A comparative risk assessment of dialysis care processes in the home and hospital care contexts

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Abstract Dialysis processes within the home care context is associated with risk factors which are not very prominent in the hospital context. This includes risk factors such as unanticipated device malfunction, or erroneous operation of the equipment, which exposes the patient to injury while undergoing dialysis. Importantly, the mentioned risk factors are further attributed to technical aspects such as sub-optimal equipment maintenance or following improper clinical procedures when administering care to the patient. Hence, it is important to follow a methodological approach to identify and assess hazards embedded within the dialysis treatment process, and on this basis, formulate effective strategies to mitigate their negative consequences on patient safety. This paper presents a comparative risk assessment for in-hospital versus in-home dialysis care. For the two cases, the risk assessment considers expertise of care givers involved in administering dialysis. The findings show that performing risk assessment for hospital environment, is more structured owing to expertise of clinicians and care givers responsible for administering dialysis. However, assessing risks for the home-care environment is more challenging owing to absence of domain knowledge, hence a survey approach to structure the risk assessment

process is necessary. Moreover, risks in the home care context is influenced by logistical aspects, and lack of domain knowledge for maintaining dialysis equipment. Overall, insights from the comparative studies yields important learning points expected to improve dialysis care as more healthcare providers transfer care to the home environment.

Keywords Risk assessment · Patient safety · Medical devices · Technical risks · Operational risks · Mitigation strategies

1 Introduction

Clinical treatment and diagnostic processes often vary in complexities depending on the nature of patient pathologies (Chemweno et al. 2016a, b). Hence to support such processes, different resources are required along the patient's care pathway, while administering dialysis treatment for patients with kidney diseases (Chemweno et al. 2014). Moreover, with advances in technology and treatment protocols, administration of dialysis is shifting from the hospital, to the home environment. Here, patients increasingly access point-of-care devices for self-diagnosis, and portable dialysis equipment for use at home. However, a shift from the hospital to the home care environment potentially introduces risk factors for dialysis patients. For example, (Rabinstein 2017; Fiest et al. 2018) observe that use of point-of-care (POC) devices for monitoring blood glucose level for diabetics, is influenced by the user knowledge. They allude to challenges interpreting the blood glucose level, whose results differ when other blood related illness are considered. Hirst et al. (2017) likewise cite operation of the POC device for measuring

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glucose levels, as important risk factors influencing management of care for diabetics. Similarly, erroneous calibration of devices used in the home environment is also cited as an important risk factor (Yoshioka et al. 2019). Specifically, for kidney diseases, Mullangi et al. (2018) emphasize the need for POC devices to be “accurate, precise and yield reproducible results”.

Apart from risk factors associated with using POC devices for diagnosis and treatment, domain knowledge on dialysis care is an important consideration. This is especially the case for management of dialysis in the home care environment where logistical factors play an important role for enhancing patient safety. Logistical risk aspects here include factors such as replenishment and disposal of medical material, which are important to consider (Xiao et al. 2017). As an example, proper disposal of medical waste stream is important owing to the bio-hazard nature of the materials, implying the need for implementing effective disposal strategies to mitigate potential harm to the patient, care giver or persons at home (Jiang et al. 2015). For instance, in the home care context, used bags from continuous ambulatory peritoneal dialysis forms an important waste stream where, disposal strategies in many OECD countries depends on established health facilities (Ikeda 2017).

Thus, because of multiple risk factors which arise for dialysis patients, especially when care is transferred to the home environment, it is important to identify potential risk factors for the complete dialysis treatment pathway, in a systematic and structured way. Doing so will allow care givers to formulate more effective mitigation strategies, to improve patient safety while undergoing dialysis. This also implies the need to carefully map dialysis clinical processes, considering not just the treatment phase, but the entire treatment cycle including assessment of logistical aspects, which largely influences care especially in the home environment. Furthermore, since hospital care is considered as more robust and less risk-prone, it is important to understand risk assessment processes in the hospital context and adapt learning points for the home care context. For this, assessing risks of dialysis processes in the hospital is important and structured methods are useful to structure the process of identifying hazards and risks embedded in the dialysis treatment cycle, analyzing such risks, and consequently formulating effective mitigation strategies targeting identified risk factors. The importance of adopting a structured risk assessment for enhancing care of patients is discussed in literature. Several methods for structuring the risk assessment process, are discussed, for example, the Healthcare Failure Mode and Effect Analysis (HFMEA) (McElroy et al. 2016; Franklin et al. 2012; Rosen et al. 2015; Garfield et al. 2018; De Giorgi et al. 2010), Preliminary hazard analysis (PHA)

(Schlatter 2018; Riou et al. 2017; Grespan et al. 2019, 2007; De Giorgi et al. 2010), and the Fault Tree Analysis (FTA) (McElroy et al. 2017; Rogith et al. 2017; Teixeira et al. 2016; Ong and Coiera 2010). Nonetheless, owing to the uncertain nature of risks embedded in the clinical care pathways, applying specific risk assessment methods is not straightforward because of factors such as the need for patient records (for quantitative methods), domain knowledge, or user-knowledge on using different methods while assessing risks (Chemweno et al. 2018; Beaussier et al. 2016; Paine et al. 2018).

Furthermore, mapping risks for dialysis care requires in-depth understanding of the clinical treatment processes and often in absence of domain information to perform risks, expert elicitation is often the primary point of reference. This complicates how risk assessment is structured, especially for the home care context, where embedded risks are diverse and influenced by multiple stakeholders, including the patient, care giver, hospital staff and logistical personnel (for supply and replenishment of medical material). This necessitates use of survey-based approaches targeting the multiple actors in order to gain useful insights for complex processes such as in-home dialysis care. Despite the unstructured nature of treatment processes for dialysis care in the home environment, it is important to align the risk assessment processes with the complete dialysis treatment cycle, which for the home environment encompasses installation of the device, usage, maintenance, receipt and disposal of medical materials. Moreover, applying a methodological approach better allows assessment of risk factors associated with clinical processes, by taking advantage of expert knowledge of multiple actors interacting with the patient.

However, structuring risk assessment for dialysis care, while considering multiple actors and processes interacting with the patient, introduces several research questions formulated as follows:

- Firstly, how does interaction between a dialysis patient and clinical processes influence risk factors, negatively affecting patient safety in the hospital and home care environments?
- Secondly, how can we structure risk assessment processes for the home and hospital environment while considering domain knowledge of multiple actors interacting with the dialysis patient?
- How can we assess embedded risks for a dialysis patient, considering the entire treatment cycle and what approaches or tools can we apply to structure the risk assessment process?

An important focus of this research is on understanding challenges structuring and performing risk assessment, considering two varying application cases. Specifically, the

treatment cycle considered includes usage of the device considering the varying settings, and logistical influences for the home care context. The hospital case considers the dialysis treatment processes within a large university hospital in Belgium, while the second case considers assessment of risks factors linked to both peritoneal and dialysis care in the home environment.

The objective of this paper is two-fold. First, we evaluate possible methodological approaches applicable for mapping, and hence assessing risks in two diverse clinical dialysis processes. Here, challenges associated with risk identification and mapping process are presented, followed with an in-depth evaluation of methodological steps followed for assessing clinical risks in the two diverse cases. The evaluation also evaluates how systematic assessment of risk factors for dialysis care, considering diverse application contexts, are influenced by diversity of care processes, whereof mapping of the processes is influenced by factors such as structure of the care pathway, in-depth knowledge of the process among other aspects.

Secondly, this paper discusses possible key-learning points analysts and decision makers need to look out for, in view of robustly assessing clinical risk factors in diverse application contexts, but also considering often varying care pathways depending on the patient pathologies. Important considerations here include the need to evaluate how the application context, i.e. the homecare versus the hospital care environment influences the process of identifying and mapping clinical risk factors linked to dialysis care.

This paper is organized as follows: Sect. 2 reviews key concepts of risk assessment in the healthcare context where structured tools and methods are reviewed. This includes a motivation for using the Health Care Failure Mode and Effect Analysis, which is applied for risk assessment for the hospital case. Section 3 presents the two case studies where rationale for adopting systematic and methodological approaches for the two varying cases discussed. Section 4 discusses limitations and key learning points expected in practice when assessing risk factors for dialysis care processes in the hospital and home care environments. Section 5 outlines important conclusions drawn from the comparative analysis of the case studies and possible areas of future work. Figure 1 illustrates the article structure.

2 Concepts and methodologies for risk assessment in health care

In the healthcare context, risks are broadly defined as “unwanted events whose probable occurrence may be detrimental to patient safety” (Merino et al. 2014). Hence, following this definition, we focus on occurrence of

unwanted events along the treatment trajectory of a dialysis patient (Sutcliffe et al. 2017). The events here encompass usage of the dialysis equipment, potential malfunction (leading to misdiagnosis or wrong treatment), or erroneous administration of medication owing to incorrect usage of the point-of-care device, here including the dialysis equipment. Since such unwanted events are embedded within the patient treatment trajectory, we adopt the definition by De Bleser et al. (2006) where the trajectory or pathway is defined as implying “a method for patient care management, for a well-defined group of patients, with the objective of improving the quality of care, and reduce risks of hazards”. Hence, the focus of this research is to assess, using a methodological approach, risk factors associated with clinical processes of dialysis, which are embedded in the treatment trajectory of the dialysis patient. The objective of this comparative study is to gain insights on risk factors situated in the dialysis treatment pathway, thereby, formulating effective mitigation strategies for the identified risk factors.

Several past researches have focused on developing robust frameworks for assessing and hence, managing risks along the treatment trajectory of patients. Lee and Henderson (2018) highlight several challenges faced by analysts when structuring the process of assessing clinical risks, due to among factors, difficulty selecting suitable methods for assessing clinical risks. Hence, Simsekler et al. (2018) suggest the need to carefully select suitable tools, considering the application context. For instance, where quantitative patient information is available, McElroy et al. (2017) propose a Fault Tree Analysis, where they apply the analysis to evaluate adequacy of quality reporting programs for postoperative bloodstream infections. Importantly, they focus on identifying root causes of bloodstream infections after surgical operations.

Abecassis et al. (2015) also apply a Fault Tree Analysis for assessing incidences of ‘wrong-site surgery’, incidences which though rare, compromises patient safety. Swamidas et al. (2018) further apply Fault Tree Analysis for identifying root causes of unsafe dosage rates for brachytherapy, a form of radiotherapy used for treating certain forms of cancer, such as cervical and prostate. Application of Fault Tree Analysis for clinical risk factors affecting patient safety is discussed in several studies, including assessing safety of anesthesia (Liu and Yuan 2015; Culwick et al. 2016), maintenance-related hazards of medical devices (Mahfoud et al. 2016; García et al. 2019; Labagnara et al. 2013) or assessing risk profiles of programs for stereotactic radiosurgery (Teixeira et al. 2016). More recent applications of Fault Tree Analysis for dialysis treatment is discussed for management of medical waste (Makajic-Nikolic et al. 2016), and assessing hazards of hemodialysis devices, (Leupolz et al. 2018).

Fig. 1 Structure of the article

However, the fault tree analysis is not without its limitations, which include availability of necessary information, or patient data to map pathways through which inadvertent actions or errors initiated in clinical processes, propagate to scenarios causing harm to the patient (O’Connell et al. 2019). Apart from lack of supporting information or patient data to support risk assessment, knowledge of the dialysis process also influences the outcomes of errors which could lead to clinical risks (Ong and Coiera 2010).

Thus, with absence of prerequisite criterion such as information on clinical processes, in-depth knowledge of the care pathway flows, or availability of patient data, alternative qualitative and semi-qualitative approaches are usually suggested. A widely used approach in this regard is the Healthcare Failure Mode and Effects Analysis (HFMEA), an assessment and prioritization tool for healthcare risk assessment. The HFMEA is particularly useful for care pathways characterized by insufficient availability of risk-related patient information necessary for formulating statistical models for quantifying healthcare risks. DeRosier et al. (2002) describes an early theoretical framework for assessing patient safety risks in clinical processes where general guidelines to be followed for the HFMEA process and potential pitfalls to anticipate are discussed.

As opposed to the more quantitative approaches such as FTA and simulation modelling, a more subjective

assessment of risks is usually suggested, which relies on expert knowledge of the clinical process for robustly assessing clinical risks embedded in the patient treatment trajectory (Franklin et al. 2012). Although such knowledge of the clinical process is an important consideration, overreliance on expert knowledge is highlighted as a potential pitfall to assessing risks in a non-biased way. In such cases, bias of the decision makers influences outcomes of the risk assessment using the HFMEA approach (Goodrum and Varkey 2017; Kricke et al. 2017; Abrahamsen et al. 2016).

Thus, remedial strategies proposed for addressing concerns of bias include assembling a multi-disciplinary team, which is also cited as a challenge in healthcare owing to the often highly complex nature of clinical processes within hospitals (Kricke et al. 2017). Constituting such a team for assessing safety risks for clinical process in the home care context is also a challenge (Hignett et al. 2016). Moreover, the interface between the clinical processes and usage of medical devices introduces additional complexities, and hence risks, for instance equipment failure, incorrect calibration, or incorrect use of the standard operating procedures (Hignett et al. 2016). Factors such as effectiveness of the communication also influences the risk assessment process for teams assessing healthcare risks (Hemsley et al. 2019; Martinetti et al. 2019).

The importance of considering the aforementioned challenges for robust assessment of healthcare risks is also

highlighted through mitigation strategies formulated and implemented in practice (IEC 2009). Some of the strategies include mistake-proofing of the clinical processes, or performing root cause analysis for preventing recurrence of similar or related hazards (Uberoi et al. 2007; Card 2017). Fool proofing strategies extends to standardization, simplification of clinical processes, such that care providers avoid reliance on memory to perform tasks (Qu and Young 2018). Other mistake fool proofing strategies include patient tagging to prevent risks of misdiagnosis of errors in administering treatment therapies (Uy et al. 2015; Asamoah et al. 2018; Wong et al. 2017). However, the effectiveness of mistake-proofing depends on the complexity of the treatment trajectory of the patient, hence some authors cite the need to align such a strategy to robust assessment of risk factors in the care pathway (Ebright 2014).

To structure risk assessment processes and formulation of mitigation strategy for clinical processes such as dialysis, when group decision making is involved, structured brain storming is suggested (Card 2017; Grout and Tousseint 2010; Tague 2005). Furthermore, group decision making strategies influence outcomes of risk assessment for clinical process for which there is insufficient knowledge yet. This includes new or immature care programs like human-based treatment or management of conditions such as kidney diseases, requiring dialysis. For assessment of risks, applying methods such as HFMEA or quantitative methods including FTA for analyzing sources of risks is challenging and not straightforward. Survey based approaches is preferred in such instances, as discussed in studies focusing on home-based care programs.

Examples in literature where a survey approach is discussed include Dimitrow et al. (2014), for assessing risks of dosage of medication by elderly patients in the home environment. For their study, a Delphi survey was implemented to better structure the risk assessment process. Mosquera et al. (2014) discuss a randomized clinical trial in which a survey method is used to map and measure the impact of enhanced medical care among high-risk children with chronic illness in the home care setting. Surveyed patients receiving home dialysis to understand overall survival outcomes for patients. Their survey further yielded insights including on-treatment survival and associated clinical outcomes. Several additional studies implementing a survey-based approach to assess risks and associated clinical patient outcomes is discussed in studies, e.g. (Tennankore et al. 2014; Wang et al. 2015; Krishna et al. 2017).

The objective of this article to formulate a framework for assessing risks, for dialysis processed considering the hospital and home care contexts. The approach integrates a careful mapping of the patient treatment trajectory from which, a suitable selection of risk assessment method. For

the dialysis in-hospital case, the HFMEA approach is implemented, while for dialysis-at-home care, a survey approach was implemented because of factors such as limited domain knowledge mainly by the patient or care-giver (e.g. a family member). Moreover, the dialysis treatment cycle includes actors involved in installation of the equipment, logistics of replenishing medical material. Uncertainty on domain knowledge hence influenced the choice of a survey approach compared to a more structured HFMEA for assessing dialysis clinical risks in the hospital context. The following section describes two practical risk assessment exercises for dialysis treatment processes. The cases consider two varying application context—in-patient and home care dialysis, where systematic risk assessment is performed.

The theoretical contribution of this study is to illustrate a structured approach for mapping processes and thereby the basis for identify, prioritizing and developing strategies to mitigate clinical risks embedded in dialysis processes. Importantly, this work compared two varying mapping approaches, the first, a more structured methodology for identifying and mitigating risks embedded in in-patient dialysis care. The second methodology focuses on a survey approach for mapping risks for processes with limited domain knowledge. We find the combination of these two varying approaches to be unique in literature in view of gaining insights to dialysis processes, especially for the home care setting which is gaining a lot of traction in recent years.

The practical contribution of this work is the intuitive approaches through which risk analysts and healthcare professionals can systematically map risks embedded in healthcare processes, especially for the home settings where knowledge of the processes is still limited. Moreover, risk assessment requires a multi-stakeholder approach, not just involving clinicians as is usually the case, but extending to other important stakeholders, including the patient, care givers in the home setting and equipment vendors who are often not considered in many cases in literature. An important aspect here is following a structured approach, which is often not straight forward hence a need to adopt systematic steps and inclusion of stakeholders in the risk assessment phases as discussed in latter sections of this study.

The methodology discussed in this study appeals to a wide spectrum of stakeholders and policy makers in healthcare, especially as clinical processes evolves to the home setting. As will be discussed in Sect. 4, mapping stakeholders gives insights on persons involved in dialysis care, extending beyond clinicians to involving municipal authorities who approve building plans and develop policy guidelines for waste disposal. Moreover, involving equipment vendors and care givers in the home setting implies

that as healthcare devolves to the home setting, establishing policy guidelines for ensuring patient safety is rather urgent and ultimately require a relook at existing guidelines which up till recently are skewed towards in-patient care as opposed to out-of-hospital care. Hence this study is expected to contribute towards policy initiatives for patient safety in the home care setting through the structured approach to assessing clinical risks proposed in this paper.

3 Methodology

The study discussed in this paper considers two varying cases and methodologies. For the first case, a structured risk assessment approach is used to systematically identify, prioritize, and develop strategies for mitigating risks and hazards associated with hemodialysis in-case patient care. A structured approach is considered most appropriate owing to aspects such as intrinsic knowledge of in-patient care where for the specific case, clinicians were generally knowledgeable of the process, which was helpful for mapping the treatment process and in essence, gain insights on risks embedded within the clinical care processes.

Therefore, we considered the Healthcare Failure Mode and Effect Analysis for structuring risk assessment steps as illustrated in Fig. 2 below and elaborated further in Sect. 4.1.

The main steps of the risk assessment implemented for case 1 were.

- (1) Formulating the boundary conditions, hence scope of the risk assessment exercise,
- (2) Mapping the treatment trajectory of the hemodialysis process,
- (3) Identifying potential risk factors and hazards linked to the clinical processes,
- (4) Defining acceptable thresholds and prioritizing identified risk factors,
- (5) Formulating mitigation strategies for the prioritized hazards.

The methodology for the second case is different owing to a less in-depth understanding on dialysis at-home care compared to in-patient dialysis care. For this reason, it would be interesting to map and assess risks in the home care context, and by extension, gain insights on possible methodological challenges of implementing structured risk assessment. A considerable challenge in this regard is, as opposed to in-hospital care, is lack of clearly structured functional units or departments as the case in hospitals. Furthermore, while interaction between the patient, care givers, dialysis equipment and medical material is clearer in the hospital context because of more mature domain knowledge of the dialysis process, this is not the case for

Fig. 2 Risk assessment methodology for in-hospital care hemodialysis

the home care context. Multiple stakeholders supporting dialysis-at-home programs also complicates the risk assessment process. This includes care givers at home, immediate family, municipal authorities (for authorizing disposal of wastewater from dialysis), social workers, and suppliers of medical material. For the home setting, four main phases to structure the risk assessment were considered:

- (1) *Phase 1* Defining stakeholders involved in the dialysis care, including the patient, care givers in the home setting, clinicians following up treatment processes at home, equipment vendors and logistical professionals tasked with replenishing medical material and disposing hazardous waste.
- (2) *Phase 2* Mapping process steps considering the entire spectrum of dialysis care in the home setting. Important aspects include training of the patients (and care giver at home) on dialysis process, selection of equipment vendors, management of medical material and waste disposal. As mentioned, owing to limited domain knowledge, a survey approach and semi-structured interviews were used.
- (3) *Phase 3* mapping activities underlying the process steps, with the objective of gaining insights of steps that potentially embed hazards or errors that could

lead to injury or harm to the dialysis patient. This entails factors such as wrong insertion procedures when connecting the patient to the dialysis equipment can be hazardous. For this step, we mainly relied on semi-structured interviews, walk-throughs the process and discussions with clinicians and logistical staff to understand specific steps/processes involved in dialysis care in the home setting.

The main phases for case 2 are elaborated further in Sect. 4.2.

4 Case studies

4.1 Case 1: Risk assessment of hemodialysis in-patient care

This case presents a risk assessment approach of in-hospital hemodialysis process in a large university hospital. Hemodialysis is a treatment process for kidney failure where a dialysis machine acts as an artificial kidney to filter out toxins from the patient's blood. The filtration process occurs outside the patient's body (NIDDK 2017). For the risk assessment exercise, a five-step framework was formulated illustrated in Fig. 2 below. These steps closely follow the main phases of the HFMEA, however, adapted to suite the application context of the dialysis care.

The five steps of risk assessment illustrated in Fig. 2 are further elaborated in the following sections.

Step 1 Identifying the scope of the risk assessment exercise

This step was perhaps the most involving, and important, because of complexity of the hemodialysis process as carried out at the hospital, which involved interaction between the patient, caregivers, medical resources and medical equipment. This includes medical staff, the dialysis equipment, nurses, care givers, patients and supporting departments such as the logistics department, who are responsible for replenishing medical materials and disposing medical waste. Medical materials here include, saline solution, connectors and tubing, fistula needle, and dialyzer. Importantly, since the interacting between the patient and their caregiver, medical resources and support logistic activities, potentially initiated risk factors to the patient treatment process (Tennankore et al. 2014).

Thus, mapping the boundary conditions of the risk assessment exercise was necessary. For this exercise, processes and resources interacting hemodialysis were identified, which, for the case hospital, were linked to three main organizational departments; (1) nephrology, (2)

nursing, and (3) medical instrumentation. Furthermore, insights on resources and interactions between the departments were also mapped using brainstorming, observation, walk-throughs and interviews with staff at the respective departments. Figure 3 depicts a sample of interactions derived from the exercise.

By mind-mapping potential interactions between departments, processes, resources and activities, an exhaustive layout of interaction was generated, and a selection filter defined to narrow down to the most critical interactions, which from the view of decision makers, were critical for successful execution of in-hospital dialysis. Mind-maps have previously been used to map complex healthcare processes, for instance, discussed in several studies (Merchant et al. 2017; Goel et al. 2017).

Step 2 Mapping the clinical activities and resources within the focus areas

The next important task was identifying core activities and resources within each clinical process/department interacting with hemodialysis, derived from the mind-mapping process. For this task, process maps were further defined, and complemented by a structured brainstorming approach. From the mapping, two main categories of resources were identified: human and technical resources. Critical human resources at the medical instruments focus areas, include biomedical engineers, and technicians responsible for calibrating, monitoring and maintaining dialysis equipment. On the other hand, the nephrology focus area embedded nephrologists and assistants. Intuitively, technical resources include hemodialysis machines, water filter installations, and accessories such as hypodermic needles and dialysis tubing.

Moreover, logistical activities interacting with the hemodialysis process, include, for instance, ordering and replenishment of medical materials and accessories for

Fig. 3 A sample mind-map for interactions of in-hospital care hemodialysis processes

supporting hemodialysis, e.g. hypodermic needles and sterile material. Complementary to mapping of resources at the focus areas, a process map of critical processes underlying each focus area was carried. As an example, the process steps for the clinical process ‘sample taking’ is shown in Fig. 4. This process is critical for ensuring overall quality of dialysate and treated water used in the dialysis treatment process.

Overall, from the mapping activity, four main steps were identified to influence the dialysis treatment process: (1) maintenance processes, (2) patient handling process, (3) sample taking process, (4) logistics process. These steps were viewed as synergetic in the sense that resources and activities within these steps interacted with the patients, hence exposing the patient to potential clinical hazards.

As an example, biomedical technicians often took water samples from the dialysis machines for analyzing the water quality, to verify that the water treatment unit is functioning as required. However, if not properly or correctly carried out, there was a risk of contamination, negatively affecting the quality of dialysis. Moreover, the proper functioning of the water-purifying unit, although a responsibility of the medical instrumentation department, influenced the dialysis process. Thus, mapping of the dialysis process formed the basis for the detailed risk assessment process discussed next.

Step 3 Mapping risks and hazards for dialysis processes

Fig. 4 Process activity mapping of dialysis sample taking process activities

The first step for assessing risks of mapped dialysis processes, entailed identifying risk factors associated with activities linked to the process activities illustrated in Fig. 3. Table 1 summarizes risk factors associated with the preparation of dialysis, which is a sub-activity within the sample taking process illustrated in Fig. 4.

As illustrated, the risk factors combine both operational and technical factors. For instance, failure of power supply is likely to cause potential muscle cramp for the patient, because of interrupted blood flow through the dialysis equipment. Risk of equipment failure is further influenced by aspects such as poor maintenance, which may result from improper maintenance, sub-optimal maintenance of absence of a structured maintenance program (Vala et al. 2018). Improper calibration or failure of the water purification system also influenced by similar technical factors such as lack of a robust maintenance program is also likely to lead to clinical risks such as muscle cramps.

Hence, by following a systematic identification process entailing expert discussion, review of patient records, and review of literature, the list of potential risk factors and consequences were identified. After which, the most important risk factors were prioritized using metrics adapted from the HFMEA approach. The primary reason for applying the adapted metrics is owing to the intangible nature of risk factors (Abrahamsen et al. 2016).

Step 4 Risk prioritization process (HFMEA)

Table 1 Risk factors—potential consequences of ‘preparation of dialysis’ process step

Process step	Sub-processes	Risk factors	Potential consequences
1 Preparation of dialysis	Preliminary tasks	Washing the patient’s arm with antiseptic	Potential infection of the arm
		Failure to verify patient’s hemodialysis parameters	Risk of contracting acute pulmonary oedema (APO)
	Equipment care tasks	Failure to verify:	APO, coagulation, muscular cramps
		Power supply to the equipment	Acute hemolysis
		Water supply and purification circuit	Slippage risk due to wet floor
		Output of purification circuit connected to drain	Gaseous embolism and potential hemostasis
	Connecting the purification circuits	Air ingress to the artificial kidney due to improper installation	Muscular cramps, hypotension
	Connecting the patient to the hemodialysis equipment	Incorrect determination of weight loss/hour	Infection, contamination
		Prescribing anti-coagulant medication prior to commencement of dialysis	Coagulation, allergic reaction, bleeding

The prioritization step primarily focused on assigning risk metrics to the each of the risk factors, identified in step 4. From the metrics, associated consequences of the identified risks were mapped. Two risk metrics were assigned; *probability of occurrence* of the risk factor, and the *potential consequence* if the hazardous event occurs. Table 2 illustrates examples of scoring of risk factors associated with the ‘dialysis sampling process’. Here, a scale of 1–5 scale (DeRosier et al. 2002) is applied for the risk scoring process, and each score is assigned by a multi-disciplinary team consisting of nursing staff, nephrologists, and biomedical technicians. The nurses were from two specialisms; (1) nurses handling the dialysis treatment process, i.e. setting up and connecting the patient to the dialysis equipment, and (2) nurses responsible for logistical aspects of dialysis, i.e. availing consumables and medical materials required for dialysis.

A brain storming and consensus approach was applied for scoring metrics each risk factor from which, the hazard scores were calculated as the product of assigned risk metrics, i.e. probability of occurrence, and corresponding severity. For each scored risk factor, the multi-disciplinary team participating in the exercise proposed the decision points and mitigating actions. The approach followed for reaching the decision and outcomes are discussed in the next section. Several technical risk factors were also identified and assessed through the HFMEA process, for instance, failure of seal components of the disinfection pump is likely to cause contamination of the syringe of sampling gate, thereby leading to risk of blood infection. Failure of the water pump is also a likely risk for water contamination, which is potentially mitigated by implementing a robust maintenance program.

For this step of the analysis, the HFMEA approach discussed in DeRosier et al. (2002) was adapted for

formulating the decision points for each of the hazard scores. Two decision points were defined; (1) proceed or, (2) terminate the activity or process. As illustrated in Table 2, risk factors with hazard score values exceeding eight ($HS > 8$) necessitated stoppage of associated process. For instance, the sampling procedure necessitated stoppage to mitigate potential consequences of the ‘sample gate breakage’. Mitigation measures were likewise evaluated for prioritized risk factors based on the values of the hazard scores, where activities such as review of clinical, operation or maintenance protocols, or regular inspection were suggested. For formulating the mitigation strategies, operational experience of the multi-disciplinary team was largely relied on and complemented by using decision aids such as operational manuals. However, as shall be seen for the next use case, following a such a methodological approach, to assess potential hazards and corresponding risks for the dialysis process is not straightforward, when the home care context is considered.

Step 5 Formulating risk mitigation measures

4.2 Case 2: Survey approach for assessing risk of dialysis-at-home care

Dialysis-at-home is gaining traction in the last few years, especially, in OECD countries and the European Union (Keeling 2014; Birmelé et al. 2012; Vaartio-Rajalin and Fagerström 2019). This traction is driven by initiatives aimed at optimizing healthcare financing among countries in Europe (without sacrificing the quality of healthcare delivery). Examples of such initiatives are described in the “KCE report 124A” document, where policy actions targeting financing of chronic dialysis in Belgium are discussed. In the document, uptake of home care dialysis is

Table 2 HFMEA for the dialysis sampling process

Sub-process: connecting the syringe to the dialysis sampling gate						
Potential risk factors	Scoring			Decisions and outcomes		
	Severity (S)	Probability (P)	Hazard score (S) × (P)	Decision points (proceed or stop)	Mitigating actions	
1 Blood infection	4	2	8	<i>Proceed (score = 8)</i> Continue with the sample taking process Stopping the sampling process is detrimental to the patient's safety	Follow strict disinfection protocols for the syringe and sampling gate Initiate biohazard protocols for the sampling activity	
2 Water contamination	4	2	8	<i>Proceed (score = 8)</i> Continue with the sample taking process In addition, here, stoppage of the sampling activity is detrimental to patient safety	Follow strict disinfection protocols for the syringe and sampling gate Changeover the water on detection of contamination	
3 Sample gate breakage	3	4	12	<i>Stop (score > 8)</i> Stop the sampling activity once the current patient is through with dialysis	Initiate repair of the broken sampling gate Regular inspection of the sample gate Re-design to reinforce the sampling gate	

encouraged. However, as one would expect, transferring the dialysis process to the home care context introduces risks, which are likely to differ from those expected for in-patient dialysis processes. Importantly, this implies a shift of responsibility of care, from more experienced hospital staff to the patient and caregivers at home.

The main phases of the survey methodology described in Sect. 3 are further elaborated in the next sections.

4.2.1 Phases of the survey methodology

Phase 1 Defining the stakeholders and exploratory study

The first phase involved an exploratory study, with a view of gaining insights on dialysis-at-home, and defining stakeholders involved in the process. The study focused on a semi-structured interview process with concerned stakeholders, in this case, patients undergoing dialysis at home, hospital staff and physicians working closely with the patients. In addition, vendors of home care dialysis equipment, and suppliers of medical materials were also involved for supporting dialysis within the home care context. Based on the interviews, important process steps, concerned stakeholders, were mapped.

Phase 2 Process mapping

From the exploratory study, eight sequential process steps were identified as important for supporting dialysis-at-home; (1) dialysis training, (2) selection of dialysis equipment, (3) delivery of the hemodialysis equipment, (4)

modifying the home setting to suite installation of the dialysis equipment, (5) installation of the equipment, (6) management of the dialysis process, (7) maintenance of the equipment and its hygiene, and (8) waste handling process. The process steps are summarized in Fig. 5.

From the process mapping, three main cluster of stakeholders interacted with the process steps (activities) illustrated in Fig. 5. The first cluster of stakeholders consisted of hospital staff mainly, nurses and doctors who frequently interact with patients. Often, the same cohort of patients were already undergoing dialysis in the hospital setting and expressed preference to transfer care to their homes. Varying factor motivated their preference; however, a discussion is outside the scope of this study. The healthcare practitioners participated in the process, by providing user-training to the patient and caregivers. The latter were largely immediate family and relatives. The training essentially assessed the 'readiness of transfer' of dialysis care.

The second cluster of stakeholders linked to the process steps outlined in Fig. 5 consisted of dialysis patients, all already undergoing dialysis in the home care setting. This set of patients were affiliated with three hospitals in Belgium, and FENIER-FABIR, a support group for patients with kidney diseases in Belgium (2016). The third cluster of stakeholders consisted of vendors of home care dialysis equipment, both for peritoneal and hemodialysis processes. Also included in this cluster were vendors of medical

Fig. 5 Process steps for home care hemodialysis

materials necessary for supporting dialysis within the home setting.

Phase 3 Mapping activities underlying process steps

In this phase, a more detailed analysis of activities underlying each process step illustrated in Fig. 5 was performed. For this, we conducted semi-structured interviews, using questionnaires for eliciting responses from stakeholders involved with the process steps described in Fig. 5. As an example, the questionnaire for the patient cluster targeted clinical processes such as the cumulative number of years the patient had undergone dialysis (both in the hospital and home care settings), nature of assistance accessed by the patient within the home care setting, ease (or difficulty) of accessing medical material, floor space availability and layout within the home setting.

For the vendors, the questions targeted logistical activities potentially embedding hazards, for instance, poor installation, location or maintenance of the water supply system to ensure correct quality of water used for dialysis. Other questions focused on potential hazards during delivery of dialysis equipment, medical material, and disposal of medical waste among other supporting activities.

Phase 4 Mapping hazards and risks associated with dialysis in the home setting

This phase evaluates risk factors associated with steps of the dialysis-at-home process mapped during phase 2 of the survey approach.

(1) Dialysis training

For the first process step, the training needs of the dialysis patient were identified, including training material such as brochures, user manuals, and oral explanations which were mentioned as important by patients. Moreover, it was mentioned in discussions with stakeholders, that hospital staff (doctors, nurses), equipment vendors, and suppliers of medical material and supporting accessories facilitated user-training. Although the semi-structured

interviews revealed comprehensive dissemination of information, several risks aspects were identified. As an example, the dialysis patients attached considerable importance to interaction with other patients undergoing dialysis in the home setting. Despite this importance, experience sharing through interactive forums with other patients were not included as part of training programs for patients. For instance, new patients gained knowledge much more efficiently on practical challenges such as hygiene, managing unexpected failure of the equipment, storage of medical material, and managing the replenishment of medical material and supporting accessories.

Other gaps identified from the semi-structured interviews include training needs for care givers in the home setting, mostly immediate family members on clinician tasks such as fixing tubes and connecting the patient to the dialysis equipment. Technical risks often arising in this instance, include failure of components of the dialysis equipment, e.g. the blood circulation pump, when the patient is connected to the dialysis equipment. Table 3 summarizes the strengths versus the weakness of dialysis training.

(2) Selection and delivery of dialysis equipment

In this step, the patient, in consultation with the hospital staff and device vendors selects the most appropriate dialysis equipment, e.g. devices for hemodialysis or peritoneal dialysis. The semi-structured interviews indicated that choice of the appropriate device was undertaken during the training step. Although cost was an important factor, the choice was biased towards the equipment which best suited the patient needs, e.g. ease of use, home setting where the device is installed, or technical support during the dialysis management process. However, defining the patient needs to the appropriate device was highlighted as challenge, due to varying factors such as the technological complexity of the device, user interface, ease of use, and requisite modification necessary to allow installation and use of the device. Supporting infrastructure for a specific device was also an important influencing variable. This also includes a maintenance and inspection program for the specific dialysis equipment. Technical support, including maintenance of the water supply piping or pump was also an important concern raised by the patients.

Besides, the choice of the appropriate device was also influenced by medical personnel, and device vendors who sometimes performed the needs analysis on the patient's behalf. As a result, it was common that patients usually accepted a proposed device without sufficiently acknowledging practical operational or maintenance challenges associated with its use, e.g. as mentioned, intuitiveness of the user interface, or technological orientation of the device vis a vis the patient. This implied risk associated with

Table 3 Summary of strengths and potential risks of dialysis training in the home setting

Strengths	Potential weaknesses	Hazards and risks
Complete and accurate training with support of brochures and technical manuals of the dialysis devices	Limited interactions between new patients, and patients undergoing dialysis in the home setting	Limited awareness of practical challenges for undertaking the dialysis process in the home setting, e.g. managing replenishment of medical material
Support of vendors of dialysis equipment and medical materials	Training gaps for caregivers in the home setting, e.g. relatives, or partners	Limited preparedness on the part of the caregiver for unexpected deterioration of patient's condition

selecting a correct device, including potential equipment misuse, or misinterpretation of error signal which could negatively influence the quality of the dialysis process.

To compound the likely mismatch between patient needs and the type of equipment, limited interactions between potential users of the device, and current users constrained informed choices, and hence portend hazards such as operational errors due to sub-optimal design of the user interface, or mismatch between the technological aspects of the device and the user (or care giver). Additionally, although the availability of comprehensive brochures and manuals was identified as a strength during the training step, the documentation embedded user-related risks—some manuals contained significant “technical language”, which was not intuitive to users. As a result, patients seldom review the manuals provided by vendors. Rather, the patients relied on alternative and simplified documents prepared by the medical personnel, which were more simplified and intuitive to understand and interpret. However, the simplification meant limited dissemination of information for optimal operation of the dialysis equipment. For instance, interpreting of error warnings.

In addition to selection and user related challenges, supply related logistical risks were also identified, which varied depending on the type of the dialysis equipment. The peritoneal device was mentioned as least cumbersome concerning delivery where often the patient carried the equipment with them to the home setting after completion of training. The hemodialysis device, on the other hand, was cumbersome as it could only be delivered and installed by the vendor. The transportation of the devices also implied exposure to contaminants and biological hazards if not carried out carefully. Risks of equipment failure was further mentioned by patients as an important concern.

(3) Installation of the dialysis equipment

Prior to installing the dialysis equipment, modifications to the home setting may be necessary, where the extent of the modification depended on the type of device. The modifications not only influenced the equipment installation process, but also extended to allocating storage areas for medical material. Moreover, a considerable amount of

space was required for processing medical waste. From the interviews, striking differences were apparent depending on the type of dialysis equipment. The peritoneal dialysis equipment necessitated the least modifications, where often, were limited to power supply to the equipment. In contrast, installing the hemodialysis devices required extensive modification to the home setting. First, there was the need to modify the water supply to the house to ensure conforming to specifications of the hemodialysis device, e.g. minimum supply pressure. This meant that besides the network water supply pressure, installation of water booster pump was necessary. Moreover, optimal functioning of the water purifier was dependent on the quality of water supplied to the purifier.

Secondly, similar to the peritoneal dialysis equipment, adjustments to the power supply was necessary for the hemodialysis equipment, which implied electrical hazards if not done correctly. Third, a protective plastic covering needed to be added to the floor area where the hemodialysis equipment was installed, which also implied hazards, more so if the wrong protective cover was used, or the workmanship was not up to the required standard. The protective cover ensured sterility of the floor area where the equipment was installed, hence minimizing biohazards. Importantly, the hemodialysis patient required a separate room for storing the dialysis equipment and creating a special storage area for the medical waste. This also implied exposure to biohazards for the patient, or family members.

An important concern during the modification process was the need for patient involvement, which was sometimes challenging owing to factors such as work schedules, inconvenience to neighbors during construction work, necessitating the need for official permit for the city authorities. Moreover, communication challenges arose between the patients and the contractors undertaking the adjustment, because of language barrier, e.g. Dutch or French, which are the main modes of communication within Belgium. This meant that potential risks arose, for instance, incorrect communication of instructions such as operating procedures for opening or shutting off water supply, improper storage of sterile material, or improper

maintenance of hygiene within the room where the dialysis equipment is installed.

(4) Management of the dialysis process

The management process covers aspects such as administration of the dialysis process, and the support system surrounding the process. The management also encompasses replenishment of medical material used during the dialysis process. From the survey, support was always offered during the first day when the peritoneal dialysis was done in the home setting. This was also the situation for hemodialysis where a medical professional was present with the patient when performing first dialysis processes in the home setting. Presence of the medical personnel was less required as the patient gained more knowledge of the process sufficient to manage the process by themselves.

Apart from presence during the first procedure in the home setting, periodical reviews were undertaken by the medical personnel, especially for the hemodialysis procedure, which was more complicated compared to the peritoneal dialysis. However, several risks were identified. As an example, peritoneal dialysis patients expressed challenges connecting and disconnecting the dialysis catheter tubing. Here, observing hygiene was of primary concern to prevent the risks of contracting peritonitis.

For hemodialysis patients, the risk of puncturing the fistula during coupling or uncoupling to the equipment presented considerable concerns. In the hospital setting, this task was performed by experienced nurses, hence reducing the mentioned risks. Moreover, exposure to additional risks were possible, for instance, inadvertently touching control buttons of the devices. Although the patients were aware of procedures to be followed during emergencies, e.g. difficulties with flow of the dialysis fluid, risk exposure was possible. This was especially the case for sudden deterioration of the patient's health. Thus, training of the care givers to manage the process was critical, alongside the patient.

Overall, peritoneal patients expressed the most self-control over the dialysis process, which implied that they could exercise control over hygiene, connecting and disconnecting to the device, and operating the equipment. On the other hand, hemodialysis patients relied on caregivers in the home setting which constrained their control over the process hence possibility of exposure to hygiene related hazards. The caregivers were often involved during equipment start-up, shutdown, and sometimes, disinfecting the dialysis machine.

Besides clinical process related risks, supply of medical material was identified as a critical factor for optimal management of the dialysis process. The vendors and the hospital to which the patient was affiliated facilitated the

replenishment process, where the replenishment was based on request by the patient. However, since sometimes the request was through telephone conversations, miscommunication was possible, meaning that delivery of incorrect quantities, or wrong material was possible. Moreover, the replenishment was done periodically, which implied bulk supply of medical material, implying that the patients were sometimes not able to accurately keep track of the inventory to avoid stock-outs of the material.

During transportation and supply of the medical material and accessories for supporting dialysis, it was the couriers' responsibility to maintain hygiene, and minimize the risk of contamination. However, such contamination hazards could still occur during transportation. An important concern raised by the patient was missed or incorrect deliveries, which potentially occurred when the treatment regime changed. This implied the need for modifying the type and quantities of medical materials supplied to the patient. If the change is incorrectly communicated to the vendor and/or hospital, wrong deliveries was possible which would potentially interfere with the treatment process.

The patient's work schedule was also mention as of concern since medical, although required urgently, could not be delivered to the patient during working hours. However, to mitigate this challenge, the hospital to which the hemodialysis patient was affiliated, implemented a tracking system on behalf of the patient to minimize the possibilities of missed or incorrect deliveries.

(5) Equipment maintenance and hygiene

From interviews with patients, maintaining hygiene and sterility of the equipment was indispensable, especially with the catheter, fluid lines, and the dialysis machine. In absence of a sterile environment, exposure to biohazards is possible leading to the risk of contracting peritonitis (for peritoneal dialysis patients). The infection was especially likely if the catheter was not properly cleaned and disinfected. For hemodialysis patients, the need for sterility was also important since the patients stood the risk of blood infection since connection to the device was through the fistula. Additionally, the cleaning the dialysis lines required strict adherence to sterility regimes where specific cleaning agents and warm water was used. Periodically, the dialysate was sampled to evaluate the need of replacing the salt cones.

Although the hospital provided patients with cleaning agents, it was the patient's responsibility to observe the recommended sterilization regimes to minimize exposure to biological hazards, or contaminants, which may adversely affect the patient's health. Here, time requirements and assistance from the caregivers were viewed as important considerations for ensuring correct sterility and

maintenance of hygiene. Often, the survey indicated that patients were often unaware of periodic checks required for the equipment, i.e. monthly, quarterly or yearly audits. The equipment vendor performed part of the checks; however, communication between the patient and the vendor was important for ensuring prompt audits.

(6) Managing medical waste

Patients highlighted waste management as perhaps the most important challenge for dialysis in the home setting. This is because of the amount and variety of waste generated, which varied from one patient to another. The waste generation and management were likewise influenced by aspects such as the medical material used by the patient, and the location where the patient resided. For hemodialysis patients, waste was generated at least three times each week and included non-reusable fluid tubing, hypodermic needles, and packaging material for medical material (e.g. dialysis fluids).

The medical waste was collected by the hospital the patient was affiliated with through an arrangement with the vendor of the medical material. Although limited amounts of waste were produced in each dialysis session, the peritoneal dialysis patients generated more waste due to the more frequent dialysis sessions, while the hemodialysis patients required fewer sessions. An important concern of the peritoneal patients was related to limited flexibility of the delivery/collection schedules, which sometimes interfered with the patients' schedule. For such instances, the patients relied to municipal services exposing waste handlers to biological hazards.

(7) Handling defective devices

From the interviews, the procedures followed for maintaining the dialysis equipment differed with the type of equipment. Peritoneal dialysis patients usually delivered the defective equipment to the hospital after which a replacement device was assigned to the patient within a period of 24 h. For hemodialysis device, the maintenance procedures differed from hospital to hospital, to which the patients were affiliated. This ambiguity also influenced the maintenance processes where hemodialysis patients noted challenges reporting defects to the hospital or vendors. This was especially the case where urgent repairs were needed owing to the patient's dialysis regimes. Here, communicating appropriately the nature of device defect was usually not straightforward. Moreover, absence of a robust warning system for notify the patients in case of faults was also a limiting factor, implying exposure of the patient to clinical hazards were the equipment to fail during the dialysis process.

5 Discussion

Comparing the two use cases, it is apparent that assessing risks associated with the dialysis process varies depending on the application context. Moreover, it may be seen that methods applied also differ depending on the application context. One important factor that seemingly influences the assessment approach is the structure and organization of the clinical processes. For instance, dialysis-at-home is seemingly well organized with clear organization of resources, and defined pathologies for the dialysis process. Moreover, interactions between processes and resources are situated into clearly defined departments or focus areas. For the specific use case, three departments were active in dialysis, nephrology, nursing, and medical instrumentation.

The clearly defined structure of organization of dialysis-at-home also implied that the approach for mapping hazards associated with specific interacting processes was feasible. From maps of the interactions between the processes and resources, defining potential hazards is more intuitive because of user knowledge embedded in each process step. As an example, nurses and biomedical technicians were involved in sample taking processes, to ascertain the quality of water. Thus, they were better predisposed to assess possible hazards that could occur during the sampling process. The clear organization of dialysis-at-home also meant that quantifying and prioritizing risks was much more structured, e.g. through the HFMEA.

Nonetheless, despite a clear organization of dialysis-at-home, a detailed enumeration of hazards remains challenging, especially because of reliance on expert knowledge of the clinical processes. Moreover, agreeing on hazard scores which is largely through consensus, required that first, the multi-disciplinary understands the nature of each hazard, and associated potential consequences. Despite these challenges, the HFMEA is a useful decision-support tool for assessing risks in the dialysis care pathway, and formulating mitigation strategies, e.g. more robust operational or clinical protocols for processes prone to hazardous events.

By contrast, assessing risks for dialysis-at-home processes is challenging, first because of limitation on clarity of its organization. Hence, following a similar methodology as used for dialysis-at-hospital is not straightforward. Several aspects influence the process, for instance, type of method used, where use of more structured tools such as the HFMEA is constrained. The survey methodology adopted for the use case seemed to yield more insights on organization of dialysis-at-home, from which systematic phases were decomposed. The phases here start with mapping important stakeholders supporting the dialysis process, by following a semi-structured interviewing

process with dialysis patients, medical practitioners and equipment vendors. For the hospital case, such stakeholders were identifiable in a rather straightforward way, since resources were situated within well-defined departments. This is not the case for dialysis-at-home.

Also, analyzing factors influencing the organization of dialysis-at-home, logistical related aspects featured rather prominently, for ensuring optimal dialysis processes. As seen, this is because of factors such as storage of medical material, waste handling and disposal. In the hospital setting, the aforementioned factors were clearly organized with concerned department and defined responsibilities. Aligned with the transfer of specific clinical processes to the home environment, hazards transfer was likely, e.g. biological hazards which could occur because of sub-optimal hygiene of the room dialysis is performed, or improper operation of the device. Additional aspects, which differed significantly to the hospital setting, include the need for proper training on procedures, and operation of the dialysis equipment, which for the hospital setting, were addressed by responsible departments and personnel. However, domain knowledge is an important limitation given the often-varying healthcare processes and complex organization, e.g. in large hospitals with more structured training and smaller departments with less developed training initiatives. This limitation also influences the robustness of the methodologies proposed in this study, especially mapping process steps for dialysis care in the home care setting.

For dialysis-at-home care, the ad-hoc organization of the processes, also influenced the hazard identification and prioritization process, especially using systematic and structured risk assessment methods, e.g. the HFMEA. A significant constraint in this regard, is the level of process knowledge for processes linked to dialysis-at-home, which differed considerably depending on the composition of the stakeholders. For instance, while as medical practitioners are knowledgeable on the dialysis process, and maybe aware of hazards in the hospital setting, this is not the case for dialysis-at-home care. Here, the responsibility of managing the processes is transferred largely to the patient. As an example, waste management was the responsibility of the patient, the hospital the patient is affiliated with, and the vendors of medical material assigned the responsibility of replenishing new material and collecting waste. Hence, hazards could arise from the interactions and required a systematic approach for identifying such hazards while considering all the stakeholders involved. In this sense, following a method such as HFMEA may not be immediately clear, thus may yield a sub-optimal risk assessment process.

Moreover, with several stakeholders concerned with organization of dialysis-at-home, e.g. care givers, suppliers

of medical materials, safety assurance of the process is invariably influenced. Therefore, from the contrasting use-cases, the influence of the application setting on the risk assessment process is rather critical. From the discussion, it may seem that the approach used depends on how well the clinical processes and supporting resources are organized. Similarly, mapping extensively stakeholders involved in healthcare is an important first step for assessing risks embedded in clinical processes. This limitation is especially the case for dialysis in the home care setting since often as the start of the mapping, the stakeholders involved are usually unclear. Therefore, if not well executed, it potentially negatively influences the robustness of the risk mapping process.

Identifying technical risks associated with the dialysis process was observed as an important concern since it influenced the quality of the dialysis process and furthermore, affected the clinical outcomes and quality of life of the patient. Importantly, identifying such technical risks is important for formulating technical interventions, including designing robust maintenance programs. While there was often sufficient domain knowledge within maintenance departments of hospitals, maintenance knowledge in the home care setting is not well embedded, leading to over reliance on vendors of the dialysis equipment. Moreover, equipment manual was often written in a technical language.

Hence, to better structure and formulate maintenance protocols, a more robust structure to align dialysis processes with technical risks is required. While the HFMEA is important for risk identification, it relies largely on domain experts leading to potentially biased information or non-exhaustive list of technical risks. Hence, there is need for more insights on how to achieve such alignment, which is an aspect of future work. Moreover, root cause analysis forms an important basis for formulating maintenance programs and several possible tools are discussed in the literature for aiding this analysis. Because of advances of error management, tools such as the Fault Tree Analysis, or data mining methods can potentially aid identification of potential root causes of equipment failure. The latter include cluster analysis and multivariate data analysis tools. Some examples discussed in literature in this direction include, Chemweno et al. (2016a, b) where cluster analysis methods are combined with dimensional reduction methods such as Principal Component Analysis (PCA) and failure mapping to efficiently identify patterns of equipment failure embedded in error signals. Such an approach is potentially applicable for aiding root cause analysis and formulating user-friendly maintenance programs for dialysis equipment used in the home setting. Research towards this direction is a focus of future work.

6 Conclusion

This paper presents a comparative risk assessment of two contrasting use cases for dialysis care: dialysis-at-hospital versus dialysis-at-home. The goal of the study is to understand how risk assessment process can be structured considering often varying application context. Importantly, the study presents opportunities for assessing potential risk factors that are likely to occur when healthcare management is transferred to the home setting. For the hospital case, the HFMEA approach is implemented, starting with mapping the patient treatment steps, as the patient interacts with caregivers at the hospital and utilizes the dialysis equipment. Usage of the medical material is also an important influencing factor. For structuring the risk assessment process, input of decision makers is observed an important factor for robustly identifying both clinical and technical risks. For the hospital case, domain knowledge of the process was observed as yielding a more structured approach for identifying and assessing risk factors for the dialysis patient. By contrast, we observe that structuring risk assessment for dialysis-at-home is more challenging because of unclear organization of the clinical and/or technical processes. Hence, a survey-based approach is implemented for this second case.

Moreover, identifying and assessing clinical and technical risks, including device related failure is much more challenging for the home setting, because of multiple stakeholders interacting with the patient, including the care giver at home, suppliers of medical material and authorities approving changes to the home setting to facilitate installation of the dialysis equipment, and handling of medical waste. Technical risks were more dominant for the dialysis at home case, because of the modifications needed during installation, and often limited domain knowledge by the patient or caregiver for managing maintenance aspects of the device. Overall, the study yields important insights on structuring risk assessment for dialysis processes, and the need of understanding the dependencies between the treatment process, stakeholders involved, and technical aspects of the dialysis equipment. Understanding these dependencies is especially important as more countries transfer healthcare management to the home setting.

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References

- Abecassis ZA, McElroy LM, Patel RM, Khorzad R, Carroll-IV C, Mehrotra S (2015) Applying fault tree analysis to the prevention of wrong-site surgery. *J Surg Res* 193(1):88–94
- Abrahamsen HB, Abrahamsen EB, Høyland S (2016) On the need for revising healthcare failure mode and effect analysis for assessing potential for patient harm in healthcare processes. *Reliab Eng Syst Saf* 155:160–168
- Asamoah DA, Sharda R, Rude HN, Doran D (2018) RFID-based information visibility for hospital operations: exploring its positive effects using discrete event simulation. *Health Care Manag Sci* 21(3):305–316
- Beaussier AL, Demeritt D, Griffiths A, Rothstein H (2016) Accounting for failure: risk-based regulation and the problems of ensuring healthcare quality in the NHS. *Health Risk Soc* 18(3–4):205–224
- Birmelé B, Armel LG, Benedicte S, Colette A, Vincent C (2012) Clinical, sociodemographic, and psychological correlates of health-related quality of life in chronic hemodialysis patients. *Psychosomatics* 53:30–37
- BSI-ISO (2007) Medical devices—application of risk management to medical devices. International Organisation of Standardisation
- Card AJ (2017) The problem with '5 whys'. *BMJ Qual Saf* 26(8):671–677
- Chemweno P, Thijs V, Pintelon L, Van Horenbeek A (2014) Discrete event simulation case study: diagnostic path for stroke patients in a stroke unit. *Simul Model Pract Theory* 48:45–57
- Chemweno P, Brackenier L, Thijs V, Pintelon L, Van Horenbeek A, Michiels D (2016a) Optimising the complete care pathway for cerebrovascular accident patients. *Comput Ind Eng* 93:236–251
- Chemweno P, Morag I, Sheikhalishahi M, Pintelon L, Muchiri P, Wakiru J (2016b) Development of a novel methodology for root cause analysis and selection of maintenance strategy for a thermal power plant: a data exploration approach. *Eng Fail Anal* 66:19–34
- Chemweno P, Pintelon L, Muchiri PN, Van Horenbeek A (2018) Risk assessment methodologies in maintenance decision making: a review of dependability modelling approaches. *Reliab Eng Syst Saf* 173:64–77
- Culwick MD, Merry AF, Clarke DM, Taraporewalla KJ, Gibbs NM (2016) Bow-tie diagrams for risk management in anaesthesia. *Anaesth Intensive Care* 44(6):712–718
- De Bleser L, Depreitere R, Waele KD, Vanhaecht K, Vlayen J, Sermeus W (2006) Defining pathways. *J Nurs Manag* 14(7):553–563
- De Giorgi I, Fonzo-Christe C, Cingria L, Caredda B, Meyer V, Pfister RE, Bonnabry P (2010) Risk and pharmacoeconomic analyses of the injectable medication process in the paediatric and neonatal intensive care units. *Int J Qual Health Care* 22(3):170–178
- DeRosier J, Stalhandske E, Bagian JP, Nudell T (2002) Using health care failure mode and effect analysis™: the VA National Center for Patient Safety's prospective risk analysis system. *Joint Comm J Qual Improv* 28(5):248–267
- Dimitrow MS, Mykkänen SI, Leikola SN, Kivelä SL, Lyles A, Airaksinen MS (2014) Content validation of a tool for assessing risks for drug-related problems to be used by practical nurses caring for home-dwelling clients aged ≥ 65 years: a Delphi survey. *Eur J Clin Pharmacol* 70(8):991–1002
- Diseases, National Institute of Diabetes and Digestive and Kidney (2017) Health information on kidney failure. <https://www.niddk>.

- nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis. Accessed 17 Mar 2017
- Ebright PR (2014) Patient safety. In: Brigido A (ed) Foundations of clinical nurse specialist practice. Chap 13. Springer Publishing Company, New York, pp 211–220
- FENIER-FABIR (2016) <https://www.fenier-fabir.be/index.php/en/>. Accessed 6 Dec 2016
- Fiest KM, McIntosh CJ, Demianschuk D, Leigh JP, Stelfox HT (2018) Translating evidence to patient care through caregivers: a systematic review of caregiver-mediated interventions. *BMC Med* 16(1):105
- Franklin BD, Shebl NA, Barber N (2012) Failure mode and effects analysis: too little for too much? *BMJ Qual Saf* 21(7):607–611
- García JRR, Martinetti A, Becker JMJ, Singh S, van Dongen LA (2019) Towards an industry 4.0-based maintenance approach in the manufacturing processes. In *Handbook of research on industrial advancement in scientific knowledge*. IGI Global, pp 135–159
- Garfield S, Bell H, Nathan C, Randall S, Husson F, Boucher C, Taylor A, Backhouse A, Ritchie L, Franklin BD (2018) A quality improvement project to increase self-administration of medicines in an acute hospital. *Int J Qual Health Care* 30(5):396
- Goel NA, Alam AA, Eggert EM, Acharya S (2017). Design and development of a customizable telemedicine platform for improving access to healthcare for underserved populations. In *2017 39th annual international conference of the IEEE engineering in medicine and biology society (EMBC)*. IEEE, pp 2658–2661
- Goodrum L, Varkey P (2017) Prevention is better: the case of the underutilized failure mode effect analysis in patient safety. *Israel J Health Policy Res* 6(1):10
- Grespan L, Fiorini P, Gianluca C (2019) Patient safety in robotic surgery. In: *The route to patient safety in robotic surgery*. Springer.
- Grout JR, Toussaint JS (2010) Mistake-proofing healthcare: why stopping processes may be a good start. *Bus Horiz* 53(2):149–156
- Hemsley B, Steel J, Worrall L, Hill S, Bryant L, Johnston L, Balandin S (2019) A systematic review of falls in hospital for patients with communication disability: highlighting an invisible population. *J Saf Res* 68:89–105
- Hignett S, Otter ME, Keen C (2016) Safety risks associated with physical interactions between patients and caregivers during treatment and care delivery in home care settings: a systematic review. *Int J Nurs Stud* 59:1–14
- Hirst JA, Stevens RJ, Smith I, James T, Gudgin BC, Farmer AJ (2017) How can point-of-care HbA1c testing be integrated into UK primary care consultations? A feasibility study. *Diabetes Res Clin Pract* 130:113–120
- IEC (2009). IEC/ISO 31010:2009, risk management—risk assessment techniques. International Electrotechnical Commission
- Ikeda Y (2017) Current status of home medical care waste collection by nurses in Japan. *J Air Waste Manag Assoc* 67(2):139–143
- Jiang L, Luo J, Dong W, Wang C, Jin W, Xia Y, Wang H, Ding H, Jiang L, He H (2015) Development and evaluation of a polydiacetylene based biosensor for the detection of H5 influenza virus. *J Virol Methods* 219:38–45
- Keeling DI (2014) Homecare user needs from the perspective of the patient and carers: a review. *Smart Homecare Technol TeleHealth* 2014(2):63–76
- Kricke GS, Carson MB, Lee YJ, Benacka C, Mutharasan RK, Ahmad FS, Kansal P, Yancy CW, Anderson AS, Soulakis ND (2017) Leveraging electronic health record documentation for failure mode and effects analysis team identification. *J Am Med Inform Assoc* 24(2):288–294
- Krishna VN, Managadi K, Smith M, Wallace E (2017) Telehealth in the delivery of home dialysis care: catching up with technology. *Adv Chronic Kidney Dis* 24(1):12–16
- Labagnara D, Martinetti A, Patrucco M (2013) Tunneling operations, occupational S&H and environmental protection: a prevention through design approach. *Am J Appl Sci* 10(11):1371
- Lee LM, Henderson DK (2018) Identifying, understanding, and managing patient safety and clinical risks in the clinical research environment. In *Principles and practice of clinical research*. Academic Press, pp 633–644
- Leupolz J, Habermaier A, Reif W (2018) Quantitative and qualitative safety analysis of a hemodialysis machine with S#. *J Softw Evol Process* 30(5):e1942
- Liu ZX, Yuan J (2015) Anesthesia risk assessment based on vague set and fault tree analysis. *Ind Eng Manag* 20(1):115–121
- Mahfoud H, El Barkany A, El Biyaali A (2016) Preventive maintenance optimization in healthcare domain: status of research and perspective. *J Qual Reliab Eng* 2016:1–10
- Makajic-Nikolic D, Petrovic N, Belic A, Rokvic M, Radakovic JA, Tubic V (2016) The fault tree analysis of infectious medical waste management. *J Clean Prod* 113:365–373
- Martinetti A, Chatzimichailidou MM, Maida L, van Dongen L (2019) Safety I–II, resilience and antifragility engineering: a debate explained through an accident occurring on a mobile elevating work platform. *Int J Occup Saf Ergon* 25(1):66–75
- McElroy LM, Khorzad R, Nannicelli AP, Brown AR, Ladner DP, Holl JL (2016) Failure mode and effects analysis: a comparison of two common risk prioritisation methods. *BMJ Qual Saf* 25(5):329–336
- McElroy LM, Khorzad R, Rowe TA, Abecassis ZA, Apley DW, Barnard C, Holl JL (2017) Fault tree analysis: assessing the adequacy of reporting efforts to reduce postoperative bloodstream infection. *Am J Med Qual* 32(1):80–86
- Merchant S, O'Connor M, Halkett G (2017) Time, space and technology in radiotherapy departments: how do these factors impact on patients' experiences of radiotherapy? *Eur J Cancer Care* 26(2):e12354
- Merino P, Bustamante E, Campillo-Artero C, Bartual E, Tuero G, Mari J (2014) Patient safety certification in a Department of Intensive Care Medicine: our experience with standard UNE 179003: 2013. *Medicina Intensiva (Engl Ed)* 38(5):297–304
- Mosquera RA, Avritscher EB, Samuels CL, Harris TS, Pedroza C, Evans P, Navarro F, Wootton SH, Pacheco S, Clifton G, Moody S (2014) Effect of an enhanced medical home on serious illness and cost of care among high-risk children with chronic illness: a randomized clinical trial. *JAMA* 312(24):2640–2648
- Mullangi S, Sozio SM, Segal P, Menez S, Martire C, Shafi T (2018) Point-of-care ultrasound education to improve care of dialysis patients. In: *Seminars in dialysis*, vol 31, no 2, pp 154–162
- O'Connell D, Thomas DH, Lewis JH, Hasse K, Santhanam A, Lamb JM, Low DA (2019) Safety-oriented design of in-house software for new techniques: a case study using a model-based 4 DCT protocol. *Med Phys* 46(4):1523–1532
- Ong MS, Coiera E (2010) Safety through redundancy: a case study of in-hospital patient transfers. *Qual Saf Health Care* 19(5):e32–e32
- Paine LA, Holzmüller CG, Elliott R, Kasda E, Pronovost PJ, Weaver SJ, Sutcliffe KM, Mathews SC (2018) Latent risk assessment tool for health care leaders. *J Healthc Risk Manag* 38(2):36–46
- Qu Y, Young CC (2018) Quantifying trends in Florida Hospital Medical malpractice claims using a mixed effects approach. *J Leadersh Account Ethics* 15(4):76–91
- Rabinstein A (2017) Treatment of acute ischemic stroke. *Lifelong Learn Neurol* 23:62–81
- Riou S, Parent D, Hay M, Devie I, Rey JB (2017) PS-066 use of a risk analysis method in a chemotherapy production centralised unit. *Eur J Hosp Pharm* 24:256–270

- Rogith D, Iyengar MS, Singh H (2017) Using fault trees to advance understanding of diagnostic errors. *Joint Comm J Qual Patient Saf* 43(11):598–605
- Rosen MA, Chima AM, Sampson JB, Jackson EV Jr, Koka R, Marx MK, Kamara TB, Ogbuagu OU, Lee BH (2015) Engaging staff to improve quality and safety in an austere medical environment: a case–control study in two Sierra Leonean hospitals. *Int J Qual Health Care* 27(4):320–327
- Schlatter J (2018) Risk analysis in pediatric inpatients. *Archives de Pédiatrie* 25:405–410
- Simsekler MCE, Ward JR, Clarkson PJ (2018) Evaluation of system mapping approaches in identifying patient safety risks. *Int J Qual Health Care* 30(3):227–233
- Sutcliffe KM, Paine L, Pronovost PJ (2017) Re-examining high reliability: actively organising for safety. *BMJ Qual Saf* 26(3):248–251
- Swamidas J, Khanna N, Mahantshetty U, Somesan V, Deshpande DD, Shrivastava SK (2018) Implementation of failure mode and effective analysis for high dose rate brachytherapy at Tata Memorial Hospital, Mumbai, India. *Cancer/Radiothérapie* 22(4):334–340
- Tague NR (2005) *The quality toolbox*. ASQ Quality Press, Milwaukee
- Teixeira FC, de Almeida CE, Saiful Huq M (2016) Failure mode and effects analysis based risk profile assessment for stereotactic radiosurgery programs at three cancer centers in Brazil. *Med Phys* 43(1):171–178
- Tennankore K, Nadeau-Fredette AC, Chan CT (2014) Intensified home hemodialysis: clinical benefits, risks and target populations. *Nephrol Dial Transplant* 29(7):1342–1349
- Uberoi RS, Swati E, Gupta U, Sibal A (2007) Root cause analysis in healthcare. *Apollo Med* 4(1):72–75
- Uy RCY, Kury FP, Fontelo PA (2015) The state and trends of barcode, RFID, biometric and pharmacy automation technologies in US hospitals. In *AMIA annual symposium proceedings*, vol 2015. American Medical Informatics Association, p 1242
- Vaartio-Rajalin H, Fagerström L (2019) Professional care at home: patient-centredness, interprofessionalism and effectiveness? A scoping review. *Health Soc Care Community* 27(4):e270–e288
- Vala S, Chemweno P, Pintelon L, Muchiri P (2018) A risk-based maintenance approach for critical care medical devices: a case study application for a large hospital in a developing country. *Int J Syst Assur Eng Manag* 9(5):1217–1233
- Voor de Gezondheidszorg, Federaal Kenniscentrum. Organisatie en financiering van chronische dialyse in België
- Wang K, Wang P, Liang X, Lu X, Liu Z (2015) Epidemiology of haemodialysis catheter complications: a survey of 865 dialysis patients from 14 haemodialysis centres in Henan province in China. *BMJ Open* 5(11):e007136
- Wong D, Wu N, Watkinson P (2017) Quantitative metrics for evaluating the phased roll-out of clinical information systems. *Int J Med Inform* 105:130–135
- Xiao HF, Chen Q, Cheng H, Li XM, Qin WM, Chen BS, Zhang WM (2017) Selective removal of halides from spent zinc sulfate electrolyte by diffusion dialysis. *J Membr Sci* 537:111–118
- Yoshioka J, Fukuta K, Igeta H, Ifuku T, Honma T (2019) Healthcare Technology Management (HTM) by Japanese clinical engineers: the importance of CEs in hospitals in Japan. In: *World congress on medical physics and biomedical engineering 2018*. Springer, Singapore, pp 817–821

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