REDELVE INTERNATIONAL PUBLICATIONS

Journal of Emergency Medicine and Primary Care
Volume 2019, Issue 01
REVIEW ARTICLE: RD-EMP-10006

The Patient Safety in Continuous Renal Replacement Therapies (Crrt): A Standardized Approach

Federico Nalesso[1], Francesco Garzotto[2], Giuseppe Scaparrotta[1], Barbara Rossi[1], Leda Cattarin[1], Matteo Rigato[1], Luciana Bonfante[1], and Lorenzo A Calò[1*]

*[*1]Department of Medicine (DIMED), Nephrology, Dialysis and Transplantation Unit University of Padova-Azienda Ospedaliera di Padova, Italy*
[2]Health Technology Assessment Unit, Azienda Zero, Padova, Italy

***Corresponding Author:** Lorenzo A Calò MD, PhD, Department of Medicine, Nephrology, University of Padua, Via Giustiniani, 2, 35128 PADOVA Italy. Tel. ++39/049/8213071; Fax ++39/049/8217921; Email: renzcalo@unipd.it*

***Citation:** Nalesso F, Garzotto F, Scapparotta G, Rossi B, Cattarin L, et al. (2018) The Patient Safety in Continuous Renal Replacement Therapies (Crrt): A Standardized Approach. Emergency Medicine and Primary Care: RD-EMP-10006.*

***Received Date:** 29 December 2018; **Accepted Date:** 03 January 2019; **Published Date:** 11 January 2019*

Abstract

It is known that latent, systemic, organizational and clinical errors can occur in a clinical reality considered to be safe and lead to the occurrence of a critical event with possible consequences to the patient.

The greater clinical complexity of the patients suffering from AKI (Acute Kidney Injury) or CKD (Chronic Kidney Disease) requires an interdisciplinary approach of nephrologists and other specialists involved in the diagnostic-therapeutic-rehabilitative pathway that may require a personalized extracorporeal treatment provided both in a Nephrology Unit or in an Intensive Care Unit (ICU) according to the clinical patients' conditions.

In consideration of patients' comorbidities and the presence of clinical complexity, the Patient Safety becomes a priority objective in their diagnostic-therapeutic pathways. It is therefore necessary for nephrologists, and for the nursing staff to be able to acquire a complex competence in this field and specific tool suitable for the clinical risk analysis in the specific local realities in order to introduce all measures for the identification, analysis and prevention of errors that can lead to an incident.

The aim of this article is to introduce the safety problem of extracorporeal blood purification treatments for a preliminary initial local clinical risk analysis for errors prevention. This work is addressed to all caregivers involved in the care of patients.

Keywords: AKI; Extracorporeal Treatments; Error Prevention; Patient Safety; Risk Management

Introduction

In clinical practice, risks and incidents, that were previously not detected by the system, may be better identified introducing and implementing the culture of patient safety with its tools. The term “Patient Safety” identifies the set of actions and tools aimed at preventing errors and their effects in a specific diagnostic-therapeutic process in which the patient interacts with the Health System.

While health care is becoming increasingly effective, it also presents an ever-increasing complexity due to the extensive use of new technologies, drugs and medical treatments, in addition to the multidisciplinary approach due to comorbidities that requires a continuous communication between specialists for the transmission of health information.

Furthermore, the increased economic pressure on the Health System often leads to stressful work environments with considerable work overloads.

There cannot be quality of care without Patient Safety, as this is a dimension of quality itself. In order to ensure the best grade of safety, proceeding through an analytical vision, we can understand how within the Risk Management the adverse events can derive from organizational problems, problems related to the clinical practice, procedures and medical devices.

The improvement of Patient Safety requires a systematic effort at the system level, involving a wide range of actions in order to improve medical performance, the environment, the clinical risk management and devices use.

Extracorporeal purification treatments, that are already complex and subject to errors due to their high technology complexity, are a source of possible preventable and predictable incidents for patients when they are not performed in a specific designed setting such as the Nephrology and Hemodialysis Units, where the medical and nurse staff competence and experience are able to provide a higher degree of mitigation of the intrinsic clinical risk.

Patient Safety [1] culture is still not completely integrated into the assistance processes. It has been shown that clinical practice at any level is subject to errors inherent various diagnostic-therapeutic processes including errors in the use of drugs. These events can effectively be prevented, the Patient Safety culture must be extensively promoted in the Health System by customizing procedures, protocol and operating instructions for the individual local situations and needs without a rigorous standardization due to not flexible policies that cannot be effective and protective in every single care setting [2].

The patient safety in the administration of extracorporeal blood purification treatments

Each diagnostic-therapeutic process can be intrinsically "unsafe" and, therefore, it is necessary to approach the clinical practice in a pro-active and reactive way to mitigate the clinical risk. Even in an apparently ideal clinical setting there will always be the possibility of an event that

can determine an incident with various consequences for the patient. We are not able to act on unpredictable and therefore not preventable errors while we are able to act on preventable and predictable errors by implementing all measures suitable for their interception and prevention. However, if we apply a series of tools for detection, reporting, description and analysis of identified errors and incidents, we can introduce a dynamic system in the environment that can adapt the clinical practice to the specific local needs mitigating the clinical risk. Structuring the clinical activity and the environment according to the local necessities, we can determine a positive impact on safety since the Health System adapts to clinical needs, the local resources and the clinical risks inherent in the specific environment. In this clinical setting the more complex the medical care is, the more complex the management of clinical risk is.

The extracorporeal purification treatments are a source of clinical risk due to their organizational and technological complexity. The deriving errors can cause different degree of damage to the patient. The incidents, that can occur, include common events that we can identify daily in clinical practice and include the administration of less effective treatments, loss of blood by circuit clotting or serious hypotension during an excessive weight loss. If we analyze the whole process of extracorporeal depurative treatment administration, we can identify single phases and sub-phases that are source of errors. Every single phase can contain an error and be the cause of an incident. The complexity of this process exposes the patient to a higher clinical risk and requires designing a safe system based on risk management including mapping, identification, description and analysis of errors and incidents to change dynamically the system to implement its safety.

The clinical process that leads from the diagnosis of AKI/CKD to the prescription of the treatment and its subsequent delivery is very complex. We can identify several interconnected phases in which the presence of an error, even latent, can determine the occurrence of an accident, also in other phases not directly connected to each other.

In detail, we can identify errors related to an incorrect treatment prescription in terms of treatment type, non-standardized taxonomy, flows velocity, type of anticoagulation and materials (Table 1).

Error types	Consequences	Proposed corrective action
Errors in the taxonomy of treatment (E.g.: Prescription of CVVHDF without specification of dialysate flow rate, prescription of CVVH with reinfusion flow and dialysate flow).	Mismatch between the prescribed treatment and the parameters set in the prescription. Possible misinterpretation of missing data or omission to insert data by the nurse.	Introduction of appropriate taxonomy and standardized prescription criteria for each treatment in an electronic or paper format deliverable in the specific local reality.

Errors in the prescription related to the selection of materials not compliant with the type of treatment chosen:	Mismatch of materials between selected treatment and prescribed materials.	Standardization of treatments in terms of:
• Types of fluids for hemodiafiltration		• Equipment
• Filters – plasma separators		• Types of Filter
• Lines	K concentration inappropriate for the patient's clinical condition	• Types of Circuit
• Types of Monitor		• Types of Fluids
		• Setting of Operational Parameters
		• Anticoagulation Requirements and Types of Anticoagulation
	Filter inappropriate for the treatment prescribed	• Storage of Materials for Easy Availability
		Introduction of appropriate check lists
	Prescription of an ineffective depurative treatment for wrong or missing data	for all phases of extracorporeal blood purification treatment.
Errors in the setting of operating parameters of the prescribed treatment:	Mismatch between the type of treatment prescribed and the parameters of the treatment settled in the prescription	Introduction of appropriate taxonomy and standardized prescription criteria for each treatment in an electronic or paper format deliverable in the specific local reality
• Blood Flow Rate		
• Dialysate Flow Rate		

• Reinfusate Flow Rate	Incorrect setting of the parameters for the selected method in terms of ultrafiltration rate, depurative dose achieved and inadequate patient weight loss	Introduction of procedures for the prescription of depurative treatments in terms of delivered dose and flows rate to set for the different clinical needs
• Pre- and Post-Dilution Rate in Convective Treatment		
• Maximum Weight Loss Per Hour		
• Total Weight Loss		
• Total Time	Possible misinterpretation of missing data or omission of data by the nurse	Diffusion of procedures to all staff
• Heparin Infusion Rate or Citrate/Calcium Infusion Rate		
	Errors in the dose of anticoagulation or in the citrate/calcium compensation	Introduction of appropriate check lists
		For all phases of depurative extracorporeal treatment
Types of anticoagulation:	Risk of circuit clotting if heparin is not prescribed in patients with different hemorrhagic risk	Introduction of procedures of circuit management in the absence of anticoagulation to avoid circuit loss
• None		
• Heparin		
• LMWH	Increased risk of hemorrhage when heparin or LMWH anticoagulation are used in patients at risk	Introduction of procedures for the anticoagulation prescription in the depurative treatments in terms of total dose of anticoagulation (heparin and LMWH)

• Citrate		
	Metabolic alterations, coagulation of the circuit, hypo- or hyper-calcemia in case of incorrect flows setting in regional anticoagulation with citrate.	Introduction of procedures for the preparation of heparin solutions in terms of concentration and infusion rates
		Introduction of procedures for the management of patients in citrate treatment to enable changes in the settings of the treatment with a scheduled check list
		Introduction of appropriate check lists for all phases of depurative extracorporeal treatment

Table 1: Possible errors due to incorrect prescription of extracorporeal blood purification treatment.

Therefore, the non-completeness of a prescription can exposes the patient to a clinical risk that can lead to an incident of different seriousness. In fact, the lack of several treatment parameters can induce the free interpretation by the nurse who provides the treatment with wrong or missing parameters generating a risk.

The prescription transmission to the nurse or technician, and its subsequent understanding, can expose the process of monitor setting, priming and treatment delivering to potential errors; if these processes are not codified and protected by the use of standardized procedures, check lists and customized operative instructions for each single local reality, the interpersonal variability and the interpretation of incomplete information can be a source of errors with patient's exposure to higher clinical risk (Figure 1).

The process of treatment administration presents a series of phases potentially and intrinsically source of errors (Table 2): parameters setting, parameters revision during the treatment, patient's extracorporeal circulation beginning and ending, circuit and filter patency, and control of the achieved purification target. Therefore, it is important to proceed with one or more check list and specific procedures in order to allow the nurse to verify the correctness of entered data on the monitor and their congruency with the prescribed treatment.

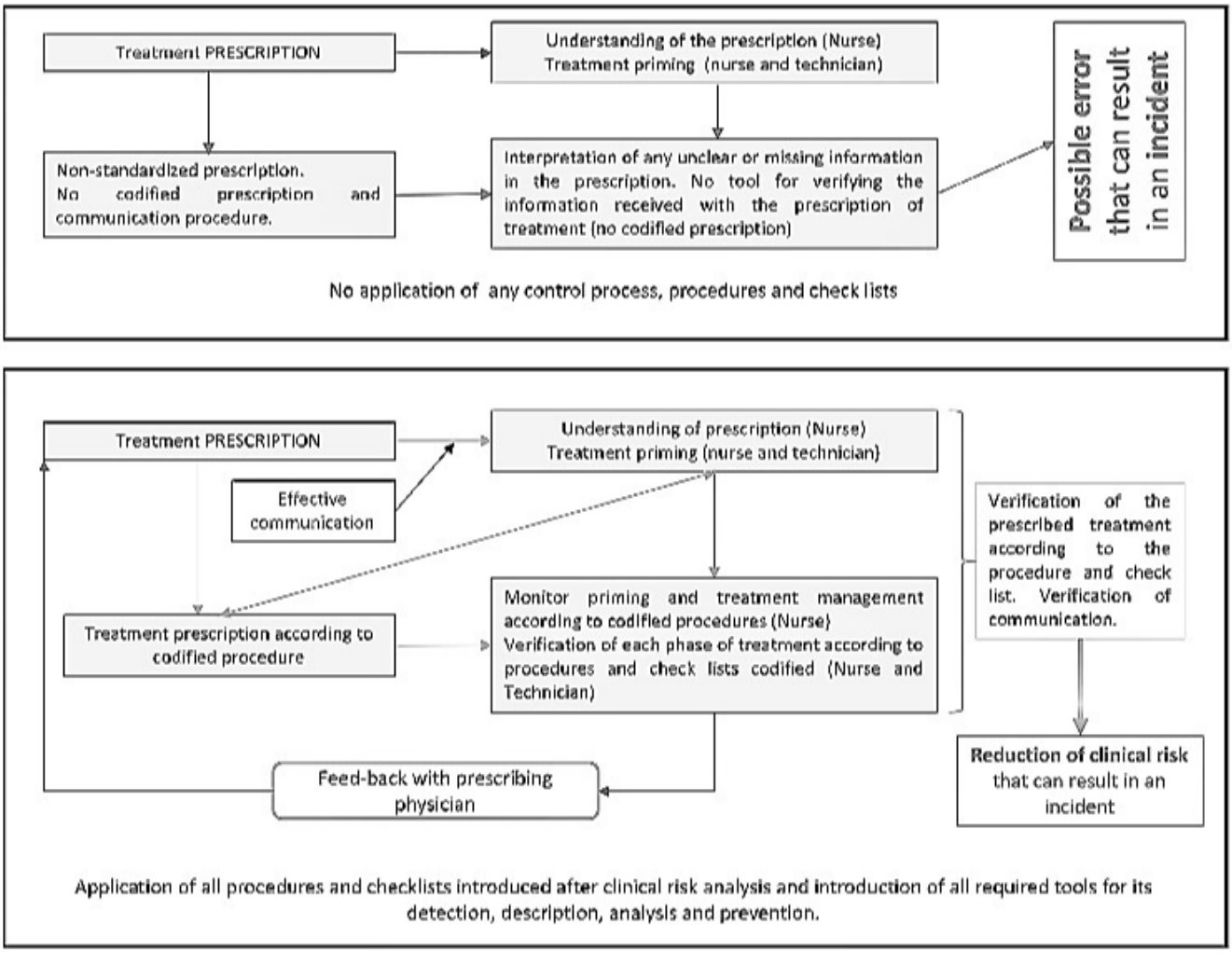

Figure 1: The interpersonal variability and the interpretation of incomplete information can be a source of errors with patient's exposure to higher clinical risk.

Types of action	Tools
Setting of the treatment parameters	1. Procedure for the management of the communication of the medical prescription to the nurse with related phase of parameters verification of the prescribed treatment and their setting in the monitor
	2. Check-list for the verification of the appropriate priming of the monitor
	3. Check-list for the correct treatment setting in the monitor in term of parameters, patient's name and weight
Connection and disconnection phases	Descriptive procedure for all phases for the connection and disconnection of the patient:
	1. Operative Instructions

	2. Materials Required
	3. Specific Recommendation According to The Possible Use of Different Disposable (Identify All Critical Issues)
Management of the treatment	Procedure for the management of the treatment. Operational parameters recording system for the monitoring of depuration efficiency
Alarm management	1. Procedure for the management of the most frequent and common alarms
	2. Easy and fast access to the treatment operative and user's manual
	3. Easy and fast access to the treatment operative and user's manual of the filter and the circuit
	4. Easy access to the monitor technical helpdesk (preferably by phone or email)
	5. Fast communication with the physician in charge for the treatment
	6. Definition of a protocol for the disconnection in case of unsolvable technical issue or clinical emergency (or monitor malfunction)
Complications management	Management of the most common complications by using a operational procedure for nurses and nephrologists (symptomatic or asymptomatic hypotension, hypokalemia at the beginning or during treatment with need of correction).

Table 2: Delivery and supervision of the treatment.

The priming phase and the administration of treatment must be described by procedures that provide also checklist to identify deviations from standards and errors. Importance is attributed to the staff training in treatments management. All nurses must be able to understand if there are "deviations" from the standard prescription, as codified by the standard procedure, or if there are functional abnormalities requiring intervention. The use of dedicated and trained personnel allows to reduce possibility of errors.

Otherwise employment of non-dedicated personnel, exposes patients to a significant clinical risk due to lack of higher competence and experiences that allow the operator to act in the environment preventing the error occurrence, rather than its late detection. Thus, it is possible to introduce a protective patient safety level directed towards a pro-active rather than re-active approach. Therefore, continuous training of all caregivers will be able to maintain a high level of competence, guaranteeing the safest administration of such treatments, even in stress situations.

Nurses, who perform the purification treatments in ICU, often are Nephrology nurses that temporarily stand out in a "not-friendly environment" where the supplying of materials,

disposable and drugs may not be prompt and corresponding to the contingent requests. It is suggested to share standardized and well-known procedures in all care environments outside Nephrology in order to make the different settings safer. It is necessary to create a communicative and collaborative alliance with the dialysis nurses to require and obtain immediate answers to technical or clinical issues, if the treatment management and supervision are provided by nurses from other Units. Nurses from ICU can occasionally perform extracorporeal treatments; this eventuality, exposes patients to higher clinical risks than the specific use of a pool of dedicated and trained nurses from Nephrology Unit.

Interdisciplinary and intradisciplinary communication is the fundamental element for the security alliance

In an environment outside Nephrology Unit where more professional figures collaborate it is necessary to implement communication; first, by standardizing and spreading the culture of extracorporeal treatments, and promoting treatments taxonomic knowledge. It is also important to use a common and shared language related to the parameters used in the blood purification techniques [3] and in the field of AKI.

The structured communication increases the safety of the information flow related to the patient's clinical conditions [4] and the extracorporeal treatment. The introduction of a communication model shared by everyone allows to "send and receive information" in a safer way [5]. For example, the use of the SBAR (Situation, Background, Assessment, Recommendations) model [6] codifies a highly secure communication system, therefore both the receiver and the sender know the quality of the shared information, speaking the same language. In the event of a communication error or lack of information, sender and receiver can identify anomalies and implement all appropriate measures to retrieve the missing information. In this modality the communication configures a "closed loop communication" reducing the probability of communication error or incorrect interpretation of transmitted information.

An additional clinical risk associated with the handover may be overcome planning that a treatment is initiated and discontinued by the same staff avoiding errors connected with lack of communication of information. Furthermore, to make the handover a safer process, it is preferable to adopt check lists and customized communication procedures, which allow the various operators to transfer in a complete and exhaustive way all information related to the purification treatment in terms of operational parameters, vascular access, real purification dose, patient complications and drugs management.

It would be preferable that the administration of drugs was performed directly by the nurse in charge. This concerns mainly the drugs that are postponed at the end of the treatment because of their "dialysability" or that are administered in additional dose before or during the treatment ensuring the effective blood concentration over time. The drug preparation and administration process should be performed by a single nurse thus the responsibility has to be attributed to the same nurse, avoiding communication errors.

The therapeutic alliance and the Patient Safety must aim to promote an effective collaboration and communication among all caregivers allowing the synergistic integration of skills for the

safe multidisciplinary management [7,8]. This is especially important when patients are treated in Units other than Nephrology or are treated in the Hemodialysis Unit coming from other Centers with specific and different medical and nurse staff.

As operational tools, it is recommended to implement the incident reporting and communication. It is suggested to promote regular briefing and de-briefing in order to evaluate, identify and analyze the clinical practice among caregivers. The promotion of "just culture" [9] and the incident reporting will increase the safety by involving all caregivers in an alliance in which everyone will be inclined to report an incident knowing that the focus is on "how and why" an accident occurred rather than "who" made the mistake. As a proactive approach, risk mapping is recommended to be performed through the use of FMEA (Failure Mode and Effect Analysis) [9] in order to assess the clinical risk associated with the issues identified during the analysis and to prioritize corrective actions according to the Risk Priority Number (RPN); it is also suggested to perform at least a six-month safety walk round [10] in every local environment to promote the safety culture [11]. All these tools and information will be useful to proceed with the introduction of procedures, operative instructions, check lists for all critical phases of the clinical setting. In case of incident we suggest performing a multi-disciplinary team approach, known as Root Cause Analysis (RCA) in order to study the event with the goal to find out what happened, why it happened, and how to prevent it from happening again.

Conclusion

The extracorporeal blood purification treatment administration is a process that presents an intrinsic degree of "unsafety" due to technological complexity and the critical patient's condition.

The problem of the competence and experience of nurses who administer extracorporeal therapy is particularly important in ICU. The possibility of having a pool of nurses dedicated to all extracorporeal purification treatments increases the competence and skill in this filed by reducing the clinical risk.

The analysis of the clinical risk in every single reality allows designing a safer system in a proactive way. The extensive use of the incident reporting system allows the description and analysis of all events with the consequent system correction in a reactive way. The set of proactive and reactive actions make the system safer by reducing the occurrence of events. The introduction of procedure and check lists allows to increase patient safety in a dynamic way according to the specific needs. This approach will be particularly effective when the safety culture is promoted and implemented by introducing the concept of "no blame" cultures by involving all caregivers in an alliance in which everyone will be inclined to report an incident, knowing that the focus is on "how and why" an accident occurred rather than "who" made the mistake.

The management of drug delivery must be codified and regulated by specific procedures, especially when the patient under extracorporeal depurative therapy is hospitalized in ICU or in units other than Nephrology.
The introduction of a communication model shared by all caregivers allows to send and receive information in a safer and complete way. Finally, the promotion of regular briefing and de-

briefing is useful in order to evaluate, identify and analyze the clinical practice and the communication among caregivers.

Disclosure

The authors declare no conflict of interest.

References

1. Kohn LT, Corrigan JM, Donaldson MS (2000) To Err is Human-Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS eds. National Academies Press. Washington DC. ISBN 978-0-309-06837-6. DOI 10.17226/9728
2. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, et al. (1991) Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. New Engl J Med 324:370-376.
3. Villa G, Neri M, Bellomo R, Cerda J, De Gaudio AR, et al. (2016) Nomenclature Standardization Initiative (NSI) Alliance. Nomenclature for renal replacement therapy and blood purification techniques in critically ill patients: practical applications. Crit Care 20:283.
4. De Meester K, Verspuy M, Monsieurs KG, Van Bogaert P (2013) SBAR improves nurse-physician communication and reduces unexpected death: a pre and post intervention study. Resuscitation 84: 1192-1196.
5. Frank JR, Brien S (2009) The Safety Competencies - Enhancing Patient Safety Across the Health Professions. Canadian Patient Safety Institute. ISBN 978-1-926541-15-0
6. Pope BB, Rodzen L, Spross G (2008) Raising the SBAR: how better communication improves patient outcomes. Nursing 38: 41-43.
7. Anderson ES, Gray R, Price K (2017) Patient safety and interprofessional education: A report of key issues from two interprofessional workshops. J Interprof Care 31: 154-163.
8. Edwards MT (2018) An Assessment of the Impact of Just Culture on Quality and Safety in US Hospitals. Am J Med Qual 33:502-508.
9. Stamatis DH (2003) Failure Mode and Effect Analysis: FMEA from Theory to Execution. American Society for Quality Press; 2nd edition, Milwaukee Wisconsin 5323, November 2003. ISBN: 978-0873895989.
10. Quality and Safety Walk-Rounds: A Co-Designed Approach: Toolkit and Case Study Report. Health Service Executive Quality Improvement Division, June 2016 ISBN 978-1-78602-019-2.
11. Thomas EJ, Sexton JB, Neilands TB, Frankel A, Helmreich RL (2005) The effect of executive walk rounds on nurse safety climate attitudes: a randomized trial of clinical nits [ISRCTN85147255] [corrected]. BMC Health Serv Res 5:28. Erratum in: BMC Health Serv Res 5:4.