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ORIGINAL ARTICLE

The burden of severe cases of Influenza disease: the Friuli Venezia Giulia Region experience

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Keywords

Influenza • Vaccination • Neuraminidase • Pneumonia • Respiratory illness

Summary

Introduction. Influenza is a matter of serious concern for clinicians, in both outpatient and in-hospital settings. Worldwide, the 2017-18 epidemic proved to be the most severe since 2003-04. We report a real-world experience regarding the management of patients with influenza admitted to a large teaching hospital in the Friuli Venezia Giulia region during the 2017-2018 influenza season. We also provide a practical guide for the management of hospitalized influenza patients.

Methods. A retrospective observational analysis was conducted among all influenza patients requiring admission to our center during the 2017-18 season.

Results. Overall, 29 patients were admitted to the University Hospital of Udine during the 2017-18 season with a diagnosis of influenza. B virus was responsible for the majority of cases. More than 65.5% of the subjects presented with a complication. We estimated that 41.4% of the patients admitted were affected by

Introduction

Influenza is still a matter of serious concern for clinicians, in both outpatient and in-hospital settings. Indeed, worldwide, the 2017-18 epidemic proved to be the most severe since 2003-04.

The "influenza season" is generally defined as the period of the year during which more than 80% of influenza cases occur. The usual length of the influenza season is of 8-12 weeks, from late autumn to early spring [1]. However this time-frame is arbitrary, as the definition varies widely across surveillance studies. Some authors, for example, regard the "influenza season" as the period when more than 10% of sentinel specimens prove positive for influenza virus; conversely, other experts consider the "influenza season" to be the interval between the diagnosis of the first case, or the week in which the vaccination campaign begins, and the week after the diagnosis of the last Influenza case [2].

The World Health Organization (WHO) estimates that influenza affects almost 10-20% of the world's population every year and causes between 250,000 and 500,000

a "severe form". All these cases required admission to the Intensive Care Unit, with 27.6% and 10.3% needing Orotracheal Intubation and Extracorporeal Membrane Oxygenation, respectively. The fatality rate was 24.1%. Notably, only 9 subjects in our cohort had been vaccinated. Based on the experience acquired during the past season, we propose a practical guide to the management of influenza cases in everyday hospital practice.

Conclusion. The cornerstones of the management of all hospitalized influenza patients are the rapid identification and treatment of severe forms. Timely and strict adherence to contact and respiratory precautions are also fundamental to reducing the risk of intra-hospital outbreaks. Despite improvements in antiviral therapies and supportive measures, influenza-related morbidity and mortality remain high. In our opinion, a universal vaccination program is the only safe and effective method of filling the gap.

deaths and 3-5 million hospitalizations [3, 4]. In Europe, it is estimated that approximately 10 to 30% of the population become infected with seasonal influenza every year, with several hospitalizations [5].

Epidemiological data on influenza circulation and influenza-related illness are provided by Flunet, an online database of the WHO Global Influenza Surveillance Network, which releases weekly reports of influenza virus circulation and influenza-related illness. Data are provided by the National Influenza Centers of the Global Influenza Surveillance and Response System (GISRS), local laboratories, and WHO regional databases [6]. Since 1999, in Italy a nationwide sentinel system (InfluNet) coordinated by the Ministry of Health regularly provides national and regional surveillance data on the influenza season. InfluNet depends on a group of sentinel practitioners and pediatricians, who cover up to 2%of the general population. Their reports are also uploaded to the European Centre for Disease Prevention and Control (ECDC) database [7].

According to the intensity thresholds currently approved by the CDC to classify influenza seasonal severity, the

2017-18 season in Europe was the first to be classified as a "highly severe" across all age-groups since 2003-2004 [1].

Compared with recent seasons, the 2017-2018 epidemic was characterized by a higher level of circulation of the B virus. Indeed, B viruses were responsible for the majority of severe cases in 2017–2018, most of which occurred in patients aged over 39 years. Moreover, in people aged 65 years and older, an excess in all-causes mortality was reported by the majority of sentinel countries.

Comparable characteristics were also observed for the 2017-2018 influenza season in Italy. According to the Italian surveillance system, since the beginning of the surveillance, in September 2017, 764 patients with laboratory-confirmed influenza were admitted to intensive care units (ICUs). Of these, 173 died [9].

The clinical pattern of seasonal influenza infection is extremely heterogeneous, ranging from mild disease to lethal forms.

The acute clinical presentation is similar to that of other influenza-like illnesses (ILI), consisting of abrupt onset of fever, sore throat, headache, cough and myalgia. The majority of cases resolve spontaneously within 1-2 weeks, without complications. Nevertheless, some patients undergo a more serious clinical course, which may be complicated by respiratory and extra-respiratory disorders [10]. Among these patients, elderly people, younger children, pregnant women and patients with underlying chronic diseases are at high risk of developing severe forms and influenza-related complications, such as bacterial pneumonia and extra-pulmonary influenzarelated disease [1].

Patients admitted to ICUs and those hospitalized because of influenza are defined as "severe cases". It has been estimated that their risk of death due to influenza and influenza-related respiratory complications is 3.6-4.8-fold higher than that of the remaining population infected with seasonal influenza [11, 12].

Despite the availability of antiviral drugs for both therapeutic and prophylactic purposes, the only effective method of preventing influenza and influenza-related complications is vaccination [13].

Currently, two main types of influenza vaccines are available. Trivalent vaccines protect against three flu viruses: influenza A (H1N1) virus, influenza A (H3N2) virus and influenza B virus. Quadrivalent vaccines protect against the same viruses as the trivalent ones, plus an additional B virus.

Different formulations of influenza vaccines exist: inactivated, live attenuated and recombinant vaccines. Inactivated influenza vaccines (IIV) are egg-based compounds, which may contain the whole inactivated virus, split virion or subunits, and induce specific antibodies against the hemoagglutinin (HA) component. IIVs are licensed for use in adults and children. IIVs also exist as adjuvated vaccines (with the inclusion oil-in-water emulsions, such as MF59) and as high-dose vaccines, which have been licensed for use in the elderly. A type of cell-based IIV has been licensed in the United States

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(US) and in some European countries [14]. A live attenuated influenza vaccine (LAIV) is available in the US and Canada for use in adults and children, and in Europe for use in children and adolescents. LAIV contains four influenza strains (H1N1, H3N2 and the two prevalent B strains) and is administered intranasally. The attenuated influenza virus replicates in the upper respiratory airways and stimulates the production of specific antibodies in serum as well as in the respiratory mucosa. The effectiveness of LAIV against influenza A(H3N2) and Influenza B viruses is similar to that of IIVs. Nevertheless, LAIV is poorly active against influenza A(H1N1) pdm09 viruses [15]. A Recombinant Vaccine (RV) has also been developed. This is made up of a purified HA subunit and is expressed in insect cells through baculovirus vectors. The RV is currently licensed for adults and destined for use in subjects who cannot receive other formulations. One major advantage of this vaccine is the short manufacturing process. It could therefore be useful during a pandemic season [16, 17].

Twice a year, the WHO organizes consultations of experts to formulate recommendations concerning the composition of the influenza vaccines for the following influenza season [18].

With regard to the 2017-18 influenza season, the trivalent vaccine included an A/Michigan/45/2015 (H1N1) pdm09-like virus, an A/Hong Kong/4801/2014 (H3N2)-like virus, and a B/Brisbane/60/2008-like (B/Victoria lineage) virus. The quadrivalent vaccine also included a B/Phuket/3073/2013-like (B/Yamagata lineage) virus [19].

Overall, the effectiveness of influenza immunization is estimated to be around 40-60%. Effectiveness varies considerably according to the circulating seasonal viruses, being good against A(H1N1)pdm09, moderate against influenza B virus, and poor against influenza A(H3N2) [20].

The WHO states that influenza vaccines should be directed to protecting the whole population, with particular attention to individuals most at risk for severe forms of influenza and influenza-related complications. These "priority groups" were originally designed by the WHO Strategic Advisory Group of Experts on immunization (SAGE) in 2012, and include the elderly, children, people with chronic conditions, pregnant women, and healthcare workers. In Italy, these recommendations are reported in the National Immunization Plan and confirmed every year in the influenza vaccination program by the Ministry of Health. According to the international recommendations, in Italy the minimum objective of influenza vaccine coverage in patients considered at risk is 75%, while the optimal coverage target is 95% [21, 22]. In this context, our study aimed to provide real-world data on patients with severe influenza admitted to a large teaching hospital in the Friuli Venezia Giulia region during the 2017-2018 influenza season. Based on our experience, we propose a practical guide for the management of hospitalized patients with influenza.

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Methods

STUDY POPULATION

We evaluated all patients admitted to the University Hospital of Udine (UHU) from October 1, 2017, to April 1, 2018. Individuals diagnosed with Influenza were enrolled in this retrospective analysis. UHU is part of the Azienda Sanitaria Universitaria Integrata di Udine, and is located in the Friuli Venezia Giulia region, in northeastern Italy. UHU has 1,000 beds and serves a population of almost 250,000 inhabitants.

DATA SOURCES

Information on the patients admitted to UHU was collected from the hospital discharge records and the Regional surveillance data forms provided by the Department of Prevention of Udine [23].

DATA COLLECTION AND DEFINITIONS

The following information was collected: the patient's demographic characteristics (date of birth, gender, place of residence), clinical history (anamnesis of comorbidities, previous hospital admissions), history of previous vaccinations. The presence of at least one comorbidity was used to classify patients as "comorbid".

Influenza-like illness (ILI) and severe acute respiratory infections (SARI) were diagnosed according to the "WHO surveillance case definitions for ILI and SA-RI" [24].

The diagnosis of influenza was based on the detection of influenza viral RNA by means of molecular essays performed on either nasopharyngeal swabs or bronchoalveolar lavage fluid. Disease severity was defined according to the "WHO Guidelines for Pharmacological Management of Pandemic Influenza A(H1N1) 2009 and Other Influenza Viruses" [25].

Influenza related-complications were diagnosed according to the ICD-10-CM diagnostic codes.

Influenza season was defined according to the timeframe proposed by Smetana et al. [1].

See Table I for a complete list of definitions.

STATISTICAL ANALYSIS

Data were analyzed by means of the software package SPSS Statistics v.20.0 (SPSS Inc., Chicago, IL). Baseline characteristics of the population enrolled were described through descriptive statistics. Quantitative variables were presented as median and range, and categorical variables as absolute numbers.

Results

Overall, during the 2017-18 season, 29 patients admitted to UHU received a diagnosis of Influenza. The characteristics of the study population are summarized in Table II. The median age of the patients admitted was 48 years (range 0-87 years); there was an equal distribution of genders (51.7% men, 48.3% women). Two women were pregnant: one in the first trimester and one in the second.

In 65.5% of cases, a B virus was isolated, in 24.1% an A/unsubtypized virus, in 6.9% an A H1N1 and in 3.4% another A virus subtype.

The seasonal peak was reached in the first two months of 2018, with 68.9% of all severe cases notified between January and February.

It was estimated that an antiviral treatment was administered (a neuroaminidase inhibitor, Oseltamivir) in 58% of cases. The median duration of antiviral therapy was 7 days.

Overall, 65.5% of the subjects developed a complication (see Tab. I for details of the definition of "complication"). The majority of these had respiratory syndromes: 44.8% complicated with bacterial pneumonia, 17.2% developed a severe acute respiratory infection (SARI) and 27.6% an acute respiratory distress syndrome (ARDS); 6.8% developed myocarditis. A case of encephalitis was also observed in a patient with Influenza B/Yamagata strain isolated from a nasopharyngeal swab.

The cases classified as "severe" accounted for 41.4% of those admitted to UHU (see Tab. I for details of the definition of "severe case"). The median age of this population was 59.5 years (range 0-84), and the gender distribution was almost equal (46.5% were males). The majority of patients (70%) had at least one comorbidity, with a predominance of cardiovascular diseases (48.3%). See Tab. II for details of "comorbidity" definition.

All patients with severe forms were admitted to the ICU. Of this group, 27.6% required Orotracheal Intubation (OTI) and 10.3% needed to be placed on Extracorporeal Membrane Oxygenation (ECMO).

Seven patients (24.1%) died; 4 had Influenza B virus isolated from respiratory samples. Overall, 3 deaths were recorded in subjects younger than 50 years old. Of these, one presented with an influenza-related myocarditis and developed cardiogenic shock; in the other two cases, the final diagnosis was multi-organ failure. None of the 3 patients aged under 50 years had been vaccinated.

Overall, 70% of the fatal cases developed pneumonia, ARDS was diagnosed in 4 cases, acute heart failure in 2 cases, and myocarditis in 1 case.

Regarding vaccination coverage, only 9 (31%) of the UHU cohort had been vaccinated. Six vaccinated subjects were older than 65 years old, 5 of whom were males. All the vaccinated patients were pluricomorbid and two of them suffered from a type of immunodeficiency. Information on the type of influenza vaccine is not available.

Details of the clinical presentation and vaccination status of patients admitted to UHU are summarized in Table III.

On the basis of the experience acquired during the 2017-18 season, we elaborated a checklist with the aim of facilitating early diagnosis and implementing a meticulous clinical approach, starting from admission.

We suggest that every patient presenting with symptoms compatible with respiratory or systemic illness (e.g.

Tab. I.	Terms	and	definitions.
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Term	Definitions
Influenza season	The period of the year during which more than 80% of influenza cases occur. The usual time-frame of the influenza season is of 8-12 weeks, from late autumn to early spring
ILI	An acute respiratory infection with: measured body temperature of \ge 38C°+ cough; with onset within the last 10 days
SARI	An acute respiratory infection with: history of fever or measured body temperature of \ge 38C° + cough; with onset within the last 10 days, and requiring hospitalization
Severe flu	Influenza presenting as SARI, requiring ICU admission and/or ECMO Influenza presenting with ARDS, requiring ICU admission and/or ECMO Influenza initially presenting as non-severe disease, and subsequently developing any of the signs and symptoms of progressive disease: shortness of breath, tachypnea, cyanosis, bloody or colored sputum, chest pain, hypotension, central nervous system complications (altered mental state, confusion, unconsciousness, drowsiness, seizures, weakness, or paralysis), evidence of sustained virus replication or invasive secondary bacterial infection
Influenza-related complications	Acute respiratory failure, pneumonia, ARDS, febrile seizure, encephalitis/encephalopathy, renal failure, multi-organ failure, septic shock, rhabdomyolysis, myocarditis, exacerbation of underlying chronic disease, including asthma, COPD, chronic hepatic or renal insufficiency, diabetes, cardiovascular conditions

ILI: influenza like illness; SARI: severe acute respiratory infections; ARDS: Acute respiratory distress syndrome; COPD: Chronic obstructive pulmonary disease

Tab. II. The demographic characteristics, seasonal distribution and outcome of patients admitted to Udine Hospital for Influenza and Influenza-related complications during the 2017-18 season.

Study population	
Total (n, %)	29 (100)
Age (median and range, years)	48.3 (0-87)
Male gender (n, %)	15 (51.7)
Female gender (n, %)	14 (48.3)
Pregnancy (n, %)	2 (6.9)
Subjects who had received seasonal Influenza vaccination (n, %)	9 (31)
Comorbidities (n, %) • Cancer • Diabetes mellitus • Cardiovascular disease • Immunocompromised* • Chronic respiratory conditions • Chronic kidney disease • Metabolic conditions° • Obesity	18 (62) 2 (6.9) 4 (13.8) 14 (48.3) 4 (16) 5 (17.2) 7 (24.1) 1 (3.4) 4 (13.7)
Seasonal distribution (n, %) • November • December • January • February • March	1 (3) 2 (7) 10 (35) 10 (35) 3 (10)
Virological distribution (n, %) • A non-subtyped virus • A H1N1 virus • A, other subtype • B virus	7 (24.1) 2 (6.9) 1 (3.4) 19 (65.5)

* Immunocompromised cases included: 1 patient affected by Common Variable Immunodeficiency (CVID), 1 allogeneic hematopoietic stem cell transplant recipient, and 2 solid organ transplant recipients; ' metabolic conditions included: obesity, malnutrition, chronic liver disease (including cirrhosis and alcoholic liver disease), alcoholism, dyslipidemia, and glucose intolerance

cough, fever, coryza, arthromyalgia during the Influenza season should undergo the following work-up:

• For patients without any risk factor for severe Influenza forms: no routine testing nor routine antiviral

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treatment, unless no spontaneous improvement in 1 week.

- For patients with one or more risk factors for severe Influenza forms:
 - Naropharyngeal swabs for the detection of major respiratory viruses (e.g. Influenza, Respiratory Syncytial Virus, Metapneumovirus, Rhinovirus, Coronavirus) and major interstitial bacterial pneumonia (*Legionella*, *Chlamydia* and *Mycoplasma*).
 - Legionella and Pneumococcal urinary antigens.
 - Nasal and cutaneous swabs to check for Methicillin-Resitant *Staphylococcus aureus* colonization.
 - Sputum collection for gram stain and culture.
 - Blood cultures.
 - Chest X-ray.
 - Computerized tomography (CT) thoracic scan and bronchoscopy should be offered to every patient with imaging abnormalities and no results from the previous tests, and to every critically ill patient.

Regarding treatment:

- In order to provide an adequate diagnosis, no antibiotic or antiviral should be started before preliminary sample collection, unless the patient presents serious instability.
- Support care must be provided for every patient (oxygen administration, non-invasive or invasive ventilation, vasopressors, intravenous fluids, etc.).
- Antivirals should be promptly administered to: critically ill people, patients affected by or at high risk of severe influenza forms, immunocompromised people, elderly and in-hospital patients. The antiviral should be started within 48 hours of symptom onset. We suggest using a neuraminidase inhibitor, such as Oseltamivir, Zanamivir, and Peramivir.

Empiric antibiotic treatment should be considered in cases of suspected superinfection and in cases at risk of complications with secondary infections. An adequate treatment for community-acquired pneumonia should be **Tab. III.** Clinical presentation of patients admitted to Udine Hospital for Influenza and Influenza-related complications during the 2017-18 season.

Clinical presentation	
Admitted (n, %)	29 (100)
Admitted to ICU (n, %)	12 (41.4)
Admitted to Infectious Disease Department (n, %)	4 (13.8)
Admitted to other departments (n, %)	13 (44.8)
Requiring OTI (n, %)	8 (27.6)
Requiring ECMO (n, %)	3 (10.3%)
Receiving antiviral therapy (n, %)	17 (58.6)
Treatment duration (median days)	6.7
Severe cases (n, %)	12 (41.4)
Complications (n, %)	19 (65.5)
• Pneumoniae	13 (44.8)
• SARI	5 (17.2)
• ARDS	8 (27.6)
Outcome	
• Deaths	7 (24. 1%)
• Cured	22 (75.9%)

ICU: intensive Care Unit, OTI: Orotracheal Intubation; ECMO: Extracorporeal Membrane Oxygenation; SARI: Severe Acute Respiratory Infection; ARDS: Acute respiratory distress syndrome selected. Oral antibiotics are the preferred choice; parenteral treatment should be selected in the case of severe pneumonia. The duration of the treatment should be decided according to clinical evolution. Generally, standard antibiotic duration for community-acquired pneumonia is adequate. Antibiotic escalation should be considered in the case of insufficient improvement within 72 hours. An algorithm to guide the management of Influenza cases is reported in Figure 1.

Discussion

The 2017-18 epidemic was the most severe in all agegroups since 2003-04. Globally, lethality rates reached 22.6%, a disproportionate burden even in comparison with the 2014-15 season, when the "Fluad case" determined the lowest vaccination coverage in recent seasons [26, 27].

During the 2017-18 season, in Italy a total of 764 cases were classified as severe. For the first time since 2009-



10, during the past season every Italian region (except Molise) reported one or more severe cases of Influenza.

The majority of cases were reported in the north of the country, with highest incidence in the Lombardy and Emilia Romagna regions [28].

Among patients with severe forms, there was a slight predominance of males over females (58% national data vs 51% in our population). The median age of these patients was 60 years, and almost 84% presented at least one pre-existing risk factor for developing a severe illness (diabetes, cancer, cardiovascular diseases, chronic respiratory diseases, immunosuppression). Fifteen severe cases involved pregnant women. Only 13 of the patients affected by a severe form presented no predisposing condition [9, 27].

Influenza-attributed deaths in Italy were 173, accounting for 22.6% of severe forms (versus 24.1% of our cohort); 90% of the deaths occurred in adults, 2 of whom were pregnant women. All (100%) patients with severe disease needed to be admitted to the ICU, 8.5 % required ECMO and 41% needed OTI [9].

In our cohort, too, the majority of severe forms were recorded in adults, and all required admission to the ICU. The rate of comorbidity among UHU patients who developed a severe form was slightly lower than that reported in the rest of Italy (70%).

Nearly half of the patients with severe disease, both in our cohort and in the national and global surveillance data, were affected by a cardiovascular disease. This finding highlights the relationship between influenza infection and poor outcomes due to underlying cardiovascular disease. In particular, a strong association with increased rates of hospitalization for cardiovascular events and a higher risk of acute ischemic events have been reported [29, 30].

Concerning the time-distribution, the 2017-18 season started early in Italy. A and B viruses co-circulated in the first few weeks; subsequently, after week 48, influenza B largely dominated over other subtypes, being responsible for 66% of cases (97% involved the B/Yamagata subtype) [31].

The cumulative rate of hospitalization due to influenza during the 2017-18 epidemic was the highest documented since 2005-2006 in all age-groups. Overall, in the 2017-18 season, a total of 30,453 influenza-related hospitalizations were reported. The majority of the hospitalized patients were \geq 65 years old [27].

Although B viruses are traditionally known to cause less severe disease than A subtypes, during the 2017-18 season the predominant circulation of B/Yamagata virus (60% of the total viruses) in Italy was responsible for severe disease in most age-classes [9].

It has been estimated that 52% (308) of the severe cases reported in Italy were attributable to influenza A/ H1N1pdm09 virus, 37% to influenza B virus, 9% to a non-subtyped A strain, and 2% to A/H3N2 virus. Of the cases requiring hospitalization, 72.3% were attributed to influenza A, 27% to influenza B, 0.4% to influenza A and B co-infections, and 0.3% to a nontyped influenza virus. Of the patients who died, 84 (49%) were infected

with virus A/H1N1pdm09, 76 (44%) with B virus, and 13 (7%) with an unsubtyped influenza A virus [9, 27].

.....

A similar distribution was also observed in our population. In UHU, B virus predominated throughout the season, with nearly 60% of the fatal cases infected with B strains.

The results of our analysis reflected the global and national epidemiology in the 2017-18 influenza season. In particular, we highlighted the necessity to strengthen the influenza surveillance system and vaccine prevention as a strategy for reducing the burden of influenza-related poor outcomes.

Our study presents several limits. First of all, we conducted a purely descriptive analysis of a small sample. Thus, no generalization of the results can be proposed. Furthermore, the retrospective design of the study makes it impossible to rule out external factors that might have interfered with the outcomes and compliance. Nevertheless, it should be underlined that Italian national and regional data are strongly influenced by the very low adherence to surveillance in some areas of the country.

Conclusions

Early recognition and prompt appropriate treatment are the cornerstones of the management of severe influenza forms. In our experience, a risk-stratified system of management is a useful strategy for the implementation of a cost-effective approach.

Every person who develops respiratory illness during the period from late autumn to early spring should be suspected of having been infected with influenza.

Patients with suspected Influenza and no risk of complicated infection should be candidates for outpatient management. The illness can be expected to resolve in 7-10 days. During recovery, the patient should be advised to stay at home and to avoid contact with vulnerable subjects. In selected cases (e.g. people at risk of developing complications due to Influenza), an antiviral should be prescribed. If no improvement is seen within 7 days, we strongly recommend that the microbiological diagnosis be confirmed through nasopharyngeal swabbing. Moreover, the virological confirmation of influenza cases contributes to epidemiological monitoring and enables the patient's contacts to be traced.

High-risk subjects and those with serious respiratory or systemic symptoms should be hospitalized and managed according to the best practice. We believe that currently approved pneumonia risk scores (e.g CURB-65, PSI) should be used for initial evaluation. However, an individualized approach is mandatory.

In cases in which high severity criteria are met, the patient should be hospitalized in a medical or an intensive ward, according to the level of clinical complexity and general condition.

As a general rule, any patient who meets the following criteria should be considered for ICU admission:

Primary viral pneumonia or high CURB-65 score (4 or 5).

How to prevent Influenza	
Hygiene rules	Universal vaccination
Hand washing	Mandatory
Healthcare workers must	Immunodepressed
use personal protection	Healthcare workers
devices and respect good	Pregnant women
practice: use of surgical masks	Children
and gloves, hand washing,	Residents in long-term
adherence to isolation rules	facilities
Isolation of index cases	Strongly recommended
Respiratory good practices	Everyone

Tab. IV. Influenza prevention strategy.

- Persistent hypoxia (PaO2 <8 Kpa) despite maximal oxygen support.
- Worsening hypercapnia.
- Severe acidosis (pH < 7.26).
- Septic shock.

A key point in the management of hospitalized Influenza cases (whether proven or suspected) is the need for strict adherence to contact and respiratory precautions. A well-trained team plays a fundamental role in avoiding in-hospital outbreaks. The recommendations are summarized in Table IV.

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Conflicts of interest statement

Matteo Bassetti serves on scientific advisory boards for Angelini, AstraZeneca, Bayer, Cubist, Pfizer, Menarini, MSD, Nabriva, Paratek, Roche, Shionogi, Tetraphase, The Medicine Company and Astellas Pharma Inc.; has received funding for travel or speaker honoraria from Algorithm, Angelini, Astellas Pharma Inc., AstraZeneca, Cubist, Pfizer MSD, Gilead Sciences, Menarini, Novartis, Ranbaxy, Teva.

Authors' contributions

MB conceived the draft of the article and supervised the manuscript. NC collected clinical data and performed a review of the literature. TG, CP, PDA, AS, and RC provided epidemiological and surveillance data. MP and EG were involved in writing discussion and conclusions. All authors read and approved the manuscript.

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ORIGINAL ARTICLE

Impact assessment of an educational course on vaccinations in a population of medical students

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Keywords

Vaccinations • Educational course • E-learning • Medical students

Summary

Background. The inadequate knowledge about vaccinations of healthcare workers, including medical doctors, has certainly contributed to the spread of the vaccine hesitancy. Therefore, it is essential to improve the level of knowledge of future doctors. The aim of the study is to evaluate the impact of a course about vaccinations on the knowledge of medical students.

Methods. Medical students were asked to complete an anonymous questionnaire before and after a seminar on vaccination that they willingly attended. The two questionnaires contained the same 10 questions about vaccines. Only the students who had attended the lecture were allowed to fulfil the post-lecture questionnaires through the learning management system (LMS) called "Moodle". A descriptive statistical analysis of the data collected through the comparative evaluation of the answers before and after the seminar was performed. Mann-Whitney test for two inde-

Introduction

Vaccinations have been very successful in the prevention of infectious diseases but – even though they save millions of human lives every year – nowadays the phenomenon of "vaccine hesitancy" is growing among a relevant part of the world population. "Vaccine hesitancy" comprises a set of negative feelings towards vaccinations, such as insecurity, doubts, and distrust; these attitudes represent a considerable danger to public health [1-3].

In order to deal with this growing phenomenon, which is the main cause of the diminution of vaccination coverage, it is important to detect the reasons for the spread of such a considerable negative perception of vaccinations all over the industrialized countries. The inadequate education and knowledge about the vaccination of healthcare workers, including doctors, has certainly contributed to the growth of the anti-vaccination movements that frequently attack the safety of vaccines by making use of non-evidence-based expositions [4].

It is, therefore, essential to adequately train university students of the Degree Courses in Medicine and Surgery with extracurricular seminars aimed at increasing the knowledge of all aspects concerning vaccination [5]. During these specific lectures, it is also important to give instructions to the students about how to rightly respond pendent samples was used to compare medians score before and after the interventions.

Results. A total of 100 medical students filled the pre-lecture questionnaire and 81 of them completed the post-lecture questionnaire. Knowledge of the students on the indication of the MMR (Measles-Mumps-Rubella) vaccine strongly improved after the seminar. Moreover, the number of students who would recommend vaccination for pertussis and influenza during pregnancy increased significantly by 37% and 19% respectively after the seminar and those aware of the need for Herpes Zoster vaccination over the age of 65 increased by 22%.

Discussion. For future doctors, a thorough knowledge about vaccinations is increasingly required in order to deal with vaccine hesitancy. Extracurricular seminars about vaccines, provided in the second half of the course of study, can have a highly positive impact.

to the attacks against the scientific world and how to properly communicate with the population with regard to vaccines [6].

It has been demonstrated that multidisciplinary formative interventions comprise the most powerful strategy to improve knowledge about vaccines of Italian healthcare workers, and this is the key tool to increase the confidence of population regarding vaccination [7].

It is, however, also important to evaluate the effectiveness of these educational interventions. The aim of the current study is to evaluate the impact of the 'Vaccines and Vaccinations' chosen course on the knowledge of students enrolled in the IV, V, and VI year of the Degree Courses in Medicine and Surgery at the University of Florence in the academic year 2017-2018.

Methods

During the spring semester of 2018, a total of 100 students from the IV, V, and VI year of the Degree Courses in Medicine and Surgery at the University of Florence decided to voluntary attend an extracurricular lecture about vaccinations.

The educative intervention was held by university personnel belonging to the Section of Hygiene,

Preventive Medicine and Public Health of the Health Sciences Department. It was divided into two classes and spread over two consecutive days. Each class lasted for four hours. The topics addressed were:

- Italian National Vaccination Plan 2017-2019 (NVP 2017-19);
- vaccine coverage trends;
- development of vaccines;
- epidemiological bases for vaccination strategies;
- duration of immunity;
- epidemiological impact of vaccines;
- real and perceived safety of vaccinations;

• risk communication methods in vaccine prevention.

In order to evaluate the impact of the intervention on the knowledge of the students, they were asked to fill in two anonymous questionnaires, the first one before the class and the second one after that. The students could fulfil the questionnaires through the learning management system (LMS) called "Moodle". Moodle is an open-source platform, where it is possible to deposit and consult educational material, to process questionnaires and tasks, to support exercises, to follow lessons in video-streaming, and to use collaborative work tools. Moodle is useful to organize and manage courses online. For this project, the teaching methodology of the Blended Learning was chosen, which involved alternation of frontal lessons and distance activities.

The students completed the pre-lecture questionnaire before attending the class. Only those who attended the class were allowed to complete the post-lecture questionnaire.

The pre-lecture questionnaire contained 13 questions (Supplementary file 1). We analysed 10 questions for this article: the first question asked students if they recalled which vaccination they had received; the second asked if they had had any kind of negative experience after vaccines; the third asked them about the source of information about vaccination they used. Six multiple choice questions evaluated the knowledge of the students about the Italian immunization schedule for each age group (first, second and sixth year of life, adolescence, elderly) and for pregnant women. Students were asked to indicate which vaccinations were mandatory or strongly recommended according to the Italian NVPP 2017-2019; the seventh question asked the students to self-assess their level of knowledge on vaccination.

The last seven questions were also asked in the postlecture questionnaire.

Since the survey data do not compromise students' privacy and the issue under investigation is a public matter, ethical approval for the study was not required.

STATISTICAL ANALYSIS

The percentage of students who claimed to recall which vaccinations they had received in their lifetime and the percentage of students who have had direct or indirect personal experiences of vaccination side effects were calculated.

Sources of information about vaccination used by medical students were also analysed: university, books,

family doctor, mass media, institutional web, non-institutional web, and word of mouth.

In order to assess the knowledge of students in terms of immunization schedule, the percentage of correct answers for each disease and for each population target were calculated (first, second and sixth year of life, adolescence, elderly and for pregnant women). In particular, a value of 1, when students correctly answered questions, a value of 0, if students did not answer the question incorrectly, were assigned. A single score for each age category and a total score for all categories were generated. Finally, all the scores were rescaled out of 100 to make them comparable with previous literature, which mostly uses percentages of correct answers was avoided to discount guessing.

In order to compare the pre-intervention and postintervention self-reported level of knowledge about vaccines, a score of 0 to "poor", 1 to "insufficient", 2 to "sufficient", 3 to "good", and 4 to "excellent" was assigned.

To verify the efficacy of the intervention, since the scores were not normally distributed, medians score before and after the interventions were compared using the Wilcoxon rank-sum (Mann-Whitney) test for two independent samples.

Results

Of the students who asked to participate in the course, 100 completed the pre-lecture questionnaire and 81 attended the class. Only those who attended the class were allowed to complete the post-lecture questionnaire; therefore, 81 students filled in the post-lecture questionnaire.

Overall, 7% of the students did not remember which vaccinations they had received in their lifetime; all the rest specified the vaccines they had undergone. Furthermore, 12% of the students declared that they have had direct or indirect personal experiences of side effects after a vaccination.

According to the answers of the medical students, the most common sources of information about vaccination were the University training/academic courses (85%), books (49%), family doctor/general practitioner (41%), mass media (39%), and institutional websites (30%). Other sources of information used by the medical students were school (25%), word of mouth (24%), non-institutional websites (17%), and other medical doctors (paediatrician, gynaecologist, etc.) (12%).

Knowledge regarding the principles and recommendation of the Italian National Plan of Vaccine Prevention 2017-19, before and after the lecture, are reported in Table I. Students who would recommend vaccination for pertussis and influenza for pregnant women increased after the seminar by 37% and 19%, respectively. The number of those aware of the recommendation for Herpes Zoster vaccination over the age of 65 increased by 22%. Future doctors who would recommend vaccination against

	1 st)	/ear	2 nd	year	6 th y	/ear	Adole	scence	Elc	lerly	Pregi	nancy
Vaccination	Pre n	Post n	Pre n	Post n	Pre n	Post n	Pre n	Post n	Pre n	Post n	Pre n	Post n
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Diphtheria	86 (86)	77 (95)	84 (84)	63 (78)	50 (50)	60 (74)	46 (46)	54 (66)	19 (19)	37 (45)	15 (15)	55 (67)
Tetanus	98 (98)	75 (92)	83 (83)	66 (82)	59 (59)	61 (75)	56 (56)	54 (66)	23 (23)	40 (49)	36 (36)	59 (72)
Pertussis	83 (83)	76 (93)	79 (79)	64 (80)	52 (52)	63 (77)	44 (44)	54 (66)	15 (15)	38 (46)	40 (40)	63 (77)
Poliomyelitis	78 (78)	73 (90)	86 (86)	68 (84)	46 (46)	61 (75)	39 (39)	53 (65)	92 (92)	64 (80)	59 (59)	74 (91)
H. influenzae B	28 (28)	66 (81)	82 (82)	68 (84)	86 (86)	69 (86)	95 (95)	77 (95)	71 (71)	69 (86)	93(93)	72 (89)
Hepatitis B	94 (94)	71 (87)	80 (80)	67 (83)	80 (80)	70 (87)	92 (92)	73 (90)	90 (90)	79 (98)	88 (88)	73 (97)
Hepatitis A	81 (81)	80 (99)	90 (90)	74 (92)	89 (89)	77 (95)	92 (92)	75 (93)	91 (91)	77 (95)	81 (81)	80 (99)
Measles	16 (16)	71 (88)	67 (67)	71 (87)	53 (53)	63 (77)	89 (89)	74 (92)	95 (95)	79 (98)	82(82)	67 (83)
Rubella	17 (17)	72 (89)	69 (69)	72 (88)	51 (51)	63 (77)	86 (86)	73 (90)	95 (95)	79 (98)	64 (64)	59 (73)
Mumps	29 (29)	71 (88)	58 (58)	66 (81)	42 (42)	63 (77)	88 (88)	76 (94)	96 (96)	78 (96)	84 (84)	66 (82)
Varicella	63 (63)	69 (87)	60 (60)	69 (85)	52 (52)	61 (75)	92 (92)	75 (93)	96 (96)	77 (95)	80 (80)	70 (86)
Meningococcal B vaccination	53 (53)	61 (75)	31 (31)	40 (49)	78 (78)	73 (91)	61 (61)	61 (76)	87 (87)	78 (96)	91 (91)	79 (98)
Meningococcal C vaccination	19 (19)	78 (97)	49 (49)	52 (64)	78 (78)	73 (91)	62 (62)	59 (72)	88 (88)	75 (93)	91 (91)	79 (98)
Pneumococcal vaccination	10 (10)	57 (70)	91 (91)	67 (83)	90 (90)	72 (89)	88 (88)	75 (93)	63 (63)	61 (75)	92 (92)	71 (88)
HPV	77 (77)	80 (99)	98 (98)	81 (100)	98 (98)	80 (99)	76 (76)	74 (91)	99 (99)	81 (100)	80 (80)	75 (93)
Influenza	86 (86)	75 (93)	91 (91)	76 (94)	92 (92)	77 (95)	96 (96)	76 (94)	86 (86)	70 (86)	35 (35)	44 (54)
Tuberculosis	91 (91)	80 (99)	96 (96)	80 (99)	100 (100)	79 (98)	97 (97)	80 (99)	98 (98)	78 (97)	98 (98)	80 (99)
Rotavirus	2 (2)	56 (69)	94 (94)	76 (94)	97 (97)	77 (95)	99 (99)	81 (100)	95 (95)	70 (97)	95 (95)	79 (98)
Herpes Zoster	99 (99)	80 (99)	97 (97)	81 (100)	98 (98)	81 (100)	94 (94)	77 (95)	44 (44)	54 (66)	87 (87)	79 (96)

Tab. I. Knowledge on mandatory and recommended vaccination for every age group and for pregnant women according to the Italian National Vaccination Plan 2017-2019 statements, before and after the educational intervention conducted.

measles, rubella, and mumps for children under one year of age decreased by 67% after the intervention.

The self-assessment of the level of knowledge on vaccinations changed significantly with educational intervention, as shown by the reduction (from 46% to 5%) of the answers, indicating a low level (poor/ insufficient), and the increase (from 54% to 95%) of the answers, indicating a high level (sufficient-good-excellent).

Median scores obtained by students before the interventions were between 73.6/100 for the vaccines recommended for adolescents to 77.6/100 for pregnant women (Tab. II). After the intervention, median scores improved for all age categories. The highest score obtained was in the adolescent vaccination group

(93.7/100), whereas the lowest score reached was in the elderly vaccination group (84.2/100).

Differences between scores before and after the interventions were all statistically significant (p < 0.001).

Discussion

In recent years, many Italian Universities modified the traditional educational system based on standard courses, developing it with the inclusion of extracurricular interventions. At the faculty of Medicine and Surgery of the University of Florence, every student, during the six years of curriculum, must attend some extracurricular courses; they can freely choose from many different seminars offered to them, concerning any scientific topics.

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Tab. II. Median of calculated scores (before and after the intervention) and p-value of the Wilcoxon rank-sum (Mann-Whitney) test for two independent samples.

		Ме	Median		
		Before (n = 100)	After (n = 81)	P*	
Schedule	Childhood	74.6/100	92.1/100	< 0.001	
knowledge	Adolescence	73.6/100	93.7/100	< 0.001	
	Pregnancy	77.6/100	88.2/100	< 0.001	
	Elderly	73.7/100	84.2/100	< 0.001	
	Total score	74.2/100	88.8/100	< 0.001	
Self-reported kno	wledge	2/4	3/4	< 0.001	

*: two-sample Wilcoxon rank-sum (Mann-Whitney) test.

Thanks to this educational pattern, the students, apart from the regular courses and exams, can also deepen their knowledge in some subjects according to their own personal interests. The aim of our study is to evaluate the efficacy of an extracurricular seminar on vaccinations and its impact on the knowledge and the attitudes of medical students, through pre-post questionnaires.

The answers to the questions concerning the attitudes and the perception of the students toward vaccinations suggest that people who have a scientific background are not hostile toward vaccination. In fact, 100% of our sample, before the intervention, were already in favour of vaccinations, and 94% of them declared that they agree with the introduction of compulsory vaccines for the school attendance.

The same concept is demonstrated by the results regarding the sources of information on vaccines used by the students: the most common ones are those that have a scientific framework. In other studies, we can observe that the general population is mostly used to get information from other sources, like word of mouth or the web, and that the general population is more likely to agree with the anti-vaccination statements compared to medical students [8, 9]. This shows that our sample might be different from the general population since the intervention was tailored to medical students, who most frequently have a good scientific background.

Before the lecture, students were not well-prepared about the schedules and organization of vaccination service in the Italian territory, according to the innovation of the National Vaccination Plan 2017-2019. In particular, our study demonstrates a gap in students' knowledge on the recommended vaccines for the first year of age: only 2% and 10% of students were aware about the recommendation for the vaccination respectively for Rotavirus and S. Pneumoniae before our intervention, and only 28% of students knew, before the lecture, that the protection against Haemophilus influenzae type B is contained in the hexavalent vaccine. Was also observed that 80% of students, before the intervention, would have recommended the vaccination against Measles-Mumps-Rubella (MMR) for children under one year of age, although it is actually not indicated before the 13th month of life.

Scores obtained from the answers about the recommendations of Human papillomavirus (HPV) vaccine are quite high and satisfying, but it would be interesting to distinguish the answers given by male students from those given by female students. In fact, according to other surveys, we should expect higher scores from female students [10].

Moreover, the students demonstrated that they are not adequately informed about some specific aspects of vaccinations, like maternal-foetal immunization; the proportion of students aware of the recommended vaccines during pregnancy sharply increased after the intervention. The diphtheria-tetanus-pertussis and influenza vaccines are extremely important for not only the new-born but also the mother herself [11].

In addition, regarding the vaccination against influenza, students proved that they adequately know the other indications for this vaccination, in contrast to the vaccine coverage for influenza among Italian Medical Residents (MRs) that was shown by previous studies. Indeed, in the past years, many studies have been conducted on MRs in order to assess the vaccine coverages of this specific group of population, particularly for influenza and hepatitis B, and also to identify the determinants of the vaccine uptake for healthcare workers (HCWs). Looking at the overall vaccination rate observed in a previous study, Italian MRs seem to have a very low compliance with influenza vaccination: acceptance of seasonal and pandemic A (H1N1) influenza vaccination ranges from 12% to 20% [12-14].

Our project shows that a formative intervention is a powerful strategy to improve the knowledge about vaccines among future Italian healthcare workers. Improving their awareness on these topics is the key tool to increase the confidence of the population regarding vaccination, so it is also necessary to understand when such interventions can have a stronger impact on the sensibility of the students. Previous studies indicate that the intention to get vaccinated is greater during the clinical phase of the university career, suggesting that this is a good time to introduce promotion strategies to strengthen this attitude [15].

Wicker et al. found differences between pre-clinical and clinical students regarding the uptake of influenza and hepatitis B vaccines, the chances of being occupationally infected with influenza or hepatitis B, and the likelihood of suffering from severe side-effects following immunization. Medical students of the clinical semesters were more likely to have been vaccinated against influenza (58.1% vs 15.3%, p < 0.001) and HBV (96.6% vs 78.3%, p < 0.001) than students of the preclinical semesters [16].

Previous studies indicated that one of the most important determinants of getting vaccinated against flu is to have been previously vaccinated or having participated to vaccination campaigns [17]. Thus, the achievement of considerable awareness and knowledge about vaccination among medical students would contribute to the accomplishment of high vaccine coverage among healthcare workers in the future [18]. Moreover, future healthcare providers should be equipped with not just the knowledge but also the skills to counsel patients regarding the importance of vaccination [18, 19].

Previous surveys show that MRs recognize the importance of the lack of a vaccine prevention culture and acknowledge that there is a need for more information and awareness on the topic. In a national survey, nearly one-third of the students in their last year of medical school in France felt inadequately prepared to deal with vaccination-related questions. These data are in tune with the data pertaining to the self-assessment of the level of knowledge given by our sample before the lecture [20, 21].

Apart from the data obtained from the responses on the vaccination calendar, the positive impact of our intervention is also demonstrated by the answers given by the students on the assessment of their level of knowledge on vaccination. After the lecture, 95% of the students considered their level of knowledge as sufficient, good, or excellent. This is key tool to increase the mastery of and the accuracy on these topics, which will be useful instruments to counter the anti-vaxxers attacks.

Our survey has some limitations. Firstly, it was not possible to match the pre-intervention answers to the post-intervention ones for each student because the questionnaires were anonymous. Therefore, the increasing percentage of correct answers after the class could be partly justified because the less prepared and less interested students had left before the intervention. On the other hand, the anonymity favoured the achievement of more frank answers, since nominal questionnaires would have been perceived as an examination by the students.

Secondly, the survey has been conducted during an optional and non-curricular intervention, which is why our sample size is relatively small compared to the numbers of medical students in the University of Florence.

Another limit to consider is that, since fewer vaccines are recommended for pregnant women, students who did not answer were more likely to get higher scores, since a missing answer was not distinguishable from a correct answer.

Conclusions

For future doctors, a thorough knowledge of vaccination will be increasingly required to deal with vaccine hesitancy. An extracurricular seminar about vaccines, provided in the second half of the course of study, can have a highly positive impact on integrating knowledge and attitudes regarding vaccinations. Medical students are one of the most important target for educational campaigns as they are still in their training period and are open to changing their habits [19]. An appropriate development of technical and cultural skills for next generation of medical doctors is of paramount importance to spread positive vaccination attitudes, also among general population. The best initiatives currently devoted to vaccinology education should join forces and the University should developed a structured platform for future training of scientists in vaccinology, especially in academic courses with a forthcoming healthcare sector employment [22].

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Conflict of interest statement

None declared.

Authors' contributions

AB, PB and SB conceived the study, held the educational course, designed pre and post questionnaires and participated in drafting the manuscript; AM, JS and MRG prepared the questionnaires to be uploaded on the learning management system and participated in drafting the manuscript; AM, GS performed statistical analysis and drafted the manuscript. All authors revised and approved the final manuscript and any revised version.

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Supplementary file 1

The pre-lecture questionnaire for medical students attending the seminar on vaccinations at the University of Florence

The pre-lecture and the post-lecture questionnaires are two brief anonymous, not evaluative, but compulsory questionnaires that are used by the teacher to get information on the level of knowledge and attitude of students towards vaccinations, before and after the lecture.

1. Which vaccinations did you get during your life? (only in the pre-lecture questionnaire)

Possible answers:

- a. Diphtheria
- b. Tetanus
- c. Pertussis
- d. Poliomyelitis
- e. Haemophilus influenzae type b
- f. Hepatitis B
- g. Hepatitis A
- h. Measles
- i. Mumps
- j. Rubella
- k. Varicella
- 1. Meningococcal B vaccination
- m. Meningococcal C vaccination
- n. Pneumococcal vaccination
- o. HPV
- p. Influenza
- q. Tuberculosis
- r. Rotavirus
- s. Herpes Zoster
- t. I do not remember

2. Have you had direct or indirect personal experience (friends, acquaintances, relatives) of side effects after a vaccination? (only in the pre-lecture questionnaire) Possible answers: yes/ no.

3. Based on the National Vaccination Plan (NVP) 2017-19, which of the following vaccinations are recommended in the first year of life (0-12 months) in Italy?

Same possible answers as in question 1 from a to s.

4. Based on the NVP 2017-19, which vaccinations are recommended in the second year of life in Italy?

Same possible answers as in question 1 from a to s.

5. Based on the NVP 2017-19, which vaccinations are recommended in the sixth year of life in Italy? Same possible answers as in question 1 from a to s.

6. Based on the NVP 2017-19, which vaccinations are recommended in adolescence (11-18 years) in Italy? Same possible answers as in question 1 from a to s.

7. Based on the NVP 2017-19, which of the following vaccinations are recommended in the elderly (> 65 years) in Italy?

Same possible answers as in question 1 from a to s.

8. Based on the NVP 2017-19, which vaccinations are recommended in pregnancy?

Same possible answers as in question 1 from a to s.

9. Which vaccinations are mandatory for school attendance according to the Italian Law 119/2017? Same possible answers as in question 1 from a to s.

10. Do you agree with the decision to introduce the vaccination requirement for school attendance? Possible answers: yes/ no/ I do not remember.

11. Are you generally in favor of vaccinations? Possible answers: yes/ no/ I do not remember.

12. *How do you rate your level of vaccination knowledge?*

Possible answers: poor/ insufficient/ sufficient/ good/ excellent.

13. Where did you get information on vaccinations? (only in the pre-lecture questionnaire)

Possible answers:

- a. Word of mouth
- b. TV, radio, newspapers
- c. Books
- d. Non-institutional websites
- e. Institutional websites
- f. Family doctor
- g. Pediatrician
- h. Gynecologist
- i. Doctor working in the immunization service

- j. Pharmacists k. School
- K. SCHOOL
- 1. University

OPEN ACCESS

ORIGINAL ARTICLE

Assessment of the belief and attitudes of Iranian healthcare personnel's toward the influenza infection and influenza vaccination

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Keywords

Healthcare professionals • Influenza • Vaccination • Attitude • Belief • Iran

Summary

Introduction. Influenza is one of the main public health problems and health care personnels (HCPs) are one of the at-risk groups for this infection. The goal of the current study was to identify the beliefs and attitudes of the Iranian HCPs about influenza and the influenza vaccine.

Methods. This cross-sectional study was performed in a general hospital in Tehran, Iran from January to June 2016. A total of 418 questionnaires were distributed among the HCPs. The Chi² test, linear regression and one-way ANOVA were used for data analysis, α : 0.05 was considered as a statistically significant level. All analyses were performed using the SPSS19 software.

Introduction

Influenza is one of the main public health issues; annually, 5-15% of worldwide populations are likely to be affected by influenza [1, 2]. The HCPs are at risk of exposure to the influenza virus in hospitals due to their contact with patients [3]. On the other hand, HCPs may transmit the virus to patients with critical conditions [4]. It is the most common cause of absenteeism and work disruption of hospital personnel's during winter [5]. Immunization of the HCPs against the influenza is a verified infection control method [6, 7]. Influenza vaccination reduces the risk of influenza infection among the HCPs. It also protects susceptible patients and could significantly decrease the patients' mortality and morbidity [8]. Despite promotional campaigns, the global health workers compliance for influenza vaccination is suboptimal, so the herd immunity is not satisfied [4, 5, 9-11]. A review of the literature on belief and attitude of respondents for not being immunized, identified some factors as responsible. These factors include: concern about influenza vaccine side effects, fear of needle, doubts as to the vaccine effectiveness, and lack of concern about the importance of flu [5, 12]. The latter also showed that self-esteem and perceived stress are associated with individuals' tendency to use influenza vaccine. A few studies have been carried out on the

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Results. The influenza vaccination coverage was 57.7%; the highest vaccine rate belongs to the allied health professionals (68.2%). Two main causes for avoiding the influenza vaccination were; the "fear of vaccine adverse effects" and the "uncertainty about the vaccine effectiveness". The linear regression analysis identified that the physicians had the highest belief score, followed by the nurses and the allied health professionals (p < 0.001).

Conclusions. Educational planning on influenza and influenza vaccination is necessary to improve the vaccination coverage and to reduce the influenza mortality and morbidity in susceptible patients.

HCPs' knowledge, attitudes and vaccine coverage for influenza virus and correlation of their belief scores with variables such as profession, age, and sex in the Iranian hospitals [13-15]. The studies reported different influenza vaccination coverage among the HCPs in different hospitals. Because of the importance of the subject, the purpose of the current study was to investigate the beliefs and attitudes of HCPs about influenza vaccine and its associated factors in the Baharloo Hospital in Tehran.

Methods

The current cross-sectional study was carried out in a general hospital in Tehran-Iran with more than 300 beds capacity, From January 2016 to June 2016, the Baharloo Hospital's HCPs were provided with an anonymous, self-administered questionnaire which was completed voluntarily. This study was approved by the ethics committee of the Hospital. The study protocol was approved by the Baharloo Hospital of Tehran University of Medical Sciences. The whole body of the HCPs working at the Baharloo Hospital was invited to participate in the present study. Two trained hospital staffs (one nurse and one physician) were responsible for distributing the questionnaires and providing instructions to the participants. The completed questionnaires were gathered on the same day. The HCPs

participated voluntarily in the study. After reviewing the questionnaires present in the literature [8, 16-18], a questionnaire was designed for the present study. A 39-item questionnaire was finalized, and a pilot study was conducted among 20 HCPs to determine the reliability of the tools. The validity of this questionnaire was confirmed by the expert's opinion using qualitative method. To assess the validity of the designed questionnaire, three groups of experts were used. The first group of experts was Content expert which include two persons of Infectious Disease Specialist who have Clinical Expertise about understudy subject. The second group was two lay experts which includes two persons of health care workers and finally one epidemiologist as a methodologist. The mentioned expertise checked all questions of questionnaire about relevancy and clarity also the comprehensiveness of questionnaire. All comments of mentioned expertise group applied in the questionnaire, and finally the questionnaire was approved by all experts.

The reliability of this questionnaire was estimated using the Cronbach's alpha test. The overall reliability of this test was about 0.72. The questionnaire included three sections. The first section was comprised of 5 items to gather the descriptive information of the respondents and included questions about history of previous vaccinations against the influenza. The second section consisted 14 items about the HCPs beliefs and attitudes about influenza infection and influenza vaccine. The third section consisted 5 items, about the reasons for declining the influenza vaccination. The questionnaire included 14 items to assess the belief, the range of Scores was from 1 to 4. 4 and 1 points have been considered for each correct and incorrect response respectively. The sum of all correct answers resulted in a continuous variable, ranging from 4 to 56.

STATISTICAL ANALYSIS

The Multicollinearity between variables was tested, but there was none. Upon the completion of data collections, the data were coded into categorical, nominal and ordinal variables. The Chi² test, linear regression and oneway ANOVA were used for data analysis. The α : 0.05 was considered as a statistically significant level. All analysis performed using the SPSS software version 19.

Results

A total of 418 questionnaires were distributed among the HCPs in the Baharloo Hospital. The response rate was about 90.4 % (n = 378). Most of the participants were from the 20-30 years age group (167; 44.2%). The majority of the HCPs were females (276; 73%). By the profession, the majority of respondents were nurses (270; 71.4%), followed by the allied health professionals (66; 17.5%) and the physicians (42; 11%). More details are shown in Table I. The influenza vaccine coverage in the HCPs was 57.7%, without significant difference between males and females (p = 0.55). The allied health professional's vaccination rate was about 68.2%, followed by the nurses (58.9%) and the physicians (33.3%)

(p < 0.001). The highest influenza vaccination rate was seen in 31-40 year age group (66%). More details are shown in Table II.

The most common causes of avoiding influenza vaccine were: the "fear of adverse reaction" and the "worry about its effectiveness" (51; 31.9% for each mentioned factors). The other causes were the "getting flu after vaccination" (39; 24.4%), "fear of transmission of the virus to other persons" (21; 13.1%), and "fear of needle" (17; 10.6%) (Tab. III). The HCPs beliefs and attitudes

Tab. I. Descriptive characteristic of Iranian HCPs in the current study.

Variables	Number	Frequency		
Age group				
20-30	167	44.2%		
31-40	159	42.1%		
41-50	39	10.3%		
51-60	13	3.4%		
Profession				
Allied health professions	66	17.5%		
Nurse	270	71.4%		
Physician	42	11.1%		
Gender				
Male	102	27%		
Female	276	73%		
Influenza vaccination done in last 6-12 months				
Yes	218	57.7%		
No	160	42.3%		

Tab. II. The vaccine coverage according to gender, professions andage group in Iranian HCPs.

Variables	N (%)	Р
Gender		
Male	56 (54.9%)	
Female	162 (58.7%)	0.556
Professions		
Physician	14 (33.3%)	
Nurses	159 (58.9%)	0.001
Allied health professions	45 (68.2%)	
Age group		
20-30	83 (49.7%)	
31-40	105 (66%)	0.020
41-50	24 (61.5%)	0.020
51-60	6 (42.2%)	

Tab. III. The most common cause for non-compliance with vaccination recommendations in Iranian HCPs.

Questions	Agree N (%)	Disagree N (%)
Fear of needles	17 (10.6%)	143 (89.4%)
Fear of vaccine adverse effects	51 (31.9%)	109 (68.1%)
Worry about vaccine ineffectiveness	51 (31.9%)	109 (68.1%)
By getting vaccinated, I getting flu	39 (24.4%)	121 (75.6%)
By getting vaccinated, the virus transmission to others	21 (13.1%)	139 (86.9%)

Questions	Totally agree	Partially agree	Partially disagree	Totally disagree
	N (%)	N (%)	N (%)	N (%)
Influenza is a serious illness	247	115	10	6
	(65.3%)	(30.4%)	(2.6%)	(1.6%)
I prefer to get flu than to be vaccinated	23	54	93	208
	(6.1%)	(14.3%)	(24.6%)	(55%)
The influenza complications are serious	95	144	107	32
	(21.1%)	(38.1%)	(28.3%)	(8.5%)
Influenza vaccine can cause influenza	28	119	123	108
	(7.4%)	(31.5%)	(32.5%)	(28.6%)
Influenza vaccine can prevent influenza	102	211	56	9
	(27%)	(55.8%)	(14.8%)	(2.4%)
HCPs must be vaccinated against influenza	195	133	43	7
	(51.6%)	(35.2%)	(11.4%)	(1.9%)
I totally disagree with influenza vaccination	21	62	102	193
	(5.6%)	(16.4%)	(27%)	(51.1%)
Influenza virus can transmit to others after vaccination	26	65	117	170
	(6.9%)	(17.2%)	(31%)	(45%)
Influenza vaccination can protect me against influenza	107	192	59	20
	(28.3%)	(50.8%)	(15.6%)	(5.3%)
By getting vaccinated, I protect my family against influenza	88	141	69	80
	(23.3%)	(37.7%)	(18.3%)	(21.2%)
By getting vaccinated, I protect my patients against influenza	94	135	69	80
	(24.9%)	(35.7%)	(18.3%)	(21.2%)
My family believe I must be vaccinated against influenza	129	164	65	20
	(34.1%)	(43.4%)	(17.2%)	(5.3%)
The pregnant woman must be vaccinated against influenza	107	112	92	67
	(28.3%)	(29.6%)	(24.3%)	(17.8%)
Hospital encourage HCPs to get vaccinated	127	164	53	34
	(33.6%)	(43.3%)	(14%)	(9%)

Tab. IV. The attitude of Iranian HCPs about the influenza and influenza vaccine.

Tab. V. Different professions' attitudes about the influenza vaccination in pregnant women.

Profession	Totally agree N (%)	Partially agree N (%)	Partially disagree N (%)	Totally disagree N (%)	Totally agree N (%)	Р
Allied health professions	29 (43.9%)	15 (22.7%)	11 (16.7%)	11 (16.7%)	29 (43.9%)	
Nurse	61 (22.6%)	79 (29.3%)	76 (28.1%)	54 (20%)	61 (22.6%)	0.003
Physician	17 (40.5%)	18 (42.9%)	5 (11.9%)	2 (4.8%)	17 (40.5%)	

about the influenza and influenza vaccine have been addressed as the followings; most of the participants were aware about the necessity of influenza vaccination (328; 86.8%), the majority of the HCPs believed that the influenza virus could not be transmitted after the vaccination (287; 78%). Also there was a significant difference among the professions about this statement: "the influenza vaccine can cause influenza" (p < 0.001). The majority of the nurses believed that the influenza vaccine can cause influenza infection (119; 44%) (Tab. IV). 219 (57.9%) of the HCPs believed that a pregnant women should be vaccinated against the influenza. However, there were significant differences among different professions about the "necessity of influenza vaccination for a pregnant women" (p = 0.03). A great majority of the physicians believed about its necessity (35; 83.4%), fol-

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lowed by the allied health professions (44; 66.6%) and the nurses (104; 38.5%) (Tab. V). Scoring the correct responses revealed that the physicians had the highest attitude and belief scores about influenza and influenza vaccination (31.92 \pm 4.57; p < 0.001) followed by the nurses (30.86 \pm 4.6) and the allied health professionals (28.81 \pm 3.89) (Tab. VI). To identify the effective fac-

 $\ensuremath{\mathsf{Tab}}$. VI. The attitude score of different Professions about the influenza vaccine.

Variables	Mean ± SD	Р
Profession of respondents		
Physicians	31.92 ± 4.57	
Nurses	30.86 ± 4.6	0.001
Allied health professional	28.81 ± 3.89	

tors on the belief or attitudes score, linear regression was applied. The profession was associated with the belief score (p < 0.001); and the physicians' score was higher than the nurses and the allied health professionals' score. There was no significant association between age group and gender with attitude score (Tab. VII). The older age group presented slightly higher attitude score about influenza and influenza vaccine.

Discussion

The present study investigated the beliefs, attitudes and the rate of influenza vaccination among the HCPs in the Baharloo Hospital. The best method for prevention of influenza is vaccination, which results in decreasing of death in the HCPs and vulnerable patients [4, 19]. The current study found that the influenza vaccination rate among the HCPs was 57.7%. Previous studies revealed that the influenza vaccination rate in the HCPs varied in a broad range, in the European and Asian countries [20]. Its acceptance rate in the HCPs of the Arabic nations was different between 24.7% in United Arab Emirate to 67.2% in Kuwait [20]. Despite decades of promotional campaigns for influenza vaccination, the outcome has been relatively low coverage, as follow: 12% in Norway and Wales in 2009/10, between 30% and 50% in England, Hungary, Portugal and Scotland in 2010/11 and between 14% and 28% in France, Germany, Norway, Slovenia, Spain and Wales in 2010/11. The mean vaccination coverage rate of European countries was 29.8% [4, 8, 21-23]. Previous Iranian studies suggested that the influenza vaccination rate in the HCPs varied in a broad range from 5.2% to 66.9% [13-15]. The influenza immunization rate for Shiraz University HCPs in the 2005-2006 seasons was found to be low at 5.2%, whereas it was found to be 66.9% for Tehran University HCPs in the 2008-2009 influenza season [13, 14]. In the present study, the high rate of influenza immunization in the HCPs may be explained by the regular annual influenza conferences and the continuous flow of relevant information that raise their awareness. The other factor that might have contributed to the rather high rate of vaccination in Iranian HCPs (i.e., as compared to the other

Tab. VII. The linear regression results about the factors affecting on attitude score in Iranian HCPs.

Variables	Regression coefficients	Standard error	Р
Age			
21-30	1	-	-
31-40	0.004	0.502	0.993
41-50	0.67	0.82	0.417
51-60	0.64	1.356	0.631
Sex (female)	- 0.676	0.550	0.22
Professions			
Nurse	1	-	-
Physician	0.76	0.797	0.337
Allied health	- 2.42	0.669	< 0.001

neighboring nations) is probably the fact that the HCPs are provided the vaccine free of charge. In the current research, it is found that there was a significant difference in influenza vaccination rate among the HCPs with different professions. The physician's vaccination rate was the lowest. The studies in Saudi Arabia identified similar result; the physician's vaccination rate was relatively low as compared with other HCPs [17, 24]. According to Durando et al. [5], being physician was independently accompanied with adherence to immunization against influenza. In the current study, 90.5% of the physicians believed that the HCPs should be vaccinated against influenza, however, they showed the least coverage rate (i.e., amongst the HCPs). Conclusively there was no relationship between the attitude score and the vaccination rate in the present study. In the current study, 38.9% of the HCPs believed that "they might get flu after influenza vaccination". In the literature review, the HCPs' misconception about getting flu after influenza vaccination was different; from as low as 38.1% to as high as 78% [15, 25-27]. The lower rate of the misperception in the present study indicates their higher awareness. Majority of the HCPs believed that there was no live virus in the flu shot 82.8% of the HCPs believed that the influenza vaccination can prevent the influenza infection, whereas, in the study by Alshammari et al., only 71.43% of the HCPs believed such [17]. In the present research, 57.9% of the HCPs agreed with the vaccination of pregnant women against influenza. This is in sharp contrast with the study by Rehmani and Memon who identified that 10% of the HPCs agreed with the pregnant woman vaccination [8]. This is a salient point because the majority of the HCPs in our hospitals are the young female, so with this level of awareness, most of them were inclined to be vaccinated against the influenza. Therefore, the mortality and morbidity risk are expected to decrease in the pregnant HCPs. Influenza vaccination for the pregnant woman appeared as a controversial issue; the subanalysis among the HCPs with different professions revealed significant differences. The approval rates were as follow: the physicians (83.4%), the allied health professionals (75.8%), and the nurses (51.9%). On the other hand, a research in 2016, disclosed that there was no significant difference between the physicians, the nurses and other health professional groups on this issue (i.e., "influenza vaccination for pregnant women") [25]. It is found out here that the widespread causes of refusing the influenza vaccine were the "fear of vaccine side effects" and the "vaccine ineffectiveness". These are similar to the other studies worldwide [18, 25]. An Iranian research in 2016 presented that 19.8% of the respondents were concerned about the influenza vaccine side effects [15]. Globally, fear of the influenza vaccine adverse reaction is one of the most important barriers for the acceptance of vaccine [2, 5]. The range of this misconception was between 11-66% in different studies [15, 25]. Another influenza vaccination obstacle was the "fear of the needle" that 10% of our respondents expressed. This was significantly lower than the 66.7% suggested in the study by Haffman et al. [27]. In a study by Alshammari

et al., the "fear of getting flu" was found to be the main reason for refusing the influenza vaccine [17]. In the present study, this figure was 24.4%. It seems that we need to improve the HCPs knowledge regarding adverse reactions of influenza vaccine. The linear regression analysis reveals the association of the profession with most of the 14 items of beliefs and attitudes, the physicians score was more than the other HCPs. One study identified that the job experience, the age, and the profession were significant factors influencing the knowledge score of the HCPs; the nurses score was more than the other HCPs [26]. The present research revealed that the older age the HCPs, the more belief score they get. Also, the female's belief score was less than their male's counterparts. However, the gender impact on HCPs belief score was not significant. Some researchers found that there was a non-significant association between the age and the gender with the attitude and knowledge of the HCPs [14]. This study has both limitations and strengths as follow respectively. All data of the current research was self-reported, we had to rely on the respondents consideration to report correct data. Also, the HCPs' knowledge of influenza and influenza vaccine was not investigated in current research. Amongst the strengths of the present study are; the sample size and response rate of our research were more than most the other studies. Also, this study reveals the responders attitudes on the influenza vaccination in pregnant women; an issue rarely regarded in the literatures.

Conclusions

Overall influenza vaccine coverage in the current study was 57.7% and the physician's vaccination rate was the lowest among the HCPs of Baharloo Hospital in Tehran. However, the physician's belief score about the influenza vaccine was the highest score. The current study identifies that there is no association between the belief or attitude score and adhering to the vaccination policies. Several factors such as concern about the influenza vaccine side effects, fear of getting flu and fear of needles are linked with declining influenza vaccination in the HCPs. Further research and campaigns are needed on the influenza vaccination along with promotional support to motivate the HCPs for influenza vaccination.

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Conflict of interest statement

None declared.

Authors' contributions

HH planned the study, contributed in data collection, data analyses, drafting the manuscript and finalizing the manuscript. ARK contributed in data collection and literature review. MG contributed in data collection and manuscript preparation. SA contributed in data collection, data analyses and drafting the manuscript. YA contributed in data analyses, drafting the manuscript and finalizing the manuscript.

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ORIGINAL ARTICLE

Long-term persistency of hepatitis B immunity: an observational cross-sectional study on medical students and resident doctors

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Keywords

Hepatitis B virus • Occupational health • Vaccination • Immunological memory

Summary

Hepatitis B virus (HBV) is a main cause of chronic and acute hepatitis. Healthcare workers (HCWs), including medical students and resident doctors, have an occupational risk of HBV infection. The study aimed to evaluate the long-term persistence of protective anti-HBs antibody levels in healthcare students and resident doctors at risk for occupational exposure to HBV at 15 years after primary vaccination course. Further objective was to evaluate the anamnestic response observed in non-seroprotected subjects receiving a booster dose.

Data were collected from the clinical documentation filled in during the occupational medical check of medical students and resident doctors undergoing Occupational Health Surveillance by the University of Ferrara.

Of the 621 included individuals, 27.7% had an anti-HBs concentration < 10 mIU/mL. Subjects vaccinated during infancy had

Introduction

Hepatitis B virus (HBV) is a serious global health concern and an important occupational risk for healthcare workers. HBV is one of the main causes of chronic and acute hepatitis, leading to a high risk of death for cirrhosis and liver cancer [1, 2].

The World Health Organization (WHO) estimates that, globally, 257 million people are infected by HBV or positive for hepatitis-B-surface-antigen (HBsAg). In 2015 HBV caused 887.000 deaths, mostly by complications [2, 3].

In Europe, a downward trend in the rate of acute cases was observed, due to the implementation of immunization programmes across several countries in this region. However, through the changes in local testing and reporting practices, the rate of newly diagnosed chronic cases is rising over time [4].

In Italy, according to the National Surveillance System (SEIEVA) data, the incidence rate of hepatitis B acute cases decreased from 5.4 per 100,000 inhabitants in 1990 to 2 per 100,000 inhabitants in 2000. This decline was even more noticeable among 15-24-year-old people, whose incidence rate decreased from 17.4 per 100,000 to 2 per 100,000 in the same lapse [5-7].

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more frequently a concentration < 10 mIU/mL than those vaccinated during adolescence (42.7% vs 6.9%; p-value < 0.001). Multivariate analysis confirmed the statistical significance of the vaccination age. 94 subjects who had an anti-HBs concentration < 10 mIU/mL received a booster dose. The proportion of subjects who had an anamestic response was higher in those vaccinated in infancy rather than during adolescence (94.1% vs 77.8% respectively).

These findings suggest that the anti-HBs concentration decreases below 10 mIU/mL more frequently in subjects vaccinated during infancy. Immunological memory seems to persist after the decline of the anti-HB titer, as observed in response to a booster dose. In conclusion, vaccinated subjects at increased risk of HBV infection should be monitored and a booster dose administered if anti-HBs titer is below 10 mIU/mL.

Since 1982, safe and efficacious vaccines are available [8]. According to the 2017-2019 National Plan of Vaccination Prevention (PNPV), healthcare workers (HCWs) are at maximum risk to get HBV infection and an adequate immunization intervention is essential to prevent and control the transmission of HBV in order to guarantee the protection in this group of workers. Furthermore, HBV vaccination is strongly advised for students involved in healthcare setting. The recommended schedule of HBV vaccine consists of three doses administered at the third, fifth and eleventh months of life. The target for HBV vaccine is a coverage rate of at least 95% in new-borns [9].

Anti-HBs antibody levels (anti-HBs) \geq 10 mIU/mL are considered protective [10, 11].

Available studies in the literature suggested that immunological memory persists even if anti-HBs titer decreases under 10 mIU/mL, as confirmed by an amnnestic response after the administration of a booster dose of HBV vaccine [3, 12-16].

Monitoring anti-HBsAg antibodies titer in serum and the eventual administration of a booster dose could be necessary in individuals at risk of exposure, like HCWs [10, 17]. According to the Italian law on Occupational Health and Safety (Law Decree 81/2008) [18] the students, the interns and the resident doctors are also included in HCWs. When exposed to biological risk, blood tests, including HBsAg assessment and anti-HBs titer [19], are evaluated. Moreover, the Italian Law Decree 81/2008 requires the employers to adopt protective measures for at risk workers, including providing safe and effective vaccines [9, 18, 20].

The recent guidelines developed by Italian region Emilia-Romagna [20] emphasise the importance of hepatitis B vaccine for all HCWs considered at risk even affecting, in some specific cases, fitness to work provided by the occupational physicians (e.g., refusing vaccination, high risk tasks, exposure prone procedures).

The aim of the study was to assess the prevalence and the persistence of a positive anti-HBs titer ($\geq 10 \text{ mIU/mL}$) in medical students and in resident doctors with an occupational risk of HBV infection, approximately 20 years after the completion of a full regular vaccination series. The immunological memory through the anamnestic response to a booster dose in subjects with an anti-HBs concentration < 10mIU/mL was also evaluated.

Methods

Study design

A cross-sectional, observational study was conducted. Demographic, clinical and laboratory data were collected through the review of clinical records filled in during the Occupational Health Surveillance Program.

SETTING AND STUDY POPULATION

The study was conducted on medical students and resident doctors undergoing periodical medical examination provided for Occupational Health Surveillance Program by the University of Ferrara from January 2011 to February 2018. Program is offered free of charge to all workers, including students, who have an occupational risk for exposure to biological, chemical or physical agents [18].

Data were collected from the clinical documentation drafted during the Occupational Health Surveillance examination and included: age, gender, occupational category, vaccination status concerning HBV (date of vaccination, age at vaccination, number of doses, type of vaccine if available), blood tests (date of blood test, anti-HBs concentration, markers of HBV infection). The vaccination status was verified through vaccination certificates (a document certifying the administration of vaccines by the Public Health Department) provided by the subjects at the time of the first visit.

Only students and residents who received three doses of recombinant HBV vaccine, at 0 and subsequent 1 and 6 months from the first dose were included.

All subjects who received incomplete cycles, doses at inappropriate intervals, additional doses prior to the assessment of anti-HBs titre or who provided insufficient documentation were excluded. All subjects with a positive HBsAg surface antigen were also excluded.

The enrolled students and residents were classified according to the age at vaccination in "vaccinated during infancy", if the vaccination course was administered between 0 and 3 years and "vaccinated during adolescence", if the vaccination course was administered between 10 and 16 years. Subjects vaccinated at other ages were classified as "other age" and were excluded from the study.

The received dose was classified as "pediatric" or "adult" according to the indications of the Ministry of Health: the compulsory vaccination for HBV was introduced in Italy in 1991 [21]; from 1991 to 2000, 3 pediatric doses were administered to all new-borns starting from the third month of life and 3 adult doses to all 12-year-old individuals.

Since 2000, however, the pediatric dose is administered up to 16 years of age to subjects who have not been vaccinated at birth [19].

According to the WHO recommendations, an anti-HBs titer equal to or greater than 10 mIU/mL was considered as protective [22]. To all subjects with an anti-HBs concentration < 10 mIU/mL a booster dose of monovalent HBV vaccine was offered, as established by Italian law [23]. The anti-HBs titer was re-evaluated at least four weeks after the administration of the booster dose, considering it protective when \geq 10 mIU/mL.

STATISTICAL ANALYSIS

Categorical variables were analysed as frequencies and percentages and compared by the Pearson's Chi-square test. The outcome of interest was anti-HBs concentration, considered as not protective when < 10 mIU/mL. Levels of anti-HBs concentrations have been dichotomized in "0" when < 10 mIU/mL and "1" when \ge 10 mIU/mL.

The anamnestic response to a booster dose among subjects vaccinated during infancy and among those vaccinated in adolescence has been evaluated with the Fisher's exact test.

To allow the calculation of the geometric mean concentrations (GMC), in the case of undetectable concentrations, an arbitrary value of 0.5 mIU/mL was assigned, while for concentrations > 1,000 mIU/mL, an arbitrary value of 1000 was assigned.

A multivariate stepwise logistic regression was performed considering as outcome an anti-HBs concentration < 10 mIU/mL. The logistic regression model was build testing the following variables: gender (0 = male, 1 = female), age at vaccination (0 = infancy, 1=adolescence), vaccine dose (0 = pediatric, 1 = adult), time since vaccination (0 = < 15 years, 1 = 15-19 years, 2 = \geq 20 years). Odds Ratios (OR) and 95% confidence intervals (95% CI) have been calculated and a p-value < 0.05 has been considered as statistically significant. Statistical analysis was performed with IBM[®] SPSS[®] Statistics, version 20.

ETHICAL APPROVAL ASPECTS

The study protocol was approved by the Local Ethics Committee. The collection of data was conducted fol-

lowing the principles of the Declaration of Helsinki, according to current national legislation and in compliance with the protection of personal data. As no information which may identify the subjects was collected, no informed consent was obtained.

Results

The overall population was composed of 678 students and resident doctors. 57 subjects were excluded: 23 because they received a fourth dose before the study, 27 had incomplete documentations, 6 were not vaccinated either in infancy or adolescence, 1 resulted HbsAg positive. 621 individuals met the inclusion criteria. 172 (27.7%) had an anti-HBs concentration < 10 mIU/mL and 449 (72.3%) had an anti-HBs titer \geq 10 mIU/mL.

None of the included subjects was vaccinated with the hexavalent vaccines Hexavac or Infarix.

The univariate analysis (Tab. I) showed that the percentage of subjects vaccinated during infancy with a titer < 10 mIU/mL was significantly higher than in subjects immunized during adolescence (154/361 or 42.7% vs 18/260 or 6.9%; OR = 0.1; 95% CI = 0.1-0.2; p-value < 0.001) (Fig. 1). The percentage of subjects who received a complete vaccination course with pediatric doses and had an anti-HBs concentration < 10 mIU/mL was significantly higher than that of the subjects vaccinated with adult doses (162/450 or 36.0% vs 10/171 or 5.8%; OR 0.1; 95% CI = 0.1-0.2; p-value < 0.001).

The average period between the completion of the first immunization cycle and the evaluation of anti-HBs was 20.4 years (SD = 2.2) for the subjects with titer < 10 mIU/mL and 18.3 years (SD = 3.3) for the subjects with concentration ≥ 10 mIU/mL. The mean age of immune subjects was 25.3 years (SD = 3.4) while in seronegative individuals was 22.6 years (SD = 2.4).

The logistic regression model (Tab. II) confirmed the statistical significance of age at vaccination (infancy versus adolescence, OR = 0.2; 95% CI = 0.1-0.8; p-value = 0.02) as independent predictive variable associated with an outcome of anti-HBs concentration < 10 mIU/mL.

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 Tab. I. Demographic and epidemiological characteristics.

As regards to age at first immunization, the 27.4% of subjects vaccinated during infancy and 2.3% of those immunized in adolescence showed undetectable anti-HBs titers (Tab. III).

The GMC of anti-HBs before booster dose was higher among subjects vaccinated during adolescence (158.2 mIU/mL with 95% CI = 128.2-194.8) than in those immunized during infancy (11.1 mIU/mL with 95% CI = 8.7-14.0).

Although a booster dose was offered to all seronegative subjects, only 94 subjects had an available blood test at the moment of the study as showed in Table IV: 85 vaccinated during infancy (55.2%) and 9 vaccinated during adolescence.

The rate of subjects showing an anamnestic response after the booster dose was higher in individuals vaccinated during infancy (80/85 or 94.1% vs 7/9 or 77.8%). This difference was however not statistically significant (p-value = 0.13).

After receiving the booster dose, 91.9% (57 out of 62) of subjects with a previously undetectable anti-HBs concentration and 93.8% (30 out of 32) of those with a previously detectable but < 10 mIU/mL titer, achieved an anamnestic response (p-value = n.s.). None of the subjects resulted non-responder since they all reached an anti-HBs titer \geq 10 mIU/mL within the secondary vaccination course (at 4th, 5th or 6th dose).

The GMC of anti-HBs after booster dose resulted 241.2 mIU/mL (95% CI = 167.7-348.7) in subjects immunized during the infancy and 72.7 mIU/mL (95% CI = 21.9-278.6) in subjects vaccinated during adolescence.

Discussion

Most medical students and resident doctors included in the study (72.3%) showed, at the occupational health surveillance check, a protective anti-HBs titer even 15-20 years after the first cycle of vaccination. This finding confirms the current knowledge concerning the long-term persistence of seroprotection levels in appropriately vaccinated subjects, as described in the literature [24, 25].

	Anti-HBs < 10 mIU/mL (N = 172)	Anti-HBs ≥ 10 mIU/mL (N = 449)	P-value
Gender			
• Male (n, %)	74, 43.0%	170, 37.9%	n.s.
• Female (n, %)	98, 57.0%	279, 62.1%	n.s.
Age at HBV vaccination • Infancy (0-3 years), % • Adolescence (10-16 years), %	89.5 10.5	46.1 53.9	< 0.001
Vaccine dose • Pediatric, % • Adult, %	94.2 5.8	64.1 35.9	< 0.001
Time since vaccination mean ± SD (years)	20.4 ± 2.2	18.3 ± 3.2	< 0.001
Age at testing mean \pm SD (years)	22.6 ± 2.4	25.3 ± 3.4	< 0.001



Tab. II. Results of a logistic regression model estimating predictors of an anti-HBs titer < 10 mIU/mL in HBV vaccinated subjects.

Outcome: anti-HBs titer < 10 mIU/mL	OR	95% CI	P-value
Gender			
Male	1.0	0.6-1.4	0.81
• Female	1ª		
Age at HBV vaccination			
Infancy (0-3 years)	0.2	0.1-0.8	0.02
Adolescence (10-16 years)	1 ^a		
Vaccine dose			
Pediatric	0.7	0.2-1.9	0.48
• Adult	1 ^a		
Time since vaccination			
• < 15 years	1ª		
• 15-19 years	1.9	0.7-5.5	0.12
 ≥ 20 years 	0.9	0.2-3.4	0.84

CI: Confidence Interval; ^a: reference category.

The study showed that, 15-20 years after the primary HBV vaccination course, there is a significant difference between the rate of subjects vaccinated during infancy who did not maintain an anti-HBs concentration ≥ 10 mIU/mL and that of those immunized during adolescence (42.7% and 93.1% respectively). Similarly to other studies [3, 26, 27], the 27.4% of subjects vaccinated during infancy also had an undetectable anti-HBs concentration and a GMC before booster dose of 11.1 mIU/mL.

Factors such as age at vaccination, vaccine dosage [1, 3] and host genetic factors [28] play a fundamental role in maintaining the anti-HBs concentration. Furthermore, the higher the antibody response after the primary vaccination cycle, the longer the persistence of an anti-HBs concentration above the 10 mIU/mL threshold [1]. The results arisen in this study reinforce the importance of age at vaccination, as highlighted by the statistical significance in the multivariate analysis (OR 0.2; 95% CI = 0.1-0.8).

Tab. III. Anti-HBs concentrations (mIU/mL) and Geometric Mean Concentration (GMC) before booster dose.

Anti-HBs concentrations	Infancy (0-3 years) N = 361 (%)	Adolescence (10-16 years) N = 260 (%)
Undetectable	99 (27.4)	6 (2.3)
• 1 to < 10 mIU/mL	55 (15.2)	12 (4.6)
 10 to < 100 mIU/mL 	150 (41.6)	82 (31.5)
 100 to < 1,000 mIU/mL 	55 (15.2)	92 (35.4)
• ≥ 1,000 mIU/mL	7 (1.9)	68 (26.2)
GMC before booster dose		
mIU/mL (95% CI)	11.1 (8.7-14.0)	158.2 (128.2-194.8)

	Infancy (0-3 years) after booster dose N = 85 (%)	Adolescence (10-16 years) after booster dose N = 9 (%)	P-value
Anti-HBs concentration before booster dose:			
• anti-HBs < 10 mIU/mL	5 (5.9)	2 (22.2)	
 anti-HBs ≥ 10 mIU/mL 	80 (94.1)	7 (77.8)	0.13
GMC after booster dose			
mIU/mL (95% IC)	241.2 (167.7-348.7)	72.7 (21.9-278.6)	

Tab. IV. Anti-HBs concentrations and Geometric Mean Concentration (GMC) after booster dose.

The immune system in childhood is characterized by an impaired T-cell function, by lower interactions between B and T cells, by a reduced assortment of immunoglobulins and by a low affinity antibody response [29].

The anamnestic response to a booster dose in individuals with an anti-HBs concentration < 10 mIU/mL was detected, particularly in subjects vaccinated during infancy: 80 subjects out of 85 (94.1%) recovered a protective titer with a GMC of 241.2 mIU/mL. The response was less pronounced in subjects with anti-HBs concentrations < 10 mIU/mL and vaccinated during adolescence, although no statistically conclusive hypotheses can be conceived due to the small number of available blood test. Among the medical students and resident doctors who received a booster dose, no significant difference was found in the anamnestic response between those who had an undetectable anti-HBs titer and those who had a detectable but not protective anti-HBs titer. These results are consistent with previous studies and seem to confirm the hypothesis that the immunological memory is preserved even after the loss of anti-HBs antibody titer [10, 30]. Such evidence acquires significance in an occupationally exposed population at greater risk for HBV. As recently pointed out by the review of Zhao and Zhou [31], whether booster or revaccination after a period of time following the primary vaccination is required remains a debated issue. Nonetheless a booster response could be observed in most of subjects vaccinated 30 years ago, as confirmed by breakthrough HBV infection with severe consequences in successfully vaccinated individuals is extremely rare.

The waning immunity against HBV should be particularly monitored in high-risk groups. Occupational Physicians should consider with particular attention the evaluation of the persistence of anti-HBV specific antibodies in medical students (in most cases vaccinated at birth age) and HCWs specifically at the time of the first employment in order to identify subjects with nonprotective anti-HBs titer [32, 33]. Occupational Physicians' contribution to reduce vaccine delays or refusals and vaccine hesitancy that are also affecting HCWs is crucial [34]. A recent study of Riccò and colleagues [35] draw attention to the knowledge, attitudes, beliefs and practices of Occupational Physicians towards vaccination in HCWs showing that severity perception of the disease and misconceptions about vaccines still influence the immunization coverage. As only evidencebased recommendations should guide occupational physicians' behaviour towards vaccination, specific training programs and formations courses are strongly needed.

The main limitations of this study are represented by the intrinsic characteristics of the study design and the incomplete data of a part, albeit limited, of the clinical documentation.

In particular, at the moment of the study, only a part of blood tests was available.

Some anamnestic data could play an important role on the long-term immunogenicity of the vaccine [36]. The reduced number of subjects with anti-HBs concentration < 10mIU/mL vaccinated during adolescence did not allow to detect significant differences in the booster dose response in this subgroup. Furthermore, not all subjects eligible for the administration of a booster dose accepted the recommendation.

Conclusions

The results of the study, accordingly to literature, suggest that anti-HBs titers have a tendency to decrease below the threshold of 10 mIU/mL in vaccinated subjects. Immunological memory, however, seems to persist in almost all individuals even after the reduction of the anti-HBs concentrations to undetectable levels, as observed in response to a booster dose. In conclusion, assessing seroprotection within public health programmes is not considered a cost-effective practice. In order to fill this gap, the Advisory Committee on Immunization Practices (ACIP) recommends testing health care personnel for anti-HBs antibodies levels before their occupational exposure. A positive result of the test ($\geq 10mUI/mL$) provides no further intervention. On the other hand, one or more additional doses of HBV vaccine and retesting is recommended in non-seroprotected subjects [37]. Occupational Health Surveillance Programs represent the best opportunity to perform these activities and recommendations, allowing also both to verify the anamnestic response to booster vaccination and the persistence of immunological memory. All these actions are supported from our results and contribute to the control of HBV transmission among HCWs and undergraduate healthcare students.

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Conflict of interest statement

GG received grants from Sanofi Pasteur MSD, GSK Biologicals SA, Novartis, Pfizer, Sanofi Pasteur, MSD Italy, PaxVax and Seqirus for taking part to advisory boards, expert meetings, for acting as speaker and/or organizer of meetings/congresses and as principal investigator and chief of O.U. in RCTs. Others authors declare no conflict of interest.

Authors' contributions

AS and GG contributed to the overall design of the study, analysed the data and drafted the manuscript. NB, FS, GD, AM, EM and SL contributed to the study design, collected the data, contributed to data analysis and reviewed the manuscript. All authors critically read and revised the drafts of the manuscript. All authors read and approved the final manuscript.

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ORIGINAL ARTICLE

HIV infection and frequency of micronucleus in human peripheral blood cells

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Keywords

HIV infection • Micronucleus • Biomarker • DNA damage • Genetic instability • Cancer risk

Summary

Purpose. People living with HIV have higher rates of malignancies than the general population in the era of active antiretroviral therapy (ART). Genotoxic effects of HIV infection and/or ART that can induce neoplastic development are not yet well known. A prospective cohort study to investigate DNA damage measured through the micronuclei (MN) frequency in HIV-patients has been performed.

Methods. Peripheral blood mononuclear cells (PBMC) were isolated from 52 HIV-patients treated with ART and 55 healthy controls.

Introduction

The Human Immunodeficiency Virus (HIV) infects cells of the host immune system, which is gradually destroyed; monocytes/macrophages and CD4+ T lymphocytes (CD4+) are the main targets of infection. Active viral replication leads to a progressive decline of CD4+ with gradual immunosuppression of host and increased susceptibility to opportunistic infections [1].

In HIV patients, CD4+ count and HIV-RNA (viral load, VL) are the markers of clinical progression used to manage and to monitor the infection. A large number of HIV patients are also coinfected with hepatitis C virus (HCV) [2, 3]; the co-infection is associated with an increased risk of progression to AIDS [4] and poor CD4 T cell recovery even after years of active antiretroviral therapy (ART) [5].

The introduction of ART in 1996 has significantly improved immune response and life expectancy of HIV infected individuals with consequent significant decline in the incidence of virus-related AIDS-defining malignancies (ADMs), as Kaposi's sarcoma, non-Hodgkin lymphoma and invasive cervical cancer [6], representing an index of clinically remarkable immunosuppression. On the other hand, several non-AIDS defining malignancies (NADMs), such as hepatocellular carcinoma (HCC), Hodgkin's lymphoma (HL), anal cancer, lung cancer, colorectal cancer (CRC), gastrointestinal cancer (GI), breast cancer, cardiovascular diseases, liver dis**Results.** By the comparison of MN frequency, a significant difference between HIV-patients (15.5 ± 9.8) and controls (6.0 ± 3.6) (p < 0.001) has been revealed. In univariate linear regression analysis, HCV infection (r = 0.31; p < 0.001), HIV-RNA (r = 0.29; p < 0.03) and duration of infection (r = -0.16; p < 0.25) were associated with MN frequency; while only viral load (VL) significantly correlates (r = 0.29; p < 0.05) in a multiple regression model

Conclusions. The association of VL with MN frequency supports a genotoxic effect of HIV infection.

eases, kidney and neurodegenerative diseases have been observed [7-9].

Nevertheless, long-term use of ART exposes the patients to an increased risk of metabolic disorders and oxidative stress (OS), all factors that can contribute to the onset of NADMs [10].

HIV patients show reduction of antioxidative activity [11], excessive production of reactive oxygen species (ROS) [12], reduced glutathione (GSH) levels and glutathione/oxidized glutathione (GSH/GSSG) ratio, that seem to contribute to an increase in DNA damage [13]. The incidence of NADMs is elevated in HIV infected patients compared with the general population and it is associated with smoking use, alcohol consumption, overweight/obesity and oncogenic virus infection [human papillomavirus (HPV), HCV and hepatitis B virus (HBV)] [14].

The levels of OS markers are generally higher in HIV/ HCV co-infected than in HIV mono-infected patients [15, 16]. To date, numerous studies have shown that ART triggers further the OS [17, 18]. High incidence of malignant tumours, epidemiologically associated with HIV infection, can be attributable to genotoxic effect of HIV that leads to double-strand breaks of chromosomal DNA [19, 20].

Some studies report that *Vpr*, an accessory gene of HIV which induces abnormality of cell cycle causing the arrest in the G2-M phase, leads to a genomic instability including formation of micronuclei (MN) [21, 22].

MN, small additional nuclei originating from chromosome fragments or whole chromosomes during nuclear division not included in the daughter nuclei in telophase [23], are used as sensitive biomarker of chromosomal damage, genome instability and intermediate endpoint in carcinogenesis [24-26].

The aim of the study is to determine MN frequency in a cohort of HIV patients compared with healthy controlgroup and to evaluate the relationship between demographic and clinical data and markers of DNA damage.

Methods

STUDY POPULATION

The study involved the enrollment of HIV-infected patients and healthy controls afferent to the Infectious Diseases Division of Santa Caterina Novella's Hospital (Galatina, Italy) and to the Department of Immunohematology and Transfusion Medicine of Vito Fazzi Hospital (Lecce, Italy), respectively.

Patients with documented HIV infection treated with ART and older than 18 years of age were included in the study. Sex and age-matched, healthy HIV-uninfected individuals were enrolled as controls. Instead, HIV patients and healthy subjects under 18 years old, pregnant and/or exposed to risk factors associated with genetic damage (such as occupational or medical exposure to ionizing radiation) were excluded.

The study was approved by the local ethics committee and all patients approached for the study gave written consent to participate (Resolution n. 811; May 3, 2012). HIV-related clinical information (mode of transmission, duration of infection, duration of ART, HCV coinfection and AIDS) including laboratory data (VL, CD4 counts and CD4 nadir), were collected from HIV-infected patients at the time of study enrollment.

Relevant data including age and sex, as well as risk factors like diabetes, obesity and smoking status were available for both HIV and controls. The patients' information and blood samples were collected at the enrollment time and the MN test was immediately carried out.

MICRONUCLEUS ASSAY

Peripheral blood samples were collected by venipuncture into vacutainer blood tubes with lithium heparin anticoagulant.

Cellular cultures from each subject were set up by mixing 300 µl of whole blood with 4.7 ml of karyotyping medium. All cultures were incubated at 37°C for 44 h in a humidified atmosphere containing 5% CO₂. For evaluation of MN frequency, cells were blocked in cytokinesis by adding cytochalasin B after 44 h. Cell cultures were then harvested after 28 h and fixed for slide preparation. Therefore, the fixed cells were dropped onto clean iced slides, air dried and stained by the Giemsa technique [27].

Only binucleated lymphocytes are scored for DNA damage biomarkers which include MN. For each sample,

1000 binucleated cells were calculated blindly under the optical microscope for MN analysis, following the criteria for MN acceptance listed by Fenech [23]. We have evaluated the MN frequency as the number of micronucleated-binucleated lymphocytes, containing one or more MN per 1000 cells.

STATISTICAL ANALYSIS

Continuous variables were reported as the mean \pm standard deviation (SD) and categorical factors as percentages. The Levene's test was used to verify the normality of the distribution of continuous variables. Differences between the means of the two continuous variables were evaluated by 2-tailed unpaired Student t test. Differences in non-continuous variables were tested by Chi-square test analysis or by Fisher's exact test, as necessary.

The association between demographic and clinical variables and MN frequency was assessed by univariate linear regression analysis followed by multiple linear regression analysis per variables with p < 0.05. Statistical calculations were performed with MedCalc software, version 11.4.1.0. A p-value < 0.05 was considered to be statistically significant.

Results

52 HIV infected patients and 55 healthy controls admitted at the Infectious Diseases Division of Santa Caterina Novella's Hospital (Galatina, Italy) and at the Department of Immunohematology and Transfusion Medicine of Vito Fazzi Hospital (Lecce, Italy) from January 2013 to January 2015 were recruited in this study. Demographic and clinical characteristics of participants are illustrated in Table I.

No significant differences were observed between HIV patients and healthy controls in age (p = 0.9658), sex (p = 0.8727), smoking use (p = 0.1053) and diabetes (p = 1.000). A highly significant difference was found only for HCV infection (p < 0.0001).

In the cohort of HIV patients, the average duration of HIV infection was of 95 months, the mean CD4 cell count was of 517 ± 314 cells/mm³ (range 5-1,305) and HIV-RNA copies/ml of $58,183 \pm 151,553$ (range 19-875, 716).

By the comparison of the MN frequency in peripheral blood mononuclear cells (PBMC), a significant difference between HIV patients (15.5 ± 9.8) and controls (6.0 ± 3.6) (p < 0.001) was revealed (Fig. 1). Table II shows the results of the univariate and multivariate linear regression analyses, demonstrating the relationships between MN and other variables. Two risk factors were strongly associated with increased MN frequency in HIV patients upon univariate analysis: HCV infection (r = 0.31; p < 0.001) and HIV-RNA (r = 0.29; p < 0.05). However, only VL significantly correlates (r = 0.29; p < 0.05) with the MN frequency in a multiple regression model, where variables with p value < 0.05 in the univariate analysis were included as independent (Tab. II).

	HIV-1+ (n = 52)	Control (n = 55)	P-value
Age, years (mean ± SD)	42.5 ± 9.6	42.6 ± 9.9	0.9658°
Gender, male, n (%)	40 (76.9)	42 (76.4)	0.8727^
Obesity, n (%)	1 (1.9)	1 (1.8)	1.000#
Smoke use, n (%)	25 (48.1)	17 (30.9)	0.1053^
HCV infection, n (%)	18 (34.6)	0 (0.0)	< 0.0001#
Diabetes, n (%)	1 (1.9)	1 (1.8)	1.000#
Mode of transmis	sion		
• Heterosexual contact, n (%)	19 (36.5)	-	
• Male-to- male sexual contact, n (%)	21 (40.4)		
 Injection dug use, n (%) 	11 (21.2)	-	
• Other, n (%)	1 (1.9)	-	
Duration HIV infection, months	95 (1-339)	-	
Duration HIV infection > 36 months, n (%)	33 (63.5)	-	
AIDS, n (%)	2 (3.8)	-	
HIV RNA (mean ± SD)*	126,042 ± 82,553	-	
Undetectable HIV viral load, n (%)	28 (53.8)	-	
CD4 cells/mm ³ , mean ± SD (range)	517 ± 314 (5-1305)	-	
Nadir CD4 cells/ mm ³ , mean ± SD (range)	233 ± 166 (2-755)	-	
Duration of ART, months	61.1 (1-203)		
Duration of ART > 36 months, n (%)	30 (57.7)		

 Tab. I. Demographic, clinical characteristics and laboratory values of patient's HIV and control group.

[°]: Independent samples t-test; ^: Chi-square test; #: Fisher's exact test;
 *: mean of viremic patients.

Discussion

The aim of this study was to evaluate the cytogenetic damage in PBMC of HIV patients, considering that DNA damage may develop ADMs and NADMs.

To this end, two groups have been enrolled: HIV patients undergoing ART treatment (study group) and subjects with no HIV-infection (control group). The HIV group included many recently diagnosed patients, which benefited from ART therapy for a limited time, with virus not yet suppressed. All the patients started therapy at the time of diagnosis.

The initial design of the study included a third group of HIV-infected subjects that did not receive therapy (naïve group). Anyhow, over the course of the study, very few new cases of HIV occurred. Therefore, it was not possible to select a sufficient sample size to make statistically significant comparison. The absence of a naïve group is a major weakness of this study because it has not allowed the dissociation of the damages induced by the infection and those induced by the therapy.

The introduction of ART has modified the natural history of HIV infection, leading to an increase of survival time and a reduced AIDS-related mortality, but also to an excess of neoplastic diseases that have becoming one of the most common cause of death among HIV patients [28, 29]. The treatment leads to viral suppression but does not completely restore the immune damage, so ineffective immune response could be the reason why HIV patients have an increased risk of developing different types of tumours [30, 31]. The role of HIV in the development of neoplastic pathologies can be linked to severe immunodeficiency with consequent impairment of immunological surveillance against infectious agents (with predisposition to the appearance of virus-associated tumours) and the cells with malignant transformation [32-34], although its role in the process of carcinogenesis has not yet been completely clarified.

Our study provides evidence that HIV infection may have an impact on the genetic damage. Indeed, MN frequency was significantly increased in the study group compared to the control group.

Our findings are in line with those of Lima and colleagues that show an increase in the frequency of multiple MN in oral mucosa cells in HIV patients compared to healthy controls [35].

The micronucleus cytome assay applied in buccal exfoliated cells is a complementary method for measuring DNA damage and cytotoxic effects caused by exposure to genotoxic agents, impact of nutrition, lifestyle factors and virus [25, 36].

Several studies, reporting the parallel application of the MN test in both PBMC and in buccal cells, have shown a positive correlation between the MN frequencies in the two surrogate tissues [37, 38], therefore the results of the two methods can be comparable. In addition, the strong correlation of MN frequency in buccal exfoliated cells with that in PBMC, implies that systemic genotoxic effects may also impact on and be detectable in buccal cells. Hence, the possible human health risks associated with high MN frequency in both tissues may also be comparable, including the association with cancer risk [24].

We have also analysed the association among the frequency of MN with baseline HIV-specific clinical variables and patient characteristics. The univariate analysis has showed a statistical significance with HCV infection and HIV-RNA, while the multivariate analysis has displayed significant association only between HIV-RNA and frequency of MN. The 54% of HIV-infected patients

Control



Tab. II. Univariate and multiple linear regression analysis of the relationship between micronucleus (MN) frequency and characteristics of HIV-1+ patients.

	Univariate		Multivariate	
	r	p-value	r	p-value
Age, years	- 0.07	0.605		
Gender	- 0.09	0.525		
Obesity	0.15	0.276		
Smoke use	- 0.11	0.440		
HCV infection	0.31	0.001	0.05	0.943
Diabetes	- 0.03	0.819		
Duration HIV infection	- 0.16	0.246		
HIV-RNA	0.29	0.032	0.29	0.022
CD4	0.05	0.701		
Nadir CD4	0.35	0.067		
Suboptimal ART	0.06	0.649		
Duration of ART	- 0.10	0.475		

enrolled, all in therapy with ART, were aviremic (with VL < 20 copies/ml). In these patients, the mean number of MN (13.2 \pm 6.5) was significantly lower (p < 0.002) than in patients with uncontrolled viremia (17.8 ± 12.4) . These data support the hypothesis that viremia plays a determinant role in the induction of chromosomal damage. The current knowledge of genotoxic effects of infection and therapy are still limited. Only few studies have tried to explain the MN formation. Shimura M et al. and Tachiwana H et al. have linked this process to the action of the accessory gene Vpr of HIV, which induces double-strand breaks of chromosomal DNA [21, 22], while Lourenco ED and colleagues justify it with a clastogenic (chromosome breakage) and aneugenic (chromosome loss) action of the therapy [39].

Our work supports the hypothesis of cytogenetic damage induced by HIV infection, but further studies in naïve and in ART therapy patients and with different therapeutic programmes, are mandatory.

Moreover, our data show that exposure to the virus plays a key role in the development of cytogenetic damage, although the precise exposure date is not known. Finally, many questions regarding the relationship between HIV and AIDS related and non-AIDS related cancer are still left unanswered.

Future researches should be focused on identifying early and sensitive risk indicators for the development of cancer.

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HIV-1+

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Conflict of interest statement

None declared.

Authors' contributions

AZ, PG and MG conceived and designed the research. PG recruited patients and PN enrolled healthy controls. MRT and AB performed micronuclei assay. MG performed the statistical analyses. AZ, PG, MGA, ADD and MG evaluated the results. AZ, MRT and MG wrote the manuscript. All Authors revised the manuscript and gave their contribution to improve the paper. All authors read and approved the final manuscript.

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ORIGINAL ARTICLE

Sexually-transmitted infections: what is the true prevalence? A cross-sectional online survey of men who have sex with men in the Veneto Region of Italy

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Keywords

MSM • STI • Prevalence

Summary

Introduction. *Rates of sexually-transmitted infections (STIs) remain high among men who have sex with men (MSM), posing serious public health concerns. The MSM population is recognized as a vulnerable, high-risk group due to barriers to preventive healthcare services and homophobic stigma.*

Methods. A cross-sectional online survey was conducted using a questionnaire based on European Man-for-Man Internet Survey 2010 (EMIS 2010) and European Centre for Disease Prevention and Control (ECDC) core indicators specific for behavioral risks. MSM were reached between June and August 2017, using Facebook and dating apps. Descriptive statistics and multivariate logistic regression were used to analyze the data.

Results. A total of 324 respondents were analyzed, 88 subjects (27.2% of the sample) reported having experienced at least one STI, the most common being gonorrhea and HPV. Ten respondents

Introduction

Men who have sex with men (MSM) are at greater risk of multiple sexually-transmitted infections (STIs), partly due to unsafe sexual practices such as unprotected anal intercourse [1]. Although most STIs cause only mild symptoms, if any, that may not be identified as being due to a STI [2], they are a serious public health concern. They are associated with severe disease, and bacterial STIs in particular are recognized as potential drivers of HIV infection among MSM [3, 4]. To be more specific, syphilis and gonorrhea are being diagnosed considerably more frequently nowadays, almost entirely as a result of higher rates of infection among MSM. Much the same picture has been emerging in the US and Western Europe since 1998 [3, 5].

Although MSM represent a population at high risk of STIs, recent data indicate that almost one in two of all European countries have no reliable estimates of the size of their MSM population and limited data on their sexual risk-taking behavior [6, 7]. Moreover, despite the high incidence of STIs among MSM, homophobic stigma or discrimination often make them unwilling to provide information to health care personnel clinic and, even if

reported having HIV infection, and 7 subjects (70%) of them were co-infected with other STIs. The 49.7% (161 subjects) had seen a doctor specifically for STIs. As concerns HPV vaccination, only 4.0% of the total respondents had been vaccinated. Restricting the sample to the 161 respondents who consulted an STI clinic, the 88 individuals who reported having had at least one STI amount to 54.6%. A more consistent use of condoms and larger numbers of sexual partners were significantly associated with a lower and higher risk of STI, respectively.

Conclusions. Comprehensive STI prevention strategies are needed to improve sexual health among MSM. Such strategies should include implementing programs to improve awareness about routine screening, and promote a consistent use of condoms by MSM.

they consult a doctor, many tend not to disclose their sexual orientation [8, 9].

With the aim of adding to the data available in the literature, the purpose of this study was to analyze the prevalence of various STIs and risk-taking sexual behavior among MSM.

Methods

STUDY DESIGN

Data were collected as part of a cross-sectional online survey on relationships, sex life, risks and precautions, and the use of health services, which was conducted from 4 June to 31 August 2017 on a sample of MSM, contacted through Facebook and instant messaging apps for MSM (i.e. Grindr, Hornet and PlanetRomeo).

QUESTIONNAIRE

The questionnaire was based on the EMIS 2010 study [10], taking for reference the core indicators specific for MSM, as indicated by the ECDC [11]. The main indicators considered were: a diagnosis of STI in the pre-

vious 12 months; testing for HIV or other STIs; percentage of HIV-positive; number of sexual partners in the previous 12 months; habitual usage of condoms; HPV vaccination status; and awareness concerning STIs.

The questionnaire was preceded by an introduction that explained the goals of the research and how anonymity was assured, and provided instructions for its completion. Respondents could not be traced back to their profiles. Data were treated confidentially in accordance with Italian legislation, and in compliance with the Helsinki declaration.

SAMPLE

All the MSM registered with lesbian, gay, bisexual and transgender (LGBT) associations in the Veneto Region, members of various Facebook pages with a specific LGBT theme, or simply users of apps for MSM were invited to take part in our online survey. The inclusion criteria adopted were: male sex and sexual attraction to, or sexual relations with other males; and age \geq 18 years. There was no restriction concerning nationality as this was intended to be a wide-ranging transversal investigation. With regard to the analysis of the risk related to STI, we restricted the sample only to the subjects who visited an STI clinic because many times the STIs are asymptomatic and the self-reported cases could be an underestimation of the real frequency of these diseases.

STATISTICS ANALYSIS

Descriptive statistics (including means and proportions for continuous variables, and percentages and absolute frequencies for categorical variables) were used to analyze the data. The prevalence of STIs was estimated as the proportion of respondents who reported a clinically-confirmed diagnosis of STI. The $\chi 2$ test, Student's t-test, and 95% confidence intervals (95% CI) were used, as appropriate. Factors independently associated with the experience of STIs in the subjects who visited an STI clinic were examined using a multivariate logistic regression, from which adjusted ORs were estimated with corresponding 95% CIs. A p value < 0.05 was considered as the threshold for statistical significance.

Results

Questionnaires answered by a total of 324 respondents meeting our inclusion criteria were analyzed. Respondents were a mean 28.8 years \pm 8.8 years of age; and 96% (311 subjects) of them were Italian. As for their sexual orientation, 261 (80.6% of the sample) reported being homosexual, and 63 (19.4%) were bisexual. At the time of completing the questionnaire, 29.0% (94 subjects) were reportedly in an exclusive relationship, while 70.4% (228 subjects) were not. Regarding their selfdisclosure, 32.7% (106 subjects) had reportedly made their sexual orientation public, 61.1% (198 subjects) had disclosed it only to some people, and 6.2% (20 subjects) had not come out. Finally, the survey established that the internet or meeting apps were the method most com-

monly used to meet casual male partners. Table I summarizes the respondents' demographic details.

This study included 119 cases of STI, affecting 88 subjects (27.2% of the sample). The most common STI reported was gonorrhea (18.0%; 29 subjects), followed by human papilloma virus (HPV) infection (17.4%; 28 subjects).

In the sample as a whole, 254 individuals (78.4%) were tested for HIV, 88/88 (100%) of those reported at least one other STI, and 116/166 (70.5%) of the remainder did not report another STI. Ten of these 254 subjects (3.9%) reported having HIV infection, and 7 of them were co-infected with other STIs, i.e. hepatitis B virus (HBV), syphilis, gonorrhea and HPV.

As concerns HPV vaccination, only 4.0% of the total respondents had been vaccinated (8.0% of those who had experienced STIs, and 2.5% of those who had not; p = 0.02). In the sample as a whole, 50.6% of respondents expressed interest in obtaining an HPV vaccination. When questioned about their awareness of STIs, 13.6% of 324 respondents considered themselves very well informed about the topic. This was particularly true of the group that had experienced STIs (21.6% vs 10.6%; p = 0.01). In 72.8% of the sample as a whole (and with much the same proportions among those who had experienced STIs, and those who had not), respondents felt that public institutions should play a primary role in ensuring the dissemination of adequate information about STIs. At the same time, 77.5% of the sample judged the information currently provided by such institutions scant or inadequate (71.6% for the group that had experienced STIs, and 79.6% for the others; p = n.s.).

Restricting the sample to the 161 respondents (49.7% of sample) who consulted an STI clinic, the 88 individuals who reported having had at least one STI amount to 54.6%. Figure 1 shows the prevalence of STIs, and HIV

Tab. I. Characteristics of men who have sex with men.

	N	(%)
Age (mean ± SD)	28.8 ± 8.8	
Education status ($n = 316$)		
University	117	(37.0)
 Secondary education 	159	(50.3)
Primary or lower	40	(12.7)
Employment (n = 324)		
• Student	136	(42.0)
Employed	166	(51.2)
Unemployed	22	(6.8)
Sexual orientation ($n = 324$)		
Homosexual	261	(80.6)
• Bisexual	63	(19.4)
Relationship (n = 322)		
Exclusive	94	(29.2)
Not exclusive	228	(70.8)
Last met casual male partners via		
(n = 300)		
 Internet web pages - Meeting 	225	(75.0)
abb	10	(0.0)
Bar-club	18	(6.0)
	52	(10.7)
• Uther	25	(8.5)



in particular, among the MSMs who underwent specific testing for STIs and HIV.

Table II summarizes the demographics and risk behavior of the 161 respondents who underwent tests, by positivity for specific STIs. Overall, the mean age of these respondents was 30.5 ± 10 years, with no difference between the group that had experienced STIs and the group that had not, and their mean age at the time of their sexual debut was 19.3 ± 5.1 years, again with no difference between the two groups.

Tab. I	II. C	Distribution	of	demographic	chara	acteristics	and	behavioral	risks,	by	positivity	for ST	٦s.
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			ST				
Variable	Ν	Yes		No			
Variable		N	(%)	N	(%)	OK (95% CI)	
	161	88	(54.7)	73	(45.3)		
Age (mean ± DS)	30.5 ± 10	30.4 ± 9.8		30.5 ±10.2		0.98 (0.96-1.03)	0.99 (0.95-1.03)
Age at sexual debut (mean \pm DS)	19.3 ± 5.1	19.5 ± 5.5		19.2 ± 4.6		1.01 (0.95-10.7)	1.02 (0.94-1.11)
No. of sex partners in the last 24 months (mean \pm DS)	12.2 ± 13	14.3 ± 14.2		9.7 ± 11.1		1.03 (1.01-1.06)	1.06 (1.01-1.07)
Sexual orientation							
HomosexualHeterosexual	127 34	69 19	(54.3) (55.9)	58 15	(45.7) (44.1)	Ref 1.06 (0.49-2.28)	Ref 1.25 (0.55-2.84)
Sexual relationships							
ExclusiveNot exclusive	46 115	25 63	(54.3) (54.8)	21 52	(45.7) (45.2)	Ref 1.01 (0.51-2.02)	Ref 1.11 (0.53-2.35)
Condom use							
Occasionally-never	95	59	(62.1)	36	(37.9)	Ref	Ref
Consistent	66	29	(43.9)	37	(56.1)	0.48 (0.25-0.90)	0.45 (0.22-0.87)
Alcohol							
• Never	22	12	(54.5)	10	(45.5)	Ret	Ret
• fes	159	70	(34.7)	05	(45.5)	1.19 (0.46-2.90)	1.24 (0.45-5.41)
• Never	62	3/1	(5/1.8)	28	(45.2)	Ref	Rof
Yes	99	54	(54.5)	45	(45.5)	0.98 (0.52-1.86)	1.15 (0.53-2.49)
Illicit drug use							
Never	119	64	(53.8)	55	(46.2)	Ref	Ref
• Yes	42	24	(57.1)	18	(42.9)	1.14 (0.56-2.32)	1.25 (0.52-2.99)
At least one behavioral risk at time of							
sexual intercourse*	47			05	(57.6)	5.6	
	4/	22	(46.8)	25	(55.2)	Ket	Ret
• Yes	114	66	(57.9)	48	(42.1)	1.56 (0.78-3.09)	1.65; (0.71-5.76)

*: sexual intercourse associated with alcohol or illicit drug use, or exchange of money.

In 71.4% (115 subjects) of cases, our respondents reported not being in an exclusive relationship, and 70.8% (114 subjects) said they were exposed to at least one behavioral risk (related to alcohol or illicit drug use, or the exchange of money) at the time of sexual intercourse; these proportions did not differ between the above-mentioned two groups. The reported number of sexual partners in the previous two years was significantly higher among individuals who had experienced a STI, whereas a significant protective role against STIs was associated with the consistent use of condoms (Tab. II). The multivariate analysis confirmed both these findings, with an adjusted OR of 1.06 (95% CI = 1.01-1.07) and 0.45 (95% CI = 0.22-0.87), respectively.

Discussion

The results of the present survey confirm that STIs are still common among MSM. Considering our sample as a whole, their frequency amounted to 27.2% but the prevalence of STIs rose to 54.6% of the subsample of respondents who had undergone testing for STIs. This difference reflects a weak inclination among MSM to undergo specific STI tests: less than one in two of our respondents had done so. This proportion is very low if compared with the 81.8% of a Scottish survey [12]. Many MSM experience discrimination, and this can prompt them to hide their sexual orientation. MSM are also few inclined to access HIV-related services for fear of a negative reaction from healthcare workers [8]. Because most STIs are asymptomatic, the majority of cases go undiagnosed in the absence of routine screening [2]. A different picture emerged for HIV testing. As in the report from the Centre for Disease Prevention and Control [13], and in line with other studies, 78.4% of our respondents had been tested for HIV [14]young (median age 29 [interquartile range 23-35], and the likelihood of having been tested was higher in the group that had experienced STIs. The rate of HIV infection in our sample was consistent with that of a recent study in which the prevalence of HIV among MSM was 3.9% [15].

As concerns HIV infection and syphilis, the epidemiological picture in Germany charted for the years from 2001 to 2015 pointed to a constant increase in the rates of both diseases among MSM [16]. Another study, conducted in Spain, found a rising trend in the cases of gonorrhea, which was more pronounced among MSM [17]. A recent analysis showed that being MSM represented a risk factor for both HPV and multiple infections [18] genotype distribution, intraepithelial neoplasia (AIN). Our survey confirmed that co-infection is quite common (one in three of our MSM with STIs), and found gonorrhea the most often reported infection (18%).

Multivariate analysis showed that the independent variables associated with STIs in our sample were a protective role of consistent condom use, and a higher risk related to larger numbers of sexual partners. Although it represents the cornerstone of STI prevention, condom use was still inconsistent in a large proportion of our population.

This finding confirms the results of other studies, and reflects a lack of awareness of the risks associated with unprotected sex [19]. Having multiple sexual partners is common in the MSM community, and still many do not use condoms consistently. Recent data indicated that less than 60% of MSM reported using a condom [18] genotype distribution, intraepithelial neoplasia (AIN, and evidence of a limited use of condoms emerged from another study too [19]. One of the reasons for this situation lies in that "safer sex" campaigns have lost traction in this population. In the United States, for example, the percentage of men reportedly using condoms at least for anal sex dropped from 41% in 2011 to 35% in 2014 [8]. HPV is one of the most common STIs, affecting both genders and responsible for several related cancers in both men and women. The infection is highly prevalent among MSM [20] and, by comparison with the general population, MSM are more susceptible to developing HPV-related anal cancer [21]. HPV vaccination in males has proved effective in reducing HPV-associated anogenital infection and disease [22]. In the Veneto Region, free anti-HPV vaccination has been offered to males in their 12th year of life since 2015, and it remains available free of charge up until their 18th birthday, then offered in co-payment up until they are 26 years old [23]. In our survey, only 4.0% of respondents reported having been vaccinated against HPV, but about half of them (50.6%) expressed interest in obtaining HPV vaccination. MSM would benefit more from this vaccination than the general male population, and it would be well worth targeting this particular group with HPV vaccination campaigns. Several studies have revealed an association between substance use and sexual risk-taking, especially among MSM [15]. The use of alcohol and illicit drugs is sometimes a part of this community's socializing behavior. These behavioral risks can lead to unprotected sex, and a higher number of sexual partners, raising the chances of HIV transmission [8]. In our sample too, exposure to at least one behavioral risk at the time of sexual intercourse was greater in the group reporting having experienced STIs.

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Our findings should be interpreted in the light of some limitations of our study. The most important limitation lies in that we relied on self-reported information. Respondents may have under-reported any behavioral risk factors, and any hesitation to disclose such information would result in a response bias [24]. On the other hand, the anonymous nature of the questionnaire may have helped respondents to feel more free to express themselves. A second limitation lies in that, because STIs can occur without any symptoms [25], affected individuals may have a limited capacity to recognize them, and this would again result in an under-reporting of the phenomenon. A third limitation concerns the fact that this survey only recruited MSM online, so our findings may not be generalizable to the MSM population less inclined to use internet.

Despite these limitations, our analysis corroborates the known links between risk factors, STIs and MSM, highlighting the immense need to develop targeted screening and intervention schemes to prevent risk-taking in their sexual behavior.

Conclusions

To improve the sexual health of MSM and prevent STIs, targeted interventions to reduce any risk-taking sexual behavior are warranted. Prompting change in people's behavior is always a challenge, but it would certainly be useful to involve this target population in the design, implementation and assessment of any such prevention strategies. Finally, given the high prevalence of STIs among MSM, and their weak inclination to undergo screening, greater efforts will have to be made to improve their awareness of the importance of routine testing for sexually-active MSM.

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Conflict of interest statement

None declared.

Authors' contributions

MP: study conception, design and data collection; SC: statistical analyses, data interpretation and drafting of the manuscript; CR: study conception and design; MAB: statistical analyses and study conception; VB data interpretation, drafting of the manuscript and supervision. All authors have read and approved the final manuscript.

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ORIGINAL ARTICLE

Smoking behaviour among nursing students: attitudes toward smoking cessation

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Keywords

Surveys and questionnaires • University students • Sicily • Students nursing • Smoke

Summary

Introduction. The purpose of the study was to assess tobacco smoking habits among nursing students and how these are influenced by family members and cohabitants.

Methods. Cross-sectional study. An anonymous paper questionnaire was administered to nursing students of the three-year course of the University of Palermo. Adjusted Odds Ratio (aOR) are presented.

Results. 301 nursing students (63.12 % female) completed the questionnaire (response rate 61.17%). The average age of the sample is 21.88 years (SD \pm 2.80). Considering as a dependent variable: "I currently smoke", the statistically significant inde-

Introduction

Nurses constitute the largest occupational group among health professionals and are employed in variety of settings such as schools, colleges, community and mental health settings, and others.

As shown by systematic reviews [1] the behaviors of nurses influence public perception of the profession, are a powerful vehicle for promoting health, and have been used to influence public health in the worldwide. When nurses engage in behaviors that are contradictory to health, they put the profession in a negative light. Nursing leadership has been aware of the negative image of the nurse as smoker for decades.

They are a potentially powerful resource for influencing the society smoking patterns and could play a key role in smoking cessation [2]. Recently published studies confirmed that smoking rates among nurses and nurse students are relatively high worldwide [3]. One of the main motivational reasons to become a health care worker is to assist people in achieving their full health potential, on the contrary, smoking is the most hazardous and avoidable health risk in our society. Tobacco smoking is a serious public health problem worldwide that the leading preventable causes of morbidity and mortality, leading to the death of more than 7 million people each year. More than 6 million of those deaths are the result of direct tobacco use while around 890,000 are the result of non-smokers being exposed to second-hand smoke [4]. Tobacco smoking, inclusive of secondhand smoke, is a leading risk factor attributable to 6% of global disabilitypendent variables associated are: "Male gender" (aOR 2.09), "Single" (aOR 2.06), "Second year of study of the degree course in nursing" (aOR 0.46), "Third year of study of the degree course in nursing" (aOR 0.43), "Don't think that warnings and pictures on cigarette packs can help stop smoking" (aOR 6.38), "Mother smoked in the past" (aOR 2.25) and "Brother or sister smoked in the past" (aOR 5.50).

Conclusions. Students and graduate nurses need to be aware of current knowledge in the smoking cessation field and they have an influential role in modifying patient behavior in order to assist them to smoking cessation.

adjusted life years [5]. As healthcare costs continue to rise, much more attention is being focused on unhealthy behaviors that contribute to the increasing expenses. An estimated that more of 960 million smokers are living in 187 countries of world and this number is expected to increase with the growing population and worsening tobacco epidemic in developing countries [6]. Around 80% of the world's 1.1 billion smokers live in low- and middle-income countries [4].

In Italy, the Ministry of Health provides free smoking cessation information and support through various websites and telephone services [7]. Furthermore, many healthcare organizations have designed and implemented smoking cessation initiatives at local and regional levels, such as territorial services for the cessation of tobacco smoke (Centri Antifumo - CAFs, in the Italian language). The Smoking, Alcohol and Drug Observatory of the Istituto Superiore di Sanità every year update the census of the CAFs active at the National Health Service, at the Italian League for the Fight against Cancer and at the private social sector. In 2017, 366 CAFs are active, of this 307 at the National Health Service, 56 at the Italian League for the Fight against Cancer and 3 at the private social sector [8].

The World Health Organization (WHO) developed the Global Health Professions Student Survey (GHPSS) to collect data on tobacco use among health professional students in all WHO member states. According to study GHPSS, prevalence of smoking was highest in eastern Mediterranean (10-23%) and European countries (7-13%). 41.5% of third year nursing students are current

smokers. 89.4% of the nursing students believed health professionals should teach their patients about smoking cessation and 96.7% believed they should be trained in smoking cessation, but only 22.6% actually received formal training [9].

The WHO Framework Convention on Tobacco Control (WHO FCTC) is the first treaty negotiated under the auspices of the World Health Organization. The WHO FCTC is an evidence-based treaty that reaffirms the right of all people to the highest standard of health. WHO FCTC recommends that the global tobacco epidemic be monitored through population-based surveys conducted through the Global Tobacco Surveillance System. WHO FCTC underscores the importance of the role played by health workers in cessation and prevention of tobacco use by providing brief counseling or even simple advice [10]. Italy is one of the member states of the WHO FCTC.

According to data from a survey of the Istituto Superiore di Sanità in collaboration with the Mario Negri Institute for Pharmacological Research average age of the first cigarette in Italy is at 17.6 for man and at 18.8 for female. Moreover, the study reveals that 16.2% of young people between the ages of 15 and 24 smoke [11].

Nurse students in Italy are mostly part of this age class. The majority of the European Countries, including Italy, have adopted the pictures health warnings on tobacco product in 2016 [12]. Health warnings constituted an important policy to inform on the health impact of adult smokers and in may 2016 the Italian Minister of Health issued a decree for the introduction the pictures health warnings on tobacco product [13].

The aim of the study was to assess tobacco-smoking habits among nursing students and how these are influenced by family members and cohabitants. A further objective was to investigate about the power of tobacco package health warning messages to implement the attitudes for smoking cessation.

Methods

The study employed a cross-sectional study design. In May 2018, an anonymous paper questionnaire was administered to nursing students attending the 3 year fulltime course at the University of Palermo, Italy, in the academic years 2015/2016, 2016/2017 and 2017/2018, after giving informed consent. Data collection was selfcompleted, anonymously and voluntarily. The students were not coerced in any way into participating, and it was clearly explained that participating in the survey would not have any repercussions. The questionnaire was created by the authors for this study and consists in two sections. The first section of the survey consists of 18 questions and asked for personal data, information on the course of study undertaken, on the perception of the economic and health status and on voluptuary habits. In the second part of the questionnaire, the Fagerström Tolerance Questionnaire (FTQ) [14] test was administered, this questionnaire was used in similar studies [15-19].

The FTQ consists in 6 questions with answers to which are assigned a score ranging. Based on the score the subjects are assigned to one of the following categories: 0-2 low dependence, 3-5 medium dependence, 6-7 high dependence, 8-10 very high dependence. The FTQ consist in 6 questions with answers to which are assigned a score ranging (Tab. I).

The FTQ has a scoring range of 0-10 points, with a score of 0 assumed indicative of minimum nicotine dependence and a score of 10 indicative of maximum nicotine dependence. Based on the score the subjects are assigned to one of the following categories: 0-2 low dependence, 3-5 medium dependence, 6-7 high dependence, 8-10 very high dependence. The FTQ correlates with nicotine dependence but connection between FTQ scores and withdrawal symptoms is weak [14].

The 18 questions asked in the survey and the categorization of the results of the Fagerström test are shown in Table I. The variable "age" was dichotomized in in "Age class \geq 22 years old and < 22 years old" considering that the mean age was 23.41 years old. For the statistical analysis, continuous variables were expressed as means and standard deviations (SD). For all qualitative variables absolute and relative frequencies have been calculated; categorical variables were analyzed by Pearson's Chi-square test (χ 2). A multivariable logistic regression model was used. Adjusted Odds Ratio (aOR) are presented, each independent variable is adjusted for all the other independent variables. The Statistical significance was established with p-value less than 0.05. Returned completed questionnaires were coded numerically, and the results were analyzed using the STATA statistical software version 14 [19]. Results are expressed as adjusted Odds Ratio (aOR) with 95% Confidence Intervals

Tab. I. Fagerström Tolerance Questionnaire. The final score is obtained from the sum of the individual scores of each question.

How soon after waking do you smoke your first cigarette?					
Within 5 minutes	3 points				
5-30 minutes	2 points				
31-60 minutes	1 point				
> 60 minutes	0 points				
Do you find it difficult to refrain from smoking where it is forbidden?	ng in places				
Yes	1 point				
No	0 points				
Which cigarette would you hate to give up?					
The first in the morning	1 point				
Any other	0 points				
How many cigarettes a day you smoke?					
10 or less	0 points				
11-20	1 point				
21-30	2 points				
31 or more	3 points				
Do you smoke more frequently in the morni	ng?				
Yes	1 point				
No	0 points				
Do you smoke even if you are sick in bed most	t of the day?				
Yes	1 point				
No	0 points				

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Results

Table II shows descriptive analysis of the sample. 301 nursing students agreed to the informed consent and completed the questionnaire (response rate of 61.17%). The average age of the sample is 21.88 years (SD ± 2.80), 63.12% of the interviewees are female, 100.00% were

Tab. II. Description of the sample (N = 301).

born in Italy, 45.51% are single, 41.20% were in-site students, 79.73 % report a low perceived economic status, 80.07% report a medium-high perceived health status. Regarding the smoking behavior: 32.89% currently smoke and only 35.05% of the whole sample think that warnings or pictures on cigarette packs can help to smoking cessation. The 63.12% of the sample live with their families and 59.46% currently live with smokers. At Fagerström test, the 67.68% of smokers have low dependence for nicotine, 25.25% have a medium dependence, 3.03% have a high dependence and 4.04% have a very high dependence.

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Variables		N (%)
Age class	≥ 22 years old	146 (48.50)
	< 22 years old	155 (51.50)
Gender	Female	190 (63.12)
	Male	111 (36.88)
Country of birth	Italy	301 (100.00)
	Other	0 (0.00)
Perceived economic status	Medium-high	61 (20.27)
	Low	240 (79.73)
Perceived health status	Medium-high	241 (80.07)
	Low	60 (19.93)
Are you engadged or single?	Engadged	164 (54.49)
	Single	137 (45.51)
Year of study	First	89 (29.57)
	Second	98 (32.56)
	Third	114 (37.87)
Are you in-site, commuter or off-site student?	In-site	124 (41.20)
	Commuter	65 (21.59)
	Off-site	112 (37.21)
Who are you living with now?	With my family	190 (63.12)
	Not with my fimily	111 (36.88)
Do you currently smoke?	No	202 (67.11)
	Yes	99 (32.89)
Warnings and pictures on cigarette packs can help stop smoking?	Yes	102 (35.05)
	No	189 (64.95)
Do you currently live with smokers?	No	120 (40.54)
	Yes	176 (59.46)
Does your father currently smoke?	No	209 (69.44)
	Yes	92 (30.56)
Does your mother currently smoke?	No	242 (80.40)
	Yes	59 (19.60)
Does your brother/sister currently smoke?	No	253 (84.05)
	Yes	48 (15.95)
Does your father smoked in the past?	No	178 (59.14)
	Yes	123 (40.86)
Does your mother smoked in the past?	No	235 (78.07)
	Yes	66 (21.93)
Does your brother/sister smoked in the past?	No	268 (89.04)
	Yes	33 (10.96)
Fagerström Tolerance Questionnaire (FTQ)	Low dependence	67 (67.68)
	Medium dependence	25 (25.25)
	High dependence	3 (3.03)
	Very high dependence	4 (4.04)
Age	21.88 (SE	$(2.80)^*$

*: mean Standard Deviation.

Table III shows the bivariate analysis. Only statistically significant results are reported in this section. 45.05% of male nursing students currently smoke compared to

25.79% of female students. 41.61% of students that are single currently smoke compared to 25.61% that are engaged in a relationship. To the question: "Warnings

 Tab. III. Bivariate associations between the students currently smoke or not and the variables of the questionnaire. Used Pearson's Chi-square test. Statistically significant results are highlighted in bold.

	Do you currently smoke?					
		No	١	/es	Total	P-
	N	%	Ν	%	N	value
Age class						
< 22 years old	108	69.68	47	30.32	155	
≥ 22 years old	94	64.38	52	35.62	146	0.529
Gender						<u></u>
Female	141	74.21	49	25.79	190	
Male	61	54.95	50	45.05	111	0.001
Perceived economic status					I	
Medium-high	37	60.66	24	39.34	61	1
	165	68.75	75	31.25	240	0.230
Perceived health status		00000		0.1120	2.0	
Medium-high	165	68 46	76	31 54	241	
	37	61.67	23	38 33	60	0.316
Are you engadged or single?	57	01.07	20	50.55	00	<u> </u>
	122	7/1 30	/12	25.61	164	1
Single	80	58 39	57	/1.61	137	0.003
Vear of study	00	50.55	57	41.01	157	
First	53	59 55	36	10.15	80	
Second	73	7/ /0	25	25.51	03	
Third	75	66.67	2J ZQ	23.31	11/	0.034
Are you a in-site, commuter or off-site student?	70	00.07	50	55.55	114	
	ол	67.74	40	Z2.26	124	1
Commuter	04	70.77	40	20.27	124 65	0.667
	40	64.20	19	29.25 ZE 74	442	0.005
When are you living with now?	12	04.29	40	55.71	112	
	171	70 EZ	FC	20.47	400	1
Not with my family	60	61.26	 /Z	29.47 zo 7/	190	0.099
Marpings and pictures on cigaratte packs can belo stop smoking?	00	01.20	45	30.74		
	00	07.25	17	40 7E	402	1
No	104	67.23 55.0Z	15	12.75	102	< 0.001
NO	104	55.05	00	44.97	109	
	07	60.47	77	70.07	420	1
No	00	69.17	57	Z4.00	120	0.558
Tes	110	65.91	60	54.09	170	
	470	CC F4	70	77.40	200	1
No	67	60.00	70	24 E2	209	0.737
Tes	05	00.40	29	51.52	92	
	400	CO 40	74	70.50	242	1
	7108	69.42	74	50.58	242	0.084
Yes	54	57.65	25	42.57	59	
Does your prother/sister currently smoke?	470	CO 57	77	70.47	057	1
	176	69.57	//	50.45	255	0.037
Yes	26	54.17	22	45.83	48	
Does your father smoked in the past?	407	00.40		70.00	470	1
No	123	69.10	55	30.90	1/8	0.376
Yes	/9	64.23	44	55.//	123	
Does your mother smoked in the past?	4.00	74.01	~~~	00.00	07-	1
NO	169	/1.91	66	28.09	255	0.001
Yes	33	50.00	33	50.00	66	
Does your brother/sister smoked in the past?						T
No	190	70.90	78	29.10	268	< 0.001
Yes	12	36.36	21	63.64	33	

and pictures on cigarette packs can help stop smoking?" 44.97 % of smokers think that warnings or pictures on cigarette packs cannot help to smoking cessation compared to 12.75% of smokers that think the opposite. Furthermore, 45.83% of smoker have a brother or sister that currently smoke compared to 30.43% of smoker that have a brother or sister non-smokers. 50.00% of smokers have a mother smoked in the past respect to 28.09 % of smokers who have a mother that has never smoked. Finally, 63.64% of smokers have a brother or sister that smoked in the past compared to 29.10% of smokers who have a brother or sister that have never smoked.

Table IV shows the adjusted Odds Ratio (aOR), considering as a dependent variable: "I currently smoke", the statistically significant independent variables associated are: "Male gender" (aOR 2.09, 95% CI 1.13-3.87, p = 0.018), "Single" (aOR 2.06, 95% CI 1.14-3.73, p = 0.016), "Second year of study of the degree course in nursing" (aOR 0.46, 95% CI 0.21-0.99, p = 0.048), "Third year of study of the degree course in nursing"

(aOR 0.43, 95% CI 0.18-0.99, p = 0.049), "Don't think that warnings and pictures on cigarette packs can help stop smoking" (aOR 6.38, 95% CI 2.99-13.61, p < 0.001), "Mother smoked in the past" (aOR 2.25, 95% CI 1.12-4.59, p = 0.023) and "Brother or sister smoked in the past" (aOR 5.50, 95% CI 2.09-14.50, p = 0.001).

Discussion

It is crucial, especially among youth, the quality of information, the modes of communication, the development of critical skills towards a participatory and nonimposed choice of lifestyles and healthy behaviors. Young university students represent a unique population on which the interest of public health researchers and policy is focused to promote healthy lifestyles, well-being and increase the level of knowledge. Young people utilize a diverse variety of resources to acquire health

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Tab. IV. Multivariable logistic regression. Adjusted Odds Ratio (aOR) are presented. Each independent variable is adjusted for all the other independent variables. Based on 289 observations. Statistically significant results are highlighted in bold.

	I currently sm	oke			
Indipendent variables		aOR (95% CI)	P-value		
Age class	≥ 22 years old	1	0.400		
	< 22 years old	1.68 (0.80-3.51)	0.169		
Gender	Female	1	0.040		
	Male	2.09 (1.13-3.87)	0.018		
Perceived economic status	Medium-high	1	0.000		
	Low	1.04 (0.51-2.13)	0.906		
Perceived health status	Medium-high	1	0.074		
	Low	1.01 (0.50-2.05)	0.971		
Are you engadged or single?	Engadged	1	0.016		
	Single	2.06 (1.14-3.73)	0.016		
Year of study	First	1			
	Second	0.46 (0.21-0.99)	0.048		
	Third	0.43 (0.18-0.99)	0.049		
Are you in-site, commuter or off-site student ?	In-site	1			
	Commuter	0.69 (0.31-1.52)	0.360		
	Off-site	0.84 (0.29-2.47)	0.757		
Who are you living with now?	With my family	1	0 262		
	Not with my family	1.65 (0.56-4.88)	0.562		
Warnings and pictures on cigarette packs can help stop smoking?	Yes	1	10.001		
	No	6.38 (2.99-13.61)	< 0.001		
Do you currently live with smokers?	No	1	0.070		
	Yes	0.93 (0.47-1.85)	0.656		
Does your father currently smoke?	No	1	0.546		
	Yes	0.81 (0.40-1.638)	0.540		
Does your mother currently smoke?	No	1	0.700		
	Yes	1.42 (0.65-3.08)	0.560		
Does your brother/sister currently smoke?	No	1	0.904		
	Yes	1.11 (0.47-2.61)	0.004		
Does your father smoked in the past?	No	1	0.679		
	Yes	1.14 (0.62-2.09)	0.078		
Does your mother smoked in the past?	No	1	0.027		
	Yes	2.25 (1.12-4.59)	0.023		
Does your brother/sister smoked in the past?	No	1	0.001		
	Yes	5.50 (2.09-14.50)	0.001		

information, including Internet, television, family doctor, books, magazines, friends and family.

smoking is one of the Tobacco most serious public health problems in the world. According to the WHO in the European region, people who die each year from smoking-related illnesses are 1.6 million, but in the absence of drastic control measure the figures are set to rise further [4]. This means, that Tobacco smoking is compared to a chronic disease manifesting its damage over a long period, given the latency between the beginning of habit and the onset of the disease caused.

This paper reports on a descriptive survey research design that examined nursing students' behaviour, knowledge and attitudes towards tobacco cessation among nursing students attending the 3 year full-time course at the University of Palermo.

In comparison to recent nursing students based studies, smoking prevalence in our sample was similar to other European population of healthcare students (45.05% and 25.79% of male and female nursing students are a smoker) [20].

Smokers compared to non-smokers believe that the damage caused by smoking is not immediate, moving the onset of both moderately severe and very serious diseases later, delaying their onset; this perception, which does not correspond to reality, called "Onset time delaying effect", highlights a lack of understanding of the negative consequences that smoking has on people's health and how quickly they can occur. The "Onset time delaying effect" has been defined as a new risk factor implicated both in the development of tobacco addiction and in the maintenance of such behavior, in fact it seems to be a possible risk factor in the development and maintenance of tobacco addiction [21].

WHO/Europe's new evidence brief reviews the effects of large pictorial warnings on the packaging of tobacco products on knowledge and behaviour. Studies have shown that combined written and graphic health messages on the packaging of tobacco products are more effective than text-only warnings for increase attempts to quit and decrease smoking uptake [22]. For example, in a survey conducted in Canada in 2001-2003, 44% of smokers reported that pictorial health warnings had increased their motivation to quit [23]. In Romania, combined text and pictorial warnings prompted 31% of smokers to try to quit [24]. In the United Kingdom, the Department of Health has estimated that the introduction of larger text-warnings prompted an additional 2,000-4,000 calls to the toll-free number for the National Health Service smoking helpline, which was provided on tobacco packaging before the introduction of pictorial health warnings [25]. However, in our study 44.97 % of smokers affirm that warnings and pictures on cigarette packs cannot help stop smoking and they have a greater risk of thinking that cigarette package health warnings do not help to smoke cessation (aOR 6.38, 95% CI 2.99-13.61, p < 0.001). The influence of family and friends on attitudes of the young to smoking it has been widely demonstrated in the literature [26] especially in the

evolutionary age. As shown in Table IV, our sample is strongly influenced by family members who smoke. The risk of becoming a smoker is higher among those with a mother that smoked (aOR 2.25, 95% CI 1.12-4.59, p = 0.023) and a brother or sister that smoked in the past (aOR 5.50, 95% CI 2.09-14.50, p = 0.001).

To underline the greater awareness acquired with university studies about the damages caused by smoking, it is possible to see that with the increase in the years of study there is a lowering of the risk of smoking. Second (aOR 0.46, 95% CI 0.21-0.99, p = 0.048) and third (aOR 0.43, 95% CI 0.18-0.99, p = 0.049) year of study of the degree course in nursing belong to lower reference classes to the risk of smoking compared to first year of study.

The study has some limits therefore please consider that the findings represented here in should be interpreted with a degree of caution. First, it is a cross-sectional study, several independent variables could not be evaluated for the cause and effect associations. Second, the questionnaire included only a limited number of questions and probably some factors that could be associated with smoking behavior, attitudes toward cessation and nicotine dependence were not taken into consideration. Moreover, being addressed to students of a single University campus, it does not allow to generalize the results to other Universities despite number of the sample being relevant compared to number of students of the three years of the degree course in nursing.

Conclusions

Although tobacco use has declined markedly since 2000, according to a new WHO report, the reduction is insufficient to meet globally agreed targets aimed at protecting people from death and suffering from cardiovascular and other non-communicable diseases [27]. Tobacco kills over 7 million people each year, despite the steady reduction in tobacco use globally, as shown in WHO's new Global Report on Trends in the Prevalence of Tobacco Smoking 2000-2025 [28].

Health professionals' smoking habit may deter them from helping their patients, therefore cessation training for student health professionals may be a significant contribution towards tobacco use control. All of this could potentially have an impact on future professional practice by helping patients who smoke quit by either interviewing, simple advice or referrals to cessation clinics [29].

Our results show significant gender-related differences in smoking habits increased by having family members who smoke.

Our study results show relatively high smoking prevalence among nurse students who attending the University of Palermo. Our results show significant gender-related differences regarding smoking habits and strong influenced by family members and cohabitants, furthermore it is shown that for smokers the warnings and images on cigarette packets do not help to stop smoking (aOR 6.38, 95% CI 2.99-13.61, p < 0.001). So far, unfortunately, little public attention was paid to these potential and future health promoters. As a reaction to this situation, it is essential that programs and preventive interventions be increased also using new forms of communications. In this context, growth in health literacy should be the way to increase health and comprehension the risk for tobacco smoking as demonstrated in international studies. As reported by Sreedharan et al., nurses have a positive attitude in providing tobacco cessation care to their patients and they can utilize their unique knowledge and know-how to promote tobacco cessation and prevent the spread of this public health crisis [30]. The information and training campaigns aimed at promoting the correct lifestyles and risks linked to wrong habits are important for educating in order to reduce the costs of public health. Students and graduate nurses have an influential role in modifying patient behavior in order to assist them in smoking cessation. Students need to be aware of current knowledge in the smoking cessation field and students who smoke should know how to access the resources to assist them in smoking cessation.

Data from literature emphasize the importance of educational interventions and the efficacy of current smoking cessation methods and practices with a view to helping hospitalized patients to cease smoking. Nurses are clearly in a privileged position to assist hospitalized patients in establishing and implementing a personal plan to help them quit smoking [31].

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Conflict of interest statement

None declared.

Authors' contributions

AF, SP, OES and DG conceived, designed, coordinated and supervised the research project. AF, SP, OES and DG collected samples. AF, SP, OES performed the data quality control, optimized the informatics database, performed the statistical analyses and evaluated the results. AF, SP, OES and DG wrote the manuscript. All Authors revised the manuscript and gave their contribution to improve the paper. All authors read and approved the final manuscript.

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ORIGINAL ARTICLE

An epidemiological evaluation of predictors of overweight and obesity in Garhwal region of Uttarakhand

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Keywords

Predictors • Overweight and obesity • WHO STEPS

Summary

Introduction. Now a day, obesity has become a chronic disorder affecting the larger population than any other disease in the world, which made its presence felt first in the Northern Hemisphere, and has now taken a pandemic look affecting practically almost all the countries of the globe.

Method. A cross sectional study with a sample size of 632 was carried out. Multistage stratified random sampling and "Kish" method was applied for selection of study area and selection of study subjects (21-60 years). WHO STEPS for NCD Risk Factor Surveillance, was used to gather the necessary data. Percentage, Chi square, & logistic regression analysis was done and significant level was taken at p < 0.05.

Results. As per Asia Pacific classification 16.0% & 33.4% of subjects while as per WHO classification 24.5% & 8.9% of subjects

Introduction

Obesity is an intricate condition, with severe social and psychological extensity, that influence nearly all ages and socio-economic groups and endanger to devastate both developed and developing countries [1]. In the course of Millennium Development era from 1990 to 2015, India witnessed a rapid transformation in its population's lifestyle [2, 3]. Obesity and overweight remains the world's fifth cause of mortality i.e. every year 2.6 million people die due to this disorder. Additionally, obesity and overweight attributed to 44% of diabetes cases, 23% of ischemic heart diseases and 7-41% of cancers [4]. There has been a sudden increase in overweight and obesity close with an unrelenting burden of undernutrition [5]. In 2015, India along with China, recorded the maximum number of obese children globally, which indicates an even greater burden of overweight and obesity in the near future [1]. Very few national studies provide confined reports on dynamics of overweight or obesity in India [6].

Several anthropometric measures have been used as proxy indicators of central or whole-body adiposity in clinical practice. The strong association between obesity and cardio-metabolic disorders motivated the development of several techniques used to determine body adiposity, such as body mass index (BMI), waist circumferwere found to be overweight and obese respectively. It was nearly 2 times higher in urban males. Central obesity was more commonly observed in urban subjects as compared to rural. At risk Waist hip ratio was recorded in 55.9% and high Weight height ratio was recorded in 66.8% of total subjects. All the predictors showed higher percentages in females of urban area and increased with the rise in age.

Conclusion. The present study reveals that, there is high prevalence of overweight and obesity in the study population. Certainly, there has been a considerable shift in their dietary and lifestyle profile. there appears to be an urgent need to develop suitable health strategies as well as intervention programmes for combating the prevalence of overweight and obesity.

ence (WC), waist-hip ratio (WHR) and waist-to-height ratio (WHtR) [7-9]. Although BMI is the most commonly used parameter for evaluation of obesity, but as a measure for identification of body composition as well as regional body fat distribution is not reliable because it is a marker of general obesity rather than central obesity [10]. Whereas, diagnosis of central obesity which correlates with abdominal and the visceral accumulation of adipose tissue and development of subsequent metabolic abnormalities and cardiovascular morbidity is more important [11]. Visceral fats are linked with lipolytic activity and reduce insulin activity through increasing fatty acids [10, 12]. Among many anthropometric parameters, WHtR and WC are better measures of visceral and abdominal fat distribution [7, 10]. Abdominal adiposity is one of the important factors which alone can predict the risk of comorbidities among metabolic conditions of Metabolic Syndrome [13]. All these predictors of overweight and obesity are useful to provide important information on various preventable NCDs.

Now a day, obesity has become a chronic disorder affecting the larger population than any other disease in the world, which made its presence felt first in the Northern Hemisphere, and has now taken a pandemic look affecting practically almost all the countries of the globe. A number of socio-demographic, biological, socio-cultural and behavioural factors have been observed

to influence overweight and obesity [14]. However, the burden of obesity in this region is estimated by very few studies, and that too using only one parameter i.e. BMI, other parameters were not used to estimate its real burden in the state where urbanization and industrialisation is increasing rapidly and may have adversely affected the situation. There is scarcely any study in this region that have focused on multiple predictors of obesity and socio-demographic factors affecting the same.

Therefore, the need arises to estimate the burden of overweight and obesity in hilly terrains of Uttarakhand and study the influence of the different demographic, biological, and socio-cultural factors that have the potential to influence the prevalence of overweight and obesity among Indian adults.

This study was designed with the following objectives:

- 1. To evaluate the predictors of overweight and obesity in the study population.
- 2. To determine the association of socio-demographic variables with predictors of overweight and obesity.

Methods

This analysis is a part of data collected from a crosssectional survey of non-communicable disease risk factors which was carried out in Dehradun in year 2012 for 12 months. Multistage Stratified Random Sampling has been used for the selection of study area.

RURAL SAMPLE

There are six blocks in district Dehradun, out of which one block was chosen for the study purpose. It comprises of five sub blocks, out of which one was selected randomly which consists of 19 villages, of which (10%) i.e. 2 villages were randomly selected to achieve the required sample population.

URBAN SAMPLE

There are four sub zones in district Dehradun, out of which one was selected for study purpose. It is constituted by 20 wards out of which (10%) i.e. two wards were randomly selected to get the required sample population. An adequate sample was drawn to carry out the present study. The sample size was calculated following the formula $n = 4 \text{ pq} / L^2$, where p is prevalence of NCDs = 41% [15], d is allowable error = 10% of p i.e. 4.1, q = 100 - p = 59%, confidence interval of 95% and non-response rate of 10%. The final sample size came out to be 632 and was equally allocated to rural and urban areas i.e.316 subjects in each area.

Study houses were selected by systematic random sampling and sampling interval (SI) i.e. in rural area (total families 731) every 2nd house and in urban area (total families1227) every 4thhouse was visited.

Keeping in view that prevalence of NCDs and its risk factors are increasing in younger age group individuals aged between 20 to 60 years were selected for the study. In every selected household "Kish" method was applied for the selection of study subjects [16].

Ethical consideration: Ethical clearance from the institution-HIHTU/HIMS/ETHICS2012/95 dated 1.9.2012 HIHT University and informed consent from the respondents was obtained before the study.

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All Anthropometric Measurement were taken using WHO Steps guidelines [17].

BMI: The BMI was calculated using the following formula: BMI (kg/m2) = Weight (kg)/ Height (m^2) .

The WHO had proposed a redefined criterion for overweight and obesity among Asian populations and this was used to evaluate the prevalence of overweight and obesity in the present study. The BMI cut-off points utilized for the assessment of overweight and obesity were $\geq 23.00 \text{ kg/m}^2$ and $\geq 25.00 \text{ kg/m}2$ respectively. For combined overweight-obesity, the cut-off point was $\geq 23.00 \text{ kg/m}^2$ [18].

Waist circumference: Cut-off levels for Indians as per South Asia Pacific Guidelines for males it is \geq 90 cms, for females it is \geq 80 cms [19].

Waist height ratio: For both male and female cut-off value of 0.5 was taken [20].

Waist hip ratio: For females cut-off was taken as 0.81 and high risk as ≥ 0.85 ; for males cut-off was taken as 0.96 and high risk as ≥ 1.00 [19].

Statistical analysis: Percentage was calculated for all the variables, Chi square was applied for categorical variables, and binary logistic regression analysis was done using SPSS version 22.0 to develop results. Graphs were made using Microsoft Excel. Significant level was assumed at p < 0.05.

Results

A total of 632 individuals were contacted and interviewed during this survey with 254 (i.e. 40.2%) males and 378 (i.e. 59.8%) females. The overall male/female ratio was 40:60 (Fig. 1).

Distribution of different anthropometric indicators of overweight and obesity is represented in Figure 2. All predictors i.e. BMI, waist circumference, waist hip ratio, and waist height ratio have shown high prevalence in the study population. Females have higher prevalence of all anthropometric indicators as compared to males. Nearly half (49.4%) of the total studied subjects had BMI of 24.99kg/m². Prevalence of central obesity was almost double in female subjects i.e. 66.1% than their male counterparts (29.1%).

Prevalence of predictors of overweight and obesity with respect to different socio-economic, demographic and lifestyle related variables are shown in Tables I and II. It has been observed that the prevalence of all indicators increased with the rise in age. This difference was found to be statistically significant (P < 0.001). Most of the urban residents (BMI $\ge 25-45.9\%$; WC-65.2%; WHR-64.9%; WHtR-79.1%)were having high indicators as compared to rural and this came out to be statistically significant. Relation of Education with indicators showed that Illiterates were mostly having high predictors except for BMI which was almost equal in all groups. Mostly divorced/





separated and widow were suffering from obesity and it was also proven statistically. Most of the obese and overweight were shopkeepers or were unemployed. In the study population, people with overweight and obesity were in a higher percentage in the middle socioeconomic class than the lower socioeconomic class as per modified BG prasad classification in rural area and Kuppuswamy in urban area updated for time of study.

EXP (B): EXPONENTIATION OF B COEFFICIENT, ODDS RATIO

A Binary logistic regression model was fitted onto the data to observe the odds for the socio-economic, demographic and lifestyle related variables to an individual being overweight and obese (Tab. III). The results indicated that those individuals belonging to the higher monthly income (middle class) and urban residents appeared to have higher significant risks of being overweight. The results further indicated that there were significant effects of sex (female), age group (41-60 years) monthly income, marital status (divorced/widow/separated) to an individual being obese. No significant effects of occupation and education were reported in logistic analysis.

Discussion

The burden of overweight and obesity is nonuniform, it varies region-wise and state-wise. The most considerable factors are geographical conditions, lifestyle changes and dietary modifications. The past few decades have shown increase in prevalence of obesity at a faster pace. Migration of population from hard to reach areas in hills to more accessible areas in foot hills, growing rates of

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Variables		Number of individuals (N = 632)	r of Jals BMI 32)				
			Normal (18.5-23kg/m2)	Overweight (23-24.99 kg/m²)	Obesity (≥ 25 kg/ m²)	χ²; p-value	
Age	20-40 yrs	177	203 (61.3)	54(16.3)	74 (22.4)	41.08; 0.001	
	41-60 yrs	139	117 (38.9)	47 (15.6)	137 (45.5)		
Sex	Male	254	149 (58.7)	35 (13.8)	70 (27.6)	11.01; 0.004	
	Female	378	171 (45.2)	66 (17.5)	141 (37.3)		
Area	Rural	316	205 (64.9)	45 (14.2)	66 (20.9)	56.09; 0.0001	
	Urban	316	115 (36.4)	56 (17.7)	145 (45.9)		
Education	Illiterate	138	61 (44.2)	30 (21.7)	47 (34.1)	9.52; 0.147	
	Up to 8 th	157	92 (58.6)	19 (12.1)	46 (29.3)		
	Up to 12 th	169	88 (52.1)	25 (14.8)	56 (33.1)		
	Graduation	168	79 (47.0)	27 (16.1)	62 (36.9)		
Marital status	Never married	91	70 (76.9)	13 (14.3)	8 (8.8)	42.52; 0.000	
	Married	496	238 (48.0)	80 (16.1)	178 (35.9)		
	Divorced/ widowed/ separated	45	12 (26.7)	8 (17.8)	25 (55.6)		
Occupation	Employed*	114	57 (50.0)	19 (16.7)	38 (33.3)	20.55; 0.024	
	Agriculture work	118	76 (64.4)	18 (15.3)	24 (20.3)		
	Self-employed/ Shopkeeper	71	29 (40.8)	8 (11.3)	34 (47.9)		
	Student	22	12 (54.5)	4 (18.2)	6 (27.3)		
	Household/ domestic work	270	132 (48.9)	44 (16.3)	94 (34.8)		
	Unemployed	37	14 (37.8)	8 (21.6)	15 (40.5)		
Socio Economic Status	Upper Middle	50	26 (52.0)	9 (18.0)	15 (30.0)	47.78; 0.0001	
	Lower Middle	185	58 (31.4)	34 (18.4)	93 (50.3)		
	Upper Lower	234	129 (55.1)	37 (15.8)	68 (29.1)		
	Lower	163	107 (65.6)	21 (12.9)	35 (21.5)		

Tab. I. Association of BMI with socio-demographic determinants.

* Government or private job

industries and less physical activity with dietary modifications, has resulted in rising burden of overweight and obesity in this north western district of Uttarakhand. The evaluation of predictors of overweight and obesity and their association with sociodemographic variables have been established during the study.

As per WHO classification (BMI \ge 30 kg/m²) obesity was found to be relatively low i.e. in 8.9% of the population, however Asia pacific classification ($\geq 25 \text{ kg/m}^2$) showed a higher percentage (33.3%). Overweight and obesity i.e. BMI of ≥ 23 kg/m² was reported among 49.4% of the subjects, which was comparable to the findings of different several studies survey in Kerala [21-23]. On the contrary lesser prevalence of grade I overweight (BMI \geq 25-29.9 kg/m²) as compared to our study was reported by IDSP survey in Madhya Pradesh, Maharashtra, Mizoram, UK and Tamil Nadu [23] while Thankappan et al reported higher prevalence of overweight [24]. The

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reason of difference in prevalence may be due to adoption of WHO classification rather than Asia pacific classification in their study.

Among biological factors, gender is one of the substantial factor, affecting weight status. In the present study overweight and obesity (BMI $\ge 23 \text{ kg/m}^2$) was observed in more than half of the females and in 41.3% of males. Many other studies have supported our findings, that females are more prone to obesity/ overweight [25, 26]. In females, extra energy is converted into fat. This pattern of energy usage, or "nutrient partitioning," in females contributes to further positive energy balance and fat deposition [27]. Secondly many Indian studies have suggested that this gender-based difference is due to less physical activity among women as compared to men across all ages [2, 28]. Thirdly in India the society is male dominating especially in rural areas, where women have a low level

Tab. II. Association of WC, WHR and WHtR with socio-demographic determinants.										
		Number of individuals	Waist circu (W	umference (C)	W	aist Hip Rat (WHR)	io	Waist Hei (WF	ght Ratio ItR)	
Variables		(N = 632) High risk	χ²; p-value	Medium risk	High risk	χ²; p-value	High risk	χ^{2} ; p-value		
Age	20-40 yrs	177	127(38.4)	46.27;	72 (21.8)	165 (49.8)	10.12;	176 (53.2)	57.94;	
	41-60 yrs	139	197 (65.4)	0.0001	49 (16.3)	188 (62.5)	0.006	246 (81.7)	0.0001	
Sex	Male	254	74 (22.1)	83.26;	74 (29.1)	41 (16.1)	292.13;	142 (55.9)	22.60;	
	Female	378	250 (66.1)	0.0001	47 (12.4)	312 (82.5)	0.0001	280 (74.1)	0.0001	
Area	Rural	316	118 (37.3)	49.04;	59 (18.7)	148 (46.8)	32.06;	17 2(54.4)	43.39;	
	Urban	316	206 (65.2)	0.0001	62 (19.6)	205 (64.9)	0.0001	250 (79.1)	0.0001	
Education	Illiterate	138	92 (66.7)	20.54;	19 (13.8)	107 (77.5)	49.43;	112 (81.2)	18.25;	
	Up to 8 th	157	64 (40.8)	0.0001	28 (17.8)	79 (50.3)	0.0001	96 (61.1)	0.0001	
	Up to 12 th	169	82 (48.5)		30 (17.8)	78 (46.2)		102 (60.4)		
	Graduation	168	86 (51.2)		44 (26.2)	89 (53.0)		112 (66.7)		
Marital	Never married	91	17 (18.1)	55.80;	25 (27.5)	23 (25.3)	54.09;	36 (39.6)	44.11;	
status	Married	496	271 (54.6)	0.0001	94 (19.0)	292 (58.9)	0.0001	345 (69.6)	0.0001	
	Divorced/ widowed/ seperated	45	36 (80.0)		2 (4.4)	38 (84.4)		41 (91.1)		
Occupation	Employed*	114	62 (54.4)	11.98;	16 (14.0)	69 (60.5)	16.071;	74 (64.9)	8.250;	
	Agriculture work	118	44 (37.3)	0.035	35 (29.7)	51 (43.2)	0.098	67 (56.8)	0.143	
	Self employed/ Shopkeeper	71	41 (57.7)		14 (19.7)	41 (57.7)		50 (70.4)		
	Student	22	13 (59.1)		6 (27.3)	12 (54.5)		15 (68.2)		
	Household/ domestic work	270	144 (53.3)		44 (16.3)	160 (59.3)		188 (69.6)		
	Unemployed	37	20 (54.1)		6 (16.2)	20 (54.1)		28 (75.7)		
Socio	Upper middle	50	29 (58.0)	46.57;	9 (18.0)	32 (64.0)	23.75;	32 (64.0)	30.194;	
economic	Lower middle	185	130 (70.3)	0.0001	33 (17.8)	123 (66.5)	0.001	151 (81.6)	0.0001	
status	Upper lower	234	107 (45.7)		46 (19.7)	126 (53.8)		150 (64.1)		
	Lower	163	58 (35.6)		33 (20.2)	72 (44.2)		89 (54.6)		

* Government or private job

of autarchy, inadequate social support, and lack of safe working environment which inhibits them form working outside [29, 30]. Other reasons may be increasing sedentary lifestyle, gestational weight gain which tends to increase and retain with further pregnancies [31, 32]. Due efforts should be undertaken to decrease overweight or obesity in females to make an impact on overall prevalence. Both marriage and divorce can act as weight shocks leading people to put on extra weight. Overall, transitions into marriage appears to be associated with increase in weight, whereas transitions out of marriage shows weight loss. Weight gain after marriage or cohabitation may occur because of increased opportunities for eating due to shared, regular meals and larger portion sizes, more social obligations, more visits to social gatherings which also leads to frequent eating of outside food [33-37]. However, present study has reported increase in body weight both after marriage and divorced/widowed status. Another study done in northeast China also reported similar association of marriage and out of marriage with obesity [38]. This may be due to depression and loneliness, which encourages compensation in the form of unhealthy dietary habits or may be due to racial differences, the exact mechanism is yet to be explored and further research is required to establish any association.

In the present study, obesity was more than double in urban area (45.9%) as compared to rural area (20.9%). Bhardwaj SD et al in rural Nagpur reported much lower prevalence of overweight as reported in present study. The difference might be due to use of different classifications as reference. In both the studies proportion of females was more than males as regard to overweight [39]. The prevalence of overweight and obesity was higher among graduates and illiterates as shown by all predictors. The explanation for this can be increasing sedentary lifestyle with increasing education or unemployment due to illiteracy leading to depression and sedentary life style. Regression analysis showed that education and occupation had no significant association with body weight, the findings needs further evaluation as this was a cross sectional study and our ability to establish causal inference is limited, and so we are unable to comment whether or not these factors have association with obesity or not.

Variables	$BMI \ge 23kg$	g/m²		Waist circumference (WC)				Waist hip ratio (WHR)		
	Exp (B) (BMI)	CI	P-value	Exp (B) (WC)	CI	P-value	Exp (B) (WHR)	CI	P-value	
Area										
Rural	1	-	-	1	-	-	1	-	-	
Urban	2.290	1.468-3.574	0.0001	2.336	1.432-3.809	0.001	3.048	1.607-5.783	0.001	
Age										
20-30 YRS	1	-	-	1	-	-	1	-	-	
40-60 YRS	2.487	1.713-3.610	0.0001	2.751	1.778-4.256	0.0001	1.075	0.629-1.838	0.07	
Sex										
Male	1	-	-	1	-	-	1	-	-	
Female	1.550	1.065-2.255	0.022	5.221	3.381-8.063		19.399	11.042-34.05	0.0001	
SEC										
Lower	1	-	-	1	-	-	1	-	-	
Upper lower	1.165	0.737-1.842	0.514	1.181	0.713-1.958	0.518	1.037	0.574-1.875	0.904	
Lower middle	2.427	1.415-4.158	0.001	3.134	1.722-5.705	0.0001	1.55	0.748-3.232	0.237	
Upper middle	1.201	0.605-2.385	0.601	2.285	1.068-4.889	0.033	1.898	0.717-5.024	0.197	
Marital status										
Never married	1		-	1	-	-	1	-	-	
Married	3.686	2.088-6.505	0.0001	3.703	1.91-7.17	0.0001	2.870	1.466-5.620	0.002	
Divorced/widow	10.888	4.468-26.779	0.0001	10.443	3.546-30.75	0.0001	3.352	0.869-12.925	0.07	

Tab. III. Binary logistic regression analysis of predictors of overweight and obesity with respect to socio demographic determinants.

The present study reiterates the findings of other studies establishing the relationship between wealth and overweight and obesity. The people earning more are usually having sedentary lifestyle, consumption of energy dense food, less physically active and more stress, leading to vicious cycle of weight gain [2, 40].

In present study, the prevalence of high WC was observed to be 51.3% and high risk WHR was 55.9%. High WC was found more among females as compared to males. Mehan, 2006 and Iyer et al, 2011 in their studies reported comparable prevalence for high WC and high WHR including a higher prevalence among females [21, 22]. Other authors have also reported high prevalence of WHR in their study population [41, 42]. Thankappan et al reported prevalence of high waist circumference in rural area that was comparable to present study while a lower prevalence was reported in urban area. The variation might be due to difference in reference values for high waist circumference i.e. > 90cm in males and > 85cm in females [24]. Deshmukh PR in his study from rural Wardha reported comparatively lower prevalence of high risk WHR [20]. This might be due to the different geographical locations and there might be other confounding factors in our study like more number of females who are more predisposed to fat accumulation, unbalanced diet and low physical activity.

The main strengths of our study were well planned methodology with good statistical analysis and accurate physical measurements which increases the validity of the study. However, some limitations were also existed as it was a cross sectional study and data was self-reported so recall bias or non-willingness to give accurate information may have affected the accuracy of the study.

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Conclusions

The present study reveals that, there is a high prevalence of overweight and obesity in the study population. Certainly, there has been a considerable shift in their dietary and lifestyle profile. The dietary profile is changed to a mixture of rural and urban diets, with higher consumption of saturated fat and low intake of fibre. Further, most of these people used to be hard working farmers in the fields in their villages, and have changed to sitting around on the roadside as vendors, thus radically changing their activity profile. Moreover, there appears to be an urgent need to develop suitable health strategies as well as intervention programmes for combating the prevalence of overweight and obesity.

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Conflict of interest statement

None declared.

Authors' contributions

DS, JS, AKS have conceived, designed and coordinated the research. Ds has administered the questionnaire and

collected the data. DS, RJ and JS have formulated the tables and helped in analyses of the data. All authors have contributed in the review of manuscript. All authors have helped in revision of manuscript.

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ORIGINAL ARTICLE

Improving the quality of communication during handover in a Paediatric Emergency Department: a qualitative pilot study

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Keywords

Paediatric Emergency Department • Handover • Communication failures • Patient safety • Qualitative study

Summary

Introduction. There is a dearth of literature that specifically addresses the handover reporting process among healthcare staff working in children's Emergency Department (ED). Widespread gaps in service provision, such as gaps in communication in handover reports to ambulance staff have been noted in the general literature on the topic. There are also improvements observed in handover when a structured mnemonic was encouraged. Structured reports improve communication, safety and may reduce medication errors. Thus, the improvement of handover reporting in children's ED has important implications for children's healthcare practice. However, little is known about communication processes during handover reports in Italian children's ED or its consequences for errors or risks.

Introduction

Communication with children and their families is the cornerstone of family centred care [1]. Indeed, communication is an important skill in a healthcare process that ensures effectiveness, efficiency, patient satisfaction, and patient safety, in a system that strives for quality [1, 2]. Although communication is often considered primarily in the context of nurse/patient relationships, communication encompasses a wide range of skills and tasks that contribute to good patient care [3]. This includes patient assessment; education and information giving; passing information to other healthcare colleagues and verbal reporting after shifts [3]. So, it is much more than creating positive relationships with people or information passing, rather it is an all encompassing contributory factor to safety in healthcare [2, 4]. Indeed, when patient information is not clear or omitted it is "a major cause of patient dissatisfaction, and... [also] one of the largest causes of untoward incidents in the health service" [5]. A recent systematic review confirms that good communication [6] is fundamental to patient safety in ED, and one legal case study demonstrates that when communication between healthcare professionals' is not effective the consequences on patient safety and outcome can be very severe [7]. Medication errors, one of the most frequently occurring ED communication errors in the literature, are more likely to occur in this context [2].

Methods. A qualitative description methodology was used. Semistructured interviews were used to collect data from five children's ED nurses. Thematic content analysis was used to identify common themes.

Results. *Emergent themes were: interpersonal influences on handover; structural issues; and local contextual factors.*

Conclusions. The findings of this pilot study prompted the need for a standardized tool that improves communication during handover. As such, standardizing the communication process during handover could be effectively resolved by using a mnemonic tool adapted for handover in a paediatric emergency department.

The children's emergency department (ED) presents an additional challenge [2]. It is a high paced area where children and their families are often distressed and/or critically ill presenting with complex healthcare needs. In a busy ED, nurses will interact often with 100's of patients and families each week [2]. In addition to the regular ED healthcare team, their responsibilities pervade across GP and ambulance services. Clear reporting (both verbal and written) is a priority in these circumstances [8]. Importantly the "risk of making mistakes [in the ED context] is high" [2].

The ED experience can be divided into distinct phases. This includes the child's arrival to ED, assessment, transfer, and discharge [2]. Keeping track of the child's progress, while having a variety of in-hospital tests for example requires effective traceability communication [2]. A recent prospective observational examination of more than 400 communication events in one ED in Italy was revealing [2]. There were more than 22 communication failure processes. The most recurrent of these was during handover reports [2]. The issue of communication failures within ED handover reports was also recently highlighted in an American observational study (1,163 patient handovers during 130 ED shifts), which revealed significant vital sign communication errors, namely "the failure to communicate an episode of medical-recorddocumented hypotension or hypoxia" [9]. In this case,

errors were not related to ED overcrowding or interruptions.

One further mixed method study arising from some of the authors' work in an Italian context explored information passing by nurses during ED handover report [10]. While most of the nurses surveyed (74%, n = 54) believed that they received comprehensive handover, for many this was limited to medical diagnosis only. This is similar to Moharari [11] findings. Moharari and Costa (both found that within handover reports information that was often limited to medical diagnosis or reason for hospitalisation (without past history or socio-economic/vulnerability circumstance information) resulted in communication deficits and failures [10]. Interestingly, technology, while usually perceived as facilitating better communication, often hindered communication in these circumstances.

Certainly, handover as a key ED facet of communication has caused issues for nurses in other countries, and the literature is replete with discussions concerning this process and how to improve it. ED handover receives less attention and Bruce and Suserud's [12] interviews with nurses confirm Costa's findings that "ideal handover" (from the ambulance nurse to the ED nurse in this case) needs to be comprehensive and holistic. Conversely the "non-ideal handover" arose from not being able to form this holistic picture, due in part to patients' "ambiguous mental health", the difficulty with specific diagnosis of symptoms or difficult social circumstances [12]. So, barriers to communication arise in the nurse, patient and the environment [13] and are not always necessarily nurse mediated. Less research attention has been concentrated on the communication processes in children's ED.

Internationally, a reduction in overall ED failures, errors, and increased mortality rates has been reported with the implementation of medical emergency teams (MET), which comprise nurses and doctors working together to provide early and co-ordinated responses in critical situations [14]. While neither the ED errors reported within the literature nor the MET specifically address communication as an issue, certainly addressing "inadequacies in hospital organizational systems" was at the heart of the initiative [14]. Moreover, this closer working team by default is potentially more likely to avoid lapses and errors related to patient transfer information for example (as they are all working together). Indeed, one recent Swedish study indicated that "teamwork failure" contributed significantly to ED errors [15]. As communication is a vital feature of any team, it likely contributes to these events.

The MET is specifically targeted at the increasingly sick population presenting to ED, which are often complex cases with multiple co-morbidity [14]. Certainly, organizational structures, including physical space and the way that work is organized can have either a positive or detrimental effect on communication within the health care team [16] particularly in those at-risk communication features previously identified such as tracking patients, patient handover, and patient transfer [2].

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Communication during patient transfer appears to be a key area where improvement is needed. The use of standardized patient handover and transfer forms can assist with this [10, 17] These need to focus on both core and holistic elements of care such as mental status, devices and treatments, risk alerts, diet, and skin and wound care [17]. Certainly, effective record keeping and documentation is crucial to good communication in ED [18]. However, even in the context of advancing technology, verbal reports are viewed as an important feature of effective ED transfer [19, 12], particularly to groups outside the hospital such as ambulance services. One priority for improvement in these circumstances is training and education for staff [8, 19]. Indeed, on-going communication training for all staff in ED is recommended particularly in "closed-loop" systems that allow for effective closing of the gaps in the complex ED system [6].

While there is abundant research concerning nursenurse communications or with other healthcare workers, there is little information available specifically about nurse handover in the children's' ED setting. Additionally, in the Italian context communication systems in this regard may be underdeveloped, a fact which is mirrored in other countries internationally [20]. Structuring the handover process, through the use of mnemonic tools that prompt comprehensive reporting (e.g. the SBAR tool) is widely recommended for ED [20, 21]. However, recent reviews [21] reveal that even within this context there are uncertainties about reporting in some areas (e.g. responsibility and confidentiality) and a lack of consensus regarding the best tool to use. There is a dearth of literature that specifically addresses handover in children's ED. A search of CINAHL databases using the terms 'handover' [or] 'handoff' and 'children', 'paediatric' and 'emergency department' yielded only six citations. Only four of these papers related directly to children in ED and all revealed widespread gaps in service provision, such as gaps in communication handover with ambulance staff [22] but also improvements in handover when increasing structure was applied [23, 24]. Hsiao and Shiftman (2009) [25] revealed omissions leading to errors in their analysis of 353 visits to the children's ED by children with asthma. In this study, handover to community teams following discharge was found to be substandard, however this study related to written discharge information rather than directly to the verbal staff-to-staff handovers, which are the focus of this review. Recently Gopwani [24] noted improvements in handover and reduction in errors within children's ED with the introduction of mnemonic based reporting systems (SOUND). Similarly, Mullan implementation of another structured handover system (with mnemonic prompt) revealed a high number of reported of events that threatened the child's safety but had been picked up through the use of the structured reporting system.

Little is known however about communication in handover processes in children's ED in Italy. The conceptual background of this study is based on the fact that the best care process is the one that facilitates communication, collaboration, and integration, not just among health professionals, but also between health professionals and patients and their families (Family Centred Care) [26]. Each child should be cared for in a way that leads to the best possible outcome, with the least possible risk, and with maximum family satisfaction. The purpose of this pilot study was therefore to investigate ED nurses' perceptions of handover in a Children's ED as a basis for further research on how to develop future practice in this area.

Methods

ETHICAL APPROVAL

Ethical approval was obtained from the Local Research Ethics Committee.

DATA COLLECTION

Data were collected using semi-structured interviews that asked participants two questions: "Could you tell me how handover took place today?" and "Could you talk to me about a handover that you consider complete?". Interviews were integrally audio-recorded and then verbatim transcribed. Thematic content analysis was conducted to identify common themes. Five female paediatric nurses took part, with an average working experience of 17.5 years. Participants replied orally and had all the time they needed to answer. Further questions were asked in relation to what the interviewees said.

DATA ANALYSIS

The data collected from the interviews were analysed after listening carefully to the audiotapes several times. Consistency between the audio-recording and the verbatim transcription was confirmed by two researchers, who separately analysed them. Transcriptions of each interview were repeatedly read, and emergent themes were identified using content analysis [27].

Results

In this context, the health professionals working in the department did not identify any issues with the handovers [10]. However, the themes that emerged from the interviews were: 1) interpersonal influences on handover; 2) structural issues; and 3) local contextual factors.

1) INTERPERSONAL ASPECTS OF HANDOVER

This highlights how communication during handover can be influenced by personal aspects, such as emotions, and mood. Another important aspect of this theme was the lack of a spirit of collaboration among team members.

Personal aspects

Emotional aspects, the type of relationship with patients and their families was perceived to influence the health professional's mood so much that handover can be positively or negatively impacted by communication. For this reason, personality can influence the type of communication and relationships among colleagues:

"... you can make comparisons... if people let you... it depends on your character and confidence" (Paediatric Nurse 5).

"... other than providing information about the patients' treatments, we also have to provide information about the parents' behaviours... and the feelings that they expressed... in a rather exuberant way..." (Paediatric Nurse 1).

"... during handover some colleagues show their uneasiness due to the stressfulness of their workload... to organizational problems... and shortage of nurses... but also and especially when parents show their fear in a very assertive and sometimes imposing manner" (Paediatric Nurse 1).

Subjectivity prevails over method, no matter how long a nurse takes to complete handover, you should always focus on the key points. Atmosphere, one's own experience, and emotiveness influence work and therefore on the health professionals' mood. As a consequence, experience in the ward (i.e. working stress, relations with patients and their families, and excessive workloads) appeared to impact the effectiveness of handover.

Collaboration among professionals

Poor collaboration between nurses and physicians was revealed by participants and entailed divergent health plans among the two professions. From our data emerged also a lack of teamwork and therefore of shared decisions, changes made but not communicated, which were aspects that created obstacles at work:

"... we are quite far from considering our collaboration as teamwork ... physicians make decisions and these are immediately changed... without informing us and sometimes when we realize it is late... and this impacts on the how, when and what type of treatments we as nurses should administer..." (Paediatric Nurse 1).

"... the best handovers are in the afternoon... because physicians have mostly already decided what sort of treatment patients need and nurses know what to do in the next few days..." (Paediatric Nurse 2).

"... during handovers sometimes a physician comes in and takes away a clinical record from our hands..." (Paediatric Nurse 3).

2) STRUCTURAL ISSUES

This theme highlighted how the quality of handover communication also depends on the availability of appropriate tools for the classification of patient complexity, and not just limit handover information to the reasons for hospitalization, which are not enough to ensure patients safety and high-quality care. This theme also highlighted the need to identify means for handover that are both easy to use and effective.

Handover organization

From the interviews emerged the need for a tool that enabled to classify patients according to the level of healthcare complexity, and not by numbers. This aspect was important, because it entailed an uneven distribution of the workload among nurses:

"... I frequently receive handovers according to the level of complexity, but the type and the order of the information they give me depends on the individual nurse... however the information is often sufficient so that I know what to do" (Paediatric Nurse 1).

"... often working in an emergency environment and with urgent cases, nurses omit to handover important information... this is due to heavy workload and poor teamwork" (Paediatric Nurse 1).

"... to avoid being interrupted we often use the medical room for our handover, but we still get disturbed by bells, telephones, people who come in and out, physicians who intervene to say their things... with no respect for our priorities" (Paediatric Nurse 2).

"... handovers need to follow a method... starting from infusion needed, admission, feeding... because sometimes important things are mistakenly not considered... and due to emergency situations not all nurses give the same importance to things like if a child prefers solid food or blended food..." (Paediatric Nurse 2).

Handover topics

The handover appeared in many cases to be limited to the reason for hospitalization:

"... many nurses handover information that regards only the patients they have cared for and at the wrong moment, so they get distracted and lose their own concentration and that our the group, and either forget to do things or give the wrong information..." (Paediatric Nurse 1).

"... I think that the best handovers are when they tell you a little bit about the history of the patient, and what happened before the patient arrived..." (Paediatric Nurse 2).

Moreover, different health professionals attribute different levels of importance to the content of handover. Handover was also seen as a time for professionals to exchange views on certain healthcare topics. However, the time used to exchange views was not considered helpful, but rather a waste of time, because health professionals preferred to just report the main points during handover. Sometimes, by dwelling too much on one topic they often ended up omitting important aspects:

"... too many details are sometimes useless and then you end up forgetting the most important thing... it is important to focus on what you should say, see, and on what you can omit..." (Paediatric Nurse 3).

Missed communication was also perceived as a source of error:

"... sometimes due to time pressured emergency activities we do not read all the information on the clinical record... but on the other hand clinical records sometimes

do not contain all the information you need because we forget to write some things..." (Paediatric Nurse 1).

"... you omit things that then turn out to be important for the continuum of care... You forget to say... They were supposed to...All this means that something is missing in communication..." (Paediatric Nurse 1).

Ideally the child's handover should include medical history, especially if they have a complex condition. The need to communicate in a concise and methodical way was deemed preferable as this could serve to avoid forgetting important aspects of care during handover.

Means used for handover

Verbal communication appeared to be the pivotal mode of handover:

"I have to write everything, in chronological order, my notes are my mind... I tick the things as I do them... I principally listen to what they tell me during handover and then I read them, maybe at the end..." (Paediatric Nurse 3).

The notes nurses wrote in the nursing diary were very important. Witten handovers enabled nurses to mentally order their work, also in a chronological sequence. The availability of a computerized clinical record, although it was considered to be very useful, it however appeared to be less handy than paper clinical records. The diary was not always read immediately. First nurses tended to see their patients, even because due to the heavy workload they did not always manage to read the diary at the beginning of their shift. For this reason, oral handovers were considered to have more value:

"... I write the things my colleagues tell me during handover on a piece of paper... I pay a lot of attention to what I write, it is my personal opinion; technology, computers are very good, but twenty years ago I had everything clear before my eyes. Now instead you read everything on a computer, but it is not the same... in my opinion it is not the same thing" (Paediatric Nurse 5).

What emerged was that oral handover was more practical and handier that written handover.

3) LOCAL CONTEXTUAL FACTORS

Finally, this theme underlines how contextual factors, such as the continuously changing rules and standards, as well as interruptions, make it challenging for nurses to work well. Sometimes, also excessive bureaucracy and use of computers are mainly seen as obstacles rather than facilitators.

Changes

The rapidly changing standards that nurses are required to meet obliged nurses to think and work differently from the way they were initially educated:

"All our colleagues' education is not up-to-date, in the meantime they have had to continuously change and adapt to new rules and standards, and this rapidly changing context makes it even harder to work well" (Paediatric Nurse 1). Therefore, every time a change is introduced, it was seen as a further burden rather than an occasion for professional development.

Time

Nobody declared exactly how much time was dedicated to handover, but if someone took "too much" time to say things, the other person's level of concentration went down:

"... too many details are sometimes useless and then you end up forgetting the most important thing... it is important to focus on what you should say, see, and on what you can omit..." (Paediatric Nurse 3).

"... anyway we often don't have the time to go and read written handovers..." (Paediatric Nurse 1).

"... the best time for handover is at the beginning of the afternoon shift... because this is the time when both those who leave and those who come are less tired..." (Paediatric Nurse 2).

"Handover required the time necessary for the things our colleagues had to tell us... the time was respected" (Paediatric Nurse 4).

Bureaucracy

Bureaucracy and computers were not seen as facilitators but rather as obstacles. Charts are filled in only because: "this has to be done, although it is almost considered a waste of time", "... the implementation of the nursing plan, ...is clear in the minds of nurses..." (Paediatric Nurse 1).

"... the introduction of the computerized clinical record hasn't improved things... on the contrary it often makes us lose even more time because either there aren't enough computers for all, or because they are slow or for downtime..." (Paediatric Nurse 1).

Discussion

In this first exploration of nurses' experiences of handover in children's ED in Italy, many of the findings are reflective of international research findings across adult ED. Communication failures were inherently possible as was the potential for lapses in healthcare safety and accuracy [2] Similarly like Costa's [10] study, all too often nurses' verbal reports were found to be verbose, and spent too much time explaining matters that lost the attention of others. For the first time it is revealed that nurses' personal characteristics and their relationships with the family and other health professionals, influences the way they communicate and listen during handover. Confusion during handover, such as interruptions and phone calls, presented barriers to effective handover. Like many other studies there was a tendency, during handover, for nurses to focus on medical diagnosis only,

and to omit important details about complex health or social/mental health history [10, 12, 17]. Sometimes, health professionals focused their attention entirely on one critical situation, without reporting the rest of the case, and thus transmitted incomplete information. Overall the participants believed that the lack of structure and availability of a common standardized approach negatively influenced the quality of handover. The findings revealed that health professionals reported that standardizing the language of communication would not just improve the daily planning of their clinical practice but could prevent them from mentioning irrelevant items and help them to focus on key points to effective and efficient care.

Conclusions

The strong perceived need to standardize the communication process during handover in this study led us to implement a mnemonic prompt tool in this ED to facilitate a more accurate and rigorous flow of information in the children's ED [28, 29]. Structured handover tools, which are commonly used means of information transmission in ED while useful in improving communication of care also entail risks [30]. Their implementation does not negate the need for good verbal and written communication skills, and their use might also be influenced by personal and local factors, as has been identified in this study. Follow up evaluation is therefore required to establish the effectiveness of such tools, perhaps using observation approaches. Additionally, as many structured tools have been developed in English speaking countries, they are not necessarily validated or known to be culturally appropriate for the Italian setting. Good handover in ED is vital to ensure quality holistic care and to avoid mistakes and omissions. The findings of this study reveal gaps in current local practice and demonstrate that despite widespread use of evidence-based practice internationally; the best available evidence does not always translate to into practice. It is important that nurse researchers and universities continue to commit to research that explores local problems and develops good practice. Qualitative and action research are important contributors to this practice development [31]. Although this type of research remains low on the perceived hierarchy of research evidence [32] they both have a vital contribution to practice development. Modern approaches to nursing research encourage a shying away from local based projects in favour of seeking out large funded research grants, regardless of their importance for nursing and/or healthcare practice [31]. Projects such as this one emphasise the need to continuously explore local practice, in an exploratory and subjective way, to uncover potential for risks to patients and their families [31]. It is only by continuously reflecting on practice in this way that the nursing profession can progress to an appropriate evidence-based profession, one that keeps the patients first [33].

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Conflict of interest statement

None declared.

Authors' contributions

All authors have agreed on the final version and meet at least one of the following criteria:

- substantial contribution to conception and design, data collection, or data analysis and interpretation;
- drafting the article or revising it critically for important intellectual content.

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OPEN ACCESS

ORIGINAL ARTICLE

Behaviours monitoring and infection control in neonatal intensive care unit: how to improve ourselves?

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Keywords

Hand hygiene • Healthcare-associated infections • Infection control • Neonatal intensive care unit

Summary

Introduction. *Healthcare-associated infections are important events in neonatal intensive care unit.*

Hand hygiene is considered one of the most important procedures to control these complications.

Methods. Healthcare workers procedures for patient's approaching were directly monitored from February to April 2018 in the Neonatal Intensive Care Unit of Istituto Giannina Gaslini, Genoa, Italy.

Number and type of total contacts with patients or "patient unit" (e.g.: ventilator, monitor, isolette) were recorded as well as errors

Introduction

Hospital-acquired infections in neonatal intensive care unit (NICU) have a relevant role in morbidity and mortality as well as prolonged in hospital stay [1, 2]. Considering some patients as reservoir of potentially dangerous microorganisms, spreading vectors of nosocomial infections were recognised in healthcare workers hands [3]. Since 2005 WHO started the "Clean Care is Safer Care" program to promote hand hygiene in order to improve infections control and direct monitoring was considered probably the best tool to evaluate adherence to hand hygiene recommendations [4]. Despite protocols and recommendations, in-hospital diffusion of drug-resistant pathogens is a current problem. Aim of this study was to identify by direct observation potentially harmful behaviours that could increase patients' infection risk in a NICU of a tertiary care paediatric hospital.

Methods

Istituto Giannina Gaslini, Genova, Italy, is a tertiary care children's hospital in northern Italy serving as a local pediatric hospital for the Genova area, but representing a tertiary care referral hospital for the whole Italy and many foreign countries.

Neonatal Intensive Care Unit (NICU) is a 21 beds ward (7 isolettes of highly intensive care) that admit about 90-100 very low birth weight (< 1,000 g body weight)

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related to lack of hand hygiene after and before performing procedures.

Results. A total of 1,040 actions were observed on patient or patient unit: 560 actions by nursing staff, 240 by residents and 240 by consultants. The most common misbehaviour was the "double touch" in nursing staff (30%), "glasses, hair or nose" in residents (35%), and "double touch" and "glasses hair or nose" in consultants (25% and 23% respectively).

Conclusions. Extemporaneous contact is the more frequent potential "high risk" moment for transmission of healthcare associated infections in NICU.

neonates per year. Healthcare workers procedures for patient's approaching in NICU were directly monitored from February to April 2018 by a team of observers composed by a component of nursing, resident and consultant staff [5]. Standard hand hygiene procedures consisted of standard antiseptic hand washing or hand decontamination with isopropyl alcohol gel before and after any patients' approaching, according with specific needs (e.g. sterile or-non sterile procedure) [6].

Number and type of total contacts with patients or "patient unit" (e.g.: ventilator, monitor, incubator) were recorded as well as errors related to lack of hand hygiene before and after performing procedures [5, 7-11].

"Incorrect behaviours" were observed and summarized as follows:

- absence of hand hygiene before/after patient touching. This action was further divided in two subgroups: no hand hygiene after complete assistance or examination (e.g. catheter positioning or medication) and lack of hand hygiene after extemporaneous contact (e.g.: abdomen palpation or stimulation);
- touching patient unit, taking off a hand (or both) from the isolette to adjust monitor or other devices and reintroduce the hand into isolette without hand hygiene (double touch misbehaviour);
- closing neonatal isolette doors (still considered patient unit) with bare hands without hygiene procedure;
- using mobile phone or computer keyboard without hand hygiene before touching patient unit;

• touching operator's "dirty zones" (e.g. glasses, hair, nose) without hand hygiene before performing a procedure on patient unit.

Results

A total of 1,040 actions were observed on patient or patient unit: 560 actions by nursing staff, 240 by residents and 240 by consultants.

Different proportions of incorrect behaviours were observed according to the type of patient's care. Table I summarizes the proportion of incorrect behaviours that was 16% in case of complete patient assistance versus 27% in case of extemporaneous contact, with similar distribution among professional roles.

Table II summarizes the type of wrong behaviours by type of professional role. Glasses-hair-nose touch was the most frequent misbehaviour (27%), even if there were differences in the distribution among the different professional roles. The most common misbehaviour was the "double touch" in nursing staff (30%), "glasses, hair or nose" in residents (35%), and "double touch" and "glasses hair or nose" in consultants (25% and 23% respectively).

Discussion

This observational study identified occasional contact not followed by hand hygiene as the clue moment of potential incorrect behaviours in NICU. We also identified "double touch" to be the commonest misbehaviour in nursing staff, probably due to the very high rate of intervention on patient unit and often the need to adjust monitors or ventilators during patient manipulation in daily practice. On the other hand "glasses-hair-nose touch" was the most frequent misbehaviour among physicians (resident and consultant) and this, together with mobile phone use, is a well known behaviour that increases the risk of pathogen transmission from patient to patient and from the hospital environment to patients [12, 13]. Correct hand hygiene procedures during healthcare reduce the risk of pathogen transmission, but they must be performed during any step of patients' care in a correct "sequence" [4]. In a previous study we estimated the mean number of daily hand hygiene procedures per patient in different units of our hospital and found that in NICU there was a large compliance with this procedure [6]. However, the direct observation of health care workers behaviours reported in this study found the presence of many "wrong" actions by all the components of the team, confirming the role of direct observation to more precisely identify areas of intervention.

The study has also limitations, the major being the shortterm, with relatively low number of observations, and the absence of stratifications of risk by staff shift (day or night) and period at risk of understaff (e.g. week-end, holiday periods) [10]. Moreover, it not takes into account also ward overcrowding by concomitant presence of staff, training doctors, parents [11] that can increase the risk of misbehaviours and decrease the possibilities of correct cleaning of environment [14] in some way increasing the risk of health care workers', and indirectly patients', contamination.

Conclusions

This observational study clearly indicates patient's extemporaneous contact as the more frequent potential "high risk" moment for healthcare associated infection transmission in patient care. Our data supports the need to improve staff education in sporadic patient body contact because of the higher frequency of these short procedures, compared to the more complex ones (e.g. positioning central lines, lumbar punctures).

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Staff member	"Complete" assistance (total number)	Wrong behaviours in complete assistance	Occasional contact (total number)	Wrong behaviours in occasional contact
Nurse	160	26 (16%; 95% CI 10-22)	400	112 (28%; 95% CI 24-32)
Resident	40	7 (17,5%; 95% Cl 6-29)	200	52 (26%; 95% CI 20-32)
Consultant	40	6 (15%; 95% Cl 4-26)	200	50 (25%; 95% CI 19-31
Total	240	39 (16%; 95% Cl 11-21)	800	214 (27%; 95% CI 24-30)

Tab. I. Distribution of different behaviours during patient's care stratified by professional roles.

95% CI: 95% Confidence Interval

Tab. II. Distribution of different misbehaviours during patient's care stratified by professional roles.

Staff member	Observations (total number)	Double touch	Mobile phone	Glasses-hair-nose touch	Incubator doors				
Nurse	560	169 (30%; 95% Cl 26-34)	60 (11%; 95% CI 8-14)	146 (26%; 95% Cl 22-30)	25 (4%; 95% Cl 2-6)				
Resident	240	20 (8%; 95% CI 5-11)	23 (9%; 95% Cl 5-13)	85 (35%; 95% Cl 29-41)	46 (19%; 95% Cl 14-24)				
Consultant	240	60 (25%; 95% Cl 20-30)	37 (15%; 95% Cl 10-20)	56 (23%; 95% Cl 18-28)	12 (5%; 95% Cl 2-8)				
Total	1040	249 (24%; 95% Cl 21-27)	120 (11%; 95% CI 9-13)	287 (27%; 95% Cl 24-30)	83 (8%; 95% Cl 6-10)				
OFIL CL OFIL Confidence Interval									

95% CI: 95% Confidence Interval.

Conflict of interest statement

None declared.

Authors' contributions

FMR performed study design, data analysis and manuscript preparation, DM performed data analysis and manuscript preparation, MM performed data collection and analysis, SS performed data collection and review, AP performed data collection and review, DLM carried out data collection and analysis, EC performed data analysis and manuscript preparation, LAR performed study design and manuscript preparation.

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ORIGINAL ARTICLE

Study and implementation of a performance set of indicators for the nurse manager in a frailty hospital

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Keywords

Indicator • Performance • Nurse manager • Healthcare • Management

Summary

Introduction. Hospitals are known to be the most complex entities to manage. In fact, the main problem in healthcare are the expensive needs with limited resources. During the last years the complexity of the nurse manager role has gradually changed from assistance to management. However, nowadays the methods for quantifying the nurse managers' skills and performance are not available. The aim of this study is to implement a method to assess and measure the skills of the nurse managers. An innovative indicator to globally evaluate the features, the professional skills and their performance is described.

Methods. The authors started with an interview with the directors of all the nurses as the top experts of the nurse managers' technical skills. The purpose of this step was to understand what were

Introduction

The main problems in the healthcare are the expensive needs with limited resources. Furthermore, nowadays more attention is paid on the quality improvement of the output of each specific process. Quality is part of the daily routine for healthcare professionals [1]. Most of the interest on the quality of care has been developed as a response to the recent transformations of healthcare system [2]. Hospitals are known to be the most complex entities to manage [3, 4]. Quality can be improved without being measured, but its measurement plays an important role to achieve concrete results [5]. For this reason, during the last years, there has been a surprising increase of the international emphasis on the measurement of competencies and performance in healthcare occurred [6-8].

The nurse manager (NM) is responsible to achieve hospital strategic goals and to provide administrative and clinical support [9-11] but this role has gradually changed from assistance to management over the years [12, 13]. Recently, Europe has followed the model of the USA by implementing some performance indicators [14].

Merkely et al. [15] developed a nursing balanced scorecard to acquire or refine strategic approaches to measuring nursing performance. Krugman et al. [16] implemented a nurse manager (NM) performance the features of a valuable nurse manager. The methods identified three different aspects (qualitative, quantitative and relational) that were transformed in a single indicator. These parameters also enable to identify the strengths and weaknesses of each professional. An important implication of this score is the possible improvement of loss-making skills.

Results. A total of 18 centres, with their nurse managers, were evaluated in this study. All the results confirmed the judgment of the Healthcare Professions Structure Manager.

Conclusions. This assessment method, validated with these tests, evaluated the nurse manager's ability to deal with personnel, resources and patients and to quantify his/her organizational and welfare performances. It is useful for planning actions that allow nurse managers to improve their skills.

profile to provide a comprehensive evaluation of staff and unit trend. Although several papers described the performance indicators and their correlation to the quality of care, the method to quantify the skills of NMs skills and their performance is still missing.

The purpose of this study is to describe the quantitative and qualitative assessment of the skills of NMs, and implement a method to assess and measure NM skills.

Methods

This study was conducted in level I hospital care from January to December 2015.

Figure 1 shows the organizational charts of the nurses in this institution.

The authors followed the method described by Fain et al. [17] (Fig. 2).

STUDY DESIGN

Phase 1

A literature review was conducted to identify the variables describing the skills of the NM.

A list of hypothetically identified variables describing the skills of the NM has been validated with the interview of the director of nurses and technicians.





Three main aspects to include in the final assessment were:

- qualitative items;
- quantitative items;
- *complains* reported to the Public Relation Office (PRO).

Phase 2

The design of the study is a quantitative research.

The *qualitative items* (QL*) were strictly connected to patient safety and the quality of care and consisted of six features:

- 1. hygiene;
- 2. organization;
- 3. health;
- 4. drugs and narcotics;

5. kanban:

6. staff room (only for the wards).

All the defined qualitative items were assessed by the head of NM of each level (Fig. 1) through the objective evaluation template designed by the authors to critically detect all the parameters through physical inspection.

Figures 3-8 show the evaluation template used in the setting of the present study by the head of NM of each level to conduct the inspection. The inspection started with the extractions of three random Hospital Discharge Registers (HDR). The correctness of the following parameters has been assessed: completing HDRs, use of devices according to the law, patient identification bracelets, therapy administration and management of prosthetics containers, presence of hand cleaning solutions and hygienic conditions. "Kanban" referred to the correct application of the hospital strategical project. The wards applied this lean technique to manage the product supply. The head of the nurses and the technicians customized the relative weight applied to each ward in order to have balanced data. All relative weights applied for the analyzed ward are reported in Table I.

Qualitative parameters were translated into a single qualitative indicator (QL*).

The quantitative items (QN*) measured the ability of NMs to organize the work of their center with the assigned staff.

Each ward was compared with the ward of the same level according to intensive care model (Fig. 1).

The management of the overtime hours of the nurses was assessed. The parameter was calculated by summing the two items: R* and HO*. The ratio (R) between the days really worked by the nurses and the days of patient hospitalization was used as a parameter to compare

Structure	Hygiene	Organization	Health	Drug and narcotic	Staff room	Kanban
Wards	25%	10%	30%	25%	5%	5%
Emergency department	35%	15%	20%	30%	0%	0%
Intensive Care Unit	30%	10%	30%	30%	0%	0%

Tab. I. Weights of the different structures for the qualitative aspect.

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	HYCIENE													
_														
		entrance	toilet	room	room	room	room	room	room	nurses' room	stairs	elevator	dirt storage	dean storage
1	Does the floor show stains, organic residues or anything else?													
2	Does the wall show stains, cobwebs or infiltrations?													
3	Do doors, windows and switches show dust, grease stains or anything else													
4	Is the doorbell present and functioning?													
5	Does the bed's structure show stains or dust?													
6	Are bedpan and urine bottles clean?													
7	Do the closet, the bedside table, the chair and the ? Does it show stains or dust?													
8	Do shelves, desks and closets show stains or dust?													
9	Is the WC without stains, biological liquid or anything else?													
10	Is the toilet rim present, fixed and intact?													
11	Are there toilet paper, paper towels and soap?													
12	Is there the alcoholic hand cleaning solution?											YES		NO
13	Are there recycling bins?											YES		NO
14	4 Is there unsuitable material in the organic waste bin?					YES		NO						
15	Is there unsuitable material in the paper bin?											YES		NO
16	Is there unsuitable material in the plastic bin?											VES		NO

Fig. 4. Organization evaluation template.

	ORGANIZATION							
1	Is there the expected staff, as per shift posted in the ward?	YES	NO					
2	Does the staff show the badge?	YES	NO					
3	Is the staff's uniform in compliance with dispositions?	YES	NO					
4	Are there municipality's handouts at the mortuary rooms?	YES	NO					
5	Is there the funeral service nomination form?	YES	NO					

different wards (by number of beds and staff) of the same level (Fig. 9).

R compared the amount of time work nurses' (hours of daily work) with the amount of time dedicated to the patients. A small ratio reflected a better performance of the NM and higher ratio a worse parameter.

Finally, the mean value of R for each level (μ RL) and the standard deviation (σ RL) were calculated. The Gaussian distribution method was used for the attribution of the score R* as shown in Figure 10. The range of R* was from 2,5 to 15 points: 2,5 points reflected a worse performance whereas 15 points an excellent performance comparing it to the average of the level.

This means that for each ward R* was calculated as the result of the distance ($\pm \sigma$) of it between the average (μ) for the belonging level (Fig. 10). Moreover, the overtime hours of each nurses for each ward (HO) has been considered. The overtime hour average for each level (μ HOL) and the standard deviation (σ HOL) of each level were calculated. Thereafter the score, HO*, was attributed using the Gaussian method (Fig. 10). The HO* score ranged from 2.5 to 15 points and also in this case 15 points meant an excellent performance whereas 2.5 a minimum value.

The quantitative items (QN*) was the sum of R* and HO* and it ranged from 5 (minimum value of performance) to 30 points (maximum value of performance). For clarity we converted QN* into a number in scale 0-100 with a proportion. The last aspect of the analysis focused on commendations and complaints submitted to the Public Relation Office (PRO) by patients and their relatives. The PRO collected each day the voluntary opinions of the patients and of their relatives for each ward. A score was assigned depending on the number of commendations and complaints.

The number of commendations (C1) and complaints (C2) for each ward were summed up and the average of C1 and C2 for each level (μ C1L and μ C2L) was calculated with standard deviations (σ C1L and σ C2L) of each level. The relative scores, C1* and C2*, were attributed using the Gaussian method (Fig. 10). The same approach used for the quantitative item was used as showed in Fig. 10 with a range from 2.5 to 15 points. The indicator for this aspect was C* and it was the sum of C1* and C2* and ranged from 5 to 30 points. For clarity, C* has been converted in a number on a scale between 0-100 with a proportion.

The final performance indicator of each nurse manger's P was calculated as the sum of QL*, QN* and C* and it was translated, for clarity, into a 0-100 scale through the proportion (P*).

Phase 3

The data collection for the qualitative aspect was conducted during the routine ward inspection (3 times a year) as prescribed by law. The survey, reported in Figures 3 to 8, was composed by four pages signed by the NM level (the inspector) and by the NM (the person inspected). Thereafter,

		HEALT	н								
	Is the nursing documentation in use correctly filled out?	general part	needs detection	healt interve	h en ain	ns	assessm ent	health	diary	diso f	charg orm
1	SDO	YES/NO	YES/NO	YES/N	IO YES/	'NO	YES/NO	YES/	'NO	YE	S/NC
	SDO	YES/NO	YES/NO	YES/N	IO YES/	'NO	YES/NO	YES/	'NO	YE	S/NC
	SDO	YES/NO	YES/NO	YES/N	IO YES/	'NO	YES/NO	YES/	'NO	YE	S/NC
	Are these prevention and management forms used?		Conley sc	ale B	raden-Norto	on scale		LDP ma	nagemer	nt	
2	SDO		YES/NO		YES/NO	D	YES/NO				
	SDO		YES/NO		YES/NO	D		YE	s/NO		
	SDO		YES/NC	,	YES/NO	D		YE	s/NO		
3	Is the practice containments monitoring form present and filled out? SDO								YES/N	0	
	For these medical devices are insertion date, size, type and replacement da registered?	ate	Baldder catheter CV		CVC/PICC/Midline		LDP management				
4	SDO		YES/NC	>	YES/NO		YES/NO				
	SDO		YES/NC	>	YES/NG	0	YES/NO				
	SDO		YES/NC	>	YES/NG	0	YES/NO				
	Has the following devices the protection and safety mechanism? Is it used	Has the following devices the protection and safety mechanism? Is it used correctly?									
	Introducer needle (cannula)								YES/N	0	
	Introducer needle (eclipse)								YES/N	0	
	Winged needle								YES/N	0	
5	EGA syringe								YES/N	0	
	Insulin syringe								YES/N	0	
	Scalpel blade YES/NO										
	Lancing device YES/NO										
6	Are the following individual protection devices present and correctly used?		Gloves	Gown	vns Headset		Safety glasses and protective visors	Surgical mask		F	FP2 emas
			YES NO	YES N	IO YES	NO	YES	YES	NO	YES	NC
7	Are the following devices present and correctly used?		Introducer needle (eclipse)	Wingen	ed Scalpel	blade	Insulin syringe	Insulin s	syringe	Intro ne (ec	oduce edle lipse
			YES NO	YES N	IO YES	NO	YES	YES	NO	YES	NC
8	Has the patient the identification bracelet?								YES		NO
9	Is the therapy administred after the barcode reading of the patient's bracele	et?							YES		NO
10	Is the therapy administred after the barcode reading of the drug's AIC code	?							YES		NO
11	Are there prosthetics containers (denture, etc.)?								YES		NO
12	Have patients received the prosthetics containers?								YES		NO
13	Is there the alcoholic hand cleaning solution?								YES		NO
_	Is the patient in satisfaction hygienic conditions?				hands	foot	head	navel	oral cavity	1	bed
14	Ward N° SDO				NO	YES	YES	NO	YES	YES	NC
	Ward N° SDO				NO	YES	YES	NO	YES	YES	NC
	Ward				NO	VEC	VEC	NO	VEC	VEC	NC

the results were anonymously reported by a secretary in Microsoft Excel table that automatically converted the results in the vote. This excel file has been assessed by an industrial engineer. For each positive answer a point was assigned.

The quantitative aspect was calculated through the data provided by:

- the human resources office of the hospital. These data consisted of the nurses' timesheets divided by those belonging to the ward.
- The informatics unit of the hospital. These data consist of the sum of the length of stay of the patients divided by those belonging to the ward.

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The commendations and complaints data is a list of them divided by those belonging to the ward.

Phase 4

Three parameters for 18 nurse managers of the hospital were calculated following the method reported in Phase 2.

Results

A test on two different wards was conducted to verify the validity of the analysis. The two wards selected for the test were selected by the head of the nurses and technicians.

ig. 6	Drugs evaluation template.							
	DRUGS							
1	Are cupboard without stains or dust?			YES	NO			
2	Are cupboard closable?			YES	NO			
3	Are in the cupboard expired drugs?			YES	NO			
4	If the answer is YES, how much are they?	from 1 to 5	from 5 to 10	more than 10				
5	Is the therapy cart without stains or dust?			YES	NO			
6	Are on the therapy cart expired drugs?			YES	NO			
7	Is the cart without stains or dust?			YES	NO			
8 Are on thecart expired drugs?								
9	9 Are cart wheels clean and functioning?							
10	10 Are multidose containers closed after use?							
	Reconstituited drugs and eye drops:							
	1. Do they show the reconstitution date?							
11	11 2. Are they kept in the fridge?							
		YES	NO					
	Are drugs that require refrigeration kept in the fridge?			YES	NO			
12	Are there sample of medicines?			YES	NO			
13	Are samples and/or drugs for clinical trials kept separately?			YES	NO			
14	Are there concentrated potassium solutions?			YES	NO			
15	Are there concentrated potassium solutions already diluted and ready to use?			YES	NO			
16 Are concentrated potassium solutions kept separately from the other drugs?								
17 Is the cuboard containing the concentrated potassium solutions closed? Does it show the alarm signal attached to the operational instruction?								
18 Is at the moment of the inspection the diluited potassium solutions infusion going on by the staff of the ward?								
19	If the answer is YES, is the content and the dosage reported on the bottle?			YES	NO			
20	If the answer is YES, for the administration is an infusion pump or a flow precision regulator used?			YES	NO			
21	Are cupboard for medical devices without stains or dust?			YES	NO			
22	Are cupboard for medical devices closable?			YES	NO			
23	Are there expired medical devices?			YES	NO			
24	If the answer is YES, how much are they?	from 1 to 5	from 5 to 10	mor	e than 10			
	NARCOTICS							
25	Are substances being tested kept in a locked closet all the time?			YES	NO			
26	Are all the loading and unloading movements recorded in the appropriate register within the scheduled tim	ne (24 hours)?		YES	NO			
27	Does the accounting hold correspond to the real one?			YES	NO			
28	Are there expired drugs to be returned to the pharmacy (waiting for collection stored separately in an enve	elope)?		YES	NO			
29	Is the register filled in with legible calligraphy?			YES	NO			
30	Is the register compiled in all its parts as required by the company procedure?			YES	NO			
31	Is the register signed by the Director of the Structure?			YES	NO			
32	Are any corrections countersigned?			YES	NO			
33	Are partial administrations correctly managed according to Law 15/02/95?			YES	NO			

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	CUPBOARDS AND KANBAN CONTAINERS		
1	Are there cupboards and/or Kanban container in the ward?	YES	NO
2	If the answer is YES, is there only clean and orderly material?	YES	NO
3	Does the material contain correspond to that described in the check-list affixed inside the closet (type and quantity)?	YES	NO
4	Do open packages of multidose products (gloves, disinfectants, lotions, etc.) show the opening date?	YES	NO
5	Is the cupboard's cleaning with sodium hypochlorite and/or alcohol carried out once a week?	YES	NO
6	Is the cleaning documented on the specific sign-in sheet with the date?	YES	NO
7	Are there rigid containers for the sharp components?	YES	NO
8	Are there stains, organic residues, waste, butts, writings or anything else in the dressing room for staff?	YES	NO
9	Are there stains, organic residues, waste, butts, writings or anything else in the dressing room for staff?	YES	NO
10	Are there stains, organic residues, waste, butts, writings or anything else in the refreshments area?	YES	NO

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	STAFF ROOM		
1	Does the floor show stains, remains of food, other waste or water?	YES	NO
2	Does the wall show spots, cobwebs, grease marks? Is it peeling?	YES	NO
3	Does the ceiling show spots, cobwebs or moisture spots?	YES	NO
4	Do windows show spots or visible marks of grease or other?	YES	NO
5	Do switches show spots or visible marks of grease or other?	YES	NO
6	Is the refrigerator free of odors and water leaks? Is the freezer free of ice packs?	YES	NO
7	Is the temperature of the refrigerator included in the range and recorded on the appropriate card?	YES	NO
8	Are there expired food items, visibly damaged or unpackaged, inside the refrigerator?	YES	NO
9	Are the foods of the patients separate from those of the staff?	YES	NO
10	Are there unpleasant odors in the room?	YES	NO
11	Do staff's room closets show stains, grease marks, dust or food residues?	YES	NO
12	Is the food trolley working?	YES	NO
13	Are aprons for distribution free of stains?	YES	NO
14	Does the staff wear apron and headgear during the food distribution?	YES	NO
15	Does packages for food transport arrive intact in U.O.?	YES	NO

Fig. 9. R formula.

 $R = \frac{\text{Days really worked by the nurses}}{\text{Days of patients' hospitalisation}}$

Ward 1 was hypothesized to be the most well managed of the hospital and ward 2 the worst one. The method proposed by the authors reflects exactly this situation because ward 1 achieved a total result of P1* of 83/100 instead ward 2 obtained a P2* of 46/100.

After this initial test, the analysis was extended to all the other departments: inpatient wards, Emergency department and intensive care unit. The ward names and the names of the NMs were converted in anonymous form for the conduction of this study. A total of 18 structures, with

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related NMs, were evaluated in this study. Four of these structures belong to Level 1, 5 to Level 2_surgical, 4 to Level 2_medical and 5 to Level 3. Final results are ordered in a classification reported in Table II.

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Discussion

This study was carried out for the increasing attention on the role of NM into clinical nursing skills [18]. A proof of this is that a literature review has been conducted on this topic [19]. According to Boomer et al. [20] the NMs play an essential active role for the growth of the performance of the nursing staff. In fact, a deep association exists between the leadership of the NM and the nurse performance [21]. The staff members are strongly influenced by their leader's practices who can



Level	Nurse manager	Qualitative aspect (QL*)	Quantitative aspect (QN*)	Relational aspect (C*)	Tot/300 (P)	Tot/100 (P*)
1	С	83	92	75	250	83
2_surgical	0	90	67	83	240	80
3	Т	71	75	92	238	79
2_surgical	Ν	76	83	75	234	78
3	S	62	75	92	229	76
1	А	81	75	50	206	69
1	В	83	50	67	200	67
2_surgical	М	62	75	58	195	65
2_medical	Н	77	67	50	194	65
2_medical	E	82	83	25	190	63
2_surgical	L	80	50	58	188	63
3	Р	78	58	50	186	62
3	Q	74	67	33	174	58
2_medical	G	74	50	42	166	55
3	R	71	25	67	163	54
2_medical	F	74	42	42	158	53
1	D	90	25	33	148	49
2_surgical	I	72	50	17	139	46

Tab. II. Final results of the study.

make the difference in their performance [21]. A successful leader achieves important results for the team whereas an incapable one is unable to encourage the group. Krugman et al. [16] studied the method to implement a NM profile in order to improve th unit performance. In addition, Krugman et al. [16] underlined how... "Traditional methods of evaluating NMs, such as meeting budget targets, employee ratings, or facility benchmarks, may not provide a complete picture of performance". A 1-page 2-sided visual graphic picture of quality data has been used in this paper to develop the manager profile. Many parameters have been measured from different databases including specific nurse scales. All these parameters have been reported in the poster. The result of this work is, on the one hand, an extremely detailed report and, on the other, not immediately understandable by everyone results such as the final outcome implemented in the present work (Tab. II). In fact, an in-depth study of the document is required to understand all the data. In addition, much strictly nursing performance has been reported instead of performance directly related to the NM. Moreover, all the NMs are evaluated in the same way without characterising the skill required for the different wards. It is essential that each NM is valued with a key performance indicator and a related target value fitting with the actually required skills according to the ward or to the emergency department directed by the NM. In this paper the head of the nurses of the hospital customized it. Furthermore, the present method allows to assess the ability of the NM to manage personnel, resources and patients and to quantify his/her organizational and welfare performances. This partition of the evaluation into the three parameters has allowed to highlight the different characteristics of each NM and the most effective areas besides those where improvement is needed.

Another applicability of the present system was to plan actions to improve personal skills and to identify strengths and weaknesses. In addition, from the NM point of view, the hospital requests have been quantified. Monitoring their own performance year by year, head nurse could understand if they were on the right way to improving their professionalism.

This study has some limitations, especially in the aspect concerning commendations and complaints. The latter are spontaneously expressed by patients and family members. Unfortunately, the PRO collects all the commendations and complaints but, at the moment, it is not able to separate the reason of the reporting. In other words, a patient can report a complaint for the collapsing infrastructures or for the bad manner of a doctor. In the method showed all the complaints and the commendations are attributed to the skills of the NM. In a future study the authors will also implement a method to evaluate the performance of the nurse and technician managers of different structures in reference to operating rooms, labs and ambulatory care. With this article, we hope also to increase interest on performance indicators for NMs and stimulate research

performance indicators for NMs and stimulate research activities on their validity in different national set-ups in Europe.

Conclusions

In this study the authors implemented a unique NM performance indicator. This indicator is formed by quantitative and qualitative items. This method allowed to numerically quantify the technical skills of NM.

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Conflict of interest statement

None declared.

Authors' contributions

IC and CP conceived, designed and coordinated the research. IC defined the feature to evaluate the skill of an NM and CP implemented the index and the tool to assess it. IC customized the relative weight applied to each ward. LC and FG calculated the index and assessed the literature review. IC evaluated the results. CP wrote the manuscript. PC reviewed the manuscript. All Authors revised the manuscript and contributed to improving the paper. All authors read and approved the final manuscript.

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ORIGINAL ARTICLE

Using intervention mapping approach to finding socio-cognitive determinants of diabetes preventive behaviors

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Keywords

Fear • Perceived barrier • Behavior change

Summary

Introduction. Diabetes is one of the most common chronic illnesses with complications. The objective of this study was to determine socio-cognitive determinants of diabetes preventive behaviors among sample of at risk group based on intervention mapping approach (IM) in Kermanshah, the west of Iran.

Methods. This cross-sectional study conducted among a total of 200 male and female aged more than 30 years old referred to health centers that randomly selected to participate voluntarily, during 2018. Participants filled out a self-report questionnaire. Data were analyzed by SPSS version 16 using bivariate correlations and linear regression at 95% significant level.

Introduction

Diabetes has been known as a major health problems and the most common metabolic disorder with several complications [1]. About 2% diabetics' patients experience blindness after 15 years, visual impairment after 10 years and 50% neuropathy; overall, the risk of death for diabetics is twice higher than of non-diabetics [2]. According to the World Health Organization, the number of diabetics' patients will double by 2030; the prevalence of diabetes among Iranian adults was reported 10.3%, including 9.3% in men and 11.1% in women, it was estimated that the prevalence of diabetes among the population over 30 years old in Iran was more than 14% in 2016 [3]. The proportion per diabetic patient, there is at least one undiagnosed patient in developed countries, while in developing countries; the situation is completely different so that the proportion per diabetic patient, there may be up to four undiagnosed patients [4].

Type 2 diabetes accounts for about 90 to 95% of all diagnosed cases of diabetes, which is the major cause of it related to lifestyle and genetics [5]. There is strong evidence that alterable risk factors such as obesity and physical inactivity are the most important determinants that are fundamentally dependent on the lifestyle [6]. Considering the increasing the number of diabetic cases **Results.** The mean age of respondents was 38.4 years [95% CI: 37.3, 39.4], ranged from 30 to 56 years. Socio-cognitive determinants were accounted for 40% of the variation in diabetes prevention behaviors F = 35.559, P < 0.001. As well as, perceived self-efficacy, perceived severity, and perceived barrier were the most influential predictors on diabetes preventive behaviors.

Conclusions. It seems that planning health promotion programs to reduce barrier to perform diabetes preventive behaviors and increase confidence towards ability to perform preventive behaviors, and seriousness about sides effect of diabetes may be usefulness of the results in order to promotion of diabetes preventive behaviors among at risk group.

globally, one of the main strategies for preventing and controlling the disease among the at-risk group is to increase the knowledge of predisposing factors, complications, and disease progression [7]. Recent research also suggests that changes in lifestyles among the at-risk group can prevent, control or, at least, delay Incidence of disease [8]. Lifestyle includes a range of daily activities such as eating, sleep and rest habits, physical activity and exercise, weight control, and smoking, which can largely be effective in prevention and control of chronic lifestyle-related diseases such as diabetes [9]. Although identification of all determinants affecting on health behaviors is complicated, identifying some of the effective determinants can facilitate predicatively of the healthy behavior and helps to health promotion professionals to develop intervention programs [10-13]. Several studies pointed out the role of cognitive determinants in the prevention or control of diabetes [14-22]. Therefore, it seems that the first step in identifying effective determinants by behavioral science professionals is the use of scientific frameworks and one of the common themes is the intervention mapping approach, which has been commonly used in the past three decades [23]. Intervention mapping approach has been used in several studies of diabetes [24, 25].

Regarding the importance of the problem and also the absence of similar studies in this regards with using of the intervention mapping approach among Iranian population, our intervention mapping approach based study addressed on determining of the socio-cognitive determinants of diabetes preventive behaviors among a sample of the at-risk group in Kermanshah, the west of Iran.

Materials and methods

PROCEDURE AND SAMPLING

This cross-sectional study was conducted among 200 male and female aged more than 30 years old referred to health centers in Kermanshah city, the west of Iran, during 2018. Diabetes screening program in Iran is done with the aim of diabetes early detection among people more than 30 years old [26]. The sample size was calculated at a 95% significance level according to the evidence [3] and a sample of 200 was estimated. To enroll the subjects and data collection the following stages were done. Forasmuch as Kermanshah city has eight geographical regions and twenty-two health centers, at the first stage, the city was classified based on the division of the geographical region, next for each social class one health centers were randomly selected (a total of eight health centers were selected). Then, among the subjects accessible in the health centers some of them randomly enrolled. Only the subjects aged more than 30 years old were eligible to participate. Of the population of 200, 162 (81%) signed the consent form and voluntarily agreed to participate in the study.

MEASUREMENTS

Questionnaire included three sections that comprised of 48 items.

(A) Demographics

Demographics variable were; age (year), sex (female, male), level of education (under diploma, diploma, and university), occupation (employed, self-worker, and house-wife) and positive family history of diabetes (yes, no).

(B) Socio-cognitive determinants

The items which had evaluated the socio-cognitive determinants were driven from the scales of diabetes prevention behaviors [14-22] and also used the first and second steps of the intervention mapping approach [24]. There were 40 items which measured the six determinants includes; 1) attitude, 2) subjective norms, 3) perceived susceptibility, 4) perceived severity, 5) perceived barriers and 6) perceived self-efficacy. Three items measured attitudes towards the diabetes preventive behaviors (e.g., I believe that regular physical activity is effective in preventing diabetes). Three items measured the subjective norms towards the diabetes preventive behaviors (e.g., if I doing diabetes preventive behaviors, my friends will confirm it). Four items measured the perceived suscepti-

bility towards the diabetes preventive behaviors (e.g., If I don't have physical activity, maybe I get diabetes complications). The perceived severity towards the diabetes was measured by six items (e.g., I think that diabetes is a serious disease). Seven items measured perceived barrier to doing diabetes preventive behaviors (e.g., I don't have enough time to doing diabetes preventive behaviors). Moreover, ten items were designed to perceived self-efficacy towards the diabetes preventive behaviors (e.g., I believe that I can do regular physical activity). In order to facilitate participants responses to the attitude, perceived susceptibility, perceived severity, perceived self-efficacy, and perceived barrier items were standardized to a five-point Likert type scaling, ranging from 5 (strongly agree) to 1 (strongly disagree). As well as, A two-order response scale yes (score 1), no (score 0) was developed to measure construct of subjective norms. Estimated reliability using alpha Cronbach coefficient for each cognitive determinants questionnaire were as follows: attitudes ($\alpha = 0.68$); subjective norms ($\alpha = 0.70$); susceptibility ($\alpha = 0.74$); severity ($\alpha = 0.88$); barrier ($\alpha = 0.87$); self-efficacy ($\alpha = 0.95$); and behavior $(\alpha = 0.71)$. Furthermore, alpha Cronbach of the measurement tool was equal to 0.78. The results from reliability analysis suggested an acceptable internal consistency for the questionnaire.

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(C) Diabetes prevention behaviors

Three questions with yes or no response developed to evaluate diabetes prevention behaviors, "Have you doing regular physical activity, healthy diet, and Blood glucose measurement during last week?". The reliability coefficient for the diabetes prevention behaviors was 0.71.

ETHICAL CONSIDERATIONS

The Research Ethics Committee of Kermanshah University of Medical Sciences (KUMS) approved the study protocol (KUMS.REC.1397.813).

Data analysis

Quantitative determinates were expressed as means with SDs, and qualitative/categorical ones as frequencies and percentages. Bivariate correlations were performed to determine the correlation between socio-cognitive determinants of diabetes preventive behaviors among the participants. As well as, linear regression analysis for predict the variation in diabetes prevention behaviors based on socio-cognitive determinants. The level of significance was (P < 0.05). Data were analyzed by the SPSS version 16.

Results

The mean age of respondents was 38.4 years [95% CI: 37.3, 39.4], ranged from 31 to 56 years. The mean age of women was 38.38 (SD: 6.58), and mean age of men 38.63 (SD: 6.33); and there was no significant difference between age among men and women (P: 0.809).

58% (94/162) of participants were women and 42% (68/162) were men. 19.1% (31/162) of participants reported positive family history of diabetes. Respectively 30.2% (49/162), 30.9% (50/162), and 38.9% (63/162) of participant's were reported employed, self-worker and housewife.

Correlations between the socio-cognitive determinants and diabetes preventive behaviors were shown in Table I. Our results indicate that for the sample, perform diabetes prevention behaviors was significantly related to attitude (r = 0.272), subjective norms (r = 0.219), perceived susceptibility (r = 0.205), perceived severity (r = 0.336), and perceived self-efficacy (r = 0.542), while inversely correlated with perceived barrier (r = -0.444). In addition, we use of multivariable linear regression models and backward methods for predict the variation in diabetes prevention behaviors based on socio-cognitive determinants. As can be seen in Table II, collectively, socio-cognitive determinants were accounted for 40% of the variation in diabetes prevention behaviors, F = 35.559, P < 0.001. Final model selected in the step 4.

Discussion

The aim of this study was to determine socio-cognitive determinants related to perform diabetes preventive behaviors among male and female at risk for diabetes in Kermanshah, the west of Iran. The results of the present study indicated that participants was received about half of score of perform diabetes preventive behaviors. This result is similar to the results reported by other studies in Iran [3, 27]. For example, Abedini et al carried out a research on diabetic's patients with aim investigate the knowledge and practice of patient self-care in Qom and reported that diabetic patients had average of self-care behavior [27]. Our finding indicated perform diabetes preventive behaviors was not appropriate; in other hand, several studies indicated comprehensive preventative health education programs need to focus on socio-cognitive determinants that explain health-related behaviors [23]. In addition our findings indicated that three determinants of perceived self-efficacy, severity

and barrier were the main predictors of perform diabetes preventive behaviors among participants.

In many studies was reported the positive role of selfefficacy in preventing or adherence to treatment behaviors among diabetic patients. For example, Stuifbergen et al. [14] showed that promoting self-efficacy related to health behaviors helps to develop and improve these behaviors. In addition, Berg et al. [15] and Tamirat et al. [16] suggested similar findings in their studies, which was in line with findings from our study. These studies showed that increasing self-efficacy correlated with following the recommended behaviors in the adherence treatment and control of diabetes. Self-efficacy involves the individual's confidence in the ability to organize the activities and successfully conduct the desired behavior in order to achieve the desired result under given conditions, and the more this assurance is, the more easily the health behaviors is performed [28]. In line with activation of self-efficacy construct, professionals should use methods such as verbal persuasion, modeling, encouraging emotional and behaviors along with the acceptance of failure as a natural part of the learning process to improve patient self-efficacy [23]. Considering the influential role of self-efficacy in adopting preventive behaviors, compliance treatment and control, it is suggested that health-care intervention planners must pay special attention to promoting community-based interventions. The perceived severity construct in this study was introduced as the second predictor of the model. In this regard, Tan et al. suggested that weak performance of diabetes prevention behaviors had a significant relationship with patients' low perceived severity [17]. Pinto et al. also suggested perceived risk as the most important construct to predict adopting health behaviors among diabetic patients [18]. This finding stresses the importance of perceived severity while designing health interventions. To design interventions for promotion of perceived severity among diabetic patients, Patino et al. suggested that the focus of programs should be on the short-term complications of diabetes, in order to see an appropriate increase in perceived threat levels among patients [16]. A high level of perceived severity may also increase adherence to health behaviors. For exam-

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Tab. I. Correlation between socio-cognitive determinants of	of diabetes preventive behaviors among the participates.
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Determinants	Mean (SD)	Range	X1	X2	X3	X4	X5	X6
X1. Attitude	11.70 (2.94)	3-15	1					
X2. Subjective Norms	2.24 (1.03)	0-3	0.099	1				
			0.212					
X3. Susceptibility	15.22 (2.97)	4-20	0.215**	0.244**	1			
			0.006	0.002				
X4. Severity	20.60 (5.14)	6-30	0.055	0.165*	0.210**	1		
			0.495	0.036	0.007			
X5. Barrier	15.96 (5.86)	7-35	- 0.340**	-0.265**	- 0.236**	- 0.096	1	
			< 0.001	0.001	0.003	0.224		
X6. Self-efficacy	34.70 (9.42)	10-50	0.394**	0.261**	0.198*	0.128	- 0.495**	1
			< 0.001	0.001	0.011	0.104	< 0.001	
X7. behaviors	1.29 (1.16)	0-3	0.272**	0.219**	0.205**	0.336**	- 0.444**	0.542**
			< 0.001	0.005	0.009	< 0.001	< 0.001	

*: P < 0.05 Level; **: P < 0.01 level.

Model	Un-stan coeffi	dardized icients	Standardized coefficients	Т	P value
	В	Std. error	Beta		
Step 1					
Constant	- 1.197	0.715		- 1.674	0.096
Attitude	0.014	0.034	0.029	0.421	0.674
Subjective norms	0.015	0.075	0.013	0.201	0.841
Susceptibility	0.006	0.026	0.015	0.226	0.822
Severity	0.059	0.014	0.260	4.057	< 0.001
Barrier	- 0.042	0.015	- 0.211	- 2.851	0.005
Self-efficacy	0.048	0.009	0.386	5.123	< 0.001
Step 2					
Constant	- 1.181	0.708		- 1.667	0.098
Attitude	0.014	0.034	0.028	0.411	0.681
Subjective norms	0.007	0.026	0.017	0.264	0.792
Severity	0.059	0.014	0.261	4.111	< 0.001
Barrier	- 0.042	0.014	-0.213	- 2.918	0.004
Self-efficacy	0.048	0.009	0.388	5.221	< 0.001
Step 3					
Constant	- 1.102	0.640		- 1.723	0.087
Attitude	0.015	0.034	0.031	0.450	0.653
Severity	0.060	0.014	0.264	4.248	< 0.001
Barrier	- 0.043	0.014	- 0.216	- 2.988	0.003
Self-efficacy	0.048	0.009	0.389	5.252	< 0.001
Step 4					
Constant	- 0.945	0.535		- 1.766	0.079
Severity	0.060	0.014	0.264	4.258	< 0.001
Barrier	- 0.044	0.014	- 0.221	- 3.129	0.002
Self-efficacy	0.049	0.009	0.398	5.608	< 0.001

Tab. II. Predictors of the Diabetes preventive behaviors among the participants.

ple, Ayele et al. in their study among diabetic patients in Ethiopia showed that high levels of perceived severity could significantly elevate self-care behaviors by 12.3% odd ratio [20]. According to our finding, and introducing perceived severity as the second influential construct in the hypothesized model, it seems necessary to focus on it while designing interventions. Regarding the perceived severity, which was chosen as one of the predictive constructs in this study, it should be mentioned that although in several studies the less role of constructs based on fear in encouraging and modifying behavior has been emphasized [29], contrary to these results, studies on Iranian society reported the stronger role of these constructs [30] which needs to be further reviewed and perhaps in the closest analysis, these results are attributed to the cultural context of the Iranian community, especially in more traditional societies.

Another finding of the present study was the importance of perceived barriers as the third determinant in predicting the hypothesized model. In this regard, Chao et al. described the high level of perceived barriers as the most important predictor to noncompliance of proper treatment among diabetic patients [21]. In line with the findings of this study, Rickheim et al. introduced perceived barriers as the most important predictor to diet and metabolic control among diabetic patients [22].

Finally, the findings of our study indicated that investigated constructs could predict 40% of the variance of

diabetes prevention behaviors among at risk grope. This finding was largely in line with other studies in this area. For example, Chen et al showed that self-efficacy; history of diabetes and awareness estimated 59% of the variance in self-care behaviors among pre-diabetic patients [31].

Though this research faced several strengths such as using intervention mapping approach to assess the cognitive-related behaviors of diabetes prevention in Iranian society; it had some limitations such as being limited to Kermanshah city in western Iran that made it difficult to generalize it to the whole society. About thirty-eight participants did not finish the study and rejection rate of our study was 19% was another limitation to the present study, which suggests that similar studies should be carried out in other communities with a larger sample size, so that the generalizability of the results cannot be addressed.

Conclusions

The results of the present study indicated that sociocognitive determinants were accounted for 40% of the variation in diabetes preventive behaviors and perceived self-efficacy, severity and barrier were the most influential predictors on perform diabetes preventive behaviors.

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Conflict of interest statement

None declared.

Authors' contributions

Study design: MM-A and FJ. Data analysis: FJ and MMA. Study supervision: MM-A. Manuscript writing and revisions: MM-A, FJ, MIM, FJ and TAJ.

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OPEN ACCESS

ORIGINAL ARTICLE

The Workplace Health Promotion (WHP) programme in an Italian University Hospital

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Keywords

Health promotion • Workplaces • Chronic diseases • Risk factors • Evaluation

Summary

Introduction. Description of the lifestyles of employees of the Siena University Hospital (Azienda Ospedaliera Universitaria Senese: AOUS), as assessed through a Workplace Health Promotion (WHP) project in the two-year period 2017-18; assessment of possible short-term effects of integrated health promotion interventions in the workplace, within the framework of the Tuscany WHP network, as applied in the AOUS and involving about 1,000 workers.

Methods. A cross-sectional study and a pre-post evaluation of data collected by means of anonymous questionnaires in two phases: before the beginning of the programme and after 12 months.

Results. Twelve months after the start of the programme regarding diet (consumption of fruit and vegetables) and physical activity, the positive effects that emerged were not statistically significant. No differences were observed between gender or profes-

Introduction

Workplace Health Promotion (WHP) programmes are coordinated strategies for promoting the health of workers; they include policies, environmental support and activities in the workplace that are aimed at fostering the adoption of behaviours conducive to wellbeing [1]. The WHP project differs from programmes of health and safety in the workplace, in that the latter focus on the prevention of injury, while the WHP is aimed at preventing non-communicable, lifestylerelated diseases [1]. Owing to the shortage of controlled studies in this area, and to the heterogeneity of the interventions assessed, good levels of evidence have not yet been reached. Nevertheless, in recent years, evidence of the efficacy of some health promotion interventions in working environments (WHP) has grown [2-8]; these initiatives have been particularly effective in reducing general risk factors for health and absenteeism due to illness [9]. Moreover, some of these risk factors, such as smoking, alcohol consumption and behaviour while driving vehicles, are also closely connected with workrelated risks; they might therefore be better controlled if tackled both from the point of view of safety at work and from that of health promotion [10].

It is very difficult to evaluate complex programmes. However, the best results are achieved when the proposed sional categories. The employees' perception of the programme was satisfactory.

Conclusions. Albeit within the methodological limits of the assessment, the results showed that the diffusion of some major risk factors for chronic diseases had not decreased after 12 months' exposure to the programme. However, monitoring of these risk factors needs to be continued over a longer period, in order to detect the appearance of the expected changes in the long term. Moreover, it is essential to continue monitoring by sex and professional category, in order to pick out any differences and, if possible, take remedial actions. Further studies, in collaboration with the pertinent physicians, are desirable, since integrating data collected during health surveillance with a limited set of indicators of general risk factors may help to promptly identify possible health needs among employees.

interventions are supported by evidence of efficacy, when several risk factors are tackled (multicomponent programmes) over a medium-long period, when interventions are integrated with programmes to promote safety, and when significant modifications are introduced into the working environment [11-13], as in the case of the WHP project. As testified by the literature, the benefits accruing to employees of the companies participating in the WHP project include a lower risk of non-communicable diseases and an improvement in healthy practices (e.g. physical activity and eating habits) [14-18]. In addition, the companies themselves benefit in terms of improved market value [19] and returns on investments [15, 20]. Evidence of the impact of WHP on productivity is mixed; a recent review [21] was inconclusive, while a meta-analysis found limited benefits for health and productivity [22]. It should, however, be pointed out that the Return On Investment (ROI) utilised in studies conducted in North American companies cannot be directly transferred to the Italian setting, in which the benefit yielded by a reduction in absenteeism due to illness can be expected, while the benefit of insurance savings cannot. Clearly, the evaluation of such programmes is problematic [23]. A systematic review conducted in 2013 [24] identified 307 studies that had assessed WHP programmes, only nine of which were deemed to be of good methodological

quality, and only seven used adequate methods to evaluate the efficacy of the interventions. Nevertheless, a recent meta-analysis [25] of the efficacy of single WHP interventions concluded that the evidence accumulated over the last three decades indicated that programmes which were well designed, well implemented and based on the principles of evidence could yield positive outcomes in terms of both economy and health.

With regard to the implementation of effective interventions, certain limitations of the currently available evidence-based indications have been identified: the absence of operative indications, the lack of a standardised reproducible model of intervention, and the lack of adaptation of these interventions to the Italian setting [11].

The aim of the present study was to analyse the first results of the WHP project in the University Hospital of Siena (AOUS) after application of the programme for 12 months, by comparing the diffusion of risk factors before and after implementation of the interventions, with a view to determining whether changes in the risk profile of workers had already taken place in the short term.

Methods

THE TUSCANY REGION'S WHP

The Tuscany Region is currently running a structured, multicomponent, standardised WHP programme (Workplace Health Promotion: http://www.regione. toscana.it/lavoraresicuri/whp) based on a pathway of free accreditation for companies that adopt good practices for the control of the main risk factors for chronic non-communicable diseases. Designed and tested by the European Network Workplace Health Promotion (ENWHP) [26], this system has been adopted by the Tuscany Region, which in 2016 adhered to the programme through the Regional Council's resolution n. 1078 2/11/2016. The Tuscany Region's programme of health promotion in the workplace was recognised by the ENWHP as a model of good practice, both because it was in line with the Luxembourg Declaration and because it was deemed to contribute to the diffusion of a new culture of health and safety in the workplace.

Organisations that take part in the Tuscany Region's WHP can apply to join the ENWHP and, if they can demonstrate that they have fully implemented the provisions of the regional programme, can obtain certification by the network.

The good practices required are enacted by the companies themselves through the use of internal resources and with consultation and monitoring by the personnel of the pertinent Local Health Authorities. Each year, the companies choose two different topics (from the 6 proposed: Diet, Smoking, Physical Exercise, Alcohol and Addiction, Road Safety, and Well-being and Life-Work Reconciliation). In each of these areas, they are required to implement at least three "good practices",

which are chosen from among those listed in a specific manual [27] (q.v. for a detailed description of the individual interventions proposed). The WHP manual is equipped with numerous annexes that refer the reader to instruments, materials and contents drawn up by national (Ministry of Health, National Health Institute, "Gaining Campaign...) and international (WHO, Health" EU - Occupational Safety and Health Administration, ENWHP) institutions. The good practices suggested include both interventions supported by solid evidence and initiatives aimed at communication and raising awareness. The sixth topic area of the program, "Wellbeing and Life-Work Reconciliation", encompasses a wide variety of initiatives, all of which help to improve quality of life, but the results of which are difficult to measure in terms of health. The programme includes a monitoring system, which enables indicators to be produced on the basis of anonymous questionnaires administered to employees at different time-points. In the AOUS, where testing of the programme started in 2016, a total of about 1,000 employees were recruited, which corresponds to over 40% of the entire workforce. In 2018, the data-collection system first yielded enough information to enable comparison of the diffusion of the main risk factors among the workers who had participated in the programme for at least 12 months. The aim of the present study was to assess any tangible short-term effects of this programme of health promotion in the workplace.

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Study design

The study entailed a randomised pre-post comparison of indicators recorded after the implementation of specific interventions for health promotion. The data were gathered by means of a self-administered, anonymous, internationally validated, online questionnaire.

Before proceeding to fill in the online questionnaire, the participants gave their consent to the use of the data in aggregate form. The judgement of ethical propriety was provided by the Ethics Committee of the Local Health Unit Tuscany South-East.

INSTRUMENTS

The comparison was carried out on the aggregate data on the diffusion of risk factors among the workers. The questionnaire comprises 35 items concerning: sex, age, occupational level, anthropometric parameters (weight, height), habitual level of physical activity, eating habits, smoking, road accident risks, consumption of alcohol and other drugs, and the quality of relationships with family members, colleagues and superiors. The text of the questionnaire is available online [27]. The anthropometric parameters (weight, height) are selfreported. The duration of exposure to the interventions contained in the programme was 12 months.

INCLUSION CRITERIA

The sample population is very heterogeneous, consisting of subjects from several healthcare, medical, technical and administrative professions. For this reason, any differences among the various categories of workers will be taken into account in the analyses. Online administration of the questionnaire was publicised by means of both the internal newsletter and e-mail contacts with employees on the hospital mailing list; potential respondents were informed that they could participate in the project within a one-month period, starting from a specific date. During this one-month period, two reminders were sent to those on the mailing list, to encourage participation. All those who accessed the website through the link provided, and who gave their consent to participate, were enrolled in the study. On a total population of about 2,400 employees, 968 completed the pre-intervention questionnaire, and 1,108 completed the post-intervention questionnaire. The number of participants and the random nature of their participation ensure that the sample is representative.

INTERVENTIONS IMPLEMENTED

Diet

First good practice

In the refectory, fresh fruit and vegetables were made available at least three days a week, and notices were posted to publicise the "Tuscan Dietary Pyramid" (Piramide Alimentare Toscana, PAT), the IARC guidelines, instructions for calculating Body Mass Index (BMI) and material regarding the project "Anche al lavoro... e vai con la frutta - Eat fruit even in the workplace" [28].

Second good practice

The refectory staff was specifically instructed as to the correct sizes of portions to serve, and notices indicating the appropriate quantities of food were posted in the refectory. Employees were also informed about portion sizes through the hospital's official communication channels (leaflets in wage packets, hospital newsletter and mailing list, and a page devoted to the project in the intranet network).

Promotion of physical activity

Third good practice

Notices encouraging the use of the stairs were posted in lifts; promotional posters (at least 1 for every 60 workers) were affixed in highly frequented areas; and messages were circulated in wage packets (at least 3 per year) and in the hospital newsletter and mailing list.

BMI was calculated by applying the formula: body weight (kg)/height (m^2) and was analysed both as a continuous and as a categorical variable. According to the World Health Organization Growth Reference, normal-weight participants have a BMI between 18.5 and 24.9 kg/m², overweight participants have a BMI between 25.0 and 29.9 kg/m², and obese participants have a BMI of 30.0 kg/m² or greater [29].

Sedentariness was assessed by means of specific items in the questionnaire. As an indicator of result, we used the proportion of individuals who stated that they hardly ever engaged in physical activity outside working hours (multiple-choice item); the option "outside working hours" was used because it describes the amount of physical activity that depends directly on the individual's volition.

STATISTICAL ANALYSIS

The results of the questionnaires completed in 2017 and 2018, on the two groups of employees, were initially analysed by means of descriptive techniques, in order to ascertain the main characteristics of the respondents. We then carried out an analysis aimed at assessing the homogeneity of the groups of respondents in the two years with regard to their main personal characteristics (sex, age, BMI, class of nutritional status and profession). In the third phase of the statistical analyses, we compared the propensity to consume some types of foodstuffs (fruit, vegetables, sweet foods and sweetened beverages) and the propensity to engage in physical activity (at work, outside work, and the overall number of hours of physical activity) between 2017 and 2018. These comparisons were made by means of non-parametric tests of the hypotheses. Specifically, Fisher's exact test and the chi-square test were applied to qualitative variables, while the Mann-Whitney test was applied to quantitative variables, once the assumption of normality of distribution had been excluded on the basis of the Shapiro-Wilk test. All of the above-mentioned comparisons were also carried out within the four professional categories into which the respondents were classified (physician, nurse, healthcare assistant, and "other professions"). The analyses were performed by means of IBM-SPSS® v. 23, and the level of significance was set at p < 0.05.

Results

In both years considered (2017 and 2018), the majority of respondents were females (70.0% in 2017 and 70.8% in 2018); this reflects the gender distribution of AOUS employees. The mean age of the participants was almost identical (47.6 years in 2017 and 47.2 years in 2018), as were BMI values and the prevalence of overweight/ obese subjects (Tab. I).

The distribution of respondents in the various professional categories was also very similar in the two years: in 2018, the number of nurses who participated was slightly higher than in 2017, while subjects in the category "other professions" decreased. However, the differences recorded did not prove to be statistically significant, which testifies to the fact that in both years the respondents displayed equivalent characteristics. Table II shows the behaviour reported with regard to the consumption of some types of foods. Regarding fruit and vegetables, the percentage of subjects who reported a low consumption increased: those who never ate fruit, or who ate no more than two daily portions, increased from 62.6% in 2017 to 64.6% in 2018; those

		2017	2018	Statistics	Р	
		(n = 968) (%)	(n = 1108) (%)			
Cox	Female	588 (70.0)	701 (70.8)	Fisher test	0 740	
JEX	Male	252 (30.0)	289 (29.2)	FISHER LESL	0.719	
Age (years)		47.59±9.42	47.18±10.16	Mann-Whitney, U = 410021.5	0.634	
	Underweight	37 (4.4)	33 (3.3)			
BMI class	Normalweight	500 (59.7)	609 (61.7)	Chi-square, χ^2 (2) = 1.786	0.409	
	Overweight/obese	301 (35.9)	345 (35.0)			
	Physician	182 (21.16)	220 (21.9)			
Drofossion	Nurse	247 (28.72)	331 (32.9)	(h) converse $2(4)$ 7.272	0.005	
Profession	Social/health worker	93 (10.81)	118 (11.7)	C = 7.252	0.065	
	Other	338 (39.3)	338 (33.6)			
BMI		24.25±4.16	24.24±4.22	Mann-Whitney, U =4 10321.5	0.773	

Tab. I. Characteristics of participants in 2017 and 2018 (data are expressed as absolute values and percentages for qualitative variables, and as

Tab. II. Propensity to consume some types of foods in the groups of respondents in 2017 and 2018 (data are expressed as absolute values and percentages).

		2017	2018	Statistics	Р	
		(n = 968) (%)	(n = 1.108) (%)			
Daily portions of fruit	From 0 to 2 portions	517 (62.6)	630 (64.6)	Fisher test	0.404	
Daily politions of fluit	3 or more portions	309 (37.4)	346 (35.5)	Fisher test	0.404	
Daily portions of	0 or 1 portion	211 (25.5)	285 (29.2)	Fisher test	0.090	
vegetables	2 or more portions	615 (74.5)	691 (70.8)	FISHER LEST		
	Never or once	337 (42.6)	387 (41.7)			
Weekly consumption	2 or 3 times	263 (33.2)	294 (31.7)	$(bi cquare x^2(Z) = 4.492$	0.696	
of sweet foods	4 or 5 times	109 (13.8)	144 (15.5)	$CIII-SQUALE, \chi_2(5) = 1.482$	0.000	
	Every day	83 (10.5)	104 (11.2)			
	Never or once	514 (75.0)	603 (76.6)			
Weekly consumption	2 or 3 times	112 (16.4)	114 (14.5)	(bi coulors - 0/2) = Z Z Z	0.740	
beverages	4 or 5 times	29 (4.2)	25 (3.2)	$CIII-SQUARE, \chi_2(5) = 5.555$	0.540	
beverages	Every day	30 (4.4)	45 (5.7)		1	

Tab. III. Physical activity in the groups of respondents in 2017 and 2018 (data are expressed as absolute values and percentages for qualitative variables, and as means and standard deviations for quantitative variables).

		2017	2018	Statistics	Р
		(n = 968) (%)	(n = 1108) (%)		
Physical activity	None or less than 30 min	580 (73.0)	665 (72.3)	Eisbor tost	0 796
DURING work	At least 30 min almost every day	215 (27.0)	254 (27.6)	FISHER LESC	0.760
Physical activity	None or less than 30 min	481 (59.6)	574 (61.5)	Fisher test	0.474
OUTSIDE work	At least 30 min almost every day	326 (40.4)	359 (38.5)	FISHER LEST	0.451
Total hours of physical activity per week		6.3 ± 4.3	6.2 ± 2.7	Mann-Whitney, U = 380967.5	0.320

who never ate vegetables, or who ate no more than one daily portion, increased from 25.5% in 2107 to 29.2% in 2018. Analysis of the consumption of sweet foods and sweetened beverages revealed an opposite trend. Although the frequent consumption of sweet foods and sweetened beverages involved a minority of subjects within each group of respondents, the overall consumption of such products, especially sweet foods, seemed to have risen; indeed, the percentage of subjects who reported eating sweet foods four or more times per week increased from 24.3% in 2017 to 26.7% in 2018. In this case, too, the differences did not prove statistically

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significant differences, indicating that dietary behaviour did not change over the two-year period considered. The consumption of these foodstuffs over the two years was also compared within each professional category and each BMI class; again, no significant differences emerged.

Over the two-year period, the propensity to engage in physical activity, both during and outside working hours, did not change (Tab. III). Specifically, while physical activity during working hours did not display any notable variation, such activity outside work declined slightly from 2017 to 2018; indeed, in 2018 the percentage of subjects who did no physical activity, or did less than 30 minutes per day, was 61.5%, as against 59.6% in 2017. The total number of weekly hours devoted to physical activity was practically identical in the two groups. The statistical tests performed revealed that the differences observed between 2017 and 2018 were not significant. Likewise, no significant differences emerged between the two years when the results were stratified by professional category and BMI class.

From the second administration onwards, the questionnaire includes a few questions on the respondents' appreciation and perception of the interventions implemented by the company; these questions explore the participants' subjective assessment of the interventions on diet and physical activity, of the company's level of commitment, and of the utility of the programme. With regard to diet, it emerged that 63.0% of participants judged the interventions to be very or quite useful, while 37.0% thought that the company had done "a lot" or "enough". Similarly, 53.0% of employees stated that the interventions on physical activity were very or quite useful, and 26.0% judged that the company had done "a lot" or "enough" in this area.

The second aspect to be explored is the respondents' perception of improvement in their own habits with regard to diet and physical activity. In both spheres, many subjects reported a partial improvement. With regard to diet, the percentage of subjects who reported an improvement was higher than that of those who reported no change (31.0% vs 27.0%). By contrast, with regard to physical activity, the opposite pattern emerged: 37.0% stated that they had not changed their habits, while only 25.0% reported that they had.

Discussion

Evaluating health promotion programmes implemented in a very varied and heterogeneous setting – such as that of a hospital facility – is a decidedly complex task. Although many literature reports have indicated the efficacy of health promotion initiatives in the workplace [2-8, 30], a very recent systematic review of American trials found that the available evidence of the efficacy of such interventions was insufficient and inconsistent. Moreover, it was unclear whether such strategies were economically effective, or indeed whether they might even have unintentional negative consequences [31]. However, the limited number of studies identified suggests that programmes of this kind are still in their infancy, and that further research is required in order to obtain evidence of their efficacy.

The *WHP programme*'s data-collection system was not designed for the purposes of epidemiological research. Rather, it is, first of all, a self-assessment tool for the worker. Secondly, it is a system for the overall monitoring of the prevalence of risk factors for chronic diseases; as such, it can be used by companies to plan and assess their interventions.

As the data used are self-reported, most of the measurements display a certain degree of approximation. Moreover, in the field of health promotion, issues concerning the choice of indicators and the timing of measurements are somewhat complex and controversial. On the one hand, for example, a short-term change in behaviour does not necessarily mean that the behaviour will be maintained in the medium/long term. On the other hand, anthropometric parameters, such as mean BMI and the class of nutritional status, are very unlikely to change in the short period.

The chief limitation of this type of investigation, however, lies in the use of anonymous data, which precludes the analysis of intra-subject variations in risk factors. This markedly restricts the possibilities of analysis. However, notwithstanding these limitations, the results of our study deserve attention on account of the size of the samples analysed in both phases. Moreover, to our knowledge, few studies have been published on health promotion interventions in this type of company setting. The results presented seem to indicate that, in a context such as that of the AOUS, lifestyle improvements, in terms of healthier eating and increased physical activity, cannot be registered in the short term. Our evaluation indicates the need to identify new, evidence-based, good practices to be added to the list of interventions in those thematic areas in which positive changes have not yet been seen. However, it should be borne in mind that the interventions proposed to companies are mainly of an organisational (policy, procedures, regulations) or informative nature, and that, as such, their expected effects are limited, especially in the short term.

To the best of our knowledge, the present study is the first to be conducted in a university hospital in Italy. Others have been carried out in companies of different kinds, particularly in the Province of Bergamo [32]; this latter study found that positive early effects (after 12 months) were related to the consumption of healthier foods (fruit and vegetables) and to increased rates of smoking cessation, and that these effects were more evident among males and white-collar workers. An important step will be to monitor the trend in the distribution of risk factors over three or more years after the start of the programme and in an even larger number of employees. We therefore intend to continue to publicise this project throughout the hospital, in order to track its long-term effects. One clearly positive finding of this study was the approval expressed by the respondents, which reveals that workers are well aware of the importance of the themes raised.

A final important consideration concerns the collaboration of various professionals, and particularly that of the physicians charged with implementing health promotion programmes in the workplace. The possibility to utilise some data from employees' health records for research purposes, and the gathering of a few further data on general risk factors, would enable us to overcome the main limitations imposed by the use of anonymous questionnaires: i.e. the impossibility of monitoring intra-subject variations; low or variable rates of participation

Our hope is that, at the end of the three-year period, the WHP project will be implemented systematically, as the approval expressed by the respondents suggests that the interventions may prove efficacious in the long term; this outcome may be favoured by the creation of workgroups to deal with specific topics, thereby making the workers themselves an active part of the process of change.

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Conflict of interest statement

None declared.

Authors' contributions

Conceptualization: GL; Methodology: GL, FF; Statistical analysis: FF; Writing, review and editing: GL, FD, AP, RG, EV, VG, FF.

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ORIGINAL ARTICLE

Quality improvement of medical records through internal auditing: a comparative analysis

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Keywords

Medical records • Clinical audit • Quality improvement • Quality of healthcare

Summary

Introduction. The systematic evaluation of the quality of medical records is crucial. Nevertheless, even if the improvement of medical records quality represents a priority for every health organization, it might be difficult to realize.

This is the first study to assess the efficacy of internal audit as a tool to improve the quality of medical records in hospital setting. Methods. The program was carried out in a third level teaching hospital. Trained ad hoc evaluation teams carried out two retrospective assessments of quality of medical records using a random sampling strategy. The quality assessment was performed using a 48-items evaluation grid divided into 9 domains: General; Patient Medical History and Physical Examination; Daily Clinical Progress Notes; Daily Nursing Progress Notes; Drug Therapy Chart; Pain Chart; Discharge Summary; Surgery Regis-

Introduction

With the increasing numbers of observations documented about patients in their records, clinicians are faced with an overwhelming amount of data, registries and charts. This phenomenon has been observed in several care settings, from outpatient clinics to hospital admissions, for each care process and all the medical departments [1]. Over the last decades, it became increasingly interesting to measure the quality of health care and hospital documentation in order to strengthen both transparency, continuity of care and accountability which are essential targets of the health systems. In this context, governments, scientific associations, hospital directorates as well as insurance companies released quality indicators for various kinds of hospital admissions, investigated through medical records' data [2].

In the actual economic context, with increasing health needs, efficiency and efficacy represent fundamental keyword to ensure a successful use of the resources and the best health outcomes. Furthermore, medical record, completely and correctly compiled, is an essential tool in the patient diagnostic and therapeutic path, aimed to facilitate continuity of care and patient safety and promote structured and effective communication between caregivers. Inadequate

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ter; Informed Consent. After the first evaluation of 1.460 medical records, an audit departmental program was set up. The second evaluation was carried out after the internal auditing for 1.402 medical records.

Results. Compared to the first analysis, a significant quality amelioration in all the sections of the medical chart was shown with the second analysis, with an increase of all the scores above 50%. The differences found for each section of medical records between the first and second analysis are all significant (p < 0.01).

Conclusions. Internal audits are not just measurement activities but a necessary activity to support the organization in achieving its objectives and assessing the quality of clinical care and maintaining high quality professional performance

communication between different health professionals is associated with discontinuity of care, which can lead to errors [3-6]. The consequences of discontinuity of care are linked to increased cost and length of hospital stay, readmissions, poorer patient satisfaction, adverse events, delays and mistakes in treatment and diagnosis [7]. Furthermore, proper management of health records and accurate, comprehensive recordkeeping is becoming more and more essential for the administrative reporting and legal claims as well as an absolute condition for any structure that wants to be an excellence within a health system [8]. The systematic evaluation of the quality of medical records is crucial, emphasizing the role that an accurate, readable and accessible medical record can play in reducing medical errors and increasing integration between the different ways of assistance and the efficiency of delivery of services [9].

Nevertheless, even if the improvement of medical records quality represents a priority for every health organization, they may find that difficult to be realized. Through the tools of clinical governance, aimed to promote the change in a health care organization, audit seems particularly suitable [10]. Furthermore the Italian Ministry of Health supports the importance of promoting the systematic and continuous adoption of audit in all

QUALITY IMPROVEMENT OF MEDICAL RECORDS THROUGH INTERNAL AUDITING: A COMPARATIVE ANALYSIS

areas of the National Health Service to develop the ability to assess, innovate and meet the expectations of patients and professionals, in a constantly changing reality [11].

Through audit, hospital management should therefore encourage a better quality in clinical documentation to improve the quality of health services and the standard of clinical practice.

Aim of this study is assessing the differences of medical records' quality before and after internal audit in an Italian third level teaching hospital.

Methods

TEAM OF ANALYSIS AND SELECTION OF SAMPLE

Two different evaluation teams trained *ad hoc* carried out in 2013 (June-November) and 2015 (July-December) a retrospective assessment of quality of medical records. The teams were composed of 3 physicians and 1 nurse, supervised by the hospital's health directorate. The sample, selected using a random sampling strategy, is representative of at least 3% of the total amount of hospitalizations of the previous year, in accordance to the criteria provided in the most recent guidelines by the body checking [12]. In order to ensure an equitable distribution of the sample among the wards, a proportional selection of medical records based on the number of admissions of the previous year for each ward has been made.

Assessment methodology

The quality assessment was performed using a 48-items evaluation grid divided into 9 domains: General; Patient Medical History and Physical Examination; Daily Clinical Progress Notes; Daily Nursing Progress Notes; Drug Therapy Chart; Pain Chart; Discharge Summary; Surgery Register; Informed Consent. A more detailed description of the instrument is published elsewhere [13]. The items were expressed as yes/no questions. 1 point was assigned if the item was satisfied, 0 if not. Considering the different types of medical department, if one (or more) item was not applicable, 99 was assigned and it was excluded from the analysis. A guide of the analysis with the criteria of assessment was built in order to support the teams and standardize the analysis.

The overall and specific area scores were calculated as proportions of satisfied items excluding the not applicable ones:

Score = $\frac{\text{Number of items satisfied}}{\text{Total of evaluable items}}$

Therefore the final score can be shown as percentage (0% if none of the evaluable items were satisfied, 100% if all the evaluable items were satisfied).

The results obtained were aggregated by the evaluation teams for each ward and medical department, preparing specific report showing the aim of the analysis, methodology, results and conclusion as well as possible future actions and further issues.

AUDIT

An audit departmental program was set up between November 2013 and June 2014, after the first evaluation of medical records, in order to share the results with the personnel of the departments investigated and promote the culture of transparency and accountability. Audit were structured following the 4 phases proposed by the Italian Ministry of Health [11] and English National Health Service [14] to facilitate the understanding of organizational processes and identify the best interventions to improve the quality of hospital documentation. According to the NHS score, our audit model could be considered a good project (score of 20/25).

The first part of audit consisted of showing the methodology used and a sample of medical records to replicate the assessment. In the second part participants were divided in small groups and invited to actively discuss the results, identify the weaknesses and define the cause of problem (professional, organizational or structural). Finally a report of the meeting was recorded and a satisfaction questionnaire was administered to all the participants. The questionnaire's items are listed in Table I.

STATISTICAL ANALYSIS

In both analysis (2013 and 2015), data were collected in a Microsoft Office Excel 2010 database where frequencies, means and percentage scores were calculated. An overall score was computed for the hospital (total score). Separate specific scores were calculated for each investigated area. Scores were compared before and after the internal departmental audit with independent t test, using the Stata/SE version 10.1 package.

Results

In 2013 and 2015 respectively, 1.460 and 1.402 medical records were evaluated, representative of almost 3% of hospitalizations.

The results coming from the first analysis in 2013 showed a good accuracy in the surgical area (90.2% of items satisfied), informed consent (77.7% of items satisfied), discharge summary (71.4% of items satisfied) and general part (69.5% of items satisfied). Below the overall hospital mean (59.5% of items satisfied) the patient medical history and physical examination (50.9% of items satisfied), daily nursing and clinical progress notes (54.7% and 47.2% of items satisfied, respectively), drug therapy chart (40.3% of items satisfied) and finally the pain chart (only 29.3% of items satisfied) were found. The most common criticality across all the areas lies in

Tab. I. Items of the Audit Program Satisfaction Questionnaire.

n	Question
1	Were the aims and methods of the audit clearly conveyed?
2	Did the team leading the audit show expertise in the examined area?
3	Were you able to understand the essential issues and the main problems?
4	Were you able to express your opinion during the audit and fruitfully interact with the leading team and colleagues?
5	Generally, how would you rate the professional enhancement gathered from the audit?
6	Generally, how would you rate the efficacy of the audit?
7	Do you consider the methods learned during the audit useful to better evaluate your own activity?
8	Did/will you intend to share the audit contents with colleagues who did not participate?
9	Do you consider the methodology of evaluation of appropriateness (PRUO) feasible and repeatable?
10	Do you consider the methods of quality assessment feasible and repeatable?
11	How do you feel important a complete and accurate clinical documentation?
12	How do you feel important that the hospitalization fits the appropriateness criteria in addition to the clinical criteria?
13	Do you consider helpful the support given by the Health Directorate to address and improve these issues?
14	Do you consider that the final recommendations gathered from the audit are practical, repeatable and effective in your activity?
15	Do you consider worthwhile to include in the budget targets a systematic assessment of quality and appropriateness?
16	Was the audit duration reasonable?
17	Was the interval between the first and the second audit adequate?
18	Do you consider additional meetings on this topic necessary?
19	If yes, would you prefer practical or theoretical meetings?
20	Do you believe that other professional figures should be involved?
21	If yes, specify who
22	Do you consider the audit a useful tool and helpful to improve the system?
23	Any further comments

the signature lack by health professionals, especially physicians.

Discussion

In order to share and discuss the results with the personnel, 34 audit were carried out: in 16 audit entire departments were reached and a theoretical approach was adopted while 18 audit were organized to reach small groups of operators, though interactive discussions. 351 physicians and nurses were reached. The overall satisfaction score was 3.3 (score scale between 1 and 4; 1 = inadequate; 4 = excellent) and most of participants (92%) indicate the available time as congruent with the purpose. Furthermore, 99% of participants considered audit a useful tool for continuous improvement of hospital care quality, 93% would appreciate to be involved in additional audit, especially with a practical approach (as in the second part of the audit).

The second evaluation in 2015, after audit, showed a general improvement in all the sections of medical records investigated compared to the first analysis, with an increase of all the scores above 50%. The overall total score of the hospital increased of almost 20%, from 59.5% to 77.3%. The surgical area, informed consent and discharge summary areas increased to 94.2%, 91.4% and 89.9%, respectively, followed by the daily nursing progress notes (86.3%), general part (71.0%), drug therapy chart (70.7%), daily nursing and clinical progress notes (67.7%), patient medical history and physical examination (65.9%) and pain chart (53.6%) (Fig. 1). The differences found for each section of medical records between the first and second analysis are all significant (p < 0.01).

This study shows a significant amelioration in the quality of medical records before and after an internal audit program carried out in a third level teaching hospital. The baseline quality assessment performed in 2013 showed several deficiencies, due to 40% of minimum level of acceptability not completely satisfied with great discrepancies among departments and among Care Units.

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These findings are consistent with those described in previous studies. Attena et al in 2010 reported a quality of compilation quite far from the reference standard value of 100%, with the worst data concerned the completeness of the physical examination (56.2%) and the low presence of the patient chart (12.9%) and the discharge summary (18.0%). Important differences were found across the diseases for various items and higher accuracy was found in teaching hospitals and some private hospitals [15]. In 2002 a study carried out in various Italian Regions by the Agency for Regional Health Services showed that only 0.5% of the medical records fully satisfy the 26 quality criteria and even in the hospital with the best performance, the indicator of acceptability stopped at the value of 6.7%. The main deficiency was represented by the traceability of signatures in the medical journal [16]. This remains a problem still in the present study, with the quality of the pain assessment (29.3%) and the completeness of the Drug Therapy Chart (40.3%) that represent the greatest concern before the intervention.

Fig. 1. % of medical records fulfilling the quality items for each domain before (2013) and after (2015) audit program 100 90 80 70 60 50 40 30 20 2013 10 2015 0 Surgery Patient Medical History and Physical Total Informed consent General Drug Therapy Chart Pain Chart Discharge Summary **Daily Nursing Progress** Daily Clinical Progress Notes Examination

Two years later, the overall hospital score and all the areas investigated showed a significant improvement, in some cases reaching an increase higher than 30%, such as for the Daily Nursing Progress Notes (+31.6%) and the Drug Therapy Chart (+30.4%). However, this cannot be considered completely satisfactory because, as known, the criteria of completeness, clarity and legibility must be entirely satisfied. Nevertheless, none of the investigated domains shows a worsening and the progresses are higher than previous reported. Attena et al. in 2010 evaluated and implemented a medical records quality program sending a letter to each ward containing their specific results and the guidelines to fill out the medical record correctly [17]. In their follow up evaluation, they found several, but modest, improvements. Furthermore, they reported some worsening in the sections regarding the completeness of information and clarity of handwriting of patient charts and in the completeness and legibility of the clinician's signatures. These findings could be partially explained by the adoption of audit as the tool for showing and discussing the problem related to the quality of medical records. As a matter of fact the active feedback engaged the interest of the clinicians and received a good appreciation from the involved health professionals, which declared a professional enrichment and required further meeting [13].

This study deal with a very relevant topic for all the health care organizations, both for clinical, and for economic reasons. Dunlay et al found that medical records for patients with Acute Coronary Syndromes often lack key elements of the history and physical examination and that patients treated at hospitals with better medical records quality have significantly lower mortality and may receive more Evidence Based Medicine [18]. Furthermore, Farhan et al showed a positive correlation between the accurate documentation and correct coding [19]. The positive relationship between better medical charting, coding accuracy and good medical care should lead the hospital medical directorates to increase their efforts towards the amelioration of the quality of medical records. Several organizations have provided hospitals and health systems with guidelines for clinical documentation improvement programs, but there is evidence of strong disparities among hospital about the level of adoption of these guidelines.

To the best of our knowledge this is the first study to assess the efficacy of audit as a tool to improve the quality of medical records in hospital setting and it is one of the main strength of our program. As a matter of fact, Attena et al. failed to implement an intervention for improvement by the active and direct involvement of the operators (plenary meetings with all the operators, presentation of the results of the first survey, illustration of the guidelines of correct compilation, discussion), and they adopted an approach by written communication.

Audit has been used in different health care contexts to evaluate patient care from assessment through outcome [20, 21]. It is a useful tool in improving the quality of care provided by a health service across the organization, both in surgical [22] than in clinical setting. Furthermore, audit and feedback can be effective in improving professional practice, as well as an effective

way to stimulate clinicians to keep going in continuous improvement [23].

The benefits of undertaking internal audit are promotion of good practice, providing opportunities for training and education, better use of resources and increase in efficiency. In time of financial constraint it could be useful to reduce the health care costs [24]. However patient outcomes were less likely to be influenced by audit and feedback interventions and its real impact especially is still controversial [23, 25].

Another key factor of our program is represented by the use of a quantitative, reliable and validated tool to assess the quality of medical records of all the wards of the hospital. Anyway this study has some limitations. The first is represented by the study setting. The third level hospital where the study was conducted has a peculiar legal framework for the Italian context, being both a teaching and private hospital, highly competitive and with a high propensity for quality improvement programs. This could lead to an overestimation of the audit effect and limit the generalizability of the results. Secondly, the follow up was limited to one year after the program implementation. This means a good result in the short and middle period, but little is known about long-term effects.

Bearing in mind that one of the main obstacles to the quality improvement is represented by the resistance to modify well-established behaviors, the obtained improvement should be maintained promoting an integrated approach based on continuative evaluation and appropriate trainings.

Conclusions

Internal quality assessment could be used as one of the departmental performance indicator and every clinicians could use the 48-items evaluation grid could as a useful instrument to assess the quality of a sample of its own medical records. Waiting for the full development and application of the electronic medical record that should improve the quality of clinical documentation, our results suggest the importance of actively involve health professionals in audit, giving them formal responsibilities for improving the quality of clinical documentation.

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Conflicts of interest statement

None declared.

Authors' contributions

Study design: EA, GF and AP. Data collection: EA, GF and AP. Data analysis: EA and AP. Study supervision: AC and MV. All authors gave substantial contribution to manuscript revising and editing.

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ORIGINAL ARTICLE

The prediction incidence of the three most common cancers among Iranian military community during 2007-2019: a time series analysis

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Keywords

Time series • Cancer • Iranian military community

Summary

Objective. Cancers are one of the most important public health problems in Iran. Because of the importance of cancers, the purpose of the current study was to the prediction of the future incidence of the most common cancers among Iranian military community (MC) by using the time series analysis during 2007 to 2019.

Methods. In the current cross-sectional study, all registered cancers among Iranian MC entered the study. To select the best model of prediction, various methods including autocorrelation function (ACF), partial autocorrelation function (PACF), and Akaike

Introduction

In recent decades, the Non-communicable diseases such as cancers have become a public health concern globally. Different factors such as population aging, change in lifestyle and increase unhealthy behaviors such as increasing cigarette smoking, lack of physical activity, unhealthy diet has an important role in increasing this problem [1]. According to researches, lung, breast, and colorectal cancers are the most common cancers in the world [2]. In 2000, cancers were the cause of death for over 7 million cases in the world (13% of total mortality). In 2008 the estimation showed that 169.3 million years of healthy life in all people were lost due to cancers like as Colorectal, lung, breast, and prostate cancers. Also, those mentioned cancers were caused about the 18-50% of the total burden of cancers and the main cause of total Disability-Adjusted Life Year (DALY) in different countries [3]. In 2014 about 1,665,540 of new cancer cases and 585,720 cancer deaths occurred in the United States [4]. More than 60% of deaths due to cancers and approximately half of new cases occurs in developing countries [5]. In Iran such as other developing countries, cancers are one of the main public health problems. Due to the change in lifestyle and increas-

information criterion (AIC) statistics were used. All analysis was performed by using ITSM, stata14, and Excel2010 software. **Results.** The most prevalent cancers among Iranian MC were breast, prostate, and colon cancers respectively. The time series analysis was shown that the trend of all mentioned cancers in Iranian MC will increase in the coming years.

Conclusions. The trend of most prevalent cancers among Iranian *MC* was increasing but the different factors like the growth of population size and improving the registration system should be regarded.

ing the risk factors, the incidence of cancers in Iran is increasing [6]. According to the last reports of the Iranian ministry of health, cancers are the third cause of death after coronary heart disease and injuries [7, 8] and it was the second cause of no traumatic death in the population during the last 30 years [9]. The most common cancers among Iranian general population in both sexes is stomach, esophagus, breast, prostate and colon cancer Due to the type of the job, the military community and their family are more prone than other groups to the risk of the chronic diseases. The level of anxiety in the military population is high. So this factor can have an important role in determining the health status of this population [10-12]. The prediction of the future pattern of cancers by using current pattern can play an important role in identifying future trends of cancers and designing the prevention programs. Due to lack of similar study in Iranian population especially in the military community (active, retired, family, veterans) = MC the purpose of the current research was to determine the most prevalent cancers among Iranian MC and Forecasting incidence of them in the coming years by using time series methods.

Methods

In this cross-sectional study, the required data were extracted from the registered cases in the insurance organization of the Iranian MC. These data included variables such as age, gender, type of cancer, time of diagnosis (month - year) and the last status of patients (death or live).

INCLUSION CRITERIA

All registered cancers in the Iranian MC (active, retired, family, veterans) which have been diagnosed and registered during the March 2007 to March 2017 entered in this study.

DATA ANALYSIS

First, all data entered into Excel, and after cleaning they provided to the main analysis.

REMOVING NON-STATIONARY IN DATA

One of the pre-assumption for performing the time-series analysis on data is stationary of mean and variance in data in over time. Due to the non-stationary nature of the data, in the mean and variance terms, the needed transformation performed for stationary of data to remove of Non-stationary variance and mean, Box-Cox transformation and differencing were used respectively.

SELECTION OF MODELS

To select the best forecasting model, time series graphs such as partial autocorrelation function (PACF) and autocorrelation function (ACF) were used to determine Autoregressive (AR) (p) and Moving Average (MA) (q) parameters. So the best model for prediction was determined by using the PACF and ACF graphs with minimum Akaike information criterion (AIC) statistic that was earned from comparing among different models. AIC is a statistical technique that used for selection of a good model. The best model is the model that has the minimum AIC among all models [13].

Assessing the fitness of the selected models

For assessing the fitness of the selected models for forecasting, we used tests of randomness on residuals such as Ljung - Box statistic, McLeod - Li statistic, Turning points, Diff sign points, Rank test statistic, Jarque-Bera test statistic (for normality) and the schematic checking of the residual graph.

PREDICTION

After selecting the best model according to minimum AIC and assessing the fitness of the selected models using different tests the ARIMA (p, d, q) model were used to the prediction of the future trend of cancers by using current data. The p and q parameters were extracted from the PACF and ACF graphs and d parameter shows the order of differences for setting the stationary in the mean. By considering monthly time intervals, 120 months from 21 March 2007 to 20 March 2017 were accounted for the time series model and the prediction was made from March 21, 2017, to 20 August 2019. Subsequently, time series analysis methods were used to analyze the data. Data analyses were conducted using the ITSM (Interactive Time Series Modeling) software, STATA14, and Excel 2010 at the significance level of 0.05.

Results

The total registered cancers in the Iranian MC from April 2007 to March 2016 were about 29057 cases. The mean age of registered cancers was 63.36 ± 15.20 . Overall 53.04% of total cases were females and 46.96% of cancer cases were males (Tab. I). The most prevalent cancers among Iranian MC during these years were breast 8,244 (28.37%), prostate 2876 (9.90%) and colon cancers 2,118 (7.29%) respectively (Tab. II).

In the prediction of the incidence of breast cancer, the results showed an increasing trend in this cancer for the coming years (Fig 1). For prediction of the trend of this cancer the autoregressive integrated moving average (ARIMA) model with AR = 7, MA = 6, and Akaike information criterion statistics (AIC) = 350 were used [2, 6, 7]. In the prediction of the incidence of prostate cancer in the Iranian MC, the results of time series analysis showed an increasing trend in the incidence of this cancer for the coming years (Fig. 2). For prediction of the trend of this cancer the autoregressive integrated moving average (ARIMA) model with AR = 12, MA = 1, and Akaike information criterion statistics (AIC) = 275 were used [1, 2, 12].

In the prediction of the incidence of colon cancer, the results of time series analysis showed an increasing trend in the incidence of this cancer for the coming years

Tab. I. Descriptive characteristic of cancer patients among Iranian military community during 2007-2017.

	N (%)
Sex	
• Female	15,413 (53.04%)
• Male	13,644 (46.96%)
Job	·
• Retired	16,927 (58.26%)
Pensioner	7,418 (25.53%)
Employed	3,724 (12.82%)
• Soldier	184 (50.63%)
• Other	803 (2.76%)
Total	29057

Tab. II. The most prevalent cancers among the Iranian military community during 2007-2017.

Type of cancer	N (%)
Breast cancer	8,244 (28.37%)
Prostate cancer	2,876 (9.90%)
Colon cancer	2,118 (7.29%)
Stomach cancer	1,741 (5.99%)
Bladder cancer	1,640 (5.64%)
Non-Hodgkin's lymphoma	977 (3.36%)
Liver cancer	948 (3.26%)
Other cancers	10,513 (36.18%)





(Fig. 3). For prediction of the trend of this cancer the autoregressive integrated moving average (ARIMA) model with AR = 12, MA = 1, and Akaike information criterion statistics (AIC) = 353 were used [1, 2, 12].

In the prediction of the incidence of colon cancer among male and female, the results of time series analysis showed an increasing trend in the incidence of this cancer for the coming years (Fig. 4). For the prediction of the trend of this cancer among males the autoregressive integrated moving average (ARIMA) model with AR = 11, MA = 11, and Akaike information criterion statistics (AIC) = 664 were used [2, 11] And for females the autoregressive integrated moving average (ARIMA) model with AR = 11, MA = 11, and Akaike information criterion statistics (AIC) = 663 were used [2, 11, 12]. All the Related coefficients for prediction incidence of cancers among Iranian MC were shown in Table III.

Discussion

According to results of the current study, the most prevalent cancers among Iranian MC were breast, prostate, stomach and bladder cancers respectively. It seems

the pattern of cancers among the Iranian population is changing and with the aging population, it is expected to have an increasing trend of cancers such as prostate and breast cancers in the population.

The increasing trend of breast cancer among women had been shown in many reports [14-16]. These results are similar to the current study results. In fact, the time series analysis results showed that the incidence cases of breast cancer among Iranian MC have an increasing trend. It can be due to improving cancer registration system. Also, different factors like changing in lifestyle, increasing the risk factors such as obesity, aging, decreasing parity, changes in menstrual and reproductive patterns among women and using menopausal hormone therapy should be regarded. Furthermore, the role of screening programs such as self-examination and mammography should not be neglected because using these methods can increase the number of diagnosed new cases in the early stage of the diseases [17-23].

The pattern of prostate cancer is different between countries [24, 25]. Although the lowest incidence and mortality rates of prostate cancer were reported in Asian countries [26], these indicators for mentioned cancer is increasing in many Asian countries [27]. The incidence





cases of prostate cancer in Iran is similar to some Asian countries such as China and Kuwait but In comparison with the western countries like the USA, Iran has the lower incidence rate of prostate cancer [28]. The results of the current study showed that the reported cases of prostate cancer in Iranian MC are increasing and we will have more cases of prostate cancer in Iranian men in the future. The Increasing trend of prostate cancer among Iranian MC may be due to many different factors such as increasing the use of PSA testing [29], duration of the occupational physical activity, intensity of occupational physical activity, body mass index, marriage status, dietary meat consumption, and aging [30, 31]. Indeed improving cancers registry system in Iranian public health system especially in MC should be regarded.

According to the different reports, the incidence of colon cancer in Asian countries and among the Iranian popula-

tion is increasing [32-36]. These results are close to the current study results. According to time series analysis in the prediction of colon cancer among Iranian MC the trend of reported colon cancer among this group is increasing. Some part of this increasing trend may be due to carrying out some screening program like as fecal occult blood tests (FOBT), flexible Sigmoidoscopy (FS) and total colonoscopy [37]. Other reasons for this increase may be related to factors such as behavioral and lifestyle changes, toward urbanization, high consumption of total energy and animal fat, lower dietary fiber and other factors [38]. Also according to our prediction results, the number of the incidence of colon cancer among males was higher than females. This result is similar to other study results [39, 40]. The difference between two genders may be related to different reasons like different environment and lifestyle factors such as food consump-

Tab. III.	The related	coefficients for	prediction i	incidence of	cancers among	Iranian I	military	community.
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	Breast cancer	Prostate cancer	Colon cancer	Male colon cancer	Female colon cancer
Box cox	200	200	300	500	900
AR	7	12	12	11	12
MA	6	1	1	11	11
AIC	0.350984E + 03	0.275184E + 03	0.353478E + 03	0.664421E + 03	0.663679E + 03

tion pattern, smoking, and physical activity [41, 42]. These mentioned risk factors in men were higher than women, for example, using more meat among men so the incidence of cancer among men is more than women. Finally, the current study was according to the registered cancers in the Insurance organization of Iranian MC and we don't have any information about the total size of Iranian MC Population to calculate the incidence rate of cancers, so the quality of all analysis is dependent on the quality of registered data.

Conclusions

According to the time series analysis, the trend of most prevalent cancers among Iranian MC was increasing. But it's maybe because of increasing Iranian MC Population or improving in quality and quantity of data registration in Iranian military medical services. So these two important factors should be regarded in future studies.

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Conflict of interest statement

None declared.

Authors' contributions

All Authors have made a substantial contribution to the conception, design, analysis, and interpretation of data, drafting the article and revising it critically for intellectual content; all Authors approve the final version submitted to the Journal of Preventive Medicine and Hygiene.

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THE PREDICTION INCIDENCE OF THE THREE MOST COMMON CANCERS AMONG IRANIAN MILITARY COMMUNITY DURING 2007-2019: A TIME SERIES ANALYSIS

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ORIGINAL ARTICLE

Socioeconomic inequalities in metastasis, recurrence, stage and grade of breast cancer: a hospital-based retrospective cohort study

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Keywords

Socio-Economic Status • Inequality • Concentration Index • Breast Cancer

Summary

Introduction. This study aims to estimate the Socio-Economic Status (SES) inequality on the metastasis, recurrence, stage and grade in Breast Cancer (BC).

Methods. This retrospective cohort study conducted on 411 BC patients in Arak, Iran. Asset-based questionnaire used to estimate the household SES. For calculate of SES inequality was used from Concentration Index (C). Moreover for investigate the association between recurrence and metastasis with other variables were used from multilevel logistic regression and analysis of variance were used to investigate the relationship between SES and other variables. The data were analyzed with Stata (v.13) software.

Results. Results of analysis of variance showed statistical significant

Introduction

Breast cancer (BC) accounts for about one-third of all cancers in women. This cancer is the second most common cancer after lung cancer and the most common cause of cancer deaths among women [1].

BC with nearly 1.7 million cases was considered as the most prevalent cancer among women in 2016 [2]. Breast cancer has led to 535,000 deaths and 15.1 million DALYs [2]. The incidence and mortality rate of BC has increased in recent years in Asian countries as well as Iran [2-4].

Some factors such as age, estrogen receptor status and lymph node involvement as factors influencing recurrence [5]. One of the most important problems in this cancer was the metastasis of cancer cells to other organs, which was, in fact, one of the main causes of failure in the treatment [6]. The metastasis was seen among the 5-10% of patients [7]. Also, the factors affecting the metastasis was identified, such as the initial size of the tumor, lymph node involvement, disease grade, estrogen receptor status, and the interval between surgery, and local recurrence [8]. Moreover, the tumor stage, access to health-care services,

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relationship between SES with, insurance, surgery, grade, stage, recurrence and metastasis (p-value < 0.05). Moreover the Odds Ratio (OR) were significant of recurrence with age, academic level of education, supplementary insurance history of BC in first-degree relatives, stage and grade, also, metastasis with age of > 80 years, insurance, supplementary insurance, history of BC in first-degree relatives, chemotherapy, radiotherapy, stage and grade four. The total C index obtained 0.015 (0.002, 0.026), 0.011 (0.003, 0.031), - 0.014 (- 0.034, - 0.001) and - 0.042 (- 0.061, - 0.002) for metastasis, recurrence, stage and grade of BC respectively.

Conclusions. Our results showed evidence of inequality in the metastasis, recurrence, stage and grade in BC patients.

comorbidity, cigarette smoking, Body Mass Index (BMI), stress, and social support were associated with the prognosis and the risk of death of BC. The SES was related to hormone therapy, smoking, and access to health-care and affects metastasis, recurrence, stage, and grade of diagnosis [9]. The SES and the level of education lead to a difference in the stage and subsequently survival of BC [10, 11]. Early diagnosis with treatment was an appropriate strategy for improving prognosis. Population-based screening programs reduce the incidence and death of cancer, due to extensive population coverage and improved followup and control. The SES was referred to socio-economic factors such as education level, income and occupation, which can affect a person's or group's situation in the community [12]. However, the role of SES inequality in outcomes of BC cancer remains uncertain.

Despite the many efforts in different periods to reduce the difference between the poor and the rich, through the redistribution of wealth to create an equal society, social inequalities have not disappeared and even seems increased globally. Health inequality is one of the most important indexes of inequality. It has been shown in various studies, that the overall incidence and mortality

rates in poorer economic groups are higher, due to an increase in inequality index in particular areas [13]. The relation between inequality and health is an important issue. Inequality is an issue at the social level that imposes a lot of costs on society. Health is one of the most important indicators of human capital. Therefore, inequality has the greatest effect on health [14]. Income inequality affects people's health in many ways. The high level of inequality undermines social capital, also, caused stress among individuals in the community, which set these behaviors affects general health [15]. At the individual level, the person's income increases the health, but community-based studies do not endorse this theory. Because there are countries that, although lower income than high-income countries have high health status, because they have less inequality [16]. The BC is curable and also can be prevented with early detection and if does not metastasize to other tissues. Achieving health care and screening services can lead to early diagnosis and prevention of disease severity. SES inequality can also play an important role in people's health. To date, no study has been performed yet, that can identify the role of SES inequality in recurrence, metastasis, grade and stage of BC. This gap was addressed in this study.

Methods

STUDY DESIGN AND SAMPLING

This retrospective cohort study conducted on 411 BC patients referred to hospitals of Arak University of Medical Sciences. The sampling method is accessible (non-randomized). In this study, we analyzed all cases during the study period.

INSTRUMENT

Two questionnaires were used to data collection in this study: 1) the demographic and disease information questionnaire includes age, marital status, education, job, insurance, supplementary insurance, history of BC in first-degree relatives, chemotherapy, radiotherapy, surgery, stage and grade of BC patients; 2) a questionnaire designed by Gorramoodi et al. was used to measure the SES. This questionnaire includes questions about the level of women's education, the education of her husband, the area of the infrastructure, the cost of home, the number of rooms and the facilities and amenities (personal car, personal computer, more than one TV, refrigerator, washing machine, dishwasher, mobile phone and traveling abroad. The correlation of these factors with a score reliability was obtained 0.87 and validity was obtained 0.88 respectively [17].

STATISTICAL ANALYSIS

To investigate the relationship between recurrence and metastasis with other variables, binary logistic regression was used because these two variables were dichotomous. Using this method, the OR for each variable is calculated with constant considering effect of other variables. Moreover to evaluate the relationship between SES with other variables, analysis of variance was used. All statistical analyzes were performed using Stata (v.13) software.

MEASUREMENT OF SES AND INEQUALITY

In this study, a new variable was created as an SES, using the Principal Component Analysis (PCA) method. The PCA method identifies the variables that have the greatest effect on the variance of the total variables, and then constructs the new variable. The first component derived from the analysis, explains the most variance in the variables and gives each family a score that is considered as an indicator of its SES [18, 19].

The Concentration index (C) was used to determine the inequality in this study. The value of this index varies between + 1 to - 1. When the line of equality and the C curve fit together, the C index will be zero, which means that there is no inequality. The C index is defined by the area under the C curve multiplication in two. With the greater interval between the C curve of the inequality line the amount of inequality also increases. When the C curve is above the equality line, the C index will be negative, which means that, the concentration of the investigated factor (in this study: metastasis, recurrence, stage and grade of BC is more in lower SES. Also when the C curve is under the equality line, the C index will be positive, which means that the concentration of the investigated factor is more in highest SES [20, 21].

The C index is a common inequity measure in health outcomes and has been used continually in recent studies [20, 22]. The C was calculated by the Kakwani et al. formula [20] (formula 1).

$$C = \frac{2}{\mu} \sum_{t=1}^{T} f_t \mu_t R_t - 1$$

In this formula, μ is the mean in studied patients with cancer and μ_i is that for the tth group. In addition, f_i , is the group share of patients. Also, R_i , is the relative rank of the tth educational level of the participating patients, which was obtained through formula 2:

$$R_t = \sum_{t=1}^T f_r - \frac{1}{2}f_t$$

Therefore, R_i indicates the cumulative proportion up to the midpoint of each SES group interval. The correspondence confidence interval for C is calculated based on Wagstaff and Van Doorslaer method [20, 23]. This method has been used in other studies [24-29] and is as given below.

$$Var(C) = \frac{1}{n} \left[\sum_{t=1}^{T} f_t a_t^2 - (1+C) \right] + \frac{1}{n\mu^2} \sum_{t=1}^{T} f_t \sigma_t^2 (2R_t - 1 - C)^2$$

In this formula σ_t^2 is the variance of μ_t ,

 $a_t = \frac{\mu_t}{\mu} (2R_t - 1 - C) + 2q_{r-1} - q_t$ and $q_t = \frac{1}{\mu} \sum_r^t \mu_r f_r$, which

is the ordinate of L(P), $q_0 = 0$ and $p_t = \sum_{r=1}^t f_r R_r$

Results

In total, 411 women with mean age of 20-87 participated in this study. Mean score of SES was 0.29 ± 0.94 (-2.71, 2.2). Of all patients, 19.7% had a good SES, 71.04% had a middle and 9.26% had a poor SES.

Tab. I. The crude and adjusted OR of recurrence with other variables.

The crude and adjusted OR of relationship between the recurrence and other variables showed in Table I. According to these results, the OR was significant for relationship between recurrence and supplementary insurance, history of radiotherapy, stage 4 and grade 3 of BC patients.

The crude and adjusted OR of relationship between the metastasis and other variables showed in Table II. According to these results, the OR was significant for relationship between the metastasis and history of surgery, stage 4, grade 2, and grade 3 of BC patients.

Differences in mean of subgroups of variables in this study by SES showed in Table III. These results shown significant relationship between SES with supplementary insurance and grade of BC (p-value < 0.05).

C index obtained -0.0025 (-0.0153, 0.0103) and -0.00001 (-0.01623, 0.01620) for recurrence and metastasis respectively. Also for stage and grade of BC, C index obtained 0.0013 (-0.009, 0.011) and -0.004 (-0.0145, 0.0059) respectively, that showed there was not concentration of metastasis, recurrence, stage and grade by SES levels (Tab. IV). In addition, the concentration curve for recurrence and metastasis showed that there was no concentration of these outcomes by SES level (Figs. 1, 2).

Variables	Subgroups	Crude	Adjusted*	
		OR (95% CI)	OR (95% CI)	
Age	< 40	Reference	Reference	
	40-60	2.91 (0.36, 23.27)	4.28 (0.48, 37.84)	
	> 60	3.54 (0.43, 28.94)	2.91 (0.26, 32.25)	
Marital status	Single	Reference	Reference	
	Married	1.65 (0.20, 13.65)	2.29 (0.26, 19.71)	
	Widow/divorced	0.94 (0.09, 9.53)	1.39 (0.12, 15.60)	
Education	Illiterate	Reference	Reference	
	Primary	0.33 (0.12, 0.87)	0.27 (0.08, 0.89)	
	Diploma	0.85 (0.31, 2.32)	1.06 (0.3, 3.71)	
	Academic	0.27 (0.05, 1.27)	0.43 (0.05, 3.69)	
Job	Housewife	Reference	Reference	
	Retired	0.31 (0.04, 2.45)	0.28 (0.02, 2.81)	
	Unemployment	2.26 (0.41, 12.28)	2.73 (0.44, 16.81)	
	Permanent/temporary	0.75 (0.16, 3.49)	1.14 (0.18, 7.29)	
Insurance	No	Reference	Reference	
	Yes	0.48 (0.04, 4.80)	0.43 (0.02, 6.69)	
Supplementary insurance	No	Reference	Reference	
	Yes	2.19 (1.00, 4.77)	2.94 (1.21, 7.14)	
History of BC in first-degree relatives	No	Reference	Reference	
	Yes	1.43 (0.66, 3.13)	1.12 (0.47, 2.68)	
Chemotherapy	No	Reference	Reference	
	Yes	2.91 (0.98, 8.71)	2.67 (0.82, 8.61)	
Radiotherapy	No	Reference	Reference	
	Yes	2.42 (1.12, 5.24)	2.73 (1.17, 6.34)	
Surgery	No	Reference	Reference	
	Yes	0.32 (0.13, 0.78)	0.38 (0.14, 1.05)	
Stage	One	Reference	Reference	
	Two	0.17 (0.01, 3.00)	0.15 (0.001, 2.99)	
	Three	1.04 (0.12, 9.02)	1.09 (0.10, 10.86)	
	Four	27.5 (3.03, 249.48)	49.24 (4.06, 596.2)	
Grade	One	Reference	Reference	
	Two	3.42 (0.91, 12.77)	2.93 (0.75, 11.44)	
	Three	9.47 (2.52, 35.59)	9.43 (2.34, 38.06)	

*: adjusted for age, marital status, education level, and job.

Variables	Subgroups	Crude	Adjusted*	
		OR (95% CI)	OR (95% CI)	
	< 40	Reference	Reference	
Age	40-60	1.29 (0.45, 3.67)	1.91 (0.59, 6.15)	
	> 60	1.32 (0.44, 3.91)	2.07 (0.53, 8.06)	
	Single	Reference	Reference	
Marital status	Married	0.68 (0.20, 2.30)	0.73 (0.20, 2.61)	
	Widow/divorced	0.57 (0.14, 2.26)	0.58 (0.13, 2.46)	
	Illiterate	Reference	Reference	
Education	Primary	0.77 (0.39, 1.52)	0.83 (0.37, 1.86)	
Education	Diploma	0.80 (0.34, 1.90)	1.06 (0.39, 2.84)	
	Academic	1.03 (0.44, 2.40)	2.31 (0.68, 7.86)	
	Housewife	Reference	Reference	
lob	Retired	0.68 (0.22, 2.11)	0.42 (0.11, 1.62)	
00	Unemployment	1.85 (0.42, 8.02)	1.82 (0.39, 8.39)	
	Permanent/temporary	0.65 (0.21, 1.99)	0.44 (0.12, 1.58)	
	No	Reference	Reference	
Insurance	Yes	0.39 (0.08, 1.80)	0.29 (0.05, 1.63)	
Supplementary	No	Reference	Reference	
supplementally insurance	Yes	1.38 (0.79, 2.43)	1.52 (0.81, 2.86)	
History of BC in first-degree	No	Reference	Reference	
relatives	Yes	0.99 (0.57, 1.74)	0.90 (0.50, 1.64)	
Chamatharapy	No	Reference	Reference	
Спептоспегару	Yes	1.07 (0.57, 2.01)	0.95 (0.48, 1.88)	
Padiothorany	No	Reference	Reference	
	Yes	1.06 (0.60, 1.88)	1.14 (0.62, 2.07)	
Surgery	No	Reference	Reference	
Surgery	Yes	0.38 (0.19, 0.78)	0.35 (0.16, 0.76)	
	One	Reference	Reference	
Stago	Two	1.10 (0.76, 3.23)	0.91 (0.05, 8.41)	
Stage	Three	1.87 (0.65, 4.56)	1.92 (0.23, 8.42)	
	Four	9.72 (2.11, 73.21)	11.28 (3.56, 45.12)	
	One	Reference	Reference	
Grade	Two	4.02 (1.67, 9.65)	3.91 (1.58, 9.62)	
	Three	8.27 (3.18, 21.50)	9.24 (3.35, 25.44)	

Tab. II. The crude and adjusted OR of metastasis with other variables.

*: adjusted for age, marital status, education level, and job.

Tab. III. Relationship between SES and other variables.

Characteristics	Subgroups	Mean	SD	P-value
Insurance	No Yes	- 0.46 0.04	1.08 0.93	0.055
Supplementary insurance	No Yes	- 0.08 0.16	0.91 0.95	0.006*
Chemotherapy	No Yes	- 0.058 0.079	0.89 0.96	0.160
Radiotherapy	No Yes	0.05 - 0.02	0.96 0.90	0.421
Surgery	No Yes	-0.032 0.042	0.87 0.95	0.578
Grade	One Two Three Four	- 0.1 0.063 0.094 0.022	0.84 0.93 0.89 0.49	0.011*
Stage	One Two Three Four	0.16 - 0.12 0.30 - 0.50	0.65 0.99 0.85 0.95	0.865
Recurrence	No Yes	0.02 0.04	0.90 0.72	0.926
Metastasis	No Yes	0.07 0.04	0.88 0.93	0.785

*: significant.

Tab. IV. Calculation of C indexes and their 95% CI, for metastasis, recurrence, stage and grade of BC patients.

Outcomes	Concentration index	95% Confidence intervals
Recurrence	- 0.0025	- 0.0153, 0.0103
Metastasis	- 0.00001	- 0.01623, 0.01620
Stage	0.0013	- 0.009, 0.011
Grade	- 0.004	- 0.0145, 0.0059

Discussion

The results of our study showed that most patients were housewives, also were in middle level of SES. Moreover the most of patients had a primary level of education. In a study, most of the patients, had a under diploma level of education. In evaluating the status of employment, the results showed that most of the patients were housewives and other were employed, also had a middle level of income, which is consistent with our study result [30].

The results of this study showed that there was no the significant relationship between the metastasis and





recurrence of BC with age of patients. In some studies, it has been concluded that metastasis occurs at an earlier age, which is not consistent with our findings [31]. In some studies the role of age has proven to be an important factor in causing a bad prognosis in patients with a variety of cancers [32]. Results of Bennier's study in French showed the probability of recurrence and metastasis of BC was higher in patients older than 35 years. Also shown that patients with age of 35 years, before menopause had a better prognosis than the first group and patients over 60 years of age had a worse prognosis than the second group [33].

In our study, there was no the significant relationship between education levels with metastasis and recurrence. In various studies, appropriate prevention and treatment of BC have relationship with education. Also, there is a significant relationship between knowledge of risk factors for BC and the level of education, which this knowledge can prevent the metastasis and recurrence [34]. Our results showed that there was a significant relationship between the existences of supplementary insurance in patients with recurrence. In other words, the recurrence in patients with supplementary insurance was occurred more than

other patients. Having supplementary insurance helps to encourage individuals for treatment and screening and causes more diagnosis and sooner discovering the disease. Therefore, it can be concluded that SES directly affect the stage, grade, recurrence and metastasis of BC [35]. Also, in a study, the insurance status had an important role in the outcomes of BC, even with adjusting for SES [36].

Some studies had identified a number of genes that causes metastasis in various tissues in BC [37]. However, there was not association between history of BC in first degree relatives with recurrence and metastasis. Cancer patients receive different therapies after surgery that can affect the survival, recurrence and metastasis [38]. In our study, the effect of surgery on metastasis was evident. In some studies, the role of radiotherapy has been shown to reduce metastasis [39]. Also results of our study showed grade and stage of BC had a relationship with recurrence and metastasis. Other studies showed a significant correlation between tumor size with recurrence and metastasis also with staging of BC [40].

The C index for health expenditure has always been positive, stating that health costs in higher deciles is
higher than lower deciles. This can be due to the low pay ability of low income deciles or lack of access to health services. The C index is closer to zero, indicating a more equality concentration on health costs among different deciles. The C index was 0.498 at 2009 in Iran, which indicates significant inequalities in health costs. An increase in inequality could be affected by rising prices due to economic policies or discriminatory health policies. An increase in inequality, can have a more negative effect on the health expenditure of lower SES groups [41]. According to the results of this study, there was not SES inequality in recurrence, metastasis, stage and grade of BC. This was the first study in this field. Although the role of SES inequality in health has been evaluated in some studies [42-45]. In some studies, the effect of SES on the incidence of cancer is reversed. For example in a study by Tweed et al., BC had a low incidence in areas with lower SES [46]. In a study in European countries the role of SES inequality evaluated in health. The C index varied from 0.0034 in the Netherlands to 0.0218 in Portugal. Also in this study patients with high SES are more likely to use diagnostic and therapeutic test, which leads to early detection of the disease [47].

Conclusions

BC is the most common cancer among women. Many complications of this cancer can be prevented with early detection. To date no study has been performed that evaluate the role of SES inequity in recurrence, metastasis, grade, and stage of BC. Therefore, our study results can be good evident of the importance of this topic. Due to the important role of SES and the existence of insurance and supplementary insurance, in early detection and treatment of BC, it is suggested that measures be taken to allow BC diagnostic and screening services to be available at a lower cost to the public. Also, with the reduction of SES inequality and increase in screening test, BC can be detected earlier and metastasis and recurrence decrease eventually.

Ethical statement

The Research Ethics Committee of Shahid Beheshti University of Medical Sciences approved this study and participants provided written informed consent for voluntary participation in the study (Ethical Code: IR.SBMU.RETECH.REC.1396.839).

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Conflict of interest statement

None declared.

Authors' contributions

MT, MT, MEA, AAH, RA, AAA and MT contributed to project design and its development. MT, MT, AAH, RA and MA wrote the manuscript. MT, AAH, MT and MA analyzed data.

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