User Validation of the viQtor RPM solution during Home-Based Blood Transfusions; a promising advancement in home care

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Abstract

<u>Background</u>: Blood transfusions for cancer patients are increasingly being administered at the patient's home to reduce hospital burden and increase patient comfort However, the presence of a nurse throughout the transfusion period is mandatory despite of the very low risk of apparatus malfunction, sensitivity reactions, or an acute haemolytic transfusion reaction. The viQtor wearable enables continuous remote monitoring of important vital signs (Pulse Rate, Respiratory Rate, and Oxygen saturation), potentially allowing nurses to leave the patient's side, thereby improving efficiency and relieving the burden on ever increasing limited nursing resources.

<u>Objective</u>: This study aims to evaluate the usability and acceptance of the viQtor wearable among patients and nurses during home-based blood transfusions.

<u>Methods</u>: In an eight-week single-center qualitative cohort study conducted with Savant Zorg in Southeast Brabant, the Netherlands, seven patients receiving home-based blood transfusions were monitored using standard care, supplemented by the viQtor RPM solution. Semi-structured interviews with patients and a focus group with seven nurses provided insights into their use perspectives. Supporting thematic analyses were separately conducted to assess usability and acceptance of the viQtor RPM solution based on patient and nurse experiences.

<u>Results</u>: Both patients (N=7) and nurses (N=7) recognized potential benefits of the viQtor, including eliminating the need for spot checks, time savings, enhancing patient autonomy, and potentially enabling nurses to assist more patients simultaneously. Additionally, they noted benefits such as uninterrupted sleep without manual checks. This new technology and way of working still requires nurses and their organisations to get familiar with it, but they are optimistic about future implementation as the new standard of care.

<u>Conclusions</u>: In conclusion, this exploratory study provides valuable insights into the experiences of patients and nurses with the viQtor during home-base blood transfusion. Both patients and nurses recognize viQtor's potential to improve care by increasing work efficiency, ensuring safety, and predicting clinical deterioration early. Although the nurses still feel unfamiliar with leaving patients unattended based on this limited study period which doesn't lead yet to a conclusive picture of using viQtor, there is a positive expectation about the future use of RPM for this use case. With additional practice, training, familiarity and support, nurses are expected to gain more insight and tris in the benefit to risk ratio of this technology and way of working. Additionally, to mitigate perceived risks, nurses suggested adding video call options for remote clinical assessments by monitoring nurses.

Key words: remote monitoring; home monitoring; telemedicine; continuous vital sign monitoring; wearable wireless monitoring; clinical deterioration; e-health; telehealth; vital signs; blood transfusion; home transfusion; qualitative research.

1. Introduction

Cancer incidence rates continue to rise globally, posing a significant healthcare challenge [1]. In the Netherlands, there has been a shift towards administering treatments like blood transfusions in the home environment as part of the 'Integraal Zorgakkord (IZA)' efforts to ensure that the right care is provided at the right place (optimal care delivery) [2]. However, this transition has inadvertently transferred a burden to nurses, who must stay with the patient throughout the entire home-based transfusion time which can be as long as 4 hours, for safety reasons. Despite the necessity for constant supervision, the likelihood of equipment malfunctioning or adverse reactions is minimal, with severe adverse events occurring at an overall rate of just 0.05% [3, 4] The need for constant oversight leads to inefficiencies in resource allocation and time management. This exacerbates the burden on health care professionals (HCPs), amidst a growing shortage of healthcare personnel. The pressing need for a future-proof, more effective, and efficient healthcare solution becomes increasingly apparent to ensure the sustainability of our healthcare system.

To address these challenges and optimize home-based transfusion care delivery, continuous monitoring technologies offer promising solutions [5, 6]. Among these, a Remote Patient Monitoring (RPM) solution like smartQare's viQtor system stands out as a potential solution. Designed to continuously measure vital parameters on the upper arm, viQtor provides real-time insights into patient health status during transfusion procedures, including Pulse Rate, Respiratory Rate, Oxygen Saturation, and skin temperature.

This study aims to explore the benefits and challenges associated with integrating the smartQare's viQtor system into home-based clinical practice. Insights from nurses and patients are crucial for enhancing the implementation of viQtor in home-based transfusions and can also be valuable for other home-based therapies, such as immunotherapy, that also require nurse supervision. By emphasizing the benefits and challenges of RPM, we aim to equip HCPs, policymakers, and stakeholders with the insights needed to enhance patient care and optimize resource allocation within the context of home-based medical interventions

In this whitepaper, we describe an investigation into the implementation prospects of integrating the viQtor wearable into home-based transfusion protocols.

2. Methods

2.1 Study Design and Setting

A single-center observational cohort study was conducted from March to May 2024 during homebased blood transfusion administration. The study was led by a Healthcare Innovation researcher in collaboration with Savant Zorg nurses and patients under the care of oncologists at the Elkerliek Ziekenhuis in the Netherlands.

2.2 Participant Selection

Patients scheduled for home-based blood transfusion between March and May 2024 were approached by the nurse planner to participate in the viQtor study and sign informed consent. A minimum of six patients was required. Inclusion criteria were as follows: age ≥ 18 years, medical indication for blood transfusion, under the care of a specialist at Elkerliek, and having undergone at least one previous transfusion.

In addition, nurses responsible for administering home-based blood transfusions were invited to attend a training session with the viQtor and participate in a focus group. A minimum of six nurses were targeted for the focus group. Inclusion criteria were: employed by Savant Zorg and involved in administering home-based blood transfusions.

2.3 Remote Home Monitoring

The viQtor device is a wearable RPM device, certified by the Medical Device Regulation (MDR) Conformité Européene (CE), designed and used for monitoring patients in various clinical and home settings. This RPM device, worn on the upper arm, continuously measures vital sign parameters such as Pulse Rate (PR), Respiratory Rate (RR), Oxygen Saturation (SpO2), skin temperature, and activity level with a battery life of 5-7 days. Additionally, it calculates a continuous Early Warning Score (c-EWS) based on the three key vital parameters (PR, RR and SpO2), providing valuable insights into the patient's health status. In addition, viQtor is equipped with a personal assistance request button and fall detection capability. In case of an event, such as exceeding a measurement threshold, falling, or sending an assistance request, the device sends a notification to the viQtor cloud platform.

One minute measurement data are transmitted securely every 5 minutes via a mobile NarrowBand Internet of Things/ LTE-M (NB-IoT/LTE) network to a cloud environment. In the cloud, the data are securely stored and accessible through the viQtor web portal. This platform offers multiple features, including visualization of vital sign data and configurable event notifications.

2.4 Study Procedures

At the beginning of the data collection period, seven patients scheduled for home-based blood transfusion were approached by the nurse planner. They received information about the home monitoring study and were asked to provide informed consent via mail

Before the start of the data collection period, fifteen nurses received training on the use of viQtor and its associated platform.

Subsequently, upon initiation of the home-based blood transfusion, the viQtor wearable was applied at the upper arm of each patient. In addition to this, nurses adhered to the standard of care protocol, which involves performing manual spot checks of blood pressure, pulse rate, and core temperature at the start, ten minutes in, and at the end of each packed cell transfusion.

In addition, after completing the initial manual checks, the nurse relocated to a separate room near the patient to log into the web portal. They responded to events from the portal, with threshold values for vital signs set according to the 'Modified Early Warning Score' (MEWS) [7]. They received event notifications whenever PR, RR, and/or SpO2 values exceeded the orange/red thresholds (Table 1). Whenever an event occurred or the patient requested assistance, the nurse checked on the patient and performed additional manual checks following the standard protocol.

The nurse remained present throughout the entire administration, not in the same room but in close proximity to the patient. This scenario suggests that, in the future, a nurse may no longer need to be physically present.

Parameter	Red	Orange	Green/Yellow	Orange	Red
SpO2	< 85	85-89	≥90%	-	-
Pulse Rate		< 40	41-110	111-129	≥130
Respiratory Rate		< 9	9-20	21-29	≥ 30

Table 1. Threshold values based on the MEWS, orange and red resulting in event notifications [7].

2.4.1 Patient Experience - Interviews

Following the transfusion session, the researcher conducted an online interview with the patient (once per patient) using Microsoft Teams and following a semi-structured format. The interview format was derived from the validated Dutch System Usability Scale questionnaire (D-SUS) [8], which assesses user experience, usability, motivation, needs, and thoughts of the respondent (Appendix I, see Appendices).

A score above 68 is generally considered the threshold for "good" usability. This means that a score of 68 or higher indicates that the system is generally perceived as usable by users. These interviews were audio-recorded, automatically transcribed, and corrected by the researcher when necessary. To minimize the burden on patients, interviews were limited to a maximum of 15 minutes.

2.4.2 Nurse Experience – Focus Group

Two weeks before the data collection ended, a focus group session with seven nurses was conducted to gather their experiences with viQtor. The session, lasting about two hours, was audio- and video-recorded, led by an external moderator, and observed by a researcher. Nurses first listed positive and negative experiences, followed by the "I like, I wish, I wonder" evaluation method to provide comprehensive feedback. The moderator then reviewed the results with the nurses. Afterward, the session was transcribed by the researcher for thematic analysis, and the session dynamics were evaluated.

2.5 Data Analysis

To analyze the qualitative data, a directed content analysis was performed using a codebook derived from interview and focus group guidelines. Patient interviews and the nurse focus group data were analyzed separately. Initially, patient transcripts were repeatedly reviewed, with relevant data categorized into subcodes and grouped into main codes according to the guidelines. In the second phase, transcripts were re-read to identify any remaining uncoded text, which led to the creation of new subcodes and main codes. The main topics were then updated, and the findings are presented according to these themes in the results section.

3. Results

3.1 Study Characteristics

Table 2 shows the patient characteristics (N=7) and Table 3 shows the nurse characteristics (N=7).

Patient	Gender	Age	Frequency of	Years of experience with
ID			transfusion	home-based transfusion
P1	Female	58	1x per 3 weeks	1
P2	Male	80	1x per 2 weeks	2
P3	Male	59	1x per week	3
P4	Female	66	1x per 3 weeks	2
Р5	Female	78	1x per 3 weeks	4
P6	Male	81	1x per week	3
P7	Male	59	1x per week	3

Table 2. Patient characteristics.

Nurse	Gender	Age	Educational level	Years of experience with
ID				home-based transfusion
N1	Female	53	HBO	2
N2	Female	59	НВО	4
N3	Female	47	MBO	2
N4	Female	34	MBO	5
N5	Female	33	НВО	3
N6	Female	51	MBO	5
N7	Male	31	MBO	1

HBO: higher professional education, MBO: secondary vocational education.

3.2 Patient Experiences

Patients had extensive experience with home transfusions. The duration of patients receiving intermittent home transfusions ranges from one to a maximum of four years, with the frequency varying from weekly to once every three weeks (Table 1). Over the past four years, no (severe) adverse events have been reported. Patients with one to four years of home transfusion experience expressed a clear preference for home transfusions over hospital transfusions due to the comfort of their homes and travel time savings. They feel more at ease in their own environment and appreciate the reduced dependency on informal caregivers for transportation. "Yes, I really like that it can be done at home, that I don't have to go to the hospital because then I lose a whole day, and here I am in my own environment. And yes, I actually feel more at ease" (P4).

None of the patients had personal experience with RPM. Some had read about it in the newspaper or had indirect experiences through family members who had used RPM. The coding scheme of the thematic analysis can be found in the Appendices.

User experience from patient perspective

The use of the wearable viQtor device was generally positively evaluated by the patients. They indicated that wearing the device was hardly noticeable, the size was acceptable, and the band was generally comfortable to wear. Additionally, patients experienced the use of viQtor as not complicated.

Technological advantages mentioned by the patient were fall detection, the ability to send an personal assistance request, and the continuous measurement of vital signs. While these features were highly valued, some patients also expressed a desire for real-time access to their health data on the wearable viQtor device. It is important to ensure that this access does not lead to unnecessary anxiety, particularly when health deterioration is detected. Striking a balance between patient empowerment and minimizing distress is crucial and should be further investigated.

Privacy

Patients indicated that they had no concerns about privacy and the stored measurement data. "I don't have much trouble with it, it must be safe, of course, but yes, that's in healthcare" (P7).

Interaction with the nurse

During the study, the nurse stayed in a different room whenever possible during the transfusion. Some patients noticed a difference in interaction with the nurse, while others did not. This highlights the importance of balancing technology with personal care, ensuring that the human element remains an integral part of care.

Safety and trust

There is confidence in the measurements recorded by viQtor: "It's just good, I don't notice anything, so it's just good." (P6) and there is no distrust: "No, I don't worry about that at all." (P4). Patients were asked if they could imagine the nurse leaving temporarily to provide other care and how they would feel about this. The majority of patients could imagine this: "If they were to perform another task nearby, say pulling someone's socks off or something. No, I wouldn't mind." (P5). Some patients expressed concern that the distance to the nearest patient could affect their sense of safety. They emphasized the importance of knowing that a nurse could return quickly if needed.

3.3 Nurse Experiences

Nurses had between one and five years of experience with home transfusions and their experience with home transfusions has been positive (Table 3). Most of the nurses have also performed this treatment in the hospital. They express enthusiasm about engaging with innovation and view remote monitoring as the future of healthcare. "*I think it's good that this is being looked into. I also feel really positive about working with it.*" (N7). The coding scheme of the thematic analysis can be found in the appendices.

User experience from the nurse perspective

The use of the viQtor solution, which allowed nurses to access measurements during home transfusion, provided them with peace of mind to perform other tasks in a different room. "Yes, you just have the measurements visible on your screen while you're somewhere else. Measuring is knowing." (N1).

Continuous measurement of vital signs was also positively received, as it provides ongoing insight into the data and ensures that health decline will be early detected and communicated: "Continuous monitoring is a luxury at the moment because normally we measure at the start, then again after fifteen or ten minutes, and that's it!" (N2). Nurses also indicated that continuous monitoring benefits patients since they can sleep without being disturbed for spot checks. They found the viQtor easy to use. The band was easy to apply, and the device was simple to operate. Since this was the first time nurses were introduced to RPM and they had used viQtor for a short period on a relatively small patient group, they are not yet fully comfortable leaving patients unattended. However, there is a positive outlook for the future use of RPM. With further practice, training, and support, nurses are expected to gain more confidence in this technology.

Vital signs

The continuous measurement of three vital signs was viewed positively. Measuring Oxygen Saturation was seen as advantageous. "With this client, I quickly realized there was an issue with the saturation, which we don't normally measure during blood transfusions. Even a manual measurement gave no result. This, combined with what I observed—a man with cold extremities and increasing shortness of breath—led to the decision to have him picked up by ambulance for a check-up at the hospital" (N2). The ability to measure multiple parameters simultaneously, reducing the need for nurses to perform spot checks, was highly appreciated. Nurses indicated that adding blood pressure measurement to the viQtor could provide significant value, offering extra confidence for leaving the patient unattended during home transfusions.

Interaction with the patient

Nurses indicated that they often enjoy the time spent with patients during home transfusion. "Some nurses initially expressed concerns about whether they would still have enough patient contact with the introduction of RPM. However, through this brief study, participants observed that there is still ample opportunity for meaningful communication while connecting the infusion bags. At the same time, the process has become more efficient, allowing the nurses to manage their time more effectively.

Trust and safety

Some nurses look forward to the time when they can actually work with this system. It is important to allow them sufficient time to familiarize themselves with the new technology and integrate it into their current workflow: "Yes, I am looking forward to deploying it, if innovation goes well, I think it could become something. I see the positive side of it." (N7).

When asked about their feelings on leaving a patient alone, nurses mentioned feeling a strong sense of responsibility and uncertainty. The thought that a situation might arise with the patient that they cannot respond to immediately causes concern. Situations that nurses believe could occur include subcutaneous infiltration or an infusion pump alarm. However, with the viQtor as a RPM solution, early signs of patient deterioration can be detected, which is a significant benefit. Despite this, nurses acknowledged that they need more time to become familiar with the device and fully integrate it into their practice. *"Yes, maybe it's a bit of insecurity, as I wrote down. I don't know if it's just me, but it does make me a bit insecure because I have a very strong sense of responsibility." (N4)*. When asked if something serious could go wrong, they said: *"It doesn't happen often, but the chance isn't zero." (N2)*. Nurses indicated that confidence in leaving the patient unattended could be enhanced if someone, such as an informal caregiver, household helper, or volunteer, were present with the patient during home transfusion. This

approach could be beneficial during the initial implementation phase, as it would ease the transition and gradually build trust in the ability to monitor the patient independently.

Acceptance

Nurses could imagine viQtor being used in the future for home transfusions. "I think it fits this time; we have to provide care differently, and this is an example." (N2). They also mentioned that more patients could be helped simultaneously and that it could save time. They enjoyed working with new technology and believed that the organization and insurers expected them to. "How can it be otherwise? Using fewer nurses, so we can use them for more patients instead of sitting there for hours, letting them do something else in the meantime." (N2).

According to the nurses, there are still prerequisites that must be met before viQtor can be employed during home transfusions, such as establishing clear protocols and making agreements on who is responsible for acting on data. "*There needs to be an emergency plan in place [...] and, of course, more practice is necessary.*" (N7).

4. Discussion

4.1 Principal findings and comparisons to previous work

The study explored the potential and challenges associated with implementing Remote Patient Monitoring for home-based transfusions, offering insights from patients and nurses. Patients and nurses both acknowledge the potential of the viQtor solution. Patients appreciate the convenience of continuous monitoring, the autonomy it provides, and its alerting capabilities. Nurses emphasize its user-friendliness, time-saving benefits, and the potential to support more patients concurrently. While there are considerations about ensuring patient safety in the absence of a nurse, nurses are optimistic about addressing these through creative solutions. They see opportunities to enhance acceptance, safety, and trust by involving informal caregivers more actively and incorporating video calls, which could provide additional reassurance and strengthen the overall care experience. ViQtor can enhance patient autonomy and nurse efficiency by necessitating change in nurses' clinical decision-making and workflow. Key prerequisites for acceptance include trust in measurements, health deterioration detection capabilities, and direct communication options.

Despite limited familiarity with RPM, currently patients expressed confidence in viQtor. This confidence often stems from patients' trust in healthcare professionals' competence, as indicated by Montague et al. (2010). Patients in this study have longstanding relationships with nurses, reinforcing their trust.

Some nurses highlighted the importance of viQtor's measurement reliability, aligning with insights from Areia et al. (2021). They recognize the value of incorporating blood pressure and core temperature measurements to enhance its ability to detect deterioration. However, recent studies emphasize that blood pressure (BP) and core body temperature (CBT) are often considered late indicators of clinical deterioration [18, 19]. These vital signs tend to change after other parameters, such as respiratory rate and oxygen saturation, which can provide earlier signs of worsening health. Therefore, it is essential to further investigate the true significance of BP and CBT monitoring during home blood transfusions, to determine how critical these measurements are in detecting early health deterioration and improving patient outcomes.

Nurses also emphasize the significance of their clinical assessment skills, which they believe are important for ensuring patient safety. They see these considerations as opportunities to further refine and improve the system for optimal patient care.

Studies by Card et al. (2012) and Nishikawa et al. (2021) support the effectiveness of continuous monitoring in early detection during transfusions [12,13]. Clinical examples of patient deterioration detection based on PR, RR, and SpO2 could help with obtaining nurse's trust. For now, they are used to measuring blood pressure, temperature, and pulse rate so it is logical that they feel like they need those measurements to assess the patient.

Most patients valued personal interaction with nurses during home transfusions. Therefore, the introduction of RPM raised awareness about the potential loss of personal contact in the absence of a nurse, supported by Al-Naher et al. (2022). The included patients were all used to home transfusions, with the additional personal contact. However, with the growing nursing shortage, this may not be an essential component of transfusion care fulfilled by the nurse. For new transfusion patients unaccustomed to this additional contact, the absence of it may not necessarily be perceived as lower quality of care. Personal contact opportunities would still be available during setup, blood bag changes, and conclusion of the transfusion.

To enhance the successful implementation of a RPM device such as the viQtor, nurses mentioned the option of involving informal caregivers, as highlighted by Madgwick and Yardumian [15]. Trained caregivers can facilitate the patient's transition to self-care, ensuring both personal contact and necessary assistance. This approach supports the monitoring nurse in case of any issues, alleviating safety concerns providing extra confidence, particularly important during the initial implementation phase.

Besides, access to on-site support from a dedicated nursing ambassador is vital for boosting nurses confidence and competence with the technology. A knowledgeable and enthusiastic nursing ambassador can provide effective guidance to new users, ensuring a smooth transition to RPM. Consistent with the findings of Taylor et al. (2015), effective training and clear instructions are critical to the successful adoption of RPM [16]. Increased knowledge not only enhances acceptance and enthusiasm but also strengthens trust in the technology.

Trust is further reinforced through regular use, personalized training, and instruction tailored to the individual nurse's needs and digital skills, as described by De Leeuw et al. (2020). These strategies collectively ensure that nurses are well-equipped to embrace and excel in remote monitoring practices.

4.2 Limitations

This study has a few limitations. Only a small participant group of both patients and nurses was included; therefore, the results only reflect this specific cohort. However, given the exploratory nature of the study, a smaller sample group is appropriate to gather preliminary insights into the usability and acceptance of the viQtor. Additionally, interviews via Microsoft Teams may have introduced response bias, which should be considered when interpreting the patient's results. Finally, the short study duration may limit familiarity with the viQtor and RPM, yet is still provided valuable information on initial user experiences. In fact, the quick recognition of benefits such as interrupted sleep, increased efficiency, and patient autonomy suggests that extended use will only strengthen these positive outcomes.

4.3 Future directions

Based on these findings, the following recommendations are proposed to enhance the use of RPM for home blood transfusions. First, identify the necessary vital signs to detect patient deterioration during blood transfusions. Additionally, train caregivers and involve them in home transfusions during the initial implementation phase to alleviate concerns and enhance safety, promoting remote monitoring acceptance, and increasing autonomy for both patients and caregivers while reducing dependence on HCPs. Develop tailored training programs that focus on the technical aspects and troubleshooting of RPM, ensuring they meet the individual learning needs of the nurses, regardless of their digital skills. Lastly, appoint nursing ambassadors with comprehensive knowledge of RPM to inspire and support new users, thereby boosting nurses' confidence and competence in remote monitoring utilization.

4.4 Conclusions

In conclusion, this exploratory qualitative study highlights both the potential and challenges of implementing remote patient monitoring (RPM) for home-based transfusions with the viQtor system. The findings suggest that RPM can significantly enhance patient autonomy and nurse workflow efficiency by providing continuous monitoring and supporting a larger number of patients simultaneously. Patients appreciate the convenience and alert capabilities of the system, while nurses value its user-friendliness and time-saving aspects. The study underscores the importance of involving caregivers informal during the initial implementation phase, ensuring robust training, and providing onsite support to foster trust and competence in using the technology. Overall, RPM with viQtor presents a promising advancement in home transfusion care. Its successful implementation will depend on addressing safety concerns, maintaining personal contact where possible, and supporting both patients and nurses through adequate training and resources.

5. Abbreviations

CE	Conformité Européene
c-EWS	continuous Early Warning Score (viQtor)
D-SUS	Dutch System Usability Scale MEWS Modified Early Warning Score
NB-IoT/LTE-M	Narrowband Internet of Things/Long-Term Evolution for Machines
PR	Pulse Rate
RR	Respiratory rate
RPM	Remote Patient Monitoring
SpO2	Blood Oxygen Saturation

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7. Appendices

Note: "The appendices containing supplementary data are available upon request by contacting the author(s).