

# Hemodialysis Patient Safety Instruments: A Systematic Review

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#### ABSTRACT

Hemodialysis is a technically complex procedure with many potential adverse events that can harm patients when they occur. However, hemodialysis services have not been fully implemented in standard operating procedures such as the administration process or hemodialysis programming, resulting in discomfort, adverse events, and the possibility of mild to severe patient incidents. This study aimed to review and criticize various instruments that discuss research and development of instruments to prevent adverse events in hemodialysis services. Articles from 2013 to 2023 were chosen from Scopus, Pubmed, ScienceDirect, and Web of Science. The terms used were hemodialysis safety, hemodialysis patient safety, and hemodialysis patient safety instrument based on paper, website, and technology. Overall, the review consists of 12 articles. This review discusses strategies for developing innovation, technology, or patient safety instruments and reporting to reduce adverse events and improve patient safety. The development of patient safety instruments can reduce adverse events and improve patient safety so that it can impact the aspects of improving the quality of service of a health care institution, especially hemodialysis services.

*Keywords: Dialysis patient safety instrument, Hemodialysis, Hemodialysis patient safety instrument.* 

#### **INTRODUCTION**

Management of patients with Chronic Kidney Disease (CKD) can be conservative or undergo renal replacement therapy (TPG), one of which is hemodialysis (Braun & Khayat, 2021). Hemodialysis is a hospital service sector with a significant potential risk for Adverse events (AEs); this occurs due to several factors such as complicated procedures, the use of high technology, characteristics of chronic kidney disease, and the use of high-alert drugs (Rocha, 2022). Hemodialysis services have not fully implemented standard operational procedures in the administration and programming of hemodialysis, so that mild to severe incidents in patients (Fitrianeti & Dominata, 2021).

It is estimated that 2-4% of CKD patient deaths can be attributed to hemodialysis-related complications (Bray & Metcalfe, 2015; Thomas et al., 2016). A Brazilian study on the prevalence and factors related to the incidence of AEs in hemodialysis services recorded 1110 AE with prevalence in 98.03% of patients, medication errors (45.2%) and inadequate blood flow (42.9%).



Regarding the level of danger, most of the events were mild (93.8%), followed by moderate (5.9%), and severe (0.3%) criteria (Lessa et al., 2018).

A way to ensure patient safety is to create strategies that can prevent patient safety incidents that exist in health services, especially complex services such as hemodialysis units, which, based on the characteristics of their procedures, are at risk of patient safety incidents (de Oliveira Lessa Mendes et al., 2020). The potential deviation of safety procedures and hemodialysis service quality impact on the emergence of AEs because one of the factors is the absence of instrument-based communication to ensure patient safety (Marcelli et al., 2015). The checklist instrument is one solution to improve safety culture in hemodialysis services. Three different researchers developed the instrument checklist regarding the safety of hemodialysis procedures. These three checklists combine three phases of patient safety checks, namely pre-HD session, HD initiation session, and post-HD session, which have been proven to influence the improvement of safety culture and quality of care (Galland et al., 2013; Marcelli et al., 2015; Thomas et al., 2016).

Based on the search results, there needs to be more study about preventing patient safety incidents in the form of an innovation or a particular instrument of patient safety hemodialysis services. This study conducts a systematic review of journals that discuss any innovation or development of hemodialysis patient safety instruments and their effectiveness so that it is likely to refer to the implementation of special patient safety procedures hemodialysis services in clinics or hospitals to be more optimal.

### MATERIAL AND METHODS

### **Search Method and Identification**

The literature search method used in this systematic review was selected from four indexed electronic databases: Scopus, Science Direct, Web of Science, and Pubmed. Keywords used the term Medical Subject Heading (MeSH). Keywords and subject titles are used in searching for articles with keywords "Hemodialysis" OR "Dialysis" AND "Patient Safety" OR "Safety" AND "Instrument" OR "Innovation" in English. Search articles using boolean operators (AND, OR NOT, or AND NOT). Article search results are written with flow charts. The feasibility of the study was assessed using the PICOS framework with Population: Patients undergoing regular hemodialysis and hemodialysis patient safety in health care facilities, Intervention: hemodialysis patient safety instruments improve hemodialysis patient safety, Study design & publication type: quantitative and qualitative study, Publication years: Year of article used 2013 – 2023.

Searches through the above keywords resulted in 36 articles from *Scopus*, 63 articles from *Science Direct*, 48 articles from *Web of Science*, and 143 articles from *Pubmed*, with a total of 290 articles from all articles after being re-studied according to the topic then obtained 12 articles in English. This systematic review aimed to collate, summarise, and report on related study findings to identify evidence gaps,draw conclusions from the existing literature review and criticize various instruments that discuss research and development of instruments to prevent adverse events in hemodialysis services.

### **RESULTS AND DISCUSSION**

### RESULT

### **Population**

The population in this study is 12 international journals related to the theme of patient safety instrument development in hemodialysis services. Based on the population characteristics

mentioned in the inclusion and exclusion criteria. The criteria for inclusion and exclusion have been explained in Table 1 of the PICOS framework.

Table 1. FICOS framework										
PICOS	Inclusion Criteria	Exclusion Criteria								
Population	Patients undergoing regular hemodialysis	Other kidney replacement therapies								
	in health care facilities	(Continuous Ambulatory Peritoneal Dialysis or								
	Hemodialysis patients safety in health	Kidney Transplantation)								
	care facilities	Home hemodialysis services								
Intervention	Instruments or aids for patient safety	Not related to patient safety procedures								
	procedures									
Comparasion	No comparison factors	There are comparative factors								
Outcome	Quality of Service	Standard Infection Prevention Procedures								
	Hemodialysis patient safety	Other service standards								
Study design &	Research and Development	Systematic Review								
publication type	Cross sectional study	Scoping Review								
	Cohort retrospective study	Literature Review								
	Descriptive qualitative study									
	Experiment study									
	Mixed Method									
Publication years	2013 – 2023 research	Pre-2013 research								
Language	English	-								

Table 1	PICOS	framework
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### **Characteristic of Studies**

This research method is a systematic review using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) method, which aims to compile, summarize and report related research findings to identify gaps in evidence, and draw conclusions from existing literature reviews and explain various developments instrument that discusses prevention of adverse events in hemodialysis services.

The results include journal results from Scopus, Science Direct, Pubmed, and Web of Science database searches using the keywords "*Dialysis*," "*Dialysis patient safety instrument*," "*Hemodialysis*," and "*Hemodialysis patient safety instrument*." The journal was a quantitative or qualitative research design. Journals are taken based on the 2013-2023 publication years. Full-text articles and abstracts are reviewed to choose a theme that matches the criteria. The priority intervention in this systematic review is the hemodialysis patient safety instruments.

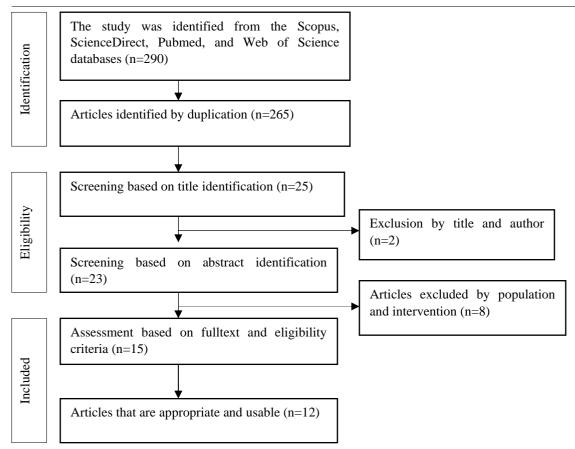


Diagram 1. PRISMA diagram flow (Page et al., 2021).

### **Characteristic of Intervention**

The interventions taken in this study are various instrument developments that discuss preventing adverse events in hemodialysis services. The intervention aims to prevent patient safety incidents in hemodialysis services with various strategies, innovations, the development of an instrument based on conventional (paper) or websites and mobile applications that are more up-todate with technology. The instrument was developed based on a structured analysis of patient safety risk factors and management strategies for implementing hemodialysis patient safety procedures. Effective communication is an essential intervention element in implementing patient safety procedures in hemodialysis services. The interventions taken in this study are instruments that are described in the following table:

	Tuble 2. Characteristics of intervention								
No.	Authors	Types of Interventions							
1.	(Lin et al., 2022)	Healthcare Failure Mode and Effect Analysis (FMEA) and the development of a real-time mobile application for Modified Early Warning Score (MEWS) Notification: Improve Patient Safety During Hemodialysis							
2.	(Pássaro & D'Ávila, 2018)	Nursing educational intervention for the identification of adverse events in hemodialysis: develop an educational tools program aimed at the qualification of the nursing technicians that makes possible the understanding of adverse events (AEs).							
3.	(La Russa et al., 2022)	Proactive Risk Assessment Through Failure Mode and Effect Analysis (FMEA) for Haemodialysis Facilities: A pilot project of Failure Mode and Effect Analysis (FMEA) tools.							

<b>Table 2. Characteristics</b>	of Intervention
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No.	Authors	Types of Interventions
4.	(Thomas et al., 2016)	The Hemo Pause safety checklist: Feasibility of a hemodialysis safety checklist for nurses and patients to quality improvement.
5.	(Aguiar et al., 2018)	Construct and validate a safety assessment instrument for chronic renal patients on hemodialysis.
6.	(Hu et al., 2022)	Leakage-detection device and IoMT (Internet of Medical Things): For detecting blood leakage during hemodialysis using a Novel Multiple Concentric Ring Sensor.
7.	(Yang-Kun et al., 2019)	Blood Leakage Detection Device: blood leakage detection device for patients during hemodialysis sessions.
8.	(Silver et al., 2015)	Development of a hemodialisis safety checklist using a structured panel process. A novel 17-item Hemodialysis Safety Checklist (Hemo Pause) for use by nurses and patients
9.	(McGrath et al., 2020)	Handoff communication forms in an outpatient hemodialysis: increase patient safety by preventing errors through improving staff handoff communication in an outpatient hemodialysis unit.
10.	(Flythe et al., 2019)	Development and content validity of a hemodialisis symptom patient-reported outcome measure. Research product is Symptom Monitoring on Renal Replacement Therapy-Hemodialysis (SMaRRT-HD): determine the early symptoms of physical emergencies in hemodialysis patients.
11.	(Flythe et al., 2020)	Tablet-based electronic patient-reported outcome measures (ePROMs): improving symptom communication dan quality services at hemodialysis clinic.
12.	(Marcelli et al., 2015)	Safety checklist for haemodialysis sessions: 15-quality indicators checklist. Application of such checklists enhances the overall quality and safety hemodialysis treatment.

#### **Clinical Outcome**

The interventions were given to improve patient safety during Hemodialysis. Implementation of the instrument can provide convenience and applicability for nurses in taking measures to prevent patient safety incidents and improve patient safety culture in hemodialysis services. Developing patient safety instruments in hemodialysis services is still feasible based on standardized patient safety goals specific to hemodialysis procedures.

### **Risk of Bias**

Based on the bias risk assessment, there are 12 articles that are assessed the risk of bias with *Critical Appraisal tools for use in JBI Systematic Reviews* (Aromataris et al., 2015), in which there are 8 articles with the results of the assessment are: score 100% (n=4 Articles), score 91% (n=5 Articles), and score 82% (n=3 Articles). Twelve citations after being assessed with *JBI* meets 9 assessments then it is worth reviewing. Score of 91% where there is 1 of 11 points and score 82% where there is 2 off 11 points. *Critical Appraisal Checklist for Systematic Reviews* is not appropriate.

No	Critical		Author number										
	Appraisal Item	1	2	3	4	5	6	7	8	9	10	11	12
1.	Is the review question clearly and explicitly stated?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

**Table 3. Critical Appraisal Checklist** 

No	No <i>Critical</i> Author number												
110	Appraisal Item	1	2	3	4	5	6	7	8	9	10	11	12
2.	Were the	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	inclusion criteria												
	appropriate for												
	the review												
	question?	TT 1	TT 1	Yes	Yes	Unclea	Yes	Yes	Yes	Uncle	Yes	Yes	Yes
3.	Was the search	Uncle ar	Uncle ar	res	res	r	res	res	res	ar	res	res	res
	strategy					-							
4.	appropriate? Were the sources	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4.		1 08	108	108	168	108	168	108	108	105	105	105	168
	and resources used to search for												
	studies adequate?												
5.	Were the criteria	Yes	Yes	Uncle	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.	for appraising			ar									
	studies												
	appropriate?												
6.	Was critical	Uncle	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	appraisal	ar											
	conducted by two												
	or more												
	reviewers												
	independently?												
7.	Were there	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	methods to												
	minimize errors												
	in data extraction?												
8.	Were the	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
0.	methods used to	105	105	105	105	105	105	105	105	105	105	105	105
	combine studies												
	appropriate?												
9.	Was the	Yes	Yes	Yes	Yes	Unclea	Yes	Unclea	Yes	Yes	Yes	Yes	Yes
	likelihood of					r		r					
	publication bias												
	assessed?												
10.	Were	Yes	Yes	Yes	Yes	Yes	Uncle	Yes	Yes	Yes	Yes	Yes	Yes
	recommendation						ar						
	s for policy												
	and/or practice												
	supported by the												
11	reported data?	Va-	Var	Yes	Var	Vac	Unal-	Var	Va-	Va-	Va-	Yes	Unal-
11.	Were the specific	Yes	Yes	res	Yes	Yes	Uncle ar	Yes	Yes	Yes	Yes	res	Uncle ar
	directives for												
	new research appropriate?												
	appropriate:												
	Scoring	82%	91%	91%	100%	82%	82%	91%	100%	91%	100%	100%	91%
	Scoring	l		L			I			I	I	I	

## DISCUSSION

Structured analysis of patient safety risk factors and management strategies for implementing patient safety procedures were often found in the 12 articles reviewed. Effective communication is also essential in implementing patient safety procedures in HD services.

## Hemodialysis patient safety

The complexity of treating patients with chronic kidney disease (CKD) includes the level of chronicity of the disease, the involvement of several health professionals, and different treatment

activities. Given the frequency with which patients undergo procedures involving high technology, it is important to evaluate issues related to patient safety. Hemodialysis is a therapy that has benefited many patients in recent years. However, on the other hand, the process has potential dangers that cannot be underestimated. Hemodialysis is one of the hospital service sectors with a considerable potential risk for the occurrence of AEs; this occurs due to several things such as complicated procedures, use of high technology, characteristics of chronic kidney disease, use of high-alert drugs (Rocha, 2022).

Patient safety in hemodialysis services is one of the crucial aspects in hospitals that require a standard service procedure to ensure patient safety. The hospital as a health service organization must be able to build a system that makes the patient care process safer, both for patients, health workers, and families/visitors, as well as hospital management to ensure patient safety. Patient Safety Goals reflect commitments that must be achieved as indicators of a safer health care system (Wardhani, 2017).

### Hemodialysis patient safety instrument

Based on the results of a review of the 12 articles that have been carried out, an overview of the majority of articles discusses research on specific patient safety to prevent patient safety incidents from occurring in hemodialysis services with various strategies, innovations, and the development of an instrument both conventional-based and more modern applications following the latest technological developments such as websites or mobile applications.

### Hemodialysis patient safety instrument based on technology

The application of technology as an instrument for hemodialysis patient safety was found in 5 articles reviewed.

Healthcare Failure Mode and Effect Analysis (FMEA) and the development of a real-time mobile application for Modified Early Warning Score (MEWS) Notification (C. H. Lin et al., 2022) help evaluate the potential risk of patient safety incidents during the hemodialysis process. This application can reduce the potential for patient emergencies during hemodialysis and significantly increase communication effectiveness between health workers on duty.

Proactive Risk Assessment Through Failure Mode and Effect Analysis (FMEA) for Haemodialysis Facilities: A pilot project of Failure Mode and Effect Analysis (FMEA) tools (La Russa et al., 2022). FMEA application to hemodialysis is a valuable tool, easy to implement, and likely to nimbly reveal the practical and potential solutions to the critical steps of the procedure.

Leakage-detection device and IoMT (Internet of Medical Things): For detecting blood leakage during hemodialysis using a Novel Multiple Concentric Ring Sensor (Hu et al., 2022). The feasibility of using a novel detector combined with an IoMT system to monitor multi-bed blood leakage automatically. The innovative concentric-circle design could more precisely control the warning blood-leakage threshold in any direction to achieve clinical cost-effectiveness. The system reduced the load on medical staff and improved patient safety.

Blood Leakage Detection Device: Blood leakage detection device for patients during hemodialysis sessions (Yang-Kun et al., 2019). The results suggested that patients believed the device could reduce their mental anxiety, and the nursing staff considered the device reliable and that it would enhance the quality of care. The proposed detection device can be extended to similar applications to prevent catheter dislodgement, and to improve patient safety and reduce the stress of clinical nursing staff.

Symptom Monitoring on Renal Replacement Therapy-Hemodialysis (SMaRRT-HD: determine the early symptoms of physical emergencies in hemodialysis patients (Flythe et al., 2019). SMaRRT-HD is a 14-item PROM intended for use in hemodialysis patients. It uses a single treatment recall period and a 5-point Likert scale to assess symptom severity. Qualitative interview data provide evidence of its content validity. SMaRRT-HD is undergoing additional testing to assess measurement properties and inform measure scoring.

Tablet-based electronic patient-reported outcome measures (ePROMs): improving symptom communication and quality services at hemodialysis clinics (Flythe et al., 2020). Symptom ePROM administration during hemodialysis is feasible. Trials investigating the effectiveness of symptom ePROMs and optimal administration strategies are needed.

### Adverse event risk assessment instrument

Safety checklist for haemodialysis sessions: 15-quality indicators checklist. Applying such checklists enhances the overall quality and safety of hemodialysis treatment (Marcelli et al., 2015). This study reports the results of a feasibility study for achieving improved safety and quality in a hemodialysis session by implementing a 15-point checklist. Fifteen quality indicators were compiled and tested in a Portuguese dialysis clinic from 1 February 2012 to 30 June 2013. The nursing staff completed the checklist, which comprised three parts: Pre-session Safety Checks, Session Initiation Checks, and Post-session Quality Checks. The maximum score that could be reached per session was 15. Implementing checklists for hemodialysis is feasible in routine clinical practice, even in clinics where only part of the staff is employed full time. The application of such checklists enhances the overall quality and safety of the delivered treatment.

A novel 17-item Hemodialysis Safety Checklist (Hemo Pause) for nurses and patients (Silver et al., 2015). Hemodialysis Safety Checklist (Hemo Pause) for use by nurses and patients has been developed to standardize the hemodialysis procedure. Further quality improvement efforts are underway to explore the feasibility of using this checklist to reduce adverse events and strengthen the safety culture in the hemodialysis unit.

The Hemo Pause safety checklist: Feasibility of a hemodialysis safety checklist for nurses and patients to quality improvement (Thomas et al., 2016). The Hemo Pause safety checklist was acceptable to nurses and patients over three months. Our next step is to spread this checklist locally and conduct a mixed methods study to determine mechanisms by which its use may improve safety culture and reduce adverse events.

Construct and validate a safety assessment instrument for chronic renal patients on hemodialysis (Aguiar et al., 2018). The assessment instrument was considered understandable, relevant, and compatible with safety standards, showing content validity and compatibility to assess patient safety in hemodialysis treatment environments.

## Hemodialysis patient safety education instrument

Nursing educational intervention for identifying adverse events in hemodialysis: Develop an educational tools program aimed at the qualification of the nursing technicians that makes understanding adverse events (AEs) possible. Nursing educational tools on AEs in hemodialysis effectively increase nurses' knowledge about AEs in hemodialysis services (Pássaro & D'Ávila, 2018).

The review results also illustrate that similar research on instrument development in service areas other than hemodialysis is still rare. Most articles conclude that the instrument can provide

convenience and applicability for nurses in preventing patient safety incidents and improving patient safety culture in hemodialysis services. Developing patient safety instruments in hemodialysis services is still feasible based on standard patient safety goals specified in the hemodialysis procedure.

### **CONCLUSION AND SUGGESTION**

This systematic review synthesized the available experimental evidence research and development of instruments to prevent adverse events in hemodialysis services. Prevention of hemodialysis patient safety incidents can be solved with clear, understandable, and effective communication by developing innovation, be it disciplinary incident reporting, technology development, or new instruments. The development of patient safety instruments can reduce adverse events and improve patient safety so that it can impact the quality of service of a healthcare institution, especially hemodialysis services. Most articles conclude that using the instrument can provide convenience and applicability for nurses in preventing patient safety incidents and improving patient safety culture in hemodialysis services. Effective communication is also crucial in implementing patient safety procedures in hemodialysis services. Developing patient safety instruments in hemodialysis services is still feasible based on patient safety target standards specified in hemodialysis action procedures.

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## **CONFLICT OF INTEREST**

The authors state that they received no financial reward for conducting this research. This study was conducted in an academic environment by independent researchers.

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