Benefits of healthcare simulation on occupational stress of ICU nurses

Hospital Programme for Nursing and Paramedical Research

Manager: Assistance Publique - Hôpitaux de Marseille

Principal Investigator: Radia El Khamali – Hôpital Nord – Assistance Publique des Hôpitaux de Marseille – Réanimation Détresses Respiratoires et Infections Sévères – URMITE CNRS-UMR 7278 – Aix-Marseille Université

Co-Principal Investigators: Atika Mouaci, Valérie Attard, Amel Allal, Marion Cano-Chervel, Julie Malardier

Associate Investigators: Cécile Vankiersbilck, Laurent Papazian, Magali Delfino, Pierre Rostini, Nicole Chevalier, Véronique Chardon, Claude Martin, Catherine Guidon, Nicolas Bruder, Marc Gainnier, Jacques Albanese, Jacques Durand-Gasselin, Jean-Louis Blache, Bernard Garrigues, Caroline Brousse, Frédéric Iride, Béatrice Cresta, Karine Berthias, Stephan Aguilard, Josiane Avallero, Laurence Hullard, Nathalie Coconi, Valérie Reynaud

Coordination and Logistics: Radia El Khamali-Atika Mouaci

Methodology and Data Processing: Karine Baumstarck


1. BACKGROUND AND RESEARCH OBJECTIVE

PART I BACKGROUND

Over the past decade there has been a keen interest for studies on psychosocial risks, occupational exhaustion (burnout) and stress as well as their consequences on health, productivity and efficiency of healthcare professionals. Occupational exhaustion has been widely studied especially for nursing staff. Staff working in Intensive Care Units (ICU) are particularly exposed\(^1\). Thus, it was shown that one third of nurses suffered from burnout\(^2\) linked to a high level of exposure to stress factors. These factors are related to work organisation (task interruption, role ambiguity, work load), work conditions (conflicts with co-workers and with physicians, alteration of the care relationship, lacking social support, being faced with suffering and death, feeling unrecognised or lacking autonomy) or to the environment (noise, lights, the particular contact with patients’ families, ...). Burnout is the result of stress becoming chronic. Incorrect handling of these risks can have:

- a direct impact on the carer (deterioration of their health, increased absenteeism, intents to leave/change position) and
- an indirect impact on coordination and quality of care\(^3\).

Occupational stress is estimated to have cost 2 to 3 billion euros in France in 2007\(^4\). This context led to multiple actions being set up on several different levels to prevent occupational stress. This impulse reflects a national preoccupation with occupational health. The French occupational health Plan “Santé au Travail 2010/2014”, recommends that preventive actions are to be developed for occupational risks, especially psychosocial risks as stated in axis 2 objective 4 (Continue the active policy of occupational risk prevention especially psychosocial risks).

Acting on the root cause of stress factors is the most direct and effective way of reducing stress in an organisation. There are two ways of preventing occupational stress and its consequences on the organisation and on the individual: one is to modify the work environment, the other is to act on the person’s capacity of coping with stress. For this, training seems to be the ideal approach\(^5\) to improve a person’s capacity to adapt, by encouraging effort and designing a personal means of coping with stressful situations. This is done by acquiring cognitive abilities, identifying and making the individual aware of his/her way of thinking, detecting any distortions in his/her situation appraisal, suggesting different ways of thinking, new attitudes and applying a different cognitive strategy in situations

\(^{1}\) Mieux vivre la réanimation, CC 2009, SRLF (in French)

\(^{2}\) Poncet 2007

\(^{3}\) Ricou 2012


\(^{5}\) Taormina 2000

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considered to be stressful. Healthcare simulation, an innovative training tool which remains seldom used however for paramedics, enables:

- to acquire and update knowledge and skills, whether technical or not technical (teamwork, communication...)
- to practice handling situations identified as “high-risk for the patient” and to improve the capacity of coping with them
- to reconstruct situations which led to the occurrence of adverse events, to understand them during debriefing and to introduce actions which improve healthcare quality and safety
- to analyse personal work practices by adopting a new outlook on oneself during debriefing

A specific training course including healthcare simulation was offered by the PYTHEAS centre [Public Assistance-Marseille Hospitals (APHM) simulation centre] to ICU nurses at the demand of APHM healthcare management. First there was a pilot trial (before/after) where a sample of nurses working in APHM emergency wards followed this course, because of decreased motivation, leaves and absenteeism. The nurses reported improvements in their motivation, in stress management and in personal efficiency (Communication SRLF 2012, M. Delfino). After this first experiment, simulator training was offered to a small group of ICU nurses who, at the end of the programme, felt the same way as the emergency nurses. This is an innovative and unique training course which led us to look into the potential benefits it may have on critical carers’ well-being. Up until now, there has been no study to show the efficacy of this type of approach on psychosocial risk prevention. In view of carrying out an interventional study in order to improve healthcare practices, we studied scientific and institutional literature looking for elements on:

- Psychosocial risks and the role of occupational stress in order to clarify our research topic
- Prevention of psychosocial risks via the identification of factors of imbalance observed in ICU nursing situations and potential levers for action
- Healthcare simulation as a tool today and its uses.

HAS-Guide des bonnes pratiques en matière de simulation en santé- décembre 2012 (in French)
I. From psychosocial risks to the psychosocial risk in ICU: occupational stress

Psychosocial risks cover all occupational risks which may alter a worker’s mental and physical health. Psychosocial risks include, according to the French national institute for scientific research (INRS), stress at work, internal violence (committed within the firm by employees: conflicts, bullying, moral harassment etc.) external violence (committed on employees by people external to the firm), occupational exhaustion (or burnout), different forms of uneasiness, suffering and malaise felt by employees.

Stress, lack of motivation, burnout, turnover, absenteeism, overachievement, dissatisfaction at work, violence at work, harassment, addictions etc., this wide variety of topics classed as psychosocial risks leads to considerable confusion.

These topics notably cover determinants and effects, without distinguishing between causes and consequences. This confusion arises not only from the diversity of these risks but also from the complexity of connections between them and which are not always linear because, given that they interact so strongly with each other, they are circular or systemic instead. Effectively, these risks, which often have the same causes (workload, lack of clarity in task sharing, higher job demands, work organisation, mode of management etc.) may interact.

Thus:

- Stress at work nurtures abuse among employees which thus increases workplace stress.
- Anxiety or depression may occur as consequences of stress, violence at work, harassment or a traumatism.

Regarding addictions, they may well be a consequence or a cause.

Many international studies\(^7\) show stress as being the most frequent of all psychosocial risks. Thus, in the European Union, an estimated 22% of employees suffer from stress at work, while 5% are subject to harassment and 5% are victims of physical violence. According to the European Agency of Safety and Health at Work, stress is the most widely spread health issue at work and the number of people suffering from work-related or work-aggravated stress will probably rise.

For the European Agency of Safety and Health at Work, “people experience stress when they perceive that there is an imbalance between the demands made of them and the resources they have available to cope with those demands. Even though the evaluation process of demands and resources is psychological, the effects of stress are not always of the same sort. They also affect physical health, well-being and productivity”.

\(^7\) Fondation européenne pour l’amélioration des conditions de vie et de travail (Dublin). 4\(\text{ème}\) enquête européenne, Luxembourg, Office for Official Publications of the European Communities, 2007
From an interventional point of view, with regards to the research topic we wish to study, the comprehension of causes, evaluation and the pertinence of actions to be carried out are extremely dependent on the type of psychosocial risk detected.

However, when one looks at literature on issues of well-being in the hospital sector, more specifically literature targeting a population of nurses, what can be found?

Harm done to the well-being of ICU nurses has been objectivized in the concept of burnout or occupational exhaustion, which is defined as being “a syndrome of physical and emotional exhaustion, which leads to the development of an inadequate self-image, negative attitudes at work with a loss of interest and of feeling for patients”\(^8\). Conceptualisation of the burnout syndrome in the 70’s and 80’s by H. J Freudenberger (a psychoanalyst) and C. Maslach (a research scientist in social psychology) brought to light the existence of a phenomenon of work-related social suffering, and the first victims recognised as such were from professions associated with help. Effectively, carers, social workers and teachers are professions characterised by devotion and a strong vocational dimension. In the same era, two models of occupational stress were designed, which are widely used today, R. Karasek’s model\(^9\) (an American psychologist and sociologist) and J.Siegrist’s model\(^10\) (a Professor in medical sociology).

In 2007, Poncet and Embriaco measured the extent of burnout in ICU nurses. In a study carried out in 165 services, 33% of the nursing staff suffered from severe burnout i.e. the third and final stage of the illness. However, when we look at its definition, one notes that this occupational exhaustion is considered to be a transactional process made up of work-related stress, worker’s constraint and psychological adjustment. This process has three stages of progression:

- The stress stage, caused by the imbalance between work demands and personal resources involved to cope with them.
- The constraint stage in response to this imbalance. On a subjective level this is expressed as feelings of anxiety, tension, fatigue and exhaustion.
- The adjustment stage which manifests itself by changes in attitude and behaviour; a victim of burnout tends to treat patients in a detached or mechanical manner; however he/she seeks to fulfil his/her own needs.

The interaction between stressors (stimulus causing stress) and the individual’s attempt to cope with them can lead to occupational stress which, if it is not treated early enough, ends in a burnout.

\(^8\) Le Gall JR, Azoulay E, Embriaco N, Poncet MC, Pochard, 2011  
\(^9\) Karasek, 1979  
\(^10\) Siegrist, 1996
This risk can be prevented by reducing this state of stress, giving the person tools to restore a balance and to avoid deterioration into more serious situations such as a burnout. This analysis led us to mainly focus on occupational stress.
II. Occupational stress: theoretical framework

Occupational stress or work-related stress is directly derived from a more general field of study on stress. Originally, stress was studied by physicians and biologists as being a “general syndrome of the organism’s adaptation to various toxic agents”. Nowadays, it is based on studies in psychology and social psychology, relying upon retroactive mechanisms and providing a good means to analyse the behaviour of people in their workplace. Stress is therefore universal and, at any moment in time, an individual may feel stressed by his/her family environment or work environment.

Stress in an organisation therefore needs to be considered with a dynamic perspective involving the individual and his/her surroundings. An individual is a system made up of psychological conflicts, emotions and defences. An organisation is a dynamic system, criss-crossed with conflicts between groups. It is a place where conflicts begin, end and are also avoided. In this way, collective social functioning and personal psychological functioning interact with each other. The individual at work is indeed solicited both physically and mentally. Research on work-related stress indicates that sources of stress are as varied as they are multiple. The illness would therefore be the result of an individual’s incapacity to efficiently react to aggression, rather than the direct effect of the latter\(^\text{11}\).

There are two fundamental approaches to stress, the transactional approach and the interactional approach.

II.1. The transactional approach

The transactional approach to stress is based on the concept that stress does not rely on the environment nor on the individual, but instead on the specific interaction of the person with their environment. This approach emphasizes the role played by coping mechanisms (coping, adjustment or adaptation processes), i.e. personal strategies developed in order to reduce strain, by altering the causes (problem-focused coping) or emotions (emotion-focused coping). These strategies depend on personal characteristics, therefore transactional models take into account the perception the individual has of his/her environment as the primary determinant for a stress reaction. The transactional approach by Lazarus and Folkman\(^\text{12}\) (1984) defined a dual appraisal model, in which an individual faced with a situation first gives an appraisal of the stress potential of the situation, then gives a secondary appraisal of the resources he/she has to cope with the situation. The process and the results of these appraisals depend not only on reality (constraints of the situation, resources the individual disposes of) but also on particular characteristics of the individual making the appraisal, which influence his/her judgment.

\(^\text{11}\) Neboit et Vezina, 2002.

\(^\text{12}\) Lazarus, R. S., 1984
Siegrist’s model (1996), suggests that chronic stress can be defined in terms of an effort/reward imbalance. In this model, the amount of effort made by an individual will be attenuated by the feeling that this effort is “rewarded”. This “reward” is not only material (money), but also social (recognition) and symbolic (a sense given to the effort).

II.2. The interactional approach

The interactional approach to stress suggests that the degree of fit between a person and their work environment explains a person’s behaviour better than individual or contextual differences. According to this approach, stress appears when a person and their environment do not match. The models are quite mechanistic, behavioural, in which a combination of some of the situation’s characteristics lead individuals to react differently.

The most frequently used model is the “Job demand-control model” by Karasek (1990). In this model, what is demanded of an individual is attenuated by the control the individual has over their own tasks. It puts forward two determinants: decision latitude (degree of control, decision authority) and job demands (amount of work, intellectual requirements). The hypothesis is that a high level of decision latitude or control reduces the negative effects of high job demands on a person’s health. A third dimension has been added to this model, which is social support. The combination “high job demands/low control/absence of support” is the most detrimental situation for the individual in terms of health risks.

Each one of these approaches explains part of, but never all stress-related issues. It is evident that, depending which model one chooses, the definitions of stress, as well as the approaches recommended for evaluation or prevention are going to be different.

We can quote the conclusion of the European study on “stress impact” 13 to this avail:

“If it is important to pay genuine attention to the transactional model by Lazarus, which should be considered as a very valuable theoretical model, we must also consider the difficulty of putting it into practice. On the other hand, Karasek’s and Siegrist’s models are reasonably clear and easy to implement at field level, whereas they are limited however, with regards to understanding stress development processes.”

We believe that when approaching psychosocial risks, especially occupational stress, it is important to refer to international standards for the definition of work-related stress. These are widely acknowledged, and represent the current opinion in France in this field, and particularly that of the INRS (Institut National de Recherche et de Sécurité, 13 Stress Impact Consortium. Impact of changing social structures on stress and quality of live: individual and social perspectives. Rapport non publié, réalisé par 6 pays européens sous l’égide de l’Université de Surrey. UK : Surrey University, 2006
French National Institute for Research and Safety). Scientific research has already widely explored work conditions with regards to their detrimental effects, especially psychosocial risks, using Karasek’s epidemiological model which enables measurement of occupational stress. Karasek’s model is interesting because its primary objective is to provide a theoretical framework for the development of recommendations which improve the quality of life at work. Moreover, it is the evaluation tool which was used in a transversal descriptive study carried out in the Nord Hospital from April to September 2011 by the Medicine and Health at Work Department of the AP-HM. This study was on organisation factors which influence strain at work and the psychological quality of life of hospital agents from emergency and ICU wards).

For the sake of completeness we shall also be using another tool to enable a better comprehension of the phenomenon: this is the COPSOQ questionnaire (See Experimental Design).

III. Occupational stress and its implications for ICU nurses: a public health issue

It is acknowledged in the healthcare profession that poor management of psychosocial risks is at the origin of intents to leave or to change positions, and of absenteeism which can all have a direct impact on the quality of patient care and management. An American study\(^{14}\), published in March 2012 in the British Medical Journal took twelve European countries (France was not included) and the United States, and examined the different satisfaction surveys amounting to tens of thousands of questionnaires. The results showed that, despite major differences in health organisation and financing in the 13 countries, all of them encountered quality and safety problems reported by patients and healthcare personnel, as well as dissatisfaction and excessive workloads. Nurses having a burnout, who are dissatisfied with their job, have difficulty investing in patient care. This established fact is correlated with a higher risk of mortality for patients and a higher rate of failure to rescue in emergencies\(^{15}\). Care quality and safety is behind a better management of stressful work situations according to papers on the subject, but there have been no studies which provide the effects of stress on care quality and safety. At the most, they reveal an opinion, maybe enlightened, given by the nursing staff. It would have been interesting to have been able to study this here but, given the number of items which need to be measured in a research study on care quality and safety (adverse events, infections, evaluation of work practices etc.) and the budget required to carry it out, it did not qualify for a hospital nursing research programme. We have therefore focused on our research topic: occupational stress of critical care nurses. If our study turns out to be positive, then, in a second phase, we shall assess its impact on the quality of care in a new study.

\(^{14}\) Aiken LH and al.2012

\(^{15}\) Aiken LH 2002
Given what is at stake, multiple actions have been carried out to prevent occupational stress at all the different levels of prevention [primary (training on burnout syndrome, stress management), secondary (continuing education, group discussions, practice analysis) and tertiary (counselling support units, occupational medicine...)].

In the light of carrying out an interventional study, we first:

- **identified** the **factors of imbalance** present in **these workplaces** for critical care nurses,
- **found** from scientific literature **levers of action used to restore balance**.

### III.1. Factors of imbalance in work situations: stressors in critical care

A certain number of stressors were identified within the critical care sector.

They were:

- Stressors due to work organisation (interruption of tasks, role ambiguity, workload, number of hours worked).
- Stressors due to work conditions (alteration of the care relationship, lack of social support, conflict situations, lack of discussion, technology, pathologies, confrontation with suffering and death, feeling unrecognised, lack of autonomy).
- Environmental stressors (the work environment with its difficulties to communicate sometimes leading to conflicts between nurses and with physicians, noise, light...).

Nursing burnout is essentially linked to the organisation of the ward or to the strategies of end-of-life care. The presence of conflicts is a predictive factor for burnout. Workload has been identified as a risk factor. An alteration of professional relationships could foster mood disorders in such a context. Surprisingly, the severity of patients’ condition is not a factor contributing to depression\(^\text{16}\).

### III.2. Actions to help cope

Setting up work groups, improved communication on end-of-life care, conflict prevention and control within the department are all preventive measures which seem necessary in order to improve the well-being of ICU carers\(^\text{17}\).

The reduction of stressors at base-level is the most direct and the most efficient way of attenuating stress within an organisation. In literature on stress management, this category of intervention is known as “primary prevention”.

There are two categories of means of prevention for occupational stress and for its consequences on the organisation

\(^{16}\) Poncet 2007

\(^{17}\) *Mieux vivre la réanimation*, CC 2009, SRLF (in French)
and the individual: one consists of modifying the work environment, the other is to act on the person’s capacity of
coping with stress.

In critical care, given the complexity of the work environment and safety requirements, it is recommended:\n\begin{itemize}
\item For nurses new to critical care: an induction period with adaptation to the job (unit organisation, treatments,
      multidisciplinary approach...), accompanied by a tutor, then training such as continuing education.
\item Furthermore, there is strict legislation concerning the quota of patients per nurse per shift.
\item A budget for material is granted and is specifically for critical care unit activity.
\end{itemize}

The other action to prevent stress recommends interventions which increase the person’s capacities of adaptation,
by encouraging effort and developing personal means of coping; the aim is to acquire cognitive abilities, to identify
and make the subject aware of his/her way of thinking, to detect any distortions in situation appraisal, to propose
different ways of thinking, new attitudes and to apply a different cognitive strategy in situations considered to be
stressful.

**Example 1: Stress Inoculation Training** is a technique which teaches people how to deal with stressful situations by
stress inoculation by building up “psychological antibodies”. It has given positive results on attitude changing such as
on self-esteem, self-confidence, job satisfaction, appraisal of supervisors, colleagues and promotion. There are,
however, very few studies on intervention programmes in organisations on stress management and assessment of
their results.

**Example 2: Team building** to improve team spirit and cohesion could possibly reduce tension within the team, enable
a better support of one another and, above all, encourage better communication in order to encourage discussions,
weight sharing, the weight of decisions, of workloads and of responsibility. However, the field of action remains
vast, with this being a core issue and given the extent of the human and financial stakes.

Among the innovative experiments reducing occupational stress in critical care, at the junction between these two
means of action, there is a potentially favourable new tool emerging: simulation in healthcare;

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18 JORF n°0141 du 20 juin 2013 page 10240 texte n° 5 \textit{Arrêté du 4 juin 2013 relatif à la
formation d’adaptation à l’emploi des membres du corps des assistants médico-administratifs de la fonction
publique hospitalière (branche assistance en régulation médicale)}(in French)

19 Meichenbaum, D. 1996

20 Reader TW, Flin R, Mearns K, Cuthbertson BH 2009

21 Orledge 2012
IV. Simulation in healthcare

Simulation in healthcare is the use of material (such as a manikin or procedural simulator), virtual reality or data from a standardised patient, to reproduce situations or care environments, in order to teach diagnostic and therapeutic procedures, and to allow healthcare professionals or a team of professionals to practice processes, clinical situations or decision-making.

In only a few years simulation has imposed itself as an essential tool in training for high-risk professions as was concluded by a report ordered by the French Higher Health Authority (HAS) on simulation in healthcare: *State of the art (national and international) for simulation practices in healthcare within the framework of continuing education and the prevention of healthcare-related risks*. It literally enables one to dive into reality, to reproduce extremely various situations, often rare in real-life, and of course to learn technical skills without running the risk of genuine error. Its principle is applied internationally nowadays throughout industry: nuclear, chemical, aeronautical, rail, maritime, and of course in medicine and more recently in nursing. In France, simulation in healthcare, even though it is not yet a very dense network, is present all over the national territory and covers all fields of study [HAS Report 2012 (in French), Simulation dans le domaine de la santé (Simulation in healthcare)]. There are many topics and fields covered by simulation even if some are more recurrent than others, such as those concerning anaesthesia-resuscitation, emergency medicine and perinatal care (neonatology and obstetrics), as well as those concerning nursing. The HAS recommends use of this approach in training programmes for carers with the objective of care quality and safety:

“Training using methods of simulation in healthcare must be included in all the teaching programmes for healthcare professionals at all stages of their education (initial and continuing). One ethical objective should be a priority: “never the first time on a patient”.

The importance of the impact of training via simulation on human factors and team work, as well as its utility in healthcare safety must be extensively studied.”

HYPOTHESIS

Working in critical care exposes nurses continuously to stressors. We hypothesize that specific training incorporating simulation techniques offered to nurses working in ICU would have a positive impact on primary and/or secondary prevention of the psychosocial risk of occupational stress.

The objective of this observational study is to show the positive impact of training incorporating simulation methods on reducing occupational stress and psychosocial risks of nurses working in ICU.

22 S. Boet, JC. Granry, G. Savoldelli. 2013
PART II RESEARCH OBJECTIVES

I. Main objective

The main objective of this study is to evaluate the impact of specific training incorporating simulation, on the occupational stress of nurses working in ICU.

This training is in the institute’s training catalogue and is included in the continuing education policy for nursing staff in critical care.

The main evaluation criteria will therefore be the reduction of stress assessed at 6 months. Here stress is defined as having a high level of job strain, and is evaluated using a Karasek survey.

II. Secondary objectives

The secondary objectives are to evaluate the impact of this training in terms of:

- Nurses’ occupational stress assessed at 1 year
- Nurses’ psychosocial risks
- Nurses’ occupational exhaustion
- Number of nurses’ intents to leave, number of nurses actually leaving
- Nurses’ absenteeism
- Nurses’ quality of life
2. POPULATION CONCERNED

I. Inclusion criteria

- Adult state-registered nurses working in adult ICU on day or night shifts, with at least 6 months seniority in the unit where he/she is working at the time of inclusion
- Nurses who do not intend to leave the ward within 6 months from inclusion

II. Non-inclusion criteria

- State-registered nurses with less than 6 months’ work experience in the unit at the time of inclusion
- Nurses who intend to leave within 6 months from inclusion
- Nurses who have already done the training course offered in the study
- Women who know they are pregnant at the time of inclusion

III. Exclusion criteria

- Nurses who are moving and going to work in another hospital centre during the study
- Pregnant women with more than 4 weeks of absence during the study period
3. OBSERVATION OR INVESTIGATION METHOD RETAINED

I. Experimental Design
Study Diagram

1. Check selection criteria
2. Sign consent form
3. Initial evaluation
4. Randomisation

Start:
- Evaluation at baseline
- Continue usual ICU work schedule
- Randomisation
- Group with TRAINING
- Control group

End:
- Evaluation at 6 months
- Evaluation at 1 year/OR on the agent's departure

Control arm:
- D1
- D2
- D3
- D10
- D11
- D + 6 months
- D + 1 year

Training arm:
- Evaluation at baseline
- Beginning of training
- End of training
- Evaluation at 6 months
- Evaluation at 1 year/OR on the agent's departure

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This is an observational, randomised, open-trial study, including two parallel groups. Recruitment will be prospective. The two groups under study are:

- Training group (training with simulator)
- Control group (no training)

The experimental diagram chosen corresponds to the one which will give an optimal level of proof, according to current literature on the subject.

The choice of an open-trial is the only one possible for this project. Evaluation a long time after training should mean that we will obtain an objective opinion from the participants. While a cross-over study design would have enabled us to take intra-individual variability into account, this could not be applied to this project, as indeed we cannot assure that the participant returns to base level between the 2 training sequences. However, the stratification per ICU ward will enable us to control the heterogeneity of practices between the different ICU wards. Thus, for each ICU ward, there will be the same number of individuals included in the control group as there are in the training group.

II. Associated teams

This is a multicentric and multidisciplinary study, associating ICU wards and clinical research structures.

The ICU wards participating are the following:

- The Medical and Emergency ICU (RUM) at the University Hospital Centre (UHC) TIMONE
- The Heart Surgery ICU (URCC) at the UHC TIMONE
- The medico-surgical ICU at the UHC TIMONE
- The medico-surgical and liver failure ICU at the UHC TIMONE
- The medico-surgical ICU at the UHC CONCEPTION
- The medico-surgical ICU at the UHC NORD
- The Respiratory distress and severe infections ICU (DRIS) at the UHC NORD
- The ICU at the CENTRE HOSPITALIER GENERAL D’AIX EN PROVENCE

A total of 8 ICUs from the French region PACA (Provence Alps Côte d’Azur)-West are partners in this project.

III. Two strategies

Two parallel groups:
A control group: the individuals will have the usual ward practices for coping with daily “stressful” situations (this list is not necessarily complete, it accounts for all of the methods used in the different ICU wards, collected via a survey intended for executives):

- Lectures, given by physicians and/or advanced practice registered nurses, on pathologies and healthcare techniques specific to the ward.
- Weekly ward meetings with executives and healthcare staff.
- Debriefing meetings organised by the health executive and staff who wish to discuss events from difficult situations, and which act as emotional “safety valves”, where every member of the team is free to express their feelings about the situation in question, and to think up solutions so that they do not occur again.
- Practice analysis (evaluation and professional assistance group) followed by a debriefing, in order to analyse problematic situations between the patient, the patients’ family and the nurse or between members of the same team. These discussions encourage an analytical approach, team spirit and professional respect.
- If there is one, help from the “burnout unit” of the institute.
- Others.

A training group: the individuals enrolled in this group will be given, as well as the usual practices on the ward, a training course with a high fidelity simulator, details are given below.
IV. CLOSE-UP on the training course

It takes place over 2 weeks

1. The centre

The simulation centre, PYTHEAS, is directed by Dr Pierre Rostini: Head of Teaching.

He works with two training instructors: Mrs. Magali Delfino, Nurse Anaesthetist, Vocational adult training instructor’s certificate, University Diploma in Teaching and Education using a simulator in healthcare, instructor with a Certificate of Training in Emergency First-Aid (A.F.G.S.U.)

Mrs. D’Anna Fifina, Nurse Anesthetist, instructor with a Certificate of Training in Emergency First-Aid (A.F.G.S.U.), University Diploma in Teaching and Education using a simulator in healthcare.

2. Training

The group is made up of 6 nurses from the same ICU ward or from different ICU wards meeting the defined inclusion criteria (See Inclusion criteria chapter).

The training course lasts for 5 days which are split accordingly: 3 consecutive days during the first week then 2 consecutive days during the second week.

i. General training objective

To progress in management of healthcare-related risks and in critical incident management. To enable the healthcare professionals to train without any risks, by experimentally reproducing “real-life conditions”. To develop the skills expected in nursing practice in ICU. To analyse the impact of stress and the emotions felt by the nurse dealing with a difficult situation. To define strategies which allow him/her to ignore them. To get to know their team and to manage the quality of team relationships in order to improve patient care.

Supporting documents in French are available for ICU training:

- “Le Référentiel de compétences des infirmières de réanimation” (Framework of skills for ICU nurses)
- “Le livret adaptation à l’emploi des infirmier(e)s de réanimation” (Booklet on adaptation to the job of being an ICU nurse)
These documents were drawn up in collaboration with several French Learned Societies:

- The Society of Critical Care in the French Language (SRLF)
- The College of Critical and Emergency Medicine from Non-University Hospitals in France (CREUF)
- The French-speaking Group of Paediatric Critical and Emergency Care (GFRUP)
- The French Society of Anaesthesiology and Critical Care (SFAR)

### Programme

The training course includes a theory recap in the morning then situation role-play on the simulator in the afternoon followed by debriefing sessions on soft skills and discussions about practices.

**The first four days:**

- **Morning:** Theory recap (See Topics Chapter)

  Theory recaps enable participants to mobilise their knowledge and know-how as well as their technical skills.

- **Afternoon:** Situation role-play on the simulator

  These are genuine professional situations based on best practices. Each scenario is written after having defined the learning objectives:

  - Technical dexterity
  - Clinical approach
  - Decision making
  - Application of procedures
  - Aptitude to working in a team
  - Task prioritisation

  The topics treated are multiple and linked to the theory recap studied in the morning.

**Examples:**

Handling a:

- Cardiopulmonary arrest
- Chest pain
- Haemorrhagic shock
• Difficult intubation
• Anaphylactic shock

The situation does not need to be unnecessarily complicated for the participant. It is a dynamic situation which will evolve accordingly with the objectives. Simulation must provide the opportunity to reproduce varied clinical situations.

The fifth day:

Situation role-play on the simulator all day.

iii. Topics

Every day a different topic is covered.

Respiratory failure (Example: Physiology and pathophysiology of alveolar ventilation, monitoring respiratory function: respiratory rate, pulse oximetry, capnography, the principles of respiratory care: oxygen therapy, rapid sequence intubation, difficult intubation),

Circulatory failure,

Neurological failure.

iv. Training session plan

A simulation session begins with a first “introduction briefing”, an essential step in preparation, with the following objectives:

– To prepare the participant for the simulation session.
– To create a positive learning environment.
– To encourage the participants’ emotional security.
– To guarantee the respect of non-disclosure rules.

This briefing ends with a visit round the simulator laboratory, with a detailed presentation of the environment, material and the High Fidelity manikin SINMAN 3G.

Before the scenario, there is a shorter briefing, a “pre-brief”. This gives the situation’s context and defines the number of participants. Each actor receives a clinical sheet introducing the clinical situation being simulated. A patient medical record including an ICU admission flowsheet, a medical prescription and a nursing interventions’ sheet are given to the role-playing student.
The student, or the team, then begins the simulation which lasts between 10 and 15 minutes. Each scenario is adapted to the skills which need to be developed or perfected. Simulation sessions are recorded on video.

Once the objectives aimed for have been reached, the instructor stops the scenario. Actors and observers meet up for debriefing. This feedback is considered to be the most important aspect of the simulation sessions. It is a moment of analysis and synthesis.

The main objective of this debriefing is the participants’ reflexivity. It enables the “actors” to discuss it straight away and to start a reflective process on what has just happened.

Debriefing is made up of three phases:

- phase of reaction or descriptive phase:
  The participants describe their impressions, share their emotions, what they felt, the stress caused by the simulation session.

- a phase of analysis adapted to the learning objectives:
  The method used is a reflective process derived from a communication tool called the SBAR (Situation, Background, Assessment, Recommendation). This phase studies the reasons why actions were, or were not done, and analyses the underlying clinical reasoning behind the decisions which were made. Video recordings are used as a debriefing support and enable a more pertinent analysis of human behaviour and the relational aspect.

- a phase of summary or synthesis:
  This is the phase which concludes the debriefing. It is a means of reinforcing learning and of going back over the important messages identified during the phase of analysis. It is also the opportunity to formulate future learning objectives.
4. ORIGIN AND TYPE OF NOMINATIVE DATA COLLECTED

(JUSTIFICATION OF WHY IT IS USED)

I. Main evaluation criteria

The main evaluation criteria is having a high-strain job assessed using Karasek’s Job Content Questionnaire [1998]. Evaluation 6 months after inclusion is retained as the main criteria.

Karasek’s questionnaire evaluates the psychosocial environment and well-being at work, exploring both environmental aspects and individual stress aspects. It is a standardised survey which is validated, has good psychometric properties and is available in French. It is made up of 26 questions which define 3 dimensions: psychological demand, decision latitude and social support.

Psychological demand is the psychological strain associated with the quantity and the speed of tasks (3 items), their complexity and intensity (3 items), their division and predictability (3 items). Decision latitude takes into account the degree of latitude in task completion (3 items), use of skills (3 items), and skill development (3 items). Social support concerns professional support from superiors (2 items) and from co-workers (2 items), as well as the amount of emotional support from the same superiors (2 items) and co-workers (2 items). Karasek’s model splits employees into four groups according to psychological demand and decision latitude. “Job strain” is defined as a situation with high psychological demand and low decision latitude, which represents a health risk. This group where there is the highest risk of a damaging effect on health.

Three other subgroups are defined: 1. “low-strain jobs”: high decision latitude, low psychological demand, 2. “active”: high decision latitude, high psychological demand, 3. “passive”: low decision latitude, low psychological demand.

It is a consensual questionnaire which is frequently found in large studies evaluating occupational stress.

23 Karasek 1979 and Karasek 1998
II. Secondary evaluation criteria

Secondary evaluation criteria are the following:

- Psychosocial risks will be evaluated using another questionnaire, the COPSOQ (Copenhagen Psychosocial Questionnaire). This questionnaire evaluates a broad array of psychosocial factors at work. It evaluates more stress components than Karasek’s questionnaire. It includes the “demand/control/social support” components from Karasek’s model, the “effort/reward” components from Siegrist’s model, as well as other dimensions such as the relationship between individuals, interactions between life at work and at home, motivation and implication at work, leadership, etc. This questionnaire is based on several different models of the psychosocial environment at work, especially the work “Job-Control” model (Karasek) and the “Burnout” model (Maslach); as well as on different personal dimensions: health (perceived health, stress, occupational exhaustion), strategies for adapting to stressful situations, work satisfaction. This questionnaire was designed, about a decade ago, by a research team from the Danish National Institute of Occupational Health in Copenhagen and adopted by Scandinavian countries (Denmark, Sweden, Norway and Finland). It is also widely used for large surveys. Since it was validated in Danish, the COPSOQ has already been adapted into English, German, Japanese, Spanish and Dutch. The current French version is made up of 46 items grouped into 24 scales with six dimensions.

- Occupational exhaustion (burnout) will be evaluated using the COPSOQ questionnaire.

- Intent to leave.

- Actual departure (corresponding to leave that was accepted and carried out by the nurse for any reason), leave for extended education, leave without pay, leave to move to another ward within the institute during the year of participation.

- Absenteeism will be measured by counting the days of absence.

- The nurses’ quality of life will be assessed on a scale of 0 to 10, at the 3 stages of the study, for each participant, i.e. at the beginning of the study, at 6 months and at 1 year.

- Occupational stress measured using Karasek’s questionnaire will also be assessed at 12 months.

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24 Dupret Émilie 2012

25 Kristensen TS 2002 and 2005
III. Study Plan

i. Beginning of the study and list of inclusions

The randomisation list will be drawn up before the study is set up. It will be done under the responsibility of the Unit for Methodological Assistance in Clinical Research (Research Department, AP-HM). The method retained uses blocks of individuals swapped by layers. Layers retained are represented by the centre and by employee seniority (between 6 months and 2 years or > 2 years).

The randomisation list will be issued and kept by the centre in charge of coordination (ICU DRIS Nord Hospital - Marseille). The procedure retained for each inclusion is the following: referring research nurses from external centres send a fax applying for inclusion to the coordinating centre. The coordinating centre will tell the external centre which group the person is included in, according to the randomisation list. On their list, the coordinating centre will be able to follow the progress of each agent included via the following codes T0 = inclusion questionnaire filled in, T6 = questionnaire at t=6m filled in, and T12 = questionnaire filled in at t=1yr or on agent’s departure if this is before the end of the 12 month period. Each participating centre will keep a correlation table up to date listing the identity of the agents participating in the study.

ii. Nurse recruitment

Nurses will be recruited via research nurses in collaboration with the resource person identified for each of the ICUs participating in the study, and the instructors from the simulation centre. The research nurse will be in charge of identifying the individuals who meet the selection criteria given above. He/she will be in charge of orally giving necessary information, providing the study objectives, its precise sequence; of handing out and explaining the information sheet and getting the No Objection Form signed (Annex 1). The nurse investigator must follow the instructions defined in the precedent chapter.

iii. Initial evaluation

Initial evaluation is programmed in such a way as to have certain parameters at the time of inclusion. This evaluation is for participants (nurses) and also for executives of each partner ICU.

Data collected for the carer:

26 2 years is the lapse of time after which an agent may be considered as being genuinely independent in his/her job.
- data concerning socio-demographic and socio-organisational characteristics: gender, age, ICU ward, working hours, seniority in the profession, seniority on ICU ward, seniority in the institute.

- The “SISTRESSREA” questionnaire which is a combination of:
  - Karasek’s questionnaire,
  - the COPSOQ questionnaire

Initial evaluation is performed after at least 2 days of consecutive rest and at the beginning of a work shift. All of the questionnaires used in our study have been translated into French and validated. Psychometric qualities have also been checked.

Questionnaires will be filled in on paper and collected data will be entirely anonymous and confidential.

The research nurse in charge of the protocol will ensure that the questionnaire is filled out anonymously and discreetly. It should take 10 to 15 minutes to fill in.

Data collected from executives of partner departments:

Data concerning ward characteristics will be collected.

- Number of beds, number of carers, rate of occupancy, rate of mortality.

They must also provide the following elements.

Usual practices used on the ward to cope with daily “stressful” situations:

- Lectures, given by the physicians and/or advanced practice registered nurses, on pathologies and healthcare techniques specific to the ward
- Weekly and/or monthly meetings
- Counselling support units between the executive and the carer
- Practice analysis (evaluation and professional assistance group) followed by debriefing
- If there is one, help from the “burnout unit” of the institute
- Others

At the end of the initial evaluation, “control” group members will go back to their usual work schedule. “Interventional” group members will start the training course 7 days later at the most.
Six and twelve months after this first evaluation, or at departure if the agent leaves before 12 months have passed, the nurses included in the study will again be asked to fill in the following questionnaires, this time on a tablet computer:

- Karasek’s questionnaire,
- the COPSOQ questionnaire

The executives will also be required to give the number of beds, the number of carers, occupancy rate and mortality rate. They will also have to provide the number of days of absence for each agent participating in the study.
5. **MODE OF DATA TRANSMISSION**

The nurses included in the study are asked to fill in a questionnaire at T0, T6 (6 months) then at T12 (12 months). Data is collected anonymously. The questionnaire is numbered so as to guarantee the anonymity of the person who fills it in. These questionnaires are centralised by the resource person identified in each collaborating centre. They will then be collected by the project leader research nurse, at the different collaborating centres during the “progress” meeting held for this study. Indeed, collaborating centres will receive visits in order to explain to the ward executive the role of the project leader, how inclusion is carried out and to make filling the questionnaires in easier. These visits will take place according to the training schedule proposed by the simulation centre PYTHEAS.

Data will then be recorded by the project leader research nurse through an input mask prepared by the Unit for Methodological Assistance in Clinical Research (Pr Auquier, AP-HM) in the study’s managing centre.

6. **RESEARCH DURATION AND METHODS OF ORGANISATION**

I. **Expected study duration**

**Beginning of training courses**: First trimester 2016

**Total study duration**: 48 months

**Inclusion period**: 36 months

This length of inclusion period was chosen to adjust to the organisation of each ward. It would effectively be impossible to send half of a ward’s staff on a training course in a span of one year, especially given the current difficulties encountered in healthcare institutes.

**Duration of participation for one nurse**: 1 year

IV.1. **Expected research calendar**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2015</td>
<td>South Mediterranean Research Ethics Board I</td>
</tr>
<tr>
<td>May 2015</td>
<td>CCTIRS (French advisory committee for processing of</td>
</tr>
</tbody>
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7. METHOD OF DATA ANALYSIS

I. Statistical analysis

Methodology will be based on CONSORT Consolidated Standards of Reporting Trials Statement guidelines (CONSORT, [http://www.consortstatement.org/consortstatement/](http://www.consortstatement.org/consortstatement/)). Data analysis will be performed using SPSS version 17.0 software for Windows, by the statistician from the Unit of Methodological Assistance for Clinical Research, AP-HM (supervisor Pr Pascal Auquier, referring doctor Dr Karine Baumstarck). The main principles of analysis are given below. However a specific analysis protocol will be drawn up in further detail and submitted for validation (coordinating investigator, associate investigators, head of analysis, biostatistician).

Statistical processing will only begin once the validity of the database has been checked (requests transmitted to clinicians involved in the study, coherency checks). There is a procedure and an anonymisation algorithm which assigns a number to each individual. A correlation table will be available, separate from the exploited database. Only the number will be entered into the database. The database will then be frozen. Once it is frozen the consolidated data will be analysed by the statistician.

- Populations analysed

Statistical analysis will focus on the intent-to-treat population (principal analysis), excluding individuals for whom a major breach of protocol is observed (no objective data post-analysis, individual erroneously included). Complementary analysis will be performed on the per protocol population (secondary analysis).

- Population description, initial comparability of the groups

First, there will be a descriptive analysis of the entire sample. Qualitative variables will be given as numbers and proportions, while quantitative variables will be given as averages and standard deviation, or medians and quartiles. The proportion of missing data will be provided for each variable. Parameter normality will be checked using frequency histograms and Shapiro-Wilk
normality tests; simple mathematical transformations may be used to normalize non-normal data. Comparability of the 2 groups will be calculated for all of the variables available at inclusion in order to check initial comparability: using chi-squared tests for qualitative variables, and ANOVA or Kruskall-Wallis tests for quantitative variables. Comparative analysis will be blinded, so that neither the statistician, nor the project leader will know the groups’ identities. Once the analysis is finished the groups’ identities will be revealed.

- Analysis of evaluation criteria

Analysis of the main criteria, i.e. the comparison of the proportion of individuals with high-strain jobs in both groups, will be calculated using a chi-squared test. This procedure will be repeated at 12 months. Scores from the COPSOQ will also be calculated and compared between both groups, at both evaluation times. The number of intents to leave and actual departures will be compared between both groups.

- Multivariate analysis

Multivariate analysis will be performed using linear regression models. The variable which needs explaining will be represented by the presence of a high level of job strain at 6 months; explanatory variables will be selected either with a univariate approach to identify variables with a p-value of 0.20 or below (leading to selection of the variable group), or with a prior identification of variables potentially associated to these parameters. Results will be given in standardised beta form. This procedure will be repeated at 12 months, and used for other continuous parameters (COPSOQ scores).

II. Ethical and legal aspects

a. Regulations

This research protocol comes under Act n°78-17 of 6 January 1978 on information technology, data files and civil liberties, known as the loi informatique et libertés, (French Data Protection Act) amended on 6 August 2004, by Act n°2004-801 relative to the protection of individuals with regards to personal data processing, due to processing personal data, due to non-automatic processing of personal data appearing in a file. This protocol will be submitted to the Comité de Protection des Personnes Sud-Méditerranée I (South Mediterranean Research Ethics Board I).

b. CCTIRS/CNIL Submission

This research protocol therefore comes under Act n°78-17 of 6 January 1978 on information technology, data files and civil liberties (French Data Protection Act) amended on 6 August 2004, by
Act n°2004-801. Before it effectively begins, processing of data collected for research will be submitted to the CCTIRS (French advisory committee for processing of information in healthcare research) due to it being a multicentre protocol, then to the CNIL (French National Commission for Data Protection). Information concerning the rights of the participants in this research study will be given on the information sheet/No Objection Form.

**c. Data confidentiality**

Medical and non-medical staff participating in this research study are bound by medical and professional secrecy with regards to the collected data.
8. JUSTIFICATION OF SAMPLE SIZE OR POWER ANALYSIS

The sample size necessary was calculated from the main criteria for judgment, which is to determine the proportion of people who have high levels of job strain using Karasek’s questionnaire. If we look at the French paper by Pougnet [2012], which is the only international publication to provide this information, and also a study carried out within the AP-HM [Lehucher 2011], 60% of carers would have high levels of job strain. If our hypothesis is to reduce this proportion to 45%, for 80% power and an alpha risk of 5%, considering a study plan with one intermediate and one final analysis, according to the O'Brien-Fleming design we would need 188 individuals per group. Intermediate analysis will be carried out halfway through the inclusion period for the main judgment criteria (Intermediate p-value of 0.003). Final analysis will be carried out at the end of the inclusion period (final p-value of 0.005) [N PASS 14.0.8]. We think that we therefore have the 400 nurses necessary for the study.