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PhD Thesis

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Fluid balance charting

- evaluating charting quality and nursing perspectives and validating a digital technology

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TABLE OF CONTENT

English summary

Maintaining fluid balance is pivotal for human health, and fluid balance disturbances are related to various diseases and increased risk of complications. Hospitalised patients are particularly at risk of disturbances. The monitoring fluid balance is of key relevance for ensuring correct treatment.

Fluid balance charting has been a nursing task for a century, and in many departments, the procedure is done in the traditional way, namely using paper-based fluid balance charts. The literature highlights fluid balance charting as an essential task for patients' well-being, with crucial effects on morbidity and mortality. As the quality of fluid balance charting is known to be insufficient and inaccurate, several studies have aimed at improving it. However, no overview exists of the quality of fluid balance charting across borders and clinical specialities. Neither have the nursing staffs' perceptions and experiences of fluid balance charting been sufficiently investigated.

The innovation and implementation of digital technologies are considered a means of streamlining and improving monitoring. We developed novel equipment for measuring fluid balance based on fluid intake and output measurements. Each of the four studies of the present PhD project contributes to the development of the innovation, either by expanding our knowledge of the scope of the problem and of end users' perspectives or by validating and evaluating the technology.

Studying procedures across medical, surgical and intensive care units, we found incomplete fluid balance charting and frequent calculation errors. The observed interventions to improve charting quality contained several components with varying effects. Although it was clear that the nursing staff considered fluid balance charting a fundamental nursing task crucial to treatment planning, they were challenged in maintaining control and overview of patients' fluid balance. They highlighted consensus and routines as necessary to maintain quality and expressed positive expectations of technological solutions and their ability to simplify and improve documentation.

The studies presented here provide key knowledge concerning the quality of traditional fluid balance charting and surveys various measures to improve quality. Our exploration of the nursing staff's perspectives offers an in-depth understanding of the dilemmas facing the professionals and points to reasons for the insufficient quality, which is found despite their awareness of the importance of fluid balance charting. We are hopeful that such insights can further the development of future solutions.

Once the first prototype of our liquid balance monitoring system (LICENSE) had been validated in a laboratory environment, we evaluated it in a controlled study undertaken in a realistic setting. The accuracy of the technology was proven to be equivalent to or better than the standard procedure of manual reading.

LICENSE was thus validated from a technological perspective. We proceeded by demonstrating the efficacy of the technology in daily clinical practice. This study identified inaccuracies and sources of error in the manual charting, but likewise revealed challenges related to the oral LICENSE device. We thus obtained valuable knowledge for further development of the technology.

The nursing staff, including registered nurses and healthcare assistants, expressed confidence in the ability of digital technology to optimise workflows and improve the quality of fluid balance charting. We therefore expect digital technology for monitoring fluid balance to be perceived as a positive initiative. LICENSE has been validated technologically but needs further development to ensure reliable measurements in daily clinical practice. This project furthermore emphasises the importance of testing medical devices in real-life clinical settings.

Dansk resumé (Summary in Danish)

Væskebalancen er afgørende for menneskets sundhed, og forstyrrelser i væskebalancen er relateret til forekomst af sygdomme og øget risiko for komplikationer. Særligt indlagte patienter er i risiko for forstyrrelser i væskebalancen. Derfor er det vigtigt at monitorere væskebalancen for at sikre den korrekte behandling.

Væskeregistrering har været en sygeplejefaglig opgave i et århundrede og udføres mange steder stadig på samme måde, nemlig ved hjælp af papirbaserede væskeskemaer. Litteraturen fremhæver væskeregistrering som en væsentlig opgave for patienternes velbefindende, med betydning for morbiditet og mortalitet. Alligevel er kvaliteten af væskeregistreringen kendt for at være utilstrækkelig og unøjagtig og flere studier har forsøgt at forbedre kvaliteten. Alligevel mangler der et overblik over kvaliteten af væskeregistrering på tværs af landegrænser og kliniske specialer, ligesom sygeplejepersonalets opfattelser og oplevelser af væskeregistrering ikke er tilstrækkeligt undersøgt.

Innovation og implementering af digitale teknologier anses som et middel til effektivisering og forbedret monitorering. Vi har udviklet nyt udstyr til måling af væskebalancen baseret på målinger af væskeindtag og udskillelser. Alle de fire studier, der indgår i dette PhD projekt, bidrager til udvikling af innovationen, enten ved at tilvejebringe viden om problemets omfang og brugernes perspektiv eller ved validering og evaluering af teknologien.

Vi fandt, at væskeregistreringen er unøjagtig og påvirkes af regnefejl på tværs af medicinske, kirurgiske og intensive afsnit. Interventioner målrettet forbedring af væskeregistreringen indeholdt mange forskellige komponenter med varierende effekt. Sygeplejepersonalet anså væskeregistrering for at være en grundlæggende sygeplejeopgave, som var afgørende for planlægning af patientens behandling. De fandt det vanskeligt at bevare kontrol og overblik over væskebalancen, og fremhævede konsensus og rutiner som nødvendige for at opretholde kvalitet. Endelig udtrykte de positive forventninger til teknologiske løsninger og forventede at teknologi kunne simplificere og forbedre dokumentationen.

Studierne, som er præsenteret her, bidrager med vigtig viden om kvaliteten af væskeregistrering, samt et overblik over forskellige kvalitetsforbedrende tiltag. Udforskningen af sygeplejepersonalets perspektiver giver en dybdegående forståelse af hvilke dilemmaer, sygeplejepersonalet står i, og peger på årsager til at kvaliteten ofte ikke er tilfredsstillende, til trods for personalets bevidsthed om vigtigheden af væskeregistrering. Denne forståelse kan fremme udviklingen af fremtidige løsninger.

Da den første prototype af teknologien LICENSE (LIquid balanCE moNitoring SystEm) var valideret i et laboratorie, blev den evalueret i et kontrolleret studie i et realistisk miljø. Teknologien var tilsvarende eller

mere nøjagtig end standard metoden, som er manuel aflæsning. Dermed var LICENSE valideret fra et teknologisk perspektiv. Herefter ville vi demonstrere teknologien i daglig klinisk praksis. Dette studie påviste unøjagtigheder og fejlkilder i den manuelle registrering, men afslørede også visse udfordringer relateret til den orale LICENSE-enhed. Vi opnåede dermed værdifuld viden, som vil blive anvendt i den videre udvikling af teknologien.

Ifølge sygeplejepersonalet kan digitale teknologier bidrage til at lette arbejdsgange og forbedre dokumentationen. Vi forventer derfor, at digital teknologi til monitorering af væskebalance vil blive opfattet som et positivt tiltag af sygeplejepersonalet. LICENSE er valideret fra et teknologisk perspektiv, men der er fortsat behov for videreudvikling for at sikre troværdige målinger i daglig klinisk praksis. Dermed understreger dette projekt desuden vigtigheden af at medicinsk udstyr afprøves i en virkelig klinisk praksis.

Abbreviations

CASP – Critical Appraisal Skills Programme

CE – Conformité Européenne

CI – Confidence Interval

GRRAS - Guideline for Reporting Reliability and Agreement Studies

ICU – Intensive Care Unit

IQR – Inter Quartile Range

JBI – Joanna Briggs Institute

LICENSE - LIquid balanCE moNitoring SystEm

LOA – Limits Of Agreement

OECD - Organisation for Economic Co-operation and Development

PDSA – Plan-Do-Study-Act

R&D – Research and Development

RoB - Risk of Bias

ROBINS-I – Risk Of Bias In Non-Randomized Studies - of Interventions

NOS – Newcastle-Ottawa Scale

SD – Standard Deviation

TRL – Technology Readiness Level

WHO - World Health Organisation

List of tables and figures

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SCIENTIFIC PAPERS INCLUDED IN THE THESIS

Paper 1:

The quality of fluid balance charting, and interventions to improve it: a systematic review

Lisbeth Roesen LEINUM, Marianne KROGSGAARD, Sara TANTHOLDT-HANSEN, Ismail GÖGENUR, Anders Ohlhues BAANDRUP, Nessn AZAWI. *BMJ Open Quality 2023;**12:**e002260, doi: 10.1136/bmjoq-2023-002260.*

Paper 2:

Nursing staffs' perceptions of fluid balance charting: a focus group study

Lisbeth Roesen LEINUM, Marianne KROGSGAARD, Sören NORDH, Ismail GÖGENUR, Anders Ohlhues BAANDRUP, Nessn AZAWI. Manuscript

Paper 3:

Digitizing fluid balance monitoring may offer a solution for optimizing patient care.

Lisbeth R LEINUM, Anders O BAANDRUP, Ismail GÖGENUR, Marianne KROGSGAARD, and Nessn AZAWI. *Technology and Health Care,* 2024; 32: 1111-1122. DOI: 10.3233/THC-230664.

Paper 4:

Evaluation of a Real-Life Experience with a Digital Fluid Balance Monitoring Technology

Lisbeth Roesen LEINUM, Anders Ohlhues BAANDRUP, Ismail GÖGENUR, Marianne KROGSGAARD, and Nessn AZAWI. Under review. *Technology and Health Care, 2023.*

INTRODUCTION

Maintaining an appropriate fluid balance is essential to the body's health and vital physiological functions by ensuring the supply of oxygen and nutrients and the excretion of waste materials in a continuous water exchange with the environment[1, 2]. Fluid balance disturbances are among the most common challenges encountered in clinical practice[2], associated with increased risk of complications and death[3-7]. Monitoring fluid balance is thus crucial in assessing and guiding treatment.

Fluid balance charting is notorious for being inaccurate and inadequate[8-12]. The challenges of maintaining high-quality charting are well-known although the procedure seems relatively straightforward. This was confirmed by secondary data from a study performed in Zealand University Hospital's Department of Urology, which showed that charting tended to be sporadic and insufficient despite guidelines and physicians' prescriptions[13]. However, an overview of the quality of fluid balance charting and interventions to improve it is lacking.

An innovative approach inspired by interdisciplinary conversations regarding the quality of fluid balance charting led to a collaboration on advancing a digital solution to enhance charting quality and a first prototype was developed. The digital technology was named by the acronym LICENSE (LIquid BalanCE moNitoring SystEm).

This thesis reviews the literature to evaluate the quality of fluid balance charting. It offers relevant knowledge on the nature of fluid balance charting and examines the nursing staff's perceptions of the procedure. The included studies furthermore validate and evaluate prototypes of a digital technology (LICENSE) aiming to enhance the reliability of fluid balance charting.

BACKGROUND

Fluid balance

Fluid balance is defined as "a state in which the volume of body water and its solutes (electrolytes and non-electrolytes) is within normal limits, and there is a normal distribution of fluids within the intracellular and extracellular compartments"[14].

The definition demonstrates the complexity of fluid balance as it includes not only the amount of fluid contained in the body, calculated as fluid output subtracted from fluid intake, but also the distribution of fluids between compartments and the presence of relevant electrolytes. Although the influence of fluid balance and the interaction between fluids and electrolytes on patients' health has been known for decades[15], evidence is still inconsistent in many cases[16].

Overhydration is linked to increased morbidity and mortality in the critically ill[3, 4, 17-20]. A large multicentre study has found that a higher cumulative fluid balance after three days in the ICU was associated with increased risk of death in patients with sepsis. Although cumulative fluid intake was equivalent between survivors and non-survivors, the non-survivors' lower urine output resulted in a higher positive fluid balance[3]. This finding is supported by a recent study of ICU patients with sepsis and septic shock, which also found lower urine output, resulting in a higher positive fluid balance associated with an increased risk of acute kidney injury and death[20].

Among critically ill patients with cardiovascular disorders, a positive fluid balance of > 1000 ml was associated with increased mortality[4]. A positive fluid balance was likewise associated with a prolonged stay in the ICU and longer hospital stays when compared with a negative fluid balance in critically ill trauma patients[18].

In the postoperative course, overhydration is linked to prolonged hospital stays[21] and a higher risk of infection as well as neurological, cardiovascular and respiratory complications[22]. A Danish study has found that a fluid regimen to prevent weight gain significantly reduced the incidence of postoperative cardiopulmonary and tissue-healing complications after elective colorectal resections[23]. A separate randomised controlled trial showed reduced incidence of gastrointestinal and cardiac complications and shorter hospital stays among patients receiving a restrictive intraoperative fluid regimen during radical cystectomy[6].

Dehydration may also negatively affect the postoperative course by increasing the risk of complications[24, 25]. Among elderly patients undergoing orthopaedic surgery, dehydration was found to be associated with an increased incidence of respiratory, gastrointestinal and haematological complications[24] and increased length of stay[25]. A low fluid intake is furthermore associated with constipation among patients with dementia[26], increased risk of urinary tract infections[16, 25], and falls[27].

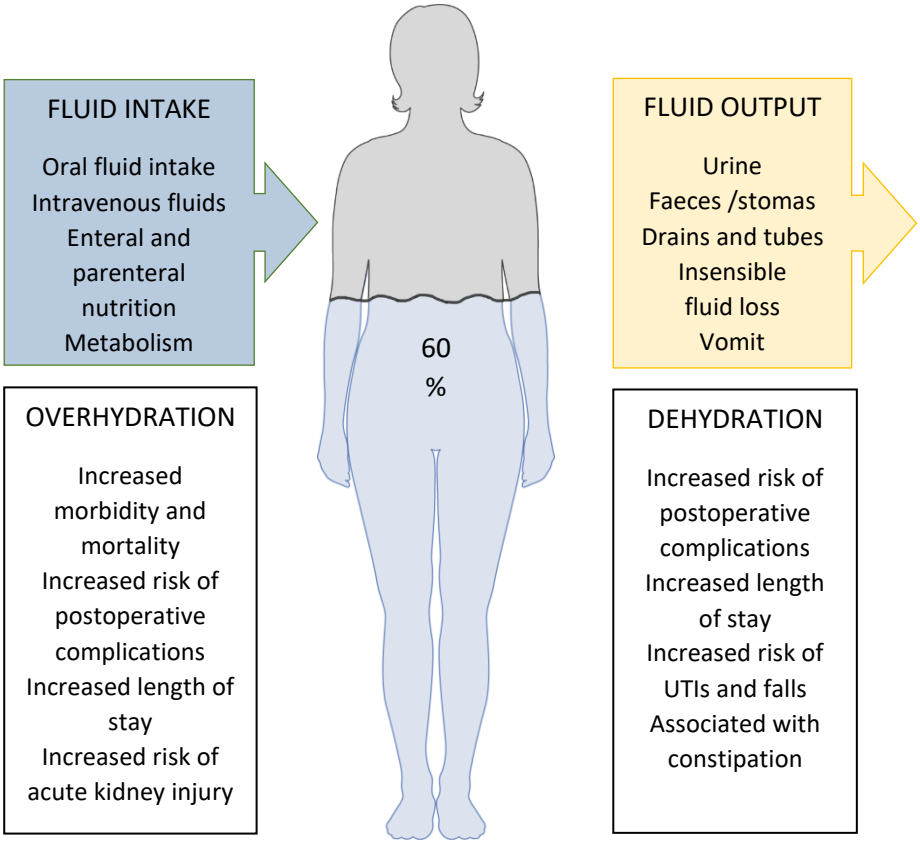

Figure 1: Fluid intake and output and consequences of overhydration and dehydration. (UTI; urinary tract infection). The Figure was partly created using Servier Medical Art, licensed under a Creative Commons Attribution 3.0 unported license.

Monitoring fluid balance

Fluid balance is established primarily through clinical assessment, blood testing and fluid balance charting[1]. As early as 1950 daily weighing, fluid intake and output measurement and knowledge of the electrolyte content of fluid losses were highlighted as the most important factors in planning treatment in the postoperative course[28].

Clinical assessments usually relies on a combination of evidence-based knowledge and non-specific elements based on experience. Daily weight measurement and observation of vital signs, patients' skin, tissue turgor, mucous membranes as well as thirst and urine colour all form part of a clinical assessment[1].

Blood chemistry elements relevant to fluid balance include creatinine, urea, and electrolytes such as sodium and potassium[12]. In addition, fluid balance charting is widely used to assess patients' states of health and disease.

For more than a century, charting fluid intake and output has been recognised as a key nursing task. Bertha Harmer's *Text-book of the Principles and Practice of Nursing*[29], published in 1922, emphasises fluid intake and output monitoring as a fundamental nursing task. For instance, 24-hour urine output was to be recorded, and oral fluid intake adhere to prescriptions and be carefully charted[29]. A fluid balance chart is defined as "an input/output chart documenting everything an individual has taken in over a 24-hour period, and how much he or she has passed out over the same period"[9]. The fluid balance chart should indicate whether the patient is in fluid balance, dehydrated or overhydrated. The documentation of fluid input comprises intravenous fluids and medications, oral intake, and enteral or parenteral nutrition. There is no consensus regarding the inclusion of blood products[9]. The fluid output consists of all fluids lost through drains, tubes and stomas or with urine, diarrhoea and vomit. Additionally, insensible losses from the respiratory tract and skin may be included[1, 9].

Quality of fluid balance charting

Fluid balance charting has been shrouded by uncertainty as noted already by Harmer, who emphasised the importance of truthful and accurate charting[29]. Since the 1920s numerous papers have addressed the challenges of fluid balance charting, including evaluations of the effect of re-designed fluid charts to increase accuracy and reliability[30-34]. However, contemporary anecdotal knowledge shows that the issue remains[8-10, 35].

Even though fluid balance charting may seem a relatively straightforward task, it is nonetheless recognised as challenging to complete, calculate and interpret adequately[35]. The challenges mentioned include lack of training and equipment, staff shortages and time constraints[8, 10, 12, 36]. Research has indicated that the quality of charting is influenced by the type of ward with less nursing care being missed in intensive care units compared to bed wards[37, 38]. The charting procedure has always been considered as time-consuming[31 39], while chart designs remain predominantly analogue and changes have been negligible.

Our systematic review (Study 1) addresses knowledge gaps regarding current practices, including the range of challenges, characteristics and causes[40]. Study 2 reports on focus group interviews conducted to gain an in-depth understanding of nursing staffs' experiences and perceptions of fluid balance charting[41]. It appears that it is necessary to rethink fluid balance charting innovatively to instigate a sweeping change of nursing

practices; however, a solution must be technologically validated and proven effective in clinical practice (Studies 3 and 4)[42, 43].

Innovation in healthcare

On a global level as well as on national levels, healthcare innovations are vigorously driven by the prospect of improved safety, new effective treatments and better utilisation of resources[44, 45]. The World Health Organisation (WHO) global strategy on digital health[46] states that digital technologies have the potential to improve patient outcomes, for example by supporting data-based decision-making and providing more evidence-based knowledge[46].

According to a Danish commission investigating methods to achieve a more robust healthcare system, healthcare technology and digital solutions are key prerequisites for handling the challenges facing our healthcare system[47]. The commission recommends establishing a framework to facilitate the introduction of new labour-saving technologies and supports a principle of digital solutions as the first choice and enhancing healthcare workers' and managers' digital skills. Further, involving health professionals in developing and implementing technology increases user friendliness and adaption to conditions in the clinic[47].

To exploit the full potential of digital technologies, strategies to empower healthcare workers are required. The Organisation for Economic Co-operation and Development (OECD) points to three main strategies to address the concerns of health professionals, including building trust in the benefits of digital development and avoiding technologies that obstruct their work[45]. There is a need to advance the skills and expertise of healthcare professionals by including technology in the health education curricula and providing sufficient time for training current staff. Legal, structural and organisational frameworks should furthermore be adapted to more technology-reliant future hospitals[45].

Technological solutions for fluid balance charting include electronic health records for automatic calculation of fluid balance based on manually entered data[48, 49]. Infusion pumps integrated with electronic patient records can likewise improve patient safety[50]. Although various digital technologies for measuring urinary output[51, 52] and oral fluid intake[53] have been developed, a complete system that includes parameters such as urinary output, oral intake and intravenous fluids is, however, lacking.

The digital technology LICENSE (Liquid balance monitoring system)

During the course of this PhD project, a set of three digital technology devices was developed and tested. These devices are designed to monitor different aspect of a patient's fluid management. The first device measures intravenous fluids administered to the patient. The second device is conveniently placed on the patient's bedside table and measures oral fluid intake. Lastly, the third device monitors the patient's urine output (Figure 2). To ensure the patient's mobility and comfort, the devices for measuring intravenous fluids and urine output are attached to a drip stand to allow patients to move around freely[42].

Each device transmits data wirelessly to a database that calculates hourly fluid intake and output and presents the analysed data in graphs and numbers (Figures 3 and 4).

LICENSE and its basic technological functions were initially validated in a laboratory environment[42].

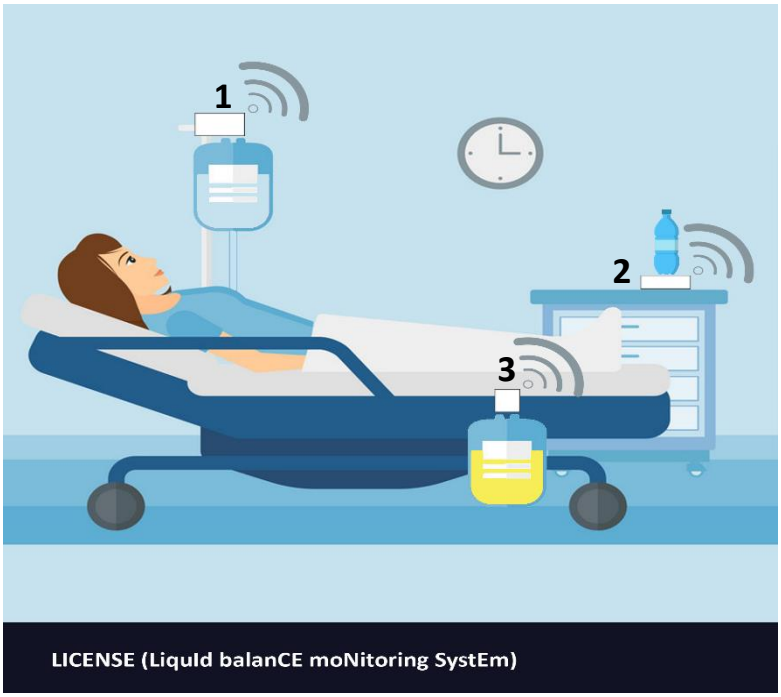

Figure 2: The three devices of LICENSE version 1.0

Patient Report

Patient name: Patient 47
Patient ID: P47
Date admitted: 29.03.2022 11:39
Current date: 30.03.2022 10:29

Date	Hour	IV	Oral fluid	Urine bag	Total
29.03.2022.	20:00 - 21:00	259	1	87	173
29.03.2022.	21:00 - 22:00	349	106	132	323
29.03.2022.	22:00 - 23:00	255	72	123	204
29.03.2022.	23:00 - 24:00	5	0	163	-158
30.03.2022.	00:00 - 01:00	85	0	155	-70
30.03.2022.	01:00 - 02:00	4	60	58	6
30.03.2022.	02:00 - 03:00	0	5	41	-36
30.03.2022.	03:00 - 04:00	0	0	47	-47

Figure 3: Numerical data as presented by patient report in user interface

Figure 4: 10-hour display view

Theoretical frameworks

This thesis relies on two distinct theoretical frameworks for the description of the innovation process and its phases. Firstly, the Diffusion of Innovations theory describes the innovation-development process, with emphasis on the integration of innovations into daily practice[54]. The developmental levels of our prototypes are furthermore explained by referring to technology readiness levels (TRL) as described and adopted by the European Union[55].

The Diffusion of Innovations Theory

In his book *Diffusion of Innovations*[54], first published in 1962, the communication theorist E.M. Rogers describes the innovation-development process and the diffusion of innovation, understood as the planned and spontaneous dissemination of ideas and adoption of innovations. Noting that technology is not necessarily involved, innovation is defined as "an idea, practice, or object that is perceived as new"; Rogers treated in particular the adoption and diffusion of innovations[54].

Although LICENSE is not a fully developed innovation, Rogers's theory of diffusion is relevant to our study. Firstly, its description of the innovation-development process helps determine the current stage of LICENSE's development and clarifies its subsequent phases. Secondly, the theory is relevant to explaining factors concerning the adoption of innovations, e.g., their compatibility with users' values and past experiences[54]. Qualitative research methods are particularly suitable for exploring experiences and

attitudes. As the nursing staff are the primary stakeholders and potential adopters of any innovation in the context of fluid balance charting, it is crucial to investigate their experiences and perceptions. This enables the development of a solution that appears advantageous to potential adopters and is compatible with their values and beliefs. It is further relevant to obtain knowledge of the social system in which potential adopters are located, as this can be a barrier to change[54]. Rogers divides the innovation-development process into six main steps (Figure 5), stressing that they may occur in a rather arbitrary order[54]. This serves to emphasise that although described as linear, the innovation process may as well be cyclical and unplanned[56].

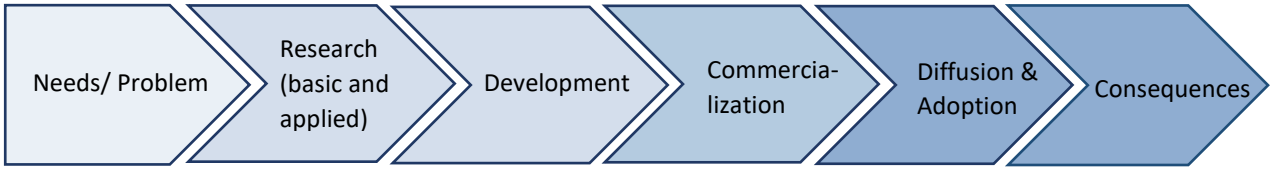

Figure 5: The innovation-development process, adapted from Rogers[54]

Technology Readiness Levels

Technology readiness levels (TRL) are useful in describing the maturity of a given innovation. The TRL scale was initially developed in 1974 and adopted by NASA in the 1990s. The scale is used as a tool to describe systematic technology development in industry, organisations and governmental departments[55, 57]. We use it as described by the European Union[55] and consider it a relevant tool to describe the maturity levels of LICENSE during the developmental process.

An overview of the nine TRL scale levels, from initial idea to market entry is given below.

Table 1: Technology readiness levels[55]

TRL	Description
1	Basic principles observed
2	Technology concept formulated
3	Experimental proof of concept
4	Technology validated in a lab
5	Technology validated in a relevant environment
6	Technology demonstrated in a relevant environment
7	System prototype demonstration in an operational environment
8	System complete and qualified
9	Actual system proven in an operational environment

Development of LICENSE

The innovation process typically begins with the recognition of a problem or a need, whether new or long known, without being considered a high priority[54]. When secondary results of a study by this author et al.[13] indicated the need for improved fluid balance charting in the Urology Department at Zealand University Hospital, Denmark, we initiated research to explore the problem and identify the needs through a systematic approach. Study 1 was conducted to define the problem and identify its extent. In the UK, findings of insufficient quality of fundamental nursing[58, 59] likewise led to increased attention on fluid balance charting[1, 9, 12, 32, 60, 61], as reflected in our systematic review[40], in which more than 40% of the included studies had been conducted in the UK. We further conducted a qualitative study to understand the setting, perceived barriers and enablers, and nursing staff's attitudes and beliefs (Study 2).

Technological innovations mainly emerge from an interaction between research and practical problems[54] and are usually derived from basic research (TRL 1). The work presented in Studies 1 and 2 thus advanced scientific knowledge in the field and identified challenges, followed by applied research intended to resolve challenges (from TRL 2)[54, 55]. The development of LICENSE reflected the cyclical nature of innovation[56], involving multiple iterations from initial research to prototype development to testing and modification. These developmental steps correspond to TRL 3-7 for medical devices, such as LICENSE. At TRL 3 experiments support the ideas, a proof-of-concept model is created, and the technology is deemed feasible from a scientific point of view[55]. At level 4, a prototype is built, and the technology is validated at a laboratory level. It should be noted that this thesis does not aim to give a detailed description of TRL 3 and 4 in the development of LICENSE.

In study 3, LICENSE progressed to TRL 5 with testing in a controlled environment closer to real-world conditions. At this stage, LICENSE was feasible from a technological perspective[55]. Study 4 aimed to demonstrate LICENSE in a real operational setting, corresponding to TRL 6. We were, however, unable to prove that LICENSE was safe and reliable in a real-life setting, and adjustments to the prototype were deemed necessary.

Once an innovation achieves its final form and is considered technologically reliable, it has reached TRL 6 and 7, and accreditation is completed[55]. Commercialising the final product constitutes the next phase[54]. At TRL 8, the system is completed and approved for clinical use, ready for manufacture and implementation. TRL 9 indicates that the technology is ready for end users and seen as commercially viable[55].

According to Rogers's diffusion of innovations theory, commercialisation is followed by diffusion and adoption, which determines the solution's potential to meet end users' needs[54]. Diffusion and adoption should be considered already in the development phase in order that the innovation is compatible with users' attitudes and experiences[54]. To that end we conducted qualitative focus group interviews with nursing staff to explore their perceptions of fluid balance charting and attitudes to developing new solutions (Study 2). Their perspectives and aid offered valuable knowledge concerning the needs and problems in the settings in which LICENSE was intended to serve and enabled us to consider them in the development and further adaption of the product. Study 2 thus modifies the identification of the needs while supporting the subsequent development and adoption of the specific innovation. The consequences of an innovation and the changes resulting from its adoption are evaluated in the final phase.

Table 2 depicts relationships between the four studies and their corresponding phases in the innovation-development process and TRLs.

Table 2: The innovation-development process adapted to the innovation and development of LICENSE

The Innovation-Development Process By Everett M Rogers Adapted to innovation and development of LICENSE		
1. NEEDS/PROBLEMS Own department, Anecdotal knowledge of quality issues		
	2. RESEARCH	**3. DEVELOPMENT**
Basic research Exploring the problem	**Study 1:** Literature review - Mapping extent and nature of problem - Identifying needs	TRL 1
	Study 2: Focus group interviews - Potential users' perspective - Exploring past experiences, values and beliefs	Idea - TRL 2 Developing prototype LICENSE 1.0 TRL 3-4
Applied research Solving the problem	**Study 3**: Validation study - Validating the first prototype - Potential compared to standard procedure	TRL 5 Improving LICENSE 1.0
	Study 4: Technology in daily practice - Observational study	TRL 6 Developing LICENSE 2.0 including knowledge from real-life experience and users
4. COMMERCIALISATION CE-approval Market analysis		
5. DIFFUSION AND ADOPTION Implementation Implementation research		
6. CONSEQUENCES		

RATIONALE OF THE THESIS

Anecdotal knowledge and previous research has shown the inadequate quality of fluid balance charting in urology and other hospital departments. This is untenable considering the relevance of fluid balance charting for the choice of treatment, nursing care, and improvement of patient outcomes. We performed a systematic review of the literature to provide an overview of the extent and attributes of the problem. Then we reviewed interventions to identify the most influential interventions. To enable us to develop a high-quality innovation compatible with clinical practice ee furthermore wished to expand our knowledge of the nursing staffs' experiences with fluid balance charting and their perceptions of its challenges.

Although innovations in healthcare have improved the quality of care, e.g. through more accurate monitoring[62-64], manual and paper-based fluid balance charting is still prevalent. To our knowledge, studies of automate and digitised charting have been conducted solely in relation to a restricted number of parameters[51, 52]. To improve charting accuracy we developed a technology addressing the principal measurable fluid balance parameters. The development process included the validation of technological function and measurement accuracy, followed by evaluation of the technology introduced in daily clinical practice, as shown above.

Hypotheses and assumptions

The hypotheses or assumptions underpinning our four studies varied according to the applied research method. While the systematic review (Study 1) and the qualitative study (Study 2) aimed at exploring and gaining a deeper understanding of the problem, neither of them were intended for hypothesis testing. However, our assumptions may be viewed as preconceptions and preliminary hypotheses[65].

Study 1

It was our assumption that the quality of fluid balance charting was inadequate, with incomplete fluid balance charts being common.

Study 2

Our assumption was that the nursing staff considered fluid balance charting difficult and failed to consistently prioritise it.

Study 3

We hypothesised that LICENSE (liquid balance monitoring system) measured fluids more accurately compared to the standard procedure of manual reading of volumes.

Study 4

We hypothesised the existence of a divergence between fluid balance measured by LICENSE and by standard procedure and that the divergence would exceed 500 ml in >35% of fluid balance charts due to inaccurate manual charting.

Aims

The overall aim of this thesis was to assess the quality of fluid balance charting and explore the perspectives of nursing staff concerning the charting procedure. A further aim was to develop a digital technology solution for fluid balance charting and evaluate its accuracy compared with the standard procedure.

The specific aims of the separate studies were:

Study 1

1) To review the current literature on fluid balance charting in hospitalised patients measured by completeness
2) To identify interventions to improve the quality of fluid balance charting

Study 2

1) To explore nursing staffs subjective experiences with fluid balance charting
2) To identify barriers and enablers in fluid balance charting and their influence on charting quality as perceived by nursing staff
3) To explore nursing staffs' attitudes and opinions relating to fluid balance charting and how they affect motivation and behaviours

Study 3

To evaluate the precision of LICENSE compared with accurate manual measurements and the standard procedure under controlled conditions.

Study 4

To assess the functionality and accuracy of LICENSE compared with standard manual charting in routine clinical practice including both the total fluid balance and each of its constituents (urine, intravenous and oral intake).

METHODS & RESULTS

This PhD study includes the four studies listed in Table 3 and conveyed in their entirety in the Appendix. This chapter presents the methods, results, and strengths and limitations of each study. In the following chapter, the overall outcomes are discussed. Finally, we shall draw an overall conclusion and point to perspectives and their implications for practice and future research.

Table 3: Overview of studies

Study	Design	Methods	Participants	Phenomenon of interest/outcomes
1	Systematic review	Narrative synthesis	-	Completeness of fluid balance charts Interventions used
2	Focus group interviews	Phenomenological-hermeneutic analysis	n = 25, nursing staff (Registered nurses and healthcare assistants) in Denmark and Sweden	Experiences and perceptions of fluid balance charting.
3	Validation study	Comparing methods with Bland-Altman plots	n = 20, admitted Urology Department patients requiring fluid balance charting	Agreement between methods
4	Real-Life Experience	One-sample proportion test, differences depicted in histograms	n = 55, admitted Urology Department patients requiring fluid balance charting	Differences between methods

Ethics

Nursing staff participating in focus groups received written and oral information prior to receiving request for written informed consent. The regional Committee on Health Research Ethics received information about the study; no approval was required (EMN-2023-02327). The study was reported to and approved by the regional Data Protection Agency (REG-010-2023). Swedish regulations did not require official approval of the study.

The two clinical studies evaluating the digital technology were approved by the regional Committee on Health Research Ethics (ID: SJ-848). The studies followed all relevant regulations and were conducted in accordance with the Helsinki Declaration[66]. Participants were recruited consecutively during hospital admission and given written and oral information about the studies prior to request for written informed consent. They were informed that they could withdraw consent at any time until submission of papers based on the studies.

STUDY 1

The quality of fluid balance charting, and interventions to improve it: a systematic review[40]

Materials & Methods

Systematic literature reviews aim to review the available literature on a specific topic. The topic is defined by eligibility criteria, and rigorous and transparent methods are used[67, 68] to provide a comprehensive and unbiased summary of the evidence[67]. Our review aimed to evaluate the completeness of fluid balance charting and identify relevant interventions. This corresponds to the initial research phase of the innovation-development process, during which an idea is formed and the potential clarified[54].

Data collection and search strategy

We searched MEDLINE, Embase, CINAHL and The Cochrane Library for relevant studies. PROSPERO and ProQuest were searched for systematic reviews and grey literature[40]. The following criteria formed the basis for inclusion:

- Presentation of quantitative data concerning completeness or accuracy of fluid balance charting
- Inclusion of hospitalised patients of 18 years or more
- Reporting the number of patients or fluid balance charts reviewed
- Studies published between and including 2010 and 2021

We excluded studies regarding released patients out of the hospital, invasive monitoring procedures or procedures conducted in the intraoperative setting. Case reports and conference abstracts were excluded[40, 69]. The Covidence.org was used to remove duplicates, screen titles, abstracts and full-texts. Data extraction was performed using a customised instrument; disagreements were resolved through discussions until consensus was reached[40].

Quality appraisal

All included studies and their methodological qualities were assessed using quality appraisal tools developed by the Joanna Briggs Institute (JBI)[67]. As approximately half the studies were pre-/post-audits evaluating interventions to improve fluid balance charting, we used the quality appraisal tools for quasi-experimental[70] and prevalence studies[71, 72]. We deemed some of the studies to be prevalence studies despite their authors' description of them as cohort studies. Further, we included retrospective and prospective audits. We rated study quality as low, moderate or high depending on the percentage of positive answers according to the JBI instrument[40, 73, 74].

Results

The study selection process is illustrated in the simplified PRISMA diagram below[75].

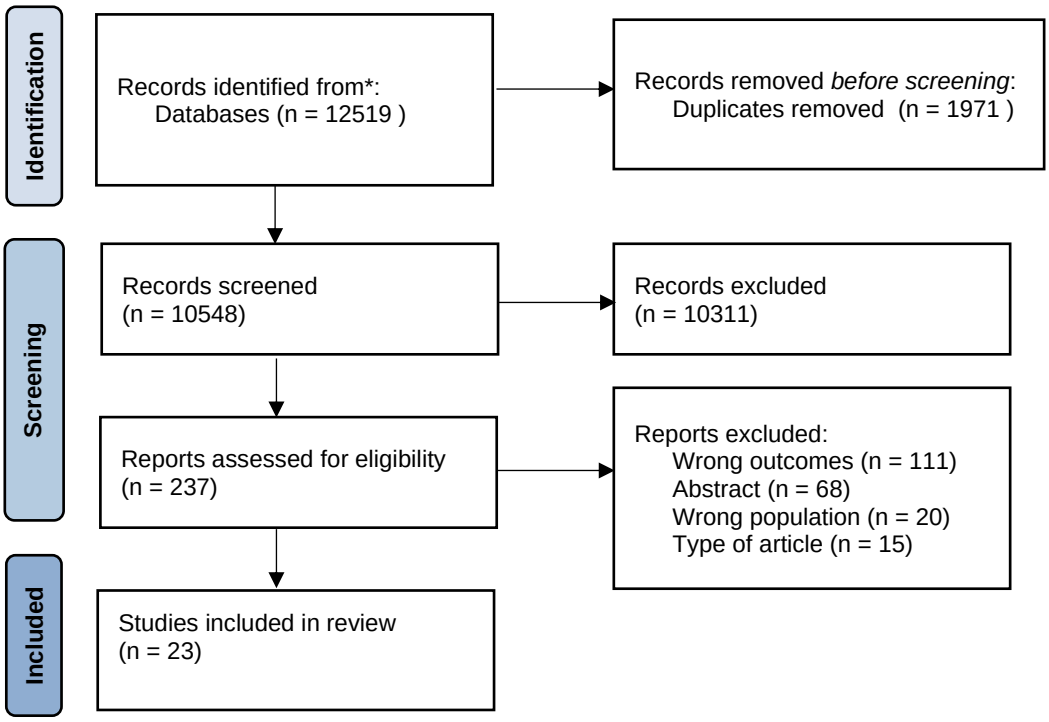

Figure 6: Study selection process, adapted from Paper 1[40]

The included studies originated in ICUs and medical and surgical wards. Eight studies involved separate wards or entire hospitals. In the quality appraisal process eight studies were deemed to be of low quality, 12 of moderate quality and three of high quality. Additional study characteristics are presented in Table 4 while details about all the included studies are shown in Table 1 in Paper 1[40].

Table 4: Study characteristics

		n (%)
Study design (n=23)	Cohort study	3 (13)
	Cross-sectional	8 (34.8)
	Quasi-experimental	12 (52.2)
Quality assessment (n=23)	Low	8 (34.8)
	Moderate	12 (52.2)
	High	3 (13)
Specialities (n=23)	ICU	4 (17.4)
	Medical	5 (21.7)
	Surgical	6 (26.1)
	Mixed	8 (34.8)
Outcomes†	Completeness	18 (78.3)
	Calculations errors	7 (30.4)
	Other	4 (17.4)

† some studies addressed more than one relevant outcome

Of the 18 studies that reported the proportion of complete fluid balance charts, seven[33, 60, 76-80] found that no more than 25% of charts had been completed. Three studies[32, 81, 82] found 26-50% of charts had been completed, while five studies reported rates between 51% and 75%[48, 83-86]. Only three studies[87-89] found more than 75% of the fluid balance charts had been completed (Table 5). The results shown in Table 5, illustrating fluid charting completeness stratified by ward type, suggest that ward type influences quality.

Table 5: Fluid balance charting completeness stratified by type of ward

	Medical wards	Surgical wards	ICU	Mixed	Total
Completeness					
≤25 %	3	2	0	2	7
26-50%	0	2	0	1	3
51-75 %	0	2	0	3	5
>75%	0	0	2	1	3
Total	3	6	2	7	18

Calculation errors were typically addressed by studies conducted in ICUs. They found that calculation errors were common, occasionally exceeding several litres[87, 89]. The errors had often been caused by underestimation of fluid intake, particularly during intravenous drug therapy[48]. Interventions to improve fluid balance charting were described in 13 studies[32-34, 60, 76-78, 80, 82, 84-86, 90], typically comprising several components, such as education and equipment. The impact of the interventions on fluid balance charting quality varied, as shown in Table 6.

Table 6: Intervention characteristics

		n(%)
Intervention (yes/no) (n=23)		13(56.5)/10(43.5)
Components in interventions (n=13) †	Education	12(92.3)
	Equipment	11(84.6)
	Visual aids	7(53.8)
	Disseminating results	4(30.8)
	Organisational/Policy	3(23.1)
	Surveillance	2(15.4)
Achieved improvement measured by completion rate (%, n=10)	≤25	1 (10)
	26 – 50	2 (20)
	51 - 75	3 (30)
	>75	4 (40)
Achieved improvement measured by percentage points (n=10)	≤25	6 (60)
	26 – 50	0 (0)
	51 - 75	3 (30)
	>75	1 (10)
Last evaluation of interventions conducted after (months, n=13)	0-2	6(46.1)
	2-6	4(30.8)
	6-12	1(7.7)
	> 12	2(15.4)

† some studies include several interventions

Strength and limitations

Cochrane reviews typically concern evidence regarding the effect of interventions and are primarily based on RCTs[68]. However, the tendency to include real-world observational evidence in systematic reviews has led to the development of an assessment tool for systematic reviews including non-randomised studies[91]. The review reported in Study 1 aimed to assess fluid balance charting in daily nursing practice. Our strategy of including various study designs, e.g., quality improvement studies applying plan-do-study-act (PDSA)[92] and clinical audits[93] carried some challenges concerning study quality as reflected in the quality appraisal.

By reporting our assessment of the quality of the included studies in a transparent way (Table 2, Paper 1) readers are allowed to judge the credibility for themselves[94]. Methodological quality was assessed to determine the risk of bias in the design, conduct and analysis of the studies[70]. We applied thresholds to assess study quality as either low, moderate and high[73]. In a different quality category division[74], our study included six studies of moderate quality and nine of high quality. To avoid omission of relevant research, no studies were excluded due to low quality. However, deficient quality will limit the certainty of conclusions[40].

To evaluate study quality, we used the critical appraisal tools developed by JBI, thus adding rigour and credibility to the assessment. Other instruments include the RoB 2[95] for RCTs, and ROBINS-I[96] for non-randomised studies, as recommended in the Cochrane Handbook[97, 98]. The Newcastle-Ottawa Scale (NOS) provides a suitable tool for evaluating case-control and cohort studies[99]; the Critical Appraisal Skills Programme (CASP)[100] has introduced instruments for both quantitative and qualitative studies. However, we chose JBI suite because of its array of tools designed specifically for study types relevant to our review This ensured that the questions asked were suitable for the studies under evaluation. Applying other tools including non-applicable or unanswerable questions, would have jeopardised reliability.

Meta-analysis was infeasible due to heterogeneity in the definition of outcomes or incomplete descriptions and reporting of outcomes across studies[101]. Further, only high-quality studies should be included in meta-analyses[94]. Instead, we conducted a narrative synthesis inspired by the relevant guideline[102]. Adhering to guidelines generally lends credibility and reliability to findings. Our findings were thus reported in accordance with the PRISMA guideline[75].

Although our restriction of the search to studies published in 2010 or later may be viewed as a limitation, we consider it appropriate as our aim was to evaluate contemporary nursing quality relating to developments in nursing care, such as documentation practice and working conditions[103]. Had we chosen to include older literature, it might have changed our objective and conclusions.

STUDY 2

Nursing staffs' perceptions of fluid balance charting: a focus group study[41]

Materials & Methods

Qualitative research methods enable us to collect rich data and discover nuances in experiences and attitudes thereby helping us obtain deeper and more detailed understanding[104]. Nurses and healthcare assistants are the groups closest to work on fluid balance charting, and they hold unique perspectives and expertise regarding bedside barriers and potential solutions[105]. Hence, this study aimed to explore the experiences and perceptions of nursing staff.

Participants

Nurses and healthcare assistants permanently employed in hospital departments where fluid balance charting is routinely conducted were eligible. We included nursing staff across specialities with different educational seniority and tenure in current departments.

Data collection

Focus group interviews are suitable for gaining insight into participants' perspectives on fluid balance charting as they enable the collection of qualitative data regarding actors' experiences, opinions, and values in a collective context[104, 106-108]. Nursing staff shared, debated and challenged each other's perceptions of fluid balance charting and brought out nuances in perspectives that allowed us to understand the complexities of motivation[107-109]. As focus groups are furthermore valuable for obtaining key stakeholders' perspectives, we included nursing staff with firsthand experience of fluid balance charting. In developing interventions it is essential to take note of their views on potential solutions[108] as compatibility of LICENSE with existing values and user needs is crucial for adoption[54]. Our systematic review showed that challenges concerning fluid balance charting were recognised across clinical settings[40]. To ensure appropriate variation and homogeneity[104, 107], we selected participants from different departments through purposive sampling[65, 71]. Our focus group interviews were semi-structured, following an interview guide, also known as a 'moderator guide'[110] or a 'questioning route'[107]. However, we use the former phrase as this is most prevalent in our primary literature[104, 106, 109].

All of the researchers involved harboured preunderstandings of the field. Those who trained as nurses had extensive knowledge of fluid balance charting from several years of clinical experience; the physicians held experience in fluid balance prescription. Preconceptions were further shaped by reading of the literature and conducting a systematic review. Complete neutrality is unlikely as a researcher's background and perspectives will inevitably influence the study approach[65]. However, if researchers are aware of their

preconceptions and report their existence, it does not indicate bias[65]. A preconception existed that fluid balance charting may be of low-quality and that members of nursing staff were likely to consider it irrelevant.

Data analysis

We investigated the professionals' perceptions of fluid balance charting by applying the French philosopher Paul Ricoeur's interpretation theory[111]. According to Ricoeur, when transcribed into text, the participants' utterances become detached from the interview situation and the original author's intentions. The text holds its own meaning and is open to everyone who can read[111, 112]. Ricoeur describes this process of objectifying the text as 'distanciation'[112]. The meaning of a text is not hidden behind but in front of the text, and understanding a text means to follow the direction of thought opened up by the text[111].

Our three-phased interpretation included a naïve reading, a structural analysis and a critical interpretation, leading to a comprehensive understanding (Figure 9)[113]. The naïve reading formed the initial understanding of the text's meaning as a whole, as presented in a narrative[113, 114]. The structural analysis divided the text into meaning units of 'what is said' (quotations), interpreted and condensed in an essential meaning concerning 'what the text speaks about'[111, 113, 114]. Three main themes were then identified. Our reflections on the findings were informed by further reading of the literature, leading to a comprehensive understanding[113, 114]. Our reflections on the reading ensured consistency between the phases of analysis[113], enabling us to validate our interpretation by arguing that it held greater probability compared with alternative interpretations[111].

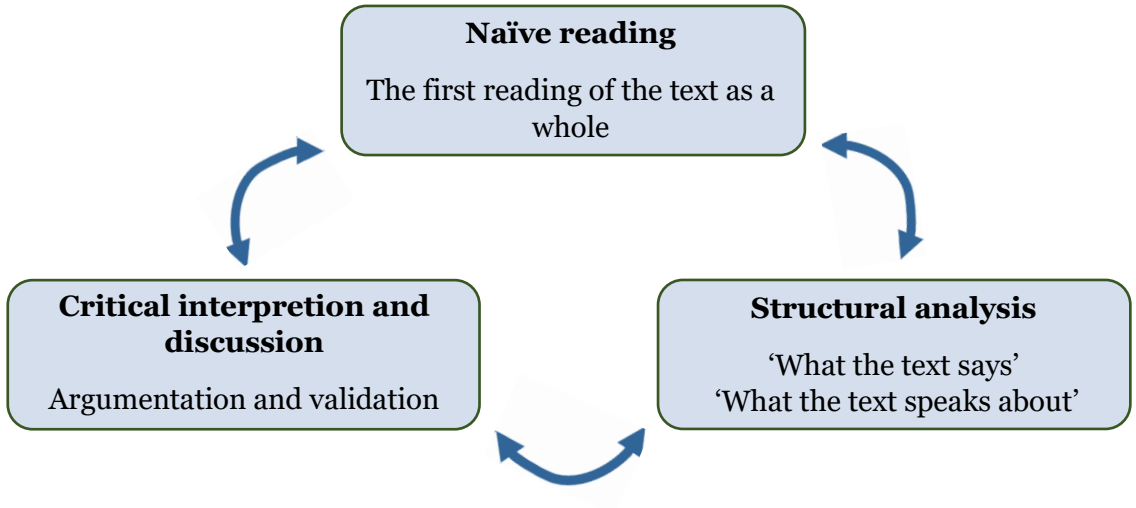

Figure 9: Three-phased Ricoeur-inspired analysis showing relationship between phases (adapted with permission[115])

Findings

Eight focus group interviews were conducted during April and May 2023. A total of 25 nursing staff participated in the study: 17 registered nurses and eight healthcare assistants representing different specialities, both medical and surgical wards, emergency departments and intensive care units. Their seniority ranged between zero and more than 16 years.

Through the structural analysis, three themes emerged: 1) Nursing staff consider fluid balance charting a fundamental nursing task relevant to targeting treatment, 2) Fluid balance charting is beyond individual control and inaccurate due to the involvement of multiple persons and the lack of time, 3) Achieving consensus among colleagues and simplifying the charting method may offer a way forward[41]. The three themes are described in Figure 10.

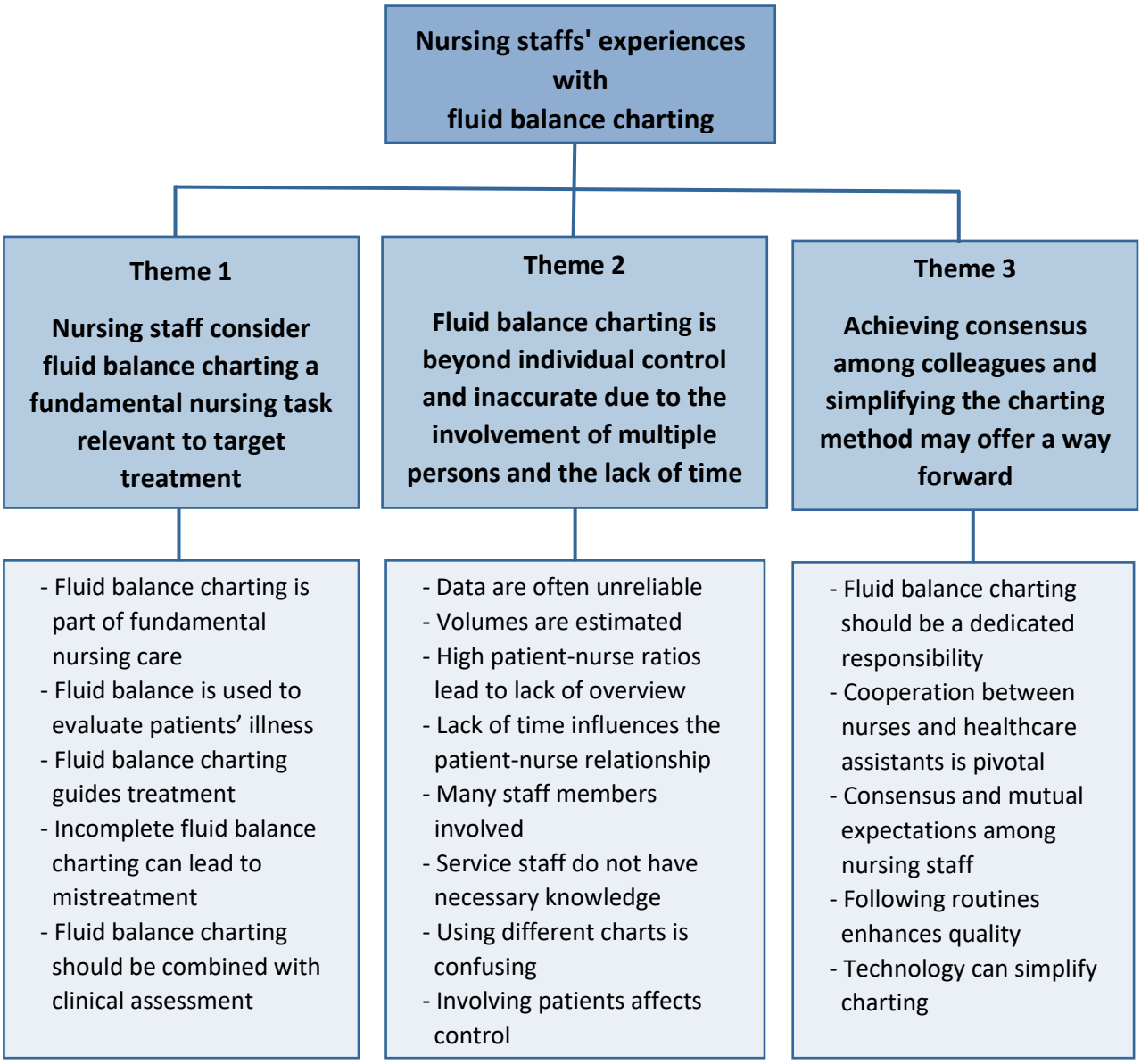

Figure 10: Three themes describing nursing staffs' experiences and perceptions of fluid balance charting.

The nursing staff regarded fluid balance charting as relevant and described how it guided proactive treatment. They were well aware of the risk of incomplete charting and emphasised that fluid balance charting should be combined with clinical assessment. The procedure was considered inaccurate by many. High patient-nurse ratios implying less time per patient affected the relationship between patients and nursing staff and was seen to lead to a lack of overview and negligence of charting. To reduce nursing staffs' workload, fluid balance charting was often delegated to other staff without healthcare training, which led to a lack of control. Involving patients was viewed positively but deemed relevant with only a minority. As ways to enhance quality the nursing staff described dedicating responsibility for fluid balance charting and achieving consensus among themselves regarding routines. Further, they expected digitisation and technological aids to simplify the charting process.

Strength and limitations

To capture the experiences of nursing staff, focus groups with nursing staff were established. All participants had extensive experiences with fluid balance charting and were aware of various challenges concerning charting quality. Discussions were lively, and participants interacted by sharing experiences and viewpoints, contributing tips and tricks and expressing feelings and frustrations, thus providing rich and vivid data[71, 107, 116].

We were aware of the risk that the group influences the nature of the produced data, whether due to a wish to reach a consensus or to polarisation[109]. Focus group participants may tend to portray themselves in an overly positive way[107], e.g., by claiming that fluid balance charting was a high priority even though this did not correspond to actual practice. We sought to prevent this by creating a tolerant environment in which confidentiality was endured and by asking questions from different perspectives. This enabled us to uncover a nursing staff dilemma concerning the contrast between what should be done and the necessity of rationing nursing interventions[117].

The difficulty of recruiting participants prevented us from overrecruiting to the focus groups as recommended[109], but despite our flexibility in scheduling and sending reminders by text or e-mail on the day of the focus group interview or the day before, the drop-out rate was 28.6%. This meant that all groups were relatively small, with two to four participants. However, as the participants were highly experienced and interested in fluid balance charting, the focus group interviews produced rich data. As rather inexperienced moderators we thus avoided the challenge of having to moderate large groups of strongly involved participants. Having larger groups, with less time per participant[104, 109] could have prevented us from gaining an in-depth understanding of the complex attitudes and behaviours of nursing staff.

We decided to include nurses and healthcare assistants in the same focus groups, despite their different educational backgrounds. Although it has been argued that this may lead to a power differential[107], we maintain that healthcare assistants often hold a high level of expertise regarding fluid balance charting. A nurse in one focus group claimed that healthcare assistants were better trained in performing fluid balance charting. Observing no asymmetry between the two groups during focus group interviews, our experience was that they contributed to the discussions from their individual perspectives and addressed different issues related to fluid balance charting.

At the end of each focus group interview, we summarised the conversation to enable participants to clarify or expand upon their viewpoints. This process is known as member checking during data collection[71]. However, we did not perform formal member checking where transcripts were sent to participants as this would contravene Ricoeur's recommendation, which stresses the transcribed text's detachment from the speaker and holds its own meaning[111].

Our data analysis involved three methodological steps: a naïve reading ensuring spontaneous understanding of the transcripts as a whole, followed by a structural analysis dividing the text into units of meaning and restructuring them into themes. The critical interpretation included other research literature. The analytical steps supported a hermeneutic analysis, which involved a dialectical movement between the individual parts of the text and the text as a whole, as well as between understanding and explanation[112].

The analysis was performed using the NVivo14 software as decribed in Appendix VII. This supported the structural analysis, in which the text was divided into units of meaning and restructured according to themes. Use of the software furthermore allowed us to alternate among the analytical steps, e.g., from the naïve reading to the structural analysis, and between the parts and the whole by enabling us to move between the codes and the complete focus group transcripts. The Nvivo 14 software thus added transparency and systematicity to the analysis in accordance with the methodology described by Pia Dreyer[118].

Originating from grounded theory, the concept of saturation is used to describe whether a sample collected in qualitative research is sufficient[119]. Saturation indicates that further data collection is redundant based on the collected or analysed data[119-121]. Based on recommendations, our initial plan was to complete six focus group interviews[107] while eight focus group interviews were conducted to compensate for the small size of groups. Despite the observed repetition in the participants' replies, which may have been interpreted as data saturation, we were aware of the possibility of something new emerging[120]. As our exploration aimed at expanding the current knowledge and enriching our understanding of what is at stake in fluid balance charting from a nursing perspective, we consider that our aim was achieved[121]. The

abundant and nuanced descriptions revealed that across borders and clinical settings, the same recognisable elements appeared from the participants' responses: i.e. an awareness of the importance of fluid balance charting and the challenges of maintaining control.

STUDY 3

Digitising fluid balance monitoring may offer a solution for optimising patient care[42]

Materials & Methods

In preparation for this study, we developed a prototype of the LICENSE technology and validated its technological features in a laboratory environment corresponding with TRL 4[55]. The study compared LICENSE and the standard method using a reference measurement. To evaluate agreement we applied the analysis for method comparison studies recommended by Bland and Altman[122, 123].

Participants

The study included 20 consecutively admitted patient in the Urology Department. They met the following inclusion criteria:

- Catheterised and in need of fluid balance charting
- Capable of providing informed consent
- 18 years or above

Data collection

The weight-based reference method was considered accurate, objective, and reliable. It furthermore allowed precise measurement of oral and intravenous fluids without removing them from their original containers. Urine bags were emptied once every hour and weighed on portable digital scales. The reference method was compared with the standard method of manual reading from measuring lines of jugs and plastic cups. In daily clinical practice, oral fluids are often estimated based on knowledge of their approximate volumes in unmarked glasses or mugs. Reading based on the printed measuring lines on intravenous fluid bags is unreliable and rarely used. Fluid volumes are routinely documented when the bag is emptied. LICENSE collected and transferred data wirelessly to a database. We were thus blinded to LICENSE data during manual measurements. The LICENSE data were retrieved from the database enabling us to read the hourly measurements at the same time points as for the reference and standard measurements.

Statistics

The agreement between measuring methods was evaluated as proposed by Bland and Altman[123]. We conducted three comparisons; between LICENSE and the reference, between the standard method and the reference, and between LICENSE and the standard method.

Bland-Altman plots are used to evaluate agreement by plotting the differences between measurements on

the vertical axis against the mean of the pairwise measurements on the horizontal axis[124]. If the line of equality is outside the confidence interval of the mean difference, systematic bias between methodsis indicated[125]. The plot moreover displays the 95% limits of agreement (LOA), indicating the variance between methods and encompassing 95% of the differences when normal distribution applies. If differences are not normally distributed, the non-parametric LOA can be defined by applying the 2.5 percentile and the 97.5 percentile. In typical situations this will not significantly impact the LOA[123]. The Bland-Altman plot furthermore displays positive or negative skewness and tendencies, e.g., a tendency towards proportional bias while it cannot determine whether the agreement is acceptable, which should be decided based on clinical knowledge[125].

Results

Observation of the included patients for an average of 6.4 hours (SD 1.7) yielded 946 measurements[42]. We found LICENSE to marginally underestimate volumes, with a mean bias of less than 2 ml in all devices, whereas the standard method overestimated volumes slightly, with mean biases of 6.6 to 10.8 ml. As the differences shown in our Bland-Altman plots were not always normally distributed, we present in Table 7 the LOAs using both parametric and non-parametric methods. The intervals were approximately equal although the non-parametric LOA intervals were wider, except for manual reading of oral fluids.

Table 7: Performance parameters, LICENSE and manual readings

		n	Mean bias (95 % CI)	LOA (parametric)		LOA (non-parametric)	
				Upper	Lower	Upper	Lower
Urinary output	LICENSE	112	-1,8 ml (-3.2 to -0.5)	12.1 ml	-15.7 ml	9.8 ml	-18.3 ml
	Manual readings	118	10.8 ml (9.6 to 11.9)	23.3 ml	-1.8 ml	33 ml	-3.0 ml
Oral fluids	LICENSE	118	-1.3 ml (-2.5 to -0.2)	10.9 ml	-13.5 ml	8.2 ml	-20.0 ml
	Manual readings	124	6.6 ml (4.2 to 8.9)	32.5 ml	-19.4 ml	33.0 ml	-7.8 ml
Intravenous fluids	LICENSE	111	-0.7 ml (-1.5 to 0.04)	7.5 ml	-8.9 ml	8.4 ml	-12.3 ml

LICENSE, Liquid balance monitoring system; LOA, Limits of agreement; CI, Confidence interval. Table modified from Paper 2[42]

The standard Bland-Altman plots illustrating the agreement of urine and oral fluid measurements indicated a tendency of increased bias with increasing volumes and a positive skewness when the standard method was used[42]. This trend is especially evident when LICENSE is compared with the standard method, as

disagreements increased due to the systematic underestimation of volumes with LICENSE and overestimation with the standard method. The positive differences increased with volumes increased, as demonstrated in Figures 7 and 8 (A) by the addition of a regression line showing associated confidence and prediction intervals. The standard plots illustrated an increased variability in differences as the volumes increased; expressing the differences as a percentages rather than in volumes may be useful (Figures 7 and 8, B)[125]. Both in measuring urinary output and oral intake, the variability is more considerable in low values, with some extremes very close to zero.

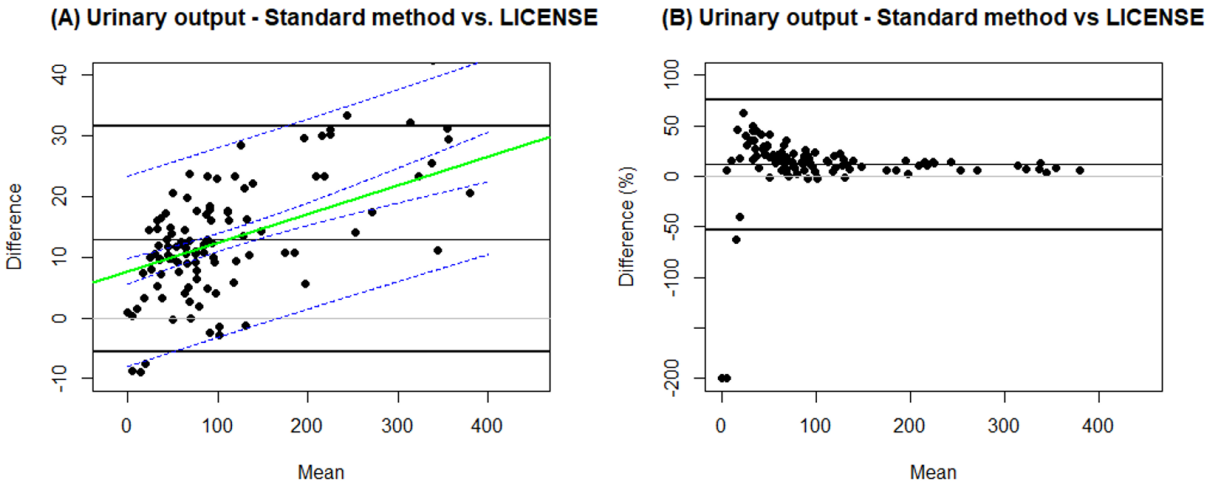

Figure 7: Agreement between urinary output measured by LICENSE and standard method (Bland-Altman)
(A) Regression line, associated confidence and prediction intervals illustrating tendency
(B) Differences between methods in percentages

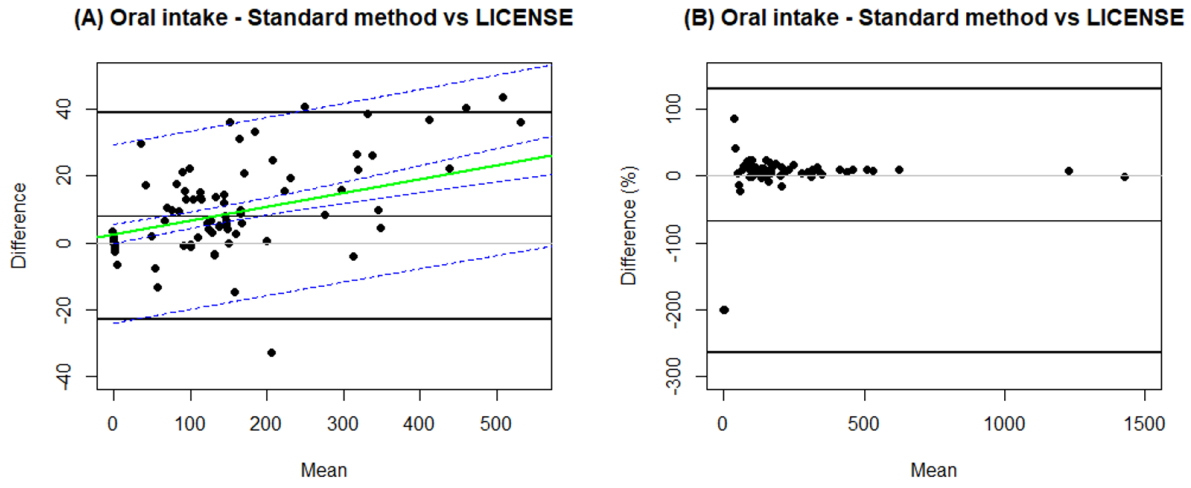

Figure 8: Agreement between oral intake measured by LICENSE and standard method (Bland-Altman)
(A) Regression line, associated confidence and prediction intervals illustrating tendency
(B) Differences between methods in percentages

In conclusion, LICENSE yields equally or more accurate readings compared with the standard method for measuring fluid intake and output. LICENSE was validated in a relevant environment and reached TRL 5[55].

Strengths and limitations

The study design ensured validation in a relevant environment by including hospitalised patients needing fluid balance charting. Appropriate control of measurements was maintained by appointing a researcher to conduct all measurements. The reference measurements were reliable as volumes could easily be weighed on the portable digital scales, ensuring independence from subjective estimation. The placement of drip chambers caused some variability in weighing intravenous fluid bags, which was minimised by repeated weighing. Further caution may have been taken by comparing intravenous fluid measurements with volumes measured by infusion pumps, although this is not standard procedure in most bed wards. Alternatively, we chose not to compare with the standard procedure for weighing of intravenous fluids.

Study rigour and reliability were ensured by adhering to the Guideline for Reporting Reliability and Agreement Studies (GRRAS) where applicable[126].

Correlation can measure the relationship between results obtained using two different methods. A linear association is to be expected as the same variable is measured while a correlation coefficient close to 1 or -1 does not necessarily indicate good agreement[125]. We opted for Bland-Altman plots[123], which are widely used for comparing methods. The strength of plotting include visual illustration of data and its intuitive interpretation. The Bland-Altman plots used in this study enabled us to compare our methods with each other and against a reference measurement. They furthermore helped identify and highlight challenges relating to the various methods, such as systematic bias and tendencies towards skewness or increased bias with increased volumes. We reported the parametric LOA, as applying the non-parametric LOA did not impact the conclusions to a significant extent, and because the standard plot is easier to interpret for our readers.

While only 20 patients were included in this study, we obtained at least 111 paired measurements for each comparison. The sufficiency of the sample size was determined by power calculations as proposed by Lu et al.[127] We quantified the uncertainty of the estimated LOA through numerical reporting and illustration of the confidence intervals of the LOA[128]. Although it is recommended to establish acceptable LOA a priori[128-130], we did not predefine the acceptable LOA due to our study design. We compared both LICENSE and the standard method with a reference measurement to identify the most appropriate method based on agreement with the reference measurement. The assessment was based on LOA and mean bias, establishing greater accuracy of LICENSE measurements in comparison with standard measurements.

STUDY 4

Evaluation of a Real-Life Experience with a Digital Fluid Balance Monitoring Technology[43]

In Study 2[42], LICENSE was validated under controlled circumstances and achieved TRL 5. To reach TRL 6, the equipment would have to be demonstrated in a real operational environment[55]. As randomised controlled trials may not always reflect the real conditions, real-life testing is essential to the investigation of medical devices' feasibility and practical usability in clinical situations[131]. We investigated the feasibility and effectiveness of LICENSE in everyday clinical life[132].

Materials & Methods

Participants

A total of 55 patients were consecutively recruited on their admission to the Urology Department. To be eligible, participants had to meet the following inclusion criteria:

- Catheterised and adult patients (≥ 18 years)
- In need of fluid balance charting
- Expected length of admission ≥ 24 hours
- Able to understand information and provide written informed consent

Data collection

After enrollment participants were introduced to the use of the weight-based oral device (depicted in Figure 2) and the nursing staff responsible for the patient was informed. The staff received relevant training, a manual and a contact number for advice. Patients and nursing staff were instructed to leave alone glasses and cups on the oral device to prevent inappropriate use. The patient's manual fluid balance chart was updated and LICENSE devices were connected. Fluid intake and output were documented simultaneously using the standard manual procedure. Methods were compared with the patient's total fluid balance as the primary outcome, and each parameter or device as secondary outcomes. Differences were calculated by subtracting the standard measurements from LICENSE results, with positive differences indicating that LICENSE measured higher volumes, negative differences lower volumes.

Statistics

The sample size was calculated to be 51 patients based on a one-sample proportion test with the hypothesis that for 35% of patients, the difference between methods exceeded 500 ml in total fluid balance. Methods were compared using paired t-tests or Wilcoxon signed–rank tests according to the

normal distribution. To test our hypothesis, the proportion of fluid balance charts displaying a difference of more than 500 ml was calculated by applying a one-sample proportion test.

Results

Participants were observed for an average of 22.9 hours (SD 3.6). Concerning total fluid balance the mean difference between methods was -44.2 ml (SD 891.9 ml), the absolute difference 566.5 ml (IQR 189.2; 984.5). For total fluid balance the difference exceeded 500 ml in 57.4 % (95 % CI 43.2 to 70.8) of patients (Table 8, further results in Paper 4, Table 2 [43]). We included 55 patients; data regarding fluid balance measurements were missing for one patient, however.

Table 8: Fluid balance measurements	
Mean difference (License minus standard), n=54, ml, mean (sd)	-44.2 (891.9) †
Absolute difference in total fluid balance, ml, median (IQR)	566.5 (189.2; 984.5)
Patients with an absolute difference > 500 ml, % (CI), n=54	
Total fluid balance	57.4 (46.2; 100)**
Urinary output	18.5 (9.2; 31.4)
Intravenous input	11 (4.2; 22.6)
Oral intake	42.6 (29.2; 56.8)
Intravenous fluids missing in the electronic fluid chart, % (CI), n=35	77.1 (59.9; 89.6)

† non-significant mean difference in paired t-test (p=0.7172)
**p-value below 0.01 in one-sample proportion test testing the hypothesis that >35 % of fluid balance charts had a divergence of ≥500 ml (p=0.0003).
Table modified from Paper 4[43]

The differences between LICENSE and the standard procedure are shown in histograms (Figure 12). The dark blue columns illustrate differences within a ±500 ml limit; and the lighter blue columns differences in excees of 500 ml. The figure shows that almost all measurements of urine output and intravenous fluids (Figure 11, B and C) fell within the ±500 ml limit, whereas 57.4% and 42.6% exceeded 500 ml in total fluid balance and oral intake, respectively (Figure 11, A and D, Table 8). The obtained differences for total fluid balance depend on the included parameters (urine output, intravenous fluids, and oral intake). The figures for oral intake are particularly imprecise, with large differences leading to significant differences in total fluid balance.

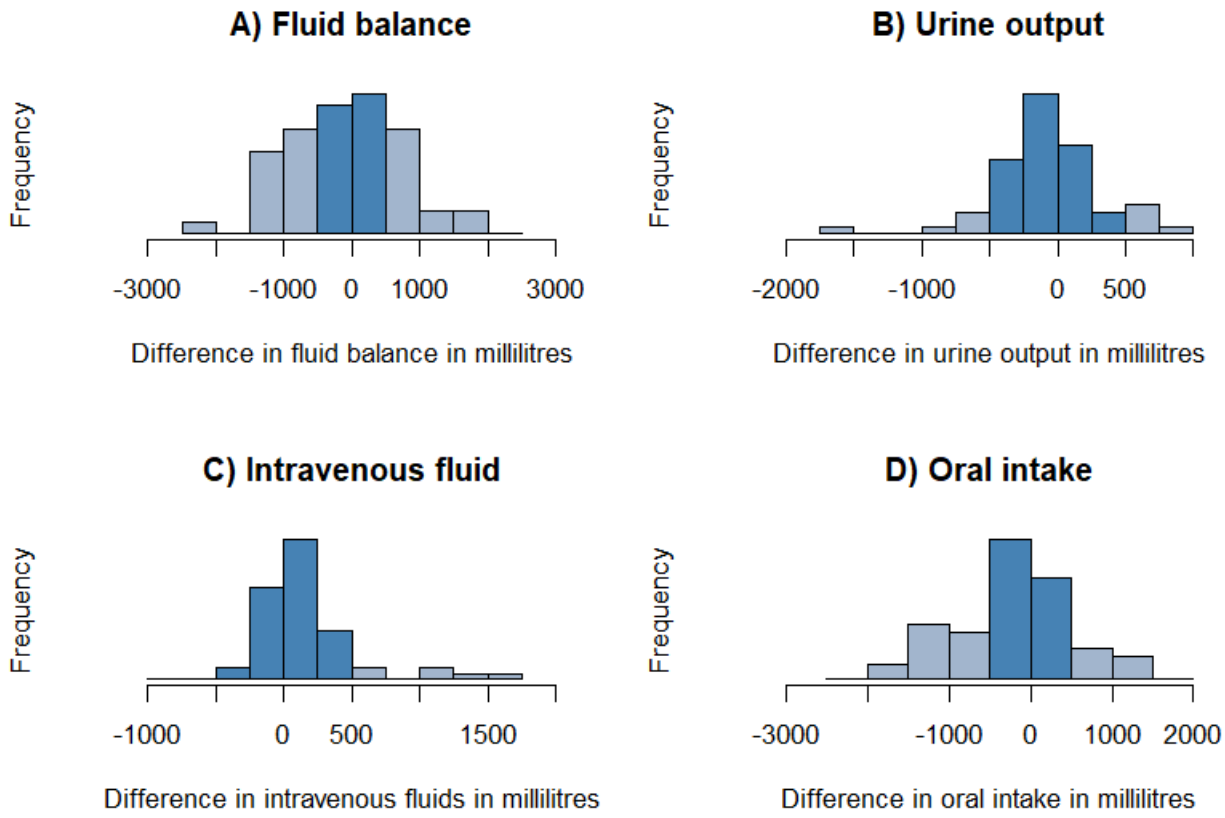

Figure 11: Differences between methods calculated as LICENSE values minus standard procedure values (darker blue areas within ±500 ml range). Figure modified from Paper 4[43]

Strengths and limitations

As expected, this study identified inaccuracies and missed manual documentation. We noticed errors as well concerning the oral LICENSE device. This made it difficult to draw valid conclusions concerning differences in total fluid balance, our primary outcome. Shifting our focus to the secondary outcomes to identify potential explanations of the observed differences, we gained crucial knowledge regarding the commonest errors in manual charting and necessary adaptions in an improved LICENSE prototype.

The illustration of discrepancies between methods in histograms (Figure 11) illustrated the differences between devices by depicting both the total fluid balance and each of the three LICENSE devices in a single graphic. The data could have been visualised further by applying Bland-Altman plots, scatterplots, and the calculation of Pearson's correlation coefficients.

Based on the study results we concluded that further adaptions and improvements of the LICENSE devices were necessary. The inclusion of 55 patients in our study was redundant as we might have gained similar knowledge with far fewer participants in a smaller-scale feasibility study. This would have led to analysis at an earlier stage, enabling us to identify challenges and adapt the devices before enrolling a large number of patients. However, relying on the results of Study 3 [42], we expected the LICENSE devices to be well-functioning while we underestimated the influence of changing the study environment to a real-life setting. In the controlled experiment (Study 3), the researcher interacted with devices in a predetermined way, following a detailed study protocol to obtain accurate data to validate devices, in contrast to the present less uncontrolled study.

As found in our focus group interviews (Study 2), fluid balance charting in clinical practice involved multiple persons, causing a lack of control. To ensure reliable data collection by LICENSE, all staff need to be aware of the correct use of devices. Especially related to oral fluid intake, the several individuals involved in serving fluids may have presented challenges. The nursing staff's perceptions of fluid balance charting and the use of technological devices may furthermore have affected the quality of manual charting as well as their attitudes towards using LICENSE.

It has been claimed that the most complex part of any medical device is the person using it[133]. To develop efficient medical devices, we must take into account how people think and act[133]. Challenges associated with the oral LICENSE device revealed embedded habits, e.g., concerning pouring and drinking fluids, which led to unexpected difficulties[134]. When thirsty a patient would pour the fluid into the container and drink immediately without allowing the oral LICENCE device to weigh the poured amount. Our study thus shed light on deeply ingrained habits related to pouring and drinking fluids. Such routine activities, in which we engage automatically, are typically performed without conscious awareness and leave no trace in memory. As actions not controlled by intentions are difficult to change[135], the LICENSE devices required adaption for successful integration into nursing practice.

Our study demonstrated the relevance of real-life studies. It showed that unforeseen challenges may arise when medical devices are tested in the messy conditions of everyday life, leading to surprising and perhaps disappointing results[132, 136]. The study documented the need and potential for research conducted in a real-life scenario to uncover practical challenges that a controlled study may fail to identify.

MAIN DISCUSSION

Nurses' perceptions of fluid balance charting

This thesis aimed to assess the quality of fluid balance charting and explore the perspectives of nursing staff in order to understand the challenges faced in clinical practice. A further aim was to develop a digital technology for fluid balance charting that meets the needs of future users and to evaluate its accuracy. Validation of the technology was followed by real-life testing.

We introduced the innovation-development process[54] as a framework for describing the connections between the included studies and their underlying rationale. Although this PhD project solely concerns the research and development phases, it is essential to see it in a broader context in which social and organisational factors are considered, and to raise awareness of preceding as well as subsequent processes. While the Diffusion of Innovation theory emphasises the relevance of the planned users' perspectives in developing LICENSE[54], it fails to describe the practical development of medical devices. This led us to apply the Technology Readiness Levels (TRL)[55] to detail the steps involved in innovating a digital technology.

Having identified the need for improved fluid balance charting, we conducted a literature review to clarify the extent of the problem. The focus group interviews with nursing staff provided significant knowledge concerning the phenomenon, and both the focus group interviews and our literature reading supported the observation that nursing staff are well aware of the significance of fluid balance and its dependable charting[36, 41, 137-139] and not least the risks induced by inaccurate charting[77, 138]. However, both the literature[40, 48, 60, 77] and our focus group interviewing[41] demonstrated that the quality of fluid balance charting is often inadequate.

Effective countermeasures rely on identifying the characteristics of fluid balance charting and analysing the challenges leading to inaccurate charting. The results of the literature review indicate that charting quality is influenced by the characteristics of the individual wards. The finding that less than 25% of fluid balance charts were completed accurately in medical wards[60, 76, 78] contrasts with the results of two studies evaluating completeness in ICUs which found at least 75 % of fluid balance charts were completed[87, 89]. Research has shown that in general missed nursing care is less frequent in ICUs than in medical and surgical wards[37, 38].

The participants in our focus group interviews highlighted various factors contributing to low charting quality. Overcrowded wards and nursing staff shortages leading to high patient-nurse ratios[39, 138, 140] and little time available per patient jeopardises patient safety by increasing the risk of missed charting[39, 141, 142].

Previous research has found high frequencies of missed nursing care, with up to 55.6 % of nurses reporting incomplete intake and output monitoring[143].

Nursing staff may handle the dilemma caused by high workloads by unwittingly rationing their care efforts[117] in an effort to bridge the gap between ideal care and the realities[144]. This was described by focus group participants as unconscious prioritisation. However, a high workload preventing staff from providing sufficient care leads to emotional exhaustion and feelings of insufficiency[117, 145, 146]. The implicit rationing of nursing care is guided by intuition without reference to guidelines or analytical models and as such strongly dependent on nurses' clinical experience and the quality of their individual decision-making[144]. Ideally, the prioritisation of patients and tasks should be systematic and in accordance with guidelines to ensure professionally justified actions and prevent overlooking at-risk patients[32, 41, 144].

As further barriers to accurate fluid balance charting, nursing staff mentioned the imprecise estimation of fluids due to insufficient equipment or inappropriate routines[41, 60, 138, 140, 147]. The lack of consensus and established routines was likewise brought up during the focus group interviews[39, 138, 140], where it became clear that tasks were delegated to service staff to reduce nursing staff's workload[41]. Research has shown that the delegation of tasks to staff without adequate healthcare training, along with the frequent change of caregivers, lead to a lack of control and missed charting[90, 140].

Our systematic review surveyed interventions to improve the quality of fluid balance charting. The training of nursing staff, physicians and patients was identified as the most commonly used intervention[32-34, 60, 76-78, 80, 82, 84, 85, 90]. Its impact varied, likely due to differences in its relevance, delivery, and extent. Educational interventions targeted at nursing staff or patients were suggested by focus group interviewees as a way to enhance quality[41]. The instruction of patients[32, 76] or involving them in fluid balance charting[77, 90] was included in four of the top five most effective interventions, implying the benefits of involving patients in self-monitoring, as confirmed by previous research[148, 149]. Nevertheless, some patients' lack of cooperation or motivation for participation may also be challenging[39, 41, 77, 90]. We recommend a person-centred approach to target patients who may benefit from involvement in their care.

Other popular interventions to improve charting quality included the introduction of various equipment such as care bundles, visual aids, redesigned fluid balance charts and electronic calculators[32, 33, 60, 82, 84]. Fluid balance charts printed in eye-catching colours, posters and magnets were suggested as valuable reminders whereas different paper charts or combining electronic and paper-based documentation was considered confusing and complicating[41]. The focus group participants generally took a positive view of technical equipment. Nursing staff experienced in using technological tools such as mobile pocket devices for timely documentation were overall positively inclined and found that technology improved patient safety while

they pointed to challenges such as time-consuming login procedures[41]. The ubiquity of such challenges is confirmed by other authors, emphasising the importance of technologies being dependable, fast-working and accessible to prevent stress and frustration among nursing staff[150, 151].

The focus group interviews highlighted the importance of cooperation between nurses and healthcare assistants and the explicit dedication of responsibility for fluid balance charting[41]. Other research has confirmed that the lack of ownership and accountability causes inaccurate fluid balance charting[32, 140]. A separate focus group study reported concerns about employing healthcare assistants demanding nursing staff to work in teams, leading to the lack of a primary carer and reduced overview and continuity of nursing care[144].

In our focus groups it was indicated that sustaining quality requires consensus among nursing colleagues and aligned routines[41] because control and stability can be maintained only by following routines and structured work. Although routinisation may prevent a person-centred approach due to the greater focus on task-solving[144], we consider appropriate routines supported by clinical guidelines to be key tools to ensure quality of care. This applies in particular for fluid balance charting where agreement on routines is a prerequisite for achieving sustainable quality, as several staff members are involved across shifts. Sustained adherence to guidelines relies on support from leaders who demonstrate ownership in their words and actions[105].

Developing LICENSE – a digital technology and a possible solution

Our focus group interviews with nursing staff offered several suggestions for improving the quality of fluid balance charting. Viewing the current method as time-consuming and bothersome, the nursing staff agreed that a simpler way of charting to ease their workload was desired[41]. With the paper-based fluid balance chart in use for almost a century, with various adjustments and redesigns[30, 152], it may be timely to consider a replacement, for example by introducing technological solutions.

The role of technology in nursing has been discussed extensively, with many nurses experiencing technology as incompatible with good nursing care and as distracting and intruding[153], even objectifying and dehumanising[154, 155]. However, by taking over routine nursing activities, technology can support nursing staff in devoting time and attention to relational care[155]. Although relatively demanding, fluid balance charting is a routine task as quality can be maintained only with systematicity and persistence. The digitisation of fluid balance charting may be an obvious possibility.

Expressing a positive attitude to technology's contribution to nursing care, the focus groups interviewees expected digitisation to simplify and ease work processes[41]. They had high expectations for future technology to improve charting, although several had experienced time-consuming login procedures, a lack of available computers, duplicate documentation and technical problems[41, 150, 151]. Some found that the electronic patient record implied burdensome documentation procedures and hampered accurate description of the patient's situation[156]. The encounters with previous or existing technologies mentioned here emphasise the importance of well-developed technologies that are integrated with nurses' workflows.

LICENSE was developed through interdisciplinary collaboration between physicians, nurses, and engineers. After initial testing of a prototype in a laboratory environment to validate technological functions (TRL 3-4), a study aimed at validating the devices in a controlled and relevant environment[42] indicated that LICENSE was reliable and able to measure fluid intake and output accurately. With better accuracy than the standard procedure, LICENSE thus reached TRL 5[55]. To the best of our knowledge there is a lack of research on the digitisation of the complete fluid balance as calculated based on fluid input and output. However, there is previous research evaluating other digital technologies aimed at measuring urine output[51, 52, 157] and studies evaluating nursing staffs abilities to estimate fluids[139, 158, 159].

Previous evaluations of electronic technologies recording urine output found mean biases between 0.08 and approximately 5-8 ml[51, 52, 157] and LOA intervals of 30.4 ml[51], 50 ml[52] and 139.5 g[157] compared with a LICENSE LOA interval of 27.8 ml. From a clinical viewpoint, we consider the mean biases of all technologies acceptable; however, the LOA are no less important in assessing the applicability of a digital technology. In our study[42], the LOA of the manual procedure with which we compared LICENSE was below 40 ml. We thus consider LICENSE and the technology developed by Eklund et al.[51] acceptable as they provide more accurate measurements. As the assessment may vary depending on the clinical case, data concerning accuracy should always be reported clearly and in an easily accessible manner.

Oral fluids are typically given in containers without measuring lines, leaving the nursing staff to estimate volumes. As estimates have shown to be influenced by the shape of fluid containers[160, 161], the volumes administered will not always be accurate. One study found that 50% of nurses estimated volumes within a 10% margin of error[158], whereas another study reported that only 27% of estimations were within a 10% error margin[159]. Another evaluation of nurses' ability to estimate fluid input and output in various containers revealed significant differences[139].

Demonstration in a real, operational environment (TRL 6) was the next step in the advancing LICENSE in relation to TRL[55]. Conducting our study in a real-life setting, we applied LICENSE for approximately 24 hours

comparing measurements with those obtained by the standard manual method[43]. Although we failed to succeed in reaching TRL 6, valuable lessons were learned.

The differences in urine output measurements obtained were likely due to inaccuracies or overestimated volumes[162] or to negligence in documentation. Divergences in intravenous fluid measurements were presumably caused by missed manual documentation of, e.g., intravenous antibiotics in the electronic fluid balance chart, as shown in previous research[48, 163]. Other studies have demonstrated discrepancies between the volumes indicated on fluid bags and the actual volumes given and raised attention to fluids remaining in infusion lines[164, 165]. The unreliability of the data are indicated by the large differences observed and caused by imprecise estimations[158-161], calculation errors[87, 89] and negligent manual charting[140, 166].

The relevance of real-life studies is likewise underscored by errors identified when the oral LICENSE device was tested in a real-life clinical setting. Comparing study setting conditions with a fashion catwalk, where clothes are rather different from what people wear in the street, Harari and Caminati[131] argue that randomized clinical trials may not always reflect the real-life settings. Consequently, LICENSE needs further development to align with actual pouring and drinking behaviours.

To adopt LICENSE, nursing staff would need to find it advantageous compared with manual charting and compatible with their values and previous experiences[54]. This is what the Diffusion of Innovations theory denotes the perceived attributes of innovations[54]. Thus, the future success of a medical device depends not only on the specific product and its technological attributes, its ability to meet the needs of the end users, and the users' emotional experience related to the device[167].

The complexity of the medical device, i.e., the difficulties encountered in use or comprehension, may moreover determine its reception by planned users[54]. The complexity of medical devices should be minimised as far as possible to avoid non-compliance[168] as illustrated by the fact that focus group participants admitted to using paper-based fluid balance charts before transferring data to the electronic patient record that was designed to allow direct entry of data. When nursing staff find their work complicated by electronic charting tools, they revert to paper-based methods[151, 169].

The users' experience in implementing and using LICENSE in daily practice deserves attention. During the real-life study, our exploration of the risk of device mishandling led us to address usability issues. Rather than occurring during complex tasks, problems arose from the device's incompatability with the users' unconscious actions and habits in pouring and administrating fluids[43, 135]. Implementing technology typically demands changes in and standardisation of workflows, offering less flexibility and leading to concerns from

nursing staff as departmental and individual practice vary. To prevent workaround behaviour, the technology should be as flexible and convenient as possible[50].

The safety of medical devices and electronic tools depends in part on correct handling. Hence, the training of users is pivotal. A positive reception further depends on allowing the time needed for training and adaption of technologies[151, 170-172].

To enhance the usability of a medical device, it is essential to include the user perspective in all phases of the innovation-development process[167]. User experience broadly describes users' perceptions, including usability and perceived value[167], i.e., the tangible outcomes of introducing the device, or in Rogers's words, its observability[54]. A usable device is intuitive and functional, easy to use and timesaving[167, 168]. However, awareness concerning the influence on the overall workflow is pivotal, as previous research has indicated that although technology may reduce time expenditure on a specific tasks, the additional steps needed to handle the technology may mean that overall workload is not necessarily reduced[50]. Intraoperability allowing the integration of data from different systems is furthermore perceived as essential to maintaining an overview of the patient's condition[41, 172].

Users should be involved at the earliest stages of device development to harvest all the benefits emerging from their expertise. Profiting from nurses' expertise and preferences in medical device development is likely to increase the safety and user-friendliness of the devices and their integration into clinical practice[105, 173, 174]. Nurses' willingness to adopt an innovation is based in their unique knowledge stemming from their proximity to patient care and patient experiences[174] and on their perception of the positive impact on patient care[151]. The design of LICENSE was strengthening as it was conducted in an interdisciplinary collaboration throughout. However, to achieve a successful implementation, the perspectives of nurses from different clinical settings with different prerequisites and technological ingenuity must be obtained during the entire development phase.

CONCLUSIONS

The writing of this thesis has unfolded within the research and development phases of the innovation-development process in constant interaction between research and development. The literature review demonstrated that inadequate fluid balance charting poses a challenge across countries, clinical settings, medical and surgical specialities and intensive care units. Incomplete charting and calculation errors influence the quality of fluid balance charting. We investigated interventions implemented to enhance quality and identified several components such as policies, education, equipment, visual aids and the dissemination of results. Five studies (38%) demonstrated compliance, with at least 75 % of fluid balance charts being completed, while the majority of studies evaluated interventions within six months or less, which we deem inadequate for evaluating their sustainability. In the literature review we stated the problems concerning fluid balance charting and the need for improvement.

Convinced that the perspectives of nursing staff were essential to developing a useful innovation, we conducted eight focus group interviews with nursing staff across clinical settings in Denmark and Sweden. Emphasising that fluid balance charting is a fundamental nursing task for the evaluation of patients and treatment planning, the focus group interviewees described charting as typically inaccurate and difficult to control. To improve this situation they indicated the importance of safe routines and consensus among colleagues and the introduction of digital technology.

To address the challenges of inadequate fluid balance charting, we developed LICENSE, a novel system, to automatically measure fluid intake and output and transfer wireless data to a database. When the LICENSE devices were validated in the laboratory, we conducted a controlled study to validate the devices in a controlled and realistic environment. Our findings indicate that LICENSE devices rendered reliable and accurate measurements when compared with manual methods.

Our subsequent evaluation of the devices failed to demonstrate their operability as we did not succeed in validating LICENSE in a real-life setting. This step, however, garnered valuable insights into the challenges of manual fluid balance charting and suggestions for adjustments for better integration of LICENSE into workflows and work habits.

Overall, this study has demonstrated the need to improve the quality of fluid balance charting and offered a potential solution. It has furthermore highlighted the value of understanding end users' perspectives and the relevance of testing medical devices in a real-life scenario.

Perspectives and implications for future research and medical device development

The perspectives and implications arising from this thesis can be divided into two supporting avenues, one for research and another for medical device development. The primary goal of the development avenue is further refining the LICENSE devices until the optimal product is achieved. Based on the completed studies, an adjusted prototype needs to be developed to allow for unconscious actions. When a prototype LICENSE 2.0 is ready, Studies 3 and 4 will have to be repeated for validation with the new design, followed by documentation of its functioning in a real-life scenario.

To promote its hospital-wide implementation and integration into nursing practice, evaluations from a nurse as well as a patient perspective will be relevant to ensure that the redesigned equipment supports nursing workflows and is readily adoptable for users. Reducing the complexity of the technology while delivering an observable relative advantage for nursing staff is pivotal for nurses in adopting the technology. The usability of the equipment and the users' experience should be thoroughly researched, e.g., by interviewing nursing staff.

Commercialisation being the goal of all medical device development, CE marking is a prerequisite for entry into the European market. When the final prototypes are developed and approved LICENSE has reached the commercial stage and is ready for end users. Its diffusion and adoption in clinical practice will be determined by nurses' reception.

The introduction of the final version of the LICENSE devices promises to open up many research possibilities by providing uniquely detailed data concerning the intake and output of fluid. Studies concerning the influence of fluid balance on patient outcomes in different specialities may be conducted based on the harvested data. We expect to gain new insights into exciting challenges such as the optimal postoperative fluid strategies and the best fluid resuscitation regimes in the critically ill. Among advances in the field of urology, we hope to further explore not only the development and diagnostics of postobstructive diuresis but also accelerate the diagnosis of acute kidney injury and enable the profiling of patients at risk of fluid balance complications.

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APPENDICES

List of appendices

APPENDIX I

BMJ Open Quality

Quality of fluid balance charting and interventions to improve it: a systematic review

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ABSTRACT

Introduction Fluid balance monitoring is pivotal to patients' health. Thus, fluid balance charting is an essential part of clinical nursing documentation. This systematic review aimed to investigate and describe the quality of fluid balance monitoring in medical, surgical and intensive care units, with an emphasis on the completeness of charting data, calculation errors and accuracy, and to evaluate methods used to improve fluid balance charting.

Materials and methods Quantitative studies involving adult patients and reporting data on fluid balance monitoring were included in the review. We searched MEDLINE, Embase, CINAHL and the Cochrane Library. The risk of bias in the included studies was assessed using tools developed by the Joanna Briggs Institute.

Results We included a total of 23 studies, which involved 6649 participants. The studies were quasi-experimental, cohort or prevalence studies, and every third study was of low quality. Definitions of 'completeness' varied, as well as patient categories and time of evaluation. Eighteen studies reported the prevalence of patients with complete fluid balance charts; of those, 10 reported that not more than 50% of fluid balance charts were complete. Studies addressing calculation errors found them in 25%–35% of charts, including omissions of, for example, intravenous medications. The reported interventions consisted of various components such as policies, education, equipment, visual aids, surveillance and dissemination of results. Among studies evaluating interventions, only 38% (5 of 13) achieved compliance with at least 75% of complete fluid balance charts. Due to the heterogeneity of the studies, a meta-analysis was not possible.

Conclusion The quality of fluid balance charting is inadequate in most studies, and calculation errors influence quality. Interventions included several components, and the impact on the completion of fluid balance charts varied.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Fluid balance charting is a widely used tool in clinical practice but is well known for being inadequate. The low quality of fluid balance charting, as well as the prevalence of calculation errors, has been reported in studies across the world. However, a review of quality and interventions to improve it is lacking.

WHAT THIS STUDY ADDS

⇒ This review provides an overview of the quality of fluid balance charting and identifies interventions intended to improve it. We found that the quality is inadequate in medical, surgical and intensive care settings due to missing documentation or calculation errors. In addition, interventions often have not achieved sufficient improvement, some hardly any.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study indicates a need for further exploration of barriers and facilitators in fluid balance monitoring to gain knowledge to develop robust and effective interventions.

INTRODUCTION

A healthy body is in a state of fluid balance, but hospitalised patients are at risk of fluid balance disorders. Thus, fluid balance monitoring has clinical relevance to treating the patient correctly and helps determine the appropriate prescribing of fluids and diuretics essential to achieve or maintain homeostasis and healing.[1] The standard fluid balance monitoring method is keeping a fluid balance chart to document the patient's fluid input and output. Fluid balance charting is considered a fundamental nursing task and has been an essential tool in hospital practice for over 50 years.[2]

Fluid balance is the difference between the amount of fluid taken into the body and the amount excreted or lost. The Australian Nurses Dictionary defines it as 'a state in which the volume of body water and its solutes (electrolytes and non-electrolytes) is within normal limits, and there is a normal distribution of fluids within the intracellular and extracellular compartments'.[3]

In hospitalised patients, fluid disorders are among the most common problems encountered in clinical practice[4] across medical and surgical wards, and fluid balance disorders such as overhydration and dehydration can seriously affect patients' health. Overhydration is associated with complications such as peripheral oedema and dyspnoea[5] and

increased mortality in patients with sepsis, cerebral haemorrhage and heart disease.[6–8] Further, dehydration is associated with an increased risk of constipation, urinary tract infections and falls, prolonging hospitalisation and impairing the quality of life.[9–12] Postoperative fluid balance monitoring is pivotal[13] as both overhydration and dehydration can lead to complications and prolonged hospitalisation following an operation.[14–16]

Three main elements can assess fluid balance: clinical assessment, blood chemistry review and fluid balance charts. Clinical assessment includes vital signs, capillary refill time, tissue turgor, the amount and colour of the urine, feeling of thirst and daily weight.[17] However, some of these factors have not been proven to be significantly associated with fluid balance but are used in clinical practice. Blood chemistry review may comprise creatinine and urea as well as electrolytes such as sodium and potassium.[18]

A fluid balance chart is a non-invasive tool that aims to keep an accurate record of a patient's fluid status over 24 hours. The document should indicate if the patient is in fluid balance, deficit or overload.[1 2 18] The input consists of fluids ingested orally, parenteral nutrition and intravenous fluids including medications (eg, antibiotics). Whether blood products should be counted in the fluid balance calculation is debatable.[2] Any fluid given orally, through feeding tubes or intravenously is considered part of the fluid balance chart. The output includes all fluid losses that can be measured: urine, nasogastric drainage, vomit, liquid stool and output in drains and tubes. It differs if insensible losses from the lungs, skin and respiratory tract are included.[2 17]

Fluid balance charting seems relatively straightforward. Still, monitoring is often inadequate due to staff shortage and lack of time and training,[1 18–20] and the charts can be challenging to interpret and calculate.[21] Further, fluid volumes are estimated based on visual assessment. Studies have shown such estimations are unreliable[22 23] and affected by, for example, the colour of the fluids and the shape of the container used.[23 24] To clarify the scope and characteristics of the problem, a systematic overview of the literature can provide information on the quality of fluid balance in different wards and settings along with possible interventions to improve fluid balance charting.

This systematic review investigates and describes the quality of fluid balance monitoring with an emphasis on completeness, calculation errors and accuracy. The primary outcome of the review is to evaluate the completeness of fluid balance charts. Secondary outcomes include the frequency and size of calculation errors, the occurrence of missing calculations (totals) and fluid balance monitoring accuracy. Furthermore, it provides an overview of interventions used to improve fluid balance charting.

METHODS

This systematic review involves quantitative studies addressing the quality of fluid balance charting in medical and surgical wards and intensive care units (ICUs).

The review is registered in the PROSPERO database of systematic reviews (registration number: CRD42021249004). Throughout the review process and in reporting the results, we worked in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[25]

We did not involve patients or the public in this systematic review's design, conduct or reporting, as it referred to specific nursing care requiring professional knowledge and insight.

Search strategy and study selection

We developed the search strategy in cooperation with an information specialist and searched the following databases—CINAHL, Embase, MEDLINE and the Cochrane Library—in November 2020 and February 2021. We repeated the search in October 2022. Additionally, we searched PROSPERO for relevant ongoing or recently completed systematic reviews and ProQuest Dissertations and Theses Global for grey literature.

The nursing environment has changed enormously during the last decades with, for example, accelerated patient pathways, implementation of electronic patient records and increased workload due to staff shortage. Thus, we restricted the searches to the publication period of 2010–2021 to evaluate contemporary practice. It included a thesaurus (eg, MeSH Terms) and free-text search, which was structured according to the PI(CO) form.[26] The keywords used included "fluid balance" OR "urine output" AND "measure" OR "charting" AND "accuracy" OR "completeness" OR "quality" (search strategy as online supplemental material). Studies published in English, Danish, Norwegian and Swedish were considered for inclusion.

Two reviewers (LRL and ST-H) independently screened records using the software Covidence.org, which removed duplicates. First, we screened titles and abstracts based on the predetermined selection criteria and then assessed them for eligibility through full-text reading by four reviewers (LRL, MK, ST-H and NA). Reasons for the exclusion of full-text studies are provided in the PRISMA diagram. Any disagreements were resolved through discussion.

Eligibility criteria

We chose studies presenting quantitative data on fluid balance monitoring originating from fluid balance charts. Therefore, studies assessing fluid balance using invasive procedures requiring intubation or insertion of a catheter as required in measuring, for example, central venous pressure were not eligible. We excluded studies addressing fluid balance assessment only in the intraoperative phase. Only studies reporting data on total fluid balance based on input and output measurements

were selected so that those exclusively reporting a single parameter (eg, urinary output) were excluded. We included studies regarding the fluid balance on a specific day as recorded in a fluid balance chart, and studies addressing the cumulative fluid balance based on fluid balance charts of several days during admission. Studies conveying fluid balance disturbances developed over time, for example, prior to admission, were only included if the study addressed fluid balance charting quality.

Research involving hospitalised patients 18 years or older and specifying the number of included patients was considered eligible. We included all study designs except case reports as long as the eligibility criteria were met. Conference abstracts were omitted.[27]

Quality appraisal method

Two reviewers (LRL and MK) assessed all included studies independently using quality appraisal tools developed by Joanna Briggs Institute (JBI, https://jbi.global/critical-appraisal-tools) for rigorous assessment of their methodological quality and to determine if they addressed possible bias in the design, conduct and analysis.[28]

Studies designed as preaudits/postaudits performed before and after an intervention targeted to improve the quality of fluid balance monitoring were defined as quasi-experimental. A prevalence study is a kind of cross-sectional study undertaken to determine the prevalence[26] of, for instance, completed fluid balance charts conducted as retrospective or prospective audits. Studies were classified according to the outcome of interest; thus, for example, cohort studies could be assessed as a prevalence study if the outcome of interest was reported as a prevalence.

We rated the quality of studies as low, moderate, or high depending on the number of positive answers in the JBI instrument. The quality was rated as low if fewer than 50%, moderate if between 51% and 80%, and high if more than 80% of questions received a positive answer.[29 30] We did not exclude any studies due to their low quality.

Data extraction and synthesis

Before data extraction, we developed a customised instrument inspired by a generic template in Covidence (https://www.covidence.org/) and adjusted it as necessary. Two reviewers (LRL and MK) independently extracted all data and resolved disagreements through discussion until a consensus was reached.

The data extraction included characteristics of studies (eg, first author, country, year of publication, setting, study design), participants (age, sex, reason for admission) and results on fluid balance monitoring. Completeness was defined as the proportion of complete fluid balance charts, and a complete fluid balance chart covers all intake and output and enables calculation of the 24-hour fluid balance. If applicable, we further extracted documentation of oral fluid intake, intravenous fluids, urine output, calculated totals and calculation errors. Calculation errors were defined as discrepancies between nurses' calculations and researchers' recalculations and comprised both erroneous mathematical calculations and incorrect calculations due to omissions of certain fluids. Furthermore, we collected data on interventions, determined as any activity or action taken with the aim of improving certain outcomes.[31] We extracted the number of repeated data collections if there were multiple preinterventional or postinterventional data collections and recorded all data.

RESULTS

Study selection

We identified 12 519 titles from screening the databases and removed 1971 duplicates. The remaining 10 548 studies were screened against the title and abstract. We included a total of 237 articles for full-text reading and assessed them for eligibility. We excluded 214 papers as they did not meet the inclusion criteria. The remaining 23 papers were included in this review. The selection process is presented in a PRISMA flow diagram[25] (figure 1).

Characteristics of included studies

We identified 23 eligible studies published between 2010 and 2021; 10 were published between 2010 and 2014[32–41] and 13 between 2015 and 2021.[42–54] The studies were conducted in 12 different countries on five continents; of those, 10 originated in the UK.[32 36 40–43 45 47 49 54] A total of 6649 patients participated in the research, varying from 24 patients to 2199 in each study. Most studies addressed fluid balance charting on a specific day; however, two studies reported cumulative fluid balance. General characteristics, aims and findings are presented in table 1.

Divergent definitions characterised studies; the words 'complete', 'adequate' and 'accurate' were often used interchangeably. Moreover, in the most studies, no definition was provided. Among those defining the term, there were inconsistencies in addition to disagreements on which elements were included in fluid balance calculations.[2 17] A prerequisite for performing a meta-analysis is including at least two comparable studies. Due to substantial heterogeneity among studies concerning the definition of outcomes, a meta-analysis was not possible. Therefore, we performed a narrative synthesis of the findings.

Quality appraisal

The studies comprised 12 studies categorised as quasi-experimental,[33 40–43 45–47 49–51 54] 3 cohort studies[32 37 44] and 8 prevalence studies (cross-sectional studies).[34–36 38 39 48 52 53] All were appraised using the JBI tools for assessing quasi-experimental and prevalence studies. Thus, the cohort studies were evaluated using the tool for prevalence studies as the outcome of interest was presented as a prevalence.[32 37 44]

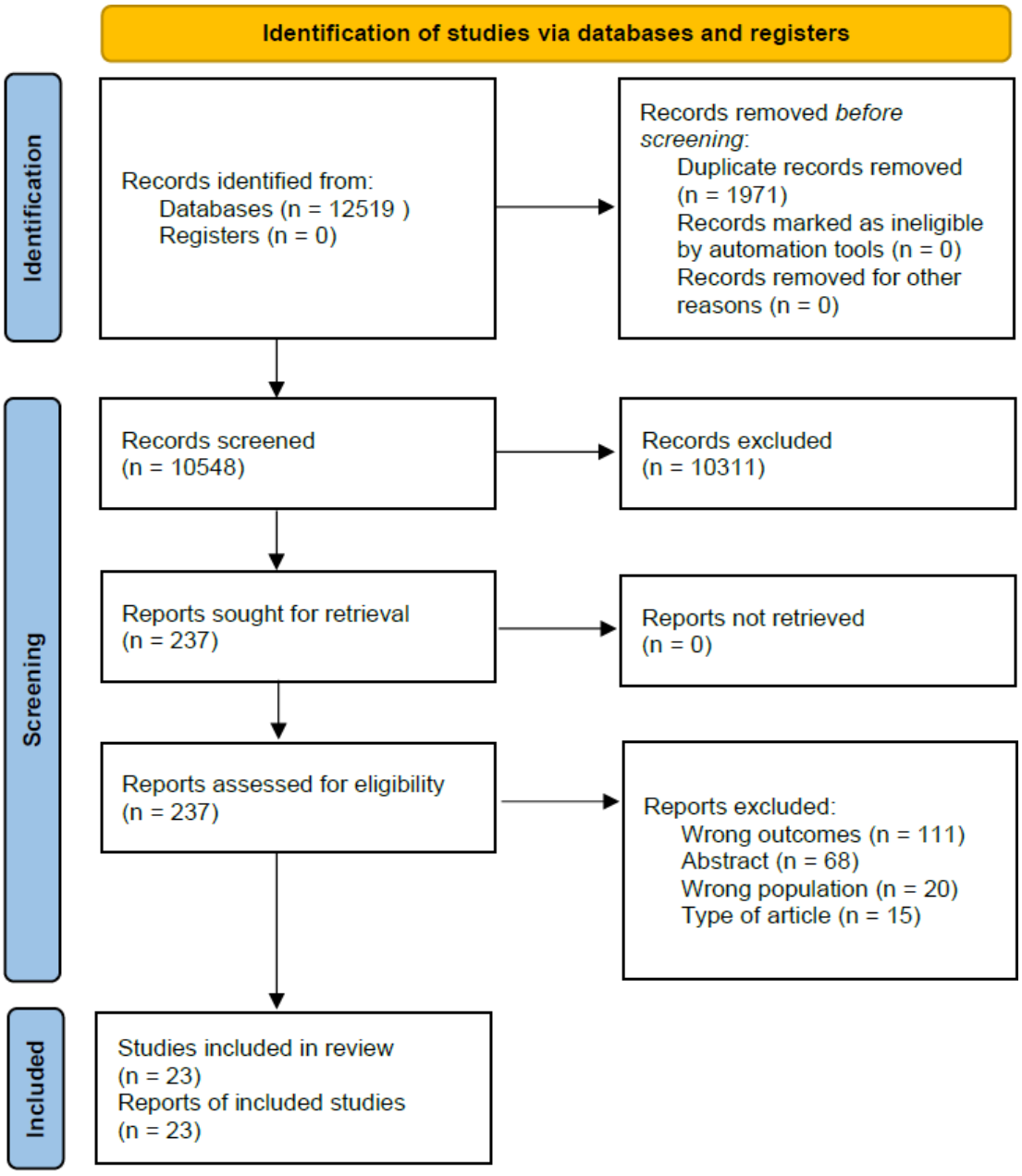

Figure 1 PRISMA flow diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Only 3 studies were of high quality,[37 48 53] 12 of moderate quality[32 34–36 38 39 43–46 50 52] and 8 of low quality.[33 40–42 47 49 51 54] Details of the quality appraisal can be found in table 2. All studies assessed to be of low quality had a quasi-experimental design, explained by the higher risk of bias in quasi-experimental studies compared with prevalence studies. Reasons for a poor assessment could be missing characteristics of study participants, lack of a control group and only one pretest.

Prevalence of complete fluid balance charts

Of the included studies, 18 reported the prevalence of patients with fluid balance monitored using a fluid balance chart. Of those, seven found a proportion of complete fluid balance charts of no more than 25%,[33 43 45 46 48 50 54] three studies found a proportion between 26% and 50%,[36 40 47] and in five studies, the proportions were reported to be between 51% and 75%.[32 37 39 41 42] Only three studies reported that more than 75% of patients had a complete fluid balance chart[34 35 38] (figure 2).

Calculation errors and accuracy

Seven studies investigated the prevalence of calculation errors in fluid balance charts.[34 36 38 39 44 49 54] Four were performed in ICUs.[34 38 39 44] One study examining miscalculations in an ICU found a median calculation error in the daily fluid balance charts of 58 mL (range 1–1464 mL) and a cumulative median calculation error of 131 (range 1–2405 mL).[44] Another study found a calculation error of more than 500 mL in 26.1% of fluid balance charts; the calculation error was between 1000 and 2000 mL in 6.8%

Table 1 Characteristics of included studies

Author(s), year, country	Aim	Design	Setting and participants	Sample size	Outcomes regarding fluid balance monitoring	Key findings
Aitken *et al*, (2013); UK[32]	AKI Quality of care	Cohort study	Medical, surgical, AKI	243	Adequate FBD (%), inaccurate FB chart (%)	51.8% of patients with AKI had adequate FBD; 43.4% of the remainder had inaccurate FB charts in case notes.
Alexander and Allen (2011) USA[33]	Policy for FB monitoring	Quasi-experimental	Medical oncology units	427	Compliance with FBD	Before intervention, 12% of patients with indication of FB monitoring had FBD vs 84% after.
Asfour (2016); Egypt[52]	Accuracy of FB monitoring	Cross-sectional	ICU except dialysis	100	Accuracy of calculated FB compared with researcher's calculation	65% of FB charts were accurate and 35% were inaccurate.
Baird *et al*, (2019); UK[42]	AKI prediction score	Quasi-experimental	Orthopaedic surgery	78	FB monitoring (%)	Before intervention, 62% had adequate FB monitoring postoperatively vs 66% after.
Davies *et al*, (2017); UK[43]	Reduce AKI alerts	Quasi-experimental	Orthopaedic trauma	75	Running hourly input, 6 hourly input subtotal, 6 hourly output subtotal and 24-hour total FB	Before intervention, 80% had running 1 hour totals vs 96% after; 36% had 6 hour output vs 68% after. Before intervention, 12% had 24-hour totals vs 72% after and 32% after 6 months.
Davies *et al*, (2019); Australia*[44]	Relationship between calculated FB and BW	Prospective cohort study	ICU, requiring CRRT	61	FB charts with calculation errors (%), median deviation in millilitres	Calculation errors prevalent in 27% of charts. Median daily calculation error: 58 mL (range 1–1464 mL). Median cumulative calculation error: 131 mL (range 1–2405 mL).
Diacon and Bell (2014); South Africa[34]	FB monitoring and measurement accuracy	Cross-sectional	ICU	103	FBD (%), calculation errors (%), deviation in millilitres	95.1% had FBD. Calculation errors: 68.9% deviated 0–500 mL, 13.5% 500–1000 mL, 6.8% 1001–2000 mL, 5.8%>2000 mL
Eastwood *et al*, (2012); Australia[35]	Patients receiving IV fluids (%)	Cross-sectional	All inpatients except ICU, ED and PACU	326	Percentage with FB charts maintained (%)	94% of patients receiving intravenous fluids had FB charts vs 44% receiving no intravenous fluids.
Herrod *et al*, (2010); UK[36]	Prevalence of dysnatraemias and precipitating factors	Cross-sectional	Surgery Na<130 or >150 mmol/L	55	Complete FB charts (%) Charts with FB calculated (%), median inaccuracy in FB calculation	28% had complete FB charts before dysnatraemia vs 44% after; 37% of charts had no FB calculation. Median calculation error: 72 mL (IQR 9–313 mL) before dysnatraemia vs 130 mL (IQR 71–400 mL) after
Joslin *et al*, (2015); UK[45]	AKI recognition and management	Quasi-experimental	AKI	192	Complete FB chart on first day of AKI (%), days with complete FBD (%)	Before intervention, 25% had completed FB charts on first day of AKI vs 34% (p=0.23) after. Before intervention, FBD was completed in 32% of patient days vs 45% after (p=0.002).

Continued

Table 1 Continued

Author(s), year, country	Aim	Design	Setting and participants	Sample size	Outcomes regarding fluid balance monitoring	Key findings
Liaw and Goh (2018); Singapore[46]	Fluid intake charting	Quasi-experimental	Acute surgery	60	Deduction of input/output at midday and over 24 hours. Calculation of 24 hours FB. Involving patients in fluid intake documentation	Before intervention, 3.3% of the FB charts were complete (midday and 24 hours totalling) vs 100% 1 month and 6 months later. Before intervention, patients were involved in 10% of cases vs 87% 1 month later and 83% 6 months later.
Lim *et al*, (2021); Singapore[53]	Ordering and documenting fluid in- and output	Cross-sectional	Acute care hospital	2199	Accuracy of FBD defined by recording in millilitres	Overall accuracy 77%. Oral and intravenous fluids 100% accurate, output accurate in 21% of cases
Madu *et al*, (2021); UK[54]	Chart completeness and accuracy	Quasi-experimental	General medicine	82	Accurate measurements, calculation errors, complete documentation	Before intervention, 25% of measurements were accurate vs 39% after 1 month and 5% after 6 months, correct daily totals in 20% vs 40% after 1 month and 15% after 6 months, 14% of charts complete vs 31% after 1 month and 5% after 6 months
Møller *et al*. (2013); Denmark[37]	Quality improvement	Prospective cohort study	Acute surgery, PPU	1650	Quality-of-care indicator: daily FBD	Before intervention, 74% had FBD vs 79% after. RR 1.07 (95% CI 1.02 to 1.13; p=0.010)
Perren *et al*, (2011); Switzerland*[38]	Accuracy of FBD; agreement w BW	Cross-sectional	ICU	147	Complete FB charts, FB charts with calculation errors	12% were excluded due to an incomplete FB chart; 33% of nurse-registered cumulative FB was inaccurate, errors: −3606 mL to +2020 mL. Mean absolute error of 445±668 mL
Pinnington *et al*, (2016); UK[47]	Complete FBD	Quasi-experimental	Three wards	120	Complete FB charts	Before intervention, 32% of FB charts were completed correctly vs 92% after. In AKI patients, 20% had FBD before vs 91% after.
Szmuda *et al*, (2014); Poland[39]	Calculation errors; FBD and chart completeness	Cross-sectional	NICU and NHDU, SAH	41	Complete FB charts, FB miscalculations	63.4% of FB charts were complete, 80.2% in NICU and 58.7% in NHDU (p<0.01). Fluid intake miscalculations in 27.4% of charts. Most common errors: underestimating intake (80.6%), omitting drugs (66.9%)
Tura *et al*. (2020); Ethiopia[48]	Managing postpartum haemorrhage	Cross-sectional	Obstetric	45	Standard of care criteria: fluid intake/output chart is maintained	In 13.3%, a fluid intake/output chart was maintained.
Vincent and Mahendiran (2015); UK[49]	Quality of FB monitoring	Quasi-experimental	General medicine	147	FBD, indication of FBD. Chart completion: boxes filled of all total boxes. Accurate totals=<10% error	Before intervention, 67% were on FBD (indicated in 53%) vs 38% after (indicated in 93%). Average chart completion rate before intervention was 50% vs 70% after. Average chart accuracy was 41% before vs 61% after.

Continued

Table 1 Continued

Author(s), year, country	Aim	Design	Setting and participants	Sample size	Outcomes regarding fluid balance monitoring	Key findings
Wakeling (2011); UK[40]	FBD and FB complications; Hydrant drinking aid	Quasi-experimental	Orthopaedic, surgery, urology	313	Complete FB charts (%)	Before intervention, 19%–50% of FB charts were complete vs 29–62% after. Completeness improved (5–18 percentage points).
Walker *et al*. (2012); UK[41]	Improve guideline adherence	Quasi-experimental	Acute wards	101	Completion of FB charts	Before intervention, 62.3% had FBD vs 70.8% after (p=0.36).
Yang *et al*, (2019); Taiwan[51]	Compliance with FB monitoring	Quasi-experimental	Congestive heart failure	24	FB charts used with electrolytes and physical assessment. Patients involved in FBD	Before intervention, 58% had FB charts with physical assessment vs 100% after; 42% were involved in recording before intervention vs 75% immediately after.
Zhu *et al*, (2018); China[50]	Non-pharmacological fever management	Quasi-experimental	Infectious disease, HIV	60	Formal assessment of fluid in- and output volume documented	Before intervention, 0% had fluid input/output documented vs 73% 10 days after intervention.

*Studies addressing cumulative fluid balance.
AKI, acute kidney injury; BW, body weight; CRRT, continuous renal replacement therapy; ED, emergency department; FB, fluid balance; FBD, fluid balance documentation; ICU, intensive care unit; NHDU, neurosurgical high-dependency unit; NICU, neurosurgical ICU; PACU, postanaesthetic care unit; PPU, perforated peptic ulcer; SAH, subarachnoid haemorrhage.

and above 2001 mL in 5.8%.[34] A third study conducted in an ICU reported inaccuracies in 33% of fluid balance charts.[38] The size of the errors was between −3606 mL and +2020 mL, and the mean absolute calculation error was 445 mL±668 mL.[38]

A study in a neurosurgical ICU and a neurosurgical high-dependency unit reported calculation errors in 27.4% of fluid balance charts. It stated that the most frequent cause of calculation error was the underestimation of fluid intake (80.6%) primarily because of omissions of intravenous drug therapy (66.9%).[39]

Another study reported a median calculation error of 72 mL (IQR 9–313 mL) and 130 mL (IQR 71–400 mL) before and after the development of dysnatraemia among surgical patients; 37% did not perform a calculation of fluid balance.[36] In a general medical ward, daily totals and balances were correct in only 20% of fluid charts before quality improvement initiatives.[54]

Moreover, an investigation of the accuracy of fluid balance charts among general medical inpatients found that the mean accuracy was 41% (<10% error was considered accurate) before initiating interventions to improve quality.[49] One study defined accuracy as recorded fluid balance calculations matching the researcher's calculated fluid balance from observation and prescription.[52] Another study defined accuracy as documenting fluid in millilitres and calculated it as each recording in millilitres divided by all recordings, finding an overall accuracy of 77%. All oral and intravenous fluids were recorded correctly, but only 21% of output recordings were correct.[53]

Quality improvement interventions

Of the included studies, 13 describe the implementation of an intervention to improve the quality of fluid balance charts evaluated by comparing preinterventional and postinterventional audits.[33 37 40–43 45–47 49–51 54] The interventions included organisational changes and adoption of policies,[33 37 45] teaching and education (physical or e-learning),[33 40–43 45–47 49–51 54] dialogue,[41 43 46] visual aids such as posters[33 43 45 47 49 54] and messages on computer background wallpapers,[41 55] surveillance (eg, through monthly audits)[50 51] and disseminating the results.[37 41 46 51] Furthermore, several interventions incorporated some equipment such as scoring tools,[42] care bundles,[45] changed fluid balance charts,[43 47 49 51] calculators[49 54] and a drinking aid.[40] Characteristics of interventions are presented in table 3.

The effect of the implemented interventions varied, and so did the time from intervention to evaluation. In five studies, the researchers achieved an improvement, indicating that at least 75% of fluid balance charts were complete and correctly filled after the intervention.[33 37 46 47 51] In another five studies, the final result was within the interval of 50%–75%.[40–42 49 50] The quality improved by 4–20 percentage points in four of the latter, but a single study reported an improvement from 0% to 73%.[50] Three studies found that less than 50% of fluid

Table 2 Quality appraisal of included studies

JBI tool	Author(s), year	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	%	Quality appraisal
Quasi-experimental studies	Alexander and Allen (2011)[33]	Y	N	N*	N	N	Y	Y	N	N	44	Low
	Baird *et al* (2019)[42]	Y	N	N*	N	N	Y	Y	N	N	44	Low
	Davies *et al* (2017)[43]	Y	N	N*	N	Y	Y	Y	N	N	56	Moderate
	Joslin *et al* (2015)[45]	Y	Y	N*	N	N	Y	Y	N	N	56	Moderate
	Liaw and Goh (2018)[46]	Y	N	N*	N	N	Y	Y	N	Y	56	Moderate
	Madu *et al* (2021)[54]	Y	N	N*	N	N	Y	Y	N	N	44	Low
	Pinnington *et al* (2016)[47]	Y	N	N*	N	N	Y	Y	N	N	44	Low
	Vincent and Mahendiran (2015)[49]	Y	N	N*	N	N	Y	Y	N	N	44	Low
	Wakeling (2011)[40]	Y	N	N*	N	N	Y	Y	N	N	44	Low
	Walker *et al* (2012)[41]	Y	N	N*	N	N	Y	Y	N	N	44	Low
	Zhu *et al* (2018)[50]	Y	N	N*	N	N	Y	Y	Y	N	56	Moderate
	Yang *et al* (2019)[51]	Y	N	N*	N	N	Y	Y	N	N	44	Low
Q1: Is it clear in the study what is the cause and what is the effect? Q2: Were the participants included in any comparisons similar? Q3: Were the participants included in any comparisons receiving similar treatment/care other than the exposure or intervention of interest? *Note: 'No' is considered good. Q4: Was there a control group? Q5: Were there multiple measurements of the outcome both before and after the intervention/exposure? Q6: Was follow-up complete, and if not, were differences between groups in terms of their follow-up adequately described and analysed? Q7: Were the outcomes of participants included in any comparisons measured in the same way? Q8: Were outcomes measured in a reliable way? Q9: Was appropriate statistical analysis used?											
Prevalence	Aitken *et al*[32]	Y	Y	N	Y	Y	Y	Y	N	Y	78	Moderate
	Asfour[52]	Y	Y	N	N	Y	Y	Y	N	Y	67	Moderate
	Davies *et al* (2019)[44]	Y	Y	N	Y	Y	Y	Y	N	Y	78	Moderate
	Diacon and Bell[34]	Y	Y	Y	N	Y	Y	Y	N	Y	78	Moderate
	Eastwood *et al*[35]	Y	Y	N	Y	Y	Y	Y	N	Y	78	Moderate
	Herrod *et al*[36]	Y	Y	N	Y	Y	Y	Y	N	Y	78	Moderate
	Lim *et al*[53]	Y	Y	Y	Y	Y	Y	Y	N	Y	89	High
	Møller *et al*[37]	Y	Y	Y	Y	Y	Y	Y	Y	Y	100	High
	Perren *et al*[38]	Y	Y	N	Y	N	Y	Y	N	N	56	Moderate
	Szmuda *et al*[39]	Y	Y	N	Y	Y	Y	Y	N	Y	78	Moderate
	Tura *et al*[48]	Y	Y	Y	Y	Y	Y	Y	N	Y	89	High
Q1: Was the sample frame appropriate to address the target population? Q2: Were study participants sampled in an appropriate way? Q3: Was the sample size adequate? Q4: Were the study subjects and the setting described in detail? Q5: Was the data analysis conducted with sufficient coverage of the identified sample? Q6: Were valid methods used for the identification of the condition? Q7: Was the condition measured in a standard, reliable way for all participants? Q8: Was there appropriate statistical analysis? Q9: Was the response rate adequate, and if not, was the low response rate managed appropriately?											

*'No' is considered good
JBI, Joanna Briggs Institute; N, no; Y, yes.

balance charts were completed and correct after an intervention.[43 45 54] A final study found an immediate quality improvement (72% complete fluid balance charts); however, after 6 months, the quality decreased to 32%.[43]

DISCUSSION

This systematic review had three major findings. First, we found that although fluid balance charting is common practice in medical, surgical and ICUs, the quality of fluid balance charting is inadequate. Second, calculation errors are also common. Third, all interventions included at least two components, but the time of evaluation and the impact on the completion of fluid balance charts varied.

Quality of fluid balance charting

Half of the included studies reported that less than 50% of the fluid balance charts were complete and correctly filled,[33 36 40 43 45–48 50 54] indicating that insufficient fluid balance documentation is a considerable challenge. Fluid balance charts guide clinical decisions, including prescription of intravenous fluid or medication and interventions to ensure appropriate care and reduce the risk of complications and fluid balance disorders. Thus, a thoroughly kept fluid balance chart contributes valuable data. On the contrary, it can be counterproductive if not adequately completed and put patient safety at risk by leading to erroneous conclusions.[19 20 56]

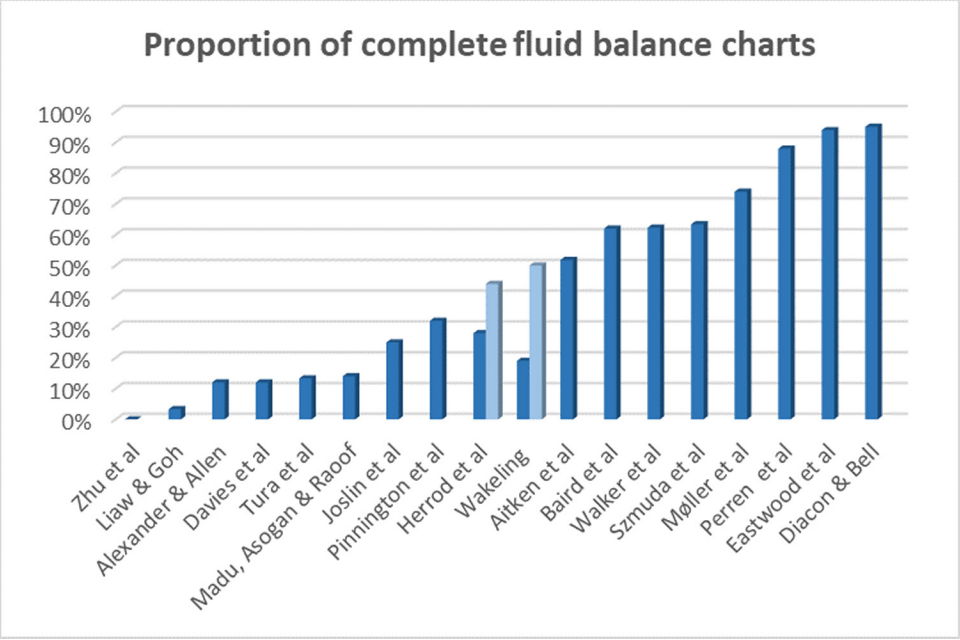

Figure 2 Overview of reported proportions of complete fluid balance charts preintervention. Two columns per study indicate that the study reported percentages from more than one ward.

A compelling question related to the quality of fluid balance monitoring is what is meant by 'complete' fluid balance charts. A fluid balance chart may seem complete even though some documentation is missing, indicating that certainty regarding the completeness of charts can only be determined through observations. Divergent definitions or no definition at all complicate the comparison of results. The variety of definitions may, thus, express a lack of shared understanding of fluid balance monitoring. Studies show that a standardised nursing language can improve communication among healthcare professionals, adherence to standards of care and quality of care.[57 58] Therefore, a shared definition of complete fluid balance monitoring may improve charting accuracy and would enable comparisons across settings.

Calculation errors

The second major finding was that erroneous calculation of fluid balance was a common and significant problem, with calculation errors in 25%–35% of the fluid balance charts.[34 38 39 44] Further, erroneous daily fluid balance chartings lead to increased cumulative errors[44] with a range of several litres.[38] Naturally, the size of calculation errors determines whether they are of clinical significance in a specific patient category. Thus, it may be of greater interest to determine how many had a calculation error deviating, for example, more than 500 mL as this may be clinically relevant. One study reports that 26.1% had a calculation error of more than 500 mL, and half of those exceeded 1000 mL.[34] However, establishing the clinically relevant accuracy threshold is difficult as it varies based on patient variables like diagnosis and age. Further, as the severity of the illness and comorbidities of patients rise, the vulnerability towards fluid balance disturbances increases, and the margin of error is reduced.[59] Anyhow, this review demonstrates the necessity of improving fluid balance charting accuracy to ensure the charts' credibility and utility.

According to several authors, the cause of errors was the manually calculated fluid balance.[34 39 44] However, calculation errors can be conceptual, arithmetical or computational[60] and may occur due to interruptions and time pressure.[61] Ensuring access to pocket calculators[44 49] or applying electronic patient records automatically calculating fluid balance based on documented information[39] may minimise computational errors. A study evaluated the effect of a clinical information system and found that it saved time, for instance, due to automatic fluid balance calculation. Furthermore, staff positively evaluated the electronic record as it improved charting quality.[62] Another study reported that most nurses (75%) believed electronic health records improved nursing documentation.[63]

Another cause of errors was a lack of documentation, such as omitting intravenous medication.[39] Omissions in nursing care are recognised as a comprehensive challenge related to the shortage of nurses and high patient-to-nurse ratios.[64] A qualitative study exploring regularly missed nursing care highlighted fluid balance monitoring as an essential theme.[55] Reasons for this lack may include staff shortage, inappropriate use of staff resources and ineffective delegation.[55]

Additional challenges are an inaccurate estimation of oral fluid volumes and potential typing errors if data are entered manually.[44] It is possible that a higher degree of automation can prevent these types of inaccuracies.

Table 3 Characteristics of interventions

Author(s), year	Type of intervention	Elements in intervention	Time from implementation to evaluation
Alexander and Allen (2011)[33]	Organisational/policy Education Visual aids	Development of fluid balance measurement policy, computerised physician order, education of nurses and medical staff, educational poster	2 months
Baird *et al* (2019)[42]	Equipment Education Disseminating results	Development of AKI prediction tool+intervention bundle including fluid balance monitoring, educating doctors to use the tool, presenting results at audit meetings	Immediately following each of four PDSA cycles
Davies *et al* (2017)[43]	Equipment Education/dialogue Visual aids	Redesign of fluid balance charts, posters, discussions at nursing handover, e-learning modules, informing junior doctors and encouraging close monitoring	1 month and 7 months
Joslin *et al* (2015)[45]	Organisational/policy Education Equipment Visual aids	Hospital-wide programme to improve AKI recognition and management, AKI care bundle, educating nurses and doctors, posters on all wards, announcements on hospital intranet and screensavers	2 years
Liaw and Goh (2018)[46]	Equipment Education/dialogue Disseminating results	Disseminating audit results to nurses, creating dialogue and developing strategies to overcome barriers, developing an intake chart for patients including pictorial guide, educating ward staff, providing a feedback box	2 months and 6 months
Madu *et al* (2021)[54]	Education Visual aids Equipment	Teaching sessions, picture messages/posters, doctors prescribing fluid balance charts, weighing scales and calculators, advising staff to engage patients in recording	4 weeks and 6 months
Møller *et al* (2013)[37]	Organisational/policy Disseminating results	Nationwide quality improvement through mandatory registration of quality-of-care indicators in the database, annual publication of results.	2 years
Pinnington *et al* (2016)[47]	Equipment Visual aids Patient education	Implementation of a hydration assessment tool, hydration chart, fluid balance chart, urine colour chart posters and a patient information leaflet	<6 months*
Vincent and Mahendiran (2015)[49]	Equipment Education Visual aids	New fluid balance chart, e-learning module for nurses and HCA, posters, attendance at nursing handover, change of chart changeover (noon–noon), calculators available	<3 months*
Wakeling (2011)[40]	Education Equipment	Teaching sessions on hydration and fluid balance charting, implementing the Hydrant drinking aid	<4 weeks
Walker *et al* (2012)[41]	Education/dialogue Visual aids Equipment Disseminating results	Audit findings presented at meetings, key messages on computer background wallpapers, prompt on general medicine admission proforma, training of medical staff, intravenous guideline, communicating the importance of FBC at nursing handovers	6 months
Yang *et al* (2019)[51]	Equipment Education Surveillance	Developing self-learning materials, modifying fluid balance charts, integrating into nursing information system, educating nurses and performing audits	Immediately after
Zhu *et al* (2018)[50]	Education Equipment Surveillance	Educating nurses and patients, patient leaflets, integrating into nursing information system, head nurse monitoring performance	Immediately after

*Estimated from information in the paper.
AKI, acute kidney injury; FBC, fluid balance chart; HCA, Healthcare assistant; PDSA, Plan-Do-Study-Act.

Interventions

The third major theme in this review was to evaluate interventions developed to improve the quality of fluid balance monitoring. Across studies, multiple components were identified as tools to improve fluid balance charting. All interventions involve several interacting components, and most target different groups or behaviours; hence, all analysed interventions can be characterised as complex. The advantage of an intervention containing several elements is that it may address various challenges simultaneously, thus increasing the probability of success.[65] On the other hand, interventions perceived as simple are more easily evaluated and implemented.[66] Therefore, an effective intervention should include all parameters in fluid balance charting as simply as possible.

All interventions except one involve education offered to doctors, nursing staff, or patients, but the impact varies. Possible reasons for this are the information's relevance, delivery and whether all stakeholders received this education. Interestingly, four of the five most effective interventions include some patient involvement either by involving patients in recording fluids[46 51] or informing patients through tailored education or leaflets.[47 50] This indicates that involving patients in their care during hospitalisation may be beneficial. Two systematic reviews found that involving patients with chronic diseases in self-monitoring motivates them to manage their condition[67] and improves outcomes such as readmission rates.[68]

In addition, the form of delivery may affect the results (eg, whether teaching was delivered to staff on all shifts, the duration of teaching). However, these details were only sporadically described. A review addressing electronic health record education found that training should be interactive and based on daily routines and nursing workflow.[69] This may also apply to fluid balance monitoring education, but studies are needed to identify effective learning strategies to enhance the quality.

Moreover, integrating equipment (eg, care bundles or visual aids such as posters) is widely used in both effective interventions and those with hardly any effect, making it difficult to determine whether these are useful solutions. A review examining barriers and facilitators in implementing care bundles found that the number and complexity of elements affected compliance. Fewer elements and low complexity were associated with increased compliance,[70] as were evaluative and iterative implementation strategies (eg, performing audits and developing stakeholder relationships). Furthermore, providing feedback was more effective than reminders such as posters and screen savers.[70]

Another tool is electronic patient records, which are integrated into nursing practice in many clinical settings. Taking advantage of the opportunities of electronic patient records, such as computerised physician orders,[33] electronic reminders, and integrating fluid balance documentation[50 51] and fluid balance calculation,[56] may improve fluid balance charting.

Hence, automating fluid balance charting by using electronic patient records combined with equipment developed to automatically measure fluid intake and output may enhance charting quality. However, understanding the barriers and enablers in fluid balance charting is necessary to create effective solutions.

Other factors may affect the effectiveness of an intervention (eg, the intervention's extensiveness, whether the components are well chosen and how they are interrelated). The implementation strategy itself is of utmost importance, addressing resistance towards the intervention and increasing acceptance.[71] However, most included studies describe these aspects superficially or not at all.

A final factor that may influence the observed effects of interventions is the time of evaluation, which varied among studies from immediately to 2 years after implementation. The timing of the evaluation can have a significant impact, as shown in one study that found an immediate improvement from 12% to 72%; however, compliance fell to 32% after 6 months,[43] indicating that a short-term improvement may not lead to long-term behaviour change. This phenomenon is described as a 'honeymoon period', and researchers should be cautious when interpreting effects less than 6 months from implementation.[72] Among the most effective interventions (≥75% completed fluid balance charts), two were evaluated 6 months or more after implementation,[37 46] whereas the three others were assessed after less than 2[33 51] and 6 months.[47]

Recommendations

Calculation errors pointed to in this review may be prevented by using electronic patient records, where fluid balance calculations are performed automatically and are no longer based on human calculation.[39 44 62] By exclusively using fluid containers with measuring lines or through automated measuring inaccuracies related to estimations can be avoided.[22 23] Additionally, interactive teaching based on daily practice for all stakeholders[54 69] and involving and motivating patients to self-monitor may enhance quality.[46 67] Care bundles should have few components, be straightforward, and of low complexity.[66 70] Continuous attention to fluid balance charting (eg, through disseminating audit results) is required to achieve and maintain improvement.[70]

Limitations

This systematic review had several limitations. To begin, we conducted a broad search for literature, including only published papers. Due to the widespread problem of fluid balance charting in clinical practice, we suspect much information is available only for internal use. Thus, this review represents the quality of fluid balance monitoring generated by a systematic method but not necessarily a complete overview. Furthermore, we limited our search to the time frame of 2010 to the present, thus excluding older literature. The rationale for this decision was that the main objective of the review was to evaluate recent quality, but by analysing previous studies, we may have obtained different knowledge.

Other limitations relate to the studies included, the quality of which varied. Every third study was of low quality; thus, the power of the conclusions drawn based on them is limited. Nevertheless, we did not exclude low-quality studies as we chose not to risk omitting research from daily practice. Second, the studies are characterised by significant heterogeneity in defining outcomes, and the patients included are not comparable. Finally, the timing of the evaluation of interventions differed, making comparisons across studies difficult.

Conclusion

In conclusion, the quality of fluid balance monitoring varies, but most studies report it as inadequate, influenced

by calculation errors. Implemented interventions designed to improve the quality of fluid balance monitoring had varying impacts, and in most studies, the effect was unsubstantial. Furthermore, a short-term improvement may not lead to long-term behaviour change.

Therefore, there is a need for in-depth qualitative knowledge to understand nurses' attitudes towards and opinions of fluid balance monitoring and the perceived barriers. Further, increased knowledge of the patients' perspective may be beneficial. Based on this understanding, innovative and robust fluid balance monitoring methods must be developed.

Contributors LRL developing study design and search strategy, screening abstracts and titles, full text reading, data extraction, analysis, writing first draft of manuscript. MK full text reading, data extraction, analysis, revising manuscript. ST-H screening abstracts and titles, revising manuscript. IG developing study design, revising manuscript. AOB developing study design, revising manuscript. NA developing study design, full text reading, revising manuscript. NA is the guarantor of this study.

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APPENDIX II

Nursing staffs' perceptions of fluid balance charting: a focus group study

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ABSTRACT

Aim: To explore nursing staffs' experiences with fluid balance charting, perceived barriers and enablers and attitudes of nursing staff towards fluid balance charting. Secondly, to explore how these factors affect motivation and behaviours

Design: A descriptive, qualitative study design

Methods: Data were collected through semi-structured focus group interviews involving nurses and healthcare assistants from a variety of clinical departments in Denmark and Sweden. The focus group interviews were analysed using a phenomenological-hermeneutic approach inspired by Paul Ricoeur.

Results: We included 25 nurses and healthcare assistants in eight focus group interviews. Among key findings was a notable discrepancy between the perceived importance and the actual accuracy of fluid balance charting. Nursing staff considered fluid balance charting a fundamental nursing task. Charting was performed in conjunction with clinical assessment to evaluate patients and guide treatment. The quality of charting affected patient outcomes. However, the involvement of multiple staff members and high patient-nurse ratios caused nursing staff to experience the charting procedures as beyond their control and consider the results inaccurate. Despite their best efforts to navigate the dilemma of prioritising patients and tasks, nursing staff were unable to consistently meet patients' needs. Quality may be enhanced by securing that colleagues follow routines and that responsibilities are clearly established. Digital technologies were suggested as means of easing workflows.

Conclusion: Although fluid balance charting is perceived as an essential nursing task with potential to reduce mortality and morbidity, nursing staff lacked control of charting, which was frequently inaccurate. Enhanced charting procedures may be achieved through consensus on responsibilities, well-established routines and the support of digital technologies.

Impact: This study describes nursing staff's experiences with fluid balance charting and perceived challenges. Charting quality may improve if nursing managers apply our findings in addressing the identified challenges and promoting enablers.

Reporting method: The Consolidated criteria for reporting qualitative research (COREQ).

Patient or public contribution: None

Keywords: Fluid-electrolyte Balance; Fluid Intake-Output Measures; Qualitative Studies; Focus Groups; Nursing Staff, Hospital; Monitoring, Physiologic; Water-Electrolyte Balance; RNs; Fluid Balance Chart; Record Keeping

What does this paper contribute to the wider global clinical community?

- Nursing staff perceive fluid balance charting as crucial to evaluating and planning patients' treatment.
- Maintaining control in fluid balance charting is challenged by the involvement of multiple staff members and constraints of time and staff resources. However, quality benefits under conditions of consensus among nursing colleagues clearly defined responsibilities and established routines.
- Nursing staff are positively inclined towards technological advancements and expect digital technologies to simplify charting processes.

1. INTRODUCTION

Maintaining fluid balance is essential to patients' health and recovery as disturbances lead to complications, prolong hospital stays and are associated with increased mortality (Besen & Taniguchi, 2017; El-Sharkawy et al., 2015). Although considered an essential nursing task for decades, the reliability and adequacy of fluid balance charting have been questioned for just as long (McGloin, 2015; Perelman, 1964). Despite the wide range of quality improvement projects that have been launched, low quality remains a well-known challenge in fluid balance charting (Leinum et al., 2023).

Gaining insight into nursing staff's perspectives on fluid balance charting and the challenges experienced in daily clinical practice can provide a more thorough understanding of the underlying reasons for the persistent difficulties in achieving high-quality fluid balance charting. Exploring ways to achieve sustainable long-term improvements is essential.

2. BACKGROUND

A fluid balance chart is defined as an input/output record of an individual's intake over a 24-hour period, the amount of fluid he or she has lost over the same period and whether the individual is in state of fluid balance, deficit or overload (McGloin, 2015). Although fluid balance charting may seem a straightforward procedure, the several measures involved create complexity. Fluid input comprises oral fluids, intravenous medication and fluids, and enteral or parenteral nutrition. Output includes urine, diarrhoea, stoma output, drainage, vomit, and nasogastric tube output. However, the insensible fluid loss through the skin and respiratory system escapes measuring and must be estimated (Holroyd, 2020 ; McGloin, 2015).

By enabling treatment planning, fluid balance charting, along with clinical examination and blood results, is crucial in determining a patient's hydration status (Scales & Pilsworth, 2008). However, a systematic literature review across continents, national health systems and surgical and medical specialties has established that the proportion of completed fluid balance charts was below 50% in more than half of included studies (N = 10/18). The causes of deficient charting quality included the omission of intravenous medications, missing or inaccurate documentation of fluids and calculation errors. Despite the wide range of interventions implemented, significant quality improvements were rarely observed (Leinum et al., 2023).

Typically conducted by nursing staff, fluid balance charting is an established nursing responsibility. Previous surveys have identified various barriers related to fluid balance charting such as inadequate communication and organisation among nursing team members (Asfour, 2016; Reid et al., 2004). The findings have further indicated that the importance of fluid balance charting may be contested by nurses (Asfour, 2016). Further

exploration of their attitudes and opinions is therefore essential. Qualitative research methods are particularly suitable for exploring experiences and perceptions, thus enabling us to gain a deeper understanding of the barriers and enablers, as well as values and beliefs affecting nursing staff behaviour.

In the single mixed-methods study we identified (Wehrle et al., 2021), the issue was examined using qualitative methodology, which found that time constraints prevented accurate fluid balance charting. Knowledge of nursing staff's perceptions regarding fluid balance charting is thus very limited; to our knowledge, no recent studies addressing this under-researched area have been conducted in a Nordic context.

Typically funded by the public, healthcare systems in the Nordic countries ensure universal and equal access (Laugesen et al., 2021). Electronic patient records are widely used, with varying comprehensiveness across the Scandinavian countries. The changing health needs caused by ageing populations and the staff shortages challenging the Nordic countries (Danish Health Authority, 2021) affect nursing staffs' working conditions and may influence their attitudes towards fluid balance charting.

Applying a qualitative approach, we aimed to gain a comprehensive understanding of registered nurses (RN)' and healthcare assistants' complex experiences and the reasoning behind their perceptions, motivations, attitudes and behaviour (Curtis & Redmond, 2007). The insights gained from this study will be crucial not only for nursing practices; they are likewise hoped to have implications for healthcare policy and patient care management.

3. THE STUDY

This study aimed to explore nursing staff's perceptions of and experiences with fluid balance charting and the significance of barriers and enablers related to fluid balance charting.

The objectives were to:

1) Explore nursing staff's subjective experiences with fluid balance charting

2) Identify barriers and enablers in fluid balance charting and their influence on charting quality as perceived by nursing staff

3) Explore nursing staff's attitudes and opinions related to fluid balance charting and their effect on motivation and behaviours.

4. METHODS

4.1 Design

We conducted a descriptive, explorative study using a qualitative approach to obtain rich, in-depth understanding of nursing staff's experiences and perceptions of fluid balance charting (Brinkmann & Kvale, 2015).

Nurses' experiences and perceptions were collected through focus group interviews, which were recorded and transcribed. Seeking to avoid interpretation while interviewing, we applied a phenomenological-hermeneutical methodology (Dreyer et al., 2016).

In reporting this study we adhered to the Consolidated criteria for reporting qualitative research checklist (COREQ) (Tong et al., 2007).

4.2 Study setting and recruitment

Permission to recruit participants from relevant departments was obtained from head managers. Ward managers provided the names of potential participants, while others contacted us directly. Six participants were employed in the same department as the moderators. The inclusion criteria were, RN or healthcare assistant with permanent employment in the hospital, with everyday experience of fluid balance charting.

Interviewees were selected through purposive sampling (Polit & Beck, 2017) to ensure representation of different departments and both RNs and healthcare assistants in each focus group to balance the concepts of variation and homogeneity (Malterud, 2012). In most departments in Denmark and Sweden, RNs and healthcare assistants collaborate on patient care, the latter group playing a crucial role in fluid balance charting as they typically perform tasks related to eating and drinking. Their perspectives are thus essential in exploring fluid balance charting.

We ensured that participants shared certain characteristics across focus groups by including RNs and healthcare assistants with long seniority and new graduates to avoid creating overly homogenous groups (Krueger & Casey, 2015). A further goal was to include nursing staff with different specialities: from surgical and medical wards, emergency departments and intensive care units, thus addressing different working flows and working conditions.

To ensure a comprehensive Nordic perspective, focus group interviews were conducted with staff in Denmark and Sweden. Although their healthcare systems are in many respects similar, differences exist, for example, concerning the use and extent of electronic health records.

4.3 Data collection

We conducted eight focus group interviews, four in Denmark and four in Sweden. Two of the authors, LL (Danish female, PhD student) and SN (Swedish male, MScN), moderated the focus group interviews in their respective native languages having received training in qualitative interviewing and supervised by an experienced qualitative researcher (MK). To ensure all questions were discussed and to make notes of non-verbal communication, a further observer was also present. The first author (LL) participated in all focus group interviews. All focus group interviews were audio-recorded and transcribed verbatim. To ensure full understanding of the Swedish transcripts they were thoroughly discussed with the co-author (SN), notes were prepared and parts of transcripts were translated. Transcripts were not returned to participants.

Focus group interviewing was chosen as this method is particularly suitable for exploring the range of opinions, perceptions and emotions concerning a specific topic and providing insight into conditions influencing behaviours and attitudes. Our aim was to gain insight into the participants' perceptions as they formulated and clarified their views in interactional discussions (Curtis & Redmond, 2007; Malterud, 2012). Discussion among participants clarified points on which they agreed or differed and elicited nuances in their perspectives (Krueger & Casey, 2015; Morgan, 1997).

The recommended number of participants in a focus group varies (Malterud, 2012; Morgan, 1997). While large groups may challenge moderators and limit participants' opportunities to share experiences, smaller groups of two or three participants require sustained interaction to fulfil requirements for focus group interviews (Malterud, 2012). Expecting last-minute drop-out, we planned to over-recruit by 20% (Morgan, 1997) and were prepared for pragmatic problem-solving (Malterud, 2012). To ensure a convenient and undisturbed location, focus group interviews were conducted in a meeting room at the participants' place of employment. We strove to create an inclusive environment, encouraging participants to share their opinions and disagreements in a respectful tone, creating a comfortable room for communication to promote self-disclosure (Curtis & Redmond, 2007; Krueger & Casey, 2015). To support interaction we further encouraged participants to comment on each other's statements (Krueger & Casey, 2015; Malterud, 2012). The interview guide consisted of three key questions. An avenue of questioning was designed with different categories of questions for openings, introducing the topic, and leading to the key questions. The questions were open-ended, supported by interrelated, and logically coherent follow-up questions (Krueger & Casey, 2015).

To engage everyone from the beginning, focus group interviews began with participants introducing themselves. The following questions included: ”What works well in fluid balance charting?”, ”Do you consider fluid balance charting useful?” and ”How can fluid balance charting be improved?” Concluding the

focus group sessions, the moderator summarised the discussions to ensure that nothing was missed and that the interviewers had correctly understood the points made (Krueger & Casey, 2015; Polit & Beck, 2017). Following all focus group interviews, the first author made field notes regarding non-verbal communication and participant interaction. The notes were used to reflect on the moderator role, the initial impression of main subjects, and interactions between participants.

4.4 Data analysis

According to Ricoeur, data analysis should aim to understand the meaning of a text rather than search for any hidden meaning behind the text or the author's intentions. Seeking to understand what the text (i.e., our transcripts) speaks about and follow the direction opened by it (Ricoeur, 1976), our study aimed to explore what the transcripts reveal about being a nurse performing fluid balance charting.

The data analysis process involved several stages in a circular process known as the hermeneutic circle. The analysis moved back and forth between understanding and explanation; from an initial understanding of the meaning as a whole through a structural analysis to a critical, in-depth interpretation (Ricoeur, 1976). Divided into three methodological phases, a Ricoeur-inspired analysis consists of a naïve reading, a structural analysis and a critical interpretation leading to a comprehensive understanding (Lindseth & Norberg, 2004). In restructuring the text its chronology is abandoned and separated from situation, context and speaker, which contributes to what Ricoeur termed "distancing" (Dreyer & Pedersen, 2009; Ricoeur, 1976).

The naïve reading ensured an initial, spontaneous understanding of the meaning of the transcribed text as a whole (Ricoeur, 1976). Applying our intuition and with open minds we approached the text to understand the phenomenon of fluid balance charting as experienced by nursing staff (Lindseth & Norberg, 2004).

The structural analysis involved repeated readings of the transcript of the focus group interviews to form an impression of "what is being said". Having divided the text into units of meaning, with reference to quotations, the units were structured and integrated into themes that were narratively described (Lindseth & Norberg, 2004). "What the text speaks about" is explained in themes and compared to the naïve reading, which may be validated or rejected (Lindseth & Norberg, 2004). Our structural analysis was conducted in cooperation between LRL and MK using NVivo 14 software for Windows (QSR International Pty Ltd., Australia).

In the critical interpretation, the resulting themes were compared with relevant literature to reach the most suitable interpretation. By including other research, we deepened and expanded our understanding of fluid balance charting practices (Lindseth & Norberg, 2004).

4.5 Ethics

The Regional Committee on Health Research Ethics deemed that no approval was required for this study (EMN-2023-02327). The Regional Data Protection Agency approved the study (REG-010-2023). Swedish regulations required no official approval. Having received written and oral information regarding study aims and researchers' roles and titles, the participants provided informed consent prior to focus group interview sessions.

4.5 Study rigour and reflexivity

To enhance the trustworthiness and rigour of the study, the following criteria were adopted: credibility, confirmability, dependability and transferability (Polit & Beck, 2017). Given that the three researchers were experienced RNs with a broad knowledge and pre-understanding of fluid balance charting, reflexivity about preconceptions was relevant (Malterud, 2001). Investigator triangulation ensured representation of diverse backgrounds and perspectives. Reflective notes and the researchers' (LL and MK) discussion of codes, themes and interpretations prevented pre-understandings from affecting the results and supported its confirmability and credibility (Malterud, 2001; Polit & Beck, 2017).

Credibility and dependability were further achieved by following a detailed protocol and questioning route. We sought to limit disparities between sites through the first author's participation in all focus group interviews. Member checking was performed in the data collection phase by presenting participants with a summary of major themes at the end of focus group interviews (Polit & Beck, 2017). The accuracy of the data was ensured by transcribing the audio-recorded focus group interviews according to a transcription manual.

Credibility and confirmability were enhanced by illustrating the process of developing themes through an example of the structural analysis. Quotations supported findings and ensured the correct presentation and interpretation of the nursing staff's views (Eldh et al., 2020). Detailed descriptions of the context, data collection and analysis increased transferability. The preliminary results were discussed with fellow healthcare researchers, and external evidence was included as further described in the discussion section (Polit & Beck, 2017).

5. FINDINGS

We included 25 nursing staff in eight focus groups interviews conducted in April and May 2023. Five RNs and five healthcare assistants, respectively, dropped out due to high workloads, sickness or failure to appear for other reasons. Four focus group interviews were conducted in each of the two countries, lasting on average 87 minutes (ranging from 77 to 95 min). Participants' median age was 38 years (range 23–60), their professional seniority varying from less than one year to more than 16 years and employment in their current departments from less than one year to more than 11 years. The majority were female (93%). Further characteristics of participants can be found in Table 1. The distribution of RNs and healthcare assistants in focus groups is shown in Table 2.

Our initial understanding of the focus group interview transcripts as a whole was based on a naïve reading. (Table 3). In the structural analysis, the text was divided into units of meaning ("what is being said") and formulated in units of significance ("what the text speaks about"). Based on those structural units, we identified the following three themes: 1) Nursing staff consider fluid balance charting a fundamental nursing task relevant to target treatment, 2) Fluid balance charting is beyond individual control and inaccurate due to the involvement of multiple persons and the lack of time, 3) Achieving consensus among colleagues and simplifying the charting method may offer a way forward.
Table 4 shows an example of the structural analysis while the three themes are presented below.

5.1 Theme 1: Nursing staff consider fluid balance charting a fundamental nursing task relevant to target treatment

Nursing staff was found to consider fluid balance charting a fundamental nursing task that all nursing staff should know about as it is essential for the evaluation and assessment of whether a patient is recovering or deteriorating. Nursing staff described fluid balance charting as an indicator of the patient's well-being and future course of illness: *It's a great indicator of where the patient is headed. If they eat and drink, they are usually healthier; if they don't eat and drink, they usually get sicker. Again, [it's] a good predictor (R6).*

The relevance of fluid balance charting and the necessary accuracy of its results was said to depend on the patient category and severity of illness. Nursing staff maintained that in some patients, accurate hourly measurements are appropriate, while others need only have their oral intake charted to ensure sufficient intake and clarify whether they need supplementary intravenous fluids. The staff considered a clear indication for fluid balance charting as essential. However, they debated whether adherence to charting was improved by involving many rather than a few patients. Patients with heart failure, kidney diseases or

sepsis, and newly operated patients were said to be high priority, and the significance of fluid balance charting in critically ill patients was highlighted: *After all, we're doing it to save their lives (G3).* Charting was likewise said to be required in patients with fluid balance disturbances; e.g., when they were overhydrated, dehydrated, or polyuric. The same was said for patients with abnormal fluid losses through stomas or otherwise. Elderly and weak patients were generally considered at risk and in need of thorough attention.

Nursing staff considered that well-performed fluid balance charting clearly indicates patients' fluid balance and actual needs and thus enables targeted treatment: *It becomes very clear what the patient needs (W8).* Fluid balance charting was used to guide and adjust treatment continuously: *We constantly monitor and assess whether we should increase the administration [of intravenous fluids or medication]. We provide a status of the fluid balance … then we reassess if we should take action on that basis (K4).* Nursing staff stated that fluid balance charting can help reveal the cause of a patient's disturbances, such as inappropriate administration of intravenous fluids or decreased urine output.

In contrast, poorly performed fluid balance charting was deemed life-threatening, capable of leading to unnecessary suffering and complications such as pulmonary oedema, prolonged hospital stays or deteriorating heart and kidney disease. Incomplete fluid charts were said to lead to possible mistreatment when treatment plans were based on inaccurate data: *If you had no fluid chart, you would make an estimate. But if you had a fluid chart showing that the patient has only had 300 mL, then you would give that patient [intravenous fluids] (…) Later it turned out that the patient was treated incorrectly due to the incomplete fluid charting (Y8).* When nursing staff had realised the consequences of missing fluid balance charting, they would acknowledge its importance and prioritise charting in the future. Some participants lacked personal experiences on the impact of fluid balance charting but were motivated by knowledgeable colleagues.

Nursing staff pointed to the link between fluid balance charting and clinical assessment, as charting was seen to enable treatment adjustment before clinical signs appear and thus help prevent fluid balance disturbance: *We're at the forefront [of treatment] through fluid balance charting of our surgical patients (L4).* Charting was not considered adequate by itself but should be accompanied by a clinical evaluation of the patient and reflections on the agreement or otherwise between charting data and the visible clinical signs. Nursing staff would observe urine to interpret the patients' condition and apply their clinical judgment in the evaluation. Understanding the risks of incorrect conclusions, they showed awareness that their assessment could be flawed.

5.2 Theme 2: Fluid balance charting is beyond individual control and inaccurate due to the involvement of multiple persons and the lack of time

Aware that missing data could lead to unreliable fluid balance charting, nursing staff often questioned the trustworthiness of the available data: *[It's been] countless times you've sat at night to summarise and having to write "incomplete list" because so much [data] is lacking [in the fluid balance chart] (W8).* Attempting to reconstruct data for the fluid balance chart was said to be cumbersome and like detective's work. Others ascribed uncertain fluid balance calculations to missing time-marking of documentation. There were occasions when intravenous fluids had been stopped prematurely without adjusting the given volume of fluid; likewise, oral fluids were frequently estimated rather than measured: *(…) it's a ballpark estimate – say, we've written 200 [mL] on a mug and only 175 [mL] is poured by service [staff] (E2).* Some nursing staff said they had tried to catch up on charting at the end of shifts; however, basing their calculations on patients' recollections and estimations was clearly unreliable: *But then again, it's pretty much on the feel. So it'll [the calculation] have to be "roughly like that" (I3).*

Increased nursing workloads was seen as having a decisive influence on charting quality: *How many patients each nurse is responsible for has a lot to do with how well you [can] focus on each patient and how much you do for them. It's not the same if I have 13 admitted [patients] compared to having six (X8).* Despite the best intention to perform fluid charting, nursing staff would sometimes postpone it and end up being unable to complete it. Following a shift where colleagues had failed to complete fluid balance charting was said to be frustrating and challenge mental capacity to regain control over patients' fluid balance. Nursing staff deemed missing documentation unacceptable and unsafe for patients.

Nursing staff showed awareness of the dilemmas of navigating conflicting demands and trusted that their colleagues' intention to perform fluid balance charting: *At first I'd think, "Oh, that's really annoying", but then again, they must've been too busy; something must have come up. (…) of course, we summarise, I know that. You're working with different colleagues … you know them well. (…) So it's not that they're unwilling to get it done (B1).* However, some pointed out that not all colleagues considered keeping track of fluid balance charts important enough. High workloads and the need to prioritise among patients and tasks affected the relationship between nursing staff and patients. Prioritising the sickest patients, nursing staff are forced to deprioritise others with the result that patients' quality of life needs are not always met: *That's why we also have to be the bogeyman and say that [a task] can't be done right now (L4).*

Several staff members were involved in serving fluids and recording intake, which affected the oversight of patients' fluid balance. While help from colleagues without responsibility for the patient was welcomed, charting would be jeopardised if they were unaware of fluid balance charting. In many wards service staff were employed to relieve nurses but lacked adequate healthcare training: *They don't really know about [fluid balance] medically or diseases. I don't think they really have the basic [knowledge] (T6).* When service staff failed to chart patients' intake, nursing staff would lose control of fluid balance.

Different paper charts for recording fluid intake, nutrition or pleural effusion were experienced as confusing and would make it difficult to keep track. Where both a paper chart and an electronic patient record were used for recording, overview and control suffered: *In our case, I think it's very simple. We shouldn't keep both a paper record and a digital record. (…) so many [chartings] are missed (…), which makes everything very complicated and very difficult to follow (N5).*

Nursing staff preferred to retain control over patients' fluid balance charting: *If [the patients] have no [relatives], we can control their [intake] relatively well (…). What we can control, we do. And we do for their own sake (V7)*. Staff recognised the importance of patient involvement and invited patients to be co-players in their care, which was often enthusiastically welcomed and helped protect patients' integrity. With responsibility for following up, nursing staff were nevertheless ready to intervene on fluid balance if necessary. Only a minority of patients were able to perform fluid balance charting, as many would take tap water or empty their catheter bags without having their urine output measured. This constituted an obstacle to maintaining control of charting.

5.3. Theme 3: Achieving consensus among colleagues and simplifying the charting method may offer a way forward

Nursing staff pointed to a lack of established routines and consensus regarding the responsibility for fluid balance charting: *We say it's everyone's job, so it easily becomes nobody's job. This could be part of the problem … that we don't dedicate the task to a specific person. (…) Then we forget everything about it (M4).* Discussing their responsibility for informing healthcare assistants about prescribed fluid balance charting and the need for charting, RNs said they were held jointly responsible in case of inaccurate charting. Successful fluid balance charting thus depends on collaboration between colleagues: *I think cooperation between healthcare assistants and nurses is very important when it comes to patients who need fluid balance [charting] (X8).*

A number of focus group participants described fluid balance charting as completely unregulated and dependent on the individual staff member and working routines: *There's a lack of consensus in the group. If we discussed it in the group, we would probably hear five or six different opinions on what should and should not be registered (R6).* In other departments, nursing staff promoted adherence to charting routines by sharing expectations among themselves: *Expectations are clear. I expect them to have done [the fluid balance charting] before they go home. There are mutual expectations that it should be done (D2).*

Establishing good routines and communication was seen as a way to enhance the quality of fluid balance charting. Likewise, teaching new employees about the department's routines was seen as helpful in maintaining consistency and consensus: *When someone starts working here, they follow some of us [with experience] to learn the routines. [How things are done] is often implicit and not put into words. That way you get to work out the routines together (J4).*

Nursing staff pointed to the possible benefits of a working environment where seeking and offering advice are part of clinical practice, paving the way for consensus and adherence to routines among nursing staff. Routines were essential in maintaining charting quality and were expected to be complied with by all nursing staff, for example in the case of handovers or bedside reports, daily weighing, serving fresh fluid with every meal, nursing rounds, and calculating fluid status in every shift. To ensure intravenous fluids were charted correctly, some nurses would save labels holding information about the patient and the fluid administered as a visual reminder until charting was completed. Others used posters, magnets or yellow paper charts as reminders.

However, consensus on routines and responsibilities was viewed as only partly resolving the issue of fluid balance charting. Existing documentation methods were considered time-consuming and bothersome, as obstacles to smoother workflows: *We need easier ways to register output. We would very much like that (…) If we could ease the workflow there (F2).* Nursing staff thus stressed the need to reform the documentation process: *It feels like we need to find another type of system. (…) As I've mentioned before, digitisation! …something that would simplify things. I think it would make the whole process a lot easier (V7).*

Nursing staff were experienced in using technological tools for fluid balance charting, for example infusion pumps with automatic data transfer to the electronic patient record and mobile pocket devices enabling patient ID scanning to ensure timely charting; *You can do fluid charting on [the mobile device], registering the data immediately. Then it´s true to time and [ensuring that] you scan the right patient (B1).* However,

complaints were voiced about the challenges that come with digital tools, such as time-consuming login procedures and unnecessary steps. Some had experienced technical breakdowns: *I've been a real fan until the damn thing broke down (H3).* Despite everything, nursing staff were optimistic about technological aids and expected digital tools to expedite the charting process by simplifying the procedure. In the discussions, innovative ideas were offered to improve fluid balance charting, such as using apps, intelligent toilets, volume scanning, speech recognition, etc.

6. DISCUSSION

Exploring nursing staffs' experiences of fluid balance charting, this study has identified three main findings. Firstly, nursing staff consider fluid balance charting an essential part of fundamental nursing care. Secondly, the involvement of numerous staff members and time constraints presents a challenge to reliable fluid balance charting. Thirdly, as ways to enhance quality, nursing staffs emphasise consensus regarding responsibilities and routines as well as simplifying fluid balance charting with technologies.

Nursing staff were well aware of the relevance of fluid balance charting, regarding it as crucial to the evaluation of patients' hydration status, the clarification of their needs and in deciding on treatment course. Similarly, a study involving 300 European nurses found that hydration issues were considered highly important (scoring 6.7 on a 7-point scale) (Holdsworth, 2012). Older studies have likewise pointed to the effectiveness of fluid balance charting in managing patients' fluid balance and deciding on treatment (Chung et al., 2002; Daffurn et al., 1994). In contrast, a study conducted in an ICU (Asfour, 2016) found that, despite considering it essential in guiding nursing care, only around half of the nurses agreed that fluid balance charting was as important as other patient care activities. These findings indicate that fluid balance charting is deprioritised compared to other tasks. Furthermore, concern has been voiced about unnecessary and prolonged charting without indication (Vincent & Mahendiran, 2015).

If a nursing task is seen as redundant, the attitudes of the nursing staff are affected, indicating a need for clear guidelines as to what situations indicate fluid balance charting. To ensure proper prioritisation among patients we suggest applying guidelines and a systematic approach to identify patients in need of charting. Further, extensive knowledge and advanced clinical skills among nursing staff must be ensured and staff resources better utilised to minimise the chances of either overlooking at-risk patients or commencing redundant work (Pinnington et al., 2016).

In accordance with recommendations, participants in our focus groups gave high priority in particular to patients with kidney and heart diseases, sepsis and to newly operated and patients with fluid balance disturbances (Pinnington et al., 2016). Emphasising the need for prioritisation, they highlighted, however,

that the diagnosis and severity of illness should be determinant in deciding whether fluid balance charting is lifesaving or more recreationally. Nursing staff were aware that inaccurate fluid balance charting involved a risk of mistreating patients (Asfour, 2016), as shown by an audit documenting that the omission of fluid intake charting led to excess fluid intake, need for diuretics and uncertain decision-making regarding intravenous fluid prescriptions (Liaw & Goh, 2018).

Several studies have observed that, in contrast to its perceived importance, nursing staff describe fluid balance charting as inaccurate and unreliable due to missed chartings, (Liaw & Goh, 2018; Madu et al., 2021; Szmuda et al., 2014). Imprecise documentation is often caused by the lack of equipment as nursing staff are forced to estimate rather than calculate fluid intake (Asfour, 2016; Lim et al., 2021; Madu et al., 2021; Reid et al., 2004).

Maintaining control of fluid balance charting was experienced as challenging due to high workloads and demanding patient-nurse ratios, as documented by previous research addressing nursing staff's perceptions (Asfour, 2016; Reid et al., 2004; Wehrle et al., 2021). As managing more patients than feasible reduces the time spent per patient, a high patient-nurse ratio was considered the most significant barrier to accurate fluid balance charting (Wehrle et al., 2021). The nursing staff in our study explained how they had to prioritise patients and tasks, causing them to feel they were unable to meet patients' needs. This corresponds to "implicit rationing of nursing care" as high workloads force nursing staff to ration nursing interventions, thus increasing the risk of adverse events and reducing the quality of care. When nurses cannot meet patients' needs, it may lead to emotional exhaustion and impact job satisfaction (Maghsoud et al., 2022).

It was nursing staff's experience that when several staff members are involved in serving fluids and charting, a lack of control may be the consequence. This is corroborated by other research describing the frequent change of caregivers (Yang et al., 2019) and inadequate communication between nursing staff and housekeeping staff as barriers to fluid balance charting, as the latter is charged with serving oral fluids (Reid et al., 2004). Patient safety suffers when RNs are forced to delegate nursing tasks to service staff without medical training.

Nursing staff were responsible for maintaining control of patients' fluid balance and would intervene if necessary. Previous research has shown that patients' motivation to participate predicts charting quality (Liaw & Goh, 2018; Wehrle et al., 2021). We learned that patients were invited to participate in fluid balance charting, possibly motivated by several studies that hypothesised that involving patients in fluid balance charting would lead to more accurate charting. However, patients who do not feel motivated tend to forget or do it half-heartedly, which confirms our finding that patient involvement may be a barrier to

reliable charting (Liaw & Goh, 2018; Yang et al., 2019). As patients' participation has been found to influence the accuracy of fluid chartings (Wehrle et al., 2021), we recommend adopting a person-centred approach to targeting patients capable of participating in fluid balance charting.

The participants in our study indicated that consensus regarding the routines and responsibilities of fluid balance charting is critical to charting quality. Previous research confirms that the lack of ownership and accountability in completing fluid balance charting causes non-compliance with guidelines and inaccurate monitoring (Pinnington et al., 2016; Reid et al., 2004). Further, insufficient understanding concerning the responsibility of training ward staff could be handled through mandatory teaching of health care professionals with particular attention to the needs of housekeepers (Reid et al., 2004).

However, mandatory training would be insufficient to achieve the desired goal. Sustainable quality improvement would require support from leaders championing the change in word and action by demonstrating ownership and legitimising the project. Likewise, the involvement of key stakeholders' perspectives, effective communication and continuous monitoring are called for to enhance quality (O'Donoghue et al., 2021). Our participants also emphasised communication between colleagues and constant alignment of routines as necessary to maintain consensus. Another challenge is posed by temporary staff without adequate training or familiarity with ward routines (Wehrle et al., 2021).

Our study shows that nursing staff expects that digital advancements and technological tools will enhance future charting quality by streamlining and simplifying workflows. Some had seen digital technologies improve patient safety, and they generally took a positive view of technology, despite common challenges such as time-consuming login procedures, complicated systems and technological issues. A 2018 report has mapped some of the challenges experienced in everyday nursing care, such as difficulties with passwords and over-complicated systems (Agnew, 2022). Nurses likewise complained about time wasted through insufficient computer access or waiting for data to be loaded. A more recent review has elucidated issues affecting nurses' use of digital technologies and highlighted the impact of technologies on patient care as a driver for their willingness to adopt them (Brown et al., 2020). According to Brown's study, nurses insisted that unless systems are reliable, fast and accessible, they lead to frustration and stress, as also documented in this study.

6.4 Strength and limitations

The qualitative approach applied for this study provided us with detailed and vivid descriptions of nursing staff's experiences with fluid balance charting across clinical settings. It may be considered a limitation that their departments' workflows, staffing and working conditions were different; our findings have

nevertheless provided insights from nursing staff and elucidated the similarities. This supports the transferability of our results to other settings in similar health systems.

Similar responses with only minor nuances were obtained in the focus group interviews, suggesting that data saturation was achieved. Although we acknowledge the possibility of something new emerging (Saunders et al., 2018), we believe the objectives of our study were met as we aimed to enhance the understanding of nursing staffs' perceptions by obtaining rich and comprehensive descriptions (Thorne, 2020).

Both RNs and healthcare assistants were included as they represent slightly different perspectives and both play a significant role in fluid balance charting. While greater homogeneity within groups could have been achieved by forming focus groups of only RNs or only healthcare assistants, we considered a division irrelevant as they typically collaborate on fluid balance charting. To retain focus on the charting of fluids we opted not to include other professional groups who are not actively involved in charting.

The challenges met in recruiting participants prevented us from over-recruiting as recommended (Morgan, 1997). Although last-minute drop-out meant that two focus groups consisted of only two participants, they can be described as focus groups as discussions were lively, with extensive interaction and exchange of experiences and attitudes (Malterud, 2012).

6.5 Implications for policy and practice

This study has outlined the significance of accurate fluid balance charting and the challenges associated with performing the task. As the charting of the fluid balance can significantly impact the patient's outcome, continuous attention from nursing staff and managers is needed. To enhance the quality of charting, continuous training and support for established routines and collaboration between colleagues should be ensured. The high workload in wards poses severe challenges to charting quality and negatively affects relationships between patient and nursing staff. Addressing these issues may be of paramount importance to efforts to retain nursing staff and prevent emotional exhaustion. We suggest that the way forward could be the implementation of digital technologies and engaging nurses with in-depth clinical experience in the development of technological solutions.

7. CONCLUSION

Fluid balance charting is a fundamental nursing task of crucial importance to the evaluation of patients' fluid balance and treatment choice. Helping to ensure targeted treatment, fluid balance charting has the potential to reduce mortality and morbidity, depending on the patient's diagnosis and the severity of illness. The focus group discussions, however, revealed that the accuracy of fluid balance charting was often challenged by hasty estimations, the involvement of several people, high patient-nurse ratios and demanding workloads. Consensus on responsibilities and routines, along with the integration of digital technologies, may enhance charting by ensuring accuracy, timeliness and efficiency. Future research is needed to explore evidence-based strategies for the improvement of charting quality and the development of intuitive digital technologies and their impact on nursing efficiency and patient outcomes. The influence of organisational structures and management on fluid balance charting quality likewise needs further exploration.

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Table 1: Characteristics of participants	
	n (%)
Sex	
Male	2 (8)
Female	23 (92)
Age (yrs) median, range	38 (23–60)
Education	
RN	17 (68)
Healthcare assistant	8 (32)
Education (yrs)	
0–2	4 (16)
3–5	3 (12)
6–10	6 (24)
11–15	5 (20)
>16	7 (28)
Employment in current department (yrs)	
<1	9 (36)
2–4	11 (44)
5–10	3 (12)
>11	2 (8)

Table 2: Focus group participants			
Focus group	Country	RN/HCA	Alias
1	DK	1/1	A, B
2	DK	2/2	C, D, E, F
3	DK	2/1	G, H, I
4	DK	4/0	J, K, L, M
5	SWE	2/2	N, O, P, Q
6	SWE	2/1	R, S, T
7	SWE	1/1	U, V
8	SWE	3/0	W, X, Y

Table 3: Naïve reading
Nursing staff regarded fluid balance charting as part of fundamental nursing care and an essential tool for clarifying patients' fluid status and guiding treatment decisions. The nursing staff had experienced the consequences of missed fluid balance charting on patient safety, and adequate fluid balance charting as a lifesaving medical tool. Nursing staff found that high patient-nurse ratios, the lack of routines and consensus among nursing staff and confusing and complex documentation challenged fluid balance charting. The challenges resulted in inadequate fluid balance charting, frustration and demanded mental strength on reconstructing data. Nursing staff viewed fluid balance charting as a shared responsibility requiring clearly defined roles. Although nursing staff appreciated assistance from service staff, their involvement led to a lack of overview. Involving patients as co-players was also perceived as a barrier to maintaining control over charting. It was nursing staff's experience that distinct communication among colleagues was required to secure efficient routines. Furthermore, the nursing staff considered digitalisation and technological aids to enhance future quality.

Table 4: Structural analysis, an example		
A part of the structural analysis regarding the finding: Nursing staff consider fluid balance charting a fundamental nursing task relevant to target treatment		
Unit of meaning	**Unit of significance**	**Theme**
So, I think it's part of fundamental nursing to make sure that something goes in and something goes out. That's insanely important, a significant part of fundamental care (A1) After all, [fluid balance charting] is part of fundamental nursing care (…). So everyone should be aware of it (C2)	Fluid balance charting is a part of fundamental nursing and used in evaluating patients' illness and treatment planning. Missed fluid balance charting may have serious consequences; but charting should always be combined with clinical assessment	Nursing staff consider fluid balance charting a fundamental nursing task relevant to target treatment
It [fluid balance charting] is a tool, just like the stethoscope is a tool, we need it to evaluate (…) It's very important (U7) You can say that you have control over the patient. If they have fluid balance charting in and out, you can see if there is an improvement or (…) nothing changes. We might have to change our plan as well. We may have to do something… (Q5) It's alpha and omega that we know what comes in and out, where we stand, and where things go wrong. Then, we can go back and see, well, it's because he drinks too much or we give him too many IV fluids, or he doesn't pee as he should (G3)		
It has the consequence, that they [patients] get pulmonary oedema or so... It physically affects the patient (K4) We have no idea [about their fluid balance], we just serve drinks all the time (…) Then we take [blood] samples of their kidneys, and it's disastrous. Maybe it was our fault because we [gave them intravenous fluids] and we didn't know they had been drinking (…) It can worsen their illness (N5)		

How strict do you have to be? There is no doubt that if you both weigh [patients] and record in- and output, look for oedema and look at the skin, then you could probably learn to be kinder to yourself [not judge yourself when you miss something] (A1) After all, you usually have a sense of your patients' fluid balance (M4) You can't just look at the chart, you have to look at the patient, the clinical picture of your patient (…) You have to turn your thoughts to 'what do I have in front of me, and what does the paper show?' The connection, I mean (S6)		

APPENDIX III

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Digitizing fluid balance monitoring may offer a solution for optimizing patient care

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Abstract.
BACKGROUND: Precise fluid balance monitoring is essential for patient treatment, as incorrect fluid balance can lead to disorders.
OBJECTIVE: This study aimed to assess the accuracy of the digital technology LICENSE (LIquid balanCE moNitoring SystEm) for fluid balance charting and compare it to the standard method (SM) to determine its usability in clinical practice.
METHODS: This prospective study included 20 patients. The results from LICENSE were compared to those from SM and a reference measurement (manual weight of fluids, RM). Three LICENSE devices were used for urine output, intravenous fluids, and oral fluid intake. The accuracy of methods was evaluated using Bland Altman plots.
RESULTS: The mean difference between LICENSE and RM was less than 2 millilitres ($p = 0.031$ and $p = 0.047$), whereas the mean difference between SM and RM was 6.6 ml and 10.8 ml ($p < 0.0001$). The range between the upper and lower limits of agreement was between 16.4 and 27.8 ml for LICENSE measurements and 25.2 and 52 ml for SM.
CONCLUSION: LICENSE is comparable to or more accurate than the standard method for fluid balance monitoring. The use of LICENSE may improve the accuracy of fluid balance measurements. Further research is needed to evaluate its feasibility in daily clinical practice.

Keywords: Digital technology, automation, equipment design, monitoring, physiologic, water-electrolyte balance

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1. Introduction

Innovations in healthcare are emerging extensively, and the advancements regarding monitoring devices have increased accuracy and enabled continuous and remote monitoring [1,2,3,4]. Innovations contribute to new knowledge, improve treatment options and change the work processes of nurses and physicians by introducing digital technologies demanding the development of digital skills [5]. However, many innovations are never implemented in clinical practice, and estimates of failure rates range from 30% to 90% [6]. This emphasizes that although the innovation process can be described as linear, it is often cyclical or unplanned [7].

In a hospital setting, the maintenance of fluid balance is a critical component of patient care, as disturbances in fluid balance can lead to serious medical conditions [8]. Overhydration and dehydration can have detrimental effects on a patient's health, including increased morbidity and mortality [9,10], prolonged hospitalization [11,12,13], and adverse outcomes such as falls, urinary tract infections, and constipation [14]. Thus, there is a need for precise and continuous measurement of fluid balance to ensure prompt and appropriate clinical intervention [8,15].

However, the quality of fluid balance charting is inadequate, which is problematic. A systematic literature review highlights the persistent inaccuracy in fluid balance monitoring despite knowledge of its significance [16]. Nursing staff currently observe fluid intake and output and document it using paper-based fluid balance charts or electronic patient records, however, this practice is flawed [17,18,19] and prone to calculation errors [20,21,22].

Multiple interventions have been researched to enhance fluid balance monitoring by incorporating various components such as policies, education, equipment, visual aids, surveillance, and dissemination of results. However, most studies were unsuccessful in achieving a compliance rate of at least 75% of complete fluid balance charts [16]. The difficulty in maintaining improvements [23] highlights the need for robust solutions.

Healthcare innovations regarding fluid balance monitoring includes Bioimpedance Spectroscopy Analysis (BIA) used in fluid balance assessments [24,25,26] and equipment designed to measure urine output automatically [27,28,29], which is valuable when hourly measurement is required. However, existing systems only address one aspect of fluid balance, and knowledge of other parameters such as oral intake is essential for identifying and addressing fluid balance disturbances.

To address these challenges, we have developed a novel monitoring device, LICENSE (LIquid balanCE moNitoring SystEm), which automatically records fluid input and output and transfers data wirelessly to a computer. Our hypothesis is that automating fluid balance charting through LICENSE will reduce human errors, free up time for other nursing tasks, and optimize staff resources.

The aim of this study is to evaluate the precision of LICENSE compared to accurate manual measurements in a relevant environment under controlled conditions and determine its practical application in clinical practice.

2. Methods

This was a prospective observational study conducted between May 2020 and August 2021 in a university hospital in Denmark. The study received ethical approval from the regional Scientific Ethics Committee (ID: SJ-848) and followed all relevant regulations and guidelines, including the Declaration of Helsinki and GDPR rules. Participants were recruited during their hospital admission and met the following inclusion criteria: Catheterized patients in need of fluid balance monitoring, at least 18 years of age and able to provide informed consent.

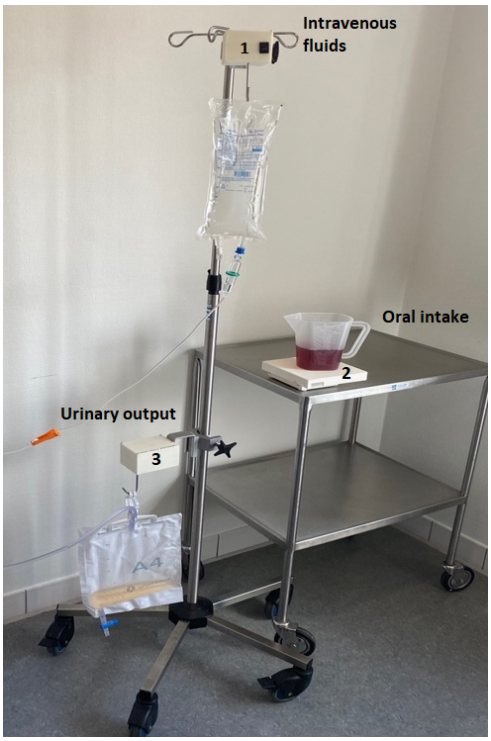

Fig. 1. LICENSE consists of three devices measuring 1) intravenous fluid, 2) oral intake and 3) urinary output.

2.1. Digital technology

LICENSE was developed in an interdisciplinary collaboration between engineers, physicians and nurses and consists of three independent measuring devices and a database for storing and analyzing data. The devices include one for measuring intravenous fluids, one for measuring oral fluid intake, and one for measuring urinary output in a catheter (as shown in Fig. 1). Devices measuring intravenous fluids and urinary output are identical except for algorithms interpreting data. These devices weigh 375 g and measure $10 \times 6 \times 7.5$ cm, not including the hook to attach to the bed or drip stand or the hook for hanging fluids. The oral device measures $17 \times 17 \times 4.5$ cm and weighs 325 g. Devices are battery-powered, with an operating time of the rechargeable battery of approximately 40 hours. Batteries are recharged by connecting devices to power. The devices are mounted in a way that allows patients to move around freely, and data is transferred wirelessly to the database every 30 seconds. The database calculates hourly intake and output and presents the results in numbers and graphs (as shown in Figs 2 and 3). Between patients, the devices were sterilized with ready-to-use cleansing wipes. Before initiating this study, LICENSE was validated in a laboratory environment with a focus on basic technological functions, and reached a Technology Readiness Level (TRL) of 3–4 [30,31]. The technology's key features include the integration of data from multiple sources of fluid balance monitoring and its high degree of automation.

2.2. Data collection and evaluation of accuracy

Both LICENSE and the standard manual procedure (SM) was compared to a reference measurement (RM). Based on the agreement with RM the accuracy of LICENSE and SM could be compared.

Fig. 2. The graphical user interface displaying data in numbers and graphs. 1) The graphs can display data for up to 10 hours, 2) the large numbers present the volumes of the last hour. 3) Further, you can type in a time period of your choice and 4) LICENSE calculates the total fluid balance for the period.

Patient Report

Patient name: Test31
Patient ID: 939495
Date admitted: 10.06.2021 07:45
Current date: 10.06.2021 15:03

Date	Hour	IV	Oral fluid	Urine bag	Total
10.06.2021.	07:00 - 08:00	13	0	71	-58
10.06.2021.	08:00 - 09:00	41	153	170	24
10.06.2021.	09:00 - 10:00	51	102	174	-21
10.06.2021.	10:00 - 11:00	44	1	45	0
10.06.2021.	11:00 - 12:00	33	151	33	151
10.06.2021.	12:00 - 13:00	20	0	20	0
10.06.2021.	13:00 - 14:00	82	130	88	124
10.06.2021.	14:00 - 15:00	92	215	94	213
10.06.2021.	15:00 - 16:00	0	0	0	0

Fig. 3. The Patient Report shows an overview of the intravenous fluids, the oral fluid intake and the urinary output as well as the hourly fluid balance.

LICENSE was attached to each participant's drip stand, and we placed the patient's catheter bag and any intravenous fluid bags on the hooks of the devices. The oral device was placed on the patient's bedside table. Devices recorded fluid intake and output, and the researchers performed manual measurements every hour. SM was defined as measuring volumes using manual reading from measuring lines on jugs or glasses. The urinary bag was emptied before performing the SM. The intravenous fluids were not measured manually, as it was considered too inaccurate due to imprecise measuring lines on intravenous fluid bags. RM was defined as the weight of the fluids and was performed by weighing fluid on a transportable scale. The exact time of SM and RM were noted, and the data from LICENSE was collected at those same time points for comparison.

The precision of LICENSE was assessed through comparative analysis with RM and SM, the latter involving manual measurements of fluid levels at hourly intervals. The concordance and discrepancies between RM and LICENSE were evaluated, along with the agreement between RM and SM, to establish the accuracy of LICENSE relative to the standard operating procedure. Additionally, LICENSE was appraised in comparison to SM. The distinct devices employed for measuring urine output, oral fluids, and intravenous fluids were subjected to individual evaluations as well.

2.3. Statistical analyses

Lu et al. [35] proposed a sample size calculation method for determining the number of participants required, which was employed in this study. The sample size ranged from a required number of pairs of 21 (for intravenous fluids) to 85 (for oral intake). We planned to observe participants for a minimum of five hours, collecting a pair of measurements every hour, leading to a minimum of 20 participants deemed sufficient.

The statistical analysis was conducted using R version 4.1.0 software, and a p-value of less than 0.05 was regarded as statistically significant. Descriptive statistics were presented as mean (SD) or median (IQR), depending on the distribution's normality. Student's t-test was utilized to compare the results for normally distributed data, whereas the Wilcoxon signed rank test was used for non-normally distributed data.

The agreement between LICENSE, SM, and RM was evaluated using the Bland-Altman method [32]. The mean bias and limits of agreement (including 95% confidence intervals) were calculated to describe the agreement between the methods. The Bland-Altman plot displays the pair-wise means on the x-axis and pair-wise differences on the y-axis. The mean bias represents the average difference between the methods and should be as close to zero as possible. The limits of agreement (LOA), calculated as bias $\pm$ 1.96 * SD, indicate the variance in measurements and should encompass 95% of measurements and be as narrow as possible. The acceptable LOA was not pre-defined, but instead, the accuracy of LICENSE was compared to the standard procedure (SM), which is considered the gold standard.

3. Results

The study included 20 patients, with a mean age of 76.3 years (SD 12.7), consisting of 18 male and 2 female patients. The patients were monitored for an average of 6.4 hours (SD 1.7). A total of 946 measurements were obtained, of which 341 were through LICENSE, 363 through RM, and 242 through SM. Each device generated between 111 to 124 paired measurements.

The distribution of the measurements was widespread, ranging from 0 to 1300 mL per measurement, with most measurements being less than 200 mL (as indicated in Table 1). The median urine output

Table 1
Distribution of measurements by quantity

		Reference measurement (RM)		LICENSE			Standard method (SM)		
		n	Median (IQR)	n	Median (IQR)	p-value	n	Median (IQR)	p-value
Urinary output	$<$ 200 ml	104	63 ml (36.3–93)	96	63.6 ml (35.8–90.2)		98	70 ml (50–100)	
	$\geqslant$ 200 ml	18	310 ml (232.5–349.8)	16	304.8 ml (222.4–338.8)		20	305 ml (237.5–362.5)	
	Total	122	72.5 ml (39.5–121.2)	112	72.9 ml (39.7–116.3)	0.031	118	80 ml (55–138.8)	$<$ 0.0001
Oral fluids	$<$ 200 ml	103	51 ml (0–127)	97	57.7 ml (0.3–127)		101	50 ml (0–130)	
	$\geqslant$ 200 ml	21	339 ml (294–462)	21	324 ml (289.3–439.7)		23	350 ml (275–465)	
	Total	124	91 ml (0–149.5)	118	89.3 ml (0.6–155.6)	0.031	124	100 ml (0–152.5)	$<$ 0.0001
Intra-venous fluids	$<$ 100 ml	96	0 ml (0–0)	89	0.1 ml (−0.6–3.6)		–	–	
	$\geqslant$ 100 ml	23	125 ml (106–174.5)	22	120.3 ml (103.8–177.4)		–	–	
	Total	119	0 ml (0–86.5)	111	0.5 ml (−0.4–93.3)	0.047	–	–	

LICENSE, Liquid balance monitoring system; n, Number of measurements; IQR, Interquartile range, All parameters are measured hourly, except n. Statistical method: Wilcoxon signed rank test.

Table 2
Performance parameters of LICENSE and the standard method (SM)

		n	Upper LOA	Mean bias (95% CI)	Lower LOA
Urinary output	LICENSE versus RM	112	12.1 ml (9.8 to 14.4 ml)	−1.8 ml (−3.2 to −0.5 ml)	−15.7 ml (−18 to −13.5)
	SM versus RM	118	23.3 ml (21.3 to 25.3 ml)	10.8 ml (9.6 to 11.9 ml)	−1.8 ml (−3.8 to 0.2 ml)
	LICENSE versus SM	109	31.5 ml (28.5 to 34.6 ml)	13 ml (11.2 to 14.8 ml)	−5.5 ml (−8.6 to −2.4 ml)
Oral fluids	LICENSE vs RM	118	10.9 ml (8.9 to 12.8 ml)	−1.3 ml (−2.5 to −0.2 ml)	−13.5 ml (−15.5 to −11.6 ml)
	SM versus RM	124	32.5 ml (28.5 to 36.5 ml)	6.6 ml (4.2 to 8.9 ml)	−19.4 ml (−23.4 to −15.3 ml)
	LICENSE versus SM	118	38.9 ml (34 to 43.9 ml)	8.1 ml (5.2 to 11 ml)	−22.7 ml (−27.6 ml to −17.8 ml)
Intra-venous fluids	LICENSE versus RM	111	7.5 ml (6.1 to 8.8 ml)	−0.7 ml (−1.5 to 0.04)	−8.9 ml (−10.3 to −7.6 ml)

LICENSE, Liquid balance monitoring system; SD, standard deviation; n, Number of measurements; LOA, Limits of agreement; CI, Confidence interval.

measured by RM was 72.5 mL/hour (IQR 39.5–121.2 mL) compared to 72.9 mL/hour (IQR 39.7–116.3 mL, $p = 0.031$) measured by LICENSE and 80 mL/hour (IQR 55–138.8 mL, $p < 0.0001$) measured by SM. The median oral intake was 91 mL/hour (IQR 0–149.5 mL) measured by RM compared to 89.3 mL/hour (IQR 0.6–155.6 mL, $p = 0.031$) by LICENSE and 100 mL/hour (IQR 0–152.5 mL, $p < 0.0001$) measured by SM. The median intravenous fluid intake was 0 mL/hour (IQR 0–86.5 mL) per hour measured by RM compared to 0.5 mL/hour (IQR −0.4–93.3 mL, $p = 0.047$) by LICENSE.

The summary statistics regarding the Bland-Altman plots are displayed in Table 2. The mean bias of

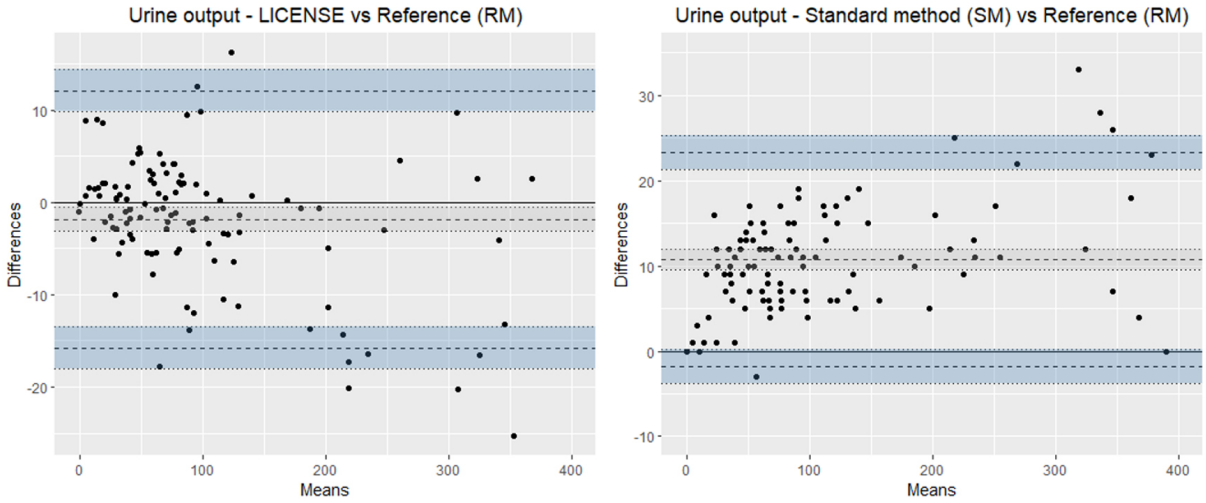

Fig. 4. Bland-Altman plots illustrating the agreement of LICENSE with the reference measurement (RM) (left) and standard method (SM) with the reference measurement (RM) (right) in measuring urine output. Note the different scales on the y-axes.

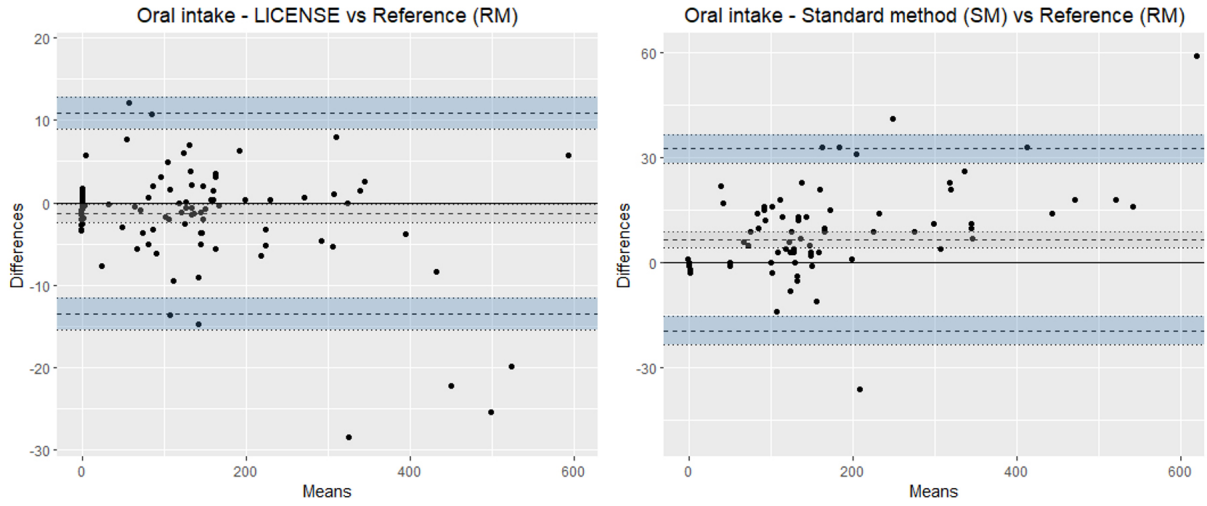

Fig. 5. Bland-Altman plots illustrating the agreement of LICENSE with the reference measurement (RM) (left) and standard method with the reference measurement (RM) (right) in measuring oral fluid intake. Note the different scales on the y-axes.

urine output measured by LICENSE was −1.8 mL (95% CI: −3.2 to −0.5 mL) compared to a mean bias of 10.8 mL (95% CI: 9.6–11.9 mL) measured by SM, suggesting that LICENSE measures are marginally lower than RM while SM measures are slightly higher. The 95% LOA interval was 27.8 mL (± 13.9 mL from the mean) by LICENSE and 25.2 mL by SM (as shown in Fig. 4). The bias increased with increasing urine volume, with a tendency toward a negative skewness in LICENSE measurements and a positive skewness in SM measurements.

The mean bias of oral fluid intake measured by LICENSE was −1.3 mL (−2.5 to −0.2 mL) compared to a mean bias of 6.6 mL (4.2 to 8.9 mL) measured by SM. The 95% LOA interval was 24.4 mL by LICENSE and 52 mL by SM (as shown in Fig. 5). There was a greater bias with increasing volumes and

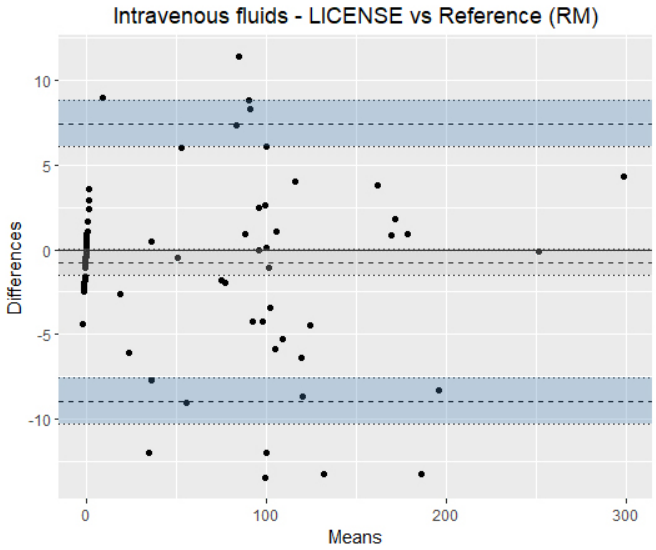

Fig. 6. Bland-Altman plots illustrating the agreement of LICENSE with the reference measurement (RM) in measuring intravenous fluids. On the right, the agreement is presented in a scatterplot.

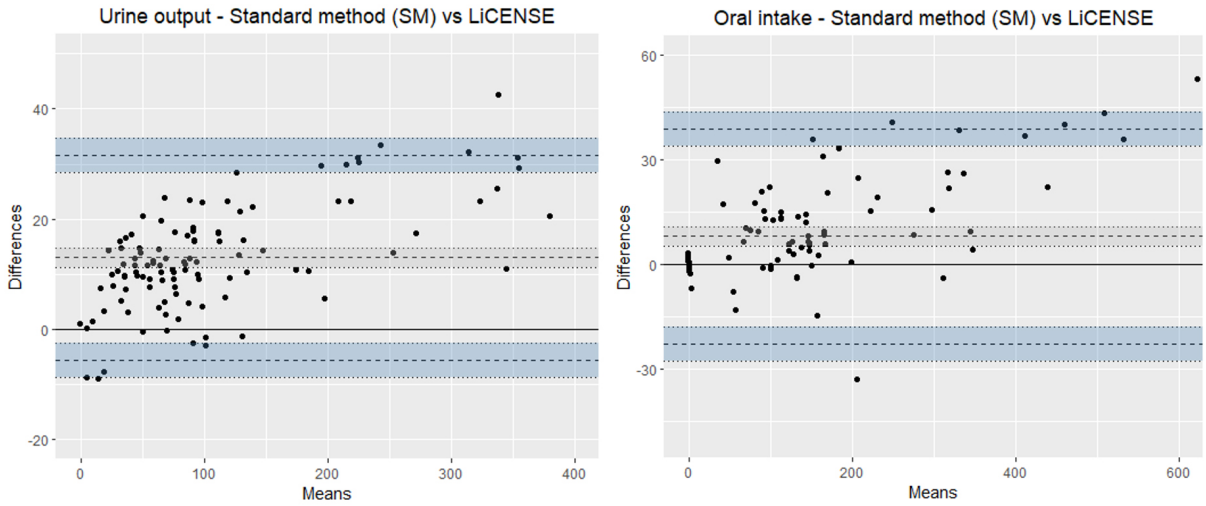

Fig. 7. Bland-Altman plots illustrating the agreement of LICENSE and the standard method (SM) in measuring oral fluid intake (left) and urinary output (right).

a tendency toward a positive skewness in SM measurements.

Only RM and LICENSE were used to measure intravenous fluids, with a mean bias of −0.7 mL (−1.5 to 0.04 mL) and a 95% LOA interval of 16.4 mL (as shown in Fig. 6). The measurements were evenly distributed.

The mean bias between SM and LICENSE for oral fluids was was 8.1 mL (95% CI: 11 to 5.2), with a 95% LOA interval of 61.6 mL (as shown in Fig. 7). The mean bias between SM and LICENSE for urine output was 13 mL (95% CI: 14.8 to 11.2 mL), with a 95% LOA interval of 37.0 mL, with a trend of an increasing positive difference with increased volumes.

4. Discussion

The LICENSE device accurately measures three parameters of fluid balance, including urine output, oral intake, and intravenous fluids. Compared to the standard procedure, LICENSE shows smaller mean biases, equivalent or narrower limits of agreement (LOA), and comparable medians of measurement. LICENSE is competitive with other devices in measuring hourly urine output and has the potential to improve fluid intake measurement accuracy by weighing fluids served instead of estimating volumes. An updated version of LICENSE that includes other fluid parameters, such as feeding tubes and fluid diversions, is currently in development.

4.1. Accuracy evaluation

The mean bias of LICENSE in all three parameters was less than 2 mL and, on average, LICENSE measured slightly less than the reference measurement (between -1.8 mL and -0.7 mL). In comparison, the manual reading (SM) showed a mean bias of 6.6 mL and 10.8 mL in measuring oral fluids and urine output, respectively, and a highly significant difference ($p < 0.0001$) was found.

The 95% LOA intervals in the Bland-Altman plots are approximately the same for LICENSE (27.8 mL) and SM (25.2 mL) in measuring urine output. However, LICENSE has a narrower LOA (24.4 mL) in measuring oral fluids compared to SM (52 mL). The medians of measurement also show better agreement between LICENSE and the reference weight (RM) compared to SM, with LICENSE medians deviating 0.4 to 1.7 mL from RM medians, while SM medians deviate 7.5 mL to 9.0 mL from RM.

Taken together, LICENSE is more accurate than the standard procedure based on mean biases, LOA, and medians of measurement. It is important to note that precision decreases at higher volumes, and this should be taken into consideration when treating patients.

To the best of our knowledge, there is a lack of research comparing digital fluid balance monitoring with traditional methods of calculating fluid balance by evaluating various fluid intake and output measurements. However, there have been a few studies that investigate the effectiveness of other devices in measuring urine output compared to standard procedures.

4.2. Measuring urine output

In the literature, several studies have been conducted to evaluate the accuracy of different devices for measuring urine output. Eklund et al. [27] compared the automatic urinometer Sippi® with a manual urinometer and found a mean bias of 1.9 ml and a range of 30.4 ml between the lower and upper limits of agreement (LOA) based on 408 measurements. Hersch et al. [28] compared a novel electronic urine output monitoring device with a manual urinometer and found a relative bias of 0.08 ml, a relative percentage deviation of 8%, and a $\pm$ 25 ml error. On the other hand, our study using LICENSE found an interval between the LOA of 27.8 ml, equivalent to $\pm$ 13.9 mL from the mean. Takai et al. [29] conducted another study evaluating a novel automated device for recording urine output measurements in both healthy volunteers and patients. They found that the accuracy was higher in healthy volunteers and described a significant difference between the manual weight and the device in patients with LOA of -75.4 to 64.1 g and an interval of 139.5 g, which is more uncertain compared to both LICENSE and the results reported by Eklund et al. [27] and Hersch et al. [28]. A bias of approximately 5–8 mL was indicated by the Bland-Altman plot in their study. In summary, the results of our study using LICENSE are competitive with other devices in measuring hourly urine output, as demonstrated by the findings from previous studies.

4.3. Measuring oral fluid intake

In the clinical setting, the measurement of oral fluid intake can be unreliable. Several factors contribute to this issue, one being the lack of clear responsibility for recording fluid intake [8]. This can lead to inconsistencies and inaccuracies in fluid balance charts due to different individuals serving and removing fluids. To address this issue, it is important to adopt an interprofessional approach that involves the participation of different healthcare professionals [19].

Another factor that contributes to the inaccuracies in fluid intake measurement is the use of containers with imprecise measuring lines or no measuring lines at all. This results in the need for approximate estimates, which can be prone to errors. Studies have shown that even trained healthcare professionals, such as nurses, have difficulty in accurately estimating fluid volumes. For example, one study found that 50% of nursing staff estimated volumes within an error margin of 10% and all nurses estimated within an error margin of 25% [33]. Another study found that only 27% of nurse's estimates were within an error margin of 10% [34].

The LICENSE device offers an opportunity to improve the accuracy of fluid intake measurement by weighing the fluids served, instead of relying on volume estimates. This reduces the risk of human error and improves the consistency of data. However, it is important to ensure that all fluids served are placed on the device to achieve maximum accuracy. This should be a consideration in the design and development of future versions of the device.

4.4. Future development and implementation

In this study, LICENSE proved to be accurate in a relevant hospital environment measuring patients' fluid intake and output and reached TRL 5. However, LICENSE needs to demonstrate its usability in a daily clinical practice setting and be developed further by providing a more comprehensive fluid balance by taking other sources of fluid input and output into account. In the present study, we considered the parameters of intravenous fluids, oral fluids, and urinary output in calculating fluid balance. Patients may have other means of fluid input and output, such as feeding tubes or fluid diversions like nephrostomies, drains, or nasogastric tubes [19], and there are also additional sources of fluid loss, like stools and insensible fluid loss through skin and respiration [8]. To address these limitations, we are currently collaborating with an engineering company to develop an updated version of LICENSE that incorporates these additional sources of fluid input and output. LICENSE needs further testing to obtain approval and certification by the CE mark, which is mandatory for medical devices marketed in The European Union and indicates compliance with health, safety and environmental standards [35].

In addition to developing technology, it is important to consider the attitudes of nursing staff towards using technology in their practice. Some nurses may resist the adoption of digital technologies and view it as an unwanted intrusion into their work [36] partly due to challenges faced with the technology, such as inadequate IT systems [37]. By collaborating with nurses across specialties and listening to their experiences, opinions and motivations, we expect to be able to deliver a well-designed technology and thus prevent nurses' resistance. Further, nurses' attitudes may improve if the technology is considered to be compatible with traditional nursing ideals, and frees up nurses' time to care for patients by automating routine tasks [37].

4.5. Limitations

Limitations of the study include the potential for bias introduced by the manual reading and weighting

methods, slight variations in weights due to differences in drip chamber placement, and the lack of measurements of intravenous fluids using standard procedures. Our department's standard practice is to document each fluid bag, rather than hourly intravenous fluid given, and an alternative approach would be to compare reference measurements with the accuracy of an infusion pump. Limitations related to the LICENSE devices include the relatively short battery operating time, which may necessitate recharging during continuous monitoring preventing the patient from moving around. In addition, there is need to thoroughly teach patients and nursing staff to ensure the correct use of LICENSE.

5. Conclusions

Our findings suggest that the LICENSE system is a reliable and accurate tool for recording fluid balance. The results indicate that LICENSE is comparable to or superior to manual methods in terms of accuracy and consistency, and has the potential to reduce the risk of human errors and increase the comprehensiveness and precision of fluid balance monitoring. It is important to note, however, that further research is necessary to fully evaluate the feasibility and usability of LICENSE in routine clinical practice and to explore methods for incorporating other fluid inputs and losses in fluid balance calculations.

Acknowledgments

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Conflict of interest

The authors declare that there is no conflict of interest.

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APPENDIX IV

Evaluation of a Real-Life Experience with a Digital Fluid Balance Monitoring Technology

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ABSTRACT

BACKGROUND: Innovations in healthcare technologies have the potential to address challenges, including the monitoring of fluid balance.

OBJECTIVE: This study aims to evaluate the functionality and accuracy of a digital technology compared to standard manual documentation in a real-life setting.

METHODS: The digital technology, LICENSE, was designed to calculate fluid balance using data collected from devices measuring urine, oral and intravenous fluids. Participating patients were connected to the LICENSE system, which transmitted data wirelessly to a database. These data were compared to the nursing staff's manual measurements documented in the electronic patient record according to their usual practice.

RESULTS: We included 55 patients in the Urology Department needing fluid balance charting and observed them for an average of 22.9 hours. We found a mean difference of -44.2 ml in total fluid balance between the two methods. Differences ranged from -2230 ml to 2695 ml, with a divergence exceeding 500 ml in 57.4% of cases. The primary source of error was inaccurate or omitted manual documentation. However, errors were also identified in the oral LICENSE device.

CONCLUSIONS: When used correctly, the LICENSE system performs satisfactorily in measuring urine and intravenous fluids, although the oral device requires revision due to identified errors.

Keywords:

Water-Electrolyte Balance; Monitoring, Physiologic;

Digital Technology; Automation; Equipment Design

1. Introduction

Innovation is increasingly seen as a solution to the challenges posed by factors such as an increase in elderly and multimorbid patients and a shortage of healthcare professionals. Technological advancements have led to transformative changes in the workflows of healthcare professionals (1), improved treatment options and enabled continuous and digital monitoring.

Monitoring fluid balance is an essential nursing task in hospitals to ensure appropriate clinical interventions. Fluid balance disorders have been linked to higher morbidity and mortality rates (2-4) and prolonged hospital stays (5-7). However, a literature review examining the quality of fluid balance charting revealed a common occurrence of inaccuracies (8). Achieving satisfactory compliance with completed fluid balance charts (75%) remains challenging despite various interventions, such as education, visual aids and equipment (8).

Automation has the potential to address issues related to incomplete documentation, calculation errors, and staff shortages. However, existing systems typically focus on a single aspect of fluid balance monitoring, such as urinary output (9, 10), while comprehensive monitoring requires knowledge of parameters like oral fluid intake. To address this gap, we have developed a novel monitoring device called LICENSE (LIquid balanCE moNitoring SystEm), designed to record fluid intake and output automatically (11).

The development of LICENSE stemmed from the ongoing need for accurate fluid balance monitoring and the commitment to fulfilling it. The concept of an automated solution encompassing all aspects of fluid balance evolved, leading to the creation of the initial prototype. While the innovation process can be described as linear (12), it often takes a cyclical or unplanned form with interrelated phases overlapping one another (13, 14). The development of LICENSE involved multiple cyclical processes, integrating research and development in an interdisciplinary

collaboration among engineers, doctors, and nurses (11). The equipment underwent initial validation in a laboratory environment, focusing on crucial technological functions such as continuous data transfer and accurate data processing, reaching a Technology Readiness Level (TRL) of 3-4 (15, 16). Subsequently, LICENSE's precision and devices were evaluated in a relevant environment (TRL 5) under controlled conditions, demonstrating that the LICENSE system accurately measures urine output, oral intake, and intravenous intake, comparable to or surpassing standard manual methods (11).

This study aims to assess the functionality and accuracy of the digital technology LICENSE compared to standard manual documentation in routine clinical practice. The primary outcome measure is the total fluid balance measured by LICENSE and the manual procedure and the agreement between the two methods. Secondary outcomes include the agreement between LICENSE and the standard procedure for each device measuring intravenous fluids, oral fluids, and urine output, respectively.

2. Methods

This prospective observational study was conducted at a university hospital in Denmark between August 2021 and June 2022. The study received approval from the Regional Scientific Ethics Committee (ID: SJ-848) and was conducted in accordance with the principles outlined in the Declaration of Helsinki (17).

2.1 Study population

Patients were consecutively recruited during their hospital admission and selected based on the following inclusion criteria: adult patients requiring fluid balance charting and catheterized patients expected to remain hospitalized for at least one day. Patients who were unable to provide informed

consent (e.g., due to cognitive impairment) or scheduled for discharge on the same day were excluded. Participating patients were provided with both oral and written information about the study and provided written informed consent.

2.2 Data collection

Data were obtained from the digital technology LICENSE and the electronic patient record to compare the standard procedure with the LICENSE measurements to determine the agreement between the two methods.

2.2.1 Digital Technology

LICENSE comprises three independent measuring devices that monitor intravenous fluids, oral fluid intake, and urinary output through a catheter (as depicted in Fig. 1). The devices for intravenous fluids and urinary output are attached to a drip stand, allowing patients to move freely. Each device wirelessly collects and transmits data to a central database for storage and analysis. The results are presented to users through a user interface, displaying numerical data and graphs (as illustrated in Fig. 2 and Fig.3). The user interface includes several functions, such as graphs depicting fluid intake or output measured by each device for up to 10 hours, hourly fluid balance calculations, and total fluid balance calculations for a self-selected period. A key feature of the LICENSE technology is its ability to integrate fluid balance data from multiple sources (intravenous fluids, oral fluids, and urine output) and its high level of automation (11).

After recruitment, a researcher registered the patient in the LICENSE user interface and ensured that all devices were powered on and ready to collect data. LICENSE was connected to the patient's drip stand, and all fluids were measured while ensuring the urinary catheter bag was emptied. Patients and staff members were educated on how to use the LICENSE devices, and a written manual was made available in the staff office.

2.2.2 Standard manual procedure

To compare the measurements obtained by LICENSE with the standard manual procedure, manual measurements were performed in accordance with clinical guidelines, as typically done in daily clinical practice. Nursing staff served oral fluids, and their volumes were estimated using measuring lines on jugs or predefined volumes in different cups and glasses. Urinary bags were emptied once per shift, and urine volumes were measured using jugs with measuring lines. Intravenous fluids were documented based on the volume indicated on the manufacturer-labeled bag when emptied. The nursing staff documented the fluid measurements in the electronic patient record.

2.3 Outcomes

The primary outcome measure was the difference between the total fluid balance measured by LICENSE and the manual procedure. Total fluid balance was calculated for the entire individual observation period. In cases where the patient was discharged, or data collection was interrupted at an unscheduled time, the total fluid balance was calculated based on the last manual measurement, and LICENSE measurements were included until the same time.

Secondary outcomes included the agreement between LICENSE and the standard procedure for each device measuring intravenous fluids, oral fluids, and urine output, respectively. For all parameters, total fluid intake or output was calculated. For instance, the total urine output measured by LICENSE was compared to the total urine output measured by nursing staff. In cases of discrepancies, a detailed analysis of the fluid balance charts was conducted to explain the differences.

All differences were calculated by subtracting the measurements obtained by the standard method from the LICENSE measurements. Negative results indicated that manual measurements were

larger than LICENSE measurements, while positive differences indicated that standard measurements were smaller.

2.4 Statistical Analysis

Previous studies have highlighted the prevalence of inaccuracies in fluid balance charts; a study in ICU found calculation errors exceeding 500 ml in 26.1% of the charts (18), while another study reported that at least 60% of charts were incorrect and inaccurate (19). Considering these findings, we conducted a power calculation for a one-sample proportion test, hypothesizing a divergence exceeding 500 ml in 35% of the fluid balance charts. The estimated sample size required was 51 participants. We considered a p-value of less than 0.05 to be statistically significant.

For the statistical analyses, we utilized R software version 4.1.0. Descriptive statistics were presented as mean (SD) or median (IQR), depending on the normality of the data distribution, and proportions were also reported. To compare the results between the LICENSE measurements and the standard manual procedure, we employed paired t-tests for normally distributed data. We used the Wilcoxon signed-rank test if the data did not meet the normality assumption. Furthermore, using a one-sample proportions test, we tested our primary hypothesis, which focused on the difference exceeding 500 ml in more than 35% of the fluid balance charts.

3. Results

A total of 55 patients admitted to the Department of Urology were included in the study. These patients were observed for an average duration of 22.9 hours (SD 3.6). The mean age of the participants was 66.8 years (SD 12.5), and 74.5% were male. Among the participants, 22% were prescribed diuretics, and 65% received intravenous fluids or medication. The current fluid status was assessed in 25% of the patients, and 71% had fluid balance charting prescribed, which involved

recording either intake only, both input and output, or hourly diuresis. The remaining 29% required postoperative fluid balance charting per local clinical guidelines. Additional patient characteristics are presented in Table 1.

The mean total fluid balance measured by the LICENSE system was -459 ml (SD 1234.1 ml), while the manual documentation, according to the standard procedure, yielded a mean of -414.8 ml (SD 1146.5 ml). This resulted in a difference between the two methods of -44.2 ml (SD 891.9 ml). Differences ranged from -2230 ml to 2695 ml, and the absolute mean difference was 566.5 ml (IQR 189.2; 984.5). In 57.4% of patients (95% CI 43.2% to 70.8%), the difference between the methods exceeded 500 ml. Detailed results can be found in Table 2.

When comparing the LICENSE system to the standard manual procedure for each fluid balance parameter, we observed that in 18.5% of patients (95% CI 9.2% to 31.4%), the difference in urinary output measurements exceeded 500 ml. Regarding intravenous fluids documentation, differences of more than 500 ml were found in 11% of patients (95% CI 4.2% to 22.6%), and in oral fluid intake, the difference exceeded 500 ml in 42.6% of patients (95% CI 29.2% to 56.8%). We refer to Table 2 for a comprehensive overview of these findings.

The differences in total fluid balance calculations displayed a normal distribution centred around zero. However, urine output differences exhibited a negative skewness, indicating an overweight of negative balances. Conversely, differences in intravenous fluids were positively skewed, with 68.5% of disagreements above zero. In the case of oral fluid measurements, differences were widely spread and roughly followed a normal distribution, as illustrated in Figure 4.

4. Discussion

The average discrepancy of -44.2 ml between LICENSE measurements and the standard procedure may initially seem convincing. However, the mean value was calculated based on a wide range of positive and negative differences that offset each other, illustrated by a mean absolute difference of 566.5 ml. More than half the patients (57.4%) exhibited a difference exceeding 500 ml, primarily caused by incomplete or inaccurate manual documentation. Nevertheless, we also identified sources of error related to the oral LICENSE device. As a result, we cannot solely attribute the differences between the methods to inaccurate manual documentation and assert that LICENSE provides precise measurements in contrast to a manual method prone to errors. Consequently, drawing meaningful conclusions regarding the primary outcome, which was the difference in total fluid balance measured by LICENSE and the standard manual method, becomes impossible. Consequently, we shifted our focus to the secondary outcomes and examined various potential reasons for the observed disparities. Nevertheless, we have acquired valuable knowledge concerning common sources of error in manual documentation and the feasibility of the LICENSE system, which will guide improvements.

4.1 Urine output measurements

When comparing urine output measurements between LICENSE and the standard manual method, we observed both negative and positive differences, with 18.5% of patients exhibiting differences exceeding 500 ml. A closer examination of individual patients' fluid balance charts revealed inconsistencies that may have resulted from inaccurate manual estimation and rounding of numbers when reading measuring lines on urine jugs. A mean difference of 10.8 ml (9.6 to 11.9 ml) was found when comparing reading measuring lines to a reference weight (11). This finding is supported by a study by Minor et al. (20), which reported that nurses significantly overestimated

hourly urine output and demonstrated that automation improved accuracy. Positive differences in urine output measurements may be attributed to missing documentation of manual readings. Another source of divergence occurred when the catheter bag was removed from the LICENSE hook and not properly repositioned afterwards.

4.2 Intravenous fluid measurements

The histogram depicting differences in intravenous fluid measurements (Figure 4, C) demonstrated positive skewness. Upon scrutinizing individual charts, we discovered that missing documentation of intravenous fluids, particularly intravenous antibiotics, in the electronic fluid balance chart was the underlying cause. Notably, 77.1% of patients received intravenous fluids or medication according to both LICENSE and the electronic medication list, but this information was not reflected in the electronic fluid chart. Consequently, fluid intake was underestimated in the electronic fluid chart, consistent with a study reporting that 66.9% of errors in fluid balance calculations were due to the omission of intravenous drugs (21). Another study reported a discrepancy between intravenous volumes documented on paper charts and those recorded electronically, with 26.1% lacking electronic recording (22).

Inaccurate manual documentation, resulting from documenting intravenous fluid volumes based on the volume indicated by the manufacturer on the fluid bag, emerged as another reason for divergence. Firstly, some fluids remained in the infusion lines when infusions ended; secondly, the volume specifications provided by manufacturers are not always accurate. A study comparing fluid weights with nurses' documentation identified a significant difference; however, it did not specify whether nurses documented higher or lower values (23). Another study of 3-liter bags reported an average overfill of 3.8%, corresponding to a mean overfill of 115.3 ml (24).

Some patients received intravenous infusions when they were recruited to the project, and the remaining volume at enrollment was estimated; however, estimating volumes from intravenous fluid bags is imprecise.

4.3 Oral fluid measurements

Significant and common differences in oral fluid measurements were observed, with 42.6% of patients exhibiting differences exceeding 500 ml. Various factors may contribute to these large differences. As reported in previous studies (8, 18, 25), calculation errors may have played a role in the current study. Also, missing manual oral fluid documentation in the electronic fluid chart would lead to positive differences. Negative differences may arise from nursing staff overestimating fluid intake due to inaccurate readings or erroneous assumptions, such as assuming a full jug (1000 ml) without precise knowledge of the actual volume served. Studies addressing inaccurate estimations of oral fluids found that only 27% (26) and 50% (27) of nurses' estimations fell within a 10% error margin. Furthermore, most volumes were overestimated (11, 26, 27), which could explain some differences, particularly those falling between 0 and -500 ml. Through subsequent tests, we identified sources of error associated with the design of the oral LICENSE device. If staff removed empty glasses or cups from the oral device without replacing them, LICENSE interpreted the weight change as fluid intake. Consequently, we instructed staff to leave cups and glasses on the device or replace them with a similar fluid container. Furthermore, LICENSE only transferred data every 30 seconds. As a result, when drinks were served, and the patient immediately consumed them, LICENSE failed to accurately register the total amount of fluids served, leading to negative differences.

4.4 Implications

This study illustrated that omissions in manual fluid balance charting play a significant role in discrepancies related to urine output, intravenous fluids, and oral fluids. Several factors have been identified as potential causes for missed nursing care, including communication issues, shift types, available nursing resources, and workload (28). In the context of fluid balance charting, causes of errors and omissions include increased workload and time constraints due to staff shortages (19, 29-31), poor communication among staff members (29, 30), and frequent change of caregivers (32). Thus, automating fluid balance charting may improve charting quality. However, LICENSE needs further revision.

Further, this study demonstrated the necessity of evaluating medical devices in real-life settings. The oral LICENSE devices performed satisfactorily in a controlled validation study (11); however, using in real life revealed possible mishandling resulting in faulty data. When a revised LICENSE prototype has been developed, preventing the risk of errors identified in the current version, the usability and feasibility need testing. Initially, in a study including observations or video surveillance to ensure the new LICENSE prototype version is indeed improved. Subsequently, a larger-scale study validating the effectiveness of the revised prototype. Another essential step for LICENSE to reach the European market is CE marking, as this is mandatory to ensure that medical devices comply with standards in the European Union (33).

4.5 Limitations

This study is subject to several limitations. Firstly, due to uncertainties primarily associated with the oral LICENSE device, we were unable to draw meaningful conclusions regarding our primary outcome. However, the study provided valuable insights for improving the digital technology and identifying sources of errors in manual fluid balance charting. Additionally, while data supported

some causes of errors, others relied on clinical experience and speculation. A more comprehensive understanding of error sources would require additional observations or video surveillance. The threshold of 500 ml is not supported by evidence and may vary depending on the clinical context, patient characteristics, comorbidities, and illness severity (34).

5. Conclusion

The LICENSE system shows promise in enhancing the quality of fluid balance charting. However, further adjustments are necessary to improve its accuracy and usability, particularly concerning the oral device. We anticipate that the implementation of such improvements will have a positive impact on the work environment of nursing staff by saving time. Nonetheless, the effects on the work environment should be investigated in future studies.

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Conflict of interest

The authors declare that they have no conflict of interest

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Tables:

Table 1. Patient characteristics	
Age, years, mean (sd), n=55	66.8 (12.5)
Male, n (%), n=55	41 (74.5)
Diagnosis, n (%), n=52	
Postobstructive diuresis	11 (21)
Urinary retention	1 (2)
Urosepsis /UTI	10 (19)
Operation*	16 (31)
Other (e.g. AKI)	14 (27)
Fluid balance assessment (Yes), n (%), n=55	14 (25)
Prescribed fluid balance charting, n (%), n=55	
No	16 (29)
Yes, intake only	5 (9)
Yes, both intake and output	18 (33)
Yes, hourly diuresis	14 (25)
Yes, output only	2 (4)
Diuretics (Yes), n (%), n=54	12 (22)
Intravenous prescription (Yes), n=55	36 (65)
Observation time, hours, mean (sd), n=54	22.9 (3.6)
*Operations include radical prostatectomy, nephroureterectomy, and heminephrectomy; AKI, acute kidney injury	

Table 2: Fluid balance measurements	
Total fluid balance (LICENSE), ml, mean (sd), n=54	-459 (1234.1)
Total fluid balance (standard procedure), ml, mean (sd), n=54	-414.8 (1146.5)
Total differences between methods (License minus standard), n=54	
Total fluid balance, ml, mean (sd)	-44.2 (891.9) ¤
Urine, ml, median (IQR)	-58.00 (-271.8; 71.8)
Oral, ml, median (IQR)	-190.0 (-828; 120.2)
Intravenous, ml, median (IQR)	58.5 (0; 258.8)
Absolute difference in total fluid balance, ml, median (IQR)	566.5 (189.2; 984.5)
Median divergences between methods in categorized total fluid balance, median (IQR), n=53	
>500 ml	952 (625.2; 1269)
0 to 500 ml	121.8 (54.5; 283)
0 to -500 ml	-171 (-224.5; -148)
< -500 ml	-824 (-1128; -714)
Patients with an absolute difference between methods > 500 ml, % (CI), n=54	
Total fluid balance	57.4 (46.2; 100)**
Urinary output	18.5 (9.2; 31.4)
Intravenous input	11 (4.2; 22.6)
Oral intake	42.6 (29.2; 56.8)
Intravenous fluids missing in the electronic fluid chart, % (CI), n=35	77.1 (59.9; 89.6)

¤ non-significant mean difference in paired t-test (p=0.7172)
**p-value below 0.01 in one-sample proportion test testing the hypothesis that >35 % of fluid balance charts had a divergence of ≥500 ml (p=0.0003)

Figures:

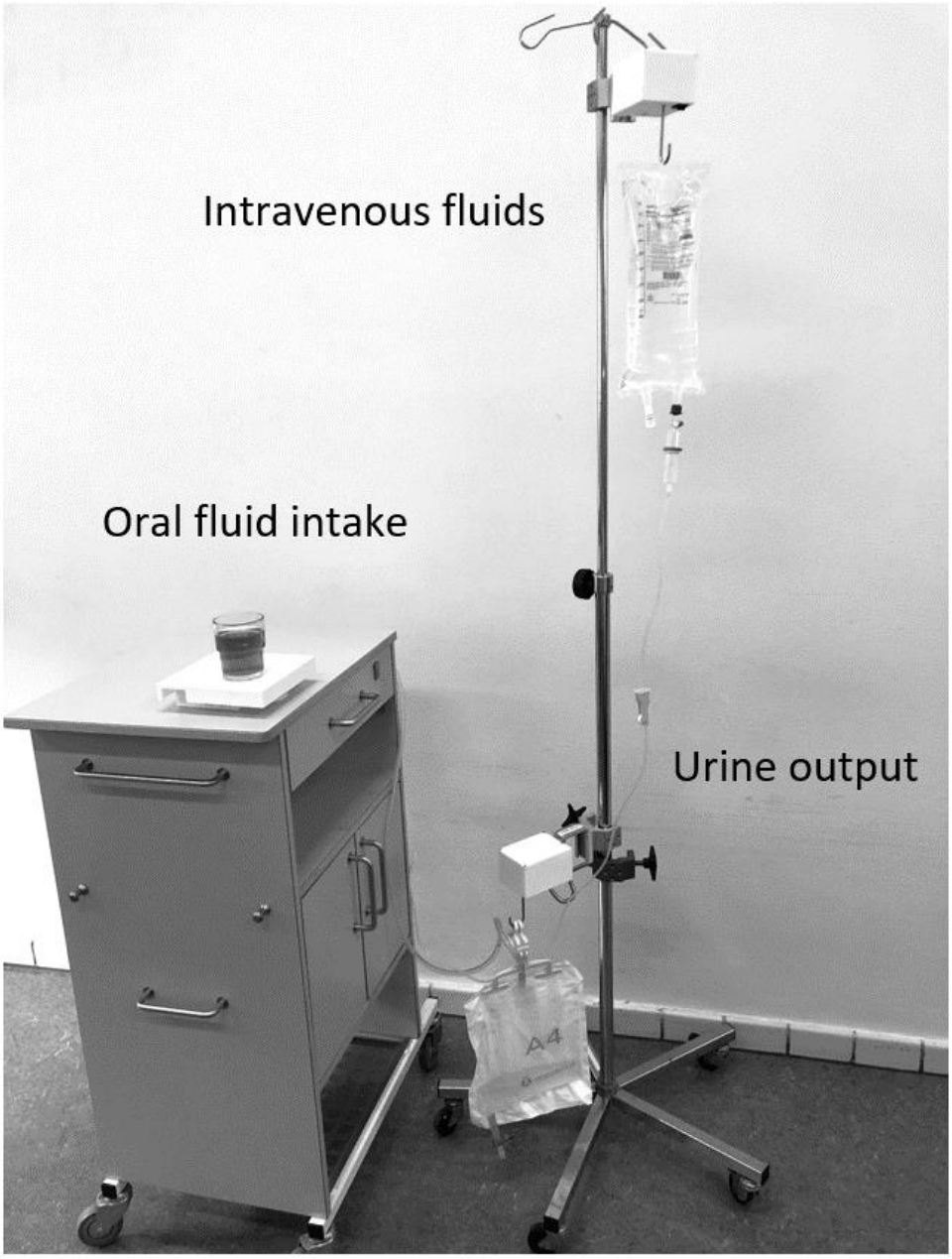


Fig 1 LICENSE consists of three devices measuring intravenous fluids, oral intake and urinary output.

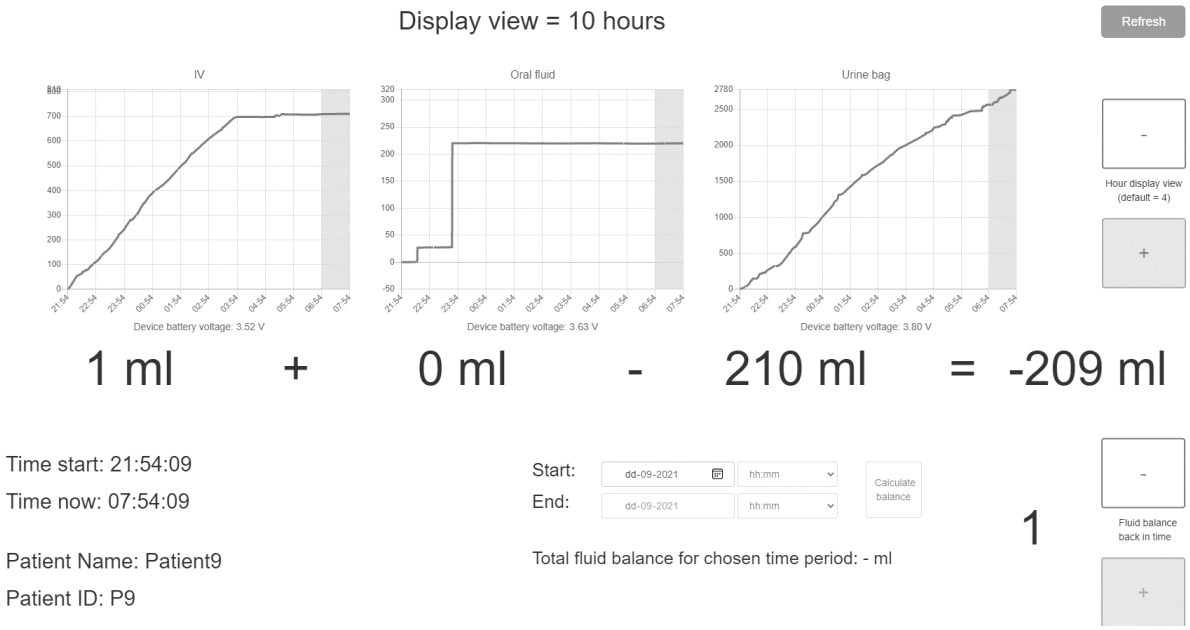


Fig 2 Graphic presentation of data in the LICENSE user interface

Patient Report

Patient name: Patient9
Patient ID: P9
Date admitted: 22.09.2021 10:13
Current date: 23.09.2021 14:23

Date	Hour	IV	Oral fluid	Urine bag	Total
22.09.2021.	21:00 - 22:00	131	0	162	-31
22.09.2021.	22:00 - 23:00	107	27	272	-138
22.09.2021.	23:00 - 24:00	137	192	346	-17
23.09.2021.	00:00 - 01:00	136	0	410	-274
23.09.2021.	01:00 - 02:00	109	0	408	-299
23.09.2021.	02:00 - 03:00	108	0	283	-175
23.09.2021.	03:00 - 04:00	79	0	272	-193
23.09.2021.	04:00 - 05:00	0	0	229	-229
23.09.2021.	05:00 - 06:00	9	0	182	-173
23.09.2021.	06:00 - 07:00	1	0	129	-128
23.09.2021.	07:00 - 08:00	0	0	209	-209

Fig 3 Numeric presentation of data in the LICENSE user interface

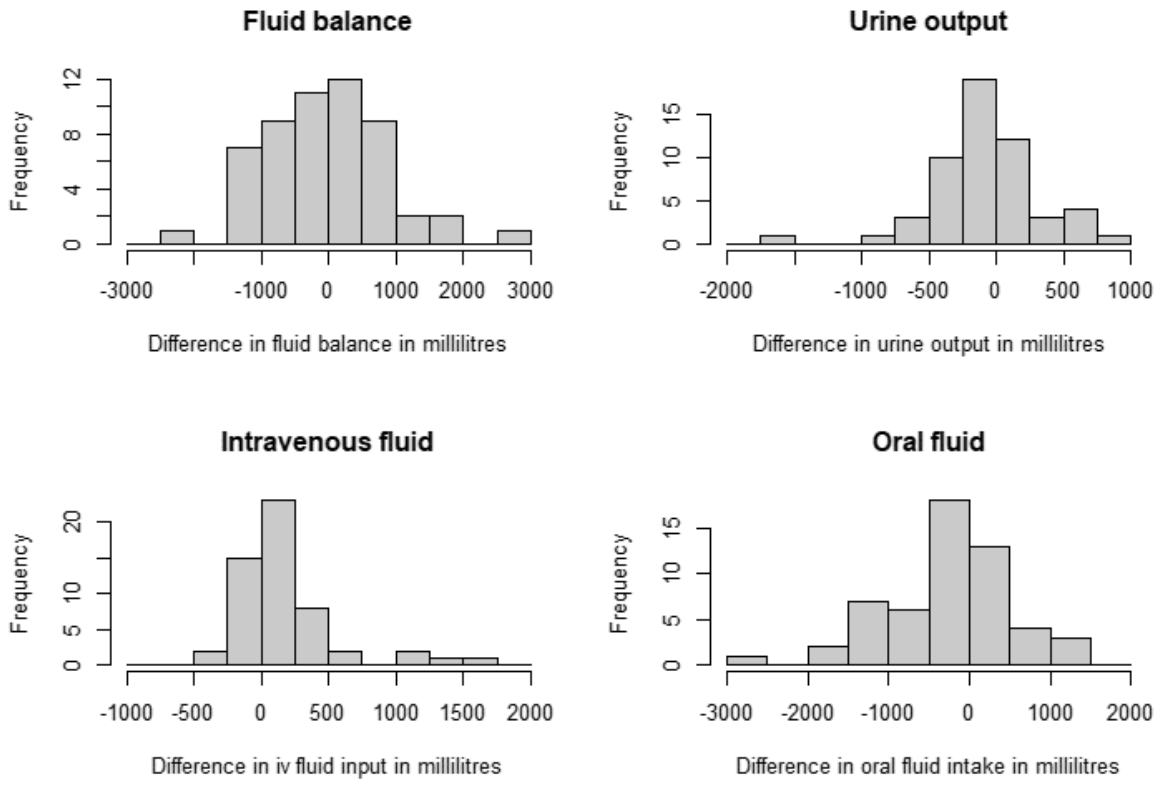


Fig 4 Histograms illustrating the difference between the standard manual method and LICENSE measurements. Differences are calculated as LICENSE minus standard.

APPENDIX V

Search strategy

Database	Keywords/search terms
CINAHL (EBSCO)	(MM ”Fluid and Secretion”) OR (MH “Fluid-Electrolyte Balance+”) OR (MH “Fluid-Electrolyte Imbalance+”) OR (MH “Fluid Intake-Output Measures”) OR (MH “Fluid Therapy+”) OR (MH “Fluid Intake”) OR (MH “Hydration Status”) OR (MH “Administration, Intravenous+”) OR (MH “Infusions, Intravenous”) OR (MH “Urine”) OR (MH “Urinary Diversion+”) OR (MH “Diuresis”) OR diuresis OR “urine output” OR “urinary output" OR ""urinary excretion” OR “frequency volume” OR “fluid administration” OR “fluid intake” OR “fluid balance” AND (MM “Documentation”) OR (MH “Charting+”) OR (MH “Medical Records+”) OR (MH “Record review”) OR (MH “Audit”) OR (MH “Nursing Audit”) OR (MM “Monitoring Physiologic”) OR (MH “Intraoperative Monitoring+”) OR (MH “Registration”) OR (MH “Measurement Error+”) OR recording OR charting OR monitoring OR documentation OR registration OR measuring OR AB measurement AND (MH “Quality of Health Care+”) OR (MH “Quality of Care Research”) OR (MH “Evaluation and Quality Improvement Program”) OR (MH “Data Quality”) OR (MH “Measurement Issues and Assessments+”) OR quality OR completeness OR accuracy OR timeliness OR improvement OR improving OR improve
MEDLINE via PubMed	((((((((((((”Water-Electrolyte Imbalance”[Mesh]) OR (“Water-Electrolyte Balance”[Mesh]) OR (“Fluid Therapy”[Mesh]) OR (“Urine”[Mesh])) OR (“fluid balance”[Title/Abstract])) OR (“fluid intake”[Title/Abstract])) OR (“fluid administration” [Title/Abstract])) OR (“frequency volume” [Title/Abstract])) OR (“urinary excretion”[Title/Abstract])) OR (“urinary output” [Title/Abstract])) OR (“urine output” [Title/Abstract])) OR (diuresis[Title/Abstract])) AND ((((((((((((“Documentation”[Majr]) OR (“Data Collection”[Majr])) OR (“Nursing Records”[Mesh])) OR (“Medical records”[Mesh])) OR (“Monitoring, Physiologic”[Majr])) OR (“Weights and Measures”[Mesh])) OR (recording[Title/Abstract])) OR (charting[Title/Abstract])) OR (monitoring[Title/Abstract])) OR (documentation[Title/Abstract])) OR (registration[Title/Abstract])) OR (measuring[Title/Abstract])) OR (measurement[Title/Abstract]))) AND ((((((((((((“Quality Control”[Mesh]) OR (“Nursing Audit”[Mesh])) OR (“Clinical Audit”[Mesh])) OR (“Quality Improvement”[Mesh])) OR (“Quality Indicators, Health Care”[Mesh])) OR (“Quality of Health Care” [Majr])) OR (“Data Accuracy” [Mesh])) OR (“Data Management [Mesh])) OR (quality[Title/Abstract])) OR (completeness[Title/Abstract])) OR (accuracy[Title/Abstract]))

Embase	exp fluid balance/ OR exp fluid intake/ OR exp fluid therapy/ OR exp urine volume/ OR urinary frequency/ OR urinary excretion/ OR fluid balance.ab,ti. OR fluid intake.ab,ti. OR fluid administration.ab,ti. OR frequency volume.ab,ti. OR urinary excretion.ab,ti. OR urinary output.ab,ti. OR urine output.ab,ti. OR diuresis.ab,ti. AND Medical record/ OR documentation/ OR medical record review/ OR monitoring/ OR patient monitoring/ OR physiologic monitoring/ OR measurement/ OR measurement accuracy/ OR measurement error/ OR measurement precision/ OR recording.ab,ti. OR charting.ab,ti. OR monitoring.ab,ti. OR documentation.ab,ti. OR registration.ab,ti. OR measuring.ab,ti. OR measurement.ab,ti. AND quality of nursing care/ OR data quality/ OR quality control/ OR quality improvement study/ OR health care quality/ Or data accuracy/ OR accuracy/ OR timeliness/ OR data completeness/ OR quality.ab,ti. OR completeness.ab,ti. OR accuracy.ab,ti. OR timeliness.ab,ti. OR improving.ab,ti. OR improve.ab,ti.
Cochrane Library [MeSH descriptor] explode all trees ”free text”	[Water-Electrolyte Balance] OR [Water-Electrolyte Imbalance] OR [Fluid Therapy] OR [Fluids and Secretions] OR [Diuresis] OR [Urine] OR [Infusions, Intravenous] OR “fluid balance” OR “fluid intake” OR “fluid administration” OR “frequency volume” OR “urinary excretion” OR “urinary output” OR “urine output” OR “diuresis” AND [Data Accuracy] OR [Nursing Records] OR [Medical Records] OR [Data Collection] OR [Hospital Records] OR [Chart] OR [Monitoring, Physiologic] OR [Documentation] OR [Dimensional Measurement Accuracy] OR recording OR charting OR monitor OR monitoring OR documentation OR registration OR measure OR measuring OR measurement AND [Quality Control] OR [Quality Improvement] OR [Quality Assurance, Health Care] OR [Quality of Health Care] OR [Quality Indicators, Health Care] OR quality OR completeness OR accuracy OR timeliness OR improvement OR improving OR improve

All searches have subsequently been limited to the period from January 2010.

APPENDIX VI

Interview guide

Indledning

Tusind tak, fordi I vil hjælpe os med at blive klogere på det at føre væskeregnskab.

I har alle det til fælles, at I er ansat på hospitalet som sygeplejerske eller social- og sundhedsassistent, og har erfaring med at føre væskeregnskab. Samtidig er I også forskellige, og har derfor også forskellige perspektiver. Vi vil derfor rigtig gerne høre jer alle sammen.

Selvom der er en vis struktur, vil vi gerne have en fri samtale, hvor I kan kommentere eller bygge videre på noget en anden har sagt.

Og så er det vigtigt at sige, at formålet ikke er, at vi skal blive enige – tværtimod er det vigtigt at forskellige synspunkter og perspektiver kommer frem.

Inden vi rigtig går i gang, vil jeg bede jer udfylde det lille spørgeskema her. Oplysningerne fra spørgeskemaet vil vi anvende til at beskrive gruppen af deltagere. Desuden vil vi bede jer udfylde en samtykkeerklæring.

	Spørgsmål	**Opfølgende spørgsmål**	**Min.**
Åbning	Vi vil begynde med en runde. Hvis I vil fortælle hvad I hedder, hvor I er ansat, og kort beskrive jeres rolle i det at føre væskeregnskab.		5
Introduktion	Hvordan organiserer I det at føre væskeskema i din afdeling? Hvad består væskeregnskab af i din afdeling?	Hvem er ansvarlig? Opgavefordeling? SSA/spl. Samarbejdspartnere? Hvem iværksætter handlinger? Inkluderes fx perspiratio, vægt osv?	10
Væskeregnskab i praksis Barrierer og fremmere	Hvad fungerer godt i forhold til det at føre væskeregnskab? Hvad kan *fremme* høj kvalitet (af dokumentationen) i væskeregnskabet? Er der noget, som ikke fungerer optimalt i forhold væskeregnskab? Hvilke barrierer kan *forhindre* høj kvalitet (af dokumentationen) i væskeregnskabet? Hvilken betydning har de nævnte forhold for dig som personale? Og for patienterne?	Det nemmeste? Hvad gør det nemt? Hvilken betydning har det for kvaliteten? Det sværeste? Hvad gør det svært? Hvilken betydning har det for kvaliteten? Prøv at give et eksempel? Eller beskriv.... Har forhold, der er enten nemme eller svære, betydning for jeres lyst til/motivation for at føre væskeregnskab?	15 15

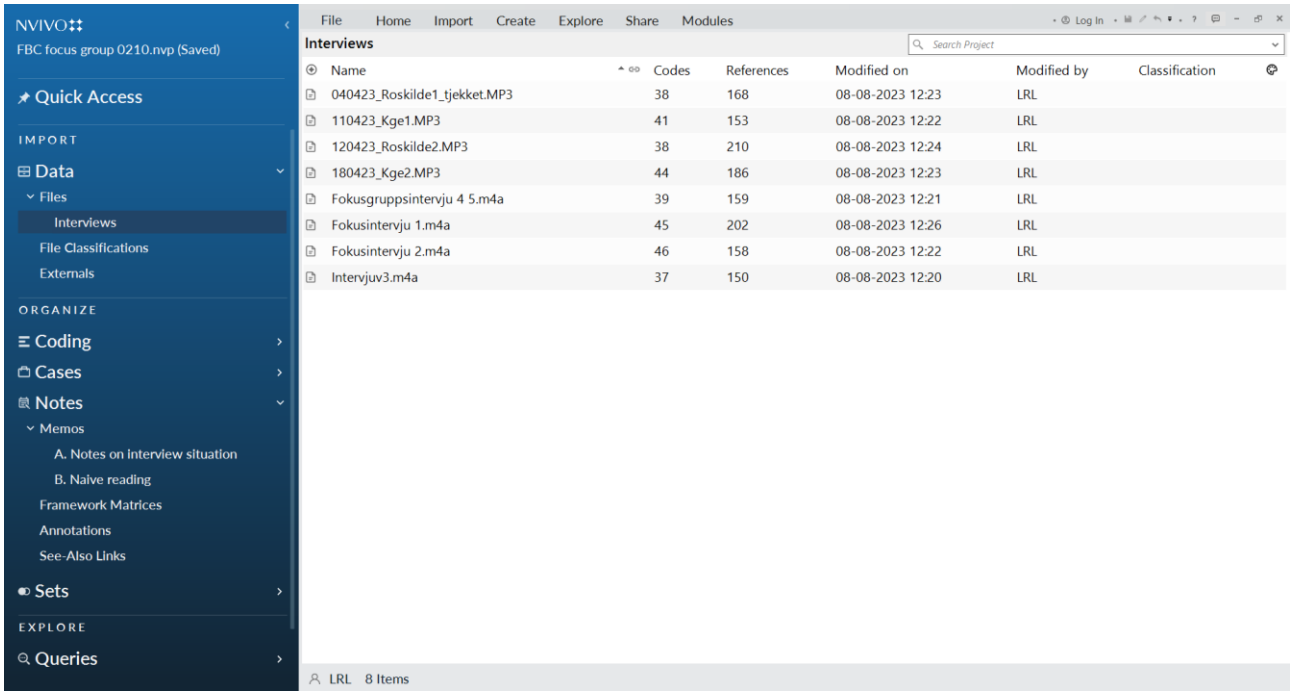
Vigtighed af væskeregnskab	Synes I, at det, at føre væskeregnskab, er brugbart? Hvor vigtigt er det at føre et væskeregnskab sammenlignet med andre sygeplejeopgaver? Prioriterer I nogle særlige patientgrupper? Er alle dele af væskeskemaet lige vigtige? Prioriteres væskeregnskab højt i jeres afdeling? Er der enighed i personalegruppen om hvor højt væskeregnskabet skal prioriteres? Påvirkes du af (sygepleje)kollegers indstillinger til væskeregnskab? Af kolleger fra andre faggrupper? Hvordan?	Hvorfor? /Hvorfor ikke? Fx medicinadministration? Servering og dok. af mad/drikke? Ernæringsscreening? Bradenscore? Personlig hygiejne? Dok af sårpleje? Hvis ikke – hvad er vigtigst? Mindst vigtigt? Hvordan kommer det til udtryk? Hvem prioriterer det? Er der forskel på prioriteringen faggrupperne imellem? (for hvem er det mest/mindst vigtigt?) Hvordan kommer det til udtryk? På hvilken måde? Kom gerne med et eksempel Kollegers dokumentation? Dokumentation i alle vagter? Fx lægers fokus på væskebalance ved stuegang?	15 20
Forbedringer og drømme	Hvordan kan dokumentation af væskeregnskab forbedres? Tror I, det er muligt at automatisere væskeregnskabet?	Hvis I skal prøve at forestille jer, den perfekte metode til at føre væskeregnskab – hvordan ser den ud?	10
Afslutning	Opsummering: Vi har talt om at væskeregnskab er…. Generelt organiseres…. Det fungerer godt at…. Barrierer er…. Det betyder at…. Væskeregnskab prioriteres… Er det en passende opsummering? Er der noget vi mangler?	Andre siger at den elektroniske patientjournal/regnefejl/tid/udstyr kan have betydning? Hvad tænker I om det?	5

Afrunding og tak for i dag	**I alt:** **95 min**
Tusind tak for i dag. Det har været spændende, at høre om jeres forskellige erfaringer og opfattelser af det at føre væskeregnskab. Det har været meget brugbart! Hvis nogle af jer er interesserede i at få tilsendt den artikel, vi vil skrive baseret på bl.a. vores samtale i dag, må I gerne sige det nu.	

APPENDIX VII

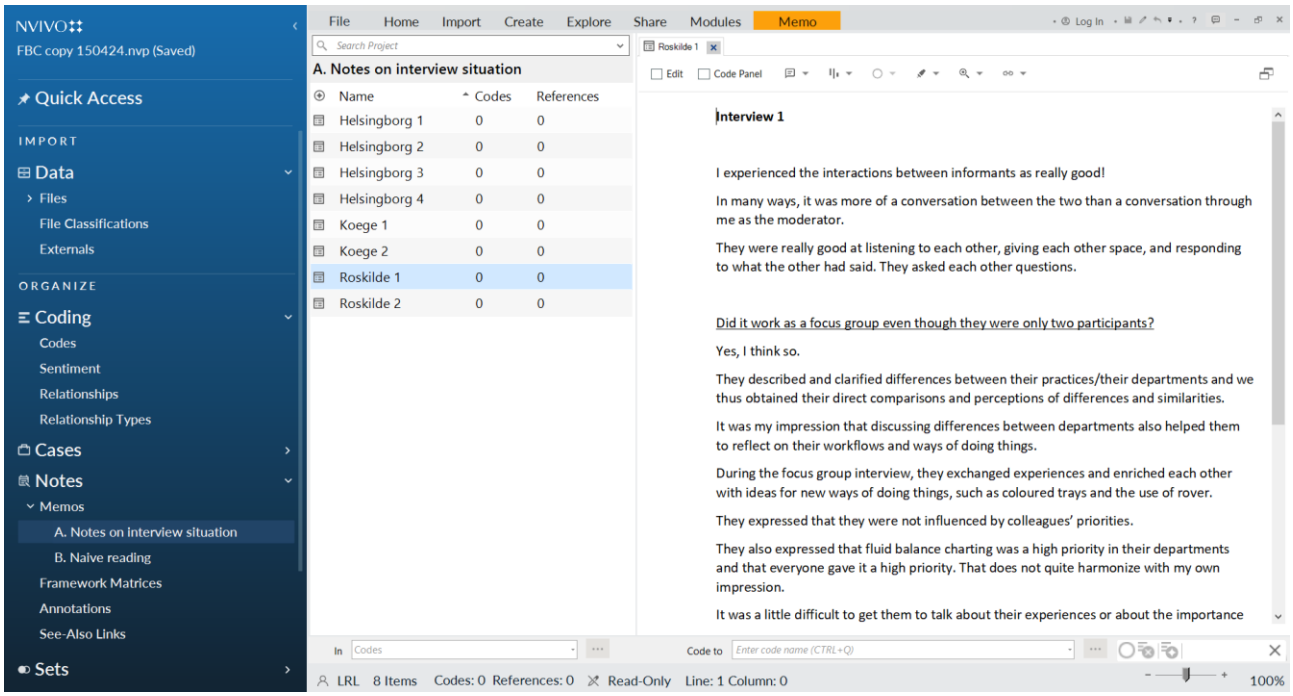
Coding and analysis in Nvivo 14

All focus group interview data were transferred to Nvivo 14 for coding.

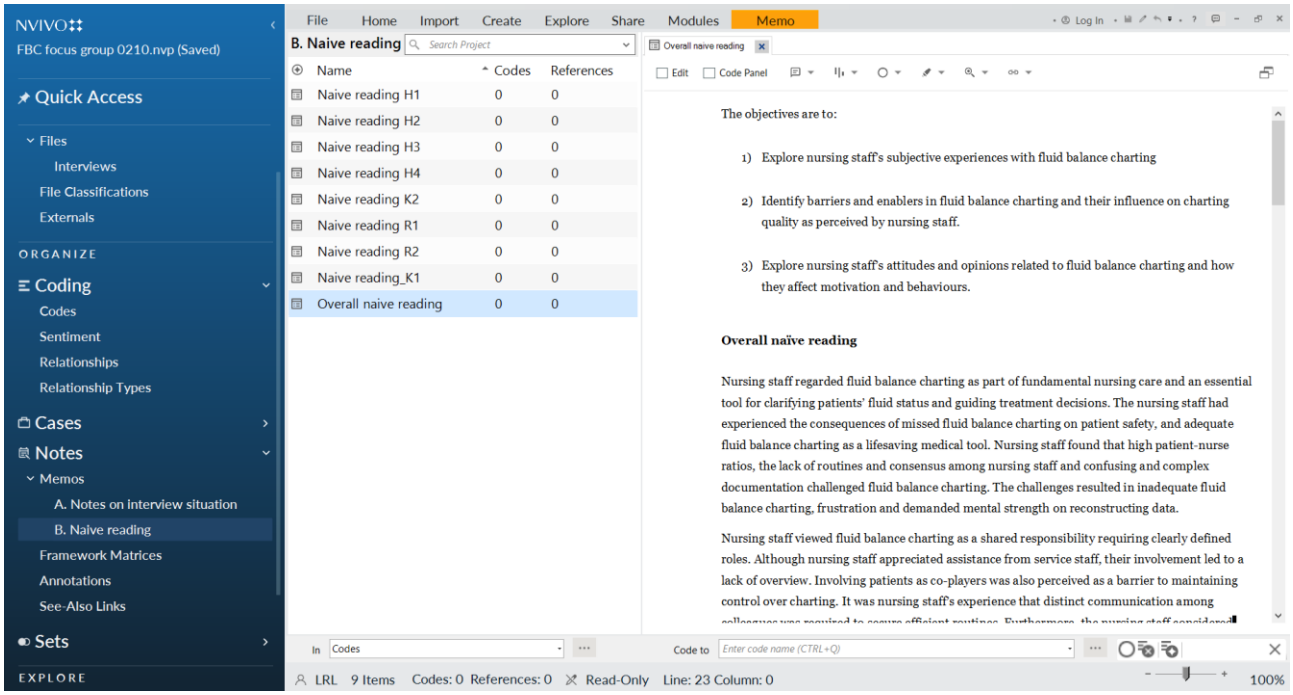


Memos were created including:

A. Notes regarding the interview situation and interactions between participants of each focus group interview



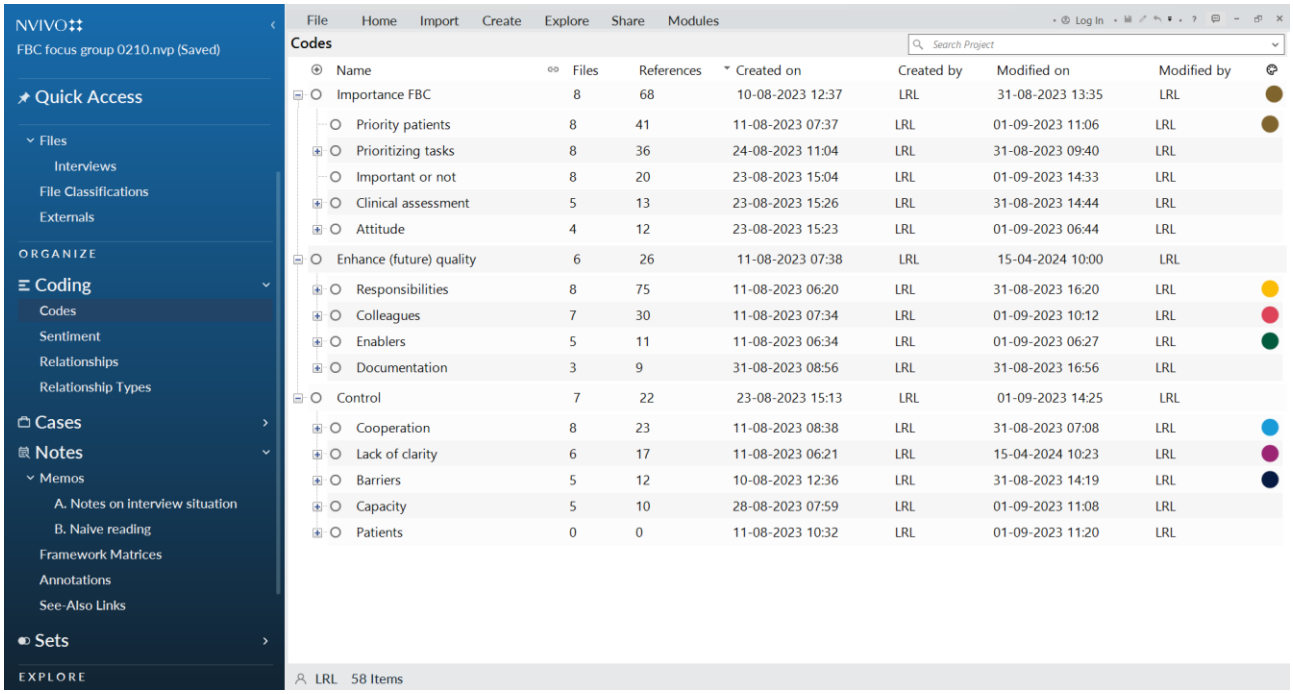
B. Naïve readings of each focus group interview and an overall naïve reading



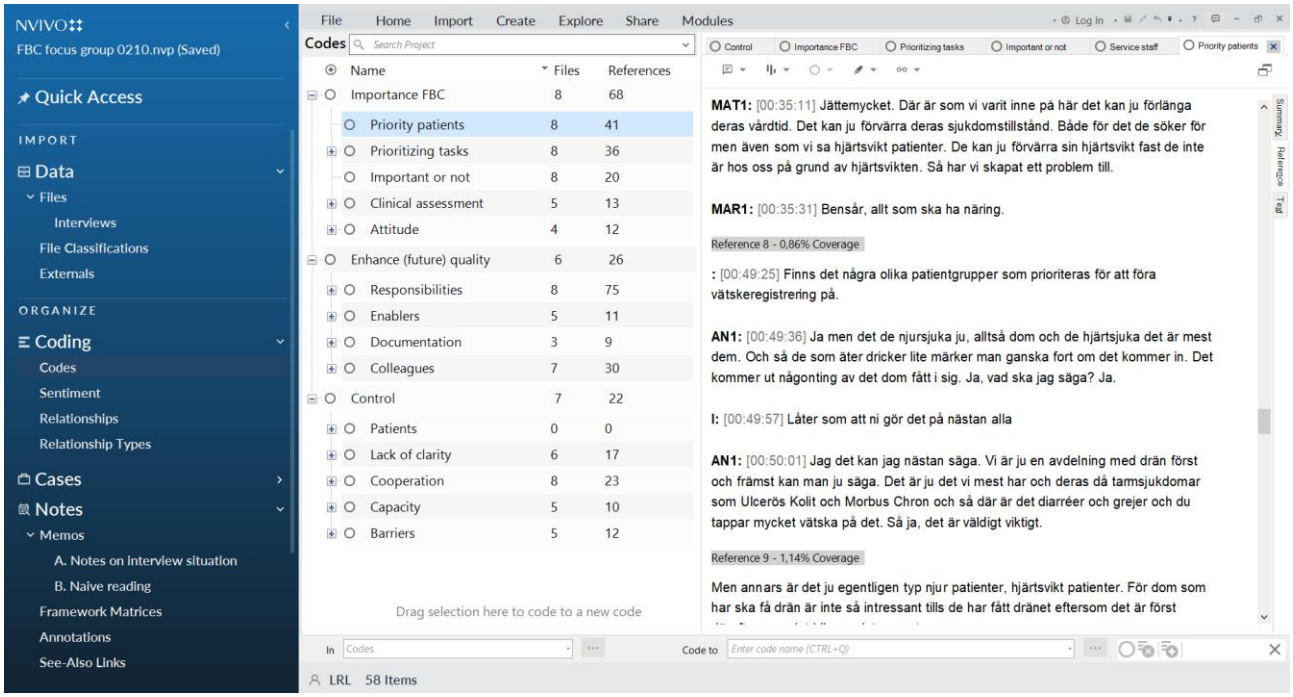
The structural analysis included coding all eight focus group interviews in NVivo.

The data coding resulted in 58 codes that were later structured in themes and subthemes/subcodes.

As depicted below the three themes were in Nvivo named 'Importance FBC', 'Control' and 'Enhance (future) quality'



The screenshot below demonstrates some quotations from the code 'Priority patients'



MAT1, MAR1 and AN1 are letter combinations that pseudonymise the participants according to an encryption key.

APPENDIX VIII

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	6
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	title page
Occupation	3	What was their occupation at the time of the study?	title page
Gender	4	Was the researcher male or female?	6
Experience and training	5	What experience or training did the researcher have?	6
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	5
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	9
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	9
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	5
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	5
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	5
Sample size	12	How many participants were in the study?	9
Non-participation	13	How many people refused to participate or dropped out? Reasons?	9
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	7
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	6
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	Table 1
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	7
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	No
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	6
Field notes	20	Were field notes made during and/or after the inter view or focus group?	7
Duration	21	What was the duration of the inter views or focus group?	10
Data saturation	22	Was data saturation discussed?	19
Transcripts returned	23	Were transcripts returned to participants for comment and/or	6

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	8
Description of the coding tree	25	Did authors provide a description of the coding tree?	Table 4
Derivation of themes	26	Were themes identified in advance or derived from the data?	10
Software	27	What software, if applicable, was used to manage the data?	8
Participant checking	28	Did participants provide feedback on the findings?	N/A
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	10-15
Data and findings consistent	30	Was there consistency between the data presented and the findings?	10-15
Clarity of major themes	31	Were major themes clearly presented in the findings?	10
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	11-15

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.