NICE National Institute for Health and Care Excellence

Adoption support resource – insights from the NHS

Implementation support

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1 Introduction

Published date: February 2017 **Last updated:** December 2019. See update information for a summary of the changes.

This resource has been developed to provide practical information and advice on NICE medical technologies guidance on HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography.

NICE's adoption team worked with contributors who use (or have used) HeartFlow FFR_{CT} in NHS organisations to gather learning and experiences.

The information presented in this resource is intended for the sole purpose of supporting the NHS in adopting, evaluating the impact of adopting or further researching this technology. It is complementary to the guidance and was not considered by the medical technologies advisory committee when developing its recommendations.

Funding and support for HeartFlow FFR_{CT} is available via the Accelerated Access Collaborative (AAC). The AAC brings together government, NHS, industry and patient representatives and aims to improve the uptake of innovations in the health and care system.

HeartFlow FFR_{CT} is coronary physiologic simulation software used to analyse cardiac CT images. It is intended for use in patients with stable, recent onset chest pain and suspected angina. See the guidance for more details.

The benefits of using HeartFlow FFR_{CT} as reported by the NHS staff involved in producing this resource include:

- improved time to diagnosis, with evaluation of coronary anatomy and functional ischaemia assessment in 1 test
- fewer downstream functional tests, reduced costs and potential reduction in further radiation exposure (SPECT)
- improved safety by reducing the need for invasive coronary angiography

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- it fits into the current care pathway with no extra scanning equipment needed
- little training is needed
- improved patient experience.

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2 Summary of NICE recommendations

The NICE guidance and this adoption support resource relate to using HeartFlow FFR_{CT} to estimate fractional flow reserve from coronary CT angiography.

Evidence supports the case for adopting HeartFlow FFR_{CT}. It should be considered as an option for patients with stable, recent onset chest pain of suspected cardiac origin and a 10% to 90% risk of coronary artery disease.

Using HeartFlow FFR_{CT} may lead to cost savings of £214 per patient, by avoiding invasive investigation and treatment.

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3 Current practice

In people with stable (non-acute) chest pain of recent onset, diagnostic tests aim to identify coronary artery disease by evaluating either coronary anatomy (narrowing) or function (flow/ischaemia). Tests can be classified as invasive or non-invasive. Fractional flow reserve (FFR) is currently measured invasively using a pressure wire placed across a narrowed artery during invasive coronary angiography (ICA).

The choice of diagnostic test is based on a number of factors such as patient characteristics, clinical features, test availability and access, local protocols and patient and clinician preferences.

The NICE guideline on chest pain of recent onset was updated in November 2016, but FFR was not considered as part of the update.

This guideline recommends 64-slice or above coronary CT angiography (CCTA) as a first-line diagnostic test. HeartFlow FFR_{CT} also needs 64-slice CCTA as a minimum.

Not all patients can have standard CT scanning. NICE diagnostics guidance on new-generation cardiac CT scanners includes recommendations on their use as a first-line imaging option in people with suspected or known coronary artery disease in whom imaging is difficult with earlier-generation CT scanners. This may include people with obesity, calcium scores above 400, arrhythmias, uncontrolled high heart rates, stents or previous bypass grafts.

There are several drivers of change in current practice around diagnostic testing for suspected coronary artery disease. These include the timing of the publication of the updated NICE guideline on chest pain of recent onset and its guidance on HeartFlow FFR_{CT}, as well as proposed CT replacement predictions in England described in the Clinical Imaging Board report (CT Equipment, Operations, Capacity and Planning in the NHS 2015).

Some trusts will already be equipped to comply with the new guidance, but for some a shift in practice may be needed. The challenges of this are set out in the British Society of Cardiovascular Imaging report (2015). The successful adoption of HeartFlow FFR_{CT} ultimately depends on the availability of adequate CCTA facilities and skills of the workforce.

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4 Tips for adopting HeartFlow FFR_{CT}

The NHS contributors to this resource considered the following to be important:

- Establish patient selection criteria to ensure that HeartFlow FFR_{CT} is used appropriately. See care pathway mapping.
- Ensure that CT is 64-slice or above and that images meet the needs for analysis, in line with Royal College of Radiology and Society of Cardiovascular Computed Tomography guidelines. See education and site specific criteria.
- Ensure that a Data Protection Impact Assessment (DPIA) and/or Data Processing Agreement is completed in conjunction with HeartFlow and local information governance leads. See information governance.
- Ensure that IT departments can host HeartFlow Connect VM appliance. See IT infrastructure.
- Consider the downstream consequences on workload (fewer functional tests or invasive coronary angiographies) in other departments (such as cardiology and stress ECHO/MRI), and how to minimise any inefficiencies that arise as a result. See care pathway mapping and the into practice guide.
- Map the affected administration tasks in advance. Consider moving tasks between departments and where administrative burden will be reduced. See care pathway mapping.
- Providers and commissioners will need to agree a local tariff for the procedure that supports adoption (See the resource impact report.)

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5 How to implement NICE's guidance on HeartFlow FFR_{CT}

Site specific criteria

Requirements for HeartFlow are consistent with the Society of Cardiovascular Computed Tomography (SCCT) Performance of Cardiac CT Guidance Document:

- 64-slice or greater CT scanner with cardiac gating capability
- dual syringe injector for 2-phase injection
- access to scheduled time on the scanner for coronary CT angiography (CCTA)
- experience, willingness and staffing to use glycerine trinitrate and beta blockers (oral or intravenous) for proper vessel visualisation and heart rate control
- accredited CCTA reader (or equivalent experience of more than 150 cardiac CTs) – may be SCCT Level 1+ or accredited through other organisations or fellowships
- at least 1 radiographer trained in CCTA and experienced with cardiac reconstructions
- ability to meet minimum quality requirements for HeartFlow process (minimum 8 out of 10 consecutive cases pass initial quality acceptance)
- HeartFlow onsite review of the institution's CCTA programme, training for imagers on HeartFlow requirements, review of CCTA best practices, and SCCT guidelines for performance of CCTA.

NHS contributors to this resource have worked with NICE to develop practical suggestions for how to implement NICE guidance on HeartFlow FFR_{CT}. Local organisations will need to assess their applicability taking into consideration the time, resources and costs of an implementation programme.

Project management

NICE has produced a generic into practice guide that includes a section on what

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organisations need to have in place to support the implementation of NICE guidance using a project management approach.

Project team

The first step is to form a local project team who will work together to implement the technology efficiently and manage the challenges specific to implementing HeartFlow FFR_{CT}.

Individual NHS organisations will determine the membership of this team and the length of the implementation process. Project team membership could include:

- Clinical champion(s): could be a senior clinician/manager with an interest in cardiology imaging such as a consultant radiologist or imaging cardiologist. They should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level.
- Project manager: could be someone in a clinical or managerial role who will be responsible for the day-to-day running of the project, co-ordinating the project team and ensuring the project is running as planned.
- Management sponsor: could be the directorate manager, directorate accountant or directorate business manager. They will be able to help assess the financial viability of the project, drive the formulation of a business case and help to demonstrate the cost savings achieved.
- Picture archiving and communications system (PACS) manager: to assist with return data if digital imaging and communications in medicine (DICOM) data are needed.
- IT manager: to work with manufacturer during the setup phase.
- Administration representative: to help map and manage the downstream shifting of tasks and to potentially support data transfer on behalf of clinicians.
- Information governance lead: to help initiate the information governance process at the hospital.
- Clinical audit facilitator: to help set up mechanisms to collect and analyse local data related to the project metrics and audit needs.

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- Interventional cardiologist or other function test operators who may wish to be involved to understand the wider impact on their service.

Early questions and considerations for the team include:

- What is the current CT compatibility (is at least 64-slice)?
- Is there capability to scan in accordance with Royal College of Radiology and SCCT guidelines to produce desired CT image quality?
- Consider any internal IT setup costs and IT infrastructure compatibility for establishing software setup.
- Consider the need for HeartFlow Analysis PACS Integration (optional): a HeartFlow FFR_{CT} DICOM pdf summary can be automatically delivered to hospital PACS systems.
- How will the project be funded? Can local payment arrangements be implemented with the clinical commissioning group to support adoption? (See the resource impact report.)
- Who should receive manufacturer training and when should this happen?
- Are there any obvious local challenges and how can these be overcome?

Care pathway mapping

Give due consideration to patient selection criteria as part of care pathway mapping. Some patients may still need invasive CT, but HeartFlow FFR_{CT} may become less cost effective if additional functional tests are done.

Information governance

During guidance development, the medical technology advisory committee considered the protection and oversight of data transferred during the administration of HeartFlow FFR_{CT} to be an important factor in its adoption. It was satisfied on the basis of the information available that the company's data transfer protocols meet regulatory requirements.

Local information governance involvement and approval is essential to adoption of HeartFlow.

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All data uploaded to HeartFlow Inc is secure via HTTPS (port 443) using TLS1.2 industry standards. Personal Identifiable Information is encrypted at rest with Advanced Encryption Standards (AES256).

CTA DICOM images are de-identified by the HeartFlow Connect VM Appliance installed onsite on the Provider's network. Personal Identifiable Information is extracted from CTA DICOM images and securely held within HeartFlow Virtual Private Cloud (UK), encrypted at rest with Advanced Encryption Standards (AES256).

De-identified DICOM images are securely uploaded to HeartFlow USA for processing.

HeartFlow FFR_{CT} is:

- evaluated against the NHS Digital Security Protection Toolkit: Organisation code: 8K799
- registered with the ICO: Notification No. ZA455456, HeartFlow Technology UK Limited
- certified with ISO/IEC 27001: 2013 standards and best practices
- CE certified indicating conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA).

Patient information

In HeartFlow contracts with Providers it is stated that all person identifiable information will remain within the EU whilst de-identified image data will be analysed in the USA.

The hospital obtains patient consent for HeartFlow fractional flow reserve CT analysis. Patient information sheets should include information on the secure transfer of data as described above.

North Tees and Hartlepool NHS Trust have shared an example of a cardiac CT checklist that includes a patient consent statement.

Measuring success

In order to demonstrate the benefits of adoption, it is important to take measurements before, during and after implementation (when appropriate). Some of these measures will

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not need to be routinely collected and sites should consider a data collection methodology that is appropriate for the service. Suggested measures from the sites involved in developing this resource are:

- number of invasive coronary angiographies (ICAs) requested
- outcome data (cardiac events/need for revascularisation) on patients discharged without further investigation
- costs (at department and trust level)
- image quality
- frequency of ordering further investigation (for clarification) after HeartFlow FFR_{CT} (clinical confidence)
- number of patients taken to catheter lab for ICA after a positive HeartFlow FFR_{CT} that was found to be incorrect (false positives)
- patient experience.

A number of NHS sites have collected (or are collecting) data as part of clinical trials and a research registry (ADVANCE). The registry includes the following clinical information and 1-year outcome data:

- basic demographic information
- medical history
- CCTA scan results
- recent invasive and non-invasive test results
- FFR_{CT} results (if the patient has had a HeartFlow FFR_{CT} analysis)
- clinic or hospital visits
- coronary procedures
- major adverse cardiac events
- resource use.

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Education

The manufacturer provides training to radiologists, radiographers and cardiologists as well as other support staff as appropriate. The planned package of training includes:

- Introductory training:
  - an overview of HeartFlow FFR_{CT}, delivered through in-person sessions and a range of media
  - didactic and case-based training on the clinical use of HeartFlow FFR_{CT}
  - the user interface, warnings and precautions
  - CCTA image specifications for HeartFlow FFR_{CT} analysis; HeartFlow's CCTA quality requirements are consistent with those of the Royal College of Radiology, British Society of Cardiovascular Imaging and the Society of Cardiovascular Computed Tomography performance of CCTA guidance document.
- Additional education programmes for radiographers and clinicians.
- Reference scanning protocols for all major manufacturer models with 64-slice or higher multi-detector CT. These include post-processing techniques.
- Bespoke training materials. These include clinical protocols and clinician led webinars on CCTA acquisition.

Users will be invited to educational seminars and there is a plan to establish a UK users group to help sharing of best practice around HeartFlow FFR_{CT}'s use.

Business case

Developing a business case should be a priority for the implementation team. Local arrangements for developing and approving business plans will vary from trust to trust, and each organisation is likely to have its own process in place.

While HeartFlow analysis is currently being funded for national spread under a zero-cost model (see NHS England Innovation and Technology Payment 2018/2019), ongoing tariff arrangements are not yet clear. The 2016/17 national tariff system did not cover the full cost of the HeartFlow FFR_{CT} analysis.

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A business case would need to emphasise the clinical and financial benefits for the trust and patients. It should also include any locally agreed tariffs based on conversations between providers and commissioners. (See the resource impact report.)

National drivers

When developing a business case, NHS trusts may find it useful to refer to table 1 for details of guidance, standards and advice at a national level that support adoption of HeartFlow FFR_{CT}. For example, an increase in the use of 64-slice CCTA will enable more widespread adoption of HeartFlow FFR_{CT}.

Table 1 Guidance, standards and advice related to HeartFlow FFR_{CT}

Driver	Significance or measure
NHS England Innovation and Technology Payment 2018/2019 – HeartFlow, plus extension for 12 months from April 2019.	HeartFlow analysis is being funded for national spread under a zero-cost model. It can be ordered directly from HeartFlow Inc. Website information and technical notes can be used in developing a business case and planning adoption.
NICE guideline on chest pain of recent onset.	Recommends a minimum specification CT scanner of 64-slices or above, which is needed for HeartFlow $FFR_{CT.}$
Clinical Imaging board: CT equipment, operations, capacity and planning in the NHS (2015).	Identifies that 74% of NHS CT has more than or equal to 64-slice capability. Recommends that all NHS radiology departments need a future CT replacement plan, looking forward at least 5 years.
Royal College of Radiologists: Standards of practice of computed tomography CG in adult patients (2014).	Includes recommendations on technical and educational needs for the use of CT scans in line with requirements for HeartFlow FFR_{CT}.
NICE guidance on new generation cardiac CT scanners.	Recommends access to new-generation cardiac CT scanners for patients in whom standard CT is challenging.

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Resource impact

At the time of publication, the current UK pricing for the HeartFlow FFR_{CT} analysis is £700 (excluding VAT). There are no other cost components specifically associated with its use.

NICE has published a resource impact report and template that can be used by NHS commissioners and providers to better understand the local costs associated with adopting HeartFlow FFR_{CT}. The national assumptions used in the template can be altered to reflect local circumstances.

NICE estimates that around 89,300 people in England may be eligible for HeartFlow FFR_{CT}. Uptake will increase over 5 years (from 2017), with around 35,600 people having HeartFlow FFR_{CT} from 2021/22 when uptake reaches a steady state. The minimum annual saving estimated from implementing the guidance is around £9.1 million. This is equivalent to around £16,800 per 100,000 population.

Overcoming implementation challenges

Table 2 shows the challenges which contributors to this resource reported may be experienced by NHS sites when implementing HeartFlow FFR_{CT}.

Table 2 Potential implementation challenges when using HeartFlow FFR_{CT}

Challenge	Suggested actions
Capital and ongoing revenue costs in the absence of an appropriate tariff and without the NHS England zero cost model.	Securing the necessary funding will need a collaborative approach between the provider and commissioner. Prepare a business case including full cost considerations for HeartFlow FFR_{CT} compared with current procedures across a complete service budget.

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Transfer of workload, decommissioning of services in other departments and/or deskilling of staff.	Identify all staff who could be affected (see care pathway mapping) and who may want to be involved in the project planning stage. Data collection to measure actual versus perceived impact on relevant services. Evaluate opportunity for trust level savings. Evaluate improvements to patient experience. See measuring success.
Data security.	Ensure local information governance teams are involved in the adoption process. The company fulfils regulatory approval standards for data confidentiality and integrity protection for remote processing. This complies with UK data protection law.
IT Department concerns around workload and support	HeartFlow Connect VM appliance requires minimal system resources unlike traditional DICOM Medical Imaging Systems. There are no provider licensing costs or requirements for future storage scalability. The HeartFlow Connect VM appliance is maintained by HeartFlow technical teams in the UK and USA - msupport@heartflow.com

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Consultant imaging cardiologist, Liverpool Heart and Chest Hospital NHS Foundation Trust. Participant in ADVANCE registry.

Dr James Shambrook
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7 About this resource

This resource accompanies NICE medical technologies guidance on HeartFlow FFR_{CT}. It was developed using the NICE adoption team: process guide for adoption support resources for health technologies. It is an implementation tool and discusses and summarises the experiences reported by NHS sites which have adopted this technology and shares the learning that took place.

It is the responsibility of local commissioners and providers to implement the guidance at a local level, being mindful of their duty to advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with this.

More information about the adoption team.

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Update information

December 2019: Resource updated to include information about funding and support from the Accelerated Access Collaborative and the NHS England Innovation and Technology Payment. Details on information technology and information governance also added.

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