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Feasibility, acceptability and usability of a thermolabile drugs storage monitoring system at patient's home: a pilot study

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This pilot study evaluates the feasibility, acceptability, and usability of an innovative sensor driven monitoring system designed to ensure the proper conservation of thermolabile medications stored in patients' homes. The system enables continuous temperature monitoring from the time of dispensing at the hospital pharmacy through domestic storage and incorporates a three tier, color coded alert mechanism (OK–Alert–Risk) to prompt timely corrective actions and prevent improper storage. Twenty-three patients receiving thermolabile medications participated over a several week period. The system demonstrated high usability, with a mean System Usability Scale (SUS) score of 82.5, indicating excellent user acceptance. Feasibility was supported by an average continuous sensor operation time of 17.5 days and a maximum deployment duration of 112 days. Patient acceptability was considered good, as reflected by a Net Promoter Score of 17.5. Thirteen alert events were detected during the study; two were successfully resolved through patient intervention, while seven progressed to Risk status, indicating improper storage. Overall, the findings support the system's potential to enhance medication safety, promote patient engagement, and provide actionable real time data for pharmacy teams, informing future large scale clinical implementation.

Temperature sensitive pharmaceutical products, or thermolabile drugs (TD), require strict storage conditions to maintain their stability and effectiveness[1]. These medications typically must be refrigerated between 2 and 8 °C, and maintaining an unbroken cold chain from manufacture to administration is essential to ensure product quality and therapeutic efficacy. Any deviation from recommended temperature ranges can compromise both safety and effectiveness.

Within established pharmaceutical distribution channels—including manufacturers, wholesale distributors, and hospital or community pharmacy departments—cold chain integrity is safeguarded through specialized equipment, standardized procedures, and adherence to the European Guidelines on Good Distribution Practice for medicinal products for human use (2013/C 343/01)[2]. These professional environments are equipped to maintain optimal storage and transport conditions (Fig. 1).

However, once TDs are dispensed to patients for home use, they leave this controlled infrastructure. Transport from the hospital to the home, as well as subsequent domestic storage, typically occurs without monitoring systems or automated alerts. As the use of high cost and highly sensitive biological medications continues to increase, ensuring appropriate storage conditions in patients' homes has become a growing concern and a shared responsibility between healthcare providers and patients.

Previous studies have shown that home storage practices are frequently inadequate. Early research in Spain reported that only 50% and 41.7% of patients maintained medications within an average temperature range of 2–8 °C[3,4]. More recent analyses of biological therapies found even lower compliance, with only 6.7% of patients achieving appropriate storage, and specific investigations—such as for golimumab—showing correct storage in just 11.6% of doses[5,6]. In our own setting, only 2.8% of dispensed TDs were stored correctly[7]. Additional work by Santin et al.[8] demonstrated that only 17.3% of patients with inflammatory rheumatic diseases maintained

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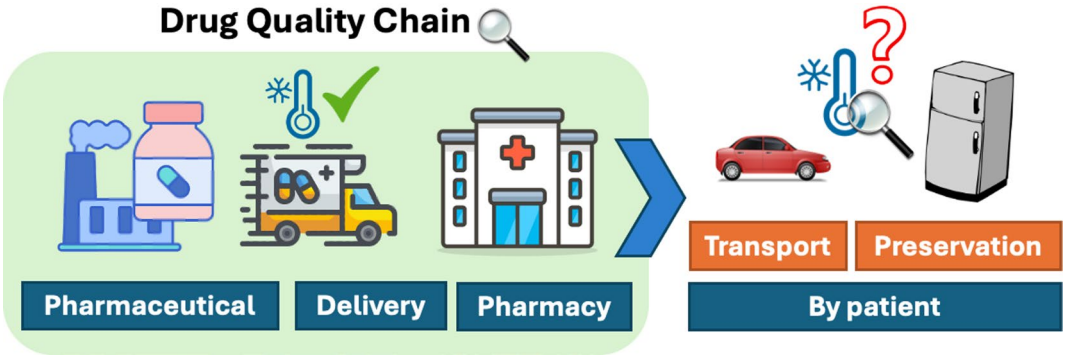

Fig. 1. Drug quality chain when involve patients should be extended.

their biological therapies (adalimumab, etanercept, golimumab, secukinumab, certolizumab, abatacept) within recommended temperature limits.

Collectively, this evidence indicates that most TDs are not stored adequately in patients' homes, highlighting a significant gap between manufacturer recommendations and real world practices. Efforts to improve storage conditions have been made; for example, Haegens et al.[9] showed that using a commercially available temperature logger paired with a mobile application improved storage conditions, although technical limitations were substantial.

Advances in digital health technologies now make it feasible to develop reliable, automated remote sensing systems that can continuously monitor medication storage conditions outside clinical environments. Building on this opportunity, we developed QChainMED, an Internet of Things based monitoring platform designed to extend cold chain oversight into the patient's home.

The primary objective of this study was to evaluate the feasibility, acceptability, and usability of the QChainMED system for monitoring TDs in real world home settings, with particular attention to adoption and user experience among both patients and healthcare professionals.

Materials and methods

Study design

This prospective observational study was conducted in outpatients receiving thermolabile drugs (TD) dispensed by the Pharmacy Department of Son Espases University Hospital (Palma de Mallorca, Spain). The primary objective was to evaluate the feasibility, acceptability, and usability of QChainMED, an Internet of Things (IoT)—based platform designed to extend the cold chain quality assurance process from the hospital setting into the patient's home. The following subsections describe the components of the quality chain extension, the characteristics of the QChainMED infrastructure, and the overall study procedures.

QChainMED: extending the drug quality chain

QChainMED was developed to ensure the preservation of TD after they leave the controlled environment of the hospital pharmacy. The system supports continuous, remote monitoring of storage conditions during the three critical stages of the medication's journey (Fig. 2):

1. Initialization,
2. Transport by the patient, and.
3. Domestic storage.

During the initialization stage, a hospital pharmacist assigned an individual sensor to one of the medication units and linked it to a patient specific gateway that was later installed at the patient's home. The sensor was calibrated and associated with the specific drug package to guarantee accurate traceability and to ensure that environmental monitoring began as soon as the medication left the hospital.

The transport stage corresponds to the period in which the patient personally transports the drug from the hospital to their home. This segment represents the most vulnerable phase regarding temperature excursions because it occurs outside controlled environments and may involve delays or exposure to adverse ambient conditions. Throughout this period, the sensor continuously recorded environmental data, enabling detection of any deviations from recommended temperature ranges.

Once the medication reached the patient's home and was placed in a domestic refrigerator, the conservation stage began. The sensor remained active throughout the entire storage period, collecting longitudinal data to verify that conditions remained appropriate until the medication was administered.

QChainMED platform and data management infrastructure

The QChainMED platform integrates three key components: the sensor, the patient's gateway, and the hospital servers. The patient gateway, specifically designed for adaptability, was installed in the participant's home. Its functions included collecting sensor data, conducting preliminary analyses of storage conditions, and generating local alerts for the patient if potential conservation problems were detected. This design reduced the need

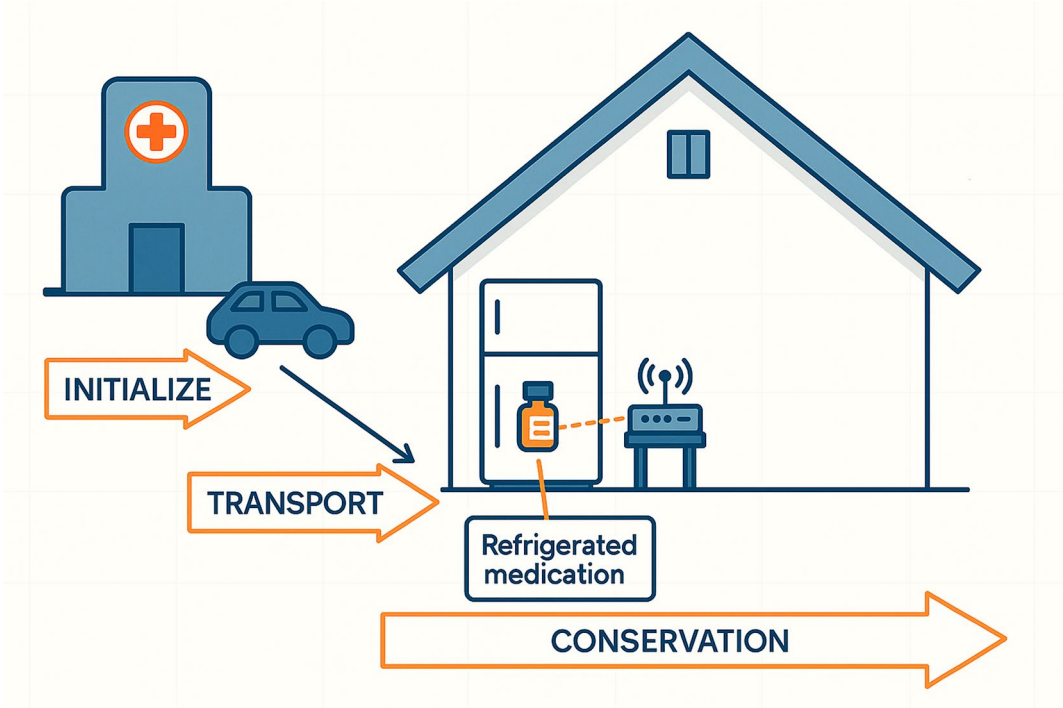

Fig. 2. Schematic drug quality chain extension when involve patients.

for external technical assistance and ensured a minimum device autonomy of four months, even without a continuous remote connection.

Communication between the sensor and the gateway was established using Bluetooth Low Energy (BLE) to minimize power consumption. Data were subsequently transmitted from the patient's home to the hospital servers through either via WiFi, when available, or LoRaWAN, via a public network deployed by local authorities (IOTIB). When transmitted via LoRaWAN, data were routed through a secure LoRa server before reaching the hospital infrastructure (Fig. 3).

A second gateway, located in the hospital pharmacy, was used exclusively during the initialization phase to activate sensors and link them to their corresponding TD units.

The server system consisted of two components: a data management server, responsible for receiving sensor data and distributing configuration parameters to patient gateways, and an application server, hosting the user interface accessed by healthcare professionals (Fig. 4).

This interface enabled management of patient gateways, visualization of sensor data, analysis of environmental conditions, and handling of alarm notifications issued to patients or pharmacists.

A more detailed description of the technological architecture and digital services implemented by the QChainMED platform can be found in[10].

Study population and procedures

Eligible participants were adults (≥18 years) receiving commonly dispensed thermolabile medications such as adalimumab, darbepoetin, etanercept, erythropoietin, omalizumab, alirocumab, or peginterferon alfa2a. Additional inclusion criteria included a dispensing interval of one to three months and the ability to provide written informed consent. Exclusion criteria consisted of refusal to participate, concurrent enrollment in other clinical studies, inability to understand study procedures, or technical obstacles preventing installation of the monitoring system at the patient's home.

At dispensing, eligible patients were invited to participate and completed a questionnaire addressing factors that could influence drug storage. Following consent, an engineer and a pharmacist visited the patient's home to install the gateway. The sensor, capable of measuring temperature, humidity, vibration, and ultraviolet exposure, was attached to one medication container.

During transport, the sensor operated in datalogger mode. Once it connected to the home gateway, it switched to continuous monitoring, transmitting data every 10 s. The gateway aggregated these data into 10 min summaries for transmission to hospital servers. Oversampling was used to improve data accuracy and reduce measurement noise. When deviations from recommended conditions occurred, the gateway issued alerts to the patient.

Definition of improper storage and real time condition classification

A medication unit was considered improperly stored if temperatures fell outside manufacturer specified limits. Temperatures above 25 °C or below 0 °C were classified as risky, while intermediate deviations (between 0

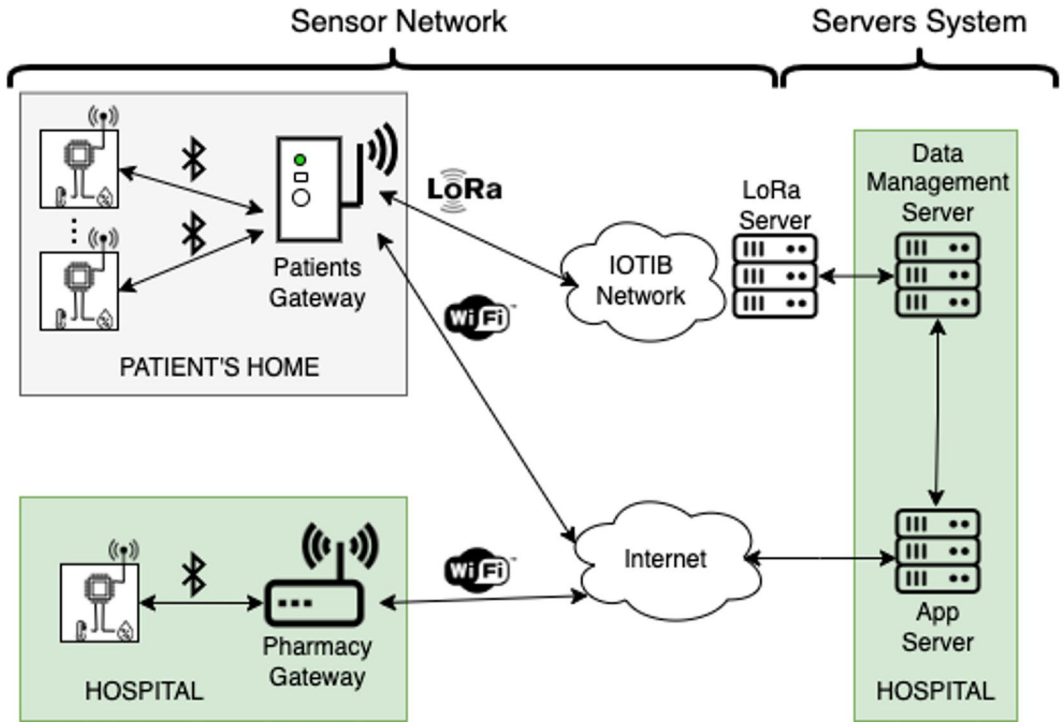

Fig. 3. QChainMED architecture with the different elements forming the monitoring system beyond hospital.

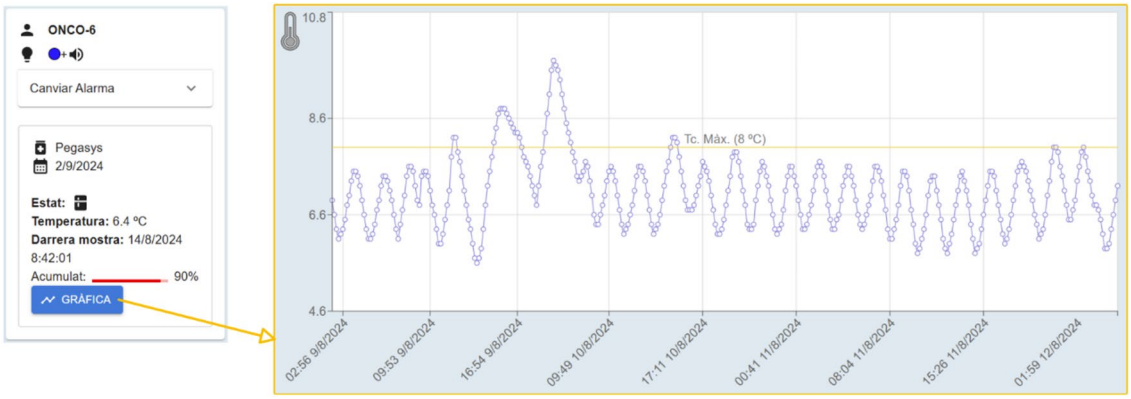

Fig. 4. Monitoring interface presenting key information and historical data.

and 2 °C or between 8 °C and 25 °C) were considered inappropriate when sustained beyond product specific cumulative exposure limits. These tolerances varied by drug type: adalimumab (Hyrimoz®), 21 days; darbepoetin (Aranesp®), 7 days; etanercept (Benepali®), 31 days; erythropoietin (Retacrit®), 3 days; omalizumab (Xolair®), 48 h; alirocumab (Praluent®), 30 days; and peginterferon alfa-2a (Pegasys®), 24 h. Pegasys® specifications were obtained directly from the manufacturers, as they are not reported in the official Summaries of Product Characteristics.

To enhance patient safety, the system incorporated a real time classification mechanism within the patient gateway. Each medication was assigned one of three states based on strictly cumulative time exposure outside recommended temperature ranges (Fig. 5):

- OK: conditions within limits or < 50% of the allowable cumulative exposure.
- ALERT: ≥50% of allowable exposure reached, generating a visual blue warning.
- RISK: cumulative exposure exceeded maximum tolerance; the gateway displayed a red warning signal.

This tiered model was designed to promote patient autonomy and enable early intervention before drug viability was compromised.

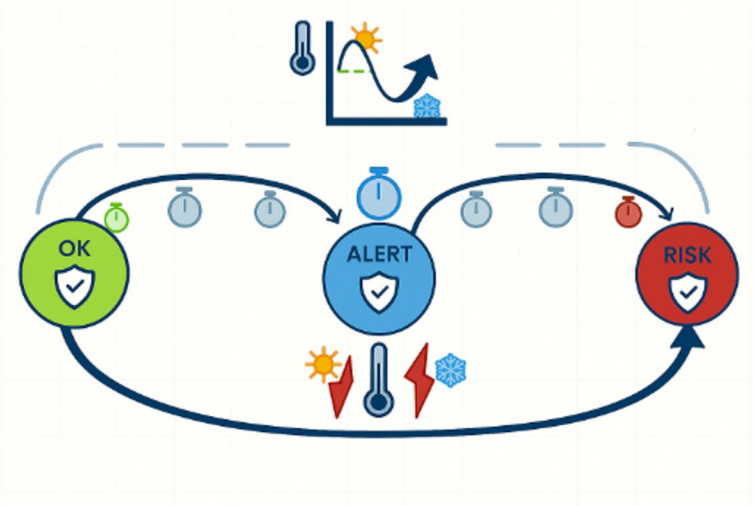

Fig. 5. Conceptual workflow of real-time storage conditions evaluation mechanism with three discrete statuses.

Endpoints

A detailed description of the feasibility, acceptability, and usability endpoints can be found in the supplementary information.

Ethics approval

This study was approved by the Ethics Committee of the Balearic Islands. Reference Number IB 5176/23 PI. All the interventions were performed in accordance with relevant guidelines and regulations.

Results

A total of 40 patients were invited to participate in the study, of whom 25 agreed (62.5%). Two participants were excluded—one due to unsuccessful installation and one for being under 18 years of age—resulting in 23 included patients. Seventeen patients completed the final questionnaires. The study flow is summarized in Fig. 6, and patient characteristics are presented in Table 1.

Feasibility

A. Recruitment:

Of the 40 patients approached, 25 (62.5%) agreed to participate. The most common reasons for declining participation were lack of Wi Fi access and reluctance to have a continuous monitoring system at home (Fig. 6). Among the 15 patients for whom a date of last administration was documented, the median follow up duration was 49 days (range 1–84 days).

B. Data:

All systems experienced at least one interruption in data transmission lasting more than 24 h. Nineteen gateways were connected via Wi Fi, two via LoRaWAN, and two remained unconnected throughout the study.

The system registered 13 total alerts: 6 blue (ALERT) and 7 red (RISK) warnings. Four of the blue warnings progressed to red, while three alerts were directly classified as red.

C. Intervention.

Seventeen of the 23 participants (74%) completed the full study protocol.

Among the six blue warnings, patients did not respond in two cases. For red warnings, only one of the six alerts did not receive patient acknowledgment.

D. Implementation.

- The estimated time required to complete patient screening and recruitment was 15.5 min per participant (range 10–20 min).
- The average time from dispensing to full installation of the sensor and gateway was 12 days, primarily due to patient scheduling limitations.
- Gateway installation itself required approximately 15 min (5 min for hardware setup and 10 min for confirmation of first data transmission).

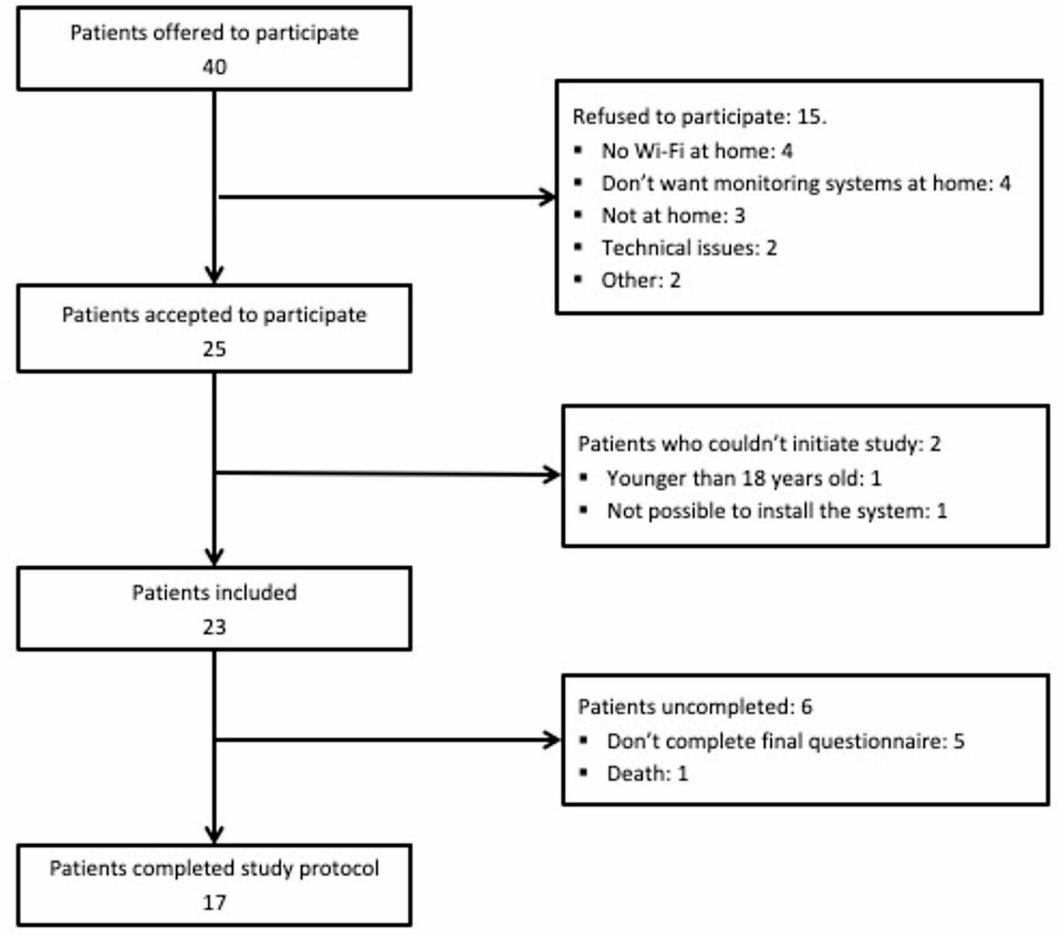

Fig. 6. Patients' flowchart.

	***n* = 23**
Sex (*n*, %)	Female (17, 74%)
Age (median years old, range)	52 (28 to 87)
Thermolabile drug (n, %)	
Adalimumab	10 (43.5%)
Erythropoietin	3 (13%)
Omalizumab	3 (13%)
Peginterferon alfa 2-a	3 (13%)
Alirocumab	2 (8.7%)
Darbepoetin	1 (4.4%)
Etanercept	1 (4.4%)

Table 1. Patient characteristics.

- Estimated manufacturing costs were 14 € per sensor beacon that can be reused by simply recharging the battery and 130 € per patient gateway.

Acceptability

Among the 17 patients who completed the study, 8 participants were classified as promoters (answered 9 to 10), 5 as detractors (answered 0 to 6) and 4 as passives (answered 7 or 8), yielding a positive Net Promoter Score of 17.5.

Usability

The system achieved a median System Usability Scale (SUS) score of 82.5 (interquartile range 70–90).

Notably, 11 patients scored the system at 80 or higher, indicating excellent perceived usability.

Discussion

The system designed to monitor TD in the patient's home appears feasible, acceptable—reflected by an NPS of 17.5—and usable, with a median SUS score of 82.5. To our knowledge, aside from the study by Haegens et al.[9], no other investigations have evaluated the feasibility, acceptability, and usability of a system capable of continuously monitoring TD storage conditions at patients' homes. This lack of comparable studies limits extensive contextualization, but underscores the novelty of our work.

There are few studies reporting acceptability using the NPS, and the results are highly variable. An application to support patients with axial spondyloarthritis by providing instructions for yoga-based home exercise therapy obtained a NPS of − 26 with only a 15% (9/65) of promoters[11], while two studies focused on reported outcomes[12] and biometrics monitoring[13] in cancer patients and their caregivers showed higher NPS scores, 30 and 55, respectively. Possibly, the different type of interventions and the different population could explain these highly variable NPS. Within this landscape, the positive NPS achieved in the present study suggests a generally favorable patient perception.

Regarding feasibility, 40 patients were offered to participate in our study and 15 refused, which represents a 62.5% of acceptance rate. The main reasons for refusing participation were the absence of an own Wi-Fi and not wanting to have monitoring systems at home. Although the systems and inclusion strategy differ, our result appears higher than the 24% reported by Haegens et al.[9], where 640 patients were invited to participate and only 151 agreed. This may indicate that an intuitive and minimally intrusive system could improve patient willingness to participate in temperature monitoring initiatives.

Technical performance revealed that all participants experienced at least one interruption in data transmission lasting more than 24 h. These interruptions were likely attributable to communication failures between sensors and gateways, or between gateways and the hospital server infrastructure. In real-world deployments, such interruptions may occasionally be unavoidable due to factors such as temporary power outages, system desynchronization, or gateways being unintentionally disconnected by patients. Importantly, no data were lost, as the system successfully transmitted stored information once connectivity was restored. This finding highlights the need for further optimization of communication reliability, but supports the robustness of the data recovery mechanism. A total of 13 alerts were detected, with some blue warnings escalating to red. In two cases, patients did not respond to blue alerts, whereas nearly all red warnings were acknowledged.

The overall proportion of patients who adhered fully to study procedures (17 of 23; 73.9%) aligns with adherence levels reported in other remote monitoring feasibility studies across diverse patient populations and disease areas. In heart failure, 19 of 25 patients (76%) completed all trial activities in a study which evaluated a 30-day digitally enabled intervention[14]. A recent study, aimed to assess feasibility of remotely monitoring spirometry and pulse oximetry in 60 patients with interstitial lung disease, found a 77% (46 of 60) and 83% (50 of 60) of adherence to spirometry and pulse oximetry, respectively[15]. In 16 older patients, 88% of participants (n = 14) adhered completely to a lifestyle program supported by an mHealth platform[16], and Weng et al.[17] found that, in 95% (19 of 20) of patients receiving radiotherapy, biometric data were successfully transmitted to the electronic medical records. Although there is room for improvement, adherence greater than 70% is frequently considered acceptable in feasibility research.

Usability results were consistent with prior digital health interventions that reported SUS scores above 80. For example, an mHealth app for children undergoing hematopoietic stem cell transplant evaluated by 21 health care providers achieved a score of 84.2[18], a wearable device in 20 patients receiving radiotherapy scored 82.5[17] and an mHealth platform in 16 older patients achieved a score of 85[16]. Conversely, the SUS score obtained in this study is slightly higher than two previous studies focused on wearable devices, which reported scores of 78[19] and 74.4[20] among 95 and 16 participants, respectively, as well as the score of 61 reported by Haegens et al.[9] among the 90 participants who completed their questionnaire. Collectively, these findings support the system's user friendliness and suitability for deployment in routine clinical practice.

Several limitations must be acknowledged. First, the small sample size and single center design limit the generalizability of the findings. As a result, minor changes in individual responses could have significantly influenced overall NPS or SUS scores. Second, the study did not evaluate the clinical consequences of inappropriate TD storage—a critical question that warrants further research, but lies beyond the scope of this pilot evaluation. Third, connectivity requirements (Wi Fi or LoRaWAN) may have influenced participation and system performance. Finally, temperature fluctuations during transport were not analyzed. Although this period is usually brief, it likely represents a vulnerable phase for exposure to non-optimal conditions.

Conclusion

The present system designed to monitor TD at the patient's home seems feasible, acceptable and usable. Future studies should focus on making it easier to use and increasing the sample size to be able to demonstrate the effectiveness of the system.

Data availability

The datasets generated during and/or analysed during the current study may be available from the corresponding author on reasonable request.

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Author contributions

F.D., B.A., E.I. and C.M. were involved in the study conception and design. Project administration and funding acquisition was mainly done by B.A and E.I. M.G., M.P., G.G, A.M., and F.D, were major contributors in the inclusion of patients. M.F., B.A., and F.D were involved in the analysis and F.D., B.A., and M.F in interpreting the data. F.D. wrote the first draft. All authors read and approved the final manuscript.

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Declarations

Competing interests

The authors declare no competing interests.

Additional information

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