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Exploring Patient Safety Risks in CAPD Services: A Qualitative Analysis Using Failure Mode and Effect Analysis (FMEA)

Anggika Yelzi Pratiwi[1], Masyitoh Basabih[1*], Fifi Mulyani[2]
** Correspondence Author: masyitoh10@ui.ac.id*
[1] Public Health Faculty, Universitas Indonesia, Indonesia
[2] Regional General Hospital Pasar Minggu, Indonesia

INDEXING

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Patient safety incident;
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CAPD

ABSTRACT

Pasar Minggu Regional General Hospital is currently developing CAPD as a new service, which is a high-risk service involving healthcare professionals and patients themselves. This research aims to identify the risk of patient safety incidents using the FMEA method in CAPD at RSUD Pasar Minggu to prevent the incident risk. The research is qualitative research with an operational research approach. Data were obtained from primary sources through in-depth interviews and focus group discussion (FGD) and secondary data through a literature review. The result showed that the post-insertion process of peritoneal access and patient self-management in CAPD was the focus of the FMEA process. The priority risks were exit site/ tunnel infection, peritonitis infection, catheter obstruction, and leakage. The root cause of the risks is the incomplete CAPD service regulatory, education and re-education plans have not been implemented, and monitoring and evaluation have not been determined. Recommendations for preventing these risks include completing CAPD regulations in the service guidelines, optimizing patient education and re-education plans with CAPD training plan matrix and patient education poster, and establishing monitoring and evaluation procedures for CAPD patient care.

Kata kunci:
Insiden keselamatan pasien;
Manajemen risiko;
FMEA;
CAPD

RSUD Pasar Minggu saat ini sedang mengembangkan layanan baru yaitu layanan CAPD, dimana layanan ini merupakan layanan berisiko yang tidak hanya melibatkan petugas kesehatan di rumah sakit namun pasien sendiri. Penelitian ini bertujuan untuk mengidentifikasi risiko IKP dengan metode FMEA pada layanan CAPD di RSUD Pasar Minggu dalam rangka mencegah risiko IKP terjadi. Penelitian secara kualitatif dengan pendekatan operational research. Data penelitian diperoleh dari data primer yaitu wawancara mendalam dan focus group discussion (FGD) serta data sekunder yaitu telaah dokumen. Hasil penelitian menunjukkan bahwa proses post-pemasangan akses peritoneal dan CAPD mandiri oleh pasien merupakan fokus proses penyusunan FMEA. Prioritas risiko yang ditemukan yaitu infeksi exit site/ tunnel, infeksi peritonitis, obstruksi kateter, dan leakage. Akar penyebab risiko terjadi yaitu regulasi layanan CAPD belum seluruhnya tersedia, rencana edukasi dan re-edukasi belum diterapkan, dan monitoring dan evaluasi perawatan CAPD belum ditentukan. Rekomendasi dalam pencegahan risiko tersebut yaitu melengkapi regulasi layanan CAPD pada panduan layanan CAPD, memaksimalkan rencana edukasi dan re-edukasi pasien dengan CAPD training plan matrix dan poster edukasi pasien, serta menetapkan prosedur monitoring dan evaluasi perawatan CAPD pasien.

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INTRODUCTION

As healthcare providers, hospitals are required to deliver comprehensive healthcare services and ensure patient safety. Patient Safety Incidents (PSIs) become a significant burden of mortality and disability worldwide, especially in middle and low-income countries, with 2.6 million deaths each year (A.Lumenta, 2021). Patient safety is a priority in hospital services and has become necessary healthcare services (Ismainar, 2019). PSIs can lead to death and disability, as well as suffering for the victims and their families. Meanwhile, from a financial and economic perspective, the cost of handling PSIs is high. The Hospital Patient Safety Committee (KKPRS) reported in the first quarter of 2011, there were 14.4% of Adverse Events

(AEs) and 18.53% of Near Misses (NMs). The Patient Safety Incident (PSI) report compiled by the Ministry of Health in 2018 showed a total of 1489 cases of PSIs, which drastically increased in 2019 to 7465 cases. These incidents include 38% Nears Misses (NMs), 31% Non-Injury Events (NIEs), and 31% Adverse Events (AEs) (Pertiwiwati et al., 2023).

Factors contributing to patient safety incidents, such as adverse events and medication errors, include organizational deficiencies, professional practice errors, procedural lapses, system failures, technical issues, and individual mistakes (Liu, 2019). One of the implementations that hospitals can do is to manage and identify potential risks of PSIs through risk management (A.Lumenta, 2021). FMEA is a risk prevention method or tool used in quality management. Hospital Accreditation Standards of the Ministry of Health (STARKES) 2022 states in their assessment elements that to reduce risks in hospitals, FMEA must be conducted at least once a year (Komisi Akreditasi Rumah Sakit, 2022). Previous studies indicated that FMEA helped hospitals in Sierra Leone, a country in West Africa, from identified risks associated with the use of a new device, Universal Anesthesia (Rosen et al., 2014), the use of Helical Tomotherapy-Total Marrow Irradiation (HT-TMI) in China (Shen et al., 2019) and the transition of using pre-diluted KCL solution in Israel Hospital (Ofek et al., 2016).

Given the significant impact of patient safety incidents in healthcare settings, applying risk management strategies across various medical services, including specialized treatments such as Continuous Ambulatory Peritoneal Dialysis (CAPD), becomes crucial. CAPD therapy is a kidney replacement modality, in addition to Hemodialysis (HD), performed through the peritoneal cavity or abdominal cavity using a peritoneal dialysis access called a Tenckhoff catheter. CAPD has been widely used in various countries since 1976 as an alternative therapy in the treatment of Chronic Kidney Disease (CKD) or End-Stage Renal Disease (ESRD) (Murat Atasoyu et al., 2014). CAPD is one of the urology services developed in regional hospitals (Ministry of Health Republic of Indonesia, 2022b). It is a kidney therapy option that must be developed due to challenges in kidney transplantation programs and HD facilities, such as limitations in human resources, skills and supporting facilities (Perhimpunan Nefrologi Indonesia (PERNEFRI), 2011).

The significant difference between HD and CAPD is that the patient independently performs CAPD, so the potential risks are from hospital factors and the patients themselves. Both CAPD and HD dialysis procedures are medical procedures that utilize advanced technology that may cause risks. Therefore, patient safety and service quality must be prioritized (Direktorat Bina Pelayanan Medik Spesialistik, Direktorat Jenderal Bina Pelayanan Medik and Departemen Kesehatan Republik Indonesia, 2008).

Pasar Minggu Regional General Hospital is a government-owned type B hospital that implements risk management through the RCA method. It has been carried out for reactive risk identification to prevent PSIs. Meanwhile, in terms of proactive risk identification, the hospital uses FMEA to prevent patient safety incidents. In 2023, Pasar Minggu Regional Hospital developed a new Continuous Ambulatory Peritoneal Dialysis (CAPD) service. The hospital needs to conduct risk identification for the CAPD service as a new offering to avoid potential risks and ensure the safety of patients from this new service method. The risk identification method used is FMEA, which, based on previous research, is an effective risk management method to help hospitals identify risks associated with new services, determine interventions for risk prevention, and conduct monitoring and evaluation to control potential

risks (Rosen et al., 2014). This study aims to identify patient safety incident risks in CAPD services using FMEA to prevent incidents, as CAPD is a new service at Pasar Minggu Regional Hospitals.

RESEARCH METHOD

A qualitative study was conducted to support data collection and information for the author and the FMEA process. The study describes three themes: Risk identification of patient safety incidents, Risk factor of patient safety incidents, and Quality Improvement and Risk Management in CAPD Services. A qualitative study was conducted using operational research.

A total of 14 informants participated, and with this number of informants, the research reached data saturation. In-depth interviews and a review of secondary data and FGD were conducted to understand the flow of CAPD services and potential risks. Once the data was collected, the FMEA process began.

Purposive sampling was chosen as informants were selected based on specific criteria, considering the quantity and quality of information. Snowballing techniques were used to identify additional informants recommended by primary informants for their relevant knowledge. The research was conducted over 2 months at Pasar Minggu Regional Hospital from October 16 to December 15, 2023. The table below shows the data collection methods, type of data, informants and instruments used in this study:

Table 1. Data Collection Technique

Methods	Data	Informants	Instruments
In-depth Interviews	Primer	Doctor in Charge of the Dialysis Unit, Head Nurse of the Dialysis Unit, Head of the Pharmacy Installation, Dialysis Unit Nurse, Surgeon, Operating Room Nurse, Inpatient Nurse, Patients.	In-depth guidelines, Observation sheets
Review of secondary data	Secondary data	The flow of CAPD services, SPO for CAPD, PSI report for a dialysis unit, education, and handover form	Document review sheets
Focus group discussion	Primer	Deputy director of Services, Head of Medical Services, Chair of the Risk Management Subcommittee, Member of the PMKP subcommittee, Head of Outpatient Installation, Doctor in dialysis unit, Dialysis unit coordinator, head nurse of the dialysis unit, head nurse of the operating room, head nurse of the inpatient ward	FGD guidelines
FMEA process	Primer & Secondary Data	Deputy director of Services, Head of Medical Services, Member of the Risk Management Subcommittee, Member of the PMKP subcommittee, Head of Outpatient Installation, Dialysis unit team, Head nurse of the operating room, Head nurse of the inpatient ward	FMEA sheet

Data processing consists of primary data obtained through interview recordings. The results of the informant interviews are then organized based on variables, the relevant information is selected, and subsequently, the transcribed data is summarized in matrix form. Document review is conducted to process secondary data by categorizing data based on

variables within a working document. The qualitative analysis method used in this research is content analysis, which requires 1) well-documented data, 2) a theoretical framework that supports data, and 3) the researcher's ability to process the data.
The FMEA process that was conducted:

Table 2. Data Collection Technique

No.	Process
1.	Selection topics and FMEA team formation
2.	Mapping of process flow and subprocess
3.	Risk identification and prioritization
4.	Identification of root cause and risk prioritization
5.	Redesign process
6.	Analysis, trial, implementation, and monitoring of the new process

Data validation in this study used triangulation methods (source triangulation and method triangulation). This research has adhered to ethical standards, and informed consent was obtained. It has passed ethical review, receiving approval from the Faculty of Public Health University of Indonesia with letter number Ket-709/UN2.F10.D11/PPM.00.02/2023 from Pasar Minggu Regional Hospital with letter number 65/KOMETHUK/XI/2023.

RESULTS AND DISCUSSION

These results describe three themes: Risk identification of patient safety incidents, Risk factor of patient safety incidents, and Quality Improvement and Risk Management in CAPD Services**.** Each is identified based on the FMEA process.

Table 3. Informants Demographic Data

Characteristic	Amount (n= 12)	Percentage (%)
Age		
20-30	1	8%
31-40	4	33%
41-50	6	50%
51-60	1	8%
Gender		
Male	3	25%
Famale	9	75%
Profession		
Specialist Doctor	2	17%
Nurse	3	25%
General Practitioner	5	42%
Pharmacist	1	8%
Patient	1	8%
Education		
Bachelor	2	17%
Master	2	17%
Specialist	8	67%

Table 4. Summary of Themes Identified Based on The FMEA Process

Themes	Categories	Sub-Categories
Risk identification of patient safety incidents	Interdisciplinary Team Collaboration in FMEA	FMEA Team Based on Relevant Departments and Positions
	Mapping of CAPD Services Process	- Pre-Peritoneal Access Placement Flow - Peritoneal Access Flow - Post-Peritoneal Access Placement and Self-Managed CAPD Flow
Risk factors of patient safety incidents	Post-Procedural Monitoring and Patient Follow-Up	- Post-Incision Control Patient - Routine Monthly Control for CAPD Patient
	Safety in Medication and Dialysis Solution Delivery	- Medication Delivery to Patient - Dianeal Delivery to Patient - Patient Received Dianeal
	Patient Self-Management and Caregiver Support	Self-managed CAPD by Patient or with Family Assistance/Caregiver
Quality Improvement and Risk Management in CAPD Services	Development and Revision of CAPD Service Guidelines	- Revision of CAPD Service Guidelines - The Revised CAPD Service Guidelines Are Under Review and Will Proceed to Approval
	Training and Educational Initiatives	- CAPD Training Plan Matrix - Educational Poster about the Replacement of Dianeal for Patients in A3 Size - The Training Plan Matrix and Patient Education Poster have not yet been implemented as no new patients exist.
	Regulations, Monitoring, and Evaluation	- Regulations, Monitoring, and Evaluation Tools for CAPD Service - Monitoring and Evaluation will use PDSA, PDCA, and KPI to ensure effective risk prevention implementation
	Outcome Measurement in CAPD Services	Measuring Outcomes Such as Peritonitis Incidence Rates in the CAPD Service Have Been Prepared

Theme 1. Risk identification of patients' safety incident

Interdisciplinary Team Collaboration in FMEA

Risks in CAPD services, both from hospital and patient factors, are determined based on the development of FMEA. Focus Group Discussion (FGD) begins with selecting topics and FMEA team formation, mapping the process flow and sub-processes of CAPD services and identifying PSI risks in CAPD services.

The first step in developing FMEA is selecting the topic to be analyzed. Hospitals can determine FMEA topics based on the highest priority in the risk register by considering high risk, high volume, high cost and the hospital's capability to address them (Hospital Accreditation Commission, 2022). According to the informant, *".. We have been using patient incident risk identification with proactive FMEA method since 2022 as part of patient safety incident prevention.."*

Forming an FMEA team based on relevant departments and positions consists of the facilitator, representatives from hospital management with decision-making authority, experts

on the selected topic, one person who is unfamiliar with the test process, and a representative from the selected service unit (VHA National Center for Patient Safety (NCPS), 2021). The FMEA team is detailed in the following table:

Table 5. FMEA team

No	Role	Position	Task
1.	Advisor	a. Deputy Director of Services b. Head of Service Department	Guides team members through the process, supports team discussions and escalates FMEA results to gain leadership support if needed.
2.	Chair & Note-taker	Chairperson & Researcher	Leads the team, ensures understanding of the FMEA process, facilitates the Focus Group Discussion, and prepares meeting notes.
3.	Representative of Related Unit/ Field Expert	a. Head of Outpatient Installation b. Head of Dialysis Unit c. Dialysis Unit Coordinator d. Head of Dialysis Unit Room e. Head of Operating Room f. Head of Surgical Inpatient Room g. Head of PMKP Committee h. Head of Risk Management Subcommittee	Shares knowledge and experiences related to the FMEA topic and actively participated in discussions.

Source: *(VHA National Center for Patient Safety (NCPS), 2021)*

Mapping of CAPD Services Process

The next step in risk determination is mapping the process flow and subprocesses to assist the FMEA team in analyzing the selected processes (VHA National Center for Patient Safety (NCPS), 2021). It begins with collecting primary and secondary data. Primary data is obtained through in-depth interviews with informants from the dialysis, pharmacy, operating room, and surgical inpatient units. In contrast, secondary data is collected by reviewing CAPD service flow documents, guidelines, and SOPs, which help identify the processes to analyze (VHA National Center for Patient Safety (NCPS), 2021). CAPD services have been planned to operate since early 2023, with several coordination meetings with related units. Coordination within the dialysis unit has resulted in the following flow:

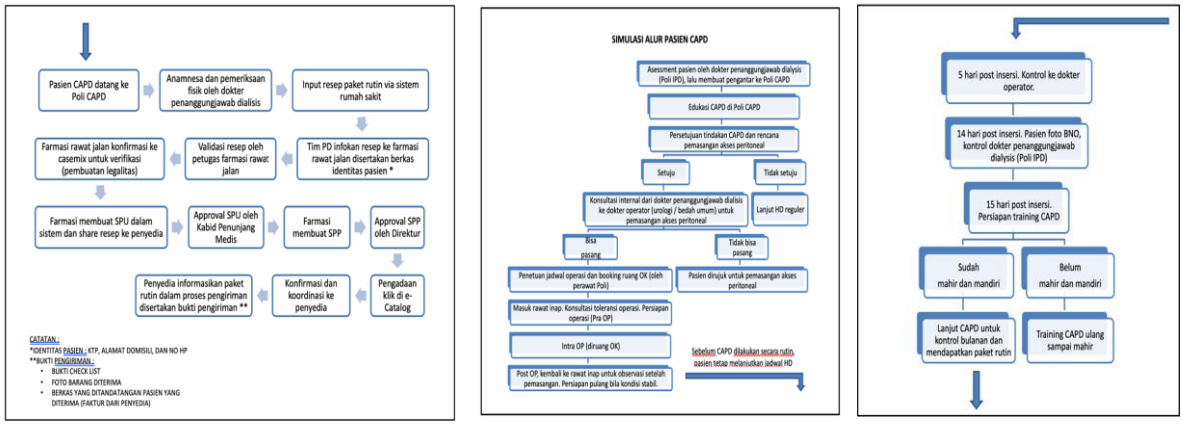

Figure 1. CAPD Service Flow by Dialysis Unit of Pasar Minggu Regional Hospital

To facilitate observation related to the service process received by patients in CAPD services, the researcher illustrates the CAPD service using a service flowchart or swimlane diagram of the process and subprocesses flow in CAPD services. The researcher divides the CAPD service flow into three main processes: pre-peritoneal access placement, peritoneal access placement, post-peritoneal access placement and self-administered CAPD by the patient.

Pre-Peritoneal Access Placement

Pre-peritoneal access placement is the process before peritoneal access is performed. This process includes patient assessment regarding the transition from hemodialysis to CAPD and surgical preparation for peritoneal access installation. The service flow for the pre-peritoneal access placement process is illustrated as follows:

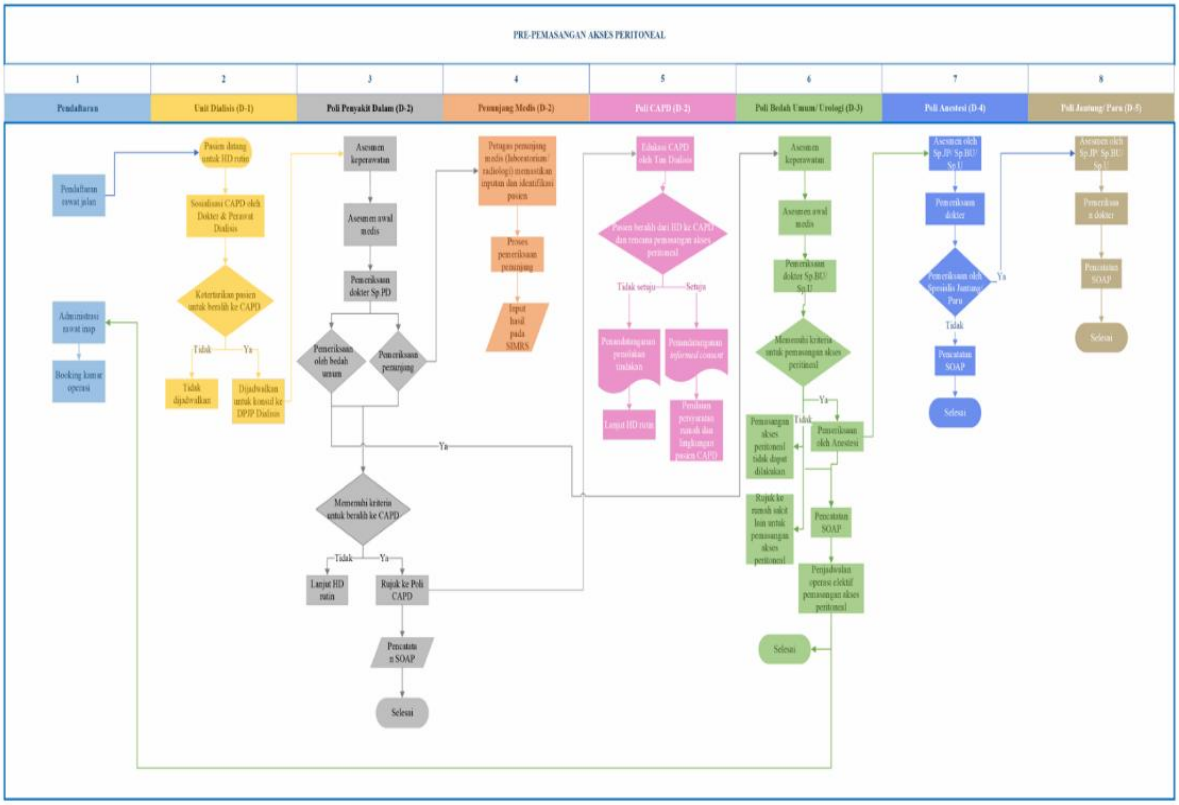

Figure 2. Pre-Peritoneal Access Placement Flow

According to the informant, *"..The initial process involves all patients with HD at Pasar Minggu Regional Hospital receiving an introduction to CAPD services by the CAPD team. The operator conducts the next step to determine whether the patient meets the criteria for Tenckhoff catheter placement.."*

Patients who meet the criteria referred to the CAPD clinic will meet with the CAPD team, including a general practitioner and CAPD nurses, for education and to sign the informed consent. After signing, patients will have a scheduled video call. Once an elective surgery date is confirmed, the CAPD nurse will inform the patient about the planned placement of the Tenckhoff catheter through the CAPD service WhatsApp group.

Peritoneal Access Placement

The peritoneal access placement process involves Tenckhoff catheter placement, focusing on the operating room and surgical inpatient unit. Below is the flowchart for this process:

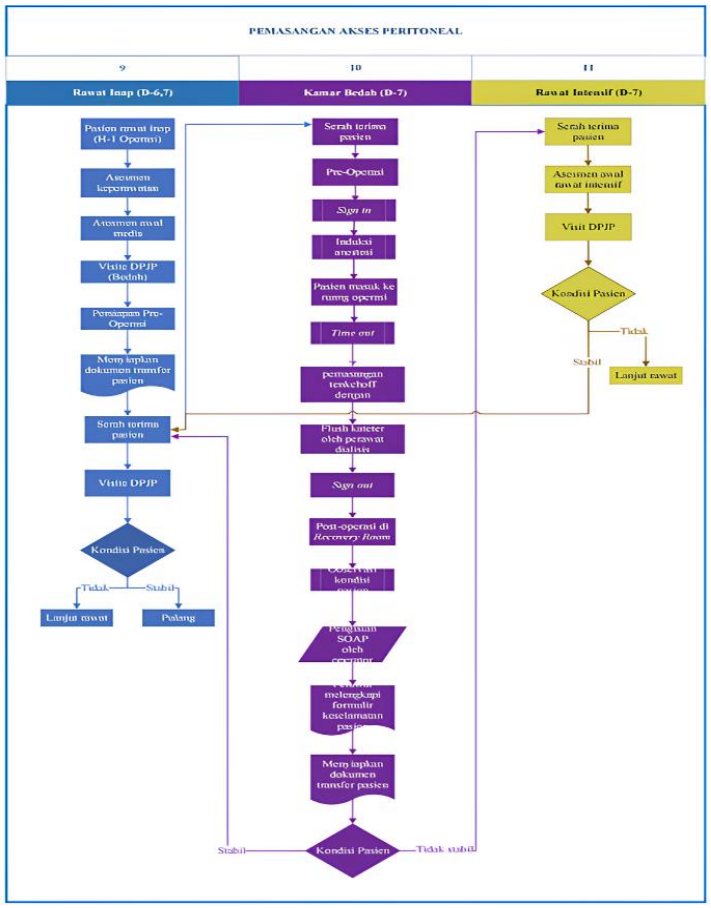

Figure 3. Peritoneal Access Flow

The peritoneal access placement occurs after patients who qualify to transition from HD to CAPD have prepared for the procedure. Patients scheduled for elective surgery for Tenckhoff catheter placement will be admitted to the surgical inpatient unit one day prior. The placement is performed by a general surgeon or urologist using laparoscopy; however, according to Informant 7, *"...I was unsure about the surgical method..."*. The CAPD nurse accompanies the surgery to flush the catheter afterward, ensuring proper inflow and outflow.

Post-Peritoneal Access Placement and Self-Managed CAPD by the Patient

The post-peritoneal access placement and self-administered CAPD process occurs after the access has been placed. It includes post-incision examination, mandatory patient training, and implementing self-administered CAPD once the patient is deemed proficient. Below is the flowchart for this process:

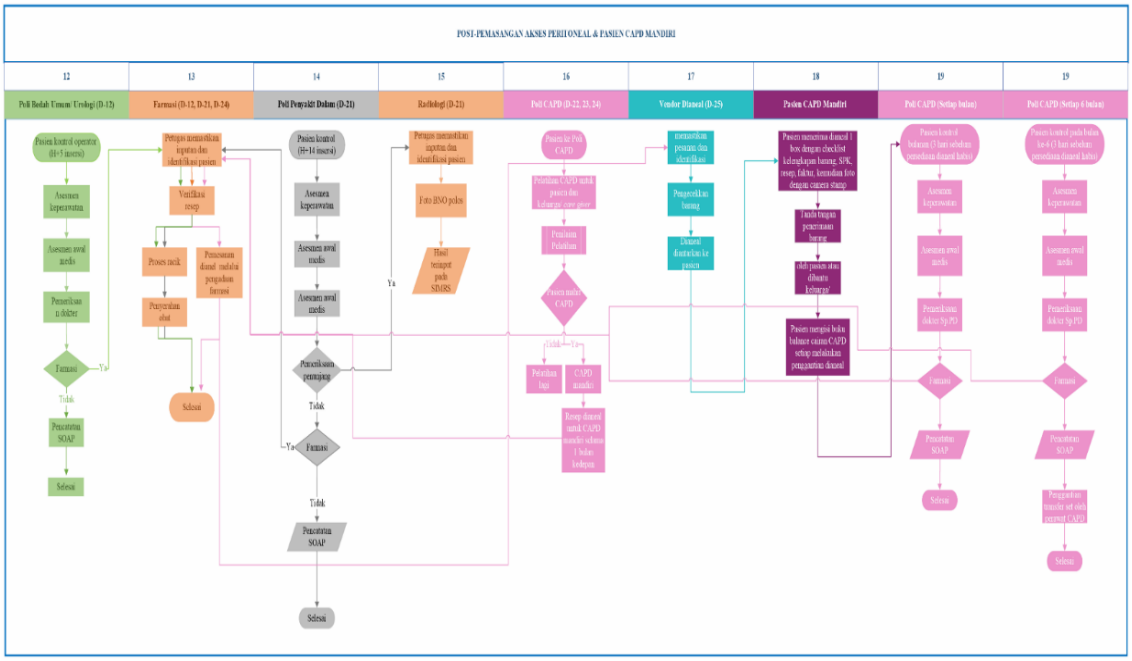

Figure 4. Post-Peritoneal Access Placement and Self-Administered CAPD Flow

Patients return to the hospital for a follow-up with the operator five days after insertion and see the responsible dialysis physician in the internal medicine clinic on the fourteenth day for a plain Blass Nier Overzicht (BNO) photo. CAPD training, mandatory for transitioning patients, lasts three days, starting on the fifteenth day. An assessment on the third day determines if the patient is proficient enough to perform self-administered CAPD. If successful, a prescription for Dianeal for the next month is issued and coordinated with the pharmacy vendor. Patients have monthly follow-up appointments with the dialysis clinician in the CAPD clinic three days before their Dianeal stock runs out. The CAPD nurse replaces the transfer set every six months, and self-administering patients will meet with the CAPD team monthly.

Based on interviews and focus group discussions (FGDs) with health workers and patients, several key risk factors affecting patient safety in CAPD services were identified. Patient safety risks during the pre-peritoneal access placement can arise in various units, including outpatient clinics, laboratories, radiology, and pharmacies. According to the informant, "*.. there are many patient incidents that can occur in outpatient clinics and ancillary services, such as medication errors, patient misidentification and patient falls..*" (Head of Outpatient Installation). Risks in outpatient clinics include patient misidentification, incomplete informed consent forms (La Russa and Ferracuti, 2022), medication dosage errors, patient falls, and infection risks(Herawati Yuwantina, 2012; Umina, 2020). Risk among health workers, according to the informant, "*...Incidents can be caused by communication issues, such as misperceptions or missed communications during coordination between healthcare workers...*" (Nurse, Dialysis Unit). Communication errors among healthcare providers were identified as a contributing factor.

Incidents can occur in the operation room based on interviews: "*...If we talk about incidents that may occur due to errors in the operating room, potential complications during Tenchkoff catheter*

insertion include malposition, obstruction, surgical site infections, vagal reflex, profuse bleeding, and placement errors.."(Surgeon). In the surgical inpatient and operating rooms, risks include patient misidentification, medication errors, falls, infection due to contamination, and failure to administer prophylactic antibiotics (Auguste et al., 2020; Lydia, 2020; Kam-Tao Li et al., 2022). Based on interviews, some patient incident risks may also occur during the post-peritoneal process placement and self-managed CAPD by a patient *"...The dianeal concentrate dose varies for each patient, so there is a risk of errors in the administration of dianeal by the vendor, whether it's swapped with another patient's or incorrect when they deliver it. Though stockouts of dianeal or delivery delays can occur, they are less common in Jakarta. They are still a risk.."* (Head of the Pharmacy Installation). Risks associated with the Dianeal vendor may occur, such as delays in delivery, stockouts of Dianeal, and errors in administering the correct Dianeal concentrate dose for each patient. Other risks may occur when patients perform self-managed CAPD care. These risks include infections, such as peritonitis or infections at the exit site/tunnel (Fang, Ni and Qian, 2014; Ueki et al., 2022), catheter flow obstruction or blockage (Peppelenbosch et al., 2008), leakage of peritoneal fluid (Cuxart et al., 2019), inadequate peritoneal dialysis, and the risk of patients returning to HD (Supono, 2010; Murat Atasoyu et al., 2014).

Theme 2. Risk factors of patient safety incident

Post-Procedural Monitoring and Patient Follow-Up

1) Post-Incision Control Patient

Risk identification on post-incision control patients includes medication errors such as wrong dosages, patients, and medicine. According to informants," Patient safety incidents that may occur when patient control post-incision are medication errors that happen at surgical polyclinic or pharmacy" (Head of Risk Management Subcommittee). According to the FGD, this risk is caused by the Doctor's negligence in inputting the patient's prescription, issues with the SIRS system in inputting and also mistakes in prescription input, preparation or errors due to miscommunication. It can lead to side effects, worsen the patient's condition, or, in the worst case, result in death.

2) Routine Monthly Control for CAPD Patient

Risk identification on routine monthly control patients, such as errors in the type of examination. According to informants,"*..Errors such as false examination may occur at CAPD clinic when patient do routine monthly control if it happens it can cause ineffectiveness of treatment or worsening patient's condition ..*" (Dialysis Unit Nurse). It may occur because of the doctor's negligence in inputting the patient's prescription or issues with the SIRS system in inputting. Other risks may occur in the laboratory during routine examinations, such as errors in laboratory tests, sample mix-ups between patients, swapped test results, and infections. These issues can arise due to patient misidentification, failure to apply SOPs, human error, contamination, or poor staff hygiene. If such errors occur, the test may not meet the patient's needs, requiring the patient to repeat the sample collection, causing discomfort, or, in the worst case, leading to death.

Safety in Medication and Dialysis Solution Delivery

1) Dianeal Delivery to Patient

Risk identification on delivery of dianeal to patients includes delay in delivery of dianeal to patients, dianeal stockout or error in administering dianeal such as wrong prescription or

wrong dosage. *"...The dianeal concentrate dosage varies for each patient, so there is a risk of errors in dianeal delivery from the vendor, whether mixed up with another patient's supply or mistakenly sent. Shortages or delays in dianeal delivery can occur, though it may be rare in Jakarta, it still poses a risk.."* (Dialysis Unit Coordinator). These risks may happen because of internal vendor issues and errors in patient identification or prescription input. Errors can lead to delays in the patient's dianeal replacement.

2) Patient Received Dianeal

Risk identification on patients receiving dianeal is that dianeal may not match the quantity or the concentrated dosage based on the patient's prescription. It can occur due to patient misidentification, incorrect input or swapping with another patient. Errors can lead to delays in the patient's dianeal replacement.

Patient Self-Management and Caregiver Support

Some risks identified in self-managed CAPD by the patient or with family assistance/caregivers include infection of the exit site/ tunnel, peritonitis, catheter obstruction, and leakage. According to the informant, *"...Risk of CAPD patients such as infection or peritonitis, this can happen because of their hygiene.."* (Head of Dialysis Unit). Risks may occur during self-managed CAPD, such as peritonitis or infections at the exit site/tunnel (Fang, Ni and Qian, 2014; Ueki et al., 2022), catheter flow obstruction or blockage (Peppelenbosch et al., 2008), leakage of peritoneal fluid (Cuxart et al., 2019), inadequate peritoneal dialysis, and the risk of patients returning to HD (Supono, 2010; Murat Atasoyu et al., 2014). These risks occur due to hygiene factors, including self-hygiene and environmental hygiene, improper use of personal protective equipment (PPE), accidental pulling or twisting of the catheter, scratching around the exit site, and lack of awareness of infection signs. These can cause patient discomfort, return to HD or, in the worst case, lead to death.

The FGD result states that post-peritoneal access placement and self-managed CAPD by the patient will focus on FMEA preparation. According to the FGD results, participants agree that the patient's role is significant in post-peritoneal access placement and self-managed CAPD. *"Many department roles, both internal and external hospital, can be involved in this process, especially when the patient and caregiver or family manage self-administered CAPD. This process can be a priority for the FMEA process.." (Deputy Director of Services).* Therefore, these processes are considered selected processes for FMEA.

The next step is determining the risk's severity if an incident occurs (severity/consequences), the likelihood of the risk occurring, and the ability to control the risk (detection). The severity, occurrence, and detection values are multiplied to generate the risk priority number (RPN), which helps determine the priority risk. The scoring of each variable is done during the FGD. The scoring result is based on the consensus from the FMEA team's brainstorming during the FGD. Below is the table for determining the risk priorities for each sub-process and related unit in the post-peritoneal access placement and self-managed CAPD by the patient:

Table 6. Risk Priority Determination

Related Unit	Sub-process	Risk Identification	Risk Causes	*Occurrenc*	Risk Impact	*Severity*	*Detection*	RPN
Surgical clinic	Post-incision control patients	Post-incision control patients	- The doctor's negligence in inputting the patient's prescription - Issues with the SIRS system in inputting	2	- Ineffectiveness of treatment - Side effects (allergies to serious reactions) - Worsening kidney condition - Decreased quality of life (symptoms & discomfort that arise) - Death	4	2	16
CAPD Clinic	Routine monthly control of patients	Routine monthly control of patients	- The doctor's negligence in inputting the patient's prescription - Issues with the SIRS system in inputting	2	- Ineffectiveness of treatment - Side effects (from allergies to serious reactions) - Worsening kidney condition - Decreased quality of life (symptoms & discomfort that arise) - Death	4	2	16
Outpatient Pharmacy	Medication delivery to patients	Medication administration errors (incorrect dosage, wrong patient	- Incorrect prescription input - Mistakes in medication preparation - Errors due to miscommunication (incorrect dosage/type)	2	- Ineffectiveness of treatment - Side effects (from allergies to serious reactions) - Worsening kidney condition - Decreased quality of life (symptoms & discomfort that arise) - Death	4	2	16
Laboratory	Routine patient examination	Errors in test type	- Negligence - Patient misidentification - Failure to apply Standard Operating Procedures (SOP)	2	- The test performed does not meet the patient's needs, where the sample has already been taken - The patient must repeat the sample collection	3	2	12
		Sample mix-up between patients	- Negligence - Patient misidentification - Failure to apply Standard Operating Procedures (SOP)	2	- Patient test results are swapped. - Patient management is not under the actual test results, potentially leading to certain side effects, decreased quality of life, and inappropriate actions that could result in death	4	2	16
		Test results were swapped with another patient	- Negligence - Patient misidentification	2	- Patient test results were swapped. - Patient management does not align with	4	2	16

Related Unit	Sub-process	Risk Identification	Risk Causes	*Occurrenc*	Risk Impact	*Severity*	*Detection*	RPN
			- Failure to apply Standard Operating Procedures (SOP)		the actual test results, potentially leading to certain side effects, decreased quality of life, and inappropriate actions that could result in death			
		Infection	- Contamination during sample collection - Staff hygiene - Failure to apply Standard Operating Procedures (SOP)	2	- Decreased quality of life (symptoms & discomfort that arise) - Patient death	4	2	16
Dianeal Vendor	Delivery of dianeal to patients	Delay in delivery of Dianeal to patients	Internal vendor issues	2	Delay in the replacement of Dianeal	3	2	12
		Dianeal stockout	Internal vendor issues	2	Delay in the replacement of Dianeal	3	2	12
		Error in administering Dianeal (not according to prescription, as each patient's concentrate varies based on needs)	- Patient misidentification - Dianeal package was swapped with another patient	1	Delay in replacing Dianeal if all is wrong; however, if not, the remaining stock can be returned	2	2	4
Self-managed CAPD by the patient	Patient receives Dianeal	Dianeal received does not match (quantity, concentrate)	- Patient misidentification - Swapped with another patient	1	Delays in replacing Dianeal may occur if all the delivered Dianeal cannot be used; however, if some can still be used, they can be used first, and the remaining stock can be returned to the vendor.	2	2	4
	Self-managed CAPD by the patient and/or assisted by a caregiver	Infection (exit site/tunnel infection)	- The environment where Dianeal replacement is done is not clear - Air conditioning/fan is on during Dianeal replacement - A patient does not wear a mask during Dianeal replacement - Improper use of a mask (should cover both nose and mouth) - Hand hygiene is not performed	4	- Impedes the CAPD process/effectiveness of dialysis - Decreased quality of life (symptoms & discomfort that arise) - The patient returns to HD	4	2	32

Related Unit	Sub-process	Risk Identification	Risk Causes	*Occurrenc*	Risk Impact	*Severity*	*Detection*	RPN
			during the Dianeal replacement - A patient does not maintain exit site cleanliness (cleans around the exit site after showering) - Failure to maintain hygiene: showering at least twice a day and wearing clean clothing - A catheter is pulled or twisted - Scratching around the exit site area - Patient compliance: the patient has received education but does not follow the proper procedures - Education implementation: whether the educational method is easy for the patient to understand, how many times this has been discussed, as it needs to be repeated and reinforced - The patient is unaware of the signs of infection that may appear					
		Infection (peritonitis)	- The environment where Dianeal replacement is done is not clear - Air conditioning/fan is on during Dianeal replacement - The patient does not wear a mask during the Dianeal replacement - Improper use of a mask (should cover both nose and mouth)	4	- Impedes the CAPD process/effectiveness of dialysis - The patient returns to HD - Membrane failure - Decreased quality of life (symptoms & discomfort that arise) - The patient returns to HD - Patient death	4	2	32

Related Unit	Sub-process	Risk Identification	Risk Causes	*Occurrenc*	Risk Impact	*Severity*	*Detection*	RPN
			- Hand hygiene is not performed during the Dianeal replacement - The patient does not maintain exit site cleanliness (cleans around the exit site after showering) - Failure to maintain hygiene: showering at least twice a day and wearing clean clothes - The catheter is pulled or twisted - Scratching around the exit site area - Patient compliance: the patient has received education but does not follow the proper procedures - Education implementation: whether the educational method is easy for the patient to understand, how many times this has been discussed, as it needs to be repeated and reinforced - The patient is unaware of the signs of infection that may appear.					
		Catheter obstruction (catheter flow blockage/impairment)	- Presence of constipation or diarrhea - Incorrect catheter position during insertion - Blockage due to Dianeal fluid clotting - Body position changes or careless movements	4	- Impedes the CAPD process - Decreased quality of life (symptoms & discomfort that arise, such as the patient feeling overloaded) - Uremia - Inadequate peritoneal dialysis - The patient returns to HD	4	2	32

Related Unit	Sub-process	Risk Identification	Risk Causes	*Occurrenc*	Risk Impact	*Severity*	*Detection*	RPN
		Leakage (peritoneal fluid leakage)	- Peritonitis - Body position changes or careless movements	4	- Impedes the CAPD process - Decreased quality of life (symptoms & discomfort that arise, such as the patient feeling overloaded) - Uremia - Inadequate peritoneal dialysis - The patient returns to HD	4	2	32

Table 7. Risk Priority

Sub Process	Risk Identification	RPN
Self-managed CAPD by the patient and/or assisted by family caregiver	Infection (*exit site/tunnel infection*)	32
	Infection (peritonitis)	32
	Catheter Obstruction (catheter flow is blocked)	32
	Leakage	32

Identification of Root Cause of Risks

The next step is identifying root causes to determine recommendations for preventing high-priority risks, which is done using problem tree analysis as follows:

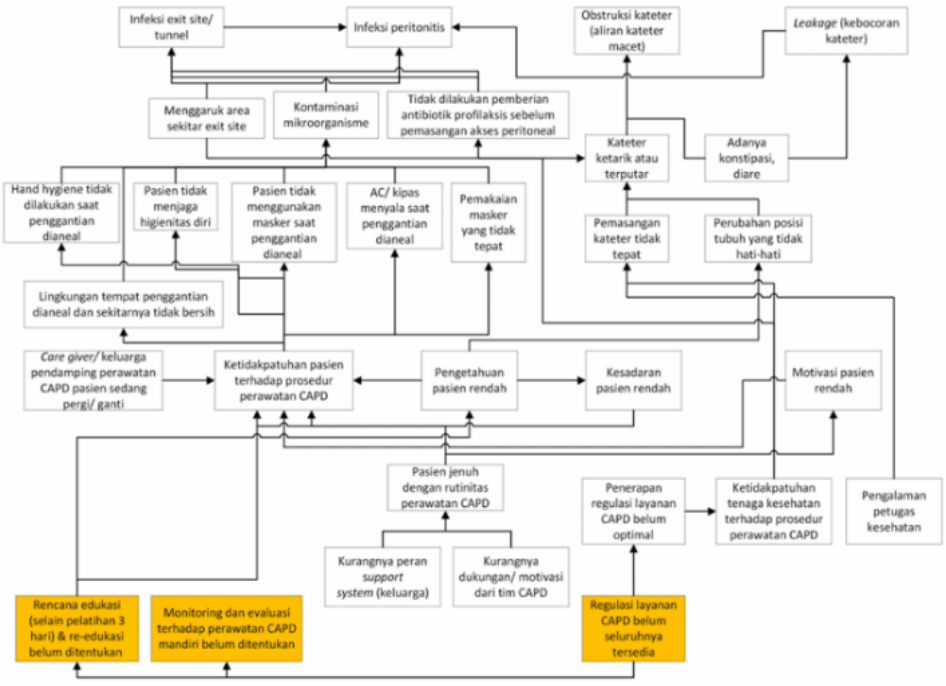

Figure 5. Problem Tree Analysis of Risk Priority

The risk of exit site/tunnel infection occurs due to scratching the area around the exit site, microorganism contamination, and the failure to administer prophylactic antibiotics before peritoneal access placement (Auguste et al., 2020; Lydia, 2020; Kam-Tao Li et al., 2022) due to patient non-compliance with CAPD care procedures, which may be caused by the caregiver or family member being away or changing, patient boredom with routines, low patient motivation, and low patient knowledge, leading to a lack of patient awareness (Jung et al., 2016; Lydia, 2020). These issues arise because the education plan (aside from the mandatory 3-day training) and re-education have not been established (Russo et al., 2006; Jaelani et al., 2023), monitoring and evaluation of independent CAPD care have not been determined (Li et al., 2022; Gursu et al., 2023; Jaelani et al., 2023), and CAPD service regulations are not fully available (Fang, Ni and Qian, 2014).

The root cause of the risk of peritonitis infection is the same as the root cause of the risk of exit site/tunnel infection. In addition, exit site/tunnel infections and leakage (peritoneal fluid leakage) can lead to peritonitis (Ueki et al., 2022)**.** FMEA stages in determining corrective and preventive measures are done in re-design.

Theme 3. Quality Improvement and Risk Management in CAPD Service

Development and Revision of CAPD Service Guidelines

The process aims to improve and prevent risks, with recommendations based on identified root causes. Document review reveals that while all SOPs are identified, the SOP for training CAPD patients and families covers the 3-5 day period post-peritoneal access. However, SOPs for dialysate provision and patient monitoring are missing during independent CAPD care. Therefore, it is essential to complete and ensure the availability of regulations for catheter insertion, patient training, dialysate provision, and monitoring of CAPD patients. Interventions have been tested, improved, and are being implemented. The revised CAPD service guidelines are under review and will proceed to approval.

Training and Educational Initiatives

Interviews and FGDs indicate that while the mandatory three-day training for patients and families post-peritoneal access is provided, additional education is needed to help patients master CAPD care procedures. A structured training program is essential to promote patient independence and reduce risks of peritonitis and other infections (Yetti, 2007; Jaelani et al., 2023). The recommended action is to develop a CAPD training plan matrix covering pre- and post-peritoneal access education, the 3-day training, and re-education or retraining for patients after infection, hospitalization, or a change in caregivers. The training plan matrix and patient education poster have been tested and improved but have not yet been implemented as there are no new patients.

Regulations, Monitoring and Evaluation

Interviews, FGDs, and document reviews reveal that if home visits are not possible, patient monitoring for independent CAPD care will be conducted via WhatsApp video calls or group chats. This stage ensures the patient's home environment and dialysate exchange location are suitable and that the patient is skilled in CAPD care (Jaelani et al., 2023). Monitoring is recommended to predict patient compliance and identify needed education

(Zhang, Hawley, and Johnson, 2016). Monitoring and evaluation will use PDSA, PDCA, and KPI to implement effective risk prevention (Shen et al., 2019; Van Hoof et al., 2022).

The likelihood of success for an intervention is greater if a trial or simulation is conducted before implementation. Below are the results of the trial for the above recommendations:

Table 8. Trial of recommendations

No	Recommendations	Trial Result	Plan of Implementation
1.	Revision of CAPD Service Guidelines	The revision results are presented as a draft, which will then be included in the revised CAPD Service Guidelines draft to be prepared by the CAPD Team.	The draft of the CAPD Service Guidelines will be prepared in December 2023 by the CAPD Team and processed to document control for approval.
2.	CAPD training plan matrix	The training plan matrix was tested on the first patient, and the nurse found it helpful as a guide for delivering structured education based on set topics and timing, making documentation easier.	The training plan matrix will be implemented for the next patients.
3.	Educational poster about the replacement of Dianeal for patients in A3 size	The poster has been given to patients, who find it helpful to remind them of the Dianeal replacement steps. It's easy to understand and visible in the fluid replacement room at home, unlike the hospital's educational book, which is difficult to use during the process.	The educational poster draft will be printed in bulk by the CAPD team through marketing and then distributed to incoming CAPD patients.
4.	Regulations and monitoring and evaluation tools for CAPD services	They have not yet been directly tested in the patient's CAPD process, as the patient has just started self-care CAPD. Testing will be conducted during the patient's first follow-up visit.	The trial will be implemented during the patient's CAPD follow-up.

Outcome Measurement in CAPD Services

The study's limitations hindered monitoring and evaluation, but tools for measuring outcomes, such as peritonitis incidence rates in the CAPD service at RSUD Pasar Minggu, have been prepared. These rates will assess if education, training, and monitoring have effectively prevented peritonitis. Quality indicators and data collection tools are set for monthly and yearly implementation at the hospital. The explanation of these indicators will be included in the CAPD Service Guidelines revision draft. The CAPD team has discussed the quality indicator profiles and tools to ensure they are relevant and feasible.

CONCLUSION

The post-peritoneal access placement process and self-administered CAPD patients at RSUD Pasar Minggu were identified using FMEA, involving subprocesses related to hospital services and home care. Various risks were identified, including infections (exit site/tunnel and peritonitis), catheter obstruction, leakage, and inadequate peritoneal dialysis. Priority risks were determined based on cut-off RPN. Root causes identified through problem tree analysis include incomplete CAPD service regulations, a lack of educational plans for patients and caregivers, and undefined monitoring and evaluation of self-administered CAPD care.

Preventive measures include completing service regulations with monitoring and evaluation procedures, enhancing education through a CAPD training plan matrix, and using A3-sized posters for Dianeal replacement reminders. The incidence of peritonitis will be measured to assess educational outcomes and patient compliance.

REFERENCES

A.Lumenta, N. (2021). *Patient Safety: Harga Mati*. Rayyana Komunikasindo.

Auguste, B. L., Girsberger, M., Kennedy, C., Srithongkul, T., Mcgrath-Chong, M., Bargman, J., Chan, C. T., & Auguste, L. (2020). Are adverse events in newly trained home dialysis patients related to learning styles? A single-centre retrospective study from Toronto, Canada. *BMJ Open*, *10*, 33315. https://doi.org/10.1136/bmjopen-2019-033315

Cuxart, M., Domingo, J., Cufí, M., Picazo, M., & Sans, R. (2019). Peritoneal dialysis catheter dysfunction caused by fallopian tube entrapment. *Nefrología (English Edition)*, *39*(5), 556–557. https://doi.org/10.1016/J.NEFROE.2018.12.002

Direktorat Bina Pelayanan Medik Spesialistik, Direktorat Jenderal Bina Pelayanan Medik, & Departemen Kesehatan Republik Indonesia. (2008). *Pedoman Pelayanan Hemodialisis Di Sarana Pelayanan Kesehatan: Vol. I*.

Fang, W., Ni, Z., & Qian, J. (2014). Key Factors For A High-Quality Peritoneal Dialysis Program-The Role Of The Pd Team And Continuous Quality Improvement. *Peritoneal Dialysis International*, *34*, 35–42. https://doi.org/10.3747/pdi.2013.00120

Gursu, M., Shehaj, L., Elcioglu, O. C., & Kazancioglu, R. (2023). The optimization of peritoneal dialysis training in long-term. *Frontiers in Nephrology*, *3*. https://doi.org/10.3389/FNEPH.2023.1108030

Herawati Yuwantina, L. (2012). Peningkatan Program Patient Safety melalui Metode Failure Mode and Effect Analysis. *Jurnal Administrasi Kebijakan Kesehatan*, *10*(2). http://journal.unair.ac.id/download-fullpapers-akk82a03b8326full.pdf

Ismainar, H. (2019). *Keselamatan Pasien Di Rumah Sakit - Hetty Ismainar - Google Buku* (Cetakan Pe). Penerbit Deepublish. https://doi.org/https://books.google.co.id/books?id=EISYDwAAQBAJ&printsec=frontcover&hl=id&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false

Jaelani, T. R., Ibrahim, K., Jonny, J., Pratiwi, S. H., Haroen, H., Nursiswati, N., & Ramadhani, B. P. (2023). *Peritoneal Dialysis Patient Training Program to Enhance independence and Prevent Complications: A Scoping Review*. https://doi.org/10.2147/IJNRD.S414447

Jung, H. Y., Jang, H. M., Kim, Y. W., Cho, S., Kim, H. Y., Kim, S. H., Bang, K., Kim, H. W., Lee, S. Y., Jo, S. K., Lee, J., Choi, J. Y., Cho, J. H., Park, S. H., Kim, C. D., & Kim, Y. L. (2016). Depressive Symptoms, Patient Satisfaction, and Quality of Life Over Time in Automated and Continuous Ambulatory Peritoneal Dialysis Patients: A Prospective Multicenter Propensity-Matched Study. *Medicine*, *95*(21). https://doi.org/10.1097/MD.0000000000003795

Kam-Tao Li, P., Ming Chow, K., Cho, Y., Fan, S., Figueiredo, A. E., Harris, T., Kanjanabuch, T., Kim, Y.-L., Madero, M., Malyszko, J., Mehrotra, R., Okpechi, I. G., Perl, J., Piraino, B., Runnegar, N., Teitelbaum, I., Ka-Wah Wong, J., Yu, X., Johnson, D. W., … Johnson, D. (2022). Special Series/Guidelines ISPD peritonitis guideline

recommendations: 2022 update on prevention and treatment. *Peritoneal Dialysis International*, *2*, 110–153. https://doi.org/10.1177/08968608221080586

Komisi Akreditasi Rumah Sakit. (2022). *Instrumen Survei Akreditasi KARS sesuai Standar Akreditasi RS Kemenkes RI 2022*.

La Russa, R., & Ferracuti, S. (2022). Clinical Risk Management: As Modern Tool for Prevention and Management of Care and Prevention Occupational Risk. *International Journal of Environmental Research and Public Health*, *19*(2). https://doi.org/10.3390/IJERPH19020831

Li, P. K. T., Chow, K. M., Cho, Y., Fan, S., Figueiredo, A. E., Harris, T., Kanjanabuch, T., Kim, Y. L., Madero, M., Malyszko, J., Mehrotra, R., Okpechi, I. G., Perl, J., Piraino, B., Runnegar, N., Teitelbaum, I., Wong, J. K. W., Yu, X., & Johnson, D. W. (2022). ISPD peritonitis guideline recommendations: 2022 update on prevention and treatment. *Peritoneal Dialysis International*, *42*(2), 110–153. https://doi.org/10.1177/08968608221080586/SUPPL_FILE/SJ-PDF-6-PTD-10.1177_08968608221080586.PDF

Liu, H. C. (2019). Improved FMEA Methods for Proactive Healthcare Risk Analysis. In *Improved FMEA Methods for Proactive Healthcare Risk Analysis*. Springer Singapore. https://doi.org/10.1007/978-981-13-6366-5

Lydia, A. (2020). The Role of Continous Ambulatory Peritoneal Dialysis in Equity of Kidney Replacement Therapy in Indonesia. *Jurnal Penyakit Dalam Indonesia*, *7*(3), 9. https://doi.org/10.7454/jpdi.v7i3.469

Murat Atasoyu, E., Tolga Taner, M., Erbas, E., Sahbaz, I., Kagan, G., Kemal Kagan, M., Enginyurt, L., & Ozgur Baslangic, S. (2014). Diminishing Complications in Continuous Ambulatory Peritoneal Dialysis Process via Six Sigma Methodology. *International Journal of Human Resource Studies*, *5*(1). https://doi.org/10.5296/ijhrs.v5i1.7088

Ofek, F., Magnezi, R., Kurzweil, Y., Gazit, I., Berkovitch, S., & Tal, O. (2016). *Introducing a change in hospital policy using FMEA methodology as a tool to reduce patient hazards*. https://doi.org/10.1186/s13584-016-0090-7

Peppelenbosch, A., Van Kuijk, W. H. M., Bouvy, N. D., Van Der Sande, F. M., & Tordoir, J. H. M. (2008). Peritoneal dialysis catheter placement technique and complications. *NDT Plus*, 23–28. https://doi.org/10.1093/ndtplus/sfn120

Perhimpunan Nefrologi Indoensia (PERNEFRI). (2011). *Konsensus Peritoneal Dialisis Pada Penyakit Ginjal Kronik*. www.pernefri-inasn.org

Pertiwiwati, E., Wibowo, H., Fakhrudin, M., Arif, M. N., Pratiwi, A. A., & Akmal, M. F. (2023). *Efektifitas Penggunaan Metode Healthcare Failure Mode And Effect Analysis (HFMEA) dalam Mengidentifikasi Risiko Kegagalan*. *8*(April), 101–109.

Rosen, M. A., Sampson, J. B., Jackson, E. V., Koka, R., Chima, A. M., Ogbuagu, O. U., Marx, M. K., Koroma, M., & Lee, B. H. (2014). Failure mode and effects analysis of the universal anaesthesia machine in two tertiary care hospitals in Sierra Leone. *British Journal of Anaesthesia*, *113*(3), 410–415. https://doi.org/10.1093/BJA/AEU096

Russo, R., Manili, L., Tiraboschi, G., Amar, K., De Luca, M., Alberghini, E., Ghiringhelli, P., De Vecchi, A., Porri, M. T., Marinangeli, G., Rocca, R., Paris, V., Ballerini, L., 11, ;,

San, O., In Augusta, G., & Healthcare, B. (2006). Patient re-training in peritoneal dialysis: Why and when it is needed. *Kidney International*, *70*, 127–132. https://doi.org/10.1038/sj.ki.5001929

Shen, J., Wang, X., Deng, D., Gong, J., Tan, K., Zhao, H., Bao, Z., Xiao, J., Liu, A., Zhou, Y., Liu, H., & Xie, C. (2019). Evaluation and improvement the safety of total marrow irradiation with helical tomotherapy using repeat failure mode and effects analysis. *Radiation Oncology*. https://doi.org/10.1186/s13014-019-1433-7

Supono. (2010). Faktor-Faktor Yang Berkontribusi Terjadinya Peritonitis Pada Pasien Continuous Ambulatory Peritoneal Dialysis (Capd) Di Rumah Sakit Umum Dr Saiful Anwar Malang. *Jurnal Keperawatan*, *1*(2), 180–189. https://doi.org/10.22219/jk.v1i2.403

Ueki, K., Tsuchimoto, A., Torisu, K., Fujisaki, K., Sayaka Tachibana, ·, Keigo Tomita, ·, Nakano, · Toshiaki, Tsuruya, K., & Kitazono, · Takanari. (2022). *A case of peritoneal dialysis-related peritonitis caused by dialysate leakage with successful treatment by intravenous and intraperitoneal antibiotic therapy*. *11*, 161–165. https://doi.org/10.1007/s13730-021-00644-4

Umina, R. (2020). *Analisis Manajemen Risiko Pasien Jatuh di Instalasi Rawat Inap RSIA Sammarie Basra Jakarta Timur Tahun 2020*. Universitas Indonesia.

Van Hoof, V., Bench, S., Soto, A. B., Luppa, P. P., Malpass, A., Schilling, M., Rooney, K. D., Stretton, A., & Tintu, A. N. (2022). *Failure Mode and Effects Analysis (FMEA) at the preanalytical phase for POCT blood gas analysis: proposal for a shared proactive risk analysis model*. https://doi.org/10.1515/cclm-2022-0319

VHA National Center for Patient Safety (NCPS). (2021). *Healthcare Failure Modes and Affects Analysis (HFMEA) Guidebook VHA National Center for Patient Safety (NCPS)*.

Yetti, K. (2007). *Peran Perawat dalam Meningkatkan Kualitas Pasien Peritonial Dialisis*. *11*(1), 25–29. http://hela13.mahasiswa.unimus.ac.id/2016/10/19/konsep-dasar-keperawatan-maternitas/