MediPi – Cost Effective, Remote Patient Monitoring Using a Raspberry Pi Single Board Computer

Authors: Richard Robinson[1], William Aspinall[2], Damian Murphy[3], Anne Dyson[4], Ian Dugdale[5]

[1] Richard Robinson, MediPi Lead, Messaging and Integration Specialist, NHS Digital, rrobinson@nhs.net

[2] William Aspinall. Assistant Director of Performance and Information at Hertfordshire Community NHS Trust williamaspinall@nhs.net. Cinnamon Digital Applications, support@cinnamondigitalapplications.co.uk

[3] Damian Murphy, Senior Solution Assurance Manager Senior Solution Assurance Manager, NHS Digital, damian.murphy@nhs.net

[4] Anne Dyson, Senior Business and Operational Delivery Manager, NHS Digital, anne.dyson@nhs.net

[5] Ian Dugdale, Principal Practitioner, NHS Digital, ian.dugdale@nhs.net

Abstract

The true clinical, economic and social value of remote patient monitoring is yet to be exploited. Trusts have been challenged to do more with less, but telehealth has suffered from expensive, proprietary systems, existing in isolation with too little thought given to security. The purpose of this study is to investigate whether cost-effective remote patient monitoring can promote pro-active self-management and can avoid expensive emergency admissions. Successful deployment is dependent on scrutiny of the details of the challenge and the solution.

The MediPi project is a clinically lead, open-source platform aimed at providing a secure, extensible, low cost, remote patient monitoring solution. Patients with Heart Failure, COPD and Diabetes were given Raspberry Pi based touchscreen units and asked to submit daily measurements from their homes using blood pressure cuffs, pulse oximeters scales thermometers and subjective yes/no questionnaires about how they felt. The MediPi Concentrator server API allows any registered clinical system secure access to the data, for clinicians to view trends, set thresholds and respond directly to the patient.

Clinician's reports showed that patients were receptive to the technology and keen to actively manage their care, with anxiety reduced in 34% patients. The cost of the monitoring per patient was lower than other studies with potential for further savings. The MediPi system proved robust but Bluetooth communication issues with certain physiological devices prevented the study from reporting on downstream economic savings.

Keywords: Raspberry Pi, telehealth, remote patient monitoring, open source, low cost, secure, integrated

Introduction

The use of technology to improve remote healthcare provision is not a new idea. There has long been a strong clinical and economic case for it. It forms a part of current and future Government strategies, addressing many of the key principles of the *Personalised health and care 2020: a framework for action*.[i]

Remote patient monitoring is expected to

- empower patients to be more involved and actively engaged in their care
- reduce preventable episodes which can avoid expensive emergency admissions.

- reduce caseloads of clinicians freeing time for better patient care
- provide immediate and downstream cost savings (for example Hertford Community NHS Trust estimate that each nurse visit to a patient's home costs >£70)

As a result, Trusts have been keen to adopt such technologies and studies have shown that the telehealth market was expected to grow by 13% CAGR (Compound Annual Growth Rate) until 2018[ii].

However, many attempts to date, despite achieving varying degrees of success, have been less than satisfactory for a number of reasons[iii]. These can be identified as including:

- Cost of provision: use of expensive and/or proprietary hardware[iv]
- Lack of integration with existing clinical systems and NHS national infrastructure.
- Concerns over security and confidentiality

This study investigates:

1. Does remote monitoring and self-assessment of patients with chronic medical conditions promote pro-active self-management?
2. Can MediPi reduce the cost of remote patient care?
3. Can early interventions of preventable episodes avoid expensive emergency admissions?

Consultation and Research

Our initial research into the problems and opportunities of remote patient monitoring resulted in a joint draft white paper: *Cost-Effective, Improved Telehealth Opportunity* [iii] - a collaboration between Damian Murphy and Richard Robinson (NHS Digital), Shawn Larson, (Digital Technology Directorate, NHS England) and Dr Neil Paul (NHS South Cheshire CCG). Through case studies and clinical and technical experience, we outlined a vision of a secure, versatile, low cost, open source, open platform telehealth solution which would meet the issues identified in the introduction above.

Through this study we were able to identify a set of key principles of the project:

1. Clinical Engagement - The single most important requirement is clinical engagement (the work to this point has been carried out with an awareness of clinical practice and need, but not the detailed understanding that involved healthcare professionals can bring).
2. Practicality - The key to the implementation of the vision is the practicality of the proposed solution – that there is no disconnect between the processes which the medical professionals follow prior to and post implementation, save for implementation itself. The solution could be dropped into the existing workflow.
3. Create a flexible, extensible remote patient monitoring framework which can be freely shared under the permissive Apache 2 licence. Additionally, to share all resources developed as part of the project where possible in the same manner: training materials and instructional guides, test results, key documentation – MHRA, Electromagnetic Conformance of the MediPi Patient Unit etc. The aim is to enable others to reproduce and extend our solution for their own requirements and benefit from our experience as quickly and easily as possible.
4. The solution should be easy to use (by patients primarily but also by clinicians) – difficulties will cause users to give up, or subject patients to stress.
5. Security - It is a standard expectation of healthcare systems to have security commensurate with the high value and personal nature of the data.

Further consultation was sought through several channels:

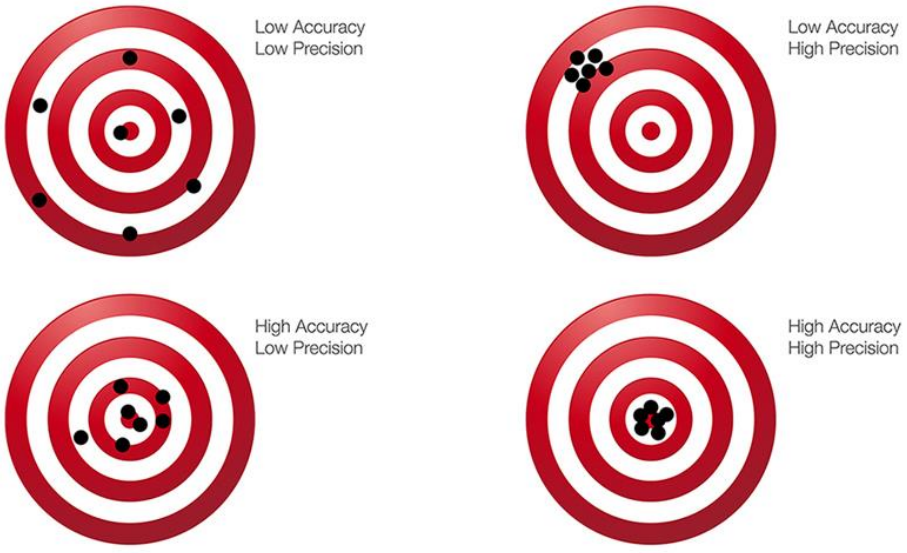
- Engagement at industry conferences (EHILive, CIO/CCIO conference) and meetings with Trusts
- We consulted with Dr David Stables (Trustee, Endeavour Health Charitable Trust and founder of Egton Medical Information Systems) regarding our proposal. He was able to advise on industry expectations for the integration and sharing of patient data between systems and how best to structure and implement our server-side solution.
- Strategies for open source projects from Dr Marcus Baw (openhealthhub.org and the Digital Health Networks)[v]
- The MediPi project received valuable national press exposure (Computer Weekly, Digital Health and Raspberry Pi Foundation), promoting and publicising it, growing our community[vi]

The overwhelmingly positive feedback to our approach from these technically minded, experienced clinicians confirmed the necessity and validity of our proposal.

Physiological Measurement Devices – Accuracy vs Precision

Medical grade measurement devices are expensive because they are calibrated and will give accurate and precise measurements, that can be compared against measurements taken in other clinical settings. Can the MediPi approach be used to access low-cost, commodity devices?

Accuracy and precision are not synonymous. Accuracy refers to the deviation of a measurement from a standard or true value of the quantity being measured. Precision tells us how close a group of measurements are to one another[vii]. A target analogy is often used:



Measurements taken by patients in the home, no matter how accurate and precise the measuring devices are, are not directly comparable with measurements taken by clinicians. The resultant data therefore needs to be categorised as such in the health information system and used with this context in mind.

Patient monitoring of all kinds relies on trends: changes over time in a measured property. The absolute empirical accuracy of this measurement is secondary to its precision as this will define the

broader change. Therefore, for remote patient monitoring data, absolute accuracy less important but high precision is essential. This opens the possibility that lower cost non-medical grade devices (which can maintain high precision) could be used at a fraction of the cost.

Developing Pilot Partnerships

During the course of the consultation and engagement stage, an early prototype was developed in order to demonstrate and enthuse potential pilot sites and test the practicality of the proposal. As a result, we were able to join in partnership with Hertfordshire Community NHS Trust (HCT) to pilot our remote patient monitoring software: MediPi with their matron-caseload patients. These are patients with Heart Failure, Chronic Obstructive Pulmonary Disease (COPD) and Diabetes who require physiological measurements and paper-based subjective questionnaires to be taken regularly to track and control their condition.
HCT sourced funding for a pilot of 50 patients for a period of up to 12 months including capital costs for the MediPi patient devices, physiological measurement devices, administration and maintenance. NHS Digital agreed to develop and maintain all the software, physically build and configure the MediPi Patient Devices and host and maintain the MediPi Concentrator and Clinical servers.
This facilitated us to meet our key principle of engagement with both clinicians and medical device experts and develop a targeted solution with a concrete real-world setting. This engagement enabled the solution to be designed to be readily slotted into the care processes.

Nurses at Hertfordshire Community NHS Trust with the MediPi Patient Unit

In a production environment, patient-sourced monitoring information would be integrated with clinical systems used by the deploying organisations. As MediPi was a pilot, GP and other clinical

systems providers were unable to dedicate resources to integrate its information, with their systems. Instead, a "mock clinical system" was developed to display patient-sourced information.

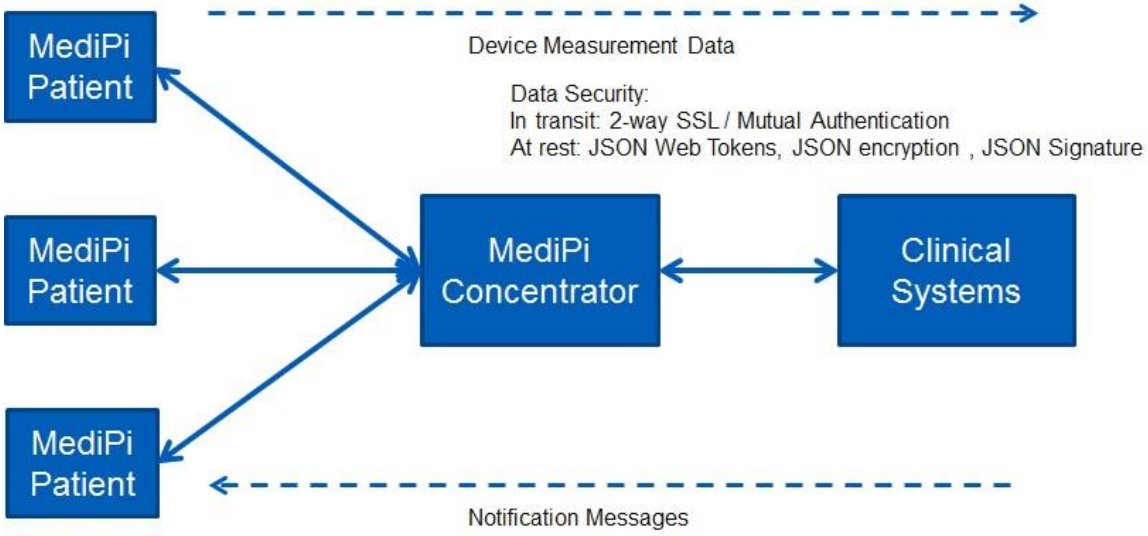
We established a partnership with Mastek[viii] software development specialists. They agreed to develop (and publish with the same open source licence as NHS Digital) the mock clinical web servers from which clinicians can view patient results and set and maintain alert thresholds for patient measurements. This partnership proved very fruitful as their knowledge and expertise complemented and filled gaps in our experience.

Methods

All sources and resources are available from the MediPi GitHub repository (www.medipi.org)

MediPi Remote patient Monitoring overview

MediPi facilitates acquisition and secure transmission of data from one or many satellite systems to a remote sever and can expose it through secure APIs to be passed to clinical systems. Additionally, data can be passed back through the API from the clinical end system to an individual satellite module. This is a flexible and extendable model which lends itself to many clinical scenarios.



Architectural Strategy

All MediPi software has been written using Java 8[ix] and so is platform independent allowing it to run on any system with a JRE (Linux, Windows, Mac) but with the potential to be ported to mobile platforms: Android, iOS systems.

Security and Data Transmission

MediPi has been designed from the ground-up to use a strong security model, constructed with the assistance of the NHS Digital Information Governance and Security team. Each patient, MediPi Patient Unit device and Clinician has their own certificate as part of the MediPi PKI. All data at rest is encrypted and signed by its originator. In transit the data is further protected using mutually authenticated TLS. All the systems and transmissions are carried out within an encrypted OpenVPN Virtual Private Network (VPN).

The servers were hardened and tested for security using Lynis[x] an auditing, system hardening, compliance testing tool. It is acknowledged that full penetration testing would be necessary for production rollout.

Flexible and Extensible Framework

MediPi software has been built as a flexible and extensible framework designed to have pluggable interfaces in several key areas:

- Flexible Patient Data Acquisition: All patient data acquisition entities are developed as discrete coded element modules so that any type of measurement device (USB, Bluetooth etc), or user input method can be programmatically plugged in and its data seamlessly handled by the system. Different/new modules can be included dynamically as part of the configuration.

- Messaging Interface: MediPi has been developed using its own data format for ease and speed of development, but strategic interfaces have been created in the framework to allow easy development and choice at runtime of any other messaging/data format e.g. FHIR
- Clinical APIs: The MediPi Concentrator has been developed with a simple API used by the clinical system to securely retrieve patient measurements. The framework allows for easy development of new APIs to support any integrating system.
- Clinical responses: The Clinical System and MediPi Patient Device software has an extensible framework for responses from the clinical system to the individual patient, allowing development of any object response

The flexibility of MediPi has been demonstrated by members of the open source community independently developing extensions for MediPi:

- Medication Management module for MediPi Patient Unit.[xi]

- Integration of MediPi Concentrator server API with BJSS's LiveOBS/openOBS server as part of an internal hack week. Submitted MediPi patient data was successfully transmitted and displayed as NEWS (National Early Warning Score) on the LiveOBS/OpenObs system[xii]

Systems Preparation and Development

Raspberry Pi based MediPi Patient Unit

The MediPi Patient unit is built using a Raspberry Pi with a touch screen display within a plastic enclosure. This computing platform was chosen for several reasons:

- Inexpensive – the MediPi Patient Unit in total costs ~£110
- Robust, secure, tried-and-tested architecture and Debian/Linux based operating system
- Previous experience of development using Raspberry Pi

Although the Raspberry Pi PC, the screen and the power supply have individually been tested by the Raspberry Pi Foundation against the Electromagnetic Conformance specification for electronic devices in the home, the integrated components for the MediPi unit had not been. As, the standard for electromagnetic radiated emissions for electronic equipment which will be used for patients who may be using sensitive medical devices such as pacemakers is higher, it was necessary to subject the MediPi Patient Unit to a higher Medical Device Directive Certification: *EN60601-1-2:2007 + Corr.20 Medical electrical equipment - Part 1: general requirements for safety. Section 1.2 Collateral Standard: Electromagnetic Compatibility – Requirements and tests.*[xiii]

To achieve this standard, the MediPi Patient Unit required copper tape shielding and ferrite EMI suppression rings.[xiv]

Patient Measurement Devices

To adequately monitor the matron-caseload patients, the clinicians specified that the following patient measurements were necessary:

Blood pressure, weight, heart rate, blood oxygen saturation, body temperature.

Bluetooth enabled, medical grade devices were specified by HCT. It was felt by the HCT Medical Devices Team that medical grade devices were strategically the right choice as they could be reused at the end of the pilot. This decision necessarily limited the range of devices available to us. We were further constrained by the NHS Digital Legal Department advice that we could not enter into any Non-Disclosure Agreements, thus removing the possibility of using those devices with proprietary protocols. Consequence only 3 of the 4 devices that were eventually chosen were able to natively communicate via Bluetooth. The thermometer required the user to take the reading and type the measurement in a user input page as no thermometer could be found with an open communication protocol.

Bluetooth Devices:

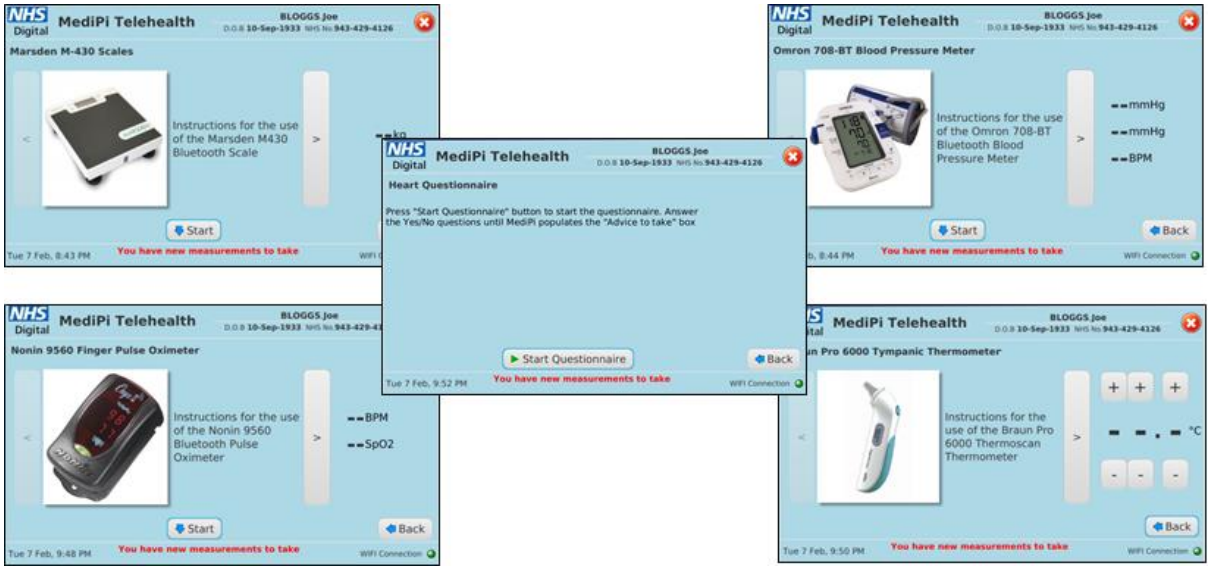
- Omron708BT Upper Arm Blood Pressure Monitor[xv]
- Marsden M430 Scales[xvi]
- Nonin 9560 Finger Pulse Oximeter[xvii]

Manual Entry

- Braun Pro 6000 Tympanic Thermometer[xviii]

Subjective self-assessment Questionnaire:

We developed a questionnaire framework to assess the patient's condition based upon yes/no responses to clinical questions posed by the MediPi Patient Unit. This is a programmable on-screen questionnaire which replaces an existing paper-based flowchart devised by HCT clinicians and provides standard, generalised advice based upon the path through the responses. Its configurable nature means that the questions and pathways through the questionnaire can be changed through a text-based ruleset without any programming changes. There are 3 different questionnaires, one for each of the 3 conditions of the patient cohort.



Testing[xix]

Functional testing of the end-to-end functionality of the MediPi remote patient monitoring system was designed and performed by the NHS Digital Compliance testing team. This included, but was not limited to, black box and exploratory testing of the user interfaces of both the patient and clinical systems.

Some basic non-functional load testing was carried out using Apache JMeter 3.1.

Legal and Clinical Assessments

Clinical Safety Hazards and Safety Workshops

A clinical risk management support for the pilot was provided by NHS Digital's Clinical Safety subject matter expertise, who co-ordinated contributions from clinical and technical subject matter experts in accordance with DCB129[xx]. Patient safety Hazards were identified and assessed, the residual risks were reduced to acceptable levels, demonstrating that the system did not present any unacceptable risks to patients.

The clinical front end was assessed as being Class I Medical device standalone software[xxi], as such in addition to DCB0129 NHS Digital completed a self-assessment and registered the device with the MHRA [Medicines and Healthcare products Regulatory Agency].

The overall risk profile of this 12-month pilot implementation by NHS Digital and Hertfordshire Community Trust of MediPi was assessed as low risk

Information Governance - Threats and Vulnerabilities Analysis

The MediPi Threats and Vulnerabilities Analysis was a risk assessment to consider the information security risks associated with the MediPi pilot at Hertfordshire Community Trust (HCT). The project team ran a risk identification workshop with an information security subject matter expert, where a series of potential threats were considered and evaluated against their likelihood and impact. Controls and mitigations were then assigned to determine the pilot's residual areas of risk. The Threats and Vulnerabilities Analysis is an Annex to the Privacy Impact Analysis (see below) which served as the single, consolidated position detailing how patient data would be managed during the project and disposed of on its completion. Once the analysis had been compiled and reviewed by NHS Digital, it was sent to HCT for their review and approval. This was mandatory as HCT have the legitimate relationship with the patients and therefore have a legal obligation to protect and actively manage their data.

Information Governance - Privacy Impact Assessment

This was created to document how the MediPi solution would manage, protect and store the patient data that it transmitted. It summarises the approach to be taken for patient consent (in this instance, patient consent was managed by HCT) and explained how data flows in the MediPi system. The Privacy Impact Assessment was used as a means of ensuring the pilot conformed with its legal, regulatory and policy requirements to ensure patient privacy was upheld.

Preparation for Deployment

50 MediPi Patient units were built and delivered to HCT. Each of these was configured and paired with physiological devices appropriate to the patient by the Medical Devices Team at HCT and bundled into a MediPi Patient set.

Patient Selection

The most technically able and interested patients were identified by clinicians from their cohort and were asked if they would be willing to participate in the pilot. As a result, the eventual cohort of participants in the pilot was not necessarily typical of the matron-caseload. The patients were required to have an existing broadband internet connection with Wi-Fi access. The typical profile of patients in the matron-caseload (with heart failure, COPD and diabetes) tends to be older patients. 31 suitable patients were identified by the clinicians including nine red referrals with complex needs.

Training

The NHS Digital MediPi team trained the clinicians, Transformation team and Medical Device team at HCT through training days backed up with comprehensive documentation.[xxii]

Configuration in the Patient Home

For the pilot each patient was given a MediPi Patient Unit, several physiological devices appropriate to their condition, brief training at home by HCT Transformation staff and written guides to the use of the devices[xxiii]. The rollout of the MediPi Patient sets to participants was gradual as each patient required a home visit from the HCT Transformation team. Here the device was connected to their home Wi-Fi and tested as part of the patient training.

Pilot Processes/Method

Each day during the pilot, patients are required to turn on the MediPi Patient unit and log in with a secret PIN. The software calculates if there are any scheduled measurements to be taken and informs the patient. The scheduler software then guides them through the process of taking each scheduled measurement (whether taking a physiological measurement or answering questionnaires). For each measurement an illustrated on-screen guide is available for patients to reference. After all the necessary measurements have been taken, the patient is shown a summary of the data to be transmitted and asked whether to proceed. Upon successful submission and after a short period the MediPi Patient Unit receives a response from the clinical server with a configurable message indicating how many successive sets of data have been submitted, along with an encouraging message. Note: Initially this response gave details of each measurement and whether it was in or out of the clinically defined threshold. During the consultation period with the clinicians, this was thought to be overwhelming to patients and likely to cause anxiety.

Patients were informed that measurements could be taken and submitted as often as they wished, but it was expected that they would make a measurement submission each day in the morning.

MediPi Concentrator

The MediPi Concentrator receives and stores data from all the satellite MediPi Patient units and exposes APIs for clinical systems to request patient data from. It orchestrates notification messages sent to specific patients and software updates to specific MediPi Patient devices. As part of the security model, it serves patient certificates to the clinical system to allow notification messages to be encrypted so that they can only be read by the intended recipient.

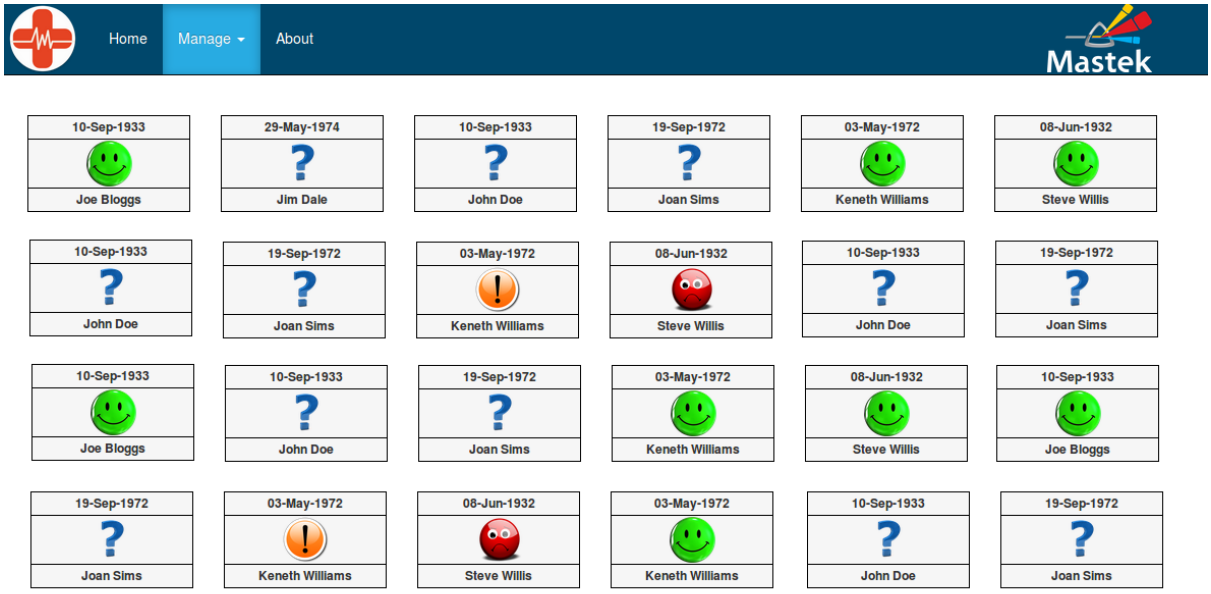
The concentrator server is written using Java Spring Boot, Hibernate, Postgres Database technologies and hosted on a Centos 7 server.

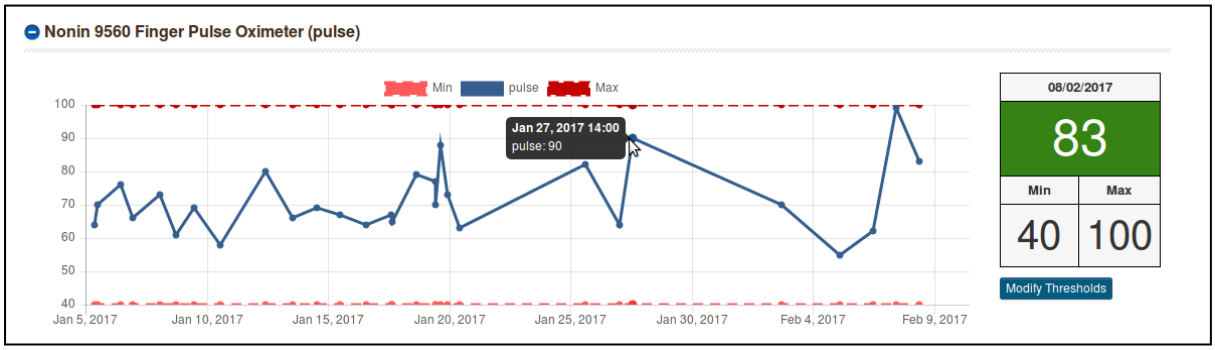
MediPi (Mock) Clinical Server

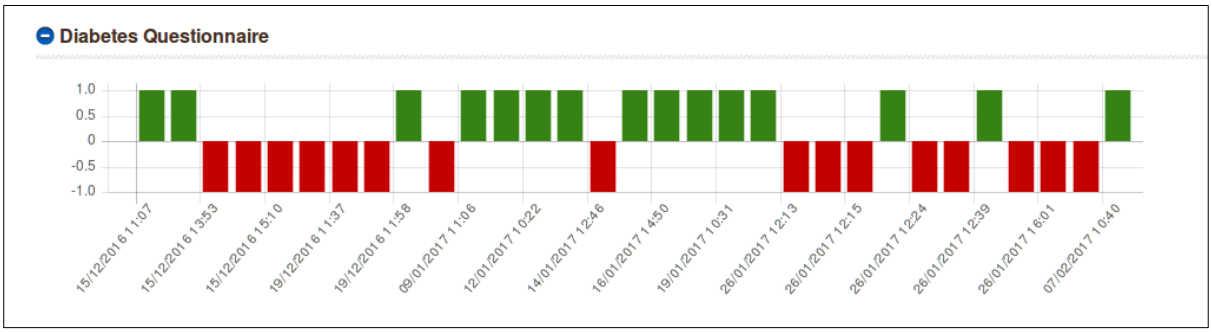
As HCT’s patient administration system provider was unable to participate in the pilot, the mock-clinical server was developed to allow clinicians access to their patient's data. However, the Clinical server is not seen as part of the core MediPi software project. The reason for this is that existing clinical systems are able to process and interpret raw clinical data far better and the intention is that they would use APIs on the MediPi Concentrator to securely request data.

MediPi Clinical Server requests data periodically from the concentrator through the concentrator's API and persists it in its database. Any new data is tested against thresholds set individually for each patient measurement by the clinicians and informational messages are sent back to the patient. These configurable messages are designed to give positive feedback to the patients.

The web based front end is used by clinicians and after they log on it presents them with a single screen digest of their cohort of patients. Each patient is displayed with a status indicator reflecting at a glance the data which they have submitted and whether it is in threshold or not. Clinicians can access each patient's record which will show graphical history of each submitted measurement and its current status. This allows them to manage the patient's condition and review and update thresholds for each device.







Results

HCT Transformation Team collected evidence and data from the pilot and published a 3-month interim report and a full-term update. The following results are from NHS Digital's evidence and HCT's report[xxiv]

31 patients were recommended by the clinicians to participate in the trial.

- 7 patients withdrew from the trial prior to having the equipment delivered, this was for a variety of reasons including:
    - Becoming too unwell to participate,
    - Being discharged from the service,
    - Changing their minds and deciding against being involved.

- 20 sets of MediPi equipment were installed in patient homes from July 2017 to September 2017.
- 3 patients have become too unwell to continue taking their own observations and consequently the nurses withdrew them from the trial.
- After October 2017, patients whose physiological devices worked fully continued to use the service (5 patients) and those who had problems discontinued.
- The trial ended on 5th May 2018

Analysis of the MediPi Dataset when in peak use

Period of data acquisition	15th August - 13th September 2017
Total number of patients	20
Total number of Clinicians	7

A submission is classed as one or more measurements taken by the patient using the MediPi Patient Unit transmitted via the MediPi Concentrator server to the MediPi Clinical system. These measurements may be taken using physiological devices and downloaded to the MediPi Patient Unit via Bluetooth or manually input depending on the device/questionnaire. If the patient was unable to download data from one physiological device, they can still submit the other data collected.

Category of submissions	Submissions	Percent of total number of attempted submissions
Full submission with all expected measurement data within threshold e.g. the patient successfully took readings with all the devices and transmitted them to the MediPi Concentrator. All the measurements were within the threshold boundaries set by the clinician.	53	16%
Submissions with some measurement data out of threshold* e.g. the scales were successfully used but when the clinical server compared the measurement against the clinician's threshold for weight for the patient it was found to be too high.	91	27%

Submissions with measurement data from one or more devices missing e.g. the patient was unable to use the pulse oximeter through malfunction or inability, but was able to use the other devices and submitted data for those	179	54%
Patient was unable to transmit data from the MediPi Patient Device to the MediPi Concentrator (Wi-Fi issue) The patient turned on the MediPi Patient Unit and was unable to continue further as it could not connect to the domestic Wi-Fi	8	2%
Patient was unable to transmit data from the MediPi Patient Device to the MediPi Concentrator (software issue). The MediPi Patient Unit software failed in use and prevented measurements being sent to the servers	0	0%
total number of attempted submissions	331	
Non-submissions of data	Submissions	Percent of total number of all submissions
Patient unable to submit due to holiday	31	8%
Patient unable to submit due to withdrawal from the pilot	6	2%
total number of all submissions	368	

% successful submissions from MediPi Patient Unit to Clinical web server	98%
% successful submissions containing a full set of measurement data from MediPi Patient Unit to Clinical web server*	16%-43% (estimated 30%)
End-to-end data loss or corruption (from MediPi Patient Unit to Clinical web server)	0%
Availability of MediPi Servers as measured by NHS Digital monitoring software (MediPi Patient upload endpoint and Clinical Web page)	100%

*It cannot be derived from the original dataset whether the submissions that were classed as being "Out of Threshold" were missing any other measurements due to the malfunction of other physiological devices. Some submissions of this classification will have a full set of other measurements and some will not. We therefore have printed a range for the percentage of full data submissions made to the database. Judging by the percentage of submissions with measurement data from one or more devices missing (54%), the real figure will most likely be in the centre of this range i.e. ~30%

Technical Issues

During the pilot the main issue the patients faced was with the finger pulse oximeter. For some the device drained its internal battery within a few days, for others it would not download data to the

MediPi Patient Device and for others it worked perfectly. From subsequent post-pilot research by the HCT Medical Devices Team the battery drain issue was due to inadvertently setting the pulse oximeter into a debug mode during the initial pairing process. It is still unclear as to why some of the pulse oximeters were unable to download data to the MediPi Patient Units.

Initially some patients were unable to download data from the pulse oximeter or the blood pressure cuff as the device's internal clock had become out of sync. 3 anomalous readings were identified from the pulse oximeter. The device's data processing protocol software was identified as problematic and updated. This update was pushed to the MediPi Patient Units which fixed this issue.

For each issue reported by a patient, a member of the HCT Transformation or Medical Device team would need to phone and/or visit their home to attempt a fix.

Patient device usage issues

Some patients experienced issues in using the physiological devices effectively – loose blood pressure cuff. Very few/no issues were reported in usage from the scales, thermometer or questionnaires

Access Issues

Early in the pilot, HCT's ICT provider of shared services had difficulties in enabling network access for clinicians to the MediPi Server within the Hosting VPN. In response, we moved the clinician facing MediPi Clinical Server to the N3 network. However, the clinicians were restricted to a limited view of patient demographics (patient initials only). After delays in approvals from Caldicott Guardians signoff, full access was available.

Patient feedback

Improving wellbeing and quality of life – in general there has been positive feedback from patients although a number are becoming anxious and frustrated with the number of attempts the pulse oximeter takes to successfully upload readings to the MediPi device.

Patients' comments include "being able to check my observations will help me manage my anxiety over my condition", "I like to feel in control of my condition" and "it's nice to feel involved and in control of my condition"

Patients reported that they found the power lead and transformer on the MediPi device not sufficiently long enough to stretch from wall plug sockets to their location. Patients are often confined to one area of their house which frequently does not have a plug socket within a one metre radius, plus extension leads are a trip hazard. As the MediPi Patient Unit does not have an On/Off switch patients have to insert or remove the cable from the back of the device or plug/unplug it at the wall which is not always accessible for this cohort of patients.

80% of the patients reported finding it difficult to tap the small buttons on the touchscreen.

Clinical Feedback

Nurses complete a survey monkey questionnaire relating to MediPi following every visit:
Has the patient experienced any technical problems with the MediPi device?
Yes - Pulse oximeter takes 2-3 times to get a reading to upload to MediPi device
Yes - Problems with transmitting data
Was your patient able to resolve the issue?
Patients have not been able to solve technical issues themselves.
Have you noticed your patient's anxiety levels changing?
Increasing – 0%

Decreasing – 34%
Stayed the same - 66%
Would you be able to make a clinical decision based on the MediPi data alone?
Yes – 67%
No – 33%

Clinical feedback has been mixed and suggests that although the MediPi will be useful in the future the problems encountered with equipment and current frequency of visits mean that the trial is adding to the nurse workload. Changes in a patient's condition were not always picked up by the MediPi but by the patients themselves as recorded observations were not always reflective of the patient's condition. It has been reassuring to the patient to have their own equipment and to check their observation themselves, but it has not been of benefit to the nurse nor has it reduced planned visits

Costs

MEDIPI COST PER PATIENT (incl VAT)	
Device & Software	£188.92
Pulse Oximeter	£360.00
BP Monitor	£120.00
Thermometer	£168.00
Diagnostic scales	£171.00
Medical Devices set up & delivery	£46.02
Transformation Team sorting equipment x 30 mins	£9.88
Installation Visit x 2 hours Nurse Transformation Team	£79.08
Total Cost per installation	£1,142.90

Discussion/Conclusion

i. The software developed by the MediPi Community (NHS Digital and Mastek) proved robust, with 100% availability and all attempted data submissions from the MediPi Device successfully transmitted across the concentrating server to the clinical front end without data loss or corruption.

ii. While the user interface on the MediPi Unit could be improved it was clear and functional.

iii. The largest and most fundamental issue which we encountered was that the majority of patients' daily submissions (54%) were missing measurements (usually one). Only an estimated 30% of the submissions had a full set of required measurements.

If data cannot be transferred seamlessly, consistently and easily from the physiological device (from the finger or round the upper arm) through to the clinical web server, then none of the subsequent questions relating to benefits of a remote patient monitoring solution can be satisfactorily addressed.

There was an inconsistency across the cohort of the taking of certain physiological measurements and downloading them to the MediPi Patient Unit. Some patients were consistently able to take all measurements, downloading them to the MediPi Patient Unit and submitting them to the server. Some patients were not able to. The MediPi software was not

at fault - in unit and system testing this process worked perfectly with all devices. However, the devices were tested on fit, healthy individuals who understood how to use the devices properly to obtain consistent measurements. There are 2 factors here:

1. Some patients had difficulty in using the devices sufficiently well to obtain a measurement.
2. Some of the physiological devices (pulse oximeters mainly) malfunctioned and stopped downloading data to the MediPi Patient Unit. This issue has not been satisfactorily resolved and may be due to one or more of several factors: incorrect use, inconsistent measurements as a result of use on a sick patient, technical failure of individual devices, incorrect initial pairing of devices, poor choice of device.

It is unclear from the results where the division lies between these 2 factors and therefore which had the greater impact.

To address the first, improvements need to be made in patient training and choice of patient cohort. Would a different clinical setting be more appropriate? Can better training counteract patient inexperience and nervousness of using technology?

In addressing the second issue it is important to note that in development of the solution we were very restricted in the choice of physiological devices, as we were prevented from entering into any Non-Disclosure Agreements with device manufacturers. We spoke to several who would have been eager to work with us but required an NDA to be signed as a prerequisite. There were no alternative choices for each of the Bluetooth enabled devices. The Marsden scales worked flawlessly, but significant issues were found "in the field" in the use of the pulse oximeter especially. With the resources and support of a willing supplier with an NDA, these issues could have been avoided.

Addressing this issue would have avoided the frustration felt by the Clinicians and HCT Transformation team staff at increased visit and calls to patients to fix issues with equipment.

The ultimate result is that the pilot was not able to reach a state of stability within the funding window which would have allowed us to properly address a proportion of the pilot aims.

It is interesting here to note recent reports of a remote patient monitoring scheme in Sheffield care homes[xxv]. Patients aren't required to take any measurements or use any electronic device. All measurements are taken by trained care home staff who can reliably take the measurements and manually input them via web forms. The physiological devices are not digitally connected to the recording devices. Their solution had a much greater support structure and organisational integration (a Central Digital Care home support team) to review observations.

iv. Patients in the cohort seemed to genuinely relish the opportunity of being more involved and actively managing their care. Perhaps this is not too surprising as they were patients that were chosen for being interested and able, but this is a group which currently does not have the opportunity. It has not been shown by this study, but it seems plausible that such patients' conditions can be improved by participation and involvement alone. The clinicians' report indicates that a third of the patients were less anxious.
However, some patients expressed frustration with non-functioning pulse oximeters which is counterproductive to this end.

This study has shown anecdotal evidence that patients were enthused and more proactive about self-management.

v. It has been recognised and acknowledged from early in the project that the most important strategic next step is porting the MediPi Patient Unit software to an Android environment. MediPi was developed on the Raspberry Pi platform for the reasons given in the development history, but porting to a mobile platform would address the findings relating to power cables and difficulty in pressing buttons. Additionally, however the following benefits can be realised:
   - Use of patients' mobile platform gives an instant reduction in hardware costs
   - Expectation of modern patients to have a mobile app
   - Explore new opportunities for interaction with the patient – cameras allow wound monitoring, remote consultation.
   - Integrated always-on nature of mobile devices mean that notification and alerts can be used more effectively
   - Integrated nature of the tablet/phone gives improved reliability and interoperability between modules
   - Integrated, reliable software management and update framework
   - Integrated calendar and scheduling functionality

   Caution should be exercised as there will be less control of the execution environment, quality of mobile hardware and potential for cross-application security breaches

vi. The cost per patient (£1142) was higher than originally anticipated. This was mainly due to the cost of the medical grade physiological devices which comprised over half the cost (£648). This cost could have been reduced with an unlimited choice of medical grade devices (unrestricted by NDAs). Alternatively, had non-medical grade devices been considered this cost would have been greatly reduced. Note: the cost of the medical grade physiological devices for this project was offset by HCT against future reuse.
   The study "*Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial*"[xxvi] states that "the average annual cost per participant for telehealth equipment and support was estimated as £1847". The MediPi costs represents a 38% cost reduction with some scope for further savings.

vii. It is clear that greater support was required for installing the devices in the patient's home and teaching patients how to use the devices.

This study demonstrated the practical implementation of remote patient monitoring. We have developed and open-sourced a full codebase, testing, documentation, certification and build guides which would allow any interested party to create a fully functional health-grade remote patient monitoring project. There is a great deal of evidence here that given a solution to the pulse oximetry issue explained above all the original questions could have been progressed greatly.

Further Work and Recommendations

- The number of missing data submissions can be reduced through improved patient training and guidance whilst taking measurements. This could be achieved through video guides

embedded into the MediPi Patient Unit interface or linked through a video website such as YouTube

- To have free reign to choose the best/most appropriate physiological devices, signing NDAs when necessary.
- Having participated in a brief UX assessment of MediPi Patient Unit it is clear that a full assessment would both improve the user experience and provide unexpected and valuable functional suggestions for improvement.
- To port the MediPi Patient Software to one or more mobile platforms.
- To consider the use of non-medical grade physiological devices

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https://github.com/rprobinson/MediPi/blob/master/documents/CEITO%20-%20Cost%20Effective%20Improved%20Teleheath%20Opportunity.docx

[iv] Whole Systems Demonstrator Study from https://www.bmj.com/content/344/bmj.e3874

[v] The MediPi Project source and resources are published on GitHub: www.medipi.org

[vi] Several well-regarded industry interviews were conducted and articles produced:

- http://www.computerweekly.com/news/4500278286/HSCIC-develops-Raspberry-Pi-telehealth-kit
- http://www.digitalhealth.net/digital_patient/47531/medipi-open-source-telehealth-kit-piloted-in-nhs
- https://www.raspberrypi.org/blog/raspberry-pi-telehealth-kit-piloted-nhs/

[vii] http://blog.wheaton.com/accuracy-vs-precision-know-the-difference/

[viii] https://www.mastek.com/

[ix] Excluding some bash scripting necessary for the instantiation of the VPN and initialisation on the raspberry Pi MediPi Patient unit

[x] Lynis software webpage https://cisofy.com/lynis/

[xi] A medication management patient module has been developed by Sam Chase - a masters student at York University as part of his final thesis. This is published at https://github.com/Samuel789/MediPi

[xii] https://twitter.com/robdykedotcom/status/913764514784563200

[xiii] https://shop.bsigroup.com/ProductDetail/?pid=000000000030218173

[xiv] A full guide to construction including EMC Testing procedure, evidence and EMC Certificate is available at https://github.com/rprobinson/MediPi/tree/master/EMCTesting

[xv] Since discontinued and no longer on the Omron webpage http://www.healthcare.omron.co.jp/bt/english/

[xvi] https://www.marsden-weighing.co.uk/index.php/medical-scales/product-finder/marsden-m-430.html

[xvii] http://www.nonin.com/Onyx9560

[xviii] https://www.welchallyn.com/en/products/categories/thermometry/ear-thermometers/braun-thermoscan-pro-6000.html

[xix] Test reports and evidence can be found at https://github.com/rprobinson/MediPi/blob/master/SoftwareTesting/README.md#non-functional-testing

[xx] https://digital.nhs.uk/services/solution-assurance/the-clinical-safety-team/clinical-risk-management-standards#dcb0129

[xxi] Medical device software applications https://www.gov.uk/government/publications/medical-devices-software-applications-apps

[xxii] Documentation guides can be found at https://github.com/rprobinson/MediPi/tree/master/documents

[xxiii] Patient Guide can be downloaded from: https://github.com/rprobinson/MediPi/blob/master/documents/MediPi_Patient_Guide_v1.3.docx

[xxiv] HCT MediPi Trial Evaluation report is available on request

[xxv] The Care Home Project webpage: http://ppptestbed.nhs.uk/projects/digital-care-home-project/ and local news report https://www.youtube.com/watch?v=v89kLTPTJOo

[xxvi] Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial https://www.bmj.com/content/346/bmj.f1035