

0

ò

Q

0

0

Ç



ď

Ò

# HeartFlow 3D map Reducing unnecessary cardiac interventions

٥q

Q

0

Q

The CPD Standards Office CPD PROVIDER: 50137 2022-2024 www.cpdstandards.com

Q

Ó



Ó

# **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 and NHS organisations.<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 personalize the management of long-term conditions. In the service areas that are not patient-facing, technology can streamline data processing tasks to enable staff to add more value, or to reduce staffing numbers where the roles are only moving data around.

The HFMA, supported by NHS England Digital Academy (formerly part of Health Education England), is delivering a 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 trusts are using a digital three-dimensional (3D) model of the heart and blood vessels to improve and streamline diagnosis and treatment planning for coronary artery disease (CAD).

# **Summary**

CAD is a major cause of death in the UK and worldwide. Patients with this diagnosis often have multiple diagnostic tests before treatment is confirmed and delays to treatment can be significant. This specialised pathway is high in volume and cost to the NHS.

HeartFlow is a digital product that takes data from a patient's coronary computed tomography angiography (CCTA) scans, and uses artificial intelligence (AI) algorithms, computational fluid dynamics and trained analysts to create a three-dimensional (3D) map of the heart and blood vessels. This map is the HeartFlow fractional flow reserve computed tomography (FFRCT) analysis (HeartFlow).

The system was recognised by the National Institute for Health and Care Excellence (NICE) in 2017 with technology assessment MTG32<sup>3</sup>. In 2021 NICE provided an updated cost analysis and continued to support the product. Also in 2021, HeartFlow was included as one of the NHS MedTech funding mandate (MTFM)<sup>4</sup> supported technologies, enabling providers to adopt it with the confidence that the care provided could be funded via commissioning routes. The payment is provided via the healthcare resource group (HRG) when the care is given, subject to an agreed business case. The reimbursement may include funding for the additional cost of the technology over the HRG price.

Services using HeartFlow have reported significant improvements to the patient pathway, ensuring patients receive appropriate treatment sooner by reducing the number of diagnostic tests. Outcomes for patients include a 14% fall in cardiovascular mortality at the two year point after HeartFlow was used. HeartFlow has also proved a useful communication tool for patients, as it is easier to see the impact to the heart's blood supply caused by CAD and understand how treatment will improve their health. In one case, Portsmouth Hospitals University NHS Trust (Portsmouth) has found HeartFlow has reduced invasive diagnostics, freed up time for system reconfiguration and supported ground-breaking changes where radiographers have taken on new responsibilities.

<sup>&</sup>lt;sup>1</sup> HFMA, Introduction to digital healthcare technologies, July 2021

<sup>&</sup>lt;sup>2</sup> HFMA, Delivering value with digital technology

<sup>&</sup>lt;sup>3</sup> NICE, HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography May 2021

<sup>&</sup>lt;sup>4</sup> NHS Accelerated access support, MedTech Funding Mandate and MedTech Support April 2021

# **Coronary artery disease (CAD)**

The term CAD describes what happens when the heart's blood supply is reduced or interrupted by a build-up of fatty substances in the coronary arteries. CAD cannot be cured but treatment can help manage the symptoms and reduce the risk of problems such as heart attacks. Treatments include lifestyle changes, such as diet and exercise, medicines, angioplasty (where balloons or stents are used to treat narrow heart arteries), and surgery such as coronary artery bypass grafts (CABG).

Over 20,000 people under the age of 75 die in the UK from CAD each year<sup>5</sup>. The British Heart Foundation reports that CAD is a leading cause of heart attacks, and people with CAD or who have had a heart attack 'are twice as likely to have a stroke as those who haven't'. Ensuring the CAD pathway is streamlined can therefore be vital for initial treatment and the ongoing risk of costly complications.

### The traditional pathway

A patient with symptoms such as chest pain and breathlessness may be referred to the cardiology service by a GP. If these symptoms are severe, the patient may also present at an emergency department, thinking they are having a heart attack, and start the pathway for suspected CAD from within the acute sector. A cardiologist will review the patient, organise diagnostic tests to assess damage to the blood vessels and plan the treatment required. The diagnostic options are shown in **table 1**.

Diagnostic test	Description	Invasive procedure/ other limitations	Resources used in the diagnostic procedure
Stress echocardiogram	Patient has a baseline echocardiogram, then either a period of exercise on a treadmill or medication is injected into the arm. The echocardiogram is repeated to compare with the baseline.	Non-invasive	Time: 45-60 minutes plus a short amount of recovery time. Staff: cardiac non-invasive test practitioner. Non-pay: contrast medium.
Single-photon emission computerized tomography (SPECT) scan	SPECT uses radioactive materials to produce three- dimensional images of organs and tissues.	Non-invasive Radioactive process is not suitable for all patients	Time: 40 minutes. Patient usually remains in the department for about 3.5 hours. Staff: Nuclear medicine team. Non-pay: radioactive material.
Coronary computed tomography angiography (CCTA)	CCTA reviews the blood vessels without entering the body, using computed tomography (CT) technology. The <i>Getting it right first time</i> (GIRFT – see <b>box 1</b> ) programme has recommended CCTA as a method of reducing	Non-invasive	Time: 20-30 minutes, plus 30 minutes recovery time for the patient before they leave. Staff: Radiographer and radiologist for reporting.

#### Table 1: Possible diagnostic options for the CAD pathway

<sup>&</sup>lt;sup>5</sup> British Heart Foundation, *England factsheet*, 2024

	invasive coronary angiograms <sup>6</sup> .		
Coronary angiography	A catheter is inserted into the groin or arm and the tip is passed into the heart and coronary arteries. A dye (contrast medium) is injected through the catheter and X-ray images (angiograms) are taken. The contrast medium is visible on the angiograms, highlighting blood vessels that are narrow or blocked (stenoses).	Invasive Performed under a local anaesthetic but is considered a significant procedure.	Time: 30 minutes in a catheter lab and several hours recovery. Staff: cardiologist, radiographer(s) and catheter lab technicians, nurse support for recovery.

#### Box 1: The role of the GIRFT programme

GIRFT is a national programme designed to improve the treatment and care of patients through in-depth review of services, benchmarking, and presenting a data-driven evidence base to support change. The programme undertakes clinically-led reviews of specialties, combining wideranging data analysis with the input and professional knowledge of senior clinicians to examine how things are currently being done and how they could be improved.

GIRFT is part of NHS England with the backing of the royal colleges and professional associations. GIRFT advice states the exemplar pathways for patient treatment, so if clinicians are not following GIRFT they are not following best practice.

### **HeartFlow**

HeartFlow uses CCTA scans to create a personalised, colour-coded 3D model of the heart and blood flow in its blood vessels. The model allows clinicians to understand each blockage's specific impact in more detail and consider the effectiveness of different treatments. The model has also been updated to enable analysis of how implants, such as stents, will affect the blood flow and whether the arteries will be strong enough to support them<sup>7</sup>.

HeartFlow can eliminate the need for invasive investigations such as coronary angiograms in many patients, help avoid unnecessary surgical treatment for patients who are not suitable for balloons or stents, and ensure that patients who will benefit from invasive treatments are identified efficiently. Prior to HeartFlow, many patients' unsuitability for a stent would only be found during the angioplasty operation, at which point much of the service time and cost has been incurred and the patient would have to recover from an unsuccessful procedure. Furthermore, HeartFlow has helped identify many patients who will benefit from invasive management but had been missed by other non-invasive tests.

The pathway is shown in **figure 1**, starting with CCTA, and if the radiologist reports the artery is blocked by between 40% and 90%, the HeartFlow model is created. Around 35% of total CCTAs go on to be used to create a HeartFlow blood flow model. The HeartFlow user interface displays the 3D model of flow measurements on screen, and a PDF version is created and routed back to the picture archiving and communication system (PACS) system as part of the electronic patient record.

<sup>&</sup>lt;sup>6</sup> NHS, *Getting it right first time radiology national specialty report* pages 60-70, 2020

<sup>&</sup>lt;sup>7</sup> The model is called the *HeartFlow planner* and is included in new implementations.

#### Figure 1: pathway for use of HeartFlow for a patient with suspected coronary artery disease

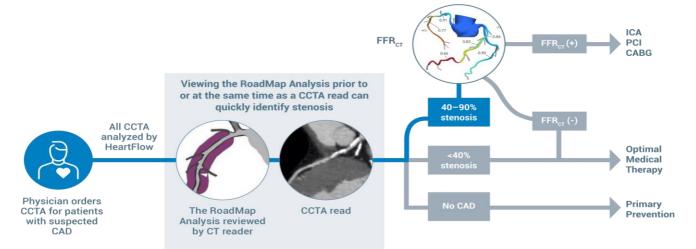


Figure 2: example of the HeartFlow 3D map of heart and blood vessels.

The HeartFlow system provides evidence-based guidance on next steps, providing a far more accurate decision-making tool than traditional imaging alone. NICE states that 'the technology is non-invasive and safe, and has a high level of diagnostic accuracy.'

The CCTA images are turned into the 3D map shown in **figure 2**, in the mean turnaround time of under 2.2 hours, so there is a significant improvement in the pathway that would otherwise include a waiting list for a coronary angiography.



### The benefit of HeartFlow

The digital 3D model provided by HeartFlow gives a clearer view of the arteries than stress echocardiogram, SPECT or CCTA alone. The HeartFlow model is not an invasive coronary angiogram, and also uses fewer resources and is therefore cheaper to perform. It negates the need for some stress echocardiograms and SPECT scans, as well as reducing the number of coronary angiograms.

HeartFlow can provide answers to the same questions as coronary angiogram, plus answer additional questions such as:

- Do the vessels have plaque (a build-up of fatty deposits)?
- Where exactly are the narrowings in the coronary arteries?
- Are the specific narrowed arteries best treated with stents and/or balloons?
- Which vessels may benefit from percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG)?
- Will the patient benefit from optimal medical therapy (OMT) a group of medications for heart, high blood pressure, cholesterol lowering and thinning the blood?

Fewer patients will need stress echocardiograms as part of the diagnosis pathway. HeartFlow has also helped doctors educate and reassure patients about their procedures. The physicians at Portsmouth found that those suffering from heart disease find it easier to understand HeartFlow's

digital 3D model than an angiogram and consequently feel more informed about proposed treatment plans.

## The FISH&CHIPS study

In addition to analytics studied by NICE, the system has been reviewed in the 2023 FFRCT in stable heart disease & computed tomography angiography helps improve patient care and societal costs (FISH&CHIPS) study<sup>8</sup> funded by UK Medical Research Council. Data from over 90,000 patients across 25 NHS sites was analysed comparing time periods before and after HeartFlow was used as part of the CAD pathway. Compared to patients on the recorded pathway using CCTA but before HeartFlow was implemented, the addition of HeartFlow produced:

- 14% relative reduction in cardiovascular mortality at 2 years
- 8% relative reduction in all-cause mortality recorded at 2 years
- 14% reduction in non-invasive cardiac testing
- 5% reduction in invasive coronary angiography.

These results were deemed significant by the study in a univariate analysis.

# **Portsmouth Hospitals University NHS Trust**

As part of the implementation of HeartFlow, the Portsmouth cardiac team found reduced cardiac testing enabled them to release enough capacity to reconfigure other parts of the service, enabling extended roles for radiographers and an increase in catheter laboratory efficiency. They re-imagined their processes, resulting in a reduction of waiting times, increase of CT scan capacity and overall improved patient experience. The team reported that incorporating HeartFlow into the catheterisation lab sped up planning for interventional procedures and helped the team manage their caseloads.

Dr Peter Haworth, consultant interventional cardiologist said of HeartFlow analysis:

'Essentially, this has overhauled the way we approach coronary heart disease within the Trust, minimising our use of invasive diagnostic techniques and developing a practice that maximises efficiency. Ultimately, that reduces the time patients spend in hospital and improves their experiences and outcomes.'

# **Finance focus**

The NICE guidance reports a cost saving of £391<sup>9</sup> per patient from the reduction in the diagnostic pathway, suggesting adoption of the technology in England would save the NHS a minimum of £9.4 million through avoiding invasive investigation and treatment. The values used in the NICE evaluation are shown in **table 2**, representing the most recent NHS England tariffs rather than cost. They are based on the national cost collection, adjusted for inflation, growth and other factors. The cost of purchasing the system has not been shown publicly but is included in the NICE analysis. HeartFlow is available to organisations via centralised procurement from NHS Supply Chain.

As shown on table 2, the cost of a CCTA is significantly lower than the cost of an interventional coronary angiogram. Even when the cost of HeartFlow is added, the diagnosis is likely to cost less than an angiogram, and many patients will have both CCTA and angiogram. The cost of SPECT and complex echocardiogram are similar to the CCTA, but they do not have the 3D modelling benefit of HeartFlow. The NICE analysis includes many additional factors to arrive at the average cost saving of £391.

#### Table 2: NICE financial value estimates for analysis update 2021

Test	Code	Cost	Source
CCTA	RD28Z	£290	NHS tariffs, 2020/21
Interventional coronary angiogram	EY43A to EY43F	£2,369	NHS tariffs 2020/21

<sup>8</sup> Fairbairn, et al, *FISH&CHIPS study*, 2023

<sup>&</sup>lt;sup>9</sup> NICE, *MTG32 Cost report*, 2020

Test	Code	Cost	Source
SPECT (nuclear medicine)	RN21Z	£282	NHS tariffs, 2020/21
Complex echocardiogram	EY50Z	£199	NHS tariffs, 2020/21
Percutaneous coronary intervention	EA31Z and EA49Z	£3,526	NHS tariffs, 2020/21
(PCI)	PCI drugs – aspirin &	£36	BNC 2020
	clopidogrel		

If a PCI is identified as not suitable for that patient and therefore prevented, at least £3,526 will be saved (or the resources redeployed to a different patient) in addition to any savings in the diagnosis.

In some regions the funding for HeartFlow has been agreed at integrated care system level ensuring the funding decision benefits all patients. However, not all major cardiac sites have yet implemented HeartFlow, with some struggling to find financial support despite the MTFM funding mandate.

# The MTFM funding mandate

The MTFM<sup>10</sup> directs the NHS funding of recognised medical technologies that benefit patients and are likely to make savings on investment. The policy aims to ensure the NHS has a sustainable approach to overcoming the financial barriers to adopting medical devices, diagnostics and digital products, including transparency and shared understanding of the benefits in the commissioning process. The MTFM products are expected to realise the NICE modelled cost savings within three years and have been assessed to not impact the NHS with overall initial cost of more than £20 million for the additional cost of the technology (see **box 2**).

#### Box 2 - Managing the cost of new technologies

Implementation of technology will have an initial cost impact, and there will be an amount of time before providers see a return on their investment. The figure of £20 million is used as a proxy for what is 'affordable', the value is calculated using the eligible population x the cost of technology. If this value is exceeded, it is deemed too high in cost, and will not be supported by MTFM.

Provider organisations make changes to processes, see the benefits to patients and reduction in the length of the pathway. The provider purchases the system, so the costs are within the trust's financial accounts, and over time this will become part of the patient level costs and the national cost collection.

Commissioners are required to fund the use of the mandated technologies when the use is clinically appropriate, although it is recognised that the prices for the care will not include the cost of the system until national guide or unit prices have been calculated for a year where the national cost collection included HeartFlow. Commissioners and providers may, under the aligned payment and incentive NHS payment scheme, negotiate local reimbursement arrangements.

The enabler of the MTFM access to funding has been of great benefit. Campbell Rogers, chief medical officer for HeartFlow in the UK, comments that 'the move from an ITP [innovation and technology payment] to the MTFM really helped trusts to implement the system'.<sup>11</sup>

# Acquiring and implementing HeartFlow

HeartFlow is live in nearly 100 UK NHS hospitals with another 12 in the implementation phase (February 2024) and further sites are having discussions. Some organisations have only recently implemented cardiac CT and are still refining that service in advance of HeartFlow adoption.

The implementation process includes clear project management process as shown in **figure 3**, and a list of the essential stakeholders including the clinical leads in cardiology and imaging, management,

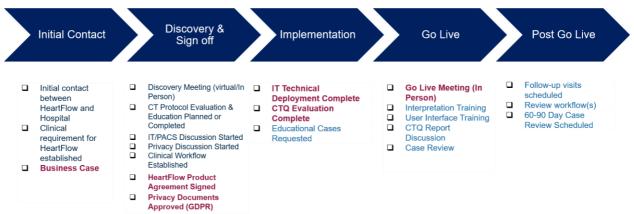
<sup>&</sup>lt;sup>10</sup> NHS Accelerated Access Collaborative, *MedTech funding mandate and MedTech support* 

<sup>&</sup>lt;sup>11</sup> NHS Accelerated Access Collaborative, *Innovation and technology payment*. This system concluded in 2021 in favour of the MedTech funding mandate structure.

IT and PACS leads and data privacy/information governance. It is recognised that appointing a project manager improves the speed and success of the project.

Figure 3: diagram showing the implementation steps for HeartFlow

# 5 Steps for HeartFlow Implementation - UK



The interventional cardiologists receive training on the user interface and the PDF model in PACS as part of the implementation and have understood it very quickly as the results are colour coded. Their confidence has enabled the review of the CAD diagnostic pathways, often reducing many possible pathways to one streamlined route to treatment. This allows improved planning for the cardiovascular team and has reduced the number of invasive and non-invasive cardiac tests.

Evaluation of the project is built in, ensuring that the business case can be monitored and the beneft to patients understood.

# **Digital focus**

As with any digital development, the system has an information technology (IT) component and has been proven compliant with NHS digital protocols. However, the support needed from local IT specialists is minimal. The imaging information flows automatically to HeartFlow, the processing is computer based, and the model is made available to the service, all on a virtual server requiring no new IT hardware. The server set up only takes a couple of hours, but implementation has sometimes been delayed by local IT teams believing it will take more time. As there are now many UK sites, speaking to a fellow IT professional that has already implemented the technology may increase confidence.

Although the model is digitally driven, human analysts are involved throughout the process, establishing the model, and validating the outputs before the information is returned to the local clinical team. The high level of verification has helped the system gain the confidence of clinicians.

Information governance protocols are often difficult to achieve in the implementations and the protocols must be established in each NHS organisation separately. However, as HeartFlow has now been widely adopted, the HeartFlow team can advise on the process.<sup>12</sup>

# **Project evaluation**

The MTFM FutureNHS page gives the final reports for the HeartFlow implementations for the review period of three years. This shows that 59% of eligible sites have adopted or are implementing HeartFlow, with around 6,000 patients benefiting from the analysis to support treatment per year.

Twenty-four eligible sites adopted HeartFlow as a result of the provider taking the decision to implement it, without additional funding from commissioners. Some 11 sites reported the commissioner funded the service. Six trusts who are known to have implemented, did not respond to the survey.

<sup>&</sup>lt;sup>12</sup> UK NHS sites with HeartFlow are available at HeartFlow Non-Invasive CAD Detection UK

The remaining sites have given the reasons for non-adoption shown in **box 3**. These are categorised in the evaluation report *The MTFM: technology graduation report.*<sup>13</sup>

#### Box 3: Reasons for non-adoption have been categorised (at March 2023)

- Financial high and recurring costs, policy non-compliance or consideration that HeartFlow is cost neutral rather than cost saving.
- Alternative provision, for example, exercise tolerance testing.
- Concerns over clinical evidence; citing papers regarding ways to treat CAD such as ISCHEMIA, or where the site was awaiting further study outcomes such as the Fish&Chips study (released post-April 2023) – (see evidence from this study above)
- Other, including:
  - no access to, or limited CT capacity
  - use of HeartFlow under the ITP and outside of the NICE guidance with negative impact on business cases under MTFM
  - the site reported that adoption was not a priority.

The estimated cost savings for HeartFlow are over £8m in the three years since the MTFM support started in England. The data is presented on FutureNHS<sup>14</sup> as the MTFM data dashboard. There is also a map showing the sites where these savings have been found, indicating there are a number of remaining provider sites still to implement the system. The NHS could therefore potentially find additional patient benefits and release costs.

Further information and templates on HeartFlow are also available on the FutureNHS workspace<sup>15</sup>.

### **Next steps**

The Health Innovation Network<sup>16</sup> is commissioned to monitor the implementation of the use of HeartFlow on an ongoing basis. They will not be actively promoting the system, but the funding mechanisms will remain for those organisations that have not yet implemented it.

The MTFM team is considering further evaluation of cost savings, and NHS Supply Chain is also investigating the product as part of their value-based procurement workstream.

<sup>&</sup>lt;sup>13</sup> FutureNHS Collaboration Platform *MTFM Graduation report HeartFlow Final* 

<sup>&</sup>lt;sup>14</sup> FutureNHS Collaboration Platform, *The MTFM data dashboard* 

<sup>&</sup>lt;sup>15</sup> FutureNHS Collaboration Platform, *HeartFlow - The MedTech Funding Mandate* 

<sup>&</sup>lt;sup>16</sup> The Health Innovation Network, Home

# **About the HFMA**

The Healthcare Financial Management Association (HFMA) is the professional body for finance staff in healthcare. For nearly 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.

The HFMA offers a range of qualifications in healthcare business and finance at undergraduate and postgraduate level and can provide a route to an MBA in healthcare finance. The qualifications are delivered through HFMA's Academy which was launched in 2017 and has already established strong learner and alumni networks.

© Healthcare Financial Management Association 2024. All rights reserved.

While every care had been taken in the preparation of this briefing, the HFMA cannot in any circumstances accept responsibility for errors or omissions, and is not responsible for any loss occasioned to any person or organisation acting or refraining from action as a result of any material in it.

### **HFMA**

HFMA House, 4 Broad Plain, Bristol, BS2 0JP T 0117 929 4789 E info@hfma.org.uk

Healthcare Financial Management Association (HFMA) is a registered charity in England and Wales, no 1114463 and Scotland, no SCO41994.

HFMA is also a limited company registered in England and Wales, no 5787972. Registered office: 110 Rochester Row, Victoria, London SW1P 1JP

www.hfma.org.uk