

Concorso n.2 posti nel profilo di Ricercatore Sanitario - Categoria DS –  
 Laureati in Scienze Infermieristiche – Ricerca Traslationale e Clinica dell'Istituto Regina Elena

### Prova teorica-pratica

1) Domanda Generale:

*Spiegare l'approccio Evidence-Based-Practice (EBP) e le sue fasi.*

2) Domanda Specifica:

*Cosa si intende per Good Clinical Practice (GCP) e quali sono le loro finalità.*



*SEP*

### BUSTA N. 2

Concorso n.2 posti nel profilo di Ricercatore Sanitario - Categoria DS –  
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### Prova teorica-pratica

1) Domanda Generale:

*Elencare e spiegare in maniera sintetica i principi basilari della Bioetica.*

2) Domanda Specifica:

*Descrivere il Regolamento Europeo 536/2014 sulle sperimentazioni cliniche di medicinali per uso umano e la sua piena operatività.*



### BUSTA N. 3

Concorso n.2 posti nel profilo di Ricercatore Sanitario - Categoria DS –  
 Laureati in Scienze Infermieristiche – Ricerca Traslationale e Clinica dell'Istituto Regina Elena

### Prova teorica-pratica

1) Domanda Generale:

*Definire il Processo di Nursing.*

2) Domanda Specifica:

*Spiegare quali sono i requisiti minimi necessari per le Strutture Sanitarie che effettuano sperimentazioni di Fase 1. Contenuti della Determina dell'AIFA n. 809/2015*



*SEP*

## DOMANDE ORALE

1. La Job Description dell'Infermiere di Ricerca: cosa inserire come Requisiti, Compiti e Responsabilità?
2. Descrivere la procedura di monitoraggio e segnalazione degli eventi avversi durante la somministrazione di farmaci sperimentali.
3. Descrivere la tracciabilità del campione biologico prelevato ai pazienti arruolati negli studi clinici.
4. Descrivere cosa è una sperimentazione clinica e le sue fasi.

Gauli

8

Or



## Domande Informatica

1. Cos'è il Provider
2. Cosa significa Login
3. Cos'è word
4. Cos'è la posta elettronica
5. Cos'è il backup
6. Definizione di account
7. Definizione di motore di ricerca
8. Definizione di browser
9. Definizione di software
10. Definizione di scanner
11. Definizione di hardware
12. Che cos'è Excel
13. Cosa significa zippare un documento
14. Che cos'è una USB
15. Definizione di file
16. La firma digitale
17. La PEC
18. Cos'è un data-base?
19. Che cosa comprende il pacchetto office?
20. A cosa serve il programma Power Point?
21. Per cosa vengono utilizzate le formule in Excel
22. Cosa indica l'estensione .xls?
23. Cosa indica l'estensione .doc?



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# Nursing role in the assessment and care of hepatic sinusoidal obstruction syndrome patients: a consensus paper by the “Gruppo Italiano Trapianto di Midollo Osseo”

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## Abstract

**Purpose** Sinusoidal obstruction syndrome (SOS) is one of the most serious complications post haematopoietic stem cell transplantation (HSCT). The diagnosis of SOS is clinical, but nurses should be involved in the pre-transplant risk assessment period and play a crucial role in the early detection of signs and symptoms during and after hospitalization. The aim of this work is to achieve a consensus on nurses' behaviour in caring for SOS.

**Methods** On behalf of the Italian Group for Bone and Marrow Transplantation (GITMO), a promoter committee was established to put in place a consensus conference approach. A multidisciplinary group of GITMO together with four nurses, three haematology physicians and one patient representative acted as jury, who reviewed the reports and wrote recommendations and suggestions. Recommendations gaining 100% of consensus were considered ‘Golden Points of Care’; if a consensus was achieved by  $\geq 75\%$  of the jury's members, those recommendations were defined as ‘Good Practices’.

**Results** Eighteen papers written by nurses as first authors have been identified. Golden Points of Care and Good Practices were worked out for the following topics: nurses' role in general, nurses' role in pre-transplant assessment, pre-transplant risk assessment and risk stratification, baseline monitoring, suspected mild or moderate SOS, suspected severe or very severe SOS and late-onset cases.

**Conclusion** SOS is relatively rare; therefore, a holistic approach to the patients' needs considering nursing role as essential may result in better care outcomes.

**Keywords** Sinusoidal obstruction syndrome · Veno-occlusive disease · Endothelial complications · Multi-organ failure · Stem cell transplantation · Nurse management

## Introduction

Haematopoietic stem cell transplantation (HSCT) is a standard therapy used to treat various onco-haematological malignancies. One of the most serious complications related to endothelial damage due to conditioning regimens is hepatic sinusoidal obstruction syndrome (SOS), also known as veno-

occlusive disease (VOD) [1]. It is a complex disease due to toxic metabolites producing endothelial activation with changes in the sinusoids' permeability, inflammation and haemostatic activation leading to sinusoids' obstruction. SOS may affect both autologous and allogeneic HSCT patients and it could result in a hepatorenal syndrome, hepatocellular fibrosis and necrosis, and hepatic failure, as well as multi-organ disease and death. Literature shows that mild and moderate SOS forms are often self-limiting or responsive to supportive therapies, whilst severe forms are associated with a high mortality rate, exceeding 80% [2]. This has a significant impact on patient outcomes [3] and costs [4–7]. On a clinical basis, SOS is characterized by increased liver volume,

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associated with right upper quadrant pain, jaundice, fluid retention and ascites [8, 9]. It may rapidly evolve towards life-threatening conditions such as multi-organ failure (MOF) [2, 10]. SOS incidence in HSCT population is about 14%, but it can vary depending on a number of risk factors (RFs) and clinical criteria used [11, 12]. The diagnosis of SOS is clinical [13, 14] because of a lack of imaging techniques or biochemical markers, which would be able to provide a disease definition [15]. Furthermore, there is a real difficulty for HSCT patients that undergo liver biopsies, especially during the early post-transplant period.

The diagnostic clinical criteria commonly used in practice, as well as in many clinical trials (Seattle [16], Seattle modified [3] and Baltimore criteria [17]), provide various disease definitions and different data on SOS incidence (Seattle 17.3%, Baltimore 9.6%) [2]. Recent changes in HSCT led to the need for new tools for prognosis in SOS. Furthermore, the lack of criteria for “late-onset forms” diagnosis, which represent about 15–20% of cases [18–20], and the need to optimize treatment-related behaviours and costs [13] required a new definition of the disease. Addressing these issues, Mohty et al. (2016) and Corbacioglu et al. (2017) presented the European Society for Blood and Marrow Transplantation (EBMT) criteria for adult [13] and paediatric [21] patients. In addition to the definitions of the “classical” forms of SOS, a specific tool for the “Late Onset Cases” diagnosis and two tools (paediatrics and adults) for the grading of suspected SOS were added.

Early recognition, diagnosis and treatment are crucial aspects to limit SOS’ severity increasing chances of success [22–25]. Some authors state that nurses should be involved in a pre-transplant risk assessment to optimize risk factor detection and that they have a crucial role in the early detection of signs and symptoms during and after hospitalization [26–33]. Many clinical issues have been investigated; nursing issues have been studied as well, but there is a lack of specific topics such as assessment, monitoring techniques and care standards.

## Materials and methods

### The consensus conference

A consensus conference (CC) approach has been put in place, focusing on caring for adult and paediatric patients undergoing HSCT who are at risk of developing SOS. The aim of a CC is to obtain useful recommendations for health care professionals to deal with critical situations. Recommendations are gained by an expert group which analyses available literature, searches for critical appraisal and synthesizes the literature on a topic with huge clinical, organizational and practical assistance differences.

### The involved professionals and their roles

On behalf of the Italian Group for Bone and Marrow Transplantation (GITMO), a promoter committee (PC) composed of a methodologist, a research nurse and two head HSCT nurses was established. An expert panel (EP) composed of 19 members (17 nurses and 2 physicians), coming from different Italian transplant centres, was identified and worked under the supervision of a research coordinator, analysing the available literature, investigating the research questions and defining the structure of the work. The PC led and supervised the whole process, establishing subgroups of the EP in relation to the topics; their leaders were selected on the basis of their specific competencies. A multidisciplinary group of GITMO (four nurses and three physicians working in adult and paediatric transplant settings) and two experts in research methodology together with one independent haematology physician and one patient representative acted as jury.

### Organization of the consensus conference

The PC identified the research questions and conducted literature research on the main databases (PubMed, Cinahl, Embase, Scopus, Cochrane Library) searching for papers written primarily by nurses. Some research, such as the nurse’s role in SOS management, pre-transplant risk assessment and stratification, risk-related baseline monitoring, assessment and monitoring of patients with suspected SOS and assessment and monitoring of “late-onset forms”, were defined previously by the PC. The selected literature was tabulated by title, year, type of question, design, population, objectives, outcomes, relevance and suggestions/recommendations and sent to the EP.

Three EP scheduled meetings were assessed between March and August 2017 and some teleconference meetings were performed. The jury reviewed the reports and wrote recommendations and suggestions, which were first managed by the CC through voting. Recommendations gaining 100% consensus were considered Golden Points of Care. If a consensus was achieved by  $\geq 75\%$  of the jury’s members, those recommendations were defined as Good Practices. A public committee of non-specialists (students, managers, health care professionals, citizens) was also invited to assist the meetings as observers.

## Results

Eighteen papers written by nurses as first authors have been identified. Five articles were preliminarily excluded by the PC



due to full-text unavailability or because of being comments or letters on other articles without adding useful input. The remaining full-text articles (Table 1) were selected for the EP work which approached them, using a critical appraisal system.

### General nurses' role

Golden Point of Care: "Nurses play a fundamental role in SOS management and should use a proactive approach managing patients".

Good Practices:

- "Nurses who work in BMT units should have advanced knowledge and documented skills about SOS diagnosis and management"
- "Nurses should promote patient's education regarding SOS"
- "Nurses are responsible for the quality of data collected during patient assessment and monitoring, their documentation and evaluation of non-conformities"

Management of SOS/VOD patients is complex due to its unpredictable features [34]. It is a shared opinion in the literature that nurses play a decisive role in SOS management [13, 30] especially during assessment and monitoring activities [27, 32, 35, 36]. The group discussed some typical relationship aspects between patients and nurses such as time of care, confidence and closeness that have been considered as facilitating factors of recognizing SOS signs. Given that a careful recognition of signs and symptoms is fundamental for early diagnosis [10, 37], it was agreed by the group that SOS management requires specifically trained nurses. BMT nursing staff should approach patients using a proactive model of care [27, 31, 32].

The group agreed that nurses are directly responsible for the quality and documentation of collected data, as well as early and effective communication with physicians about non-conformities.

### Nurses' role—pre-transplant assessment

Golden Point of Care: "Nurses should be involved during the pre-HSCT risk assessment path and share the results before patient admission in the HSCT unit".

Good Practice:

- "Nurses should refer to specific assessment protocols during the pre-transplant assessment"

A good assessment should include other than vital signs and biochemical tests, patients' personal data and lifestyle, clinical history and therapeutic program, performance status and nutritional conditions as well as abdominal evaluation and

hepatic disorder signs (jaundice, bleeding). Monitoring of weight variations will be fundamental during patient's hospital stay, a baseline measure should be registered before admission and a threshold of 5% increase should be determined.

### Pre-transplant risk assessment and risk stratification

Golden Point of Care: "Pre-transplant risk level attribution for SOS development should be put in place taking into account the results of a careful and thorough assessment performed by the multi-professional team".

Good Practice:

- "Bioethics Committees could give useful support in making transplantation decisions for very complex cases"

Objectives of pre-treatment assessment are the detection of RFs for SOS/VOD development and whenever possible the reduction of their impact before treatment [13].

Haematology physicians are responsible for therapeutic strategies that may be offered to patients; however, the assessment approach should involve different professionals such as nurses and other specialists [30]. The assessment for patients undergoing HSCT includes specific nursing responsibilities [27], and a multi-professional approach during the whole peri-transplant period. The main RFs for SOS development are summarized in Table 2. Assessment interventions cannot always be performed simultaneously by doctors and nurses but the sharing of results amongst health care professionals seems very important [31]. The EP agreed that it is fundamental for nurses to participate at the pre-transplant risk assessment process and to know the results and decisions taken in order to reduce transplantation risks before patient admission into the BMT unit.

Discussion within the EP was largely focused on SOS risk stratification. In 1993, Bearman and colleagues [38] developed an outcome-based predictive model for severe SOS. However, this model seems to be useful only in a very particular setting; therefore, it was not taken into consideration by the EP.

Some authors [37, 39] considered the odds ratio (OR) as a useful element for risk stratification, although doubts remain about its reliability and its significance when patients present multiple RFs. For this reason, a proposal based on OR was considered inadequate by the EP. The EP proposed to stratify patients as:

- Patients at high risk (HR) of SOS who present one or more RFs reported by Mohty et al. (2016) and Corbacioglu et al. (2018)
- All HSCT patients without RFs were considered at standard risk (SR) of SOS

Taking into account these considerations, a pre-transplant assessment protocol was made and synthesized in Table 3.