Continuous real-time remote monitoring of severely or chronically ill children

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Compared to parents of healthy children, parents of severely or chronically ill children have significantly worse physical and mental health and a lower quality of life, e.g. because of lack of sleep. The proposed solution aims at assisting caregivers by means of a remote monitoring service run by professional nursing staff which should allow parents to get a good night's sleep. A smart algorithm has been developed to detect if a particular parameter (heart rate, respiration rate or oxygen saturation) has exceeded a pre-defined threshold and thus may imply an emergency. Parents are only alerted after a professional nurse in the monitoring centre has cross-checked vital parameter trends and carried out an audio-visual inspection. The quality and accuracy of the system has been validated through iterative testing including a test performed in a children's hospital to ensure that the monitoring system is not inferior to a hospital set-up.

Keywords
children, digital health, home care, remote monitoring, sensors

1. Introduction

Seriously ill children and children with a severe disability need continuous monitoring, whether they are in hospital or at home. This tends to come with high costs for health authorities, insurers or for the parents. Care at home has shown to have a positive effect on the healing and development process of a child [1, 2]. In general, it is the relatives, in most cases the mother [3], who take on the responsibility of caring for their sick child with the selective support of nursing services.

This responsibility often comes at the cost of lack of sleep as well as physical and psychological strain, which may lead to chronic stress and eventually physical and mental break-down [4]. This has been confirmed by the findings of a research report commissioned by the Swiss Ministry of Social Insurance (BSV), which coincides with the finding that about half of the primary carers of children who are eligible for 'helplessness allowance' always or often feel exhausted and that one in five caregivers never or only rarely enjoys a good night's sleep [5]. The high level of stress of informal caregivers also poses risks to the health and lives of those in need of care, since it may result in their rehospitalization for longer or shorter periods, which in return may slow down their recovery or development process.

Based on the experience of its nursing staff, Kinderspitex Ostschweiz, the ambulatory care association for children of Eastern Switzerland, sees a clear need for remote medical monitoring of children in need of care. An analysis of current and past care cases and discussions with nursing staff have shown that about a quarter of the children cared for by them may benefit from a remote monitoring service. Based on the 2018 figures for the whole of German-speaking Switzerland, the potential for a monitoring service may amount to approximately 330 clients per year [6].

Thanks to recent technological advances, smart devices, sensors and new information and communication technologies (ICT) may help reduce the costs incurred by caring for people at home and assist parents taking care of a sick child. However, as shown in a recently published study, real-time monitoring of vital functions has been implemented only to a very limited extent in Switzerland even though its usefulness is rated as rather high [7].

In this paper we present the results of a research project which aimed at developing a solution for the real-time monitoring of sick children who are taken care of at home so as to lessen the burden of caregivers (parents, siblings or other informal carers). For this purpose, we use reliable data transfer

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technology as well as medical devices or sensors for capturing a variety of vital parameters such as respiration or heart rate as well as audio-visual inspections.

In the following sections we provide some detail of the background of the project, study some related works present in the literature, describe the approach taken and the methods we have applied, followed by a presentation of our solution and how this has been tested and implemented in real-life settings. We discuss the challenges we have had to cope with and how these have been dealt with. Finally, we point out the limitations of our study and the need for further research.

2. Project background and research questions

The project entitled "Continuous remote medical monitoring of children in need of care to reduce health risks and increase the quality of life of both children and their relatives" was funded by the National Commission for Technology and Innovation CTI and ran for four years (2016-2019). Its aim was to develop comprehensive services for real-time remote medical monitoring of critically ill children to relieve the burden on caregivers, usually the parents, during the night hours. This was to be achieved by having professional nurses monitor critical vital parameters at night.

The nurses involved in the project are employed by the ambulatory care association for children of Eastern Switzerland (Kinderspitex Ostschweiz), which initiated the project because they had come to realize that informal caregivers were in dire need of support. Therefore they approached the Institute for Information and Process Management of the University of Applied Sciences St.Gallen, whose researchers have a strong track record in digital health [8–10].

The researchers were joined by a software development company and a children's hospital, whose task was to make sure that the solution to be developed was not inferior to the monitoring service in the hospital with regard to reliability, safety and accuracy of measurements. Whilst the researchers were funded by the CTI, the effort of the other project partners was financed by the company that will offer and run the monitoring service once it has been further developed to reach market readiness.

Apart from the technological challenges, the solution had to be embedded in a process landscape and be associated with a detailed organizational plan with regard to authorization, roles and tasks.

The overall goal, i.e. developing a prototype for the continuous real-time remote monitoring by means of transmitting vital data, could be broken down into the following research questions:

1. Can a remote monitoring solution be established that is comparable to stationary monitoring in terms of reliability and accuracy?
2. Which are the relevant processes and how must these processes be designed?
3. How should professional nursing staff intervene to best support the relatives in case of an alarm?

Throughout the project, we were guided by these research questions.

3. Related Work

Digital, and in particular mobile, health systems based on the use of sensors and medical devices have attracted a great deal of attention over the last years [11]. They include monitoring systems which collect data either with sensors embedded in smartphones such as accelerometers, gyroscopes, GPS, microphones or cameras [12] or by means of wearables such as smartwatches, and are able to measure physiological parameters like heart rate, blood pressure, respiration rate, oxygen saturation, body temperature or electrocardiogram [13]. The big advantage of using mobile applications consists in the possibility of capturing vital data in real-time and outside clinical settings, i.e. they can easily be integrated in everyday life and thus provide cost-effective, reliable solutions for the remote monitoring of patients at home. Such monitoring systems may enable the early detection and better treatment of various medical conditions, prevent (re-)hospitalization and allow a better understanding and self-management of chronic diseases [11, 14].

In 2019, Malasinghe et al. [11] conducted a comprehensive literature review of remote patient monitoring systems which covered remote monitoring systems based on sensors attached to the body, ambient sensors and systems based on contactless camera-based methods. The authors show that remote monitoring is suitable for a wide range of conditions. Among the most common are those directed at chronic diseases such as diabetes, the cardiovascular and respiratory systems, fall detection and mobility-related diseases, which are addressed mainly at the elderly, as well as neurological disorders and mental health [15–19].

It appears that only a few monitoring systems address children, in particular [20]. These include a camera-based monitoring system for hospital environments discussed in Al-Naji et al. (2017) [21], which measures respiration rates and detects apnoea using a Kinect camera. Sendra et al. (2018) [20] propose a smart monitoring solution based on wearable sensors and a smartphone that continuously monitors a child's activity and vital signs. Whenever the system detects any deviations, it sends an alert to the caregivers (e. g. parents or teachers) as well as the physician in charge. The researchers distinguish between real emergency situations and false positives and use the data to train the decision algorithm so as to improve the system's accuracy and reliability over time. A similar system based on wearable vests is presented by Jansi et al. (2019) [22]. It can be used to monitor children who suffer from chronic illness and continuously keeps parents or carers informed about a child's health status. Malasinghe et al. (2019) also note that few contributions discuss a system's capabilities of ensuring privacy and security [11].

A recent report that covered 690 institutions for people in need of support in Switzerland revealed that the general degree of digitisation in these institutions (e.g. homes for senior citizens or for the disabled) is rather low, but particularly low in institutions that care for children even though they are aware of the potential benefits [7]. To the best of our knowledge, no study has focused on seriously ill children or children with a severe disability who need continuous monitoring that is comparable to stationary monitoring in terms of reliability and accuracy.

4. Brief description of our solution

Every year, the ambulatory care association for children of Eastern Switzerland cares for around one hundred mentally and physically handicapped or chronically ill infants, children and young adults. Its clients also include prematurely born children as well as sick, injured, convalescent children and those recovering after surgery. As set out in the introduction, parental stress due to lack of sleep is the main reason for asking professional nurses to provide night watches in a child's home. The parents often cannot or can no longer cope with the strain implied in caring for a sick child or they are afraid of seizures or exacerbations of a child's condition.

Remote monitoring may well be a good and less costly alternative to night watches where a nurse has to spend the whole night at the child's bedside. For the purpose of monitoring, sensors are attached to the body of the child and the values of the vital parameters are continuously transmitted to a monitoring centre based at the headquarters of the ambulatory care association for children where experienced nurses watch the data streams on a dashboard (see Figure 1, Application scenario). Nursing staff monitor patients in real time for up to 12 hours during the night.

Comparable to a traffic lights system, the colour red indicates danger or emergency, yellow stands for caution and green means 'go'. If vital signs exceed or fall below the thresholds set by a doctor, the colour turns yellow or red. In the case of a red alarm, the nurse can wake the parents and, if necessary, talk them through the appropriate measures by phone. In severe cases, the professional staff in the monitoring centre may contact the ambulance straight away. To prevent false alarms, a video surveillance system enables the nurse to observe the child and judge, for example, if an epileptic seizure is imminent.

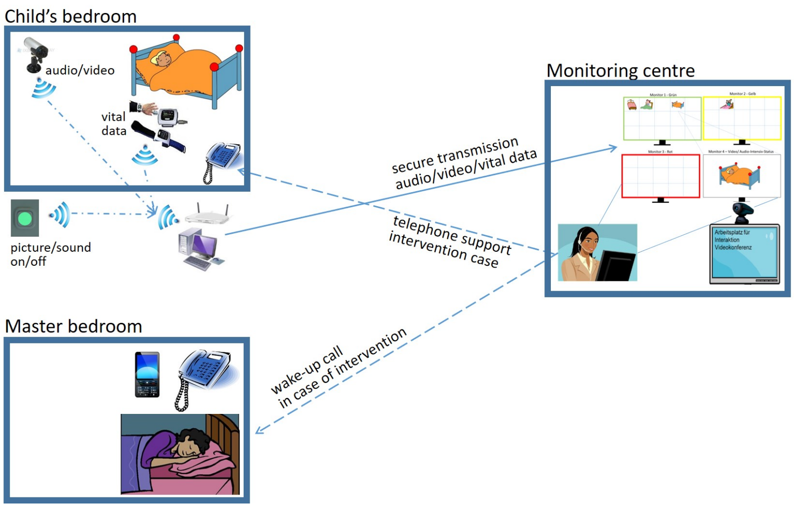


Figure 1 Application scenario for remote monitoring.

5. Implementation

5.1 Overall methodological approach

For the development of the monitoring system we relied on a design science approach which we define as the study and creation of artefacts developed and used by people with the goal of solving practical problems of general interest. Relevance has been achieved by incorporating requirements of the project partners and the technological infrastructure and by testing the monitoring prototype in various field tests. We conducted several iterations, evaluating and refining the prototype and the processes relevant for the remote monitoring solution [23].

At the beginning of the project we had extended discussions with the manager of the ambulatory care association for children as well as with the physician of the paediatric department of the partnering hospital. This helped the researchers develop an understanding of the issues involved. In line with a participatory human-centred design approach, we then conducted semi-structured interviews with the nurses who would be in charge of monitoring the sick children on a dashboard in the headquarters of the ambulatory care association for children.

The results of the discussions and interviews were analysed and subsequently translated into a set of detailed functional and non-functional requirement specifications for the monitoring application. This is composed of the following components:

- the medical devices and sensors,
- the data transfer architecture,
- an on-demand audio and video surveillance system

The need for the last components only emerged in the course of the project. It was clear from the outset that we were going to use existing devices that had already obtained medical approval and examine how these could best be integrated into the application scenario. Apart from medical approval, devices had to meet additional requirements like access to raw, non-aggregated data in real-time as well as the option to switch off the video and audio recording of the monitoring devices on the patient side so as to ensure people’s privacy.

The results from the iterative testing were continuously fed into the further development and adjustments of the various components, be it the adaptation of the thresholds, the alert process or the graphic user interfaces of the dashboard.

Furthermore, the processes relevant to remote monitoring were identified in close collaboration with representatives of the ambulatory care association for children, validated in the tests and adapted to the findings.

With a view to the later acceptance of our solution in the health care sector it is essential that our monitoring solution be not inferior to a hospital setting in terms of reliability and accuracy. To achieve this, we had to first decide on the relevant vital parameters and build the corresponding monitoring infrastructure.

5.2 Choosing and measuring relevant vital parameters

The choice of vital parameters was largely determined by the physician involved in the project and the parameters usually monitored in the hospital, i.e. respiration rate, heart rate and oxygen saturation. These parameters tend to be relevant for the majority of diseases. Besides, they swiftly respond to changes in a patient’s condition – within seconds in the case of heart rate and within minutes as far as oxygen saturation is concerned – and are therefore particularly suited for monitoring purposes.

After testing the individual devices in terms of accuracy and reliability, we performed an equivalence test in the hospital to make sure that our monitoring system was not inferior to the hospital system in terms of alerting and recognising any signals that might lead to an alert in the hospital. This implied using our monitoring prototype and the hospital system in parallel. For this purpose, healthy volunteers were attached to both systems simultaneously and had to execute four different scenarios to influence the vital parameters and simulate emergency situations to trigger system alarms. These situations included being at rest to lower the heart rate, holding one’s breath to lower the blood oxygenation, quick breathing/hyperventilation to exceed breathing thresholds and breathing under physical strain to raise the heartrate. Since it is not possible for normal people to voluntarily lower blood oxygenation, we worked with trained freedivers who were able to hold their breath for several minutes.

The test included a comparison of all triggered alerts, a video analysis of both monitors as well as a observation of the test persons by experts. Whenever a threshold was exceeded, the test system triggered alerts earlier than or simultaneously with the hospital system. We examined different approaches to measure respiration rate, which included impedance pneumography and respiration rate estimation, both from ECG and from audio signals. For the latter we used a microphone attached to the throat, a measure which because of its obtrusiveness, was only applied in the pre-tests. The respiration rate values showed some deviations compared with the manual counting performed on both systems. Besides, we found artefacts in all measurements, which is why we decided to use this parameter just in combination with other parameters to reduce the rate of false alarms.

For measuring oxygen saturation, we used a pulse oximeter, a medical device that indirectly monitors the oxygen saturation of a patient's blood (as opposed to measuring oxygen saturation directly through a blood sample) and changes in blood volume in the skin, producing a photoplethysmogram that may be further processed into other measurements. In our case, we used a small clamp-like device which is placed on a finger (earlobe, or toe would also be possible). Since there is a danger that the device might fall off during the night, especially from a small child’s finger, we chose one that could be attached via adhesive tape instead of a clamp.

5.3 Analysing and defining relevant processes

A major task consisted in defining the processes to accompany the implementation of a monitoring system, i.e. the interaction processes between nurses, caregivers at home and emergency staff, e.g. when to issue an alert and whom to alert whenever there was an emergency. The implementation of the planned monitoring solution therefore required developing a detailed process reference model that described the relevant processes associated with remote monitoring. A central issue is related to the question what to do if a threshold is exceeded. For example, should the nurse alert the parent immediately or first make sure that it really was an emergency?

The concept of emergency itself proved to be far from unambiguous and triggered lengthy discussions in the project team. It is closely related to the definition of thresholds for the various parameters, which tend to differ considerably between individuals. It also involved defining the number of children that a professional nurse might monitor simultaneously.

Given that the system issued a very high number of alerts it was decided that a preliminary check was necessary so as not to obliviate the whole purpose of the project, which is facilitating a good night’s sleep for the parents. Finding the right balance between safety or caution and running the risk of missing an emergency proved to be a major challenge.

The hospital test was followed by a test on healthy children in a home setting and further tests in a special home for seriously ill children which is supervised by the ambulatory care association for children and offers their parents temporary relief from their care responsibilities. Such a scenario comes closest to the home setting, which for both time constraints and ethical considerations could not be implemented during the project period.

6. Results

The research project produced the following results and provided answers to our research questions formulated at the beginning of the project:

6.1 Monitoring infrastructure

The tests carried out with the prototype showed that an infrastructure could be established that is comparable to a stationary monitoring system as used in hospitals. The proposed solution includes a smart algorithm to detect if a particular parameter has exceeded a pre-defined threshold and thus may imply an emergency. The test in the hospital which involved running two systems in parallel showed that the monitoring system developed for the home setting was not inferior to the hospital setting.

For the monitoring unit the following quantitative parameters were defined: Depending on the case mix and the expected number of alarms, up to 20 patients can be monitored simultaneously. A child can be placed under surveillance for a maximum of 12 hours. The service is offered from 8pm to 8am, with two active nurses and one nurse on stand-by. The set-up consists of a central dashboard and three individual surveillance stations as depicted in Figure 2.

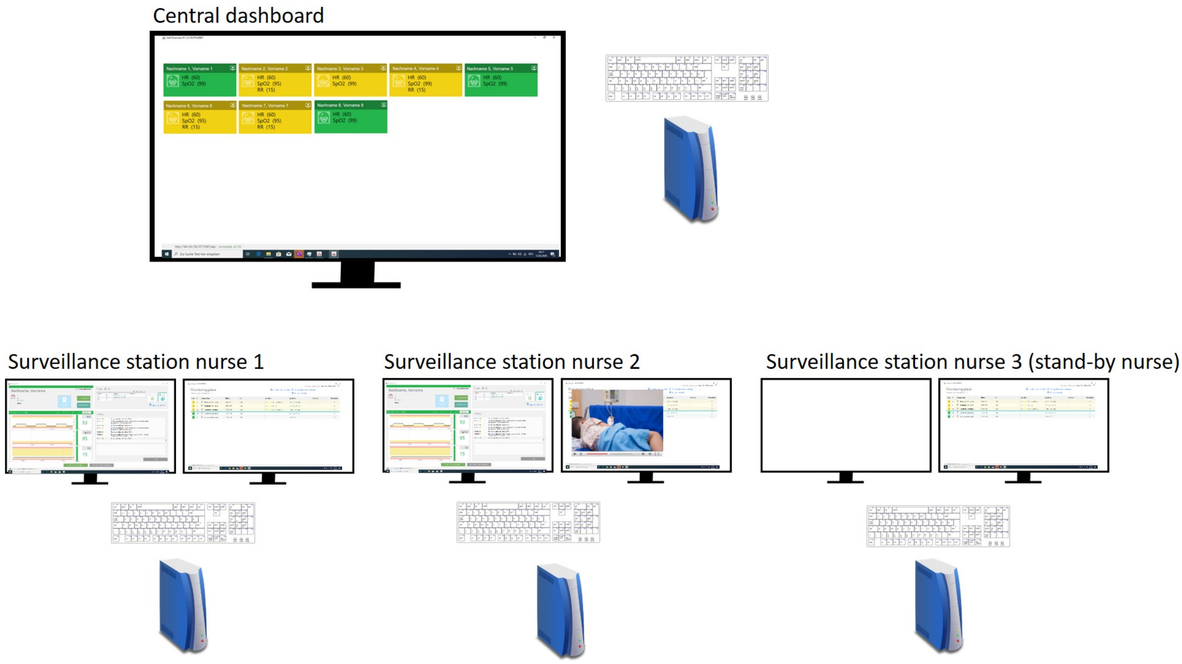
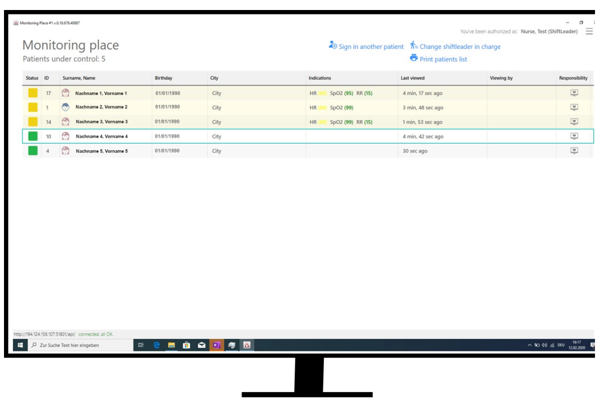


Figure 2 Schematic overview of monitoring unit.

The central dashboard provides an overview of all the patients that are being monitored. Giving their names, the most recent values of each vital parameter and the status colours (green, yellow or red). A patient's status colour can only be downgraded from red to yellow or to green if the patient has been inspected on one of the surveillance stations.

At the individual surveillance workstations, nurses are presented with a list of all children ordered by their status associated with the colours red, yellow and green, respectively (see Figure 3). Within each colour or status category, patients are listed according to the time that has elapsed since the last inspection. A nurse can inspect a patient in detail using the "patient window", provided that the particular patient is not already being inspected by her or his colleague (see Figure 4). In the patient window, each vital parameter is displayed in a separate chart and the nurse may select which period she wants to look at. The nurse can choose to permanently monitor a child via video, and in the case of a real emergency, initiate a phone call with the parents by dialling their number, ideally by just pressing a button. When completed, all inspections have to be logged.

The nurse uses the same headset for talking to the parents and listening in on the patient room. This is important because sounds may also provide an indication of a patient's condition. If the status of the child changes to red, an acoustic alarm is triggered which is repeated, if a patient has not been (re)inspected for more than 120 seconds. The status of yellow does not trigger an acoustic signal but exhorts the nurse to look at a particular patient more closely. The thresholds for triggering the alarms have to be pre-defined by the physician for each individual patient.



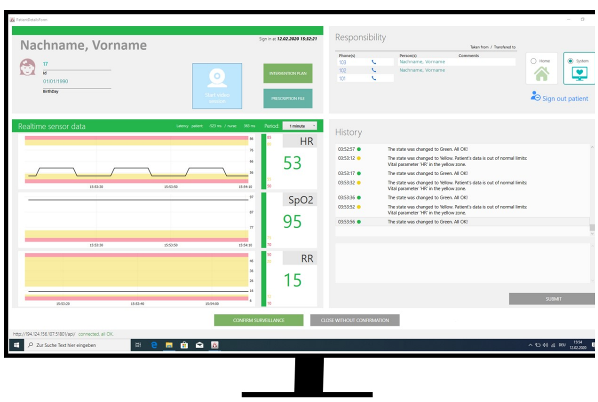


Figure 3 Surveillance station: Selection list.

Figure 4 Surveillance station: Patient window.

6.2 Monitoring service

By using medically approved devices, data collection at the patient's location could be carried out with the same quality as in a hospital. Furthermore, in the tests, the system reliably alerted the nursing staff in the event that threshold values were exceeded or if data was missing. We also discovered that during the first few nights, very close supervision by the attending physician is desirable so as to tailor the threshold values to a particular child.

Continuous remote monitoring as opposed to the selective transmission of vital data was shown to be feasible by evaluating the transmission intervals between two measured values. If the system failed to transmit any values during a pre-defined time, e.g. because of a technical breakdown or a sensor becoming detached, the alarm in the control centre was triggered. All relevant alarm situations were identified by the system, which was confirmed by the attending physician.

As mentioned before, we observed an unexpectedly high number of alarms per child and night. We were able to halve that number by correcting the algorithm. By fine-tuning the thresholds, we further managed to bring the number down per child and night (see Table 1). Although the amount of alarms was comparable to the number of alarms observed in a hospital (e.g. 33 for Patient 3), it was considered still too high for our scenario where there is no nurse on duty who might just drop into the room to check if it was a real emergency.

Table 1 Alarm recordings per night after adjusting the algorithm and fine-tuning the thresholds.

	Patient 1	Patient 2	Patient 3	Total
Green	0	0	0	0
Yellow	16	12	18	46
Red	**11**	**1**	**33**	**45**
Unjustified alarm	8	0	31	39
Justified alarm	3	1	2	6
Reasons for alarm				
Sensor lost	3	1	0	4
SpO2 data missing[1]	4	0	15	19
Data transfer issues	3	0	2	5
Awake	0	0	0	0
Respiration rate artefact	0	0	11	11
Others	1	0	5	6

This is why we introduced video surveillance which allows the nursing staff to make a meaningful assessment comparable to a visual assessment at the bedside. Warnings to the caregivers at home are only sent after a cross-check via video by a professional nurse. Even in the case of “red” alarms, parents are not woken up automatically, but an audio-visual inspection is carried out by the nurse in the monitoring centre, who decides whether or not it is a real emergency.

If this is the case, the nurse has to decide whether to call an ambulance or support the parents by talking them through the appropriate measures step by step. Thus, the parents feel reassured and are prevented from panicking.

Audio-visual inspection has emerged as an essential element in the remote monitoring service. The usefulness of camera-based methods has also been confirmed by the survey conducted by Malasinghe et al. (2019) [11].

The processes relevant to remote monitoring were identified in close collaboration with representatives of the ambulatory care association for children, validated in the tests and adapted to the findings. These included authorization and login, the actual monitoring process, informing/alerting parents, alerting emergency services, and contingency plans.

[1] SpO2 is a measure of the amount of oxygen-carrying haemoglobin in the blood relative to the amount of haemoglobin not carrying oxygen. SpO2 data maybe missing because the contact of the clamp to the finger was interrupted.

6.3 Evaluation results

To measure the acceptance of the monitoring system on the part of the nurses, the prototype was implemented in a home for up to eight severely ill children which is supervised by the ambulatory care association for children. We asked 21 nurses to rate the potential benefits of the system. The following results were obtained:

- According to the nurses' experience all parents supported by them suffer from poor sleep.
- Nurses expect that in 75% of the cases with night watches, the night watches could be replaced by remoting monitoring.
- In about half of the cases without night watches (usually the less severe cases), nurses expect that sleep problems can be reduced in over 90% of cases by remote monitoring.

As far as usability is concerned, a strong focus on user needs and the participation of those directly affected has paid off in easy-to use user interfaces. Iterative testing with nursing staff in the monitoring centre and continuous integration of their feedback has led to a high overall user-friendliness of the monitoring application (see Figures 5 and 6).

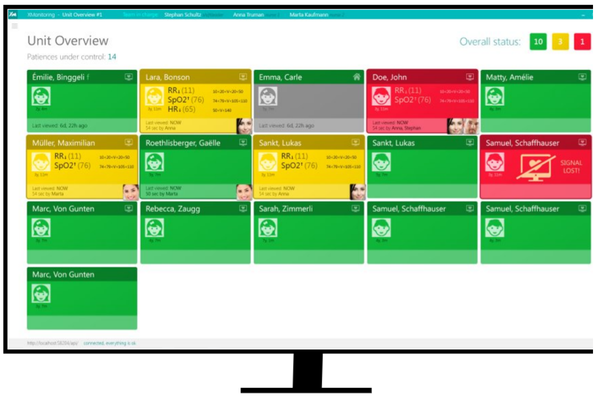


Figure 5 Central dashboard, early version.

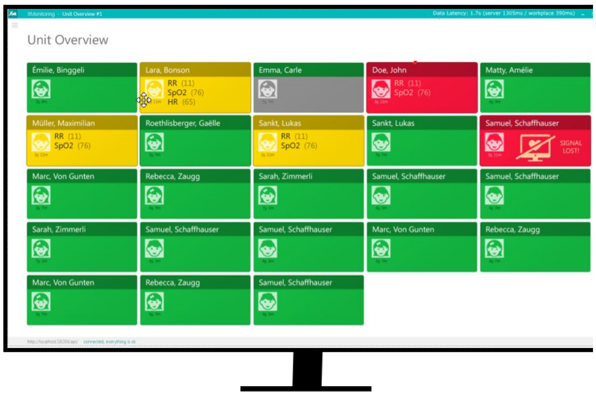


Figure 6 Central dashboard, optimized version.

The juxtaposition of the earlier and later versions shows how the information given about each patient has been considerably reduced so as to focus on the essentials.

7. Limitations

Originally, we also meant to measure user acceptance and the impact of the system on the part of the caring relatives. This was to be done by a survey of the subjective sleep quality and the effects of the monitoring solution on their quality of life.

Due to time constraints as well as ethical issues, the project did not include testing for seriously ill children in their own homes. Instead, as described above, we installed the monitoring prototype in a home supervised by the ambulatory care association for children which offers temporary relief to parents taking care of sick children.

8. Conclusions and outlook

We can conclude that from a medical point of view, continuous remote monitoring is basically feasible and, if implemented properly, is equivalent or not inferior to monitoring in a hospital environment. The main challenge consisted in reducing the high number of alarms per child per night. This was achieved by adjusting the algorithm and fine-tuning the thresholds, but also by introducing audio-visual inspection by the professional nurses. Audio-visual inspection in the case of possible emergencies actually emerged as a central element in remote monitoring, which had not been considered in the original study design.

An important ‘by-product’ of the project is a set of detailed process descriptions for the monitoring unit site. The processes comprise authorization, assignment of roles and tasks as well as how to handle alarms.

The remote monitoring system has been evaluated on the part of the nurses. They see clear benefits and expect the system to reduce the burden of the parents and contribute to their sleep quality.

In the long run, the vital data captured in the course of monitoring may well lead to the development of a decision-making aid for adjusting treatment or medication. The storage of vital data is a central component of the prototype and the basis for analysing the test data. However, any such tool will have to conform with data protection legislation, which implies anonymizing the data and/or obtaining the consent of both parents and children to use their data.

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