Quality and safety management of advanced medical technologies in home care organisations: A qualitative survey along the road to uniformity in the Netherlands.

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Research Article

Keywords: Medical technology, nursing, homecare, quality management, risk management, tactical level, qualitative study

Posted Date: March 11th, 2024

DOI: https://doi.org/10.21203/rs.3.rs-4000531/v1

Additional Declarations: No competing interests reported.

Abstract

Background:

A Quality Management System (QMS) in health care organisations encompasses not only policies, processes and necessary procedures, but should also encompass quality, safety, and risk management of medical technology (MT). Tactical and operational decision-making levels should be closely interconnected. Previous studies showed that nurses at the operational level do have a good awareness of patient safety, but especially in teams with a strong degree of self-organisation the interaction with tactical levels is an issue.

Methods:

A qualitative methodology was employed to explores the perspectives of employees who are responsible at a tactical level in homecare organisations concerning the quality and safety of advanced medical technologies (AMTs). Fifteen semi-structured interviews were conducted with purposively sampled employees across the Netherlands. Data were analyzed thematically using mainly a deductive approach.

Results:

All organisations possess a QMS, with only seven participants indicating that there is a plan for the quality and safety of AMTs. Most organisations apply the national protocols in the use of AMTs and rely on the supplier's maintenance protocols. Although some participants say that their organisation has no formal procedure for resolving malfunctions with AMTs, all know pathways to solve problems. Organisations use tailored training programs for nurses in using AMTs, but not all are testing knowledge and skills and/or demand the formal registration of competence of nurses. Professionals report an incident on a separate form in the electronic client file or via a separate reporting system. However, there is no uniformity within organisations about handling incidents. Most interviewees state that in any case, incidents are discussed in the team. On the dimension 'reporting, evaluating and learning from incidents', the prevalent patient safety culture is 'proactive' on average.

Conclusions:

There is a lack of uniformity regarding quality and safety procedures for the use of AMTs in homecare organisations and structured policies for the implementation, use and maintenance are needed. This study identified additional risk factors regarding individual competencies in the use of AMTs at home. Employees at a tactical level, seem to be more positive about the patient safety culture with AMTs in their organisations than nurses at operational level.

INTRODUCTION

A Quality Management System (QMS) serves as a tool for healthcare organisations to improve quality of care and patient safety [1–4]. The QMS encompasses not only policies, but also processes and necessary procedures. A comprehensive QMS should also encompass the quality, safety, and risk management of medical technology (MT). It's crucial to incorporate all current internal and external requirements into one plan guided by well-defined indicators and subject to assessment [2, 3, 5, 6].

For hospital care in the Netherlands, a covenant has been established outlining the principles for ensuring the quality of MT in specialized medical care [7]. The covenant covers the entire lifecycle of MTs and stipulates the need for procedures in the implementation phase, patient care phase, and decommissioning phase. However, uncertainty prevails in homecare regarding the quality requirements and indicators of MTs, and stakeholders seek uniformity regarding national field standards [8, 9].

Enhancing patient safety, there is a call for heightened transparency across healthcare levels, both within and between organisations. This approach facilitates learning from adverse outcomes for all stakeholders [5, 10, 11]. Organizational decisions made at a strategic level influence decisions at the tactical and operational levels. The interaction between tactical and operational decision-making levels is also closely interconnected [12, 13].

To further ensure the quality of home treatments involving advanced medical technologies (AMTs), increased attention should be directed towards training healthcare providers. Evidently, personnel with appropriate AMT-related competencies and levels of expertise are not always deployed [9–11, 14]. A previous survey on education and training at the operational level identified risk factors for patient safety. These

include practical training of AMTs is not always provided, additional or retraining is not always mandatory, and competencies are not always assessed [14]. While many organisations have improved quality enhancement and patient safety, integrated education into training plans is the next step [15]. Recommendations include homecare organisations establishing policies to maintain staff competency, enabling staff training, and ensuring certification and adequate training for new personnel [9][10].

Regarding incident reporting at the operational level, our findings indicated significant underreporting by homecare nurses: only 16% of incidents involving AMTs are reported following the organisation's protocol. However, a reasonable level of safety seems to be maintained given the low prevalence of incidents, and nurses predominantly discuss these within their teams [16].

As the next step, we aim shift our focus to the tactical level of the same homecare organisations. Consequently, the objective of this qualitative study is to explore the perspectives of employees responsible at a tactical level within homecare organisations concerning the quality and safety of AMTs. Specifically, we intend to investigate: (1) the quality frameworks utilized within their organisation according to these employees; (2) the extent of these employees' awareness of the procedures for safe AMTs use within their organisation; and (3) how these employees perceive the patient safety culture related to the use of AMTs within their organisation.

METHODS

Study design

This study is part of a larger mixed method research project focusing on safety and incident reporting related to the use of AMTs in outpatient practice across the Netherlands. For this study, a qualitative methodology was employed to gain insight into tactical staff perspectives of safety and incident issues within their organisations. Mainly a deductive approach has been applied to analyze the data and to a lesser extent an inductive one.

Participants and setting

Participants were purposively sampled from homecare organisations throughout the Netherlands, that had previously participated in a related study conducted by the research team. We deliberately aimed to recruit employees who are most familiar with the safety management of AMTs within their organisations. Participants were contacted via email, provided with study information, and invited to take part in an interview. In two cases, the invitee requested to be interviewed alongside a colleague, a request that was accommodated. Four invitees declined participation; three without stating a reason and one due to a lack of time.

Data collection

Overall, 15 interviews were conducted by the principal researcher and lead author (IH, female), who had been trained in interview techniques. Due to the COVID-19 pandemic, these interviews were conducted online.

A semi-structured interview guide was developed by the research team, drawing from existing literature [2, 7, 14, 16] and the expertise of a clinical physicist. The division into the lifecycle of MTs and the underlying paragraphs of the covenant for the safe application of MT in the specialist medical care in the Netherlands were used as a framework for the questionnaire, supplemented with aspects from literature. The interview guide primarily consisted of open-ended questions, supplemented by a few closed questions (see Additional file 1). The interview guide was pilot-tested with a specialized AMT nurse.

Interviews were conducted between August and December 2020, at times chosen by the participants. The average duration of the interviews was 55 minutes. All interviews were audio-recorded, and written informed consent was obtained from all participants. Participant characteristics were documented prior to the interviews. As the target was 15 sampled interviews, data saturation was not explicitly discussed.

Data analysis

Data analysis was conducted according to the phases of thematic analysis [17]. All interviews were transcribed verbatim. Participants were not asked to review their transcripts, though one participant requested to do so, and this was granted. The transcripts were thoroughly reviewed by two authors (IH and WH) to familiarize themselves with the data. The principal researcher (IH) conducted the analysis and coding using Atlas.ti software (version 9), checked by author WH.

The data analysis encompassed predominantly a deductive approach according to the covenant and to a minor extend an inductive approach [18], where underlying information is concerned. Initially, a coding framework was established based on the topics outlined in the

interview guide. All interview data were categorized using this framework. As the analysis progressed, certain underlying concepts emerged, leading to the creation of new codes, for example with regard to competence of the users and incident management.

Pertinent coded insights pertaining to these concepts were extracted into Microsoft Excel spreadsheets organized by theme, enabling the comparison, interpretation, and discussion of the data within the research team. This process resulted in a consensus on the final organization and interpretation of the data. Participants were not solicited for feedback on the findings.

RESULTS

Participant characteristics

A total of 17 participants took part in the interviews: 88% were female and 12% male. In the majority of cases, the homecare team operated as an independent organisation separate from a hospital. To a lesser extent, the homecare team had a collaboration with one or more hospitals, or was a component of a hospital. These and additional participant characteristics are shown in Table 1.

Table 1
Participant characteristics at time of interview.

Participant	Gender	Type of organisation*	Position in the organisation	Years of experience
P1	F	A	Nurse in a medical technical homecare team of a homecare organisation.	Over 20 years in care and quality management.
P2	M	A	Quality advisor at the organisation for elderly care.	30 Years in quality management, of which 13 years in healthcare, before that in industry.
P3a P3b	F F	B	P3a: Manager in a cooperative for medical technological homecare of 3 organisations for residential and homecare, and a hospital. P3b: Clinical physicist for MT in hospital and homecare.	P3a: About 25 years in quality management. P3b: One year in a hospital and before 4 years during education.
P4	F	C	Coordinator MT for 3 hospital locations and 17 centra for residential and elderly care.	One year and a half in this position and before a PhD-research project in biomedical technology into safety of medical technology.
P5	F	C	Nurse in a medical technical care team for homecare.	8.5 Years in this position.
P6	F	A	Senior nurse in a mobile care team for high- and low-complex care in outpatient and eventual inpatient care.	15 Years in the mobile care team.
P7	F	A	Nurse in a medical technical care team for homecare.	5 Years in quality management.
P8	F	A	Specialized nurse in a medical technical care team.	4.5 Years in this team.
P9	F	A	Homecare nurse for medical technical care.	26 Years in homecare.
P10	F	B	Policy advisor quality within a homecare organisation.	Almost one year.
P11	F	A	Nurse in a medical technical care team in a cooperative of 4 care organisations for specialized care.	22 Years in MT.
P12	F	A	Nurse in medical technical care in a homecare organisation	18 Years in MT.
P13	F	A	Project leader care technology.	22 Years in care and 2.5 years as a project leader.
P14a P14b	F F	A	P14a: Nurse specialist and project employee in a homecare organisation. P14b: Nurse specialist and project employee in a homecare organisation.	P14a: 11 Years as a nurse in homecare, of which 5 years as a nurse specialist and 1 year as project employee. P14b: 9 Years as a nurse in homecare, of which 5 years as a nurse specialist and 1 year as project employee.
P15	M	A	Nurse in a medical technical care team in a homecare organisation and chairman in the Shared Gouvernance Group medication safety.	About 5 years in the Shared Gouvernance Group.

*A: The homecare team is an independent organisation separate from a hospital

B: There is a collaboration with one or more hospitals

C: The homecare team is a component of a hospital

INSERT Table 1 HERE

Quality management systems and quality frameworks/guidelines

All participants confirm the presence of a QMS in their respective organisations, with the utilization of one or more national systems (see Table 2). However, three participants are unaware of the specific national QMSs being employed. National QMSs predominantly serve for periodic audits, as well as external accreditation or certification. Homecare teams affiliated with hospitals generally adopt the hospital's QMS.

Approximately half of the participants are uncertain about their organisation's existence of a plan for AMT quality and safety. Six participants acknowledge the presence of such a plan exists, while two assert its absence, '*….as the technologies are owned by the supplier, they are responsible that those devices are safe*' (P2). When present, these plans are usually integrated into another policy documents or annual plans. These plans encompass quality assurance measures for AMT, referencing user protocols, or the training for professional users. The practical implementation of the AMT quality policy is delegated to various departments within the organisations, e.g. the technical homecare team itself, specific colleagues, expert teams, the coordinator or policy advisors for AMT, or the 'Quality department'.

Few participants are acquainted with the 'Covenant on the safe application of MT in specialist medical care' [7], a mandatory systems for Dutch hospitals. Among those familiar with it, two explicitly indicate its integration into their organisation's QMS. These organisations maintain collaborations with, or are components of a hospital.

About a quarter of the interviewees confirm the involvement of a clinical physicist in their organisation's AMT quality process. Within the network of other disciplines, a pharmacist's involvement is often standard practice. Additionally, the prescriber or ultimately responsible physician, as well as ad hoc individuals like producers or suppliers (e.g. Mediq), the general practitioners, regional hospitals and a technician play a role. One participant emphasizes:

'Of course, there is regular consultation….. However, not only when an issue arises, but also for the purpose of improvement. It doesn't always have to be a problem. Sometimes, certain matters are arranged in a cumbersome manner. You might not have an issue, but there's room for enhancement or acceleration. These are also instances, of course, to convene'. (P8)

Table 2
National QMS used by organisations (multiple answers possible).

Abbreviation QMS	Used by number of organisations	Spelled out or translation	Type of system
ISO	8	International Organisation for Standardization	Quality standards
INK/EFQM	2	Dutch Institute for Quality	Management model
NIAZ	1	Dutch Institute for Accreditation of Hospitals	Accreditation/certification system
CBO	1	Central Guidance Institute for Peer Assessment (Quality Institute for Healthcare)	Quality guidelines
HACCP	4	Hazard Analysis and Critical Control Points (Nutrition/Kitchen)	Quality codes and instructions
HKZ	7	Foundation for Harmonization of Quality Policy in Healthcare Sector	Accreditation/certification system
TNO QMT	1	The Netherlands Organisation for applied scientific research–Quality for MT	Quality system
Other:			
TÜV	1	Association for Technical Inspection	Accreditation/certification system
JCI	1	Joint Commission International	Accreditation/certification system

Procedures regarding the introduction and the use of AMTs

Nine participants affirm that their organisation possess procedures linked to the introduction of AMTs. In several instances, the initiation stems from the medical technical care team, often upon the request of a hospital or a physician. These teams independently order the technologies, with or without managerial consultation. In other cases, suppliers take the lead in proposing new technologies, and the team

decides whether to adopt them or not. Four participants describe an inclusive bottom-up process across the organisation before transitioning to new technology.

Half of the participants indicate that their organisations lack a product file for AMTs. Some are uncertain, while others confirm the presence of such files. As one participant put it:

'*Yes, of course, we have a collection of the products and materials we work with, and you could call that a file, indeed. However, it's…. We don't officially refer to it as such, but it's essentially a file containing everything we work with. We can rely on it for information. And, well… It might not be named that way, but practically speaking, that's how it functions'.* (P1)

Three interviewees confirm the utilization of product files in their organisations, incorporating requirement programs and risk analysis; these organisations are affiliated with hospitals.

When asked about procedures related to AMT use, participants refer to the national Vilans Protocols1 [19] and some organisations employ hospital procedures. Supplier manuals of guidelines are also frequently cited as procedural references. One participant is uncertain about their organisation's user protocol description: *'…..at least, I have never seen them'* (P11). Typically, users have access to information about technologies, including protocols, through the organisation's document management system, intranet, or an app.

Evaluation of AMT use is primarily not conducted according to an established plan to ascertain proper device functioning, but often occurs ad hoc in practice. In a few organisations, AMT use is systematically evaluated as part of internal policy, whereas in others no evaluation occurs.

'*No, we do not evaluate that. We assume that the supplier has this in order. The pumps also have to meet all kinds of quality requirements before they can even come on the market ……..We are not going to ask him about 'Does the pump meet the quality requirements that the pump must meet?' I'm assuming it's been thought through. I trust that, we just trust that. Otherwise it gets complicated'.* (P11)

Procedures regarding the maintenance and malfunctions of AMTs

In terms of AMT maintenance, all organisations adhere to the supplier's guidelines and protocols. For hired equipment, the supplier usually initiates maintenance, conducts checks, and replaces devices if needed. Equipment owned by organisations also undergoes scheduled checks, for example indicated by stickers on the devices, specifying the maintenance date and the due date.

'Upon receiving a device, the 'Healthcare Technology department' assesses whether maintenance is required and how frequently. This assessment is guided by the associated risk score of the device. …. Subsequently, a decision is made regarding the necessity and frequency of maintenance. Of course, the supplier's instructions and recommendations are also taken into account. This is recorded in our management system, Ultimo, where the equipment is logged, and maintenance is scheduled'. (P3b)

Additionally, organisations use procedures for cleaning, disinfection and sterilization, e.g. suppliers protocols to clean pumps after each patient use. Due to the COVID-19 pandemic, two interviewees note heightened attention to hygiene and specific manufacturer-provided enhancements.

While one-third of the participants state their organisations lack procedures for addressing AMT malfunctions, all know what to do in the event of a malfunction. Nurses initially attempt to resolve malfunctions themselves. If unsuccessful, nurses can contact a 24/7 breakdown service, often provided by the supplier.

'*No, we don't have a procedure for that. It's actually something we've figured out within the team itself. It's more a mental process rather than being documented on paper. We always try to resolve it ourselves based on our knowledge. If we don't know, we call [the supplier] where we got the pumps from'.* (P5)

Two homecare teams affiliated with hospitals may avail the hospital's technical service, while two other hospital-affiliated teams are referred to external services for malfunction.

Competence of the users and environmental conditions

Various, often combined methods are employed within organisations to ensure nurses' competence in using AMT at home. Organisations offer tailored training programs, involving testing of knowledge and skills. Formal registration of nurses' competence is required according to participants, though one acknowledges not all nurses adhere to this. Peer review is utilized by a few organisations, and new employees may follow an onboarding protocol including testing. While nine participants note organisation initiate nurses' competence, three

organisations see it as nurses' personal responsibility. Periodic retraining is common in the majority of organisations; typically every three years. Often a periodic test is mandatory. However, some participants mention retraining occurs occasionally or upon team request.

For new technology, training is provided by organisations with mandatory testing in some of them. Conversely, participants indicate competence is not tested, and testing is not always obligatory.

'It is not subjected to testing in that way, but it is evaluated. So, as I mentioned, through evaluation questionnaires, they assess whether the implementation [of a new device] is successful and running smoothly. They also gauge whether people have enough confidence to work with it'. (P15)

Other methods employed to try to ensure the competence of the nurses include team discussions about new technology, practice sessions in the office, or to observe a colleague's performing the skills on a patient.

Patient and/or informal caregiver(s) operation of devices is typically allowed, with the attending physician's permission. The nurse ensures these users are competent by instructing them and supervising their skills. When deemed safe by the nurse, these users may perform tasks independently.

Organisations have requirements for the homecare environment, albeit often undocumented. These requirements include a safe, clean environment suitable for responsible care. Nurses assess this on-site and discuss it with clients and/or informal caregiver(s) when necessary. In extreme cases, patient transfer to a hospital or nursing home may be considered. However, a participant elaborates on a practical experience:

'No, it [the homecare environment] is not screened. I don't think it's ensured either. Currently, the priority is more about ensuring that if, for instance, infusion therapy is prescribed, it simply takes place. We sometimes work in very unsanitary environments. We do try to be cautious with pets in such situations and might take it outside the room, but sometimes you can't avoid a house being very dirty or excessively damp. There are cases where you have very little space to work in a clean environment. I've never experienced AMT being cancelled or postponed because of this'. (P8)

Incidents, knowledge management and patient safety culture

In the event of an incident, professionals have the option to submit a 'MIC-report', either through a separate form in the electronic client file or, in some cases, via a distinct reporting system outside the patient file. There are no specific incident reporting procedures for AMTs. In one organisation, professionals can use a transmural incident report system, which allows chain partners such as pharmacists, suppliers or hospitals to be informed. Patients or informal caregivers are typically advised to discuss incidents with nurses, who then initiate the reporting process. In some cases, informal users can also use forms in the patient file to report incidents or are directed to file complaints.

'We don't perceive incidents and complaints as shortcomings in our work, but rather as opportunities for improvement. This applies to client and family complaints as well; we are very receptive to them. We also encourage our staff to be very open about it and invite clients and families to voice their concerns wherever they're not satisfied'. (P2)

After reporting an incident, each organisation follows its own procedure for addressing it. Generally, incidents are discussed within the team, either periodically or on an as-needed basis.

'Most often, they are user errors related to equipment, and as a team, we can generally identify those ourselves and propose corrective measures'. (P3a)

Incidents are discussed in incident or quality committees, shared governance groups, or expert teams. In three cases, reported incidents are sent to the supervisors or heads of departments, and a quarterly report is sometimes submitted to management. There is a distinction in three organisations between serious and less serious incidents. Serious events often entail thorough investigations carried out by special teams, with findings shared more broadly within or outside the organisation. Some participants note that incidents are not discussed outside the team, and there is no comprehensive overview of incidents in these organisations.

PRISMA method is predominantly used for analyzing most incidents, although one participant specifies its use for only very serious incidents. Six participants are unsure about the method used for incident analysis. In one organisation no method for incident analysis is employed. One participant mentions that her organisation investigates if trends can be identified from incidents.

The interviewer informed participants about a previous study that indicated substantial underreporting of incidents involving AMT following organisation's protocol. Three participants do not recognize the low reporting rate of 16%.

'To my knowledge, optimal use is made of it, a formal report …….. Of course, I don't know what I don't know, but to my knowledge we are honest about it'. (P1)

However, twelve participants acknowledge significant formal underreporting in their organisation. One participant observes differences between teams in terms of reporting frequency:

'…..which does not mean that more mistakes are made or quality is lower there. It is known that if the team makes zero reports, it can be assumed that there is underreporting'. (P14)

Most participants who acknowledge underreporting do not have precise estimates, while others suggest that a quarter of incidents are reported, half of the incidents or that the average over the teams indeed will be about 16%. Nearly all participants note actions are taken within their organisations to increase protocol-based reporting. About half of these organisations receive central-level messages, such as communications from quality committees or official announcements, special meetings, or intranet news items. Reporting is also promoted during team meetings and sometimes included on the agenda. Two respondents report increased reporting since the introduction of these measures.

Participants were presented with descriptions of a culture ladder from the 'Instrument for Self-Evaluation of Patient Safety Culture' (IZEP) [20]. This instrument is used by Dutch hospitals to self-evaluate patient safety culture across various dimensions. Interviewees were asked to identify which situation most closely aligns with their organisation's patient safety culture in terms of 'reporting, evaluating and learning from incidents'. Half of the participants identified situation D as the closest match (see Table 3). When values are assigned to the situations (situation A = 1,…., situation E = 5), the average score is 3.8 situation C, towards D.

Table 3
Culture ladder in IZEP [20]

N (%)	Explanation
0	**Situation A Denying** Why waste time on safety; we provide good care. - Incidents are rarely reported in our department. - It is common to hide mistakes and no learning takes place. - Management and healthcare professionals do not want any hassle but want to get back to work as quickly as possible.
0	**Situation B Reactive** We take action after every incident. - Although there are formal agreements in place covering the reporting of incidents, healthcare professionals are reluctant to report incidents, neither are they stimulated to do so. - In the main, only serious incidents are reported but there is rarely any feedback on a report. - Serious incidents temporarily put patient safety on the agenda. An improvement is then devised *ad hoc* that will not be followed for long.
5 (33,3%)	**Situation C Calculating** We have systems to manage all risks. - There is a reporting system, but healthcare professionals do not feel secure enough to report all types of incidents. - The incidents are discussed at a department level. The emphasis is more on analyzing and less on seeking improvement. - Management is primarily interested in registering the number of reports.
8 (53,3%)	**Situation D Proactive** We are alert to risks. - Most healthcare professionals report almost all types of incidents. Many incidents without harm to the patient are also reported. - The incidents are discussed at a department level. Improvements are introduced with the aim of preventing recurrence. - Improvements are actively sought to prevent the incidents reported (both within and outside of our own department) in the future. Patients are typically involved.
2 (13,3%)	**Situation E Progressive** Safety is an integral part of everything we do. - Healthcare professionals are aware of their responsibilities and report all incidents to help prevent recurrence. - They provide quick and targeted feedback on the reported incidents. Improvements are fed back and monitored. - All those involved in the care process are constantly alert to risks, make improvements and share good practice with the rest of the organisation.

INSERT Table 3 HERE

DISCUSSION

For this study, we explicitly asked for tactical-level employees in homecare organisations regarding the quality and safety of AMTs and explored their perspectives. The key findings are following.

Our study reveals a significant diversity in how quality management for AMTs is structured across homecare organisations in the Netherlands. This pattern emerges consistently across various themes explored in the interviews. Multiple national quality frameworks are

employed, a multitude of formal and informal procedures, and diverse methods to ensure quality and safety. A remarkable outcome is that many participants at the tactical level of AMT involvement are unaware of their organisation's arrangements.

In a substantial number of organisations, specific plans for the quality or safety of AMTs are lacking. These organisations often lack product documentation, including requirement programs and risk analyses. Furthermore, explicit descriptions of the home environment in which these technologies are employed are frequently missing. Informal procedures appear to outweigh explicit process descriptions, especially concerning technology implementation, evaluation and resolving malfunctions. Organisations that do possess explicit, well-developed policies concerning AMTs tend to collaborate with or affiliated with hospitals. These organisations often adopt hospital frameworks and seem to have better, albeit on paper, quality and safety measures than other homecare organisations.

The covenant for the safe application of MT in the specialist medical care in the Netherlands has proven to be a valuable basis for examining aspects of AMTs. However, the findings underscore the significance of establishing a unified national framework for a cohesive approach to AMTs in homecare in line with the apparent need [8, 9]. This framework should include fundamental safety requirements specifically tailored the home environment, while providing each organisation with sufficient flexibility to devise its own strategy to meet these requirements.

Although a variety of approaches are employed to ensure nurses' competency in using AMTs at home, the results underscore risk factors associated with safe usage. Competency testing is not always mandatory, and retraining often occurs on an occasional basis or on team requests. These factors align with risks identified in a prior study among operational-level respondents from the same organisations [14]. Additional risks arise from the requirement for formal registration of nursing competence, which not all nurses fulfill, and some organisations place the responsibility of competence on nurses. Although the responsibility for achieving or maintaining competence may lie with nurses, policies to ensure the competence of home care nurses in operating AMTs are needed, and regular assessments and mandatory certifications should be implemented. Specific to the home setting, risks emerge when non-professional users, such as patients and/or informal caregivers, operate the devices. Even if nurses perceive these skills to be executed safely, guaranteed competence is not ensured.

This study highlights the solution-oriented ability of homecare teams when handling AMTs in practical settings. This aligns with the findings of studies conducted at the operational level among nurses within the same organisations: demonstrating a strong awareness of quality and patient safety within a more implicit professional safety culture, resulting in relatively few incidents [14, 16]. However, a lack of organisation-wide learning systems is evident.

Regarding formal incident underreporting, this study at the tactical level presents a more positive outlook compared to observations at the operational level. One in five interviewees denies underreporting, and two-thirds estimate it to be less prevalent than it truly is. Furthermore, interviewees express a more positive perspective on their organisation’s patient safety culture in the ‘reporting, evaluating and learning from incidents’ dimension, compared to nurses at an operational level within the same organisation. Both groups average a score of 3.8 (situation C, towards D). However, interviewees in this study scored situation C or higher, while a portion of nurses at the operational level indicated situation A (1%) or B (13%), besides C (11%), D (56%) and E (20%) [14].

Strengths and limitations

A notable strength of this study is the purposive sampling used to recruit participants. Interviewees were deliberately selected from the same homecare organisations whose nurses participated in previous studies on quality and safety of AMTs at home. This enables comparison with outcomes from these earlier investigations. Participant self-selection contributed to a diverse pool encompassing various roles within the organisation and varying years of experience. This diversity within the sample offers valuable insights into the distinct perspectives of different professionals and their respective experiences. The findings illustrate how the practical implementation of quality and safety management for AMTs manifests in practice, irrespective of whether or how it is documented. The systematic analysis contributes to the reliability and validity of the findings.

However, the diversity of participant roles within the organisation also presents a limitation. For instance, a clinical physicist possesses other expertise in AMTs compared to a policy advisor focused on quality. Moreover, not all interviewees possessed direct exposure to working within a homecare team or utilizing AMTs in practical settings. This introduces the potential for bias or limitations in the comparability of the results between organisations. Furthermore, the study did not incorporate a document analysis, thus preventing the verification of the actual existence of plans or the description of procedures as reported by the participants. However, it is difficult to acquire documents if participants deny that or do not know if documentation is available.

Future research

An important aspect in the domain of quality and safety management regarding the use of AMTs is to learn from experiences and disseminate knowledge both within and across homecare organisations [5, 10, 11]. The question arises as to how to effectively address nurses' inclination to manage quality care for AMTs at the team level. It is advisable to ascertain which aspects can be streamlined specifically within the operational domain of the team and to shift the focus towards reinforcing what is going right rather than dwelling on what is going wrong. Exploring the optimal framework of Safety II for nurses, one that systematically empowers the quality and safety of AMTs at home, and cultivates an environment conducive to cross-level learning, and what nurses need to support this way of learning, is of great importance [12, 21].

CONCLUSION

Viewed from a tactical perspective within homecare organisations, a lack of consistency is evident concerning procedures for the utilization of AMTs. A structured policy governing their implementation, usage and maintenance is needed. Additionally, the study identified supplementary risk factors associated with nurses' competence in operating AMTs within home environments: not all nurses formally register their competencies, occasions when nurses are left accountable for their own competence, and uncertainty surrounding the competence of patients and/or informal caregiver(s) using the devices. Employees who are charged with the quality and safety of AMT at a tactical level, seem to be more positive about the patient safety culture than nurses who work at an operational level. The next step involves the development of quality and safety procedures for AMTs in alignment with Safety II principles, while also fostering knowledge exchange within and across organisations.

Abbreviations

AMT Advanced medical technology

CBO Central Guidance Institute for Peer Assessment (Quality Institute for Healthcare)

HACCP Hazard Analysis and Critical Control Points (Nutrition/Kitchen)

HKZ Foundation for Harmonization of Quality Policy in Healthcare Sector

INK/EFQM Dutch Institute for Quality

ISO International Organisation for Standardization

IZEP Instrument for Self-Evaluation of Patient Safety Culture

JCI Joint Commission International

MIC Report Incident Client

MT Medical technology

NIAZ Dutch Institute for Accreditation of Hospitals

P Participant

QMS Quality Management System

TNO QMT The Netherlands Organisation for applied scientific research– Quality for MT

TÜV Association for Technical Inspection

Declarations

Ethics approval and consent to participate

The study was carried out in accordance with the ethical guidelines of the University of Twente and Saxion University of Applied Sciences. Participants were informed of the purpose of the study, how data is handled and their rights prior to the interviews. Written informed consent was obtained from all participants.

Consent for publication

Not applicable.

Availability of data and materials

All data generated and analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Authors' contributions

ITH: Conceptualisation of the study, Methodology, Validation, Acquisition of participants, Data collection, Transcript review, Data analysis and interpretation, Drafting the manuscript, Final approval of the version to be published.

SBA: Conceptualisation of the study, Methodology, Validation, Data analysis and interpretation, Reviewing and editing the manuscript, Final approval of the version to be published.

WH: Conceptualisation of the study, Methodology, Validation, Transcript review, Data analysis and interpretation, Reviewing and editing the manuscript, Final approval of the version to be published.

Acknowledgements

The authors express their sincere thanks to all participants who participated in this study and gave generously of their time.

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Footnotes

1. Vilans Protocols is an online environment for nurses and caregivers that allows users to directly access the correct work instructions from any device when needed. Vilans is the national knowledge organisation in the Netherlands for care and support [19].

Supplementary Files

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