



# **Università degli Studi di Udine**

Dipartimento di Scienze Mediche e Biologiche

Dottorato di Ricerca in Scienze e Tecnologie Cliniche

Ciclo XXVII

## **TESI DI DOTTORATO**

**SLEEP DEPRIVATION, SLEEP DISORDERS, FATIGUE, STRESS AND THE RISK  
OF OCCUPATIONAL INJURIES AND ERRORS AMONG HEALTH-CARE WORKERS:  
A MULTI-APPROACH EPIDEMIOLOGICAL STUDY**

### **Relatore**

Prof. Silvio Brusaferrò

### **Dottoranda**

Dott.ssa Francesca Valent

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## **PREFACE**

This is a manuscript-based thesis: the results of my PhD research program are reported in the form of four manuscripts, which have been submitted to international peer-reviewed journals.

I am the first author of all the manuscripts, and I had a primary role in the design of the studies, in the coordination of the data collection, in the statistical analyses, and in the preparation of all the manuscripts.

I would like to thank my co-authors who contributed to the manuscripts as follows:

- Manuscript 1: “A case-control study of sleep, daytime sleepiness, and chronotype and the risk of occupational injuries among the employees of an Italian teaching hospital”: Giulia Liva, Marika Mariuz, Fabrizio Bellomo, Daniela De Corti and Stefania Degan collected the information, collaborated to the analysis of data and revised the manuscript; Pierluigi Dolso, Fabio Barbone, Gian Luigi Gigli and Silvio Brusaferrero collaborated to the study design and reviewed the manuscript.
- Manuscript 2: “A case-crossover study of sleep, fatigue, and other transient exposures on the workplace and the risk of non-fatal occupational injuries among the employees of an Italian academic hospital”: Marika Mariuz and Giulia Liva were responsible for the interviews of the study subjects and for data entry; Fabrizio Bellomo, Daniela De Corti, and Stefania Degan collaborated with the enrolment of the study subjects; Alberto Ferrazzano provided inputs to the study design; and Silvio Brusaferrero supervised the enrolment and critically discussed the study results.
- Manuscript 3: “Maintenance of wakefulness and occupational injuries among workers of an Italian teaching hospital”: Elisa Sincig performed the maintenance of wakefulness test and critically discussed the study results; Gian Luigi Gigli provided inputs to the study design and revised the results; Pierluigi Dolso provided inputs to the study design, supervised the tests and critically revised the results.

- Manuscript 4: “Is there an association between hospital unit characteristics and proxies of work-related stress and the risk of occupational injuries and adverse events? An ecologic study in an Italian teaching hospital”: Giulia Liva contributed to the data analysis and interpretation of results; Fabrizio Bellomo, Daniela De Corti, Stefania Degan, Giovanni Cattani, Ilaria Rosa, Agnese Mizza acquired the data and contributed to the interpretation of the results and to the draft of the manuscript; Silvio Brusaferrò participated in the study design and contributed to the interpretation of the results and to the draft of the manuscript.

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# **PRIVAZIONE E DISTURBI DEL SONNO, STANCHEZZA, STRESS E RISCHIO DI INFORTUNI OCCUPAZIONALI ED ERRORI TRA I LAVORATORI DELLA SANITÀ: UNO STUDIO EPIDEMIOLOGICO MULTI-APPROCCIO**

## **RIASSUNTO DELLA TESI**

**Obiettivi.** Lo studio si proponeva di valutare gli effetti della sonnolenza acuta e cronica, di disturbi del sonno e di situazioni stressanti sul rischio di infortuni in itinere ed occupazionali tra i dipendenti dell'Azienda Ospedaliero-Universitaria di Udine. Inoltre è stato indagato l'effetto dello stress organizzativo a livello di Struttura/Dipartimento ospedaliero sul rischio di incidenti sui pazienti o near-miss.

**Metodi.** Sono stati impiegati diversi disegni di studio epidemiologico, a seconda dell'esposizione e dell'outcome considerati: case-crossover, caso-controllo, ecologico. Ad integrazione delle informazioni sulle esposizioni raccolte mediante interviste con questionari strutturati, sono stati condotti anche esami strumentali (polisonnografia) e test neurologici (test di mantenimento della veglia) per valutare le caratteristiche del sonno e le capacità di mantenere la veglia da parte dei lavoratori.

**Risultati.** Tramite lo studio case-crossover, sono state identificate esposizioni occupazionali transitorie associate ad un significativo aumento del rischio di infortunio sul lavoro: stanchezza, fretta, distrazione, situazioni di emergenza, attività didattiche, pazienti non collaboranti, campo operatorio con sangue, rumore eccessivo, procedure complesse e stati di arrabbiatura. Tramite il disegno caso-controllo, è emerso che il numero di disturbi del sonno riferito dai lavoratori si associa positivamente al rischio di infortunio, mentre il numero medio di ore di sonno non si è associato al rischio di infortunio. Benché non in maniera significativa, I cronotipi più mattutini, identificati tramite questionario di Horne-Ostberg, sembrerebbero a rischio aumentato. La capacità di mantenere la veglia sembrerebbe ridotta nei lavoratori che hanno riferito un infortunio. Lo studio

ecologico ha mostrato che la proporzione di lavoratori di sesso femminile in ogni Unità, il numero medio di giorni di malattia e di ore di straordinario, il numero di visite anticipate richieste al medico competente e il tipo di dipartimento di appartenenza sono risultati significativamente associati al numero di eventi avversi e near-miss.

**Conclusioni.** Questo studio ha permesso di individuare fattori stressanti individuali ed ambientali che si associano ad un aumentato rischio di infortuni tra i lavoratori ed errori sui pazienti, fornendo informazioni utili per la programmazione di interventi di prevenzione e il miglioramento della sicurezza in ambiente ospedaliero.

# **SLEEP DEPRIVATION, SLEEP DISORDERS, FATIGUE, STRESS AND THE RISK OF OCCUPATIONAL INJURIES AND ERRORS AMONG HEALTH-CARE WORKERS: A MULTI-APPROACH EPIDEMIOLOGICAL STUDY**

## **THESIS ABSTRACT**

**Objectives.** The aim of the study was to assess the effects of acute and chronic sleepiness, of sleep disorders, and stress on the risk of occupational injuries and commuting accidents among the workers of the University Hospital of Udine, and the effect of organizational stress at the hospital Unit level on the number of adverse events and near-misses on the patients.

**Methods.** We used different epidemiological study designs depending on the exposures and outcomes: case-crossover, case-control, ecologic. In addition to the information on exposures collected through interviews with structured questionnaires, we also conducted neurological tests (polysomnographies and maintenance of wakefulness tests) to assess the characteristics of sleep and the ability to stay awake of the workers.

**Results.** Through the case-crossover study, we identified occupational transient exposures associated with increased risk of injury: fatigue, rush, distraction, emergency situations, teaching to or being taught by someone, non-compliant patients, bloody operative/work field, excess noise, complex procedures, and anger. Through the case-control design, the number of reported sleep disturbances was positively related with the outcome, whereas no association was found between usual sleep hours and injuries. Chronotype, assessed through the Horne-Ostberg questionnaire, was not significantly associated with injury, although we noticed a decreasing trend from earlier to later chronotypes. The ability to maintain wakefulness appeared reduced among workers who reported injuries. The ecologic study showed that the proportion of female workers in a unit, the average number of sick-leave days and of overtime hours, the number of medical examinations requested by

employees, and being a surgical unit were significantly associated with the number of adverse events and near-miss.

**Conclusions.** This study allowed the identification of individual and environmental stress-related factors associated with increased risk of injuries and adverse events, thus providing useful information for planning preventive interventions and for improving safety in the hospital setting.

## CHAPTER 1: INTRODUCTION

### 1.1 Background

Sleep disorders are a common issue. For many individuals, they are a chronic problem,<sup>1</sup> with a huge impact on the health of the general population. Insomnia can be defined as a person's perception of insufficient sleep and/or poor quality sleep and includes difficulties in falling asleep at the beginning of the night, difficulties to fall asleep again after awakening during the night, awakening too early in the morning, or non-resting sleep.<sup>2</sup> People suffering from insomnia often report fatigue, attention deficits, anxiety, depression, daytime sleepiness.<sup>3,4</sup> Insomnia has been shown to be associated with reduced productivity and poor quality of life.<sup>5,6</sup> In addition, it is a potential cause of absenteeism, injuries, hospital admissions, depression, and morbidity.<sup>7</sup>

Work-related fatigue is another cause of tiredness, discomfort, and functional deficits. In particular, work shifts, especially those including the night, represent a stressful condition for the human body and may lead to negative effects for the biological structure, for the efficiency on the workplace, and for the psycho-physical well-being.<sup>8</sup>

Regardless from its origin, fatigue can increase the risk of unintentional injuries. In fact, there is evidence showing that the lack of sleep increases the risk of unintentional injuries among children,<sup>9,10</sup> adolescents,<sup>11</sup> and adults.<sup>12</sup> In addition, probably because of sleepiness, sleep apnoea/hypopnoea syndrome resulted to be associated with an increased incidence of road traffic accidents, especially of those with injuries.<sup>13</sup> An increased risk of road traffic accidents has also been shown to be associated with acute<sup>14</sup> and chronic<sup>15</sup> driver's sleepiness.

In a number of working contexts, poor sleep quality, fatigue, and sleep disorders have been shown to be very common (e.g., >50% in emergency healthcare workers,<sup>16</sup> >40% among the Police in the USA<sup>17</sup>) and these factors are associated not only with reduced sleep hours,<sup>18</sup> but also to reduced working performance, to safety issues and to the risk of injuries.<sup>16-18</sup>

In addition, recent research has shown that distraction, anger, and rush can increase the risk of incidents involving biological risk among the health sector workers<sup>19</sup> and that fatigue increases the risk of injury from sharp devices in medical trainees.<sup>20</sup>

In the University Hospital of Udine, a teaching hospital in the Northeast of Italy, occupational injuries are an important issue. In fact, according to local surveillance data, approximately 12% of the 3850 Hospital employees report every year an occupational injury, an incident involving biological hazards, or commuting accidents (approximately 450 cases per year). Over 50% of them (i.e., approximately 250 cases per year) are incidents involving biological hazards. The occurrence of incidents involving biological hazards in Italy seems more common than in other settings.<sup>21,22</sup>

In a group of Australian nurses, both the frequency of errors during the work and the frequency of near-misses while commuting increased when they reported to be fatigued.<sup>23</sup> This suggests that the clinical risk for patients may be influenced by the level of fatigue of the healthcare personnel. Since the worker's fatigue level seems to affect both the risk of injuries and the risk of errors on the patients, in the health setting the risk of occupational injuries may be considered as a proxy for working errors, which are more difficult to identify.

Sleepiness and fatigue have been shown to be associated with safety issues for workers and for those around them. Thus, screening programs, and organizational and environmental interventions should be implemented to reduce the risks.<sup>24-27</sup>

## **1.2 Objectives**

The main objective of this project was to assess whether sleep lack, sleep disorders, fatigue, and stress increase the risk of occupational injuries, including commuting accidents, and incidents involving biological hazards, among the employees of the University Hospital of Udine.

Secondary objectives were a) to estimate the frequency of errors and near-misses occurring in the University Hospital of Udine, and b) to investigate where there is an association between the frequency of those errors and near-misses in each Hospital Unit and indicators of potential organizational stress in the Units.<sup>28</sup>

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## **CHAPTER 2: METHODS**

This Chapter provides an overview of the methods of the research project. Details on the methods used in the different parts of the project are described in Chapter 3, in the manuscripts.

### **2.1 Study designs**

The research was conducted using different study designs:

- A case-control design, to assess the effect of chronic sleep deprivation and disorders, and the ability to maintain wakefulness.
- A case-crossover design, to assess the effect short term sleep deprivation, fatigue, and other transient exposures.<sup>1-4</sup>
- An ecologic study, to assess the association between indicators of work-related organizational stress and adverse events and near-misses in the Hospital Units.

### **2.2 Participants**

For the case-control and case-crossover designs, a common set of cases was recruited, among the employees of the University Hospital of Udine who reported to the Hospital Clinical Risk Unit an occupational injury (including commuting accidents) or incidents involving biological hazards, from March 25<sup>th</sup>, 2013, to July 3<sup>rd</sup>, 2014. For the case-control study, we also recruited controls who were employees not reporting any injury randomly sampled from the Hospital employees list. In the case-crossover study, each subject acts as his/her own control, thus preventing the potential confounding effect of variables which may differ interpersonally, such as sex, age, socio-economic status, job type, working experience, visual acuity, skills. Among injured cases, each subject's

transient short term exposures immediately preceding the injury (“case period”) were compared with those in a previous moment (“control period”) when no injury had occurred.

Cases with injuries which caused a leave of at least 3 days, and a subsample of controls, were invited to undergo further evaluation of sleep characteristics and of the ability to maintain wakefulness.

All the Hospital employees were informed about the study in February 2013 through a letter (Annex A) which came with their payroll, described the study objectives and phases, and provided contacts of the research team. Only workers who provided written consent to the research were enrolled. Different informed consent forms were prepared for the different study phases (Annex B).

Sample size calculations for the case-control and case-crossover study were based on the case-control design. Assuming a 20% prevalence of insomnia,<sup>5-7</sup> with  $\alpha=5\%$ , at least 172 cases and 172 controls were needed to achieve an 80% power for estimating an odds ratio (OR)=2.<sup>8-12</sup>

In the ecologic study, conducted to estimate the frequency of errors, adverse events, and near-misses in the University Hospital of Udine in 2012 and 2013, the Hospital Units were the units of interest. All the Hospital Units were included in the study.

The research project was approved by the Ethics Committee of the University Hospital of Udine on November 6th, 2012.

### **2.3 Data collection**

The data for the case-crossover study were collected through a telephone interview using a semi-structured questionnaire, investigated socio-demographic characteristics of the subject, job characteristics, injury information, sleep-related and other transient exposures, sleepiness, and chronotype (Annex C). The controls were interviewed using the same questionnaire, except the section about the injury. The interviews were carried out by trained interviewers.

In the subsample of cases with sick-leave of at least 3 days and for the subsample of controls, further data on the characteristics of sleep and on the ability to stay awake were collected through a nighttime polysomnography conducted at home and the Maintenance of Wakefulness Test (MWT) conducted at the Hospital Neurology Clinic, respectively. The MWT is a polysomnographic quantitative measure of the ability to stay awake in a laboratory setting. In two recent studies, a pathologic average sleep latency during the MWT was associated with a reduced driving ability, both during simulations and in real life.<sup>13,14</sup> The test was made of four 40-minute trials, 2 hours apart from each other, the first starting 1.5-3 hours after the usual waking time of the subject. The room where the test is performed is quiet and dim-lighted (7.5 watts, out of the subject's visual field), with a comfortable temperature. The subjects must be comfortably sitting on a bed. The subject is asked to remain sitting and to stay awake, without tricks such as singing or slapping his/her own face. The trials last 40 minutes if the subject does not fall asleep, or at the time of sleep onset otherwise. For each trial, the time of start and end and the sleep latency were recorded.

Data for the ecologic study, aggregated at the Hospital Unit level, were provided by the Hospital Clinical Risk through the incident reporting system (data on the outcomes: reported injuries, commuting accidents, and incidents involving biological hazards; medication errors; patient falls; near-misses), by the Occupational Medicine Unit (visits requested by the workers before the scheduled time), and by the Human Resource Unit (personnel characteristics, overtime work, paid vacations, sick-leaves, new hires, work cessations).

## **2.4 Data management and statistical analyses**

The data were collected on paper forms and then entered into the computer through an EpiData ([www.epidata.dk](http://www.epidata.dk)) data entry form. The statistical analyses were conducted using the SAS Enterprise Guide v4.3 and v7.1 (SAS v9.2 and v9.4; SAS Institute Inc., Cary, NC, USA).

The data for the case-control study were analyzed using unconditional multivariate logistic regression models, to assess the association of injuries with sleep-related exposures, after adjusting for potential confounders. The association was expressed by the odds ratio (OR) with 95% confidence intervals (95%CI) and p-values to indicate the precision of the estimates.

In the case-crossover study, two different analysis approaches were followed: the “pair-matched interval approach”, to compare the exposures immediately before the injury with those in a corresponding period on the last working day before the injury, and the “usual frequency approach”, to compare the exposures immediately before the injury with the average usual exposure to the same factors in the previous month. In the first case, we calculated the OR from conditional logistic regression models, in the second we calculated Mantel-Haenszel relative incidence. The precision of the estimates was expressed by the 95%CI and p-values.

The association between Hospital Unit characteristics and the frequency of adverse outcomes in the Unit was assessed through multilevel Poisson regression models using Hospital Departments to cluster Units.

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## **CHAPTER 3: THE MANUSCRIPTS**

### **3.1 Manuscript 1**

**A case-control study of sleep, daytime sleepiness, and chronotype and the risk of occupational injuries among the employees of an Italian teaching hospital**

**A CASE-CONTROL STUDY OF SLEEP, DAYTIME SLEEPINESS, AND CHRONOTYPE  
AND THE RISK OF OCCUPATIONAL INJURIES AMONG THE EMPLOYEES OF AN  
ITALIAN TEACHING HOSPITAL**

**Francesca Valent<sup>1,2,3</sup>, Giulia Liva<sup>2</sup>, Marika Mariuz<sup>2</sup>, Fabrizio Bellomo<sup>4</sup>, Daniela De Corti<sup>4</sup>,  
Stefania Degan<sup>4</sup>, Pierluigi Dolso<sup>5</sup>, Fabio Barbone<sup>2,3</sup>, Gian Luigi Gigli<sup>5</sup>, Silvio Brusaferrò<sup>3,4</sup>**

<sup>1</sup>Epidemiologic Service, Regional Health Directorate, Friuli Venezia Giulia Region, Udine, Italy

<sup>2</sup>Unit of Hygiene and Clinical Epidemiology, University Hospital of Udine, Udine, Italy

<sup>3</sup>Department of Medical and Biological Sciences, University of Udine, Udine, Italy

<sup>4</sup>Accreditation, Clinical Risk Management and performance assessment Unit, University Hospital of  
Udine, Udine, Italy

<sup>5</sup>Neurology Clinic, University Hospital of Udine, Udine, Italy

**Corresponding author:** Francesca Valent - Servizio Epidemiologico - Direzione centrale salute,  
integrazione socio-sanitaria, politiche sociali e famiglia – Regione Autonoma Friuli Venezia Giulia  
– Via Pozzuolo 330, 33100 Udine, Italy – Telephone: +39 0432 805616 – email:

[francesca.valent@regione.fvg.it](mailto:francesca.valent@regione.fvg.it)

## **ABSTRACT**

**Objectives.** Sleep disorders are commonly reported and have been associated with increased risk of occupational injuries in various settings. We investigated the association of sleep, sleepiness, and chronotype with the risk of occupational injuries in an Italian teaching hospital.

**Methods.** We conducted a case-control study among the employees of the University Hospital of Udine, Italy. Two hundred employees reporting occupational injuries (including commuting accidents and incidents involving biological risk) and 183 controls were enrolled and interviewed. Information was collected on usual sleep quantity and quality. Sleepiness was assessed through the Epworth Sleepiness Scale. Chronotype was assessed through the Horne-Ostberg morningness-eveningness questionnaire. The association of sleep-related exposures with the risk of injury was assessed through multivariate unconditional logistic regression, adjusting for potentially confounding individual characteristics.

**Results.** Various individual characteristics were associated with the risk of injury. Among sleep-related variables, the number of reported sleep disturbances was positively related with the outcome, whereas sleepiness was inversely associated with injuries. No association was found between usual sleep hours and injuries. Chronotype was not significantly associated with injury, although we noticed a decreasing trend from earlier to later chronotypes.

**Conclusions.** We identified factors associated with increased risk of occupational injury in an Italian hospital. The role of sleep-related factors in this setting is controversial.

## **INTRODUCTION**

Sleep disorders are commonly reported both in the general population<sup>1,2</sup> and in a variety of occupational settings<sup>3-6</sup> and for many individuals they are a chronic problem.<sup>7</sup> Poor sleep quality, fatigue, sleep disorders, and reduced sleep hours among workers are associated with worse occupational performances, safety issues, and increased risk of injury.<sup>4,5,8</sup> In addition, short sleep, sleep disorders and their occupational impacts have been shown to be more common among shift workers than among non-shift workers.<sup>6,9</sup>

Screening programs and environmental and organizational interventions can be implemented to manage the safety issues related with poor sleep and fatigue among workers.<sup>9-12</sup>

We conducted a case-control study to investigate the effect of sleep hours, sleep disorders, daytime sleepiness, and chronotype on the risk of occupational injuries among the workers of a large Italian teaching hospital where approximately 450 injuries, including commuting accidents and incidents involving biologic hazard, are reported annually.

## **METHODS**

This case-control study was conducted among the employees of the University Hospital of Udine, a teaching hospital employing approximately 3800 people, located in the North-East of Italy. Before the start of enrolment, all the Hospital employees had been explained the purpose and background of the study through an information letter that had been included in their payslip of February 2013.

All employees who reported non-fatal injuries (including commuting accidents and incidents involving biological risk) at the Clinical Risk Office of the hospital between March 25<sup>th</sup>, 2013 and July 3<sup>rd</sup>, 2014 were eligible as cases. When reporting the injury, they were asked to sign an informed consent form and to provide a telephone number to be contacted within the shortest possible time by two trained interviewers for a telephonic interview. The mean and median time

elapsed from injury occurrence to the interview were 4.4 and 4 days, respectively (standard deviation [SD] 4.1).

Controls were randomly selected from the list of hospital employees, excluding those in maternity leave and long-term sick leave. Assuming a prevalence of insomnia of 20%,<sup>1-3</sup> with  $\alpha=5\%$ , we estimated that at least 172 cases and 172 controls (case:control ratio=1) were needed to detect an  $OR=2^{13-17}$  with power=80%. To account for non-response, we decided to sample an extra 20% of the minimum required number of controls, so we randomly extracted 208 employees.

Controls were contacted in their workplaces by the trained interviewers and asked to provide a telephone number and a convenient day and time for a telephone interview, and to sign the informed consent form if they agreed to participate in the study.

Interviews to cases and controls were conducted through a semi-structured questionnaire which collected the following information: socio-demographic and job-related characteristics of the subject, weight and height, smoking habits, usual consumption of alcohol and coffee, sleep characteristics, the Epworth Sleepiness Scale (ESS) (<http://epworthsleepinessscale.com/epworth-sleepiness-scale.pdf>) to assess daytime sleepiness, and the Italian version ([www.ge.infn.it/~squarcia/DIDATTICA/SRS/Questionario\\_cronotipo.doc](http://www.ge.infn.it/~squarcia/DIDATTICA/SRS/Questionario_cronotipo.doc)) of the Horne-Ostberg morningness-eveningness questionnaire (MEQ)<sup>18</sup> to assess chronotype. For cases, additional questions were included to assess exposures to transient factors (not described in this article). The approximate duration of the interview was 30 minutes for cases and 15 minutes for controls.

This study was approved by the Ethics Committee of Udine, Italy.

### **Statistical analysis**

The distribution of the characteristics of cases and controls was described through the absolute and relative frequencies for categorical variables and through means, standard deviations (SD), medians, minimum, and maximum value for continuous variables.

The individual's body mass index (BMI) was calculated from the reported weight and height and subsequently categorized into 4 classes: underweight (BMI<18.5); normal weight

( $18.5 \leq \text{BMI} < 25$ ); overweight ( $25 \leq \text{BMI} < 30$ ); obese ( $\text{BMI} \geq 30$ ). The ESS was categorized into normal (0-10); mild sleepiness (11-14); moderate sleepiness (15-17); severe sleepiness (18-24). The MEQ scores were categorized into “definitely morning type” (score 70-86); “moderately morning type” (59-69); “neither morning nor evening type” (42-58); “moderately evening type” (31-41); “definitely evening type” (16-30). The statistical significance of differences in categorical variables between cases and controls was assessed through the chi-square test or Fisher’s exact test where appropriate. The differences in continuous variables were assessed through the Wilcoxon’s Rank Sums test since they resulted non-normally distributed according to the Kolmogorov-Smirnov test. P-values  $< 0.05$  were considered statistically significant. The differences in sleep-related variables between subjects working in shifts including nights and the others were also assessed.

The effect of sleep-related variables (ESS, MEQ score, usual sleep duration  $< 6$  hours; number of reported sleep disturbances (difficulties falling asleep; spontaneously waking up too early in the morning; frequent awakenings during the night; feeling tired at awakening in the morning; bad mood during the day in case of sleep lack; restless legs during sleep; snoring; sleep apnoeas; feeling tired after sleeping; feeling fatigued or in bad shape during the day; falling asleep while driving), and sleep disruption due to causes other than work) on the risk of injury was assessed through unconditional multivariate logistic regression models, adjusting for the potential confounding effect of the characteristics of the subjects. All sleep-related variables were included in the model. Of the variables regarding individual characteristics, only those with  $p < 0.20$  in the univariate analysis were included in the models. The results were expressed through the odds ratios (OR) and 95% confidence intervals (95% CI). Two different sets of models were built, one treating MEQ score and ESS as categorical variables, the other as continuous. The ESS was also analyzed as a dichotomous variable (normal vs some degree of sleepiness). Job and department type were not included in the same models because of substantial overlapping in some categories (e.g., most administrative workers were in administrative departments). One additional model was built after

excluding cases reporting a commuting accident. Models stratified by department type were also attempted to assess interactions between department type and sleep-related variables.

## **RESULTS**

In the 15 months of the study, 200 cases (47% of all the reported injuries) and 183 controls (88% of the eligible sampled workers) were recruited. The characteristics of the study subjects and their sleep are shown in Tables 1 and 2, respectively. Females tended to be more represented among cases than among controls, as were young employees. The distributions of cases and controls by job and department type were also slightly different. More cases than controls worked in shifts including nights, were exposed to weight lifting, handled potentially infected biologic materials and chemicals, and reported previous occupational injuries. Smoking habit was more common among cases, whereas the proportion of cases with normal weight, of those consuming alcohol and coffee and of those reporting chronic diseases was smaller than that of controls. The proportion of subjects sleeping less than 6 hours a day was higher among cases than among controls, as was the average number of reported sleep disturbances. However, the ESS was lower among cases than among controls, and no significant differences were seen in chronotype.

The prevalence of individual reported sleep disturbances was extremely high among the study controls: difficulties falling asleep 24.6%; spontaneously waking up too early in the morning 43.7%; frequent awakenings during the night 31.7%; feeling tired at awakening in the morning 50.3%; bad mood during the day in case of sleep lack 68.8%; restless legs during sleep 17.5%; snoring 54.1%; sleep apnoeas 8.2%; feeling tired after sleeping 77.6%; feeling fatigued or in bad shape during the day 91.8%; falling asleep while driving 29.0%. Significant or borderline significant differences between cases and controls were observed for spontaneously waking up too early in the morning (53.0% among cases,  $p$ -value=0.0694); frequent awakenings during the night (41.0% among cases,  $p$ -value=0.0589); bad mood during the day in case of sleep lack (67.0%

among cases,  $p$ -value=0.0009); snoring (36.5% among cases,  $p$ -value=0.0005); and feeling tired after sleeping (87.0% among cases,  $p$ -value=0.0156).

Among controls, although subjects working the night shifts reported a a higher number of sleep disturbances (mean  $5.4 \pm 2.0$ , median 5 vs mean  $4.7 \pm 2.2$ , median 5,  $p$ -value=0.0588), they did not differ significantly from the others with respect to short sleep (<6 hours; 14.1% vs 16.0%,  $p$ -value=0.7330), sleep disruption due to causes other than work (34.4% vs 33.6%,  $p$ -value=0.9173), daytime sleepiness (mean ESS  $6.8 \pm 3.7$ , median 6 vs mean  $7.1 \pm 4.3$ , median 6,  $p$ -value=0.8040), and chronotype (mean MEQ score  $54.8 \pm 10.1$ , median 55.5 vs mean  $56.7 \pm 10.4$ , median 58,  $p$ -value=0.3251).

Table 3 illustrates the results of the multivariate regression model including MEQ type as a categorical variable and ESS as a dichotomous variable. ESS revealing some degree of sleepiness were associated with a reduced likelihood of injury. Although not statistically significant, there appeared to be a decreasing trend in the risk of injury for morning to evening chronotypes. In the models considering those variables as continuous scores, the OR for MEQ score was 1.02 (95% CI: 1.00-1.05) and the OR for ESS was 0.93 (95% CI: 0.87-0.99). In the model described in Table 3, department type was included as a covariate, whereas job was not. The model including job instead of department type returned very similar ORs for MEQ score and ESS. Although non-significant, physicians had an increased risk of injury when compared to administrative personnel (OR=1.67, 95% CI: 0.43-6.43). When we excluded from the analysis cases reporting commuting accidents, the OR for working in an administrative department dropped to 0.83 although the estimate was imprecise (95% CI: 0.14-4.93) and the 95% CI overlapped with that resulting from the unrestricted analysis. Of the models stratified by department type, the convergence criterion was satisfied only in the one restricted to the surgical department. In this model, the effects of sleepiness and chronotype on the risk of injury were similar to those resulting from the overall model as regards the direction and magnitude of the estimates, but less precise (data not shown).

## DISCUSSION

In this case-control study, we found that workers who reported occupational injuries in the University Hospital of Udine usually slept less and had an increased number of sleep disturbances as compared to those who were not injured. In particular, the frequency of spontaneously waking up too early in the morning, of frequent awakenings during the night, of bad mood during the day in case of sleep lack and of feeling tired after sleeping was higher in cases than in controls. However, daytime sleepiness according to the ESS was more common among controls. The distribution of chronotypes was not significantly different in the two groups of workers. When adjusting for individual characteristics potentially acting as confounders of the association between sleep-related exposures and the risk of injury, there was no significant association between chronotype and the risk of injury, although the progressive decrease in the OR from the extreme morning to the evening type seems to suggest the existence of a trend. Chronotype has been shown to affect melatonin levels of night shift workers<sup>19</sup> and to reduce sleep quantity and quality in the “opposite” shifts (night shifts for earlier chronotypes and early shifts for later chronotypes),<sup>20</sup> thus a role of chronotype on predisposing workers to injuries cannot be excluded.

On the other hand, shifts including nights were not associated with increased risk of injury, contrary to what reported in the literature.<sup>21,22</sup> In a hospital setting, activities carried out during the night may be different from those carried out during the day. For example, a small Italian observational study of night time nurses’ activities showed that the prevailing activities were basic care, surveillance of patients, and drug administration.<sup>23</sup> The risk of injury may decrease by night due to reduced workload, work complexity, and hospital crowding. Thus, despite in our setting night shift workers reported poorer sleep quality, the risk of injury was not enhanced.

Although, contrary to other research,<sup>8</sup> neither daytime sleepiness nor short sleep (<6 hours) resulted as risk factors, the number of reported sleep disturbances appears to be associated with injuries and the reported frequency of several sleep disturbances was significantly higher among cases than among controls. Consistently with our finding, in a cross-sectional study in Japanese enterprises,

researchers<sup>24,25</sup> also did not find any association between short sleep and injuries, whereas some sleep habits were more likely among workers reporting injuries, suggesting that in selected settings, sleep quality, rather than quantity, may have a role in work performance and risk of injury.

The fact that daytime sleepiness was inversely related with the risk of injury, however, was unexpected. However, a Swiss study also failed to detect an association between ESS>10 and work injuries.<sup>26</sup> It is possible that in our sample workers who are aware of their excessive sleepiness take actions that counterbalance the detrimental effects of sleepiness. Another possible explanation is that workers with excessive daytime sleepiness are physically less active while at work and thus less prone to injuries. An analogous reason could explain the reduced risk of injury in workers reporting chronic diseases. The finding that ESS was inversely related with injury, however, could also be a result of selection bias. In fact, it is possible that controls were more likely to agree to participate in the study if they believed that sleepiness was a problem for them. The higher frequency of snoring among controls than among cases suggests that some degree of such a bias cannot be excluded, although the participation rate among controls was high.

Misreporting of exposures could also have occurred, although it is unlikely that it was differential between cases and controls and thus we consider information bias as unlikely. The reported prevalence of sleep disturbances in our context was very high, in both groups. Workers could be really experiencing those disorders, or those reports might have been exaggerated due to distorted perception, stress, burnout, which are common in the healthcare setting.<sup>27</sup> In any case, these data indicate that there is an issue that needs to be addressed among the hospital workers.

In the perspective of targeting injury preventive efforts in the hospital, our findings suggest that programs should involve the youngest workers, those who have already sustained occupational injuries, and smokers (who seem to be more prone to risk taking behaviours.<sup>28</sup> Overweight workers could also benefit for ad-hoc programs. In our study, consistently with others<sup>29,30</sup> being overweight increased the risk of occupational injury. Whether it is related to sleep characteristics,<sup>31</sup> or to impaired motor skills in overweight subjects<sup>32,33</sup> this finding is important for health promotion and

preventive purposes.<sup>30</sup> Being underweight also resulted associated with increased injury risk, although the result is very imprecise and we cannot exclude that this finding is due to chance.

In conclusion, this study identified a number of risk factors for occupational injuries in an Italian teaching hospital, providing information that can be used to improve safety on the workplace. The role of sleep quantity and quality, sleepiness, and chronotype was not straightforward and further research is needed to identify sleep-related factors that differentiate the employees who are likely to sustain injuries from those who are not, in a complex setting such as a large hospital.

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**Table 1. Characteristics of study subjects.**

Characteristic	Cases (N=200)		Controls (N=182)		p-value
	N	%	N	%	
Sex					0.0897
Male	37	18.5	47	25.7	
Female	163	81.5	136	74.3	
Age (years)					0.0251
20-29	33	16.5	12	6.6	
30-39	52	26.0	47	25.7	
40-49	74	37.0	71	38.8	
50-59	35	17.5	47	25.7	
≥60	6	3.0	6	3.3	
Occupation					0.0007
Physician	47	23.5	42	22.9	
Other health professional	89	44.5	86	47.0	
Administrative	7	3.5	24	13.1	
Nursing assistants	3	1.5	5	2.7	
Other	54	27.0	26	14.2	
Department type					0.0709
Medical	94	47.0	92	50.3	
Surgical	72	36.0	56	30.6	
Laboratory	19	9.5	10	5.5	
Administrative	8	4.0	19	10.4	
Other	7	3.5	6	3.3	
Shifts with nights					0.0456
Yes	90	45.0	64	35.0	
No	110	55.0	119	65.0	
Weight lifting					0.0035
Yes	129	64.5	91	49.7	
No	71	35.5	92	50.3	
Handling of potentially infected biologic material					<0.0001
Yes	156	78.0	86	47.0	
No	44	22.9	97	53.0	
Handling of chemicals					<0.0001
Yes	185	92.5	134	73.2	
No	15	7.5	49	26.8	
Previous occupational injury					0.1188
Yes	125	62.5	100	54.6	
No	75	37.5	83	54.4	
BMI					0.1891
Underweight	9	4.5	3	1.6	

Normal weight	132	66.0	133	72.7	
Overweight	49	24.5	35	19.1	
Obese	10	5.0	12	6.6	
Smoking status					<0.0001
Non-smoker	136	68.0	110	60.1	
Ex-smoker	10	5.0	44	24.0	
Smoker	54	27.0	29	15.8	
Alcohol consumption					<0.0001
Yes	90	45.0	128	69.9	
No	110	55.0	55	30.0	
Coffee consumption					0.0723
Yes	172	86.0	168	91.8	
No	28	14.0	15	8.2	
Use of hypnotics					0.3914
Yes	29	14.5	21	11.5	
No	171	85.5	161	88.5	
Chronic diseases*					0.0048
Yes	97	48.5	115	62.8	
No	103	51.5	68	37.2	

\*Any of the following: hypertension, diabetes, allergy, hypercholesterolemia, anxiety disorder, depression

**Table 2. Sleep-related characteristics of study subjects.**

Characteristic	Cases (N=200)		Controls (N=182)		p-value
	N	%	N	%	
Usual sleep hours					0.1860
<6	41	20.5	28	15.3	
≥6	159	79.5	155	84.7	
Sleep disturbances* (N) mean±SD, median	5.41±2.0, 5		5.0±2.1, 5		0.0609
Sleep disruption for causes other than work					0.3476
Yes	77	38.5	62	33.9	
No	123	61.5	121	66.1	
ESS (continuous) mean±SD, median	6.1±3.7, 6		7.0±4.1, 6		0.0405
ESS category					0.0454
Normal	176	88.0	142	78.0	
Mild sleepiness	19	9.5	29	15.9	
Moderate sleepiness	5	2.5	9	4.9	
Severe sleepiness	0	0	2	1.1	
MEQ (continuous) mean±SD, median	56.3±9.9, 56		56.0±10.3, 58		0.9683
MEQ type					0.6227
Definitely morning	20	10.0	18	9.8	
Moderate morning	63	31.5	64	35.0	
Neither	99	49.5	84	45.9	
Moderately evening	16	8.0	17	9.3	
Definitely evening	2	1.0	0	0	

\*Any of the following: difficulties falling asleep; spontaneously waking up too early in the morning; frequent awakenings during the night; feeling tired at awakening in the morning; bad mood during the day in case of sleep lack; restless legs during sleep; snoring; sleep apnoeas; feeling tired after sleeping; falling asleep while driving

**Table 3. Multivariate logistic regression of the risk of occupational injury in relation to sleep and subject characteristics.**

Characteristic	OR	95%CI
Sex		
M	1.00	-
F	1.20	0.63-2.26
Age (years)		
20-29	2.81	1.13-6.96
30-39	1.00	0.53-1.87
40-49	1.00	-
50-59	0.87	0.43-1.75
≥60	1.49	0.42-6.93
Department type		
Medical*	1.00	-
Surgical	1.17	0.68-2.02
Laboratory	1.69	0.62-4.62
Administration	1.86	0.50-6.85
Shifts with night		
No	1.00	-
Yes	0.84	0.48-1.48
Weight lifting		
No	1.00	-
Yes	0.95	0.54-1.68
Handling of potentially infected biologic materials		
No	1.00	-
Yes	2.44	0.89-6.70
Handling of chemicals		
No	1.00	-
Yes	2.70	1.50-4.86
Previous occupational injury		
No	1.00	-
Yes	1.65	0.99-2.77
Chronic diseases		
None	1.00	-
At least one**	0.51	0.30-0.85
Smoking status		
Non-smoker, ex smoker	1.00	-
Smoker	1.77	0.98-3.19
BMI		
Underweight	3.22	0.69-14.95
Normal weight	1.00	-
Overweight	1.87	1.00-3.49
Obese	0.71	0.25-2.03
Chronotype		
Definitely morning	1.37	0.58-3.26
Moderately morning	1.12	0.64-1.95
Neither	1.00	-
Moderately evening	0.75	0.31-1.82

Definitely evening	-	-
Usual sleep hours		
6 hours or more	1.00	-
<6 hours	1.01	0.51-1.97
Number of reported sleep disturbances (continuous)	1.13	0.99-1.30
Sleep disruption for causes other than work		
No	1.00	-
Yes	1.25	0.75-2.10
ESS		
Normal	1.00	-
Mild, moderate, or serious sleepiness	0.48	0.25-0.92

\*Includes "Other"

\*\*Diseases considered were hypertension, diabetes, allergy, hypercholesterolemia, anxiety disorder, depression

### **3.2 Manuscript 2**

**A case-crossover study of sleep, fatigue, and other transient exposures on the workplace and the risk of non-fatal occupational injuries among the employees of an Italian academic hospital**

**A CASE-CROSSOVER STUDY OF SLEEP, FATIGUE, AND OTHER TRANSIENT  
EXPOSURES ON THE WORKPLACE AND THE RISK OF NON-FATAL  
OCCUPATIONAL INJURIES AMONG THE EMPLOYEES OF AN ITALIAN ACADEMIC  
HOSPITAL**

**Francesca Valent<sup>1,2,3</sup>, Marika Mariuz<sup>2</sup>, Giulia Liva<sup>2</sup>, Fabrizio Bellomo<sup>4</sup>, Daniela De Corti<sup>4</sup>,  
Stefania Degan<sup>4</sup>, Alberto Ferrazzano<sup>4</sup>, Silvio Brusaferrò<sup>3,4</sup>.**

<sup>1</sup>Epidemiologic Service, Regional Health Directorate, Friuli Venezia Giulia Region, Udine, Italy

<sup>2</sup>Unit of Hygiene and Clinical Epidemiology, University Hospital of Udine, Udine, Italy

<sup>3</sup>Department of Medical and Biological Sciences, University of Udine, Udine, Italy

<sup>4</sup>Accreditation, Clinical Risk Management and performance assessment Unit, University Hospital of Udine, Udine, Italy

**Corresponding author:** Francesca Valent - Servizio Epidemiologico - Direzione centrale salute, integrazione socio-sanitaria, politiche sociali e famiglia – Regione Autonoma Friuli Venezia Giulia – Via Pozzuolo 330, 33100 Udine, Italy – Telephone: +39 0432 805616 – email:

[francesca.valent@regione.fvg.it](mailto:francesca.valent@regione.fvg.it)

## **ABSTRACT**

**Objectives.** Transient exposure with acute affect have been shown to affect the risk of occupational injuries in different industrial settings and in the healthcare workplace. We studied the association of transient factors and the risk of occupational injuries among the employees of an Italian teaching hospital.

**Methods.** A case-crossover study was conducted among the employees of the University Hospital of Udine who reported an occupational injury, commuting accident, or incident involving biological risk in a 15-month period in the years 2013 and 2014. The matched-pair interval approach was used to assess the role of acute sleep deprivation, whereas the usual frequency approach was used for other 13 transient exposures.

**Results.** Sleep hours were not associated with the risk of injuries, whereas a significant risk increase was associated with fatigue, rush, distraction, emergency situations, teaching to or being taught by someone, non-compliant patients, bloody operative/work field, excess noise, complex procedures, and anger.

**Conclusions.** We identified transient exposures that increased the risk of occupational injuries in an Italian teaching hospital, providing indications for interventions to increase workers' safety in the healthcare workplace.

## INTRODUCTION

Poor sleep and fatigue have repeatedly been associated with an increased risk of adverse safety outcomes,<sup>1,2</sup> even among the health care workers. For instance, Patterson et al.<sup>3</sup> found that, among workers of the Emergency Medical Services, injuries occurred approximately 2 times more frequently in case of poor sleep and 3 times more frequently in case of fatigue than otherwise.

Other transient exposures on the workplace have been associated with the risk of injury. For example, various studies showed that the risk of occupational traumatic hand injuries was significantly affected by transient factors on the workplace: a machine, tool, or work material that performed differently than usual; wearing gloves; performing an unusual task; doing a task using an unusual work method; being distracted or rushed; and feeling ill.<sup>4-6</sup> The effect of analogous factors has been studied in relation to the occurrence of occupational eye injuries.<sup>7</sup>

When investigating the effect of transient exposures on the risk of occupational injuries, several researchers used the case-crossover design. In the case-crossover design<sup>8,9</sup> each subject acts as his/her own control. Thus, self-matching allows to control for the potential confounding effect due to factors which differ between individuals but are fixed within the same individual over relatively short periods of time: age, gender, risk propensity, visual acuity, reflexes, job experience, etc. This design is well-suited for studying the effect of transient exposures with acute non-permanent effect: if a subject moves from exposed to unexposed states, the exposure immediately before an event, e.g., an injury, can be compared with the exposures of the same person at different times, when no event occurred. Thus, exposures that act as triggers of the event can be identified. Fisman et al.<sup>10</sup> used a case-crossover study to investigate the risk of sharp-related injuries in relation to several transient exposures among health care workers, finding that distraction, anger, and rushing were associated with the largest increases in risk.

In the University Hospital of Udine, a tertiary referral center in the North-East of Italy, employing approximately 3800 workers, about 450 occupational injuries, including commuting accidents and incidents involving biologic hazard, are recorded annually. Recently, different

components of work-related stress have been detected in the hospital wards;<sup>11</sup> in addition, situations of personnel shortage and consequent exhausting work schedules in some wards have been reported in the local media as a potential cause of errors.<sup>12</sup>

We decided to conduct a case-crossover study to identify transient factors that might affect the risk of occupational injuries among the employees of the University Hospital of Udine.

## **METHODS**

Eligible study subjects for this case-crossover study were employees of the University Hospital of Udine who reported non-fatal injuries, including commuting accidents and incidents involving biological hazard, to the Clinical Risk Office of the Hospital, from March 25<sup>th</sup>, 2013 to July 3<sup>rd</sup>, 2014, and who provided written informed consent to participate in the research. Before the start of enrolment, all the Hospital employees had been explained the purpose and background of the study through an information letter that had been included in their payslip of February 2013. Workers reporting an injury were asked to provide their telephone number and were contacted within the shortest possible time by a single trained interviewer for a telephonic interview. The mean and median time elapsed from injury occurrence to the interview were 4.4 and 4 days, respectively (standard deviation [SD] 4.1).

The interview was conducted using a semi-structured questionnaire collecting information on socio-demographic characteristics of the worker, job characteristics (occupation, department type, shifts, exposure to hazards, etc.), injury characteristics (type of injury, task performed at the time of injury, day and time of occurrence), sleep quality and quantity on the day of the injury and on the prior working day. Workers who suffered injuries other than commuting accidents were also asked to report their exposure to fatigue, rush, distraction, working in an emergency situation, teaching to someone, being taught by someone, personnel shortage, non-compliant patients, blood in operative field or work field, excess noise, complex procedure, music, and anger at the time of the injury and to estimate the usual frequency of those exposures on the previous working month,

expressed as the percent of their working time they perceived to be exposed. To collect data on the usual frequency of exposure, we adopted for questions the format used by Fisman et al.<sup>10</sup>

Our questionnaire also included sections regarding lifestyle, medical problems, chronic sleep disturbances, the Epworth Sleepiness Scale, and the Horne-Östberg morningness-eveningness questionnaire. However, these additional sections were not used for the purpose of the case-crossover study. On average, the duration of the complete interview was approximately 30 minutes.

The effect of the hours of sleep on the risk of injury was evaluated according to the case-crossover matched-pair interval approach. For each injured subject, the day immediately before the injury represented the case window for the analysis, whereas the previous working day was the control window. The statistical significance of the difference in sleep hours reported by each worker between the two windows was assessed through the t-test for paired data. A p-value <0.05 was considered statistically significant. The effect of sleep hours on the risk of injury was assessed through a conditional logistic regression model, also adjusting for the potential confounding effect of day of the week. The relative risk [RR] was reported as the measure of association. The precision of the estimate was expressed through the 95% confidence interval [95%CI]. The agreement between the sleep amount in the case and control windows reported according to the question “Compared to the previous working day, on the day of injury did you sleep less hours, more hours, or the same number of hours?” and the sleep amount resulting from the difference in the reported actual number of sleep hours in the two days was assessed through the kappa statistic and was used as a measure of validity of self-reports.

The effect of the other 13 transient exposures (fatigue, rush, distraction, emergency situation, teaching to someone, being taught by someone, personnel shortage, non-compliant patient, blood in operative or work field, excess noise, complex procedure, music, and anger) on the risk of injury was assessed according to the case-crossover usual frequency approach. The RR and 95%CI were estimated using the Mantel-Haenszel estimator for person-time data, as exemplified in previous studies,<sup>4-6,10</sup> the individual being the stratifying variable. RRs were based on the ratio of

the observed frequency of exposure to each factor at the time of injury (hazard period) to the reported frequency of exposure in the past work-month (control period).

All the analyses were performed using SAS Enterprise Guide v 4.3 (SAS Institute Inc., Cary, NC, USA).

Approval from the Ethics Committee of Udine, Italy, was obtained on November 6<sup>th</sup>, 2012.

## RESULTS

Two hundred employees of the University Hospital of Udine suffered occupational injuries and agreed to participate in the research during the 15 months of the study (47.0% of the 425 injuries reported in the same period). The characteristics of the injured subjects and of the injuries are illustrated in Table 1.

Compared to the previous working day, most subjects (N=155, 77.5%) reported “the same sleep quality” on the day of the injury, 4 (2.0%) reported having slept better and 41 (20.5%) having slept worse on the day of injury; 158 (79.9%) reported “the same hours of sleep” in both days, 3 (1.5%) reported more hours, whereas 39 (19.5%) reported less hours on the day of injury.

Comparing the reported actual number of sleep hours on the two days, 35 subjects (17.5%) reported less hours on the day of injury than on the previous working day, whereas 28 (14.0%) reported more. The agreement between sleep difference estimated with the 2 different methods is shown in Table 2. On average, the sleep hours reported on the day of injury were 6.35 (SD 1.23, median 6, range: 3-10); those on the previous day were 6.42 (SD 1.23, median 7, range: 2-10). The intra-worker difference in sleep time between the day of injury and the previous one was minimal (on average 0.06 hours, SD 1.06) and non statistically significant (p-value of paired t-test 0.4220). The RR of injury associated with each additional hour of sleep, adjusted for day of the week, was 1.25 (95% CI: 0.92-1.69).

Figure 1 shows the frequency of transient exposures in the working month before the injury and the percentage of workers exposed at the time of injury. The corresponding RRs are illustrated

in Table 3. When we stratified the analyses by role of the injured worker, the effect of several factors was much stronger among some professionals than in the overall pool of study subjects: among physicians, the RR associated with rush was 9.87 (95%CI: 6.46-15.98), distraction 27.56 (15.15-47.05), emergency situations 8.59 (4.76-15.49), non-compliant patient 13.98 (7.28-26.85), blood 13.11 (6.45-26.64), noise 37.00 (8.70-157.30). On the other hand, complex procedures did not appear to significantly increase the risk of injury (RR=1.45; 95%CI: 0.69-3.05). Among other health professionals, being taught by someone entailed a particularly high risk of injury (RR=17.50; 95%CI: 2.87-106.80), as did complex procedures (RR=31.93; 95%CI: 8.99-113.33). Among employees who worked on shifts including nights, the RR associated with fatigue was higher than among the overall pool of workers (RR=8.74; 95%CI: 6.32-12.10).

Analyses stratified by injury type showed that in case of incidents involving biological risk, rush had a particularly strong effect (RR=8.77; 95%CI: 6.03-12.74).

## **DISCUSSION**

This is the first study of the association of transient factors and occupational injuries in an Italian hospital context. Through the case-crossover design, we could identify a number of risk factors. Most of the exposures that we investigated (i.e., fatigue, rush, distraction, emergency situations, teaching or being taught, non-compliant patients, blood on operative field, excess noise, complex procedures, and anger) turned out to be risk factors for occupational injuries in our study. Some of them (e.g., rush, distraction, anger) were consistently reported as risk factors for occupational injuries in previous literature;<sup>4-6,10</sup> others (e.g., fatigue, non-compliant patients, presence of blood, complex procedures, and teaching) increased the risk of injury in our hospital but not among healthcare workers elsewhere.<sup>10</sup> In a large hospital such as the University Hospital of Udine, with approximately 4000 employees, 1000 beds, over 30,000 inpatients and 2 million outpatients, many of those exposures are likely to be common. Workers must be instructed to maintain concentration despite the chaotic work conditions that may characterize some healthcare

environments,<sup>13,14</sup> trained to cope with anger, to handle conflicts, and to sooth interpersonal relationships, both with colleagues and with patients, and educated to limit noise as much as possible. The finding that the effect of some transient exposures had different magnitude between physicians and other health professionals suggests that workers training should be tailored for each job type.

Rush, whose effect is particularly strong in case of incidents involving biologic hazard, is difficult to eliminate in a hospital, since timely interventions on patients are often crucial for ensuring favourable outcomes. Although rush may also be a consequence of personnel shortage, in our study being short-staffed was not associated with increased injury risk. Nonetheless, organizational changes should be conceived to improve work pace.

Our hospital has a teaching mission and the greatly increased risk of injury entailed by teaching to someone or by being taught by someone forces us to analyze the way students and residents spend time in the hospital and possibly rethink the organization of the presence of students in the hospital wards.

Fatigue was an important risk factor for occupational injuries in our study, as in other healthcare settings.<sup>3</sup> Employees working on shifts experienced a particularly strong effect of fatigue, confirming that the design of good work schedules, the implementation of employer's strategies to reduce fatigue, and periodic assessments of sleep and fatigue among these workers may be useful.<sup>15</sup>

Despite the effect of fatigue, we could not show an effect of acute sleep deprivation on the risk of injury. In fact, although more cases reported lower quality and less hours of sleep on the day of injury than on the previous working day, no significant differences appeared when the reported actual number of sleep hours was analyzed and no significant effect of sleep hours resulted from the matched-pair analysis. It is possible that acute sleep deprivation has little effect on the risk of injury, has we hypothesized in a previous research on sleep and road traffic accidents.<sup>16</sup> However, it is also possible that recall bias affected our results and prevented us to detect any association.<sup>8</sup> To assess

the likelihood of recall bias, we included in the questionnaire a redundant question on sleep hours on the day of injury and on the previous working day, with different phrasing, as suggested by Maclure and Mittleman.<sup>9</sup> The agreement was only fair ( $\kappa=0.35$ ), indicating that recall bias may exist to some extent. However, since we had no reliable external information to be used as the gold standard, we cannot describe the direction of the possible bias.

As with all retrospective studies using self-reports to quantify exposure, recall bias could also be present in our usual frequency analysis. We tried to minimize recall bias using a structured questionnaire and a well-trained unique interviewer. In addition, unlike case-control and cohort studies, in case-crossover studies the same subject reports exposures both in the hazard period and in the control period, making reporting more consistent. The RR estimates, however, could be overestimated (i.e., away from the null) if cases tended to underestimate the average exposure to transient factors in the past working month, while having a more vivid recall of the exposures at the time of injury. The associations that we detected, however, are quite strong and most of them are consistent with other studies.<sup>4-6,10</sup> Therefore, should some degree of recall bias exist, it is unlikely that it explains the entire magnitude of the associations.

Approximately half of the employees who reported an injury during the study period participated in the research. Case selection bias has been possible, if some of the transient factors of interest influenced participation in the study. However, none of the transient factors that we investigated had legal implications or represented a disciplinary offence; therefore, we consider differential participation according to exposure status unlikely.

In conclusion, this is the first Italian case-crossover study that identified a number of transient risk factors for occupational injuries in a teaching hospital. Findings from this study provide useful information for interventions to increase workers' safety in the healthcare workplace.

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**Table 1. Characteristics of workers of the University Hospital of Udine, Italy, injured from March 25, 2013, to July 3, 2014 (N=200).**

Characteristics	N	%
Sex		
Male	37	18.5
Female	163	81.5
Age category (years)		
20-29	33	16.5
30-39	52	26.0
40-49	74	37.0
50-59	35	17.5
≥60	6	3.0
Job		
Physician	47	23.5
Non-physician health professional	89	44.5
Administrative	7	3.5
Other	57	28.5
Department type		
Medical	94	47.0
Surgical	72	36.0
Laboratory	19	9.5
Administrative	8	4.0
Other	7	3.5
Working schedule		
Shifts, with nights	90	45.0
Shifts, no nights	48	24.0
No shifts	35	17.5
Variable	27	13.5
Exposure to lifting weights	129	64.5
Exposure to handling chemicals	156	78.0
Exposure to potentially infected biologic materials	185	92.5
Type of injury		
Trauma	62	31.0
Incident involving biological hazard	97	48.5
Incident involving chemical hazard	3	1.5
Commuting accident	38	19.0
Time of occurrence		
Morning (6:00 am-1:59 pm)	121	60.5
Afternoon (2:00 pm-9:59 pm)	68	34.5
Night (10:00 pm-5:59 am)	11	5.5
Working hour		
1 <sup>st</sup>	15	7.5
2 <sup>nd</sup> -5 <sup>th</sup>	137	68.5
6 <sup>th</sup> or more	48	24.0

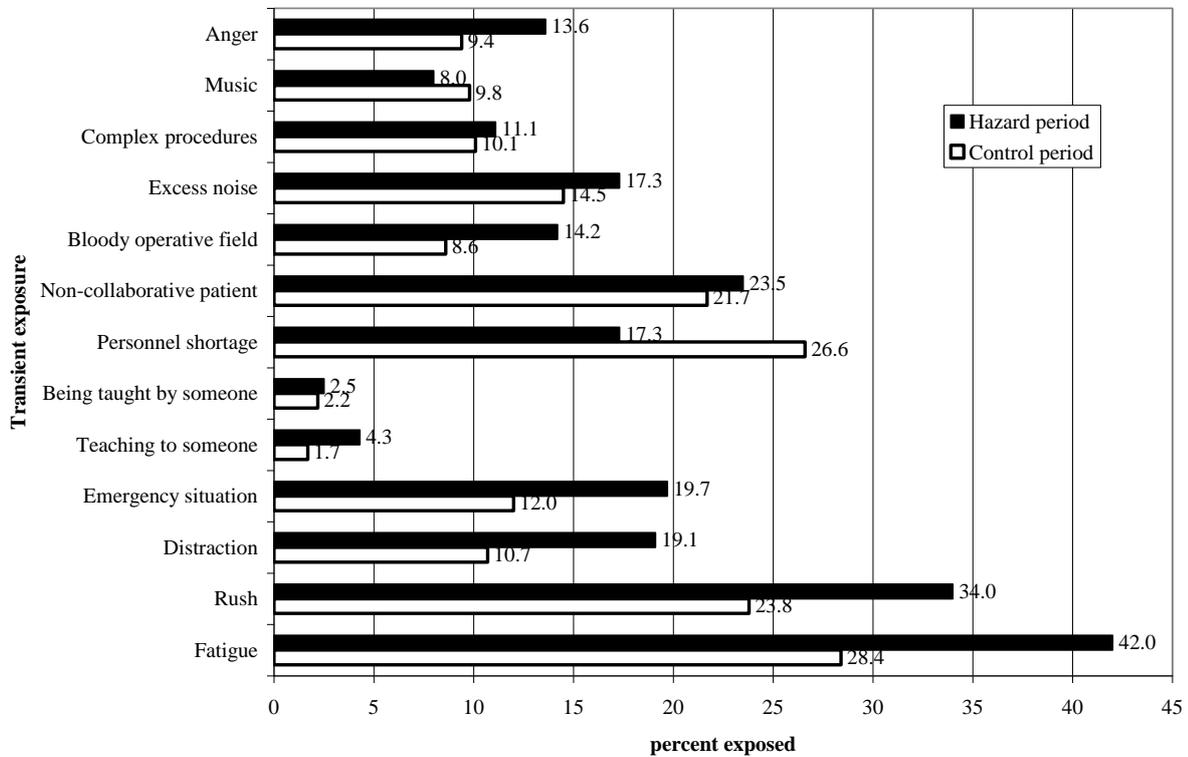
Day of the week		
Sun	11	5.5
Mon	34	17.0
Tue	33	16.5
Wed	30	15.0
Thu	39	19.5
Fri	41	20.5
Sat	12	6.0

**Table 2. Agreement between two self reports of sleep amount on the day of injury and on the previous working day.**

		Sleep amount according to the question “Compared to the previous working day, on the day of injury did you sleep less hours, more hours, or the same number of hours?”			
		Less hours of sleep on day of injury	Same hours of sleep on both days	More sleep hours on day of injury	Total
Sleep amount according to the difference between the actual number of sleep hours reported for the day of injury and for the previous working day	Less hours of sleep on day of injury	20 (10.0%)	16 (8.0%)	0 (0%)	36
	Same hours of sleep on both days	15 (7.5%)	122 (61.0%)	0 (0%)	137
	More sleep hours on day of injury	4 (2.0%)	20 (10.0%)	3 (1.5%)	27
	Total	39	158	3	200

Kappa statistic = 0.35 (95% CI: 0.22-0.47)

**Figure 1. Average percentage of subjects exposed to each transient risk factor at the time of injury (hazard period, black bars) and percentage of total person-time at work exposed to the same risk factors in the work-month before the injury (control period, white bars).**



**Table 3. Transient exposures and relative risks of occupational injuries\* among the employees of the University Hospital of Udine, Italy (usual frequency analysis).**

<b>Transient risk factor</b>	<b>RR</b>	<b>95%CI</b>
Fatigue	6.18	4.94-7.74
Rush	4.66	3.75-5.80
Distraction	5.10	4.06-6.40
Emergency situation	4.60	3.45-6.13
Teaching to someone	46.13	17.91-118.82
Being taught by someone	10.00	2.02-49.57
Personnel shortage	0.99	0.77-1.127
Non-compliant patient	2.75	2.14-3.52
Bloody operative field	5.05	3.64-7.00
Excess noise	11.23	6.68-18.86
Complex procedures	5.73	3.49-9.40
Music	1.38	0.84-2.24
Anger	2.34	1.77-3.08

\*Commuting accidents not included in the analysis.

### **3.3 Manuscript 3**

**Maintenance of wakefulness and occupational injuries among workers of an Italian teaching hospital**

## **MAINTENANCE OF WAKEFULNESS AND OCCUPATIONAL INJURIES AMONG WORKERS OF AN ITALIAN TEACHING HOSPITAL**

**Francesca Valent<sup>1,2,3</sup>, Elisa Sincig<sup>4</sup>, Gian Luigi Gigli<sup>4</sup>, Pierluigi Dolso<sup>4</sup>**

<sup>1</sup>Epidemiologic Service, Regional Health Directorate, Friuli Venezia Giulia Region, Udine, Italy

<sup>2</sup>Unit of Hygiene and Clinical Epidemiology, University Hospital of Udine, Udine, Italy

<sup>3</sup>Department of Medical and Biological Sciences, University of Udine, Udine, Italy

<sup>4</sup>Neurology Clinic, University Hospital of Udine, Udine, Italy

**Corresponding author:** Francesca Valent - Servizio Epidemiologico - Direzione centrale salute,  
integrazione socio-sanitaria, politiche sociali e famiglia – Regione Autonoma Friuli Venezia Giulia  
– Via Pozzuolo 330, 33100 Udine, Italy – Telephone: +39 0432 805616 – email:

[francesca.valent@regione.fvg.it](mailto:francesca.valent@regione.fvg.it)

## **ABSTRACT**

**Objective.** To assess in a laboratory setting the ability to stay awake in a sample of workers of an Italian hospital and to investigate the association between that ability and the risk of occupational injury.

**Methods.** Nine workers of the University Hospital of Udine, reporting an occupational injury in the study period (cases), and 7 non-injured workers (controls) underwent a polysomnography and four 40-minute maintenance of wakefulness test (MWT). Differences in sleep characteristics and in wakefulness maintenance were assessed through Wilcoxon's Rank Sums tests and Fisher's exact tests.

**Results.** Controls had greater sleep latency, lower total sleep time, fewer leg movements, and higher percentage ratio of cycling alternating pattern, were more likely not to fall asleep during the MWT and less likely to have  $\geq 2$  sleep onsets. Although not all the differences reached statistical significance, cases had lower sleep onset times on trials 1-3.

**Conclusions.** In the literature, the evidence of an association between MWT results and real life risk of accidents is weak. Our results suggest a relation between the MWT results and the risk of injury among hospital workers.

**Significance.** This study supports the evidence of an association between MWT results and real life risk of injury.

## **INTRODUCTION**

Poor sleep quality, fatigue, and sleep disorders among workers are associated with worse occupational performances, safety issues, and increased risk of injury.<sup>1-3</sup>

The Maintenance of Wakefulness Test (MWT) is a validated objective test that measures the ability to maintain wakefulness in a quiet, non-stimulating laboratory situation for a certain period of time and it has been proposed as an instrument to assess the ability to stay awake in persons whose jobs require that they remain awake for public or personal safety reasons,<sup>4-5</sup> such as hospital workers, whose excessive sleepiness and inability to maintain alertness may affect patients' safety and increase their own risk of occupational injury.

Unfortunately, normative data for the MWT are limited, as is evidence of an association between MWT findings from a laboratory environment and the actual risk of injuries due to sleepiness in the real world, where different stimuli and conditions may be present.<sup>5</sup> Additional research has been advocated to further investigate the association between MWT findings and the risk of adverse effects of sleepiness.<sup>5</sup>

The objective of the research presented in this article was to assess in a laboratory setting the ability to stay awake in a small sample of workers of an Italian teaching hospital, using the MWT, and to investigate the association between the performance on the test with the worker's risk of occupational injury.

## **METHODS**

Subjects eligible for enrolment in this study were a subgroup of a larger sample selected for a case-control study aiming at investigating the associations between sleep-related exposures, sleepiness, and chronotype and the risk of occupational injuries in the University Hospital of Udine, a teaching hospital located in the North-East of Italy. In short, in such case-control study all the hospital workers reporting occupational injuries (including commuting accidents and incidents involving biological risk) between March 25th, 2013 and July 3rd, 2014 were invited to participate

as cases and a random sample of all the non-injured workers was invited as the control group. Two-hundred cases and 183 controls agreed to participate and underwent a telephone interview based on a semi-structured questionnaire which collected the following information: socio-demographic and job-related characteristics of the subject, weight and height, smoking habits, usual consumption of alcohol and coffee, sleep characteristics, the Epworth Sleepiness Scale (ESS) [<http://epworthsleepinessscale.com/epworth-sleepiness-scale.pdf>] to assess daytime sleepiness, and the Italian version ([www.ge.infn.it/~squarcia/DIDATTICA/SRS/Questionario\\_cronotipo.doc](http://www.ge.infn.it/~squarcia/DIDATTICA/SRS/Questionario_cronotipo.doc)) of the Horne-Ostberg morningness-eveningness questionnaire (MEQ)<sup>6</sup> to assess chronotype.

From that pool of workers, we invited cases with a leave  $\geq 3$  days following the injury and a random sample of controls to undergo further testing from September 2014 to December 2014 to assess their nocturnal quality of sleep and their ability to maintain wakefulness: 9 cases and 7 controls were available and tested. Those subjects underwent a nocturnal polysomnography in their homes and, the following day, a 4 x 40-minute Maintenance of Wakefulness Test (MWT) at the Sleep Clinic of the University Hospital of Udine.

Nocturnal polysomnography was scored by a sleep technologist (ES) according to Iber et al.<sup>7</sup>

The four 40-minute trials of the MWT were performed at around 10:00, 12:00, 14:00, and 16:00. The test was administered by a sleep technologist (ES), according to the protocol recommended by the American Academy of Sleep Medicine.<sup>8</sup> Data were recorded and manually scored in 30-second epochs. Sleep onset was defined as the first epoch of greater than 15 seconds of cumulative sleep in a 30-second epoch. Trials were ended after 40 minutes if no sleep occurred, or after unequivocal sleep, defined as three consecutive epochs of stage 1 sleep, or one epoch of any other stage of sleep.<sup>8</sup> Patients who did not sleep during a trial were assigned a value of 40 minutes.

We calculated the median, interquartile range (IQR) and minimum sleep latency for each MWT trial and overall. We also classified subjects according to the categories proposed by

Doghramji et al.<sup>9</sup>: pathological (0-19 minutes); intermediate (20-33 minutes); and alert (34-40 minutes) based on each subject's average sleep onset time across the 4 MWT trials.

Gender, body mass index (overweight/obese if  $\geq 25$ ), current smoking status, night shifts, history of previous occupational injuries, current use of hypnotic drugs, sleepiness level (ESS  $\leq 10$  vs  $> 10$ ), and MEQ type ("definitely morning type" - score 70-86; "moderately morning type" - 59-69; "neither morning nor evening type" - 42-58; "moderately evening type" - 31-41; "definitely evening type" - 16-30) of cases and controls were compared through Fisher's exact tests; age and numeric continuous characteristics of nocturnal sleep were compared through Wilcoxon's Rank Sums tests.

The number of sleep onsets at the MWT among cases and controls was compared through Fisher's exact test. The median sleep latency in the two groups was compared through Wilcoxon's Rank Sums test. P-values  $< 0.05$  were considered statistically significant. All the analyses were performed through SAS v9.4 (SAS Institute Inc., Cary, NC, USA).

This study was approved by the Ethics Committee of Udine, Italy.

## **RESULTS**

Demographic, sleep-related reported characteristics, ESS and MEQ scores of cases and controls are illustrated in Table 1. Cases were slightly younger, worked on shifts including nights, had greater sleepiness as measured by the ESS, reported previous occupational injuries and current use of hypnotic drugs less often than cases, and were more morning-types than controls, although none of the differences was statistically significant. Regarding nocturnal sleep, controls had a greater sleep latency, a lower total sleep time, and fewer leg movements, although the differences were not statistically significant. The sleep structure was similar among cases and controls. However, cases might have a more disturbed sleep according to the higher percentage ratio of cycling alternating pattern (CAP rate;  $p=0.0148$ ).

Figure 1 shows the distribution of the number of sleep onsets at the MWT among cases and controls. Although the differences were not statistically significant (p-value of Fisher's exact test=0.2570), controls were more likely not to fall asleep (4 controls vs 1 case) and less likely to have 2 sleep onsets or more (1 control vs 5 cases).

Figure 2 shows the distribution of the sleep onset times on the 4 x 40-minute MWT trials. In trials 1-3, lower quartiles corresponded to lower times among cases than among controls. No controls fell asleep during trial 1, but cases were less likely than controls to fall asleep during trial 4. The difference between cases and controls reached statistical significance at trial 1. The median (and IQR) of the average onset times for cases and controls across the 4 MWT trials were, respectively, 32 (22-37) and 40 (33-40) minutes (p-value of Wilcoxon's Rank Sums test=0.1062). According to the average sleep onset times, 67% of cases and 43% of controls were classified as "intermediate", the remaining as "alert" (p-value of Fisher's exact test=0.3409).

## **DISCUSSION**

This study compared findings from the 4 x 40-minute MWT among 9 hospital workers who reported an occupational injury during the previous 18 months and 7 who did not sustain any injury in the same period. Overnight polysomnography revealed slightly longer sleep latency, shorter sleep duration, and a higher number of awakenings among controls: should these differences have affected the subsequent MWT, we would have expected controls to experience more sleepiness than cases on the four trials. Yet, controls resulted more likely to stay awake in all four trials and less likely to fall asleep in 2 or more trials. Also, the minimum and lower quartile of sleep onset times on trials 1-3 were shorter for cases than for controls. In addition, the average sleep time onset across the 4 trials was shorter among cases and a smaller proportion of cases resulted "alert" according to the classification proposed by Doghramji et al.<sup>9</sup> Despite the very small sample size that prevented most of our analyses to be performed with sufficient statistical power to reasonably exclude that the results are only due to chance, our findings suggest that subjects who are prone to injuries in real

world life are less likely to maintain wakefulness in a laboratory setting. This is consistent with the proportion of cases totaling normal ESS scores, lower than the proportion of controls, and could be explained, at least in part, by a worse sleep quality as indicated by a higher CAP rate.<sup>10</sup>

We did not find any pathological MWT (i.e., average sleep latency 0-19). However, the fact that more cases had an intermediate result (20-33) than controls is consistent with Philip et al., who reported a significant increase in the number of inappropriate line crossings during a driving session on a real car driving simulator for subjects with pathological MWT as compared with alert subjects and a smaller non-significant increase among those with intermediate result.<sup>11</sup>

Among controls, who did not suffer any occupational injury in the previous months, more than half were able to stay awake on all the 4 trials, which is what we expect from individuals who need to work at high levels of safety, often required in the hospital environment. The fact that on trial 4 the distribution of sleep onset times among controls was skewed toward shorter values than among cases was counterintuitive, also considering the fact that, on the MEQ, controls resulted more evening-type, and thus more likely to perform better in the afternoon, than cases. Our finding might indicate that the effort to remain awake for some controls was so great that after 6 hours they were exhausted and fell asleep quite soon.

The main limitation of this study is the small sample size that makes the statistical power insufficient to exclude chance as a possible explanation for most of our results. The test is very time-consuming for persons who have a regular job, thus the availability to participate was limited. However, even with this reduced number of subjects, we were able to detect a significant association (the different in sleep onset time on trial 1). In addition, although non-significant, most of our results are consistent with other research<sup>11</sup> indicating that an objective measure of the ability to stay awake might be useful to discriminate workers at increased risk of injury.

Since the normative data for the MWT is limited and the evidence of an association between MWT results and real life risk of accidents is still weak, the possible routine applications of the test in an occupational medicine setting for the primary prevention of adverse events remain

unclear. However, our results indicate that there is some relation between the MWT results and the risk of injury among hospital workers: the MWT could be used as a screening for secondary prevention of occupational injuries and adverse safety outcomes among hospital workers who have already sustained an injury.

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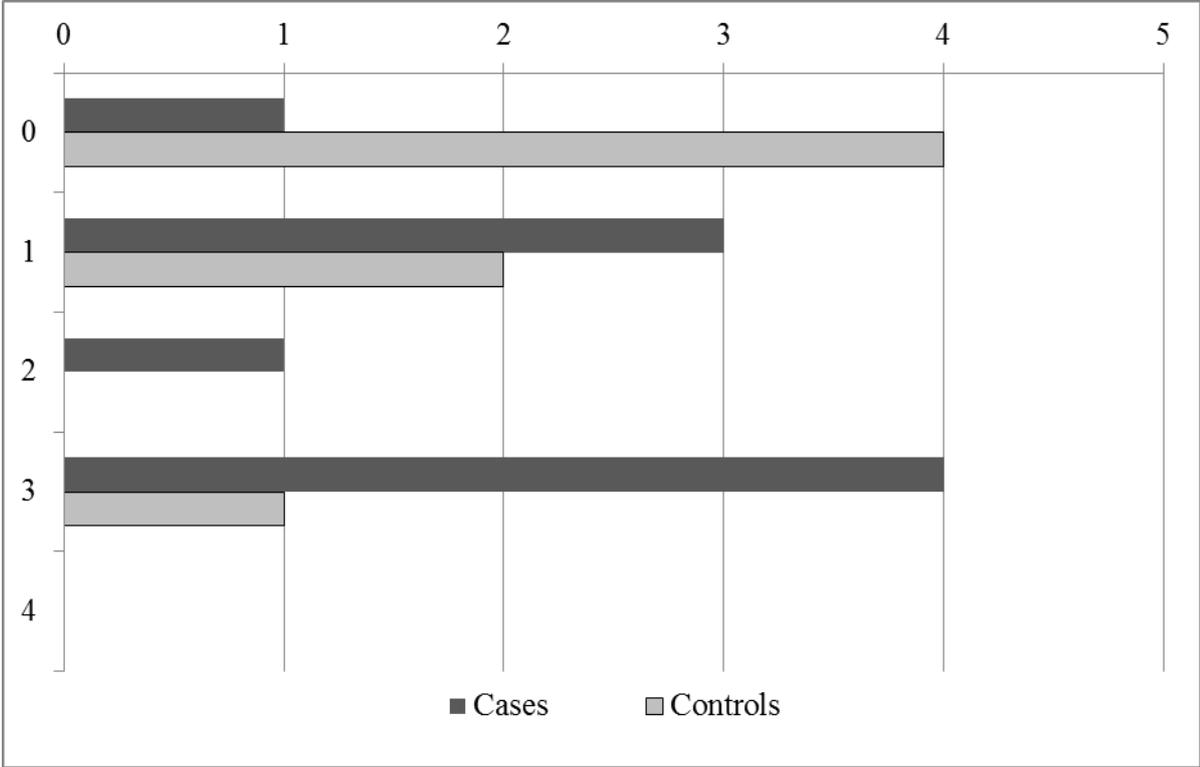
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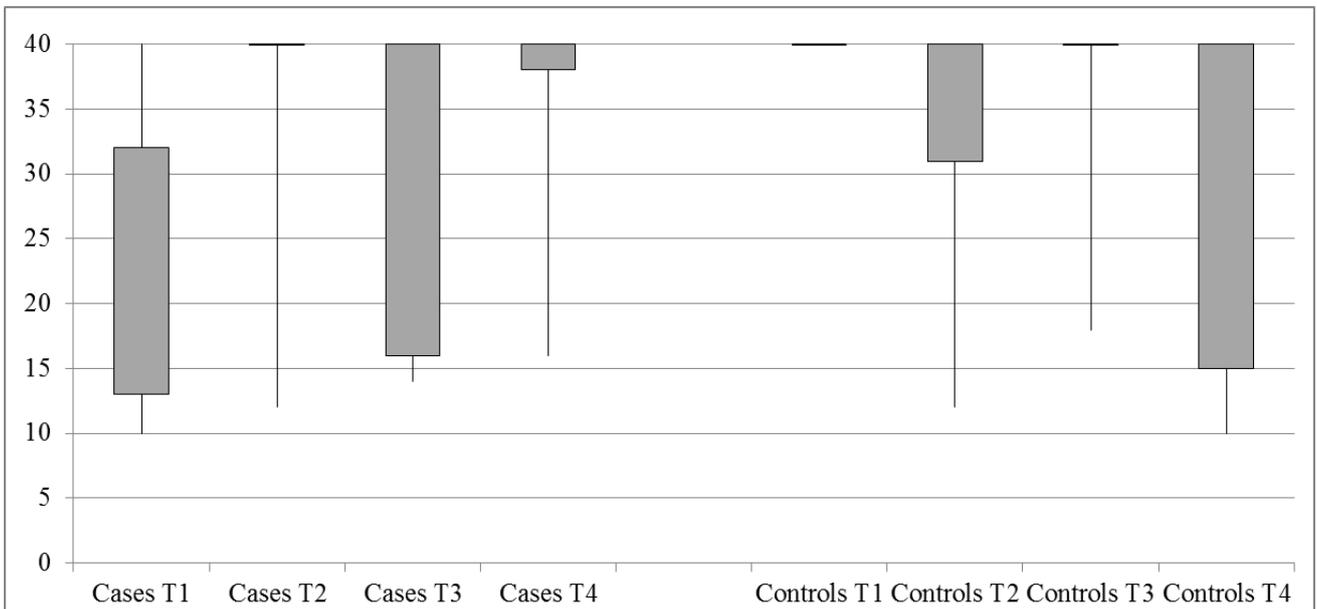
**Table 1. Demographic, sleep-related reported characteristics, ESS and MEQ scores among a sample of 9 workers of the University Hospital of Udine who reported an occupational injury between March 25, 2013, and July 3, 2014, and 7 non-injured workers.**

	Cases (n=9)	Controls (n=7)
Females (%)	89	100
Age (median, IQR)	44, 38-50	46, 44-52
Overweight/obese (%)	23	29
Smokers (%)	0	29
Night shifts (%)	33	14
Previous occupational injuries (%)	44	57
Use of hypnotic drugs (%)	11	29
Normal (<10) ESS (%)	67	86
MEQ type (%)		
Definitely morning	22	0
Moderately morning	56	57
Neither	22	29
Moderately evening	0	14
Definitely evening	0	0
Sleep latency, minutes (median, IQR)	6, 3-8	12, 1-19
Total sleep time, minutes (median, IQR)	436, 394-451	396, 377-421
Sleep stages		
Awake, % (median, IQR)	4, 4-7	5, 2-6
N 1, % (median, IQR)	4, 3-8	4, 3-6
N 2, % (median, IQR)	39, 34-46	45, 39-45
N 3, % (median, IQR)	27, 25-31	26, 23-28
REM, % (median, IQR)	21, 19-23	20, 17-23
REM latency, min (median, IQR)	94, 90-98	108, 48-114
Arousal index, n/h (median, IQR)	4.7, 3.1-6.4	4.5, 3.2-6
Number of awakenings (median, IQR)	9, 6-15	10, 6-17
Total legs movements (median, IQR)	45, 10-380	10, 0-72
Apnea-Hypopnea Index (AHI, n/h) (median, IQR)	0.7, 0.3-4.2	0.5, 0.3-2.6
Percentage ratio of cycling alternating pattern (CAP rate, %) (median, IQR)	30, 18-33	11, 7-15

**Figure 1. Distribution of the number of sleep onsets at the 4 x 40-minute MWT among cases (n=9) and controls (n=7).**



**Figure 2. Distribution of sleep onset times<sup>1</sup> on the 4 x 40-minute MWT trials among cases (n=9) and controls (n=7).**



<sup>1</sup>The grey bars indicate the lower and upper quartiles, the black continuous lines below the bars indicate the minimum values. P-values of Wilcoxon's Rank Sums test were 0.0134 at trial 1, 0.9254 at trial 2, 0.1343 at trial 3, and 0.8468 at trial 4.

### **3.4 Manuscript 4**

**Is there an association between hospital unit characteristics and proxies of work-related stress and the risk of occupational injuries and adverse events? An ecologic study in an Italian teaching hospital**

**IS THERE AN ASSOCIATION BETWEEN HOSPITAL UNIT CHARACTERISTICS AND PROXIES OF WORK-RELATED STRESS AND THE RISK OF OCCUPATIONAL INJURIES AND ADVERSE EVENTS? AN ECOLOGIC STUDY IN AN ITALIAN TEACHING HOSPITAL**

**Francesca Valent<sup>1,2,3</sup>, Giulia Liva<sup>2</sup>, Fabrizio Bellomo<sup>4</sup>, Daniela De Corti<sup>4</sup>, Stefania Degan<sup>4</sup>, Giovanni Cattani<sup>4</sup>, Ilaria Rosa<sup>5</sup>, Agnese Mizza<sup>6</sup>, Silvio Brusaferrò<sup>3,4</sup>.**

<sup>1</sup>Epidemiologic Service, Regional Health Directorate, Friuli Venezia Giulia Region, Udine, Italy

<sup>2</sup>Unit of Hygiene and Clinical Epidemiology, University Hospital of Udine, Udine, Italy

<sup>3</sup>Department of Medical and Biological Sciences, University of Udine, Udine, Italy

<sup>4</sup>Accreditation, Clinical Risk Management and performance assessment Unit, University Hospital of Udine, Udine, Italy

<sup>5</sup>Occupational Health Unit, University Hospital of Udine, Udine, Italy

<sup>6</sup>Human Resources and Administration Unit, University Hospital of Udine, Udine, Italy

**Corresponding author:** Francesca Valent - Servizio Epidemiologico - Direzione centrale salute, integrazione socio-sanitaria, politiche sociali e famiglia – Regione Autonoma Friuli Venezia Giulia – Via Pozzuolo 330, 33100 Udine, Italy – Telephone: +39 0432 805616 – email:

[francesca.valent@regione.fvg.it](mailto:francesca.valent@regione.fvg.it)

## **ABSTRACT**

**Objectives:** We explored the association of workplace characteristics and proxy measures of work-related stress with occupational injuries and adverse events in an Italian teaching hospital.

**Methods:** This ecologic study was conducted using data routinely collected in the University Hospital of Udine, Northeastern Italy. Poisson regressions models were used to investigate, at the hospital unit level, the association between five outcomes, including occupational injuries, patient falls, medication errors, and other adverse events and near-misses, and various characteristics of the units.

**Results:** The proportion of female workers in a unit, the average number of sick-leave days and of overtime hours, the number of medical examinations requested by employees, and being a surgical unit were significantly associated with some of the outcomes.

**Conclusions:** Despite the ecologic nature of the study, which does not allow for inferences to be drawn at the individual level, our results provide useful clues for approaching work-related stress and adverse events in the hospital.

## **INTRODUCTION**

Workplace characteristics are known to influence the level of stress and the health and safety of workers, and in turn work performance.<sup>1</sup> Work-related stress has financial implications on the organizations, because of poorer productivity, absenteeism, and worker turnover, and ultimately on the society.<sup>1</sup> Despite awareness of these issues among managers, dealing with work-related stress is perceived as a difficult task.<sup>1</sup> Even assessing and quantifying the level of work-related stress is challenging. Routinely collected data such as work days lost due to sickness have been often used to describe the extent of the problem,<sup>2</sup> although these data may be imprecise and not necessarily good proxies for work-related stress. On the other hand, self-reported measures of stress intuitively seem more representative of the phenomenon; however, their validity may also be questioned.<sup>2</sup>

Given this premise, we decided to explore whether measures of work-related/organizational stress and workplace characteristics are associated with the occurrence of occupational injuries and adverse events in an Italian teaching hospital, using inexpensive and readily available routinely collected data as proxies for stress.

## **METHODS**

This was an ecologic study and it was conducted at the University Hospital of Udine, Northeastern Italy, a tertiary referral center employing approximately 3800 people. For each hospital unit, data on the outcomes of interest that occurred in 2012 and 2013 were provided by the Clinical Risk Unit: the number of occupational injuries (including commuting accidents) and incidents involving biological hazards reported by the employees (outcome 1); the number of patient falls (outcome 2); the number of medication errors (outcome 3); the number of other adverse events or near-misses, either reported by people working in the unit where the event occurred (outcome 4) or reported by people working in other units (outcome 5) through the hospital incident reporting system. The incident reporting system was implemented in the University Hospital of Udine in 2008. The hospital workers who are involved in or aware of adverse events, patient falls,

or medication errors, either in their own unit or in other units, are encouraged to spontaneously report them through ad hoc forms that must be returned to the Clinical Risk Unit for an in-depth evaluation, follow-up, and eventual actions.<sup>3</sup> To encourage the employees to report any error or near-miss they notice in their own or in other hospital wards, the reporting system does not collect information on the persons responsible for the errors/near-misses, preventing individual-level analyses of adverse events.

Information on hospital unit characteristics potentially associated with the outcomes of interest were provided by the Occupational Health Office, which abstracted data on the number of medical visits requested directly by the employees earlier than the scheduled date for the periodic worker health examination, and by the Human Resources and Administration Office, which abstracted data on the number of employees, stratified by sex, on the overall number of sick-leave days, on the overall number of overtime hours, on the number of newly hired workers and on the number of those who quit for each unit in the years 2012 and 2013. Information on paid vacation days were also provided, but there was too little variability in this item. In fact, all the hospital workers are requested to complete within each year all the paid vacation days allowed for that year, otherwise there is a reduction in the target achievement bonus for the whole unit where they are employed.

### **Statistical analysis**

For each outcome variable measured at the hospital unit level, we calculated mean, standard deviation, quartiles, minimum and maximum values. We calculated Pearson's correlation coefficients to assess whether the occurrence of each outcome is associated with the others. P-values  $<0.05$  were considered statistically significant.

On the whole population of hospital units, clustered within departments, we built a multilevel Poisson regression model to assess the association of the number of injuries and incidents involving biological hazards in the unit (dependent variable) with the following explanatory variables: number of employees, proportion of female workers, average annual number

of sick-leave days, average annual number of overtime hours, average annual number of visit requests per employee and ratio of new hires and workers who quit (>1: increase in staff size; 1: no change in staff size despite hires and work terminations; <1: decrease in staff size; or no personnel changes). The logarithm of the number of employees in a unit was used as the offset variable in the Poisson regression. An exchangeable working correlation structure was specified in the model. Three dummy variables were also included in the model as explanatory variables to adjust for the potential confounding effect of the type of hospital unit (administrative, services, medical, or surgical unit) on the association between the outcome and the hospital unit characteristics.

To account for the fact that adverse events involving patients could only occur in some hospital units and not in others, we built five (one for each outcome) multilevel Poisson regression models restricted to the units whose activities are actually based on patients (thus excluding all administrative units and services not open to patients), plus an additional model having the sum of all 5 outcomes as the dependent variable (outcome 6).

Relative risks (RR) associated with each explanatory variable, adjusted for the potential confounding effect of all the others, were obtained by exponentiating the Poisson regression coefficients. The precision of the estimates was expressed through the 95% confidence intervals (95%CI).

All the statistical analyses were performed with SAS Enterprise Guide v 4.3 (SAS Institute Inc., Cary, NC, USA).

Ethical approval was obtained from the Ethics Committee of Udine, Italy.

## **RESULTS**

In 2012 and 2013, respectively 3815 and 3820 workers were employed in the University Hospital of Udine. Overall, they totalled 41205 sick-leave days, 34109.63 overtime hours, and 53 medical visit requests in 2012 and 43363 sick-leave days, 21137.22 overtime hours, and 70 medical

visit requests in 2013. The total number of events and the distribution of each are reported in Table 1.

The number of outcomes in each unit was significantly correlated with the number of people employed:  $\rho=0.83$ ,  $p\text{-value}<0.0001$  for injuries and incidents involving biological hazards;  $\rho=0.18$ ,  $p\text{-value}=0.0064$  for patient falls;  $\rho=0.28$ ,  $p\text{-value}<0.0001$  for medication errors;  $\rho=0.68$ ,  $p\text{-value}<0.0001$  other adverse events and near-misses reported by workers of the unit where the events occurred and  $\rho=0.69$ ,  $p\text{-value}<0.0001$  for those reported by workers of other units. The different outcomes were also significantly correlated with each other, as shown in Table 2.

The associations of each outcome of interest with the explanatory variables are shown in Table 3. The risk of occupational injuries and incidents involving biological hazards resulted significantly decreased in 2013, both in the analysis including all the hospital units and in the analysis restricted to units open to patients. Non-significant decreases in patient falls, in medication errors, and in the sum of all events were also observed. On the other hand, the risk of adverse events and near-misses reported by workers of other units increased in 2013. In the analyses restricted to units open to patients, the increase in the proportion of female employees was associated with significant or borderline significant reductions in the risk of all outcomes except patient falls and medication errors. The average annual number of sick-leave days was associated with a decrease in the risk of occupational injuries and incidents involving biological hazards when all the hospital units were included in the analysis, however, when considering only units open to patients, it was no longer associated with any outcome. On the other hand, the average annual number of overtime hours in a unit was associated with a decrease in the risk of medication errors in units open to patients. Visit requests were strongly associated with the risk of occupational injuries in the analysis including all hospital units and with the risk of patient falls and of other adverse events and near-misses reported by workers of the unit, in units open to patients. Compared to services, surgical and medical units have an increased risk of occupational injuries, whereas the administrative units did not result significantly different. In the analyses restricted to units open to patients, surgical units

had increased risk of occupational injuries and incidents involving biological hazards as compared with the others, whereas the risk of all the other events was not significantly different from that in the other units. Compared to units where no personnel changes took place in the year, no significant differences in the risk of injuries and adverse events were noticed in units where new personnel were hired and/or workers stopped working, except a significant increase in adverse events and near-misses reported by workers of other units.

In 2013, the risk of injuries in the analysis including all units and the risk of the sum of all outcomes in clinical units were significantly reduced as compared with the year before; however, the change in the risk of patient falls and medication errors, although strong, was not statistically significant.

## **DISCUSSION**

This analysis identified some macroscopic characteristics of the units associated with an increased risk of occupational injuries and adverse events in an Italian teaching hospital. In particular, clinical units had an increased risk of occupational injuries and incidents involving biological hazards than services and administrative units. This is not surprising, given the higher number of mechanical actions performed by employees working with patients, which determines a greater opportunity to be injured. In particular, among units open to patients, surgical wards had a higher risk than the others. In addition, surgical units had an increased risk of medication errors as compared with non-surgical ones. A recent systematic review of medication administration errors in hospitals showed that slips and lapses are common unsafe acts, but a variety of factors regarding the local workplace, such as inadequate communication, medicine storage, perceived workload, staff health status, and patient factors, were also commonly reported.<sup>4</sup> Given the level of information available, we cannot identify specific factors favouring medication errors in the surgical wards in our organization. However, our research indicates that structured approaches to the issue of

medication errors in the University Hospital of Udine should give particular attention to surgical patients.

Recent research demonstrated a higher risk of occupational injuries for females working in the healthcare sector than for males.<sup>5</sup> Our findings do not allow to assess the likelihood of being injured for women as compared to men, because we did not assess which workers were actually injured, but only how many were, given the ecologic nature of the research. The finding that the proportion of female employees in a clinical unit resulted associated with a reduced frequency of occupational injuries and biological risk incidents does not mean that women were less likely to be injured than men and deserve less attention in occupational safety initiatives. Rather, it indicates that units with larger female components have a decreased frequency of injuries overall. The female working component may affect the workplace psychological climate, the way of carrying out activities, the prevailing safety culture of a unit, ultimately having an influence on the occurrence of injuries among the whole personnel.

The balance between new hires and work terminations did not affect significantly the risk of most of the outcomes of interest, indicating that the hospital units are rather robust to variations in staff size. A Canadian study showed that younger age and shorter tenure did not increase the overall risk of occupational injuries in the healthcare sector; the young and newly hired resulted to have increased risk of cuts and punctures but a lower risk of musculoskeletal injuries.<sup>6</sup> In our context, however, units interested by personnel changes had increased risks of adverse events reported by workers of other units, even in case of an increase in staff size. Errors such as procedural irregularities, patient identification, incomplete documentation etc. are the most evident to workers of other units when patients, materials or documents are exchanged between units. It is possible that the newly hired workers either commit errors if they are not sufficiently familiar with the procedures or perturbate the pre-existing equilibrium inducing other workers to err. Thus, it is crucial that enough training is provided to the newly hired and that, despite the urgency to have the new workers operative, they have time to practice.

The average number of sick-leave days was inversely associated with injuries and incidents in the analysis including all the hospital units. During sick-leave, workers have no opportunity to suffer occupational injuries, therefore, the more the sick-leave days, the less likely are workers to experience the risk of an injury. However, on average workers missed 11 working days due to sick-leave (approximately 5% of the annual worktime) and it is unlikely that this affected significantly the risk. On the contrary, assuming that the likelihood of being sick in a year is similar across hospital units, it is possible that units where the personnel totalled fewer sick-leave days are those with greater pressure, where the phenomenon of presenteeism, i.e., sick employees being present at work, might exist.<sup>7</sup> This phenomenon, which was significantly associated with different components of psychosocial stress,<sup>8</sup> was also associated with decreased productivity and ineffective presence on the workplace.<sup>7</sup>

The European Working Time Directive requires a maximum working week of 48 hours and establishes rest periods.<sup>9</sup> A recent systematic review showed that long working hours (>48 hours/week) could increase the risk of percutaneous injuries and road traffic accidents among physicians, but could neither assess a dose-response relation nor determine a threshold of extra hours.<sup>10</sup> In our study, increasing overtime hours were inversely associated with the risk of medication errors and adverse events/near-misses reported by workers of other units. Keeping in mind that, on average, each worker totalled less than 10 overtime hours per year, which very unlikely impacted on the workers' levels of fatigue, we can hypothesize that a little extra-work was needed to perform some tasks with adequate attention and accuracy. In particular, medical prescription and therapy administration, and time-consuming but important "bureaucratic" tasks (such as form filling and documentation completion, where errors can be also detected by workers of other units) seem to benefit the most from such extra-work.

Despite the imprecision of the estimates, the number of medical visits requested by the workers earlier than the scheduled date resulted strongly associated with an increased risk of injuries and biological risk incidents in the analysis involving all the hospital units, and of falls and

adverse events/near-misses in the analysis restricted to units open to patients. The request of visits can represent a proxy for work-related stress. Requests of anticipated medical examinations are rare, however, when they happen, we consider it sensible to obtain more information on the working environment in the units concerned.

The appearing decreasing trend in the risk of adverse outcomes from 2012 to 2013 seems to indicate that the measures that were already in place in the University Hospital of Udine were effective in controlling the phenomenon. However, the decrease in patient falls and medication errors was not statistically significant and we cannot exclude that this result is due to chance alone. Continuing to monitor the temporal trend of each type of outcome will be important to assess the effectiveness of preventive initiatives.

The interpretation of the results regarding patient falls deserves particular caution. In fact, risk factors for falls among hospitalized patients can be both intrinsic (i.e., personal factors, such as balance, medications, cognitive impairment, incontinence, blood pressure, nutritional status, etc.) and extrinsic (i.e., depending on the hospital environment). Most intrinsic factors emerge consistently in the literature,<sup>11</sup> whereas the role of extrinsic factors, especially of non-physical ones, is less clear.<sup>12</sup> The results of our study, which investigated hospital unit characteristics but lacks any information on the characteristics of the patients, are likely to be confounded by unmeasured patient-related factors. Nonetheless, the number of patient falls was moderately correlated with the number of all the other adverse events, indicating that, to some extent, falls may be influenced by the same workplace characteristics that affect the other outcomes.

Another possible limitation of this study is that the number of events resulting from incident reporting is affected by the inclination of professionals to report hazardous situations and by the safety culture in the units. However, the fact that the number of events reported in the University Hospital of Udine is quite stable in time and very high as compared with other Italian systems<sup>13</sup> make us confident that the incident reporting system is valid source of information.

Finally, results of this research must also be interpreted in the light of the ecologic nature of the study. This means that we cannot assume that any of the associations between outcomes and work-related factors holds for individuals. For example, despite the fact that injuries were less likely in units with greater sick-leave days, it could be that, within the units, workers with more sick-leave days were those who actually suffered the injuries. However, aggregate data were easy to obtain and provided valuable information for approaching the issue of injuries, adverse events, and work-related factors. Ad-hoc data collection among hospital employees and individual analysis are warranted for a better knowledge of the problem and implementation of targeted preventive actions.

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**Table 1. Distribution of occupational injuries and incidents involving biological hazards, patient falls, medication errors, other errors and near-misses reported by workers of the unit, and by workers of other units in the University Hospital of Udine, Northeastern Italy, years 2012 and 2013.**

Outcome	Total events	Mean per unit	Standard Deviation	Lower quartile	Median	Upper quartile	Minimum	Maximum
Year 2012 (109 units)								
Occupational injuries and incidents involving biological hazards	365	3.3	6.5	0	1	4	0	52
Patient falls	357	3.3	7.7	0	0	2	0	54
Medication errors	188	1.7	4.0	0	0	1	0	26
Other errors/near-misses, reported by workers of the unit	337	3.1	5.5	0	1	4	0	42
Other errors/near-misses, reported by workers of other units	234	2.1	5.3	0	0	3	0	47
Year 2013 (106 units)								
Occupational injuries and incidents involving biological hazards	308	2.9	7.0	0	1	4	0	62
Patient falls	391	3.7	8.3	0	0	3	0	54
Medication errors	172	1.6	4.1	0	0	1	0	21
Other errors/near-misses, reported by workers of the unit	235	2.2	3.9	0	0	4	0	30
Other errors/near-misses, reported by workers of other units	323	3.0	6.7	0	0	4	0	42

**Table 2. Correlations among occupational injuries and incidents involving biological hazards, patient falls, medication errors, other errors and near-misses reported by workers of the unit, and by workers of other units in the University Hospital of Udine, Northeastern Italy, years 2012 and 2013.**

	Occupational injuries and incidents involving biological hazards	Patient falls	Medication errors	Other errors and near-misses reported by workers of the unit	Other errors and near-misses reported by workers of other units
Occupational injuries and incidents involving biological hazards	$\rho=1$	$\rho=0.25$ p-value=0.0002	$\rho=0.35$ p-value<0.0001	$\rho=0.70$ p-value<0.0001	$\rho=0.77$ p-value <0.0001
Patient falls		$\rho=1$	$\rho=0.36$ p-value <0.0001	$\rho=0.17$ p-value =0.0139	$\rho=0.21$ p-value =0.0017
Medication errors			$\rho=1$	$\rho=0.37$ p-value <0.0001	$\rho=0.28$ p-value <0.0001
Other errors and near-misses reported by workers of the unit				$\rho=1$	$\rho=0.60$ p-value <0.0001
Other errors and near-misses reported by workers of other units					$\rho=1$

**Table 3. Poisson regression analysis of injuries and adverse events/near-misses in the University Hospital of Udine, Northeastern Italy, and characteristics of the hospital units, years 2012-2013.**

	<b>Relative Risk</b>	<b>95% CI</b>	<b>P-value</b>
<b>Outcome 1: Occupational injuries and incidents involving biological hazards – All hospital units</b>			
Year (2013 vs 2012)	0.88	0.76-1.02	0.0906
Female % in unit (continuous)	1.00	0.99-1.02	0.6021
Average annual sick-leave days per worker in unit (continuous)	0.98	0.96-1.00	0.0165
Average annual overtime hours per worker in unit (continuous)	1.01	0.99-1.03	0.4344
Average annual visit requests per worker in unit (continuous)	49.78	2.72-1040.70	0.0126
New hirings > employment stoppings (vs no hirings, no stoppings)	1.15	0.54-2.45	0.7202
New hirings < employment stoppings (vs no hirings, no stoppings)	1.46	0.74-2.89	0.2771
New hirings = employment stoppings (vs no hirings, no stoppings)	1.34	0.49-3.69	0.5673
Medical unit (vs Services)	1.95	1.40-2.85	0.0001
Surgical unit (vs Services)	2.64	1.83-4.02	<0.0001
Administrative unit (vs Services)	1.21	0.53-3.32	0.5534
<b>Outcome 1: Occupational injuries and incidents involving biological hazards – Only Units open to patients</b>			
Year (2013 vs 2012)	0.80	0.69-0.92	0.0021
Female % in unit (continuous)	0.99	0.98-0.99	<0.0001
Average annual sick-leave days per worker in unit (continuous)	0.99	0.97-1.01	0.4626
Average annual overtime hours per worker in unit (continuous)	1.01	0.99-1.03	0.3558
Average annual visit requests per worker in unit (continuous)	1.26	0.12-13.07	0.8445
New hirings > employment stoppings (vs no hirings, no stoppings)	0.87	0.49-1.57	0.6509
New hirings < employment stoppings (vs no hirings, no stoppings)	0.83	0.50-1.38	0.4624
New hirings = employment stoppings (vs no hirings, no stoppings)	0.81	0.39-1.69	0.5825
Surgical unit (vs Non-surgical)	1.51	1.00-2.29	0.0519
<b>Outcome 2: Patient falls – Only</b>			

<b>units open to patients</b>			
Year (2013 vs 2012)	0.77	0.53-1.12	0.6596
Female % in unit (continuous)	1.00	0.99-1.02	0.6460
Average annual sick-leave days per worker in unit (continuous)	1.02	0.99-1.05	0.2988
Average annual overtime hours per worker in unit (continuous)	0.97	0.93-1.00	0.1151
Average annual visit requests per worker in unit (continuous)	593.83	20.68-17049.63	0.0002
New hirings > employment stoppings (vs no hirings, no stoppings)	1.32	0.73-2.42	0.3598
New hirings < employment stoppings (vs no hirings, no stoppings)	0.48	0.21-1.07	0.0734
New hirings = employment stoppings (vs no hirings, no stoppings)	0.54	0.19-1.52	0.2442
Surgical Unit (vs Non-surgical)	0.66	0.35-1.23	0.1862
<b>Outcome 3: Medication errors – Only units open to patients</b>			
Year (2013 vs 2012)	0.55	0.26-1.18	0.1231
Female % in unit (continuous)	0.99	0.98-1.01	0.4225
Average annual sick-leave days per worker in unit (continuous)	0.98	0.97-0.99	0.6674
Average annual overtime hours per worker in unit (continuous)	0.92	0.86-0.98	0.0072
Average annual visit requests per worker in unit (continuous)	0.03	0.00-10.44	0.2386
New hirings > employment stoppings (vs no hirings, no stoppings)	1.28	0.41-3.98	0.6701
New hirings < employment stoppings (vs no hirings, no stoppings)	0.49	0.19-1.27	0.1416
New hirings = employment stoppings (vs no hirings, no stoppings)	0.41	0.15-1.12	0.0828
Surgical Unit (vs Non-surgical)	1.90	0.91-3.97	0.0860
<b>Outcome 4: Other adverse events and near-misses reported by workers of the unit – Only units open to patients</b>			
Year (2013 vs 2012)	0.66	0.48-0.91	0.0119
Female % in unit (continuous)	0.99	0.97-1.01	0.1989
Average annual sick-leave days per worker in unit (continuous)	1.01	0.94-1.08	0.8449
Average annual overtime hours per worker in unit (continuous)	0.98	0.95-1.02	0.3698
Average annual visit requests per worker in unit (continuous)	41.32	7.37-231.53	<0.0001
New hirings > employment stoppings (vs no hirings, no stoppings)	0.93	0.38-2.30	0.8789
New hirings < employment stoppings	1.13	0.57-2.25	0.7167

(vs no hirings, no stoppings)			
New hirings = employment stoppings (vs no hirings, no stoppings)	1.04	0.50-2.19	0.9077
Surgical Unit (vs Non-surgical)	0.86	0.57-1.29	0.4620
<b>Outcome 5: Other adverse events and near-misses reported by workers of other units – Only units open to patients</b>			
Year (2013 vs 2012)	1.44	0.97-2.14	0.0695
Female % in unit (continuous)	0.97	0.96-0.98	<0.0001
Average annual sick-leave days per worker in unit (continuous)	1.02	0.96-1.08	0.5085
Average annual overtime hours per worker in unit (continuous)	0.97	0.94-1.00	0.0656
Average annual visit requests per worker in unit (continuous)	7.08	0.27-186.08	0.2457
New hirings > employment stoppings (vs no hirings, no stoppings)	1.71	1.03-2.83	0.0379
New hirings < employment stoppings (vs no hirings, no stoppings)	2.20	1.09-4.46	0.0280
New hirings = employment stoppings (vs no hirings, no stoppings)	1.84	1.00-3.35	0.0481
Surgical Unit (vs Non-surgical)	0.88	0.54-1.44	0.6045
<b>Outcome 6: Sum of all outcomes 1- 5 – Only units open to patients</b>			
Year (2013 vs 2012)	0.81	0.69-0.96	0.0125
Female % in unit (continuous)	0.98	0.97-1.00	0.0047
Average annual sick-leave days per worker in unit (continuous)	1.01	0.99-1.03	0.3717
Average annual overtime hours per worker in unit (continuous)	0.98	0.96-1.00	0.0398
Average annual visit requests per worker in unit (continuous)	24.71	3.88-157.20	0.0007
New hirings > employment stoppings (vs no hirings, no stoppings)	1.38	0.67-2.85	0.3849
New hirings < employment stoppings (vs no hirings, no stoppings)	0.98	0.55-1.77	0.9553
New hirings = employment stoppings (vs no hirings, no stoppings)	0.92	0.41-2.05	0.8420
Surgical Unit (vs Non-surgical)	0.98	0.41-2.05	0.8832

## CHAPTER 4: CONCLUSIONS

In conclusion, this project, through its different components, increased the knowledge about the effect of sleep-related exposures, fatigue, transient exposures on the workplace, and work-related stress on the risk of occupational injuries among the healthcare workers and of adverse events on patients in the setting of an Italian academic hospital.

Through the case-crossover study, we identified occupational transient exposures associated with increased risk of injury: fatigue, rush, distraction, emergency situations, teaching to or being taught by someone, non-compliant patients, bloody operative/work field, excess noise, complex procedures, and anger. Through the case-control design, the number of reported sleep disturbances was positively related with the outcome, whereas no association was found between usual sleep hours and injuries. Chronotype, assessed through the Horne-Ostberg questionnaire, was not significantly associated with injury, although we noticed a decreasing trend from earlier to later chronotypes. The ability to maintain wakefulness appeared reduced among workers who reported injuries. The ecologic study showed that the proportion of female workers in a Hospital Unit, the average number of sick-leave days and of overtime hours, the number of medical examinations requested by the employees, and being a surgical Unit were significantly associated with the number of adverse events and near-miss reported in that Unit.

This study allowed the identification of a number of individual and environmental stress-related factors associated with increased risk of injuries and adverse events, providing useful information for planning preventive interventions and for improving safety in the hospital setting.

## **ANNEX A: INFORMATION LETTER**

**Informativa e autorizzazione preventiva al contatto da inserire in busta paga.**

**Progetto di ricerca “Privazione di sonno, disturbi del sonno, stanchezza, stress e rischio di infortuni occupazionali ed errori tra i lavoratori della Sanità: uno studio epidemiologico multi-approccio.”**

Gentilissimo/a,

la dott.ssa Francesca Valent, SOC di Igiene ed Epidemiologia Clinica, in collaborazione con la Gestione del Rischio Clinico e Valutazione delle Performance Sanitarie, la Clinica Neurologica e di Neuroriabilitazione e il Servizio di Tutela della Salute e Sicurezza dei Lavoratori dell’Azienda Ospedaliero Universitaria di Udine (AOUD), sta per iniziare una ricerca che ha lo scopo di valutare se la stanchezza, lo stress di varia natura e la scarsa qualità o quantità del sonno possono rappresentare un rischio di infortunio per i lavoratori di questa Azienda. Si tratta di uno studio *osservazionale*, cioè uno studio in cui ai partecipanti sarà chiesto solamente di fornire delle informazioni, mentre **non** verranno somministrati farmaci o sostanze né verranno messe in atto procedure invasive o potenzialmente dannose.

Lo studio è finanziato in parte dal Ministero della Salute con il Bando Giovani Ricercatori 2009 e in parte dalla Regione Autonoma Friuli Venezia Giulia.

Saranno invitati a partecipare tutti i dipendenti che, nei prossimi mesi, subiranno un infortunio (e parteciperanno in qualità di “caso”) ed un campione di lavoratori non infortunati estratti casualmente tra tutti i dipendenti dell’AOUD (che parteciperanno in qualità di “controllo”). Lo studio prevede la raccolta di alcuni dati anagrafici, dati relativi al lavoro e dati sulle abitudini di vita, mediante un questionario cartaceo, con intervista di circa 20 minuti, da fare o telefonicamente o di persona.

I soggetti con infortuni più gravi (con assenza dal lavoro di almeno 3 giorni) ed un gruppetto di controlli non infortunati saranno inoltre contattati dalla Clinica Neurologica e di Neuroriabilitazione che proporrà, gratuitamente, alcuni esami strumentali assolutamente non invasivi e senza rischi per la salute, per valutare la qualità del sonno (mediante una registrazione che si potrà fare a casa ed una presso la Clinica Neurologica) e le capacità di mantenere la veglia (presso la Clinica Neurologica). Agli stessi soggetti verrà anche chiesto di fornire dei campioni di saliva, che si possono raccogliere a casa, per misurare le concentrazioni di melatonina e cortisolo, due ormoni collegati al ciclo sonno-veglia.

Aderendo a questo studio, i partecipanti avranno la possibilità di far valutare da personale specializzato le caratteristiche del proprio sonno e di ricevere preziosi consigli qualora ce ne sia bisogno. Favoriranno, inoltre, lo sviluppo delle conoscenze sui fattori di rischio di infortuni occupazionali e di errori sul lavoro, aiutandoci a tutelare la sicurezza dei lavoratori e dei pazienti.

### **Dati sensibili e rispetto della privacy**

Ai sensi del D.lgs n. 196/2003 (Codice in materia di protezione dei dati personali), vengono di seguito comunicate le informazioni relative al trattamento dei dati forniti.

- Finalità del trattamento: Lo studio osservazionale qui descritto è un’indagine epidemiologica coordinata dalla SOC di Igiene ed Epidemiologia Clinica dell’AOUD e finanziata in parte dal Ministero della Salute e in parte dalla Regione Autonoma Friuli Venezia Giulia. La partecipazione allo studio è facoltativa. I dati da Lei eventualmente forniti verranno trattati nella misura in cui sono indispensabili in relazione all’obiettivo dello studio.
- Titolare del trattamento: Il titolare del trattamento è l’Azienda Ospedaliero Universitaria di Udine (AOUD) con sede in P.le Santa Maria della Misericordia a Udine. I dati saranno raccolti in parte dalla SOC di Igiene ed Epidemiologia Clinica e in parte dalla Clinica Neurologica e di Neuroriabilitazione dell’AOUD. L’elaborazione dei dati per finalità di analisi statistica ed epidemiologica verrà effettuata presso la SOC di Igiene ed Epidemiologia Clinica dell’AOUD.
- Modalità del trattamento: Il trattamento sarà effettuato attraverso modalità cartacee ed informatizzate ai sensi del Codice in materia di protezione dei dati personali. L’analisi statistico-epidemiologica verrà effettuata previa anonimizzazione dei dati anagrafici individuali. I risultati saranno diffusi solo in forma

rigorosamente anonima ed aggregata, ad esempio sotto forma di pubblicazioni scientifiche e presentazioni a convegni.

- **Esercizio dei diritti:** Potrà esercitare i diritti di cui all'art. 7 del Codice in materia di protezione dei dati personali (es. accedere ai Suoi dato personali, integrarli, aggiornarli, rettificarli, opporsi al loro trattamento per motivi legittimi ecc.) rivolgendosi direttamente al Titolare come sopra indicato.
- **Partecipazione volontaria:** La Sua decisione di partecipare a questo studio deve essere completamente libera e volontaria. Un Suo rifiuto non comporterà penalità o perdite di benefici, pertanto Lei potrà decidere di ritirarsi dallo studio in qualsiasi momento. In tal caso, i dati da Lei forniti verranno distrutti. Non saranno inoltre raccolti ulteriori dati che La riguardano, fermo restando l'utilizzo di quelli eventualmente già raccolti per determinare, senza alterarli, i risultati della ricerca. Se acconsente a partecipare alla ricerca, Le verrà chiesto di fornire il Consenso al trattamento dei dati personali. Nel caso Lei rientri nel sottogruppo di persone a cui verrà chiesto di sottoporsi ad indagini più approfondite, Le verrà chiesto di firmare un modulo di Consenso agli approfondimenti neurologici prima di tali indagini. Se lo ritiene opportuno, non esiti a contattare in qualsiasi momento la Dott.ssa Valent al seguente indirizzo email: [valent.francesca@aoud.sanita.fvg.it](mailto:valent.francesca@aoud.sanita.fvg.it)

Gentilmente, indichi qui sotto la sua eventuale disponibilità ad essere contattato per la ricerca (nel caso subisse un infortunio o venisse estratto casualmente come controllo non infortunato), tagli dove indicato e restituisca **in ogni caso** per posta interna all'attenzione di:  
Francesca Valent – SOC Igiene ed Epidemiologia Clinica

Grazie per l'attenzione a nome di tutto il team di ricerca.

Il Principal Investigator  
Dott.ssa Francesca Valent

Il Direttore Sanitario  
Dott. Fabrizio Fontana

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Nel caso subisse un infortunio o avesse un incidente a rischio biologico o nel caso il suo nominativo venisse estratto casualmente dall'elenco dei dipendenti dell'AOUUD come controllo, acconsentirebbe ad essere contattato dai ricercatori per partecipare allo studio?

**Acconsento ad essere contattato per lo studio "Privazione di sonno, disturbi del sonno, stanchezza, stress e rischio di infortuni occupazionali ed errori tra i lavoratori della Sanità: uno studio epidemiologico multi-approccio."**                      **SI'**                       **NO**

Se sì, a quale recapito telefonico preferirebbe essere contattato ed in quali orari (l'intervista non porterà via più di 20 minuti)?

**Tel.** \_\_\_\_\_

**Giorni e fasce orarie** \_\_\_\_\_

**Data:** \_\_\_\_\_

**Nome e cognome del dipendente (in stampatello):** \_\_\_\_\_

**Struttura (SOC/SOS) di appartenenza:** \_\_\_\_\_

**Firma del dipendente:** \_\_\_\_\_

## **ANNEX B: INFORMED CONSENT FORMS**

### **Foglio informativo, Modulo di consenso al trattamento dei dati personali e di consenso informato**

Identificativo personale |\_|\_|\_|\_|\_|

**Titolo dello studio: Privazione di sonno, disturbi del sonno, stanchezza, stress e rischio di infortuni occupazionali ed errori tra i lavoratori della Sanità: uno studio epidemiologico multi-approccio.**

**Ricercatore: Dott.ssa Francesca Valent**

#### **Descrizione dello studio**

Le viene chiesto di partecipare ad uno studio osservazionale, ossia uno studio in cui le chiederemo solamente di fornirci delle informazioni su di Lei, mentre **non** Le verranno somministrati farmaci o sostanze né sarà sottoposto a procedure invasive o potenzialmente dannose. Perché Lei possa decidere se partecipare o meno, Le spieghiamo i motivi per cui viene condotto questo studio e che cosa comporterà. Legga con attenzione le informazioni riportate e, se ha dei dubbi, non esiti a porre delle domande. Se decide di partecipare, le verrà chiesto di firmare un modulo di consenso informato.

Lo scopo dello studio è di valutare se la stanchezza, lo stress di varia natura e la scarsa qualità o quantità del sonno possono rappresentare un rischio di infortunio per i lavoratori dell'Azienda Ospedaliero Universitaria di Udine (AOUD).

Lo studio è coordinato dalla SOC di Igiene ed Epidemiologia Clinica, con la collaborazione della Gestione del Rischio Clinico e Valutazione delle Performance Sanitarie, della Clinica Neurologica e di Neuroriabilitazione e del Servizio di Tutela della Salute e Sicurezza dei Lavoratori dell'AOUD ed è finanziato in parte dal Ministero della Salute e in parte dalla Regione Autonoma Friuli Venezia Giulia.

Le viene chiesto di partecipare allo studio o perché ha subito un infortunio (e quindi può partecipare in qualità di "caso") o perché è stato estratto casualmente dall'elenco dei dipendenti dell'AOUD come lavoratore non infortunato (e quindi può partecipare in qualità di "controllo"). Lo studio prevede la raccolta di una serie di dati anagrafici, relativi al Suo lavoro e ad alcune Sue abitudini di

vita, mediante un questionario cartaceo. Le verrà fatta un'intervista della durata di circa 20 minuti o telefonicamente o di persona. Se Lei ha subito un infortunio che comporta un'assenza dal lavoro di almeno 3 giorni oppure, nel caso partecipi come "controllo", se è stato selezionato casualmente per accedere ad indagini più approfondite, sarà anche contattato dalla Clinica Neurologica e di Neuroriabilitazione che Le proporrà di essere sottoposto ad alcuni esami strumentali assolutamente non invasivi per valutare la qualità del suo sonno (mediante una registrazione che potrà fare a casa ed una presso la Clinica Neurologica) e le sue capacità di mantenere la veglia (presso la Clinica Neurologica). In tutti questi esami che Le proponiamo, Le verranno applicati su varie parti del corpo degli elettrodi per registrare contemporaneamente l'attività elettroencefalografica, l'elettromiografia, l'elettrocardiografia, il ritmo respiratorio, i movimenti oculari. Inizialmente potrebbe sembrarle fastidioso o strano avere questi elettrodi addosso, ma non le impediranno di muoversi e comportarsi normalmente. Le assicuriamo, inoltre, che gli esami che Le proponiamo non comportano alcun rischio per la Sua salute. Questi esami Le saranno offerti gratuitamente.

Le verrà anche chiesto di fornire dei campioni di saliva, che raccoglierà a casa, per misurare le concentrazioni di melatonina e cortisolo, due ormoni collegati al ciclo sonno-veglia. La raccolta non è particolarmente difficile né invasiva e può farla a casa quando lo desidera. La invitiamo però a seguire attentamente le istruzioni di raccolta per evitare di farla a vuoto. Le verrà consegnato gratuitamente il kit per la raccolta e le istruzioni. Per la riconsegna dei campioni, può mettersi d'accordo con la persona dell'Istituto di Igiene che La chiamerà per intervistarLa. Tali campioni verranno utilizzati esclusivamente per gli scopi della ricerca e distrutti immediatamente dopo l'elaborazione dei dati.

Aderendo a questo studio, Lei avrà la possibilità di far valutare da personale specializzato le caratteristiche del Suo sonno e di ricevere preziosi consigli qualora ce ne sia bisogno. Favorirà, inoltre, lo sviluppo delle conoscenze sui fattori di rischio di infortuni occupazionali e di errori sul lavoro, utili per tutelare la sicurezza dei lavoratori e dei pazienti.

### **Dati sensibili e rispetto della privacy**

Ai sensi del D.lgs n. 196/2003 (Codice in materia di protezione dei dati personali), Le vengono di seguito comunicate le informazioni relative al trattamento dei dati da Lei forniti.

- Finalità del trattamento: Lo studio osservazionale qui descritto è un'indagine epidemiologica coordinata dalla SOC di Igiene ed Epidemiologia Clinica dell'AOUD e finanziata in parte dal Ministero della Salute e in parte dalla Regione Autonoma Friuli Venezia Giulia. La

partecipazione allo studio è facoltativa. I dati da Lei eventualmente forniti verranno trattati nella misura in cui sono indispensabili in relazione all'obiettivo dello studio.

- **Titolare del trattamento:** Il titolare del trattamento è l'Azienda Ospedaliero Universitaria di Udine (AOUD) con sede in P.le Santa Maria della Misericordia a Udine. I dati saranno raccolti in parte dalla SOC di Igiene ed Epidemiologia Clinica e in parte dalla Clinica Neurologica e di Neuroriabilitazione dell'AOUD. L'elaborazione dei dati per finalità di analisi statistica ed epidemiologica verrà effettuata presso la SOC di Igiene ed Epidemiologia Clinica dell'AOUD.
- **Modalità del trattamento:** Il trattamento sarà effettuato attraverso modalità cartacee ed informatizzate ai sensi del Codice in materia di protezione dei dati personali. L'analisi statistico-epidemiologica verrà effettuata previa anonimizzazione dei dati anagrafici individuali. I risultati saranno diffusi solo in forma rigorosamente anonima ed aggregata, ad esempio sotto forma di pubblicazioni scientifiche e presentazioni a convegni.
- **Esercizio dei diritti:** Potrà esercitare i diritti di cui all'art. 7 del Codice in materia di protezione dei dati personali (es. accedere ai Suoi dato personali, integrarli, aggiornarli, rettificarli, opporsi al loro trattamento per motivi legittimi ecc.) rivolgendosi direttamente al Titolare come sopra indicato.
- **Partecipazione volontaria:** La Sua decisione di partecipare a questo studio deve essere completamente libera e volontaria. Un Suo rifiuto non comporterà penalità o perdite di benefici, pertanto Lei potrà decidere di ritirarsi dallo studio in qualsiasi momento. In tal caso, i dati da Lei forniti verranno distrutti. Non saranno inoltre raccolti ulteriori dati che La riguardano, fermo restando l'utilizzo di quelli eventualmente già raccolti per determinare, senza alterarli, i risultati della ricerca. Se acconsente a partecipare alla ricerca, Le verrà chiesto di fornire il Consenso al trattamento dei dati personali. Nel caso Lei rientri nel sottogruppo di persone a cui verrà chiesto di sottoporsi ad indagini più approfondite, Le verrà chiesto di firmare un modulo di Consenso agli approfondimenti neurologici prima di tali indagini. Se lo ritiene opportuno, non esiti a contattare in qualsiasi momento il Dott. \_\_\_\_\_ al numero telefonico \_\_\_\_\_.

**Consenso al trattamento dei dati personali, raccolta del recapito telefonico e partecipazione allo studio. (da sottoscrivere al momento della presentazione dello studio e proposta di partecipazione)**

Ho avuto modo di leggere il foglio informativo del presente studio. Ho avuto l'opportunità di fare domande sullo studio al Dott. \_\_\_\_\_ e ho ricevuto risposte soddisfacenti così come ho ricevuto sufficienti informazioni sullo studio. Sono consapevole che sono libero di ritirarmi dallo studio in ogni momento, senza darne ragione e senza incorrere in problemi.

Permetto ai Ricercatori l'accesso ai miei dati per lo studio e la loro raccolta ed elaborazione in forma anonima. Ho compreso che i dati personali verranno trattati secondo le normative vigenti specificate nel foglio informativo dello studio e che potrà esercitare i suoi diritti, rivolgendosi al Titolare del trattamento in ogni momento e con le modalità specificate ai sensi dell'art. 7, D.Lgs. 30/06/2003, n. 196 (c.d. Codice Privacy).

Acconsento di partecipare a questo studio. SI'  NO

Acconsento a rilasciare il mio recapito telefonico nel caso l'intervista venga effettuata telefonicamente (l'intervista non le porterà via più di 20 minuti)

SI'  NO

Se SI' Tel. \_\_\_\_\_

Giorni e fasce orarie \_\_\_\_\_

Data: \_\_\_\_\_

Nome e cognome del partecipante (in stampatello): \_\_\_\_\_

Firma del partecipante: \_\_\_\_\_

Nome e cognome del Ricercatore che ha ottenuto il consenso a partecipare (in stampatello):

\_\_\_\_\_

Firma del Ricercatore che ha ottenuto il consenso a partecipare: \_\_\_\_\_

**Consenso agli approfondimenti neurologici.**

Ho avuto modo di leggere il foglio informativo del presente studio. Ho avuto l'opportunità di fare domande sugli approfondimenti neurologici a cui sarò sottoposto (polisonnografia, Maintenance of Wakefulness Test, eventuale Multiple Sleep Latency Test) dal

Dott. \_\_\_\_\_ e ho ricevuto risposte soddisfacenti così come ho ricevuto sufficienti informazioni su tali indagini. Sono consapevole che sono libero di ritirarmi dallo studio in ogni momento, senza darne ragione e senza incorrere in problemi. Permetto ai Ricercatori l'accesso ai miei dati per lo studio e la loro raccolta ed elaborazione in forma anonima.

Acconsento di partecipare agli approfondimenti neurologici.      SI'                       NO

Data: \_\_\_\_\_

Nome e cognome del partecipante (in stampatello): \_\_\_\_\_

Firma del partecipante: \_\_\_\_\_

Nome e cognome del Ricercatore che ha ottenuto il consenso a partecipare (in stampatello):

\_\_\_\_\_

Firma del Ricercatore che ha ottenuto il consenso a partecipare: \_\_\_\_\_

## ANNEX C. STUDY QUESTIONNAIRE

### Questionario.

#### Studio epidemiologico sugli infortuni occupazionali in sanità

- **Data intervista** |\_|\_|\_|/|\_|\_|\_|/|\_|\_|\_|\_|\_| gg/mm/aaaa
- **Sesso:**
  1. M
  2. F
- **Età:**
  1. 20-29
  2. 30-39
  3. 40-49
  4. 50-59
  5.  $\geq 60$
- **Titolo di studio acquisito:**
  1. Nessun titolo
  2. Scuola elementare
  3. Scuola media inferiore
  4. Scuola superiore
  5. Laurea
  6. Specializzazioni, Dottorati di ricerca
- **Ruolo:**
  1. Sanitario – Medico
  2. Sanitario – Non medico
  3. Amministrativo
  4. Ausiliario
  5. Altro \_\_\_\_\_
- **Ambito:**
  1. Medico
  2. Chirurgico
  3. Laboratoristico
  4. Amministrativo
  5. Altro \_\_\_\_\_
- **Che tipo di rapporto ha con l’Azienda in cui presta servizio?**
  1. Dipendente a tempo indeterminato
  2. Dipendente a tempo determinato (sostituto, incaricato)
  3. Altro \_\_\_\_\_
- **Che tipo di contratto lavorativo ha:**
  1. Tempo pieno
  2. Part time

- **Il suo orario di lavoro è:**
  1. Continuato (con pause <30 minuti)
  2. Con pausa di almeno 30 minuti
  
- **Qual è il suo orario di lavoro tipico?**
  1. Diurno senza turni
  2. Turni a rotazione che comprendono le notti
  3. Turni a rotazione senza le notti
  4. Notturmo senza turni
  5. Pomeridiano/serale senza turni
  6. Altro \_\_\_\_\_
  
- **Anzianità di servizio:**
  1. meno di 5 anni
  2. 5-10 anni
  3. 11-15 anni
  4. 16-20 anni
  5. più di 20 anni
  
- **Anzianità di servizio nel settore:**
  1. meno di 5 anni
  2. 5-10 anni
  3. 11-15 anni
  4. 16-20 anni
  5. più di 20 anni
  
- **Nell'ambito del Suo lavoro le capita di sollevare carichi?**
  1. sì
  2. no
  
- **Nell'ambito del Suo lavoro manipola sostanze chimiche?**
  1. sì
  2. no
  
- **Nell'ambito del Suo lavoro ha contatto con materiali biologici potenzialmente infetti?**
  1. sì
  2. no
  
- **Con quale mezzo di trasporto si reca al lavoro? (una o più risposte)**
  1. nessuno (vado a piedi)
  2. mezzo pubblico (treno, autobus ecc.)
  3. bicicletta
  4. motoveicolo
  5. autoveicolo
  6. altro \_\_\_\_\_
  
- **Quanti minuti impiega mediamente per recarsi al lavoro? |\_|\_|\_|\_|**
  
- **Che tipo di strada deve percorrere per recarsi al lavoro? (una o più risposte)**
  1. vie urbane
  2. strade extraurbane
  3. autostrada

➤ **Ha mai subito, precedentemente, infortuni o incidenti sul lavoro?**

1. sì
2. no

➤ **Se sì di che tipo? (una o più risposte)**

1. Traumatico
2. A rischio biologico
3. A rischio chimico
4. In itinere

**SEZIONE C - SOLO PER I SOGGETTI ATTUALMENTE INFORTUNATI (“CASI”)**

➤ **Data infortunio** |\_|\_|/|\_|\_|/|\_|\_|\_|\_| gg/mm/aaaa

➤ **Tipo di infortunio**

1. Traumatico senza rischio biologico o chimico
2. *A rischio biologico*
3. A rischio chimico
4. In itinere

➤ **Attività/compito svolto al momento dell’infortunio**

.....  
.....  
.....

➤ **Eventuale strumento che ha causato l’infortunio (se nessuno scrivere “nessuno”)**

.....  
.....

➤ **Descrizione dell’infortunio**

.....  
.....  
.....  
.....

➤ **Orario in cui si è verificato l’infortunio (cerchiare l’orario dell’infortunio):**

1. Mattina, ora: 6 - 7 - 8 - 9 - 10 - 11 - 12 - 13
2. Pomeriggio, ora: 14 - 15 - 16 - 17 - 18 - 19 - 20 - 21
3. Notte, ora: 22 - 23 - 24 - 1 - 2 - 3 - 4 - 5

➤ **Tempo trascorso dall’ inizio del servizio (cerchiare il numero di ore):**

- 1 ora - 2 ore - 3 ore - 4 ore - 5 ore - 6 ore - 7 ore - 8 ore - 9 ore - 10 ore - più di 10 ore -

**SEZIONE C1 - PER TUTTI I CASI**

- **Rispetto al solito, la notte prima dell'infortunio ha dormito:**
  1. Meglio
  2. Peggio
  3. Uguale
  
- **In termini di ore, rispetto al solito, ha dormito:**
  1. Meno ore
  2. Più ore
  3. Uguale
  
- **Che giorno della settimana ha avuto l'infortunio (cerchiare il giorno):**

- lun - mar - mer - gio - ven - sab - dom -
  
- **Per cortesia, specifichi il numero di ore di sonno la notte prima dell'infortunio** |\_\_|\_\_|
  
- **Qual è stato l'ultimo giorno, prima di quello dell'infortunio, in cui ha lavorato?**
  1. Il giorno prima
  2. Due giorni prima
  3. Un giorno ancora precedente
  
- **Che giorno della settimana era (cerchiare il giorno):**

- lun - mar - mer - gio - ven - sab - dom -
  
- **Per cortesia, specifichi il numero di ore di sonno la notte prima di tale giorno di lavoro**  
|\_\_|\_\_|

**SEZIONE C2 - SOLO PER I CASI DI INFORTUNIO NON IN ITINERE**

- **Quante volte nell'ultimo mese (ultimi 30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente? (se al momento dell'infortunio era lavato in sala operatoria indichi il numero dei suoi turni di sala negli ultimi 30 giorni) |\_|\_|\_|\_|\_|**

- **A qualsiasi ora durante il giorno dell'infortunio si è sentito stanco?**

1. sì
2. no

- **Se sì, si sentiva stanco appena prima dell'infortunio?**

1. sì
2. no

- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente sentendosi stanco? |\_|\_|\_|\_|\_|**

- **A qualsiasi ora durante il giorno dell'infortunio ha avuto fretta?**

1. sì
2. no

- **Se sì, aveva fretta appena prima dell'infortunio?**

1. sì
2. no

- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente avendo fretta? |\_|\_|\_|\_|\_|**

- **A qualsiasi ora durante il giorno dell'infortunio ha avuto dei motivi di distrazione?**

1. sì
2. no

- **Se sì, era distratto appena prima dell'infortunio?**

1. sì
2. no

- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente essendo distratto? |\_|\_|\_|\_|\_|**

- **A qualsiasi ora durante il giorno dell'infortunio le è capitato di lavorare in una situazione di emergenza?**

1. sì
2. no

- **Se sì, stava lavorando in una situazione di emergenza appena prima dell'infortunio?**

1. sì
2. no

- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente in situazioni di emergenza? |\_|\_|\_|\_|\_|**
- 

- **A qualsiasi ora durante il giorno dell'infortunio le è capitato di lavorare insegnando il lavoro a qualcuno?**

1. sì
2. no

- **Se sì, stava insegnando il lavoro a qualcuno appena prima dell'infortunio?**

1. sì
2. no

- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente mentre lo insegnava a qualcuno? |\_|\_|\_|\_|\_|**
- 

- **A qualsiasi ora durante il giorno dell'infortunio le è capitato di lavorare con qualcuno che le insegnava il lavoro?**

1. sì
2. no

- **Se sì, le stavano insegnando il lavoro appena prima dell'infortunio?**

1. sì
2. no

- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente con qualcuno che glielo insegnava? |\_|\_|\_|\_|\_|**
- 

- **Il giorno dell'infortunio c'era una momentanea carenza di personale (ferie, malattia ecc.)?**

1. sì
2. no

- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente in carenza di personale? |\_|\_|\_|\_|\_|**

- 
- **Il giorno dell'infortunio le è capitato di lavorare su un paziente non collaborante?**
1. sì
  2. no
  3. non si applica (non lavoro con pazienti)
- **Se sì, stava lavorando su un paziente non collaborante appena prima dell'infortunio?**
1. sì
  2. no
- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente su un paziente non collaborante? (se non si applica, lasci in bianco) |\_|\_|\_|\_|\_|**
- 

- **Il giorno dell'infortunio le è capitato di lavorare in un campo operatorio con molto sangue?**
1. sì
  2. no
  3. non si applica (non lavoro in sala operatoria)
- **Se sì, stava lavorando in un campo operatorio con molto sangue appena prima dell'infortunio?**
1. sì
  2. no
- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente in un campo operatorio con molto sangue? (se non si applica, lasci in bianco) |\_|\_|\_|\_|\_|**
- 

- **Il giorno dell'infortunio le è capitato di lavorare con un eccesso di rumore nell'ambiente?**
1. sì
  2. no
- **Se sì, stava lavorando in eccesso di rumore appena prima dell'infortunio?**
1. sì
  2. no
- **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente in eccesso di rumore nell'ambiente? |\_|\_|\_|\_|\_|**
- 

- **Il giorno dell'infortunio le è capitato di attuare delle procedure particolarmente complesse su pazienti o in laboratorio?**
1. sì
  2. no
  3. non si applica (non lavoro con pazienti né in laboratorio)

➤ **Se sì, stava attuando una procedura particolarmente complessa appena prima dell'infortunio?**

1. sì
2. no

➤ **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente nell'ambito di procedure molto complesse? (se non si applica, lasci in bianco) |\_|\_|\_|\_|\_|**

-----

➤ **Il giorno dell'infortunio le è capitato di lavorare in un ambiente con della musica di sottofondo?**

1. sì
2. no

➤ **Se sì, stava lavorando in un ambiente con musica di sottofondo appena prima dell'infortunio?**

1. sì
2. no

➤ **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente in un ambiente con musica in sottofondo? |\_|\_|\_|\_|\_|**

-----

➤ **A qualsiasi ora durante il giorno dell'infortunio si è arrabbiato?**

1. sì
2. no

➤ **Se sì, era arrabbiato appena prima dell'infortunio?**

1. sì
2. no

➤ **Quante volte nell'ultimo mese (30 giorni) le è capitato di svolgere l'attività/compito che stava svolgendo al momento dell'incidente essendo arrabbiato? |\_|\_|\_|\_|\_|**

Peso (kg): |\_|\_|\_|\_|

Altezza (m): |\_|\_|,|\_|\_|

➤ **Abitudine al fumo:**

1. non fumatore
2. ex-fumatore
3. fumatore --> numero medio sigarette al giorno |\_|\_|\_|

➤ **Consuma bevande alcoliche?**

1. sì
2. no

**se sì, in quali quantità in media:**

	Al giorno	Alla settimana	Al mese
Bicchieri di vino (125 mL)			
Birra (330 mL)			
Bicchierini di superalcolici (40 mL)			

➤ **Consuma caffè?**

1. sì
2. no

**se sì, quanto ne beve in media:**

	Al giorno	Alla settimana	Al mese
Tazzine di caffè normali			
Tazze di cappuccino/caffelatte normale			
Tazzine di caffè decaffeinato			
Tazze di cappuccino/caffelatte decaffeinato			

➤ **Fa uso di farmaci per dormire?**

1. sì
2. no

**se sì, quali?** \_\_\_\_\_

➤ **Quante ore per notte dorme generalmente?**

1. Meno di 5
2. 5
3. 6
4. 7
5. 8
6. 9
7. 10
8. Più di 10

- **Ha spesso difficoltà ad addormentarsi?**
  1. sì
  2. no
  
- **Si sveglia troppo presto al mattino (per motivi diversi dal doversi recare al lavoro)?**
  1. sì
  2. no
  
- **Si sveglia spesso durante la notte e ha difficoltà a riaddormentarsi?**
  1. sì
  2. no
  
- **Si sente spesso stanco al risveglio mattutino?**
  1. sì
  2. no
  
- **In caso di carenza di sonno, il suo umore durante il giorno ne risente, magari sentendosi teso, irritabile o depresso?**
  1. sì
  2. no
  
- **Presenta abitualmente una irrequietezza motoria, un bisogno di muovere le gambe associato a sensazione di fastidio, presenti esclusivamente a riposo, con un sollievo, almeno temporaneo, durante l'attività motoria?**
  1. sì
  2. no
  
- **Il suo peso si è modificato negli ultimi 5 anni?**
  1. aumentato
  2. diminuito
  3. invariato
  
- **Russa?**
  1. sì
  2. no
  3. non so
    - Se russa il suo russamento è:
      1. poco più forte del respiro
      2. forte come quando parla
      3. un po' più forte di quando parla
      4. molto forte (si può sentire dalla camera a fianco)
  
- **Quante volte russa?**
  1. quasi quotidianamente
  2. 3-4 volte alla settimana
  3. 1-2 volte alla settimana
  4. 1-2 volte al mese
  5. mai o quasi mai
  
- **Qualcuno ha mai notato che Lei smette di respirare durante il sonno?**
  1. quasi quotidianamente
  2. 3-4 volte a settimana
  3. 1-2 volte alla settimana
  4. 1-2 volte al mese
  5. mai o quasi mai

- **Quante volte si sente stanco o affaticato dopo aver dormito?**
  1. quasi quotidianamente
  2. 3-4 volte a settimana
  3. 1-2 volte alla settimana
  4. 1-2 volte al mese
  5. mai o quasi mai
  
- **Durante la giornata, si sente stanco, o affaticato o non in forma?**
  1. quasi quotidianamente
  2. 3-4 volte alla settimana
  3. 1-2 volte alla settimana
  4. 1-2 volte al mese
  5. mai o quasi mai
  
- **Le è mai capitato di avere un colpo di sonno e di essersi addormentato alla guida di un veicolo?**
  1. sì
  2. no
    - **Se sì, quante volte le succede?**
      1. Quasi quotidianamente
      2. 3-4 volte a settimana
      3. 1-2 volte alla settimana
      4. 1-2 volte al mese
      5. mai o quasi mai
  
- **Soffre di: (una o più risposte)**
  1. Iperensione
  2. Diabete
  3. Malattie di natura allergica
  4. Ipercolesterolemia
  5. Episodi di ansia
  6. Episodi di depressione
  
- **Oltre al lavoro (se fa turni notturni) e alle situazioni descritte nelle domande delle pagine precedenti, esiste qualche motivo che attualmente le impedisce di dormire adeguatamente la notte (in termini di quantità di ore o di qualità del sonno):**
  1. no
  2. sì
  
- **Se sì, quale/i? (una o più risposte)**
  1. accudire bambini piccoli
  2. accudire persone anziane/malate/disabili
  3. praticare attività in orario notturno (ad esempio hobbies, attività ricreative)
  4. rumorosità dell'ambiente
  5. temperatura dell'ambiente
  6. altro \_\_\_\_\_

- Cerchi di quantificare le **probabilità di assopirsi** nelle situazioni sotto elencate; faccia riferimento alle condizioni abituali **negli ultimi mesi**; se qualche situazione non si è verificata provi ad immaginarla e a quantificarla ugualmente.

<p><b>0 = nessuna probabilità di assopimento</b> <b>1 = lieve probabilità di assopimento</b> <b>2 = moderata probabilità di assopimento</b> <b>3 = alta probabilità di assopimento</b></p>
--

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## SITUAZIONI

## PUNTEGGIO

- 
1. Leggendo, seduto.

---

  2. Seduto, inattivo, in pubblico (teatro, cinema, riunioni).

---

  3. Guardando la TV.

---

  4. Come passeggero in macchina per almeno un'ora ininterrotta.

---

  5. Sdraiato, a riposo, nel pomeriggio, quando le circostanze lo permettono.

---

  6. Seduto dopo pranzo.

---

  7. Alla guida durante brevi soste nel traffico (per non più di un'ora).

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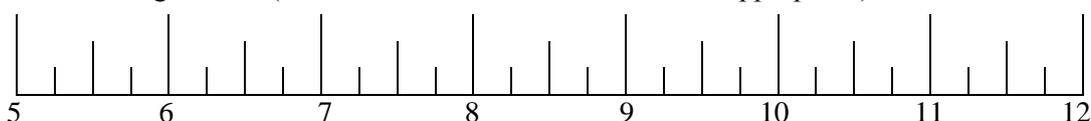
  8. Seduto parlando con qualcuno.
-

## M.E.Q. Mornigness Evenigness Questionnaire

Questionario sul Cronotipo - Modificata da Violani et al 1993

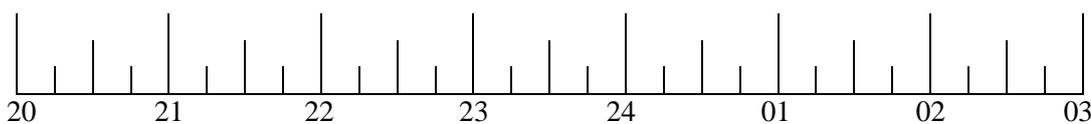
Per favore, legga molto accuratamente ogni domanda prima di rispondere. Risponda a TUTTE le domande seguendone l'ordine numerico. Risponda ad ogni domanda indipendentemente dalle altre senza tornare indietro per controllare le risposte precedenti. Alcune domande hanno una serie di risposte, per queste domande faccia una crocetta tra le parentesi accanto AD UNA SOLA risposta; altre domande hanno invece una scala graduate dove sono indicate le ore del mattino o della sera; faccia una crocetta sulla casella appropriata della scala.

1. Per sentirvi pienamente "in forma" a che ora vi alzereste se foste completamente libero di pianificare la vostra giornata? (indicare l'ora con una X nella casella appropriata)



ore del mattino

2. Per sentirvi pienamente "in forma" a che ora andreste a letto se foste completamente libero di pianificare la vostra serata?



ore della sera

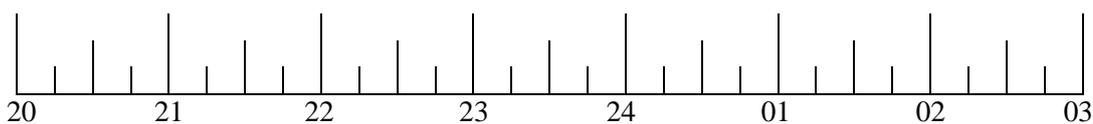
3. Se al mattino dovete alzarvi ad un'ora specifica, per svegliarvi, in che misura dovete dipendere da una sveglia?      Assolutamente indipendente.....( )  
Leggermente dipendente.....( )  
Abbastanza dipendente.....( )  
Molto dipendente.....( )
4. Al risveglio del mattino, in condizioni ottimali (stanza calda o fresca a seconda della stagione, colazione pronta, ecc.), quanto trovereste difficile alzarvi dal letto una volta svegli?      Assolutamente difficile.....( )  
Non molto facile.....( )  
Abbastanza facile.....( )  
Molto facile.....( )
5. In che grado vi sentite "sveglio" durante la prima mezz'ora dopo esservi svegliato?      Niente affatto sveglio.....( )  
Leggermente sveglio.....( )  
Abbastanza sveglio.....( )  
Molto sveglio.....( )
6. Com'è il vostro appetito durante la prima mezz'ora dopo esservi svegliato?      Molto scarso.....( )  
Abbastanza scarso.....( )  
Abbastanza forte.....( )  
Molto forte.....( )

7. Quanto vi sentite stanco durante la prima mezz'ora dopo il risveglio? Molto stanco.....()  
Abbastanza stanco.....()  
Abbastanza ristorato.....()  
Molto ristorato.....()

8. Quando non avete impegni per il giorno dopo, a che ora andate a letto rispetto alla vostra ora abituatoria? Quasi sempre alla stessa ora.....()  
Meno di un'ora più tardi.....()  
1 o 2 ore più tardi.....()  
Più di 2 ore più tardi.....()

9. Avete deciso di impegnarvi in qualche esercizio fisico. Un amico vi suggerisce che dovrete farlo per un'ora due volte la settimana e che l'ora migliore per lui è tra le 7.00 e le 9.00 del mattino. Considerando il vostro ritmo del "sentirvi in forma" come pensate che lo seguireste a quell'ora? Sarei in ottima forma.....()  
Sarei in buona forma.....()  
Lo troverei difficile.....()  
Lo troverei molto difficile.....()

10. A che ora della sera vi sentite stanco o avete bisogno di andare a dormire?



*ore della sera*

11. Desiderate dare la massima prestazione in un test che, come sapete, vi stancherà mentalmente perché dura 2 ore. Siete completamente libero di pianificare la vostra giornata; considerando solo il vostro ritmo del "sentirvi in forma" in QUALE dei seguenti quattro periodi scegliereste di svolgere il test? 8.00-10.00 del mattino.....()  
11.00-1.00 del mattino.....()  
15.00-17.00 del pomeriggio.....()  
19.00-21.00 del pomeriggio.....()

12. Se andate a letto alle 23.00 a che livello di stanchezza sareste? Nient'affatto stanco.....()  
Un poco stanco.....()  
Abbastanza stanco.....()  
Molto stanco.....()

13. Per qualche ragione siete andato a letto più tardi del solito, ma non vi è bisogno di alzarsi ad un'ora particolare la mattina dopo. Quale dei seguenti casi sperimentereste? Vi svegliereste alla solita ora, e non vi riaddormentereste.....()  
Vi svegliereste alla solita ora, dopo di che sonnecciereste.....()  
Vi svegliereste alla solita ora, ma vi riaddormentereste.....()  
Vi svegliereste più tardi della solita ora.....()

14. Una notte dovete rimanere sveglio fra le 4.00 e le 6.00 del mattino per fare un turno di lavoro. Non avete impegni per il giorno dopo. QUALE delle seguenti alternative vi sembra migliore?

- NON andrete a letto finchè non è finito il turno.....( )
- Farete un sonnellino prima e dormirete dopo il turno.....( )
- Farete un buon sonno prima ed un sonnellino dopo.....( )
- Dormirete SOLO prima del Turno.....( )

15. Dovete fare due ore di duro lavoro fisico; siete interamente libero di pianificare la vostra giornata. Considerando solo il vostro ritmo del “sentirvi in forma” QUALE dei seguenti periodi scegliereste?

- 8.00-10.00 del mattino.....( )
- 11.00-13.00 del mattino.....( )
- 15.00-17.00 del pomeriggio.....( )
- 19.00-21.00 del pomeriggio.....( )

16. Avete deciso di impegnarvi in un duro esercizio fisico. Un amico vi suggerisce che dovrete farlo per un’ora due volte alla settimana e che l’ora migliore per lui è fra le 22.00 e le 23.00 della sera. Considerando il vostro ritmo del “sentirvi in forma” come pensate che lo eseguireste a quell’ora?

- Sareste in ottima forma.....( )
- Sareste in buona forma.....( )
- Lo trovereste difficile.....( )
- Lo trovereste molto difficile.....( )

17. Supponete di poter scegliere le vostre ore di lavoro. Avendo un lavoro molto interessante (pienamente corrispondente alle vostre aspirazioni) della durata di CINQUE ore al giorno (compresi gli intervalli) e sapendo che per poter ottenere buoni risultati dovete essere in “ottima forma”, quali delle seguenti CINQUE ORE CONSECUTIVE scegliereste? (segnare con una crocetta SOLO CINQUE caselle)

0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
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18. A che ora della giornata pensate di raggiungere la massima “forma” (segnare con una crocetta UNA SOLA casella)

0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
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19. Si sente parlare di due tipi di persone: uno che è più attivo al mattino e l’altro che è più attivo alla sera. QUALE di questi due tipi vi considerate?

- Uno decisamente più attivo al mattino.....( )
- Un tipo un po’ più attivo al mattino rispetto alla sera.....( )
- Un tipo un po’ più attivo la sera rispetto al mattino.....( )
- Un tipo decisamente più attivo la sera.....( )