, to collaborate… the fact that there is such a high involvement in the group among students in the class group, with the teachers, with the tutor and with all the rotating staff figures of the course … That is, this means that the student enters a professionalizing path but, at the same time, personal…"

Professional empowerment

Regarding the skills and competences that the students have gained in the Post Graduate Specializations' path, as a first point, the tutors find that the diversification of professions within the specializations is a wealth and a particularity for the students. This heterogeneity, which we discussed earlier, that bring together professionals from various occupational fields at the public health level, different ages and different degrees of experience that are immersed in a collaborative environment, invites them to make decisions within the formative path and, consequently, to develop mainly relational skills and abilities.

"…in the sense that the specializations mainly ask for a relational and communicative competence that already starts from the teamwork. Because immediately they are asked to conform groups, to work in a group, and this already develops or, in some way, requires the student to access these skills, shall we say relational and communicative: therefore team building, leadership development, the ability to collaborate on an inter-professional level for a project..."

"...where in every specialization we talk about the management of inter-professional conflicts, we talk about the management of teamwork, we talk about leadership, of all, therefore, that part of communication… this is a skill that, specifically, our specializations help to develop..."

From the tutors' point of view, one of the most important skills that students acquire are the research methodology, which they perceive as a very useful resource in the field of work.

"…Well, definitely the project work… the whole part of the research, because, however, when someone wants to

present a new project, the specialization teach them to do it right on each phase." "Even just the request: "How can I request or how can I inform the manager that I want to carry out this project? From the start to the finish…"

"… there are also repercussions in practice … some of them already had research experiences, but related only to the basic degree course … in flashes, without a structured research methodology … and therefore also there, make them learn research principles by doing research …"

On the other hand, technological skills, such as the use of the online platform, the use of new technologies and the English language, are developed in an important way in this process.

"…people of a certain age make a great effort … they have fewer tools than necessary to carry out a research… Just, for example, in the knowledge of English language... or the use of the PC; even very trivial, basic things, basic skills. However, they all arrive to the end (of the specialization) happy with what they have done...they realize that they have done something that many of them, especially - I repeat - those with more years of experience, thought they were unable to do, so, I must say that, in the end, everyone is happy and everyone feels enriched by the path..."

"…coordinate and collaborate remotely using communication methods that, perhaps, many were not used to or were unable to do. And, therefore, this already leads to the development of a competence or knowledge…"

Satisfaction

From the tutors' perspective, there are different characteristics and modalities of the specializations that grant a greater or lesser degree of satisfaction for the students who participate in them. Students especially like the internship, who turns out to be the modality reported as mostly valued by them. It is a very rewarding experience since the way in which internships are organized puts the participants in contact with real situations addressed in the classrooms and in their areas of professional interest.

"…because the internships have allowed them to learn about foreign realities, external to their daily professional life..."

"…even the internship is something that … they go there to touch reality, some realities where there is this professional figure..."

Students particularly appreciate the simulations that exemplify situations that they experience daily in their workplaces. These simulations involve technical and practical situations related to their professions, but also imply an interactional level with other professionals, a factor that contributes to enrich their problems' vision but also the relational modalities in which they participate. The professionals who are part of these specializations have a theoretical and methodological background which is certainly very important, however, in the specializations' context, this background would lose relevance to them if it was not put into simulated practice, that is, theoretical knowledge is complemented and enriched with the interactive experience and the know-how.

"…in the sense that, through simulation the student truly obtains access to the experience and understand then what is the message, the theoretical content… So, that practicing, experiencing helps the student to take, to really learn … an experiential learning that seems to be much more effective..."

A common aspect to all the specializations is the initial students' perplexity when they are faced with the research activities. It seems less difficult to manage and negotiate with them the technical activities, which are initially more linked to their professional areas and, therefore, creates in them a greater perception of security and capacity, even when these activities are not favorites in the course.

In their work environments, students are not accustomed doing research activities, so the question is how research would be useful for their daily practices. This is a time of crisis in which tutors try to work with them to integrate the ideas about the usefulness of the research methodology in their fields of work. Although initially it seems not to be one of their favorite areas, the research modules capture their attention and interest as they get more fully into the subjects. As the research takes more form, they seem to realize the importance of disseminating knowledge and linking it to other capacities and areas of interest. For example, in several moments, the tutors report that students find a meeting point between the activities and practices developed in the internship and the application in these places of the knowledge acquired through the project work.

"…and it has often be able to notice an initial resist-

ance, due to the various reactions that can occur; even due to rejection, often due to strong reactions… then, gradually, the satisfactions come, there begins to be an enthusiasm, because then, they enter a little more into what their research theme is……when they understood the connection, the strong connection was one of the satisfactions.. and I would say it was one of the strongest results. That is, make it clear that you can be very good, but if what you learn you do not study, you don't publish it, you don't divulge it…… Because they have a profile, it is true, more clinical, but they also access research. So, for example, with Dr. A. they do their research internship, and most of them … enjoyed it…"

Professional outcomes

In terms of the ways in which the specializations have impacted the students' professional development/change, in some cases the project work has opened job development opportunities through innovation. In fact, on several occasions this research projects are carried out in collaboration with the students' workplace, opening firstly the possibility of following on the project deepening the subject and, on the other hand, favoring the students' growth and roles change.

"…in fact, some often glimpse in the possibility that the research project opens in their work… they glimpse a way of being considered by the corporation, perhaps to recognize them in another way, in the professional sense…"

"… glimpse the opportunity to also change their job role … For example, someone who says: "Yes, I really hope that this research project can be carried out … maybe this activity in my corporation …… let's say that the student has an impact at a professional and concrete level … and some students … have turned their research project into a project within their workplaces and from there have developed their own area within the company …"

For many students, the Post Graduate Specialization represents a way to deepen their own knowledge of their work but above all, to enrich the practice. This is reflected in the relationships they establish not only with their colleagues, but with users.

"… they know how important it is to develop skills at the level of relationships, to relate with the patient but also with the caregivers, with the patients' relatives; so, some lessons about this aspect are particularly appreciated …"

When the monitoring and continuity of these projects is not possible in the workplace, students try to maintain contact with the tutors once the academic path is done. In those cases it opens the possibility of making scientific publications, which represent, besides job growth opportunities, a curricular contribution for the participants. Through the project work and other particularities of the specializations, some students have acquired a catalyst of change/transformation role in their work area. At the level of individual work development, some students acquire the possibility of being transferred to other areas where they can take advantage of the acquired skills; they have agreed to promotions and work improvements. Others decide to insert themselves in academic environments and, those who are responsible for internship students, report having a different approach towards the apprentices, not only at the level of specific knowledge, but also at the pedagogical level.

"…well, I think it was also an important opportunity. And some of those students, in fact, 2 or 3 people who went ahead, wanted to continue with the research project that had started during the course or presented posters … and, therefore, in my opinion, also that kind of relapse…… then some students who requested, who applied to be transferred to critical area units; for example, I know a participant who was transferred to neonatal intensive care, she decided to work in this area in order to take advantage of these skills that she had acquired…"

"… I understood that they had a different approach even with the students in the internship … some educational strategies, which they had learned during the course and then reflected … they also used them with their students…"

The tutors report that sometimes the impact of this specialization process is not reflected in work environments; there seems to be no formal recognition of the implications of the training. This can be negatively reflected in a lack of economic and professional growth, which implies a low motivation of those affected.

"… what is lacking is a formal acknowledgment … of participation in the courses … by the workplace. But … we hope that there may be implications, because otherwise, all the personal motivation that a professional can have… in summary, formal/economic recognition has a great motivational weight…"

Limits of the Post Graduate Specializations

There is a particularity of these specializations that is seen as a limit but also as an advantage: the considerable burden and the level of demand they entail. It is seen as a limitation when is taken into account that the participants are professionals who already have an important workload, so their availability of time is more limited compared to those who are only students. But it also represents an advantage as regards the level of soft skills development, due to the challenge of being immersed in a condition of high demand and constant stress.

"... often, precisely, the student behaves a little, a little reluctantly, this sometimes challenging attitude is precisely because he is asked a lot ...... they had to challenge themselves and go through an evolutionary challenge. And this cannot fail to have caused a change ... the characteristic is this: that they are constantly requested from this point of view. In other words, they are always very demanded. And this is a characteristic that I think is quite distinctive, from the point of view only as a methodology..."

Some tutors argued that there is little clarity as to which of the skills students are expected to develop are transversal to all specialization courses and which are particular to each of them. There is also no formal evaluation of the training and organizational results, which makes it difficult to be clear on what aspects it is important to implement changes or improvements to the processes.

"…it would be interesting to evaluate the more specific spillover effects from an organizational point of view ... I don't know, asking the coordinators who manage the whole area, if they actually have the same perception of ours. Because of course we speak from an educational perspective…"

"…understand also their participation simply in the organization's strategic lines, comes to my mind, that is: "has their contribution been decisive?" This in my opinion would be an important area to investigate…"

Development areas

The tutors seem to have adequate but limited ability to follow the professional development of the students. It is evident that there are professional changes and improvements in the students who participate in the specializations, but the tutors feel somewhat limited in their own vision of the specific competencies offered by each training course. Transversal competencies seem clearer to them than the specific competencies of each training course.

The tutors also report that the professional impact is not very clear to them either and they consider that a feedback from the students or, more formally, an evaluation, is necessary to have more clarity on how much this formative process has had a determining effect at the professional level. The tutors make a difference between the evaluation that they can do about this aspect and the evaluation that has been done in the students' work environments because, while the vision of the tutors is from the academic point of view, the vision of the people that collaborate or direct those who participate in the specialization courses is an organizational view.

"…when, in reality, maybe training is what they need most and also understand the relapses; not only in formative terms but, in my opinion, also in organizational terms. However, this is not always the case in this evaluation phase in the training courses…"

Discussions

The results of this qualitative study offer important food for thought for the assessment of the effective areas and also of the areas for improvement of the Post Graduate Specializations in health professions proposed by the University of Parma.

Adopting a general point of view on the contents of the interviews of the tutors, beyond the categories that emerged with the analysis, some salient points that deserve to be discussed are outlined very clearly.

Several of the main categories that emerged appear totally aligned with the Vision pursued in the Post Graduate Specializations.

The first is the centrality of inter professionalism (28–33). The tutors report how the specializations are progressively more "plural" both in the composition of the class and in the teaching. This dimension represents an initial difficulty and is a form of displacement for students but, through the management of the tutor, this becomes a source of enrichment of the experience that allows them to acquire the skills related to inter-professional collaboration (47) which as a construct assumes a central role in the healthcare profession (48) and a wider way of structuring content, in line with the inter-professional education approach (49).

Another aspect, which is linked to inter-professionalism but extends across all the areas of the profession taken into consideration, is the acquisition of a set of transversal soft skills including the advanced relational and communicational skills (9,10,21–27). Moreover, still in the domain of the developed soft skills, it seems that the need to manage a doubled workload (considering the professional activity accompanied by the academic one) in the collaborative environment of the classroom implicitly allows students to learn the skills of load and stress management that are fundamental in the prevention of negative outcomes in the healthcare profession such as burnout (8,50). It is important to underline how this transversal competence is not built only by exposure to the load but, above all, through the mediation of the tutor and the support of the working group to which the students belong.

Although it may seem banal, students acquire skills and tools in the handling of technology and in the use of the English language, that belong to the domain of research literacy (12–15). This knowledge is very useful at the work level and is related not only to practicality but also to the implementation of new instruments in their work centers or, for example, in the development of research. Especially for professionals who already have an important career, this aspect is a great contribution to their professional development. These technical competencies, belong to the greater crucial area related to the approach to research. This specific domain is initially experienced negatively by students and encounters a lot of resistance as it is a new and "unexpected" field of experience. However, during the specializations and the practical exposure to the research methodology through the project work, it is reinterpreted by students as a means of keeping up to date in professional practice and empowers them in considering themselves capable of being cutting-edge professionals who have the means to acquire high-level knowledge independently and to apply it in one's work, thanks to research training. In essence, the students find themselves truly immersed in a context of evidence-based practice (51). Contrary to what can be imagined, research is also a means by which students can access professional development which, in many cases, allows them to access to work areas more in line with their specialization.

The students, in their academic process, are led to express themselves "on the field" (52) also and above all through experiences such as that of the internship and the simulations in the classroom (18–20). This allows them to learn beyond the classroom experience and beyond the purely professional aspect, entering into a multiplicity of systems that require them to acquire horizontal skills (technical, technological, linguistic, relational, psychosocial, and organizational).

In general, according to Tutors' point of view, the students' satisfaction emerges from the possibility of integrating their previous knowledge and skills with new knowledge and skills experienced in the field, which comes from the personalization of the training course (37–39) and the co-creation of the curriculum (34–36). It is also necessary to note how this occurs, in many areas, starting from initial resistances which, through the professional and relational investment of the tutors, are transformed into points of satisfaction and individual and professional growth.

We should underline that, from the interviews, a few lines emerged for the Vision domain concerning the orientation of the learners to the assisted person and his/her family (16,17). We can hypothesize that this can be linked to the sample of the study. As didactic Tutors, they mostly manage the structure and management of the courses, as well as the relationship with students, not getting deeply in touch with the contents of classes. This could have placed their focus far from the approach of the contents that are shared during the classes.

However, monitoring professional growth is one of the strongest limits of the specializations, weakening the domain of professional record (41,43) identified for the training evaluation. In fact, for some students, the acquisition of skills does not correspond with a growth in their specific context of professional activities, and this generates a loss of motivation in the acquisition of the proposed skills, for those who already see an impossibility of application in the real context.

Furthermore, at an organizational level, it emerges how difficult it is for tutors to follow up on the relationship with students and, therefore, to trace the real effects of the specialization in a transversal way. Added to this is the lack of formal evaluations in organizations that could provide data on the impact of training in terms of student professional performance.

Precisely this is proposed by the tutors, as the main area of development and improvement of the specializations: the structuring of a "follow up" path and contact over time with former students to realistically define the actual professional impact.

Conclusions

This study aimed to collect useful information to assess the effectiveness of Post Graduate Specializations in health professions offered by the University of Parma, following European guidelines which suggest the constant monitoring of the effectiveness of training, especially postgraduate.

Interesting results emerge related to the considerations of the tutors, therefore the experts at the forefront of course management, regarding the areas of empowerment, satisfaction, and professional development.

In particular, we were able to identify the most effective areas of the Post graduate specializations that emerged consistently from the interviews. This allows to hypothesize that the values and mission the Scientific Board elaborated starting from the scientific literature and the present and future challenges of the nursing professions also proposed from the European Guidelines, are effectively lived and championed in the everyday activities of the Post Graduate Specializations, having an effect on the students.

Nonetheless, there are some domains that still need to be furtherly developed, as the professional record, the absence of a "follow up" relationship with former students, and the effective management of workload both for students and tutors. The rise of these limits in this study, can be particularly fruitful, as it gives the chance to identify the development trajectory the post-graduate trainings should pursue to raise the standard of excellence.

A possible limitation of this research is based on the fact that the interpretative analysis carried out in this work corresponds only to the vision of the tutors. This could justify the weak presence, in our data, of categories related to the approach person-centered, which still is a main pillar in the Post Graduate Specializations' vision. We hypothesize that this domain could emerge when directly investigating the Post Graduate specializations' effectiveness with students and former students.

So, we propose, as a development of this study, an investigation always linked to these themes, carried out directly on the students population, to promote an independent and reliable evaluation of the areas of strength and limits detected in the specializations, so that to continuously improve the level of training.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Evaluation of midwifery students' satisfaction with regards to clinical internship

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Abstract. *Background and aim of the work*. The clinical internship is fundamental for the training of the future socio-health professional. Through the practical activity, the student develops professional skills, critical thinking and decision-making ability, internalizing the complexity of the professional role. While in the nursing field there are several tools for assessing the clinical experience of students, in the obstetric field there is a lack of validated tools. Therefore, the purpose of this work was to investigate the perception of the students of the Degree Course in Midwifery regarding the internship experience. *Method.* The study was conducted at the obstetric clinical internship where students carry out practical activities and involved all the students of the Degree Course in Midwifery at the University of Modena and Reggio Emilia. The data were collected through an anonymous online questionnaire (Google Model), which was inspired by the nursing CLES + T, simplified and adapted to the obstetric field. *Results.* In total, 54 students took part in the research (81.8% of all students enrolled in the degree program examined). They were mainly of Italian nationality (98.1%), women (94.4%), aged between 18-22 years (85.2%). In general, the third-year students were more satisfied with the internship experience than the second- and first-year students, most likely for having achieved a degree of autonomy of care, awareness and greater professional motivation. *Conclusions.* The results indicate the need to periodically investigate the quality and satisfaction of the clinical internships to ensure increasingly effective obstetric training. (www.actabiomedica.it)

Key words: satisfaction; students; setting; midwifery; training; internship

Introduction

Clinical care learning has always played an essential role in preparing students of the Degree Course in Midwifery.

It is important for the achievement of the training objectives deriving from the skills enshrined in the Professional Profile DM 740/9 (1) and the rules of the Ethics code of the Midwife, 2014 (2). Thanks to the clinical practice, the student is able to develop professional skills, diagnostic reasoning, and critical thinking (3).

The quality of the clinical learning experience, as well as the skills acquired, can be influenced by the organizational characteristics of the clinical context (3, 4) and by the positive atmosphere of the setting (5). Indeed, a department characterized by good internal relations, excellent coordinators and an adequate level of supervision by clinical tutors, leads the student to acquire a critical attitude and develop the ability to live the training experience within different contexts (3).

Therefore the student's satisfaction with the training experience becomes an important indicator of the achievement of learning outcomes (6). The experience in the various learning settings allows the student to face complex situations by putting into practice the knowledge acquired theoretically. In this case, reflexivity and active thinking become the tools and the priority attitudes to learn professional skills.

The internship therefore constitutes the test bench and the privileged channel for learning the profession (7). The tutors (8, 9, 10) and the training guides (11) also guarantee a constant supervision, so that the student increase his sense of responsibility and has continuous support from experienced professionals.

A study conducted at the Faculty of Health and Social Sciences of Bergen University College in Norway (12), used individual interviews and focus groups with students of the Degree Course in Midwifery to identify the conditions that influenced the learning process during the internship of students in various settings. The learning outcomes of the students resulted to be influenced by the midwives, who played the role of tutor, by the students themselves and by the learning environment. Tutors played a key role in facilitating students' learning by improving their self-esteem and their learning process.

Despite several nursing studies affirm that the internship represents the privileged opportunity of learning, in which the role of the tutor and the characteristics of the context are the main factors capable of influencing the quality of the experience and skills acquired (13,14), there are still few studies in the obstetrics field, both national and international, which have attempted to investigate these learning settings.

For example, a study conducted in Italy at the Degree Course in Midwifery of the University of Chieti in Italy (15) set itself the objective of exploring the level of satisfaction and clinical learning experience of Midwifery students of the first year of course, after the first clinical training, using the Italian version of the questionnaire "clinical Learning Environment, Supervision and plus Nurse Teacher (CLES + T) scales" (16, 17). The study showed the association between high student motivation towards practical activity, and a higher sense of satisfaction of the internship addressed.

Another study conducted at the University of Lund in Sweden (18) investigated the learning progression and the professional development of obstetrics students, using their daily notes written during the internship in the delivery room units. Written notes appeared to be useful for students to think, in a structured way, about their professional development. Furthermore, they were also useful for clinical tutors, to understand the cognitive needs of individual students.

Therefore, in this context it appears important to analyze and describe the quality perceived by the students of the Degree Course in Midwifery regarding the learning settings, in order to ensure increasingly satisfactory clinical training and a continuous improvement of the integration between the theoretical and practical activities. It should be considered that the clinical internship has a 60 training credits during the studies (1) with 100% attendance obligation, and therefore the training becomes essential for the future midwife.

Aims

The goal of the study was to assess the perception of students of the Degree Course in Midwifery regarding clinical experience-based learning.

The specific aim was to analyze and compare the perception of the 1st, 2nd and 3rd year of Midwifery students about the welcome process in the working-team, the learning atmosphere during the internship, to the supervision and evaluation carried out by the internship guide(s) on the student's practical activity.

Method

Instrument

The descriptive study was conducted through an online questionnaire (Google model) using the Italian version of the "Clinical Learning Environment, Supervision and plus Nurse Teacher (CLES + T) scale" (15). The instrument considered the gold standard in the nursing field (3, 16), has been adapted to the obstetric field. The questionnaire was filled up anonymously.

The CLES + T consists of 24 items relating to various aspects of the internship experience, preceded by 4 questions relating to socio-personal data, such as gender, nationality, age group and type of obtained training.

The items are divided into 5 areas, such as: 1) welcome at the internship site (4 items); 2) learning atmosphere at the internship site (4 items); 3) guidance and support at the internship site (8 items), 4) evaluation carried out by the internship guide (s) (4 items); 5) final overall judgment on the internship activity (3 items). The answers for each item are on a Likert scale where 1 means *"Definitely Yes", 2 "More Yes than No", 3 "More No than Yes", 4 "Definitely No".*

The last item asks the student to express a general assessment of the practical experience carried out that takes into account all the above variables. In this case, the expected answers are: *1 Excellent, 2 Good, 3 Sufficient, 4 Insufficient.* In order to achieve the objective of the study, the nursing questionnaire was adapted to the obstetrics field. In particular, 8 items from the 24 of the original scale were selected, as they respond to the questions strictly necessary to evaluate the perception of the Midwifery students regarding: the welcome received at beginning of the internship; to the learning atmosphere; the supervision and evaluation carried out by the internship guide(s) on the student's practical activity. The questionnaire submitted to the students is shown in Table 1.

Table 1. CLES+T adapted questionnaire

Items	Questions
1	Have the internship objectives to be achieved been clearly presented?
2	Did I carry out the various activities and procedures in a calm and peaceful way?
3	Did the internship guides give me moments to talk about the internship experience?
4	Did I receive adequate supervision based on my skills on performing procedures?
5	Did I receive exhaustive answers to my requests for clarification in the face of perplexity?
6	Have the final evaluations been contextualized to me?
7	Do I consider the internship experience at this Department useful for my professional future?
8	My overall and final judgment on the internship experience carried out is ...

Statistical analysis

The categorical variables were measured through absolute frequencies and percentages. For the 8 items of the questionnaire, measured through Likert scales between 0 and 4, the average values and the relative standard deviations were reported. The average values of the items were compared between the course years (1st vs 2nd, 1st vs 3rd, 2nd vs 3rd) using the Wilcoxon-Mann-Whitney test, using the Holm correction for multiple comparisons. Statistical analyzes were performed with R 3.4.3 (Foundation R for statistical calculation, Vienna) using a significance level of $p < 0.05$.

Participants

The questionnaire was completed by an Italian convenience sample, represented by Midwifery students of the Faculty of Medicine and Surgery of the University of Modena and Reggio Emilia.

All students ($n = 66$) attending the 1st, 2nd and 3rd year of the course (2017/2018) and who have carried out clinical internships at the locations scheduled for each year of the three-year period have been included, taking into consideration the Departments, the outpatient clinics, delivery rooms and territory assistance centers in Modena, Carpi, Reggio Emilia and Sassuolo (Emilia Romagna Region), where students carry out internships during the three-year period. The students, in the three years of the course, are divided as follows: n. 21 students attending the first year of the course, n. 23 attending the second year and finally n. 22 attending the third and final year of the Degree in Obstetrics. Each student received a link for completing the questionnaire via email. All students attending the I, II and III year of the Degree in Obstetrics (AY 2017/2018) who carried out clinical internships at the locations scheduled for each year of the three-year period from November 2017 to June 2018.

In total, 54 questionnaires were received, which correspond to 81.8% of all students of the Degree Course examined. Table 2 shows the internship locations that were involved in the study.

The socio-demographic characteristics of the students were reported in Table 3. Overall, of the 54 students who answered the questionnaire, 22 attended

Table 2. Description of internship settings and number of students for year (N = 54)

First year	**Second year**	**Third year**
• Gynecology Department (n = 5)	• GBreastfeeding (n = 2)	• Delivery room of Modena (n = 6)
• Department of Obstetrics (n = 6)	• GObstetric pathology (n = 1)	• Delivery room of Carpi (n = 2)
• High risk Pregnancy Department (n = 1)	• GHigh risk Pregnancy Department (n = 1)	• Delivery room of Sassuolo (n = 4)
• Prenatal Diagnosis (n = 2)	• GCTG service (n = 2)	
• Obstetrics Emergency Room (n = 5)	• GObstetrics Emergency Room (n = 3)	
• Clinical Record Opening (n = 3)	• GColposcopy Service (n = 2)	
	• GPerineal Rehabilitation (n = 1)	
	• GReproductive Medicine Service (n = 1)	
	• GTerritory assistance center (n = 7)	

Table 3. Socio-demographic characteristics of the participants (N = 54)

			First year (n = 22)		**Second year** (n = 20)		**Third year** (n = 12)	
Gender	Female	n %	19	86.4%	20	100.0%	12	100.0%
	Male	n %	3	13.6%	0	0.0%	0	0.0%
Nationality	Italian	n %	22	100.0%	19	95.0%	12	100.0%
	Foreign	n %	0	0.0%	1	5.0%	0	0.0%
High school	Scientific degree	n %	16	72.7%	8	40.0%	9	75.0%
	Not scientific degree	n %	3	13.6%	4	20.0%	3	25.0%
	Technical degree	n %	3	13.6%	8	40.0%	0	0.0%
Age class	18-22	n %	18	81.8%	19	95.0%	9	75.0%
	23-26	n %	4	18.2%	1	5.0%	3	25.0%

the first year of the course, 20 the second and 12 the third and last year. Most were Italians (98.1%), females (94.4%), aged between 18 and 22 years (85.2%). The majority of participants obtained a scientific high school diploma (61.1%).

Results

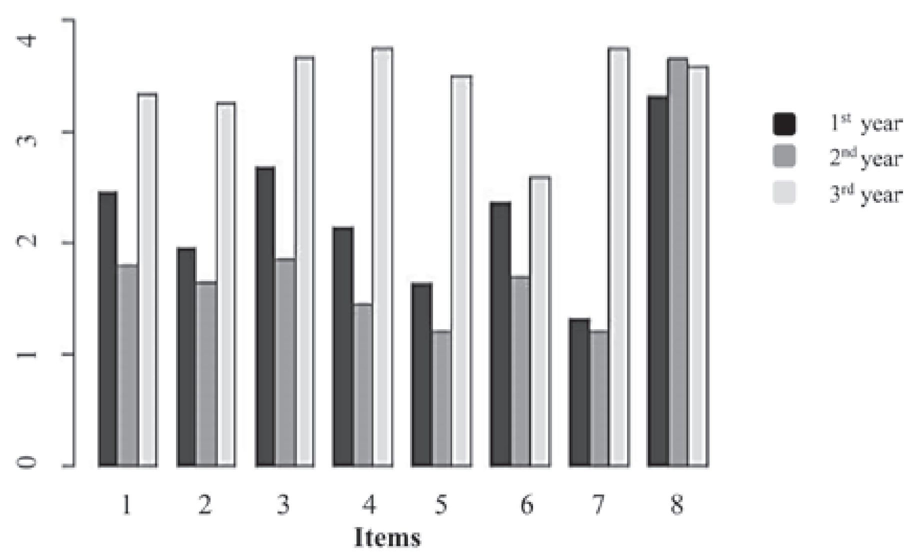
In Table 4 and in Graph 1, the values of the items relating to students attending the three years of the Course are shown in comparison. In general, third year students recorded the highest average values observed in all items. Statistically significant differences emerged in the students of the third year compared to those of the second and first year in the presentation of the objectives of the internship (III vs II year p value = 0.0004; III vs I year p value = 0.0344), in carrying out in a serene way of the various activities foreseen by the internship (III vs II year p value = 0.0002; III vs I year p value = 0.0011) and in discussing with the training guides the training experience they were experiencing (III vs II year p value = 0.0001; III vs I year p value = 0.0080).

First year students reported significantly higher scores than second year students in the presentation of the internship objectives (1st vs 2nd year p value = 0.0356), in discussing the training experience with the internship guides 1st vs 2nd year p value = 0.0082), in receiving adequate supervision during the execution of procedures (1st vs 2nd year p value = 0.0074) and on the exhaustive responses received to requests for clarification (1st vs 2nd year p value = 0.0212) .

No significant differences were observed between the three cohorts of students as regards the contextualization of the final assessments (1st vs 2nd year p value = 0.1861; 1st vs 3rd year p value = 0.6656; 2nd vs 3rd year p value = 0.1861) and in the final and overall

Table 4. Comparison between 1st, 2nd and 3rd years scores (descriptive statistics and Wilcoxon-Mann-Whitney test)

Items	First year		Second year		Third year		First vs second year	First vs third year	Second vs third year
	M	SD	M	SD	M	SD	p-value	p-value	p-value
1	2.45	1.01	1.80	0.77	3.33	0.78	0.0356	0.0344	0.0004
2	1.95	0.79	1.65	0.67	3.25	0.87	0.2080	0.0011	0.0002
3	2.68	0.99	1.85	0.88	3.67	0.49	0.0082	0.0080	0.0001
4	2.14	0.89	1.45	0.76	3.75	0.45	0.0074	0.0000	0.0000
5	1.64	0.73	1.20	0.41	3.50	0.67	0.0212	0.0000	0.0000
6	2.36	1.26	1.70	1.03	2.58	1.31	0.1861	0.6656	0.1861
7	1.32	0.72	1.20	0.41	3.75	0.62	0.7911	0.0000	0.0000
8	3.32	0.84	3.65	0.59	3.58	0.67	0.5096	0.7242	0.8293



Graph 1. Mean scores of the items among the three years of the Midwifery Course Degree

judgment on the internship experience (1st vs 2nd year p value = 0.5096; 1st vs 3rd year p value = 0.7242; 2nd vs 3rd year p value = 0.8293).

Discussion and Conclusions

Third year students, who completed the internship in the delivery rooms, were more satisfied with the internship experience than the second- and first-year students, most likely for having achieved a degree of autonomy of care, awareness and greater professional motivation. The students of the first year of the course were more satisfied than those of the second year in presenting the objectives of the internship, in discussing with the internship guides the training experience they were experiencing, in receiving adequate supervision during the execution of procedures and in obtaining exhaustive answers to requests for clarifications. The explanation for this difference could be the result of the initial enthusiasm of the first-year students in starting a completely new experience. On the contrary, second year students are already "trained" on certain techniques, but they are not yet independent and autonomous, as are third year students, so they could experience this transition phase as "less satisfactory". From the results of this study, the need to periodically investigate the quality and satisfaction of the clinical internships seems to emerge to guarantee an increasingly effective obstetric training and, consequently, a high professional competence. In order to provide a more accurate interpretation of these data, however, further studies are necessary.

Limits

Among the limits of the study, we point out that the tool used is a questionnaire that has not yet been validated in the obstetric field, even if it has been validated in the nursing field and considered the gold standard (15). Furthermore, to answer the objectives of the study, only 8 items out of the 24 of the questionnaires were selected and this could limit the vision regarding student satisfaction in its entirety. Another limitation of the research is the low number of participants which make the results obtained not generalizable to other Italian realities and to other students. To overcome these limitations, it would be interesting to use the tool on a larger sample of students who also take into consideration other degree courses in obstetrics active in other Italian universities. This could yield more interesting results to test student satisfaction with the clinical placement. Despite the limitations described, the results of the present study could be a starting point for future studies.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Third mission at the Nursing Study course University of Parma. Intervention report

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Abstract. *Background:* The term Third Mission refers to the activities with which universities interact directly with the communities and the territory of reference, combining the objectives of the third mission with the two traditional missions: teaching and research. These were the premises that guided the Nursing Studies Course of the University of Parma, with the goal of implementing a structured path of "Intercultural Nursing" on a demo-ethno-anthropological basis. *Methods:* The path taken was divided into several phases: arrangement of moments of interaction with students; teaching activity aimed at students based on the relationship between ethno-anthropological knowledge, aspects of migration medicine and social legislation; direct meetings with representatives of some communities present in the Parma area. *Results:* The interaction with students was achieved through meetings called "Cultural Coffee". The first meetings, in the measure of 4-5, took place in the period October-December 2013, subsequently, the same number of meetings was repeated in the following years. In 2019, two important results were achieved: the creation of an ADE (teaching chosen by the student) dedicated to multiculturality. Another activity of the "Intercultural Nursing" course involve the students with some communities in the Parma area. *Conclusion:* The results of this experience and the underlying idea that these aspects, if addressed in the basic training, can be for the professionals most expendable in the workplace, provide reasons to continue the path started. The international comparison on the intercultural skills of nurses, indicates collaboration and partnership with communities, as fundamental elements for a complete and effective assistance. (www.actabiomedica.it)

Key words: Third Mission, intercultural nursing, student education

Introduction

The term Third Mission refers to the set of activities with which universities interact directly with the communities and the territory of reference, combining the objectives of the third mission, which deals with the relationship between the foreign communities of the territory and the institutions ,with the two traditional missions: teaching and research (1).

The territorial communities can be divided into ethno-geographical, social, economic, and cultural one. The relevance of this aspects in Italy highlights how prevention, assistance and health education are important points in cultural activities (cultural heritage, scientific dissemination, management of museum centers, intercultural knowledge systems), social activity (public health, community benefit), educational activities (adult education, life long learning), activities aimed at civil awareness (public ethnic-cultural debates).

In general, these activities are carried out through the commitment of individual teachers and researchers, without burdens on the part of the users concerned.

This mode allows the reduction of the realization times and the possibility of a greater number of events. Third Mission activities in Italy are widespread: 71 universities report 12,636 activities (years 2004/2010), ranging from single initiatives to large-scale programs, with a prevalence of the human and social sciences areas.

In recent years there has been a greater focus of universities on the activities of the Third Mission, with an increase in contracts and funding granted to those involved.

A greater intensity of the activities of economic exploitation of knowledge is registered in the North, while a greater presence of museum activities and consortium brokerage activities in the South. The universities of Central Italy are positioned in an intermediate space. Unfortunately, the results of the Third Mission, unlike others, have not been used to define the allocation of the prize money of extraordinary funds in the sense that by working on small or very small figures, it is not possible to well define the results of the individual performed activities (2).

Aim

The aim of this project is to demonstrate the application of the Third Mission between the Nursing Course of University of Parma and some foreign communities which lives in this territory to create an important element for the course of study, an intercultural Nursing activity

Methods

The path taken was divided into several phases:

- Arrangement of moments of interaction with students;
- Didactic activity focused on ethno-anthropological knowledge, aspects of migration medicine and social legislation:
- Direct meetings with representatives of some communities present in the Parma area (center of Islamic culture, Singh Saba Association, Sikh cultural center, Zoe Mission Nigerian Pentecostal church).
- Listening to caring needs
- Analysis and research of the pathologies most present in the communities
- Comparison of ideas for future intercultural projects and transcultural nursing

Results

All stages of the course were carried out by nurses who are experts on the issues examined. In particular, reference is made to professionals with skills in ethnography, interculture, international relations, anthropology, economics of developing countries and immigration medicine.

The interaction with students was achieved through meetings called “Cultural Coffee”. The first meetings, in the measure of 4-5, took place in the period October-December 2013, subsequently, the same number of meetings was repeated in the following years.

Over the 2013-2019 period, the number of participants has steadily increased: from about 20 students per meeting, to a maximum of about 100 presences. We have seen a growing interest in intercultural nursing, confirmed by the realization of about 90 degree theses on the discipline in question.

In 2019, two important results were achieved: the creation of an ADE (teaching chosen by the student) dedicated to multiculturality, and the institution of a teaching chosen by the student equal to 3 CFU called “Multicultural Nursing”. The latter aims at a high education in transcultural nursing and provides 30 hours of lectures on the following topics: intercultural nursing, ethno-anthropology, international relations, medicine of migration, geopolitics of migratory phenomena, human rights. In support of the lectures, a 30-hour internship is provided at the structures of the various cultural communities in the area, within which health education and arterial hypertension screening can be carried out (Singh Saba Association-Sikh Temple of Parma), nursing care for women rescued from trafficking in prostitution at the protected house of Corcagnano (Zoe Mission of the Nigerian Pentecostal Church of Parma), health education at the Rosa point of the Islamic cultural center of Parma, migration medicine and roadside nursing at the Emergency mobile clinic in Milano.

Another activity of the "Intercultural Nursing" course involve the students with some communities in the Parma area (center of Islamic culture, Singh Saba Association, Sikh cultural center, Zoe Mission Nigerian Pentecostal church).

A significant conference has seen as leading actor the Sikh community in Parma, arranged by the local institutions (County, Municipality, University and Healthcare Companies of Parma), the speakers, teachers, administrators from the Municipality of Gioia Sannitica -CE-, the Roma University of "La Sapienza", and the nursing course of Pozzilli, province of Isernia. It was the first time that the Sikh community met students from Nursing Course to integrate this social community in the health culture of University of Parma. This meeting, broadcast through the medias, has had a resonance outside Emilia Romagna region and a similar event has taken place in the Municipality of Gioia Sannitica (CE).

The meeting with Sikh Community was a great promotor of the Third Mission in Nursing Course in Parma, in fact, in December 2019, the Ahmadyya community of Parma has requested the organization of a meeting with the others local communities on emerging issues health education.

Conclusion

The Nursing Degree Course, through this articulated path, has achieved objectives in line with the activities of the Third Mission of the University of Parma.

The entire project aroused particular interest from the students, especially in relation to an advanced vision of diversity and the intercultural care approach.

Cultural diversity has examined, but the most significant activities and results remain strongly connected to the human aspect and social inclusion. As part of this process, the nurse has the opportunity to contribute to the process of social inclusion, through both professional and socio-cultural commitment.

In line with the options expressed by the students during the various meetings, the network of relationships between institution and communities, have offered nursing students an important educational and personal growth opportunity.

The results of this experience and the underlying idea that these aspects, if addressed in the basic training, can be for the professionals most expendable in the workplace, provide reasons to continue the path started. The international comparison (3,4,5) on the intercultural skills of nurses, indicates collaboration and partnership with communities, as fundamental elements for a complete and effective assistance. Obviously there could be limits, which in our opinion could be dictated by the legislation on emigration, which if more restrictive could create closure by the communities, certainly not unconscious but possible. While an element of development of the project could be the new legislation on the recognition of titles for the residence permit. This undoubtedly creates a greater trust in the institutions, consequently a further opening, considering that the university itself is an institution representative of the state and the laws of the state.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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