# Cost-Effective, Improved Telehealth Opportunity (DRAFT)

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## Introduction

To use technology to improve remote healthcare provision is not a new idea and forms a part of Government strategy[[1]](#footnote-1). However many attempts to date, despite achieving varying degrees of success, have been less than satisfactory for a number of reasons. These can be identified as including:

* Cost of provision: use of expensive and/or proprietary hardware
* Limited success in addressing the problem: remote consultation for example does not save much on clinician time.
* Lack of integration with existing clinical systems and little or no use of NHS national infrastructure.
* Concerns over security and confidentiality

This paper is a result of investigative work undertaken, initially independently, by NHS England and the Health and Social Care Information Centre (HSCIC). After consultation it became clear that the two pieces of work were focussing on complementary aspects of the same problem. So it is published jointly, and identifies opportunities for addressing the above limitations, and others. In addition, it can use home-grown, British hardware.

The opportunity exists in terms of a collection of *technical* “solutions components”. It is straightforward for the non-clinical person to understand scenarios – and draw some parallels with known current practice – in which these components may be used to construct full clinical solutions. Aside from improved patient care, reducing admissions represents a potentially significant financial benefit to Trusts.

Whilst examples are presented here, clinical input is now needed to identify and to drive those solutions. This paper is presented to invite that collaboration.

## Case Studies

### Cross Gates & District Good Neighbours’ Scheme [[2]](#footnote-2)

Cross Gates & District Good Neighbours’ Scheme works to tackle social isolation in old people. CGDGNS is working in partnership with Leeds City Council and a company called Yecco to pilot a TeleHealth scheme. Participants are given an Apple iPad and a range of medical devices to measure things like heart rate, blood pressure and blood sugar.

### Airedale NHS Foundation Trust Telemedicine[[3]](#footnote-3)

Airedale Telemedicine is provided by Immedicare[[4]](#footnote-4). It supports remote video consultations between health care professionals and patients either in patients’ own homes, nursing homes, hospitals to GPs or hospitals to prisons. It helps to reduce patients’ lengths of stay in hospital and also supports care outside hospital, including early discharge, or avoids unnecessary visits and admissions to hospital. The project has been awarded Vanguard status by NHS England. It is currently limited to “screencare” - secure remote teleconferencing with a clinician.

Whilst these benefits are real, the approach does not integrate the biosensor monitoring from the Crossgates scheme. It is unclear how much it saves of clinician time or efficiently managing consultations.

## Background

### MediPi

In early 2015 the Messaging and Integration team at HSCIC Solutions Assurance were asked to look into how content from the unitary Summary Care Record could be divided up such that discrete access control became applicable to each part. The output of this work was presented via a “reference implementation” user interface that is part of the team’s ongoing open source software initiative for working with Spine and Interoperability Toolkit (ITK) messaging.

As a private initiative, Richard Robinson ported the Spine and user interfaces to a Raspberry Pi, and demonstrated integration with biosensors similar to those used in the Crossgates scheme. These demonstrations are available on request.

Spine and ITK integration solves many security and interoperability issues. It also addresses the “data leakage” concerns recently raised[[5]](#footnote-5) about “healthcare apps” running on mobile phones. Communications with Spine are encrypted in transit, ITK payloads can be encrypted from end-to-end such that only an authorised user or team can read the content, and the software at no point communicates with any insecure third parties.

### Kanteron and Device APIs

NHS England and Kanteron Systems are in the final stages of agreeing an MoU which will make available free to the NHS an ‘NHS code fork’ of open source technology comprising PACS, RIS, digital pathology, genomics, pharmacogenomics, biosensors and analytics.

The Biosensor module:

* Tracks personal data - pulse, SpO2 (blood oxygen levels), weight, sleep, meals, location, temperature, skin conductivity, activity
* Transforms biomedical device data into DICOM Wave Form (DWF)
* Supports user-defined Medical Logical Module (MLM) to turn transactional data into actionable information
* Enables API-RESTful integrations from virtually any tracker data source (Fitbit, Jawbone, Foursquare, Withings)
* Option to enter data manually
* Navigates all of the data collected - slicing, rearranging, and ordering by source, date series, weighted averages
* Display graphs and dashboards
* Enables inter system messaging via HL7 feed or DWF

This software is currently classified under FDA as Medical Device Data System[[6]](#footnote-6) (MDDS), intended to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulation 880.6310 OUG), help patients (i.e., users) self-manage their disease or conditions without providing, specific treatment or treatment suggestions; provide patients with simple tools to organize and track their health information; provide easy access to information related to patients’ health conditions or treatments; help patients document, show, or communicate potential medical conditions to healthcare providers; automate simple tasks for health care providers; or enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems.

Kanteron Systems’ solutions are currently registered under FDA and Kanteron Systems is registered as a Medical Device Manufacturer.

## Vision

MediPi is a demonstration of the components of a secure, general, low-cost telehealth device. It integrates medical measurement with two-way communication between the patient and clinicians. It uses existing NHS infrastructure, uses British designed and manufactured hardware, and free, open source software.

The Airedale telemedicine platform provides an environment in which encounters and consultations can take place. The MediPi platform, potentially coupled with use of the Kanteron device API, offers a British designed and manufactured, low-cost way to support organic, “with the patient” on-going remote medical monitoring. The Raspberry Pi may also offer a lower-cost platform for remote consultations than that currently in use.

Using Spine and “ITK Trunk” messaging monitoring data can be securely transmitted to GPs or Trust-based clinicians and used to improve care outcomes via early detection of problems, and provision of improved diagnostic information. This communication is two-way – in principle information and recommendations can be returned to the patient either from clinicians and clinical systems.

## Examples

Deployment scenarios include:

* ***Heart failure patients in end stage*** have a very high risk of admission. A good way of knowing if they are responding to treatment, or if they are getting worse, is to weigh them. Scales suitable for home use, and equipped with USB, Bluetooth or WiFi data interfaces are available for under £100, and a patient device would be able both to collect measurement data, and raise an alert if the patient either missed weighings, or if their weight showed an increasing trend indicating fluid retention.
* ***Blood pressure and sugar monitoring*** by patients suffers from a range of problems from forgetfulness, to illegible handwriting. A MediPi device would be able to remind the patient to record their blood sugar, and provide summary information or alerts to their GP.
* ***Monitoring wound recovery*** would be assisted by using a MediPi device to send photographs.

Connection via Bluetooth has various attractions although the technology has been found generally to be less well served with open interface standards. Wireless connectivity can be expected to improve, but physical and in particular USB connections make integrating many devices, achievable immediately.

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| **Device** | **Application** | **Price range, £[[7]](#footnote-7)** |
| Scales | General patient weight monitoring, especially those in treatment for heart failure who have a high risk of admission | 25-60 |
| Blood sugar monitor | Diabetes | 30-60 |
| Blood pressure cuff | General patient blood pressure monitoring | 30-60 |
| Finger pulse oximeter | Heart rate and blood oxygen monitoring | 25-40 |
| Camera | Wound monitoring, videoconferencing/remote consultation | 20-40 |

Monitoring may even be improved via the Hawthorne effect[[8]](#footnote-8), where the patient knows that their results are being sent to their physician. Are they doing their exercises? Before-and-after heart rate measurements can show that the exercises are being done even if the actual measured details are not used directly.

## Presentation

Data acquired via patient devices are assumed to be integrated with existing clinical applications, and presented through them. Whilst it would be possible to build dedicated applications to receive the data (and such may be written for presentation to the patient, using the device) greatest value is expected to be gained from providing data to existing systems. In some cases those systems may require extension, for example where patient devices are equipped with cameras and photographic data can be acquired and sent.

Different users can be expected to require different “filters” – particularly where the data is recorded continuously. In some cases a real-time plot on unfiltered output will be suitable. On others, summaries such as maximum/minimum/variation or even just alerts when a monitored physical value goes out of range. A subscription approach would be appropriate, where a device generating one or more sets of data had users “subscribe” to each data stream via a filter appropriate to their needs.

## Taking the Concept Forward

**The single most important requirement for moving the concept forward is clinical engagement. The work to date has been carried out with an *awareness* of clinical practice and need, but not the detailed *understanding* that involved healthcare professionals can bring.**

Additional clinical involvement is vital. A number of other aspects require addressing. NHS England’s Open Source / Code4Health programme and the Open Source Software Foundation have and continue to engage, fund and facilitate clinical involvement and ownership across a number of initiatives and work streams[[9]](#footnote-9). NHS England’s initial exploratory engagement with the NHS has identified individuals and organisations that have already indicated their wish to collaborate with this proposed initiative.

### Development Community

The “Vision” outlined above is predicated on the availability of a set of components and basic capabilities – and *ideas* how to use them. It offers potential to solve many real-world problems but will be most effective at doing so if it is open to be used by people who understand those problems and what is needed to solve them. NHS England’s Code4Health[[10]](#footnote-10) and “Community Interest Companies” offer mechanisms to establish and formalise exploiting the opportunities outlined here.

### Finance

The concept is recognised in the private sector, and funding has been raised before now for a similar concept (albeit one aimed at developing markets)[[11]](#footnote-11).

Additionally, via the Open Source Programme NHS England is commissioning not for profit organisations to provide custodianship and delivery services to NHS Trusts via the Open Source Software Foundation / Code 4 Health initiatives which directly address the imminent demands from front line NHS Staff that are required to determine their technology requirements, interactions with the market place and suppliers, for the purpose of supporting and improving patient care.

The above facilitation is typically enabled via grant award or direct funding to the custodian (an approved open source or code4health community, or a community interest company).

### Hardware and Software Packaging

The stock Raspberry Pi is not a clinical device. Input is required from physical device packaging experts to be able to understand and deliver a safe and appropriate hardware enclosure. Similarly, the stock Raspberry Pi operating system, Raspbian[[12]](#footnote-12), is based on Debian Linux and is intended for enthusiasts – it is not “user proof”. User-appropriate software packaging will be required that handles security (including device- and possible user-specific certificates), automated updates and the user interface. A stock Raspberry Pi comes with 4 USB ports which may also be needed to support devices such as keyboards/mice, wireless and possibly Bluetooth interfaces. USB may also be required for connection via a mobile phone, where wireless network access is not available. So production enclosures should support the option of including a USB hub to increase the number of devices that can be connected.

It should be possible to clean physical packaging, although the Raspberry Pi devices themselves are not expected to be used in “high risk”[[13]](#footnote-13) patient contact requiring sterilisation or disinfecting after use.

The software is open source and is not hardware-specific. So it is amenable to deployment on other platforms – laptops and tablets, for example – and leveraging existing hardware investment. Saying that, the Raspberry Pi approach offers an opportunity for a “walled garden” which keeps security and confidentiality measures more under project control. Deployment onto other devices – in particular with modern trends toward “user as vendor’s product” and the resultant encroachment on personal privacy – will require careful consideration about the protection of personal and clinical information.

### Certification

It is assumed that some – possibly all – deployments of such technology will be within the definitions of “medical device” and so will require certification. The programming interfaces and some of the devices used in the prototype to date have not been medically certified (in the case of the scales, presumably for legal reasons) although they generate accurate and usable data.

Typically medical device certification depends on intended use, so for example, a device that drives or influences the use of a source device with the intention to allow diagnosis or interpretation of data via an algorithm would need at minimum CE Class IIa certification. As certification is done partly via external assessment of not only the device but organisation development capability and accreditation status the best way forward in the short term would be to work with an organisation which already satisfied these criteria.

A system using Spine and ITK messaging will require some combination of Spine and ITK accreditation – the details of the combination will depend on precisely what the deployed system does. Closely-tailored accreditation and assurance processes are available for both Spine and ITK. These processes include regard for clinical safety and information governance.

### Security and Infrastructure

The available demonstrations do not connect to Spine directly – rather they use a Virtual Private Network (VPN) connecting over a mobile internet device, to a proxy. The MediPi demonstrations make and consume Spine and ITK messages but it is the proxy that is connected to Spine[[14]](#footnote-14). These capabilities are based on those available through the HSCIC Solutions Assurance test lab. Production-ready equivalents of this infrastructure, or parts of it, will also be required.

A platform for patient use will require strong authentication of the patient and/or the device – and to do so in a user-friendly way, particularly given the likely patient subset is elderly, possibly infirm and with conditions such as arthritis which makes using keyboards physically difficult. ITK messaging allows for content to be secured using public-key cryptography that identifies the originating device and will only permit specific recipients to decrypt the content. The communications chain: VPN, Spine (or Spine-protocol) messaging, and proxies offers scope for infrastructural security measures, and for strong authentication of the connecting devices and their users.

To do this requires a formal security policy to be written, and PKI design to be established and supported.

### Information Governance

The “Vision” above involves on-going (possibly real time) collection of patient medical data, and its processing and transmission. One view may be that these information flows are easily covered by over-arching consent given by the patient for the care relationship with the GP or Trust-based clinic. That may be so, however a review of consent and medico-legal aspects of the proposal is required.

1. See Health Secretary Jeremy Hunt in 2012: <https://www.gov.uk/government/news/health-technologies-to-improve-the-lives-of-people-with-long-term-conditions> and “Personalised Health Care 2020 – A Framework for Action”, from the NIB in 2014: https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/384650/NIB\_Report.pdf [↑](#footnote-ref-1)
2. See http://news.leeds.gov.uk/social-network-helping-older-people-bridge-the-digital-divide [↑](#footnote-ref-2)
3. See http://www.airedale-trust.nhs.uk/services/telemedicine/ [↑](#footnote-ref-3)
4. http://immedicare.co.uk/ [↑](#footnote-ref-4)
5. According to the BBC: http://www.bbc.co.uk/news/technology-34346806 [↑](#footnote-ref-5)
6. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=158304 [↑](#footnote-ref-6)
7. Based on commercially-available offerings, not an NHS England catalogue [↑](#footnote-ref-7)
8. http://www.economist.com/node/12510632 [↑](#footnote-ref-8)
9. https://code-4-health.org/communities [↑](#footnote-ref-9)
10. http://www.england.nhs.uk/ourwork/tsd/code4health/ [↑](#footnote-ref-10)
11. http://www.economist.com/news/britain/21661670-political-philosophy-britains-most-successful-city-getting-cambridge [↑](#footnote-ref-11)
12. https://www.raspbian.org/ [↑](#footnote-ref-12)
13. See table on p3 of http://www.newcastle-hospitals.org.uk/DecontaminationofHealthcareEquipmentPolicy201406.pdf [↑](#footnote-ref-13)
14. It should be noted that the mechanisms used for connection to Spine would work just as well for communication with a Trust- or GP- based support system. Assuming a centralised approach for communications is therefore not essential, but is based on economies of scale when considering costs of hardening, penetration testing and other requirements of a secure, reliable and production-ready infrastructure. [↑](#footnote-ref-14)