H-Links: Supporting Physicians with Objective Pain Monitoring for the Comfort of Patients at Homes

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Abstract: The following study focus on pain management during post-operative surgery treatment, it describes a solution for measuring the pain level for pediatric surgery patients at home since hospital care is trending towards ambulatory care. This solution can decrease the time in pain and optimize dosing of drug intake, and thus, improve the effectiveness of the treatment, reduce the time of post-surgery recovery and reduce the risk of chronic pain development. This can, in a global way, increase the overall quality of life of both patients and their family members. From the parent's point of view, better acceptance of ambulatory surgery can be expected together with reduced stress caused by a fear of pain management at home. From the hospital's point of view, we expect an increase in the rate of ambulatory surgery, and thus, an increase of beds availability.

1 INTRODUCTION

In the last couple of years, the hospital care is trending towards the ambulatory care because of the hospital charges for patient staying in hospital after surgery and the bed availability. Indeed, for many years, the number of hospitals beds available across the EU has decreased : available beds fell from 2.93 million in 2004 to 2.65 million by 2014, a relative decrease of 9.6% while the number of beds per 100 000 inhabitants fell from 592 in 2004 to 521 in 2014, a decline of 12% with the EU's population growth. Besides, the hospital charges for a patient in ambulatory care is lesser than the one for a patient in non-ambulatory care. For example, the patient having a unicompartmental knee arthroplasty in ambulatory care is charged $20,500 less than the patient that is not and who has to pay in average $46,845. Moreover, the average reimbursement was 55% of charges, or $25,550 for the patient staying in hospital while it was 47%, or $12,370 for the patient in ambulatory care (Richter, 2017). But this tendency gives new challenges. It implies that all the time that nurses and physicians used to spend with patients face-to-face for monitoring or guiding them will lessen, and also that post-operative care at home should become more usual.In this context, the communication between patient and physicians worsen beyond what it already was (Kyle, 2014). For example, according to a AAOS (American Academy of Orthopaedic Surgeons) survey, 75% of the orthopaedic surgeons believed that they communicated satisfactorily with their patients but only 21% of the patients reported satisfactory communication with their doctors. Additionally, the pain for patient will also worsen since acute pain is followed by chronic postoperative pain for 10 to 50% of the patients, pain cannot be measured objectively and there is no standard for feeling pain and administering appropriate amounts of drugs (Chou, 2016).

2 STATE OF THE ART

The presented solution is aiming to support post-operative surgery treatment in general and for the first step measuring the pain level for pediatric

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surgery patients. After Surgery, depending on kind of surgery, the health care professional will regularly check the health status of the patient (usually three times a day). This examination is usually paper based evaluation of questionnaires or simple patient´s observation. When the patients are sent home, the health care professionals will inform the patients about the medical prescriptions and arrange additional appointments to check on the healing process and to detect possible complications that could occur. Typically, the nurse will call the patient regularly and ask about the pain level. In hospitals, the post-operative pain level is measured usually by observation and questionnaires.

2.1 Market Positioning

Automatic physiological pain measurement systems exist but are exclusively dedicated to pain evaluation of patients during surgery under general anesthesia or in intensive care unit (Jeanne, 2014, Broucqsault Dédrie, 2016). These devices are based on measurement of heart rate variability, skin conductivity or pupillary dilatation (De jonckheere, 2015). With respect to the telemonitoring systems used for post - surgery care, there are already different solutions on the market available to connect doctors and patients before and after surgery (Yoon, 2016). The solutions differ with respect to the field of activity, the measure of pain level, hardware integration, degree of doctor interaction and targeted patients. Examples of competitive solutions in comparison to the project idea are SeamlessMD or Kardia. One identified solution, which addresses this patient group, is “Surgery Connect”. However, this service focuses only on informing the parents about the process of surgery.

There is no existing solution on the market for objective pain assessment, with additional physiological information from hardware devices for patients at home after surgery. Products that measure the pain level rely on information provided by the patients only. However, at the University Hospital in Lille the ANI monitoring system used for pain level measurement in unconscious patients during surgery has been already tested also on conscious patients during the first 2 hours right after surgery, and thus, approved as capable of measuring on conscious patients as well (Jeanne, 2014). Therefore, the unique selling proposition of the project idea addresses the integration of hardware information together with information from the patient. The project idea focuses in the first step on children which undergo surgery.

2.2 Market Potential

Different trends, like the encouragement by government bodies for digital technology in healthcare or increasing awareness of mobile based medical devices support the annual growth of the mobile health market (CAGR 32.3% until 2025), which was 33.59 billion dollar in 2018 worldwide. The market can be segmented by technology (Telehealthcare, Telecare, Telehealth, mHealth, Health analytics, Digital health system) but the project idea includes technologies from many segments and therefore the number of all patients undergoing a surgery as well as patients under 14 years in Europe was taken into account to get a clearer idea of the market. The countries with the most surgeries performed per year in Europe in million are 1. Germany (16.8 | 1.4) 2. UK (7.9 | 1.4) 3. France (5.0 | 0.9). To estimate the market volume, we assumed to collaborate with three hospitals in France for the first year, 5 in France and one each in Germany and UK for the second year and for the last year with 10 hospitals in each country. We identified the average surgeries performed each year per hospital and linked them with the cost savings we could archive with our product. The cost savings are based on the results of a survey, which indicates a saving of three days of hospital stay with a mobile application for postoperative monitoring after discharge. We assume to archive an acceptance level for each hospital of 70% (based on results of SurgeryConnect).

3 SOLUTION SPECIFICATIONS

In order to address the problem with inability to measure pain objectively among post-operative surgery patients, the team has identified medical device management systems from medical device companies which could provide the software with suitable physiological signals required to identify pain level for physicians, who can then monitor patient´s health state remotely. Our team would launch the first product module focused on pain management with eventually spanning out to other disease areas and suitable management of those diseases.

The solution will enable to:

- Provide hospitals sufficient data (both subjective and objective) related to pain management online from patients´ homes online,

- Use notifications and reminders for inter and intra-day situations where needed,
- Reduce the amount of manually register data needed to be provided by parents hanks to the connected wearable technology,
- Facilitate communication between patients/parents and hospital staff,
- Facilitate dosing of pain killers,
- Discover pain level variability both during a day and during the night also for further research purposes.

We suspect that from the patient´s point of view, this solution can decrease the time in pain and optimize dosing of drug intake, and thus, improve effectiveness of the treatment, reduce time of post-surgery recovery and reduce risk of chronic pain development. This can, in global way, increase of overall quality of life of both patients and their family members. From the parent´s point of view, better acceptance of ambulatory surgery can be expected together with reduced stress caused by a fear of pain management at home. From the hospital point of view we expect increase of the rate of ambulatory surgery, and thus, increase of beds available for patients. In addition, better awareness of surgeons (and also other HCP) about patient´s post-surgery health state can bring them relief and reduce time spend on face to face consultations, if these can be replaced by telemedicine.

4 PROPOSAL OF INNOVATIVE PRODUCT

4.1 Overview

Our solution will serve as a home-based telemonitoring platform used primarily for pain management of children after ambulatory surgery. The platform will enable the patients (or their parents, respectively) to collect data needed for proper control of the post-operative care, i.e. manually registered information about patient´s pain and daily activities, and data automatically collected through wearables, i.e. patch ECG monitor and activity tracker (Ooley, 2018, Evenson, 2015), for objective evaluation of pain level. In addition, connection with a hospital through a mobile and web application will be provided. The mobile app will serve also as a bridge for the data measured by wearable technology and transferred to a secured server (Hassan, 2018; Boulos, 2014).

In that place, the data can be processed, analyzed, and further displayed with a specific interface to both the healthcare provider and the patient/family member via the mobile or web application. Notifications and reminders will be included. Fig. 1 illustrates the whole concept proposal.

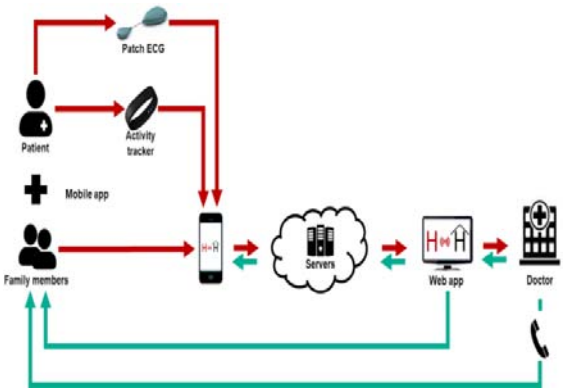

Figure 1: System workflow and components diagram.

4.2 Connected Technology

The main wearable technology includes a patch ECG monitor used (in connection with a pain management system algorithm) for the objective evaluation of patient´s pain, and an activity tracker for automatic evaluation of patient´s intensity of physical activity throughout a day and their sleeping efficiency.

4.3 Data Collection and Analysis

For the patient's monitoring, both manually entered and automatically registered data via wearable sensors will be tracked.

Manually registered data contain the following parameters:

- Subjective pain evaluation (using standardized scales for kids and adolescents)
- Mood information
- Acute pain detection needed to be immediately suppressed by medication
- Type of activity the patient performs during a day and its duration (resting, playing, sleeping, eating, walking)
- Medication intake (dose, datetime)

Automatically registered data are displayed in Tab 1 together with the explanation of their role in pain management. Based upon the results from the clinical study during which all the parameters are to

be measured, the final composition of the sensors needed to be tracked will be proposed.

Table 1: List of automatically collected data using connected devices.

Parameter	Possible device	Role in homecare pain management
Heart rate	-Patch holter -SmartWatch (if the accuracy is proved to be sufficient)	Pain level monitoring via pain management systems 'algorithms
Physical activity	-Activity tracker	Automatic evaluation of intensity of patient´s daily activity and sleep efficiency

Among to the data provided by healthcare provide, the following informations are included:

- Type of drug administration and its timing,
- Drug prescription,
- Visit appointments scheduling,
- Notifications and comments on treatment.

The data transmitted to the server will be processed using certain algorithms and displayed in form of graphs and tables to the doctor via web portal. The doctor will have the opportunity to go from the general overview on the data collected into more detailed characteristics.

Values out of the target range will be highlighted and alarms implemented. Download of a report (PDF) for upload into EMR capable of importing PDF documents, or raw data (CSV) for further analysis will be also an option for the web user.

4.4 Communication

The healthcare provider will be able to send a notification to the patient through the connected web app. Depending on the importance of the message, three levels of notifications can be used (urgent message, treatment change recommendation, general information), whereas the notifications are differentiated by a specific colour both on the mobile app and web app the patient/parent can connect to, using their unique credentials.

In case of emergency situation which needs to be treated immediately, direct call can be performed by both either the hospital or the parent.

4.5 Interoperability and Third-party Integration

The data from wearable devices will be transmitted to the server either directly (in case the communication protocol is available) or through API of given company. To create a secure and interoperable health data exchange, the Continua Design Guidelines will be followed. Following the standards, the FHIR configuration will be implemented for potential future connection with an EMR system of a hospital.

4.6 Data Security

Three main principles will be followed to ensure protection of the data: confidentiality, integrity and availability.

5 PROJECT RISK ASSESSMENT

- **External Risks:**

External risks include all influence which is resulting from the environmental influence. One risk is the development of the competitive landscape during the project time and new technical solutions. To address this risks a constant market analysis will be implemented, to allow a imitate response and agile adjustments in the project objectives, if necessary.

- **Internal Risks:**

The project requires certain competences to address e.g. certification regulations but also knowledge about country specific health care regulations and systems. During the project period the specific requirements will be identified and addressed by external consulting services or the employment of the suitable positions.

- **Financial Risks:**

In the first time period to the breakeven point the development of finance strategies for the project will be necessary. This includes the identification and implementation of the relevant financing options.

- Hospitals will not be willing to participate on the expenses for the system
- Medical insurances will not participate on the cost reimbursement

6 DEVELOPMENT PLAN

The development plan consists of 6 work packages (WPs) summarized below, whereas each WP consists of objectives, description and deliverables.

WP1: Project Management

The management part goes across the whole project lifecycle period and is responsible for leading the whole project and its team members and achievement of each particular WP to be done as required and on time. In addition, financial and administrative roles are included into this process, as a subcategories.

To ensure seamless development of the project, weekly report of the project monitoring evaluation and control will be done.

WP2: Definition of User Requirements, Technical, Clinical and Ergonomic Evaluations

Using a user-centred design approach, the user needs would be evaluated using focus groups and creation of personas. This would be done collectively for each of the stakeholders of this application. Since current standards of pain measurement are not well defined, a proof of concept with a software prototype would be designed for stakeholder's feedback. The application would initially be developed for an Android OS to be freely available for download for patients and their families. The application designed for the healthcare professionals would be connected with the hospital systems which would enable a single e-health system.

WP3: Preclinical Study

During the analysis of suitable sensors that could be used for monitoring of given parameter, the following factors will be taken into consideration: compatibility of medical device with software application, quality of signal, wireless data transmission, size of the device, it´s price and duration of battery used to charge the device.

To get sufficient data for development of algorithm, preclinical study will be performed on 20-30 subjects (children in post-operative state, age of 2-8 years) for 2 days. In these patients heart rate variability and physical activity will be monitored via selected wearable devices.

In parallel to the automatic data transfer from the wearables, patient´s manually registered information about the pain and daily activities will be registered using usual tool.

WP4: Development

First step of the development stage the software architecture will be performed. Based upon the data obtained from WP2 the design, concrete functionalities and final interface of both the mobile and web application will be made, before conducting the validation phase of clinical study.

As a first concept of the telemonitoring system we will implement the software part only, without the data evaluation obtained from connected devices.

After the validation of the accuracy of the devices and the final device composition is resolved, the upgrade version of the system, including the hardware part of the project, will be implemented, processed through the regulatory, and marketed in parallel to the software solution already approved.

The algorithm used for automatic evaluation of pain level will be developed in cooperation with the company producing the pain management system. The automatic evaluation of physical activity level will be created in accordance to the data analysis made after the preclinical study.

During the whole development period, we will also actively consult particular issues with software experts and regulatory affairs to ensure the final product will meet all the essential requirements. Requirements for quality management system will be followed based upon the ISO 9001 standard.

Each update of the software versions will be tested based on the testing processes described within the Risk assessment section. As a final control of the software testing phase, the verification and validation is performed based on the IEC 62304.

WP5: Regulatory Assessment

Certification and Standards

The commercial product we create would have to be classified as Class IIa medical device (COUNCIL DIRECTIVE 93/42/EEC, Annex IX, Rule 10).

After receiving clinical validation, we would improve the functionalities of our application to produce automatic recommendation of medication dosage to assist decision making based on multi sensor data. This might require us to move to Class IIb medical device certification (Directive 93/42/EEC, Annex IX, Rule 11).

Risk Analysis

For the methodology, the FMEA-based method is used and ISO 13485 is applied.

The protection of personal data will be treated based upon the EU legal framework, GDPR (General Data Protection Regulation).

Identification of characteristics of a medical device related to a usage that could have an impact on safety are treated based upon the international standard IEC 62366.

WP6: Validation and Usability Studies

A series of formative and summative evaluations will be conducted for this project. The formative evaluations planned for this prototype were selected from 'Product planning methods' and 'User research and validation' method. For analysing how the system was designed, evaluating which aspects of the system are lacking and identifying usability problems, a heuristic evaluation will be used.

Subsequently, focus groups and observation studies will help us identify the problems with usability of the application for the physicians and the patients before the first prototype is created and also during the testing phase of the system.

For the technical part of the solution, validation and verification will be performed during the last phase of the development period.

As a part of the validation, clinical study will be performed.

Deliverables:
Proof that our product can be used as intended, brings benefit to the end user as expected and is ease to use enough to encourage the end user for its long-term use.

7 CLINICAL STUDY

The clinical study aim to evaluate the usability and effectiveness of the whole system and the workflow process, the main evaluations of this study are:

- Comparison of the manually registered pain level data with the automatic data obtained through the wearables
- Patient level of pain
- Treatment adaptation
- Physicians and parents feedback
- Family quality of life

7.1 Criteria for Acceptance

- Age: 2-8 years old
- Orthopedic post-surgery
- No cardiac disease
- No neuropathic disorder

7.2 Clinical Study Performance

2 arms of patients (50-60 children, 2-8 years of age) who undergo an ambulatory orthopedic surgery will be recruited to the study, i.e. intervention and control group.

Intervention Group:
The intervention group will get the sensors to measure HR and physical activity. All the data will be automatically transmitted wirelessly to the connected mobile app, synchronized with the server and displayed to a doctor in a hospital. In addition, parents of the kids will provide manually registered information to the app.

Both the parents and the doctor will have an access to the data collected through a mobile/web app.

The doctor will be able to send a notification to the patient based upon the data obtained through the connected web app.

The doctor will check the data approx. 30 mins before patient´s scheduled medication, and in

case of the need of the dosage change, he will send the patient a message with the recommended dosage.

The phone call can be used in case of emergency situation.

Control Group:
As a control group the patients´ results from the preliminary study will be used. In case the treatment processes will be changed until the beginning of the clinical study the new arm of control group will be performed.

The control group will be following the standard healthcare methods used for ambulatory surgery. The parents will follow the doctor's medications prescriptions and will be able to contact a nurse 2 times a day to check the patient's health state. Paper-based questionnaires and information about patient´s daily activities will be provided by the parents and consulted at the face to face consultation with the doctor.

8 BUSINESS PERSPECTIVE AND ECONOMIC MODEL

The business model involves the software application for patients and doctors, which is connected to the database and also includes information from wearable devices. The market entrance strategy focuses primarily on the promotion of the software to enhance the connection between healthcare professionals and patients based on subjective data.

For the market entrance of the business model the end user group will be parents, whose children are under 14 years and underwent surgery.

Additionally to subjective information the main hardware information will be an objective pain measurement, which is already used during surgery. For future portfolio-expansion different solutions in different field of surgery and specifically chronic pain monitoring will be considered. For the expansion of the field of areas additional hardware devices could be implemented and the related information included into the database.

The main targeted customer groups will be hospitals and health systems, where the biggest benefit will be generated due to cost savings regarding the reduce of the length of stay in hospitals by around three days. There also exists evidence, showing that 110 clinic spots became available due to monitored patients at home after surgery. Based on the saving of three hospital stays per day a potential savings for Germany (1 billion €), France (450 million €), and UK (3.5 billion €) could be calculated. The main business core activity will be to develop the software application but also to manage the data transfer and storage. To process and analyse the received data different algorithm will be applied, which will be licensed. For the provision of the hardware devices corporations with manufacture of already existing medical device solutions on the market will be targeted.

The marketing strategy will primary rely on doctors as influencers. Therefore, the main efforts of communication will target this group. Studies, which quantify the benefits of the project solutions, will have a high priority to raise the awareness level and building trust. Nevertheless, the patients will be the user to decide to download the software and will therefore have a direct influence of the selling outcome.

The most important geographical markets where identified according to the number of surgeries performed per year in Europe. As a first stage the for the market launch the first customer will be the leading hospitals in France (e.g. Centre Hospitalier Régional Universitaire de Lille). For the following year the market entrance to one hospital each in Germany and France will be addressed. After showing evident of the quantified data for the financial benefit of the products health systems (e.g. APICIL in France) can be addressed to cover the costs. As a last step and long-time goal the data shall be provided to research institutes and companies.

9 CONCLUSIONS

Opening the doors for both subjective and objective evaluation of pain in homecare enables us to collect big data related to pain management and explore our solution to other healthcare sectors. The data collected from both home and hospital environment can give us the opportunity to explore our solution and involve machine learning algorithms enabling to provide better decision support and make some so far manual processes fully automatic (e.g. automatic recommendation of drug dose adjustment). This could significantly reduce time spent on data analysis on the side of HCP.

Healthcare providers can profit from the data in order to proof their high quality and efficient treatment practices. Researchers can get an opportunity to discover new methods for pain management treatment, and manufacturers can obtain evaluation of effectiveness of their products and tips for their further improvement.

Proving that the objective pain evaluation can work for treatment of post-surgery homecare of children, our future aim is to explore the solution to adults -considering software adjustment due to a bit different treatment procedures- and moreover, focus on its potential use also in chronic pain management, which represents a huge market opportunities.

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