



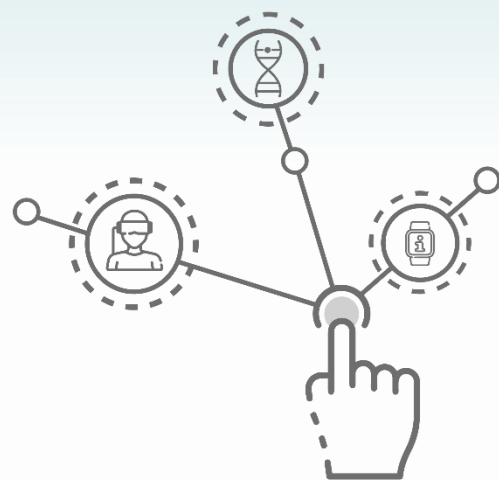
Delivering value with digital technologies  
Briefing: March 2022



# Remote monitoring of implantable cardiac devices

## Improving patient safety and reducing face-to-face appointments

Case study



Supported by



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# Delivering value with digital technologies

Digital technologies such as digital medicine, genomics, artificial intelligence and robotics have a huge potential to transform the delivery of healthcare.<sup>1</sup>

These technologies can empower patients to participate actively in their care, with a greater focus on wellbeing and prevention. They also support the prediction of individual disease risk and personalise the management of long-term conditions.

The HFMA, supported by Health Education England, is delivering a 12-month programme of work to increase awareness amongst NHS finance staff about digital healthcare technologies, and enable finance to take an active role in supporting the use of digital technology to transform services and drive value and efficiency.<sup>2</sup>

As part of the programme, the HFMA is publishing a series of case studies. Working with organisations who have started on the digital transformation journey, we will identify examples of good practice and highlight the challenges that services face. This will include specific challenges relating to NHS finance.

This case study describes how Leeds Teaching Hospitals NHS Trust has re-designed the cardiology pathway for patients fitted with an implantable device. Digital technology has supported the remote monitoring of devices, reduced the frequency of face-to-face review appointments, and enabled early detection of changes that may require intervention.

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<sup>1</sup> HFMA [Introduction to digital healthcare technologies](#), July 2021

<sup>2</sup> HFMA [Delivering value with digital technologies](#)

# Implantable cardiac devices

Implantable cardiac devices are used for the monitoring and treatment of common cardiac conditions caused by irregular heart rhythms (**figures 1 and 2**).

In 2018/19 a total of 5,362 implantable cardioverter defibrillators, 37,633 pacemakers and 11,036 loop recorders were implanted by the NHS<sup>3</sup>. Pacemaker implantation is one of the most common types of heart surgery carried out in the UK.

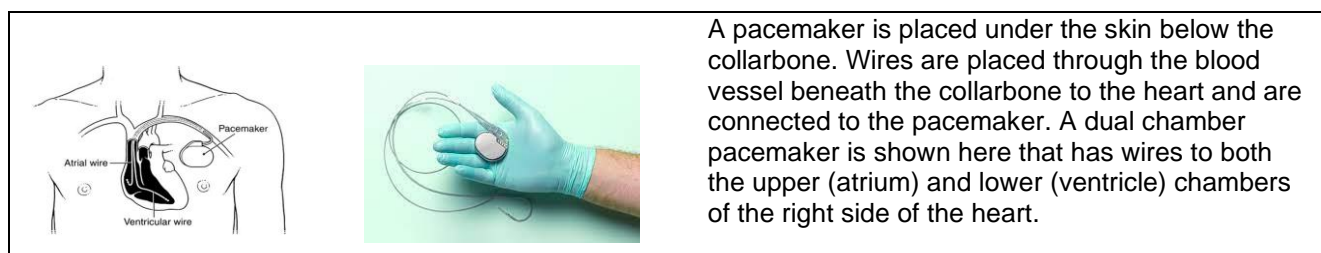
Patients fitted with an implantable cardiac device require routine monitoring by cardiac specialists to check for changes in their symptoms and diagnosis, and to ensure that the device is continuing to work correctly. Review appointments typically occur at six-monthly intervals. Patients fitted with loop recorders also require additional unscheduled appointments each time they manually activate their device.

Leeds Teaching Hospitals NHS Trust (the trust) has approximately 5,500 patients under follow up for implantable cardiac devices. This case study describes how the trust has rolled out remote monitoring for the benefit of patients and the service.

## Figure 1: Types of implantable cardiac devices

<p><b>Implantable loop recorders (ILR)</b> require manual activation by the patient when they are experiencing symptoms. An electrocardiogram (ECG)<sup>4</sup> is recorded and abnormal heart rhythm can be detected, but the ILR does not provide therapeutic input. The ECG recording needs to be downloaded from the device before the clinical team can analyse it.</p> <p><b>Permanent pacemakers (PPM)</b> monitor and regulate the heart through electric pulses. They prevent bradycardia<sup>5</sup> (slow heart rate) by not allowing a heart rate to drop below a set rate.</p> <p><b>Implantable cardioverter defibrillators (ICD)</b> act as an internal defibrillator<sup>6</sup> for patients at risk of sudden heart failure. Most can act as a pacemaker to prevent bradycardia (if required) and will treat dangerously fast arrhythmias which could cause cardiac arrest if not treated. The treatment may be in the form of anti-tachycardia pacing (ATP)<sup>7</sup> but if this is not successful the ICD may shock the heart internally.</p> <p><b>Cardiac resynchronisation defibrillators (CRTD)</b> are normally implanted in patients with heart failure symptoms and left bundle branch block<sup>8</sup>, and aim to pace the heart all of the time to make the heart beat in a more synchronised way, reducing symptoms of fatigue and shortness of breath. A CRTD will be used in conjunction with medication and may be offered to patients who would be eligible for an ICD and are also at risk of a dangerous heart rhythm.</p> <p><b>Cardiac resynchronisation therapy pacemakers (CRTP)</b> are similar to CRTDs. They are offered to patients who decide against the defibrillator component (for example HGV licence holders).</p>
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## Figure 2: How a pacemaker is implanted



<sup>3</sup> Getting it right first time, *Cardiology - GIRFT programme national specialty report*, February 2021

<sup>4</sup> An electrocardiogram is a simple test that can be used to check the heart's rhythm and electrical activity

<sup>5</sup> Bradycardia is a heart rate that is too slow, based on an individual's age and physical condition.

<sup>6</sup> A defibrillator is apparatus used to control rapid, irregular, and unsynchronised contraction of the heart by applying an electric current to the chest wall or heart.

<sup>7</sup> Anti-tachycardia pacing (ATP) aims to stop ventricular tachycardia (fast heart rhythm over 100 beats per minute).

<sup>8</sup> Left bundle branch block is a condition where activation of the left ventricle of the heart is delayed, which causes the left ventricle to contract later than the right ventricle. It does not always cause symptoms.

## Remote monitoring of implanted devices

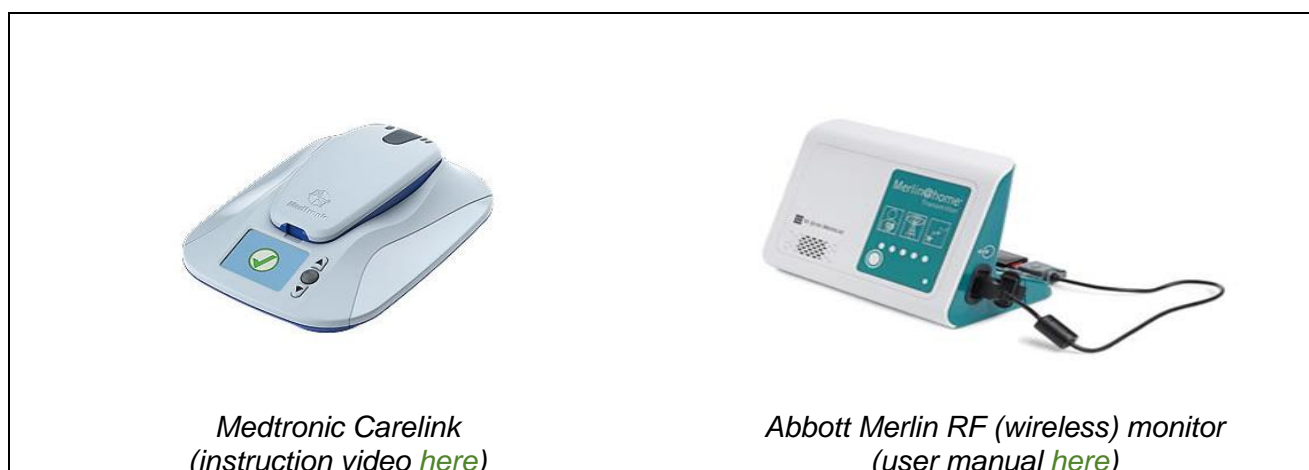
Digital technology that enables remote monitoring of implanted cardiac devices was first developed over 20 years ago and is now available for most implantable cardiac devices.

Patients can record information from their implanted devices and transmit it to their care provider without the need for a face-to-face appointment. The monitoring devices are proprietary to the implant that has been fitted and cost between £200 and £500 depending on the manufacturer. Devices are designed to last for the full lifespan of the implanted device and are generally provided new to the patient and not reused.

Two examples are shown in **figure 3**. The devices have a built-in transmitter (similar to mobile phone technology) so do not require a patient to have separate access to Wi-Fi via broadband or mobile data. Mobile phone apps are also available for some implantable devices but are not discussed in this case study.

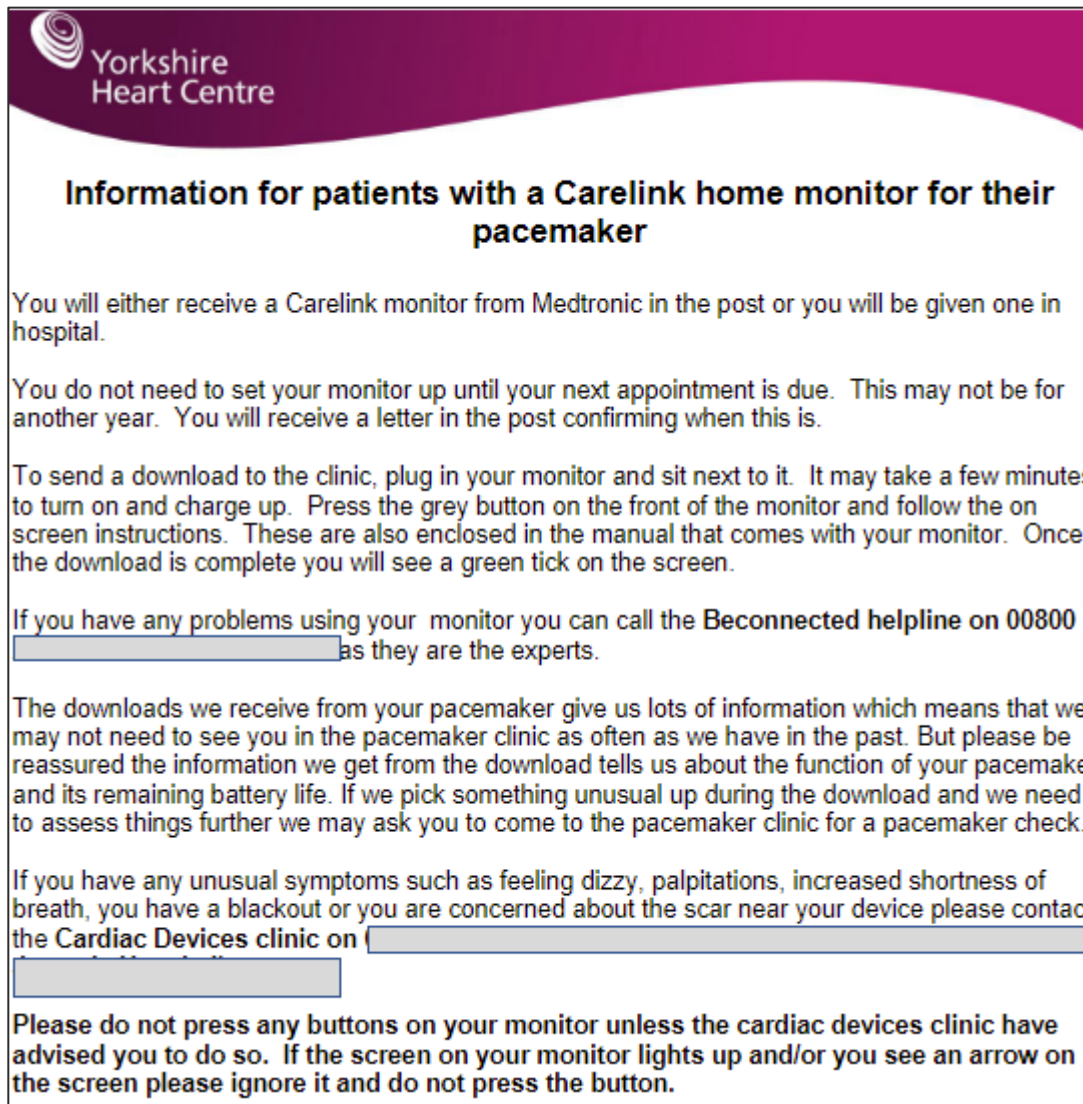
Depending on the device, transmission may be manual, automatic or a combination of both. Manual transmission is patient initiated, but automatic also allows for alert based monitoring and scheduled transmissions.

**Figure 3: Examples of remote monitoring devices**



Patients who already have an implanted device will be taught how to use remote monitoring during a routine follow-up review. For patients fitted with a new device, remote monitoring is set up while they are in hospital and the patient can start using it immediately. **Figure 4** is an example of a Leeds patient information leaflet. Each supplier also has dedicated UK helplines that patients can access.

Figure 4: Example of patient information leaflet



## Impact of remote monitoring on patient pathways

The roll-out of remote monitoring at the trust has fallen into three distinct phases, each being driven by the needs of patients and services and the availability of technology. **Figure 5** illustrates the timeline.

Figure 5: Timeline for implementation of remote monitoring at the trust

<p><b>2007 – loop recorders</b></p> <p>Patients with loop recorders make up 19% of the 5,500 patients under follow-up at the trust but due to the patient-led nature of recording they can generate significant unscheduled downloads. Early implementation of remote monitoring removed the need for a patient to attend the trust for a face-to-face appointment each time a download was required. This increased overall clinic capacity and improved the patient experience.</p> <p><b>2019 – implantable cardioverter defibrillators</b></p> <p>Until 2019, the only other follow-up patients on remote monitoring were a small group of ICD patients who needed close monitoring for issues with their devices. This included 200 patients who had the frequency of follow up increased from six-monthly to three-monthly intervals due to a field safety notice from one ICD manufacturer.</p> <p>The success of this extension in avoiding additional face-to-face appointments, coupled with clinic capacity constraints as the overall number of patients on follow-up increased, prompted the trust to roll out remote monitoring to all ICD patients in 2019.</p>
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## 2020 – pacemakers

Technology to support remote monitoring of pacemakers has only been developed in the past few years. Based on the primary benefits already described, a small pilot scheme using the technology was planned for 2020, but the onset of the Covid-19 pandemic brought forward the timing and scale of implementation due to patient safety concerns.

The introduction of remote monitoring has had an impact on patient pathways. **Figure 6** illustrates the changes to the patient pathway for all patients with implanted cardiac devices, while **figure 7** highlights the additional changes to the pathway for patients with loop recorders.

Remote monitoring does not alter the number of patients that a clinician can review in a single routine clinic. At Leeds, on average 17 patients will be reviewed in a clinic but with remote monitoring only six of these will be face-to-face appointments. This releases physical clinic capacity and increases productivity as discussed in the evaluation section below.

Remote monitoring significantly reduces the number of face-to-face appointment slots that need to be held for urgent unscheduled appointments. Instead the team needs to set aside time each day to review all unscheduled transmissions and contact the patients by telephone, but this can be structured around other clinic commitments.

**Figure 6: Impact of digital technology on patient pathway for all implanted devices**

Without remote monitoring	With remote monitoring
<ul style="list-style-type: none"><li>• all appointments are face-to-face</li><li>• first review is six weeks after surgery followed by appointments at three and six months</li><li>• regular review appointments are then scheduled at maximum 12-month intervals for pacemakers, six months for other devices</li><li>• review appointments increase in frequency once battery longevity reaches one year</li><li>• at the appointment the clinic team download and interpret data from the implanted device</li><li>• problems with a device or changes in a patient's condition are identified during the appointment and action is initiated as required</li><li>• it is unusual for patients to have contact with the service between scheduled appointments</li></ul>	<ul style="list-style-type: none"><li>• patient attends for a face-to-face review six weeks after surgery followed by a telephone appointment at six months</li><li>• regular review appointments alternate between face-to-face and telephone appointments at maximum 12-month intervals for all devices</li><li>• an automatic scheduled transmission enables the clinical team to review results ahead of the telephone appointment</li><li>• customisation of unscheduled transmission parameters ensure early detection and intervention where there are changes in a patient's condition, including where arrhythmia<sup>9</sup> is detected</li><li>• device faults are captured early through unscheduled transmissions and can be rectified</li></ul>

<sup>9</sup> An arrhythmia is an abnormality of the heart's rhythm. It may beat too slowly, too quickly, or irregularly. These abnormalities range from a minor inconvenience or discomfort to a potentially fatal problem.

**Figure 7: Impact of digital technology on patient pathway for loop recorders**

Without remote monitoring	With remote monitoring
<ul style="list-style-type: none"><li>• patient feels unwell and initiates an ECG recording</li><li>• patient contacts hospital and arranges an unscheduled face-to-face appointment for the clinician to download the ECG recording</li><li>• therapeutic input is provided if required based on reading of the ECG</li></ul>	<ul style="list-style-type: none"><li>• patient feels unwell and initiates an ECG recording</li><li>• recording is automatically transmitted to the clinical team who review with all other unscheduled transmissions the following day</li><li>• patient has a telephone consultation and is given appropriate advice</li><li>• therapeutic input and face-to-face follow up is initiated only if required</li></ul>

## Making the case for investment

### Business case

Before investing in digital technologies, a business case needs to be developed, setting out what the problem is and how the proposed solution will deliver value for the NHS body and its patients. The business case will need to set out a compelling case for investment which requires an understanding of its financial and non-financial impact. The financial argument needs to include details of the cost of the new care model, identify potential financial benefits and outline classification of expenditure as capital or revenue, along with associated accounting and funding implications <sup>10</sup>.

The complexity of the technology and level of investment required will dictate the structure and size of the business case, while approval routes will be subject to individual organisational policies.

Before the pandemic, the trust had planned to introduce remote monitoring of patients with pacemakers as a small pilot, which would have been evaluated over three to six months and the findings used to develop a full business case for approval.

However, the roll-out of remote monitoring for this patient group was accelerated in line with trust pandemic protocols, which were designed to protect highly vulnerable patient groups and avoid in-person attendance wherever appropriate. Early in the pandemic the trust board decided that finance would not be a barrier to patient safety. Any service that needed to spend over £100,000 on patient-related expenditure was required to get approval before progressing but this was usually done the same day. Services did not need to go through the usual funding decision-making protocols and processes that could take weeks.

An initial bulk purchase of monitoring devices for the most clinically vulnerable was followed by further investment approvals to extend patient numbers later in 2020. The service lead worked closely with procurement, financial management and suppliers to ensure that procurement and information governance policies were adhered to.

### Accounting for digital investment

Physical assets will often meet the definition of a tangible asset as they will be used for the supply of healthcare services for more than a year. The cost of buying assets will therefore be classified as capital expenditure (capitalised). However, the DHSC *Group accounting manual*, requires that assets that cost less than £5,000 are treated as revenue expenditure unless they meet the definition of a grouped asset (**figure 8**).

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<sup>10</sup> HFMA, *Accounting for revenue and capital: implications for the digital age*, December 2021, explores the key funding and accounting issues that NHS finance teams need to consider when developing business cases for digital transformation

## Figure 8: Determining whether expenditure is capitalised

In the NHS, the accounting policy is that assets (tangible or intangible) that cost less than £5,000 are not capitalised. The £5,000 de minimis includes non-recoverable VAT. The cost of these assets is charged to revenue as it is incurred.

However, if several low-value assets are purchased as part of a single collective asset, they are capitalised as a grouped asset. To be capitalised as a group, each of the items in the group must meet all these criteria:

- the total cost of the grouped asset is greater than £5,000
- the assets are functionally interdependent – so they can only be used together
- the assets are bought at the same time and are planned to be disposed of at approximately the same time – effectively, the plan is to use the assets together for the whole of their useful economic life
- the group of assets is under single managerial control
- each individual asset has a value of more than £250.

In this case, the total cost of the bulk purchase was more than £5,000 and most of the remote monitoring devices cost more than £250 each so they could meet the definition of a grouped asset. However, the following assessment means that the monitoring devices do not meet the requirements for capitalisation as a grouped asset and are therefore classified as revenue expenditure:

- the monitoring devices are not functionally interdependent – although they all transmit data to the same system at the hospital, each patient's device works independently of all other devices. It does not matter whether there is one device transmitting data or hundreds
- in this case, the devices were bought in bulk because of the speed of roll out of the programme but the devices will usually be purchased as required
- the device is effectively disposed of when it is replaced, or the patient dies – this will happen when necessary and not to a planned replacement schedule
- the trust has a level of managerial control through the clinicians who read the data transmitted by the device and will take action if the device indicates that there is a fault or that clinical intervention is required. However, the device is given to a patient and the expectation is that it will not be returned or used for another patient. The patient can move away from the area and take the device with them to another hospital. Therefore, the devices are not under single managerial control.

In cases like this, where the device is given to a patient, it is important to consider control of the device. To be capitalised as an asset owned by the trust, it must have control of the use of that asset so the purchase of devices that are implanted into patients or are taken home by them are unlikely to meet the definition of capital expenditure. Instead, they will be treated as inventory, and the expense will be incurred when the device is implanted in the patient.

## Evaluating the impact

While the accelerated roll-out meant that a business case for the remote monitoring of pacemakers was not developed, the finance business partner has been working closely with service leads for the past two years, evaluating the financial and non-financial impact on patient pathways. A business case is currently being developed to support full implementation of remote monitoring for all eligible patients. Evidence generated through the evaluation is being used to make the case for additional investment.



There have been two significant benefits to the roll-out of remote monitoring:

- the need to attend face-to-face appointments is reduced. This improves patient experience and releases clinic capacity
- automatic transmission based on alert and parameter-based monitoring can lead to early detection of device faults or changes in a patient's condition. Intervention at this stage may reduce complications and avoid admissions.

The next sections provide more detail on some of the resource and qualitative impacts that Leeds have identified.

## Understanding the resource impact

Understanding the resource impact of the new patient pathways is a key part of the business case and evaluation process. There are likely to be increases in some cost categories and decreases in others.

### Figure 9: Types of financial benefits

**Cash releasing benefits** reduce the cost of the care model so that the resources can be completely re-allocated elsewhere, or the cost can be removed from a budget, for example reduced number of healthcare staff required.

**Non-cash releasing benefits** provide economic value through savings from increased efficiency and effectiveness, but they do not release cash, for example reallocation of staff time.

### Additional costs

The trust has identified the additional costs of remote monitoring:

- The most significant cost is the purchase of the remote monitoring devices. This is between £200 and £500 per device, depending on the make and model, and is proprietary to the implanted device. As previously noted this is revenue expenditure.
- Monitoring devices will usually last for the life of the implanted device, so the recurring additional costs are based on the number of new implants per year. There is an initial non-recurring impact of purchasing devices for existing patients on follow-up. Under normal circumstances it may be possible to manage this within a fixed budget by controlling the speed of roll-out but the trust did not have this option in 2020.
- The team has appointed additional administrative support to manage patient queries associated with the set-up and ongoing use of their remote monitoring devices. This also supports patient education and enables the rest of the team to focus on clinical work.
- Other incidental costs are minimal but include patient leaflets which are designed in-house at the trust.

The technology does not result in significant cash savings for the trust. Reducing the number of face-to-face appointments for individual patients reduces their cost of travel. There may be a small benefit to the trust from reducing patient transport requirements depending on providers and contracts in place.

### Non-cash releasing benefits

Although the introduction of remote monitoring has not generated cash savings, it has generated non-cash releasing benefits, both for the cardiac team and the wider trust. Some of these benefits are described below.

## Cardiac team

The changes introduced have increased productivity<sup>11</sup> for the clinical team:

- reduced downtime between appointments and reduced DNA<sup>12</sup> rates allow clinicians to see more patients in a virtual/telephone clinic compared with face-to-face
- increased face-to-face clinic checks as the implanted device nears the end of its lifespan are eliminated as unscheduled parameter-based transmissions will detect device malfunctions
- urgent face-to-face appointments can also be accommodated more easily.

The number of patients on follow-up is increasing year-on-year due to both the numbers of patients fitted with cardiac devices and improved life expectancy. The productivity gains mean that more of this demand can be absorbed without needing to expand physical clinic space or workforce.

Staff time needs to be allocated daily to review the unscheduled transmissions and there are potential unintended consequences of unnecessary review if parameters are set incorrectly or if patients initiate inappropriate transmission. These consequences are likely to reduce over time with parameter refinements and patient education.

## Wider trust

Unscheduled transmissions allow earlier detection of arrhythmias which may initiate treatment to reduce the risk of stroke. Identification of lead/device integrity issues and heart failure diagnostic changes could reduce heart failure admissions. In both cases it is difficult to directly attribute any benefits as being due to remote cardiac monitoring.

Early identification of changes to a patient's condition through remote monitoring has increased referrals to other specialist teams. The most common of these are to arrhythmia nurses where atrial fibrillation (AF)<sup>13</sup> is detected. To date the specialist teams have not noted undue pressure on service capacity but this continues to be monitored, and the benefit again is that conditions are picked up earlier.

## Understanding the qualitative impact

Understanding the qualitative impact of new pathways is another key part of the business case and evaluation process.

### Figure 10: Qualitative and societal benefits

**Qualitative benefits** occur where value is added but cannot be measured in monetary terms, for example

- improvements in safety, experience or outcomes for patients
- better integrated care
- improved staff experience.

**Societal or public benefits** are non-cash releasing and the NHS does not directly benefit, for example reducing the carbon footprint, tackling health inequalities in its workforce, investing locally and improving the wellbeing of the local population.

<sup>11</sup> The ratio of a volume measure of output to a volume measure of input use

<sup>12</sup> DNA – did not attend. Where a patient fails to attend a scheduled appointment without informing the trust or with insufficient notice for the trust to book another patient into the slot.

<sup>13</sup> Atrial fibrillation is characterised by a rapid, irregular heartbeat. It can lead to a five-fold increase in stroke risk, a three-fold increase in incidence of congestive heart failure and increased mortality rates if not detected and treated.

The trust has identified a number of qualitative benefits for remote monitoring:

- the reduction in face-to-face contact with highly vulnerable patients reduces their risk of catching Covid-19
- more long-term, unscheduled parameter-based transmissions means that changes in a patient's condition can be detected earlier, allowing early intervention and reducing the risk of complications such as stroke or heart failure
- patients benefit from the convenience of not having to attend hospital appointments as regularly. This can result in not needing to take time off work, miss social events or arrange carers to look after dependants and hence the patient's measure of social value<sup>14</sup> increases. This also directly impacts on societal and public benefit.

They do however also note that the reaction to changes from both staff and patients has been mixed.

*'Staff can see the benefit but implementing requires effort. There is more buy-in from some staff and patients than others. New patients are more receptive as for them this is the norm for follow up.'*

Annabel Allan, highly specialised cardiac physiologist, Leeds Teaching Hospitals NHS Trust

All patients are given a choice of whether to adopt remote monitoring. Even with the accelerated roll-out for patient safety during the pandemic, some chose to remain with fully face-to-face appointments.

## The role of finance

Finance teams have a key role to play in supporting the use of digital technologies to transform services and drive value and efficiency.

*'The finance community are catalysts for digital transformation with their responsibility for business cases, governance and improving value'*

Patrick Mitchell, director of innovation, digital and transformation, Health Education England

Examples of this during the accelerated roll-out of remote monitoring for pacemakers at Leeds included:

- director of finance response to pandemic, citing that patient safety was paramount, was key to the prompt roll-out for the most clinically vulnerable patients
- support from the finance business partner and procurement expedited the purchase of devices
- approval of unfunded recruitment enabled appointment of an additional administrative post
- the assistant director of finance ensured expenditure was monitored and reported in accordance with the revised arrangements for contracting and payment during the Covid-19 pandemic<sup>15</sup>.

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<sup>14</sup> Social value is the quantification of the relative importance that people place on the changes they experience in their lives.

<sup>15</sup> NHS England and NHS Improvement, [Covid-19 payment arrangements](#), March 2020

By supporting the development under these circumstances and without an evaluated pilot, the finance team had to put absolute faith in clinical colleagues. This has resulted in improved relationships and increased collaborative working, which has been evident as the teams work together to develop a business case for the rolling out of remote monitoring to all eligible patients.

*'Finance teams need to be the architects of a solution that fits within the main constraints of quality and finance in the NHS. It is not our job to say no, it's our job to make sure we're getting value for the taxpayer.'*

Ben Roberts, assistant director of finance, Leeds Teaching Hospitals NHS Trust

## Future plans

The trust plans to extend the use of remote monitoring for all types of implantable cardiac devices and for all eligible and willing patients. A business case to support this, with identification of recurrent funding streams is currently in development.

There are plans to provide cardiac nurses in the community with remote access to the implant monitoring information where there is an overlap in care between the cardiac and community teams. This will require a collaborative approach and training, but is expected to have benefits for both staff groups and their patients, delivering a joined-up approach to patient care.

The circumstances associated with the rapid roll-out of remote monitoring for this patient group has facilitated an internal discussion about the risk appetite required at board and wider system level to ensure that digital transformation can deliver maximum value.

*'Investment in digital technology requires an entrepreneurial leap of faith that it will result in productivity gain and significant patient safety improvement.'*

Ben Roberts, assistant director of finance, Leeds Teaching Hospitals NHS Trust

## How to find out more

If you want to find out more about the remote monitoring of cardiac implantable devices, contact:

Annabel Allan

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Leeds Teaching Hospitals NHS Trust

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This case study is part of the *Delivering value with digital technologies* programme that the HFMA is undertaking, supported by Health Education England. The programme aims to increase awareness amongst NHS finance staff about digital healthcare technologies, and enable finance to take an active role in supporting the use of digital technology to transform services and drive value and efficiency. For more information click [here](#).

## About Health Education England

Health Education England (HEE) is part of the NHS, and we work with partners to plan, recruit, educate and train the health workforce. HEE exists for one reason only: to support the delivery of excellent healthcare and health improvement to the patients and public of England by ensuring that the workforce of today and tomorrow has the right numbers, skills, values and behaviours, at the right time and in the right place.

HEE's Digital Readiness Programme, commissioned by NHSX, aims to uplift digital skills, knowledge, understanding and awareness for all our health and care workforce. This includes:

- Supporting the right culture and environment, for example by ensuring digital is understood, embedded and championed at trust and ICS board level.
- Professionalising the digital workforce through support for professional bodies, regional Informatics Skills Development Networks, and collaborative community networks.
- Establishing learning and development through the NHS Digital Academy and specific learning and development initiatives, for example the Florence Nightingale Digital Nurse Scholarship, and through access to tailored, appropriate online learning for all.
- Building our future digital workforce by undertaking workforce analysis and demand forecasting, and sustainable models to recruit talent, for example through graduate schemes, as well as opportunities for nurturing existing talent, for example through the Topol Digital Health Fellowships.

For more information visit the [Digital Readiness Programme website](#) or follow the programme on Twitter [@HEE\\_DigiReady](#).

## About the HFMA

The Healthcare Financial Management Association (HFMA) is the professional body for finance staff in healthcare. For over 70 years, it has provided independent and objective advice to its members and the wider healthcare community. It is a charitable organisation that promotes best practice and innovation in financial management and governance across the UK health economy through its local and national networks.

The association also analyses and responds to national policy and aims to exert influence in shaping the wider healthcare agenda. It has particular interest in promoting the highest professional standards in financial management and governance and is keen to work with other organisations to promote approaches that really are 'fit for purpose' and effective.

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