NHS England and NHS Improvement

Innovation and Technology Payment - Technical Notes

2020-2021 ITP
2019-2020 ITP
2018-2019 ITP
2017-2018 ITT

Contents

NHS England and NHS Improvement Innovation and Technology Payment Technical Notes 2020-21

Version number: V8 Final
First published: 3 December 2020
Updated:
Prepared by: Innovation, Research and Life Sciences Group
Classification: Official
Publishing Approval Reference: PAR0091

Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

1. Background

In April 2017, NHS England and NHS Improvement launched the Innovation and Technology Tariff (ITT), an initiative designed to reduce the financial and procurement barriers experienced by commissioners and providers wanting to adopt innovative technologies in the NHS.

NHS England and NHS Improvement identified six themes where innovative technologies could make a difference in the two years from April 2017- March 2019. The ITT was well received by industry and the NHS with over 100 sites implementing the ITT innovations.

NHS England and NHS Improvement committed to build on this approach with the introduction of the Innovation and Technology Payment (ITP). In 2018 /19 the ITP tested four innovative products and technologies at national scale under a pilot approach.

The 2019/20 ITP was launched as an open competition in September 2018. Its focus was to attract entries for proven, cost effective, market ready innovations demonstrating potential to deliver significant patient outcomes and savings to the NHS. The competition culminated in a shortlist of innovations which were considered by a panel including clinicians, commissioners, providers, and representatives from NICE, AHSNs and patients.

For the 2020/2021 ITP we applied the following criteria to the products that have been previously supported through the ITT and ITP programmes:

- Not received a negative NICE appraisal;
- Proven to deliver clinical benefits and are cost effective; and
- Not already supported by the National Tariff Payment System.

These notes set out how commissioners and providers can access the products available via the ITP.

2. Innovation and Technology Payment Innovations

This section sets out the innovations which are funded through the ITP for the 2020/2021 financial year.

NHS England and NHS Improvement and Improvement will continue to fund:

- **Placental growth factor (PlGF)** based tests to help rule out pre-eclampsia quickly so that pregnant women receive the most appropriate care.
- **HeartFlow FFRCT** - analysis which creates a 3D model of the coronary arteries to help clinicians to rapidly diagnose patients with suspected coronary artery disease from coronary CT angiography.
- **gammaCore** - non-invasive vagus nerve stimulation therapy for the treatment of cluster headaches.
- **SpaceOAR** - an absorbable spacer to reduce rectum radiation exposure during prostate radiation therapy.
- **Non-Injectable Connector** - an arterial connecting system to reduce bacterial contamination and the accidental administration of medication.
- **Plus Sutures** - a new type of surgical suture that reduces the rate of Surgical Site Infection (SSI)
- **SecurAcath** is a device to secure catheters for patients with a peripherally inserted central catheter.
- **Endocuff Vision** - a medical device which attaches to the distal end of an endoscope and improves colorectal examination for patients undergoing bowel cancer tests.

2.1 Procurement

Feedback from NHS commissioners and providers was positive about the zero-cost model used for the ITP therefore NHS England and NHS Improvement is continuing this approach for the ITP products outlined above between 1 April 2020 and 31 March 2021.

Providers order the innovations directly from the supplier at no cost and NHS England and NHS Improvement reimburses the supplier directly.

2.2 Nationally agreed pricing for ITP innovations

NHS England and NHS Improvement will cover the costs of the innovations funded under the ITP as outlined in each specification. Additional costs associated with implementation are not covered by NHS England and NHS Improvement and should form the basis of local discussions.

This document identifies national prices agreed between NHS England and NHS Improvement and the manufacturers/suppliers providing the ITP innovations. It is likely that local commissioners and providers will choose to use these on the basis that they consider them to be the best available price. However, they are not precluded from engaging in additional negotiations, and commissioners and providers must still comply with the relevant local pricing rules set out in the National Tariff.

2.3 Support and advice

The 15 Academic Health Science Networks (AHSNs) have been closely involved in developing the ITP and supporting the roll out of the ITT and ITP programmes. Each AHSN can offer a range of support to help commissioners and providers to implement the ITT and ITP innovations in local geographies. See http://www.ahsnnetwork.com for more information on AHSNs and Appendix A for a list of AHSN contacts.

For more enquiries regarding NHS England and NHS Improvement funded programmes that support innovation please contact the Innovation, Research and Life Sciences group at england.innovation@nhs.net.

2.4 Data Collection

To inform future work in promoting innovation, it is essential that NHS England and NHS Improvement can assess both the impact of the ITT and ITP in facilitating access to innovations and the impact of the innovations themselves (i.e. the extent to which the anticipated outcomes set out in the innovation specification are met through use of the innovations).

For this purpose, providers are required to provide data on uptake and use. Payment will be contingent on reporting complete data. Details of the data reporting requirements are set out in each innovation specification.

2.5 ITP Innovation Specifications

The following section provides more information on each of the ITP innovations. It sets out the specification met by the innovations and explains the pricing and payment mechanisms applicable to each innovation.

3. Innovation Specification: gammaCore™ - Non-invasive vagus nerve stimulation (nVNS) for the treatment of Cluster Headaches

3.1 Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is included in the Innovation and Technology Payment (ITP), regarding non-invasive vagus nerve stimulation (nVNS) for the treatment of cluster headaches purchased centrally by NHS England and NHS Improvement.

3.2 Expected Outcome

The expected outcomes from using gammaCore are a reduction in symptoms for patients with treatment refractory cluster headaches and consequently an improvement in quality of life. The device gammaCore™ allows patients to self-administer nVNS therapy. This stimulation causes the body to naturally disrupt the pain signals produced during a cluster headache attack. Significant healthcare cost-savings are expected from reduced medication usage, reduced cluster headache related admissions and a lower incidence of co-morbidities.

3.3 Payment / price detail

The ITP agreed price for gammaCore™ is £625 per 93 days of treatments (excluding VAT). gammaCore™ is available under the zero-cost model and is available to patients prescribed by a headache specialist in primary or secondary care. For new patients the first 93 days of treatment is supplied free to evaluate whether the treatment alleviates cluster headache symptoms. Dispensing of subsequent treatment by the company following this trial period is dependent on clinical satisfaction that the treatment is suitable and effective in the patient. Eligible NHS sites (see 9.6) can order gammaCore™ directly from the supplier at zero-cost. The gammaCore™ device is normally delivered to the patient's home. For general enquires contact customerserviceuk@electrocore.com or call 0800 678 5632.

3.4 Population Needs

National/local context and evidence base

There are approximately 65,000 cluster headache patients in England, with an estimated 5% unable to tolerate, or not gaining adequate pain relief, from current pharmacological interventions. The non-pharmacological device gammaCore™ is designed for use in these 'treatment-refractory' patients who suffer with an incredibly poor quality of life, whose treatment can cost the NHS thousands of pounds a year, and who may face surgical interventions in the further pursuit to improve their condition.

NICE states that gammaCore™ is only effective in chronic cluster headache when used as a preventative measure. In episodic cluster headache it is only effective when used as a treatment for acute pain. Using gammaCore™ would add costs to standard care except in cases where it replaces current treatments. There are no published data to determine how likely this is. The extra costs may be offset if it reduces the number or dose of prescribed medicine or, avoids the need for more invasive treatment options.

3.5 Scope

Aims and objectives of the product

This innovation must aim to improve patient care and outcomes by effectively treating patients with treatment-refractory cluster headaches, and to reduce waste and improve efficiency by delivering more effective cluster headache management.

This innovation must:

- Be a device which allows non-invasive vagus nerve stimulation for the treatment of cluster headaches.
- Be supported by an appropriate clinical evidence-base and be compliant with the procedure described in NICE Medical Technologies Guidance MTG46
- Be a CE marked device

This innovation must be appropriate for use in:

- Patients who suffer from cluster headaches who have not responded to typical therapy offered by the NHS.

3.6 Clinical Standards

Sites adopting this technology must:

- Ensure gammaCore™ is prescribed by a headache specialist (in primary or secondary care)
- Ensure staff are trained in the correct use and prescribing of gammaCore™. electroCore provides training at no extra cost, and participation is highly recommended. Support is also available via the gammaCore™ website. To access these training programs please contact Paul.edey@electrocore.com.

NOTE: Any Qualified provider (AQP) sites are eligible for this programme, if prescribing to NHS patients. Non-NHS patients are not eligible for inclusion.

Exclusion criteria:

- Non-NHS patients
- Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
- Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
- Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
- Paediatric patients
- Pregnant women
- Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia
- Patients with a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
- Patients using another device at the same time (e.g. TENS Unit, muscle stimulator) or any portable electronic device (e.g. mobile phone)

NOTE: This list is not all inclusive. Please refer to the gammaCore™ 'Instructions for Use' for all the important warnings and precautions before using or prescribing this product.

Applicable NICE reviews:

- gammaCore™ for cluster headache: see MTG46

3.7 Reporting

At the end of each quarter, providers must report back on the following minimum data set.

Report for previous financial year:

- Number of patients using gammaCore™. This is only required for the first report.

Report for each quarter of the current financial year:

- Number of patients who have used gammaCore™ during this period of reporting
- Number of patients who have stopped treatment with the gammaCore device
- Number of patients who were using sumatriptan injections at the point they started using gammaCore for this period of reporting
- Number of patients who have reduced their sumatriptan injections usage due to use of gammaCore in this period of reporting
- Number of patients who have stopped their sumatriptan injections usage due to use of gammaCore in this period of reporting

Payment is contingent on reporting complete data by the 20th of the month following each quarter. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings: Year_Quarter_Site name_ gammaCore™ _Submission date

4. Innovation Specification: Elecsys® immunoassay sFlt-1/PlGF test and Triage PIGF – Placental growth factor-based tests for ruling out pre-eclampsia for at least 7 days

4.1 Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is covered under the Innovation and Technology Payment (ITP), regarding a placental growth factor (PIGF) based test for the rule-out of pre-eclampsia and is purchased centrally by NHS England and NHS Improvement.

4.2 Expected Outcome

The expected outcomes from using a PIGF-based test for the rule out of pre-eclampsia include better risk assessment for adverse outcomes, better resource targeting of out-patient clinic visits, ultrasound scans, cardiotocography (CTG) and hospital admissions, and lower utilisation of neonatal bed nights and intensive care bed nights.

For those women in whom pre-eclampsia has been ruled out, they may be managed as an out-patient for an alternative diagnosis, may require fewer clinic visits, and, if appropriate, can safely return to community care. Providers can make savings through a reduction in bed days and may also increase productivity through better resource targeting and increased available clinical staff time.

4.3 Payment / price detail

Two suppliers are being supported under the ITP programme 2020/21. NHS England and NHS Improvement may support additional suppliers within the programme timeframe.

NHS Trusts can order either test directly from the supplier under the zero-cost model.

Supplier	Test	Cost	Contact
Quidel Ireland Limited	Triage PlGF test	£70 per test which equates to £84 reportable	Quidel Customer Services: +44 (800) 3688248 (Option 1 for Customer Service), Web form: https://www.quidel.com/support/customer-support, or by e-mail to: emeacustomerservice@quidel.com
Roche Diagnostics	Elecsys® immunoassay sFlt-1/PlGF ratio test	£94 per reportable	burgesshill.accessinnovation@roche.com

4.4 Population Needs

National/local context and evidence base

NICE states that either the Triage PlGF test and the Elecsys® immunoassay sFlt-1/PlGF ratio, when used with standard clinical assessment and subsequent clinical follow-up, are recommended to help rule-out pre-eclampsia in women presenting with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation. NICE states that both tests are cost saving compared with standard clinical assessment.

4.5 Scope

Aims and objectives of the product

This innovation must aim to:

- To help rule-out[1] pre-eclampsia through better risk assessment for adverse outcomes
- To improve resource targeting (out-patient clinic visits, ultrasound scans, CTG, and hospital admission)
- If appropriate, in women who are ruled-out for pre-eclampsia, to return them to community care.
- To deliver savings and make more effective use of NHS resources by avoiding inappropriate hospitalisation.

[1] NB When pre-eclampsia is not ruled-out using a PlGF-based test result, the result should not be used to diagnose (rule-in) pre-eclampsia

This innovation must:

- Be a CE-marked PlGF-based diagnostic test to allow the rule-out of pre-eclampsia in pregnant women.
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in DG23.

This innovation must be appropriate for use in:

- Pregnant women suspected of pre-eclampsia

4.6 Clinical Standards

NHS Sites adopting this technology must:

- Integrate PlGF-based testing into the local pre-eclampsia pathway
- Offer PlGF-based testing to all suitable pregnant women, as defined by NICE DG23
- Engage all appropriate clinical staff in training; pathway and test interpretation
- Ensure that staff who perform PlGF-based tests have been trained and accredited
- Have access to an appropriate platform on which to process the test
- Adhere to relevant Clinical Guidelines and in line with the Trust's internally agreed clinical pathways
- Ensure that staff perform the test in line with the recommendations provided by the supplier:
- PlGF tests should be used in accordance with the system information package inserts. Contact Quidel for a copy of their package insert – Ref 98800EU or Roche Diagnostics for a copy of their package inserts - Ref 05144671 190 and 05109523 190.
- Assay results should not be reported if laboratory standards have not been met or failed to meet expected laboratory standards.

NOTE: Sites without access to the required platform who wish to adopt PlGF testing would be required to enter into a contract negotiated directly with the supplier. The ITP programme funding does not cover the costs associated with this.

Exclusion Criteria:

- PlGF-based testing should not be used for asymptomatic screening or for women in whom there is not a reasonable suspicion of pre-eclampsia.

Applicable NICE reviews:

- PlGF-based testing to help diagnose suspected pre-eclampsia, see NICE DG23

4.7 Reporting

At the end of each quarter, providers must report back the following minimum data set.

Report for previous financial year:

- Number of patients who have received a PlGF based test during each quarter

Report for each quarter of the current financial year:

- Number of women who were clinically assessed for PlGF testing in this period of reporting
- Number of patients who have received a PlGF test in this period of reporting
- Number of women admitted for treatment in this period of reporting
- Number of women discharged after PlGF test in this period of reporting.

Payment is contingent on reporting complete data by the 20th of the month following each quarter. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings: Year_Quarter_Site name_PlGF_Submission date

5. Innovation Specification: SpaceOAR™ Hydrogel – Absorbable hydrogel spacer to reduce rectum radiation exposure during prostrate radiotherapy

5.1 Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific detail as to the basis on which this product is included in the Innovation and Technology Payment (ITP) with respect to the reduction of rectal radiation exposure during prostrate radiotherapy purchased centrally by NHS England and NHS Improvement.

5.2 Expected Outcome

The expected outcome from using SpaceOAR™ hydrogel is a reduction in rectal radiation and therefore damage during radiotherapy for prostate cancer. This is associated with a reduction in long-term rectal complications and improved quality of life following radiotherapy for prostate cancer [1]. SpaceOAR™ hydrogel is also clinically proven to minimise urinary and sexual side-effects of radiation therapy. Use of the product should also help to reduce waste and improve efficiency by delivering more effective surgical interventions. This product may be conducive for the implementation of hypofractionation radiotherapy, which would free up hospital resources.

5.3 Payment / price detail

The ITP agreed price for SpaceOAR™ is £1750 (excluding delivery and VAT) per unit. SpaceOAR™ is available under the zero-cost model. Providers can order the product directly from Boston Scientific at zero-cost. Contact: Phone: +44 344 8004512 or unitedkingdomsalessupport@bsci.com

The part number is SO-1010 and orders must be clearly marked 'ITP – zero cost model'. To order the product, hospitals must send an e-mail to the above address with reference to the ITP programme, SpaceOAR™ purchase order number, number

[1] Hamstra DA, et al. Continued benefit to rectal separation for prostate radiation therapy: Final results of a phase III trial. Int J Radiat Oncol Biol Phys. 2017 Apr 1;97(5):976-85.

of units required, delivery address and zero value. Specific details on this process will be provided by Boston Scientific and the local AHSN.

Please note that participation in the scheme is limited and to be agreed with Boston Scientific prior to placing any orders. All participating SpaceOAR™ sites must agree to enter Boston Scientific's Intent to Train programme.

There is a minimum order quantity of four units per order, and the product can only be ordered in multiples of four. More information about SpaceOAR™ hydrogel is available at Boston Scientifics's website.

5.4 Population Needs

National/local context and evidence base

Radiotherapy is a proven effective treatment for prostate cancer and is continually advancing. The success of radiotherapy in the treatment of prostate cancer is dependent on several factors including the radiation dose to the tumour and the avoidance of radiation to nearby healthy structures (organs-at-risk), particularly the rectum. While higher doses of radiation have been shown to improve survival outcomes, they are also associated with increased risk of rectal toxicity and other urinary and sexual complications that can significantly reduce a patient's long-term quality of life.

5.5 Scope

Aims and objectives of the product

This innovation must aim to:

- Improve patient outcomes and care by reducing rectal toxicity following prostrate radiotherapy for prostate cancer in adults.

This innovation must:

- Be an absorbable hydrogel spacer to temporarily position the rectum away from the prostate during radiotherapy (about three months), to minimize urinary, sexual and bowel side effects for prostate cancer patients undergoing radiation therapy.
- Have a Class III CE Mark approved by a registered notified body.
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in IPG590

This innovation must be appropriate for use in:

- Those undergoing prostrate radiotherapy for the treatment of prostate cancer, who meet the acceptance and exclusion criteria outlined below. It is expected that decisions on use with individual patients are based on the quality criteria outlined in 5.6.

5.6 Clinical Standards

Acceptance Criteria:

- Indication: SpaceOAR™ System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy (about three months) for prostate cancer and in creating this space it is the intent of SpaceOAR™ System to reduce the radiation dose delivered to the anterior rectum.

NHS Sites adopting this technology must:

- Only use SpaceOAR™ hydrogel using compatible equipment, under ultrasound guidance using a transrectal ultrasonography (TRUS) side-fire ultrasound probe and stepper ultrasound stabilisation system
- Ensure staff are trained in the correct use of SpaceOAR™ Hydrogel, following the supplier's recommended training plan and making use of available online resources. Boston Scientific provides a range of training platforms at no extra cost to allow certified providers to begin offering SpaceOAR™ hydrogel to patients.
- Ensure all SpaceOAR™ providers sign up to the Boston Scientific Intent to Train Programme
- Ensure Procurement follow the guidance for ordering the product as detailed in 5.3.
- Adhere to the Instructions for Use

Applicable NICE reviews:

- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in IPG590.

5.7 Reporting

At the end of each quarter, providers must report back on the following minimum data set:

Report for previous financial year:

- Number of patients using SpaceOAR™. This is only required for the first report

Report for each quarter of the current financial year:

- Number of patients who have used SpaceOAR™ during this period of reporting

Payment is contingent on reporting complete data by the 20th of the month following each quarter. If you have any questions about the required data, please contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings: Year_Quarter_Site name_ SpaceOAR™ _Submission date

6. Innovation Specification: Non-Injectable Connector (NIC)

6.1 Purpose

This specification gives NHS providers and commissioners information on the Non-Injectable Connector (NIC), a product included in the Innovation and Technology Payment programme for use in arterial connecting systems to reduce bacterial contamination and prevent the accidental administration of medication into an artery.

6.2 Expected Outcome

Arterial cannulation is associated with complications including bacterial contamination, accidental intra-arterial injection and blood spillage. Needle-free connectors prevent blood spillage and through a one-way valve allow aspiration only thus preventing accidental administration of medication to the arterial line.

Arterial line placement is a common procedure in various critical care settings. Intra-arterial blood pressure (BP) measurement is more accurate than measurement of BP by non-invasive means, especially in the critically ill. Although rare, when wrong route drug administration occurs, it has the potential to cause serious damage to the vessel and surrounding tissue.

6.3 Payment / price detail

The ITP agreed price for this innovation is £2 per unit. This is available to providers under the zero-cost model. See section 6.6 in the specification below for reporting instructions.

The needle-free arterial Non-Injectable Connector (NIC) devices can be ordered direct from Amdel Medical (enquiries@amdelmedical.com) supplied to NHS providers under the zero-cost model. More information on the Non-Injectable Connector is available from: https://www.amdelmedical.com/products/

6.4 National/local context and evidence base

Patients in intensive care often require arterial access lines to provide blood pressure monitoring, arterial blood gas readings and to facilitate the collection of

numerous and repetitive blood samples[3]. The administration of medication via this line is not advised, and almost never procedurally carried out because of the potential to cause serious damage to the vessel and surrounding tissue. However, given the environment usually surrounding a patient with an arterial line (a busy clinical environment, many ports, many different lines, and a need for rapid interventionist care), accidental injection of IV medication into arterial lines has been reported, including cases where the resulting necrosis has led to major amputations.

Accidental injection into the arterial line currently occurs partly because the standard arterial connectors do not prevent the ability to administer medication into the line. The misadministration of medication via the wrong route is classified as a 'never event'.

6.5 Scope

Aims and objectives of the innovation

This innovation must aim to:

- Improve arterial line safety for patients
- Minimise the risk of transmission of blood borne infections from patients to staff
- Make arterial line sampling a simpler process for staff
- Prevent incorrect administration of medication

This innovation must:

- Be a needle-free connector for arterial cannulation using a one-way valve to allow aspiration only
- Be compatible with blood sampling ports and blood gas sampling devices
- Be compatible with other current NHS equipment linked with existing arterial line connectors; such as closed venous arterial blood management protection systems
- Prevent the misadministration of medication into the arterial line
- Prevent the ingress of bacteria into the arterial line

[3] The non-injectable arterial connector (NIC): A cost effectiveness assessment to improve arterial line safety - Dr Maryanne Mariyaselvam, Dr Mark Blunt, Dr Peter Young (The Queen Elizabeth Hospital, Kings Lynn), The Eastern Academic Health Science Network, Patient Safety Study FC171013/11

- Be suitable to remain on the arterial line for the duration of time the arterial line is used (according to individual hospital policy, between 3-7 days)
- Require minimal training for staff
- Not require any additional facilities or technologies to use the device
- Be CE-marked as a Class IIa medical device
- Be supported by a sufficient clinical evidence-base: the NIC is the only such CE-marked device currently available, as per NICE Medtech Briefing [MIB85].

This innovation must be appropriate for use in:

- Adult patients with arterial lines in critical care facilities, operating theatres, and emergency departments

Exclusion Criteria:

- The NIC is not licensed for use in children.

Applicable Service Standards:

- Needle-free arterial non-injectable connector. Medtech innovation briefing MIB85.

6.6 Reporting

Providers using the NIC are required to report to NHS England and NHS Improvement if an injection into an arterial line occurs: england.innovation@nhs.net

7. Innovation Specification: HeartFlow FFRCT - Rapid diagnosis of patients presenting with new onset chest pain which is suspected to be Coronary Artery Disease (CAD) using advanced image analysis software

7.1 Purpose

This specification gives NHS providers and commissioners information on HeartFlow analysis, a software product included in the Innovation and Technology Payment programme, which is used to estimate fractional flow reserve from coronary CT angiography.

7.2 Expected Outcome

HeartFlow FFRCT Analysis is a novel software technology which estimates Fractional Flow Reserve (FFR) in coronary arteries, using CT coronary angiography (CCTA). FFR measured from invasive angiography has been used widely in clinical practice for many years and helps determine whether a person's coronary disease warrants revascularisation. Examples of revascularisation include the insertion of stents or surgical bypass grafting. The HeartFlow Analysis helps clinicians determine whether such an intervention is likely to improve a patient's longer-term outcomes or not. Improved resolution and gating of CT coronary angiography has allowed the extent and anatomical severity of coronary lesions to be assessed non-invasively, and 'HeartFlow Analysis' is the first technology to allow an assessment of FFR to be made during the same investigation.

The expected outcomes from this innovation are:

- Improved diagnosis of coronary artery disease (CAD)
- Better treatment decisions for patients who have suspected CAD

7.3 Payment / price detail

The agreed price for this innovation is £700 per analysis excluding VAT available to providers under the zero-cost model. It can be ordered directly from HeartFlow Inc. (https://www.heartflow.com/). Participating sites must meet the criteria set out in this document below7.7. Contact info@heartflow.com for information.

7.4 Population Needs

National context and evidence base

CT coronary angiography is now recommended as the first diagnostic test in around 40,000 people presenting with new onset chest pain suggestive of stable angina (2017).[4] 'HeartFlow Analysis' technology is approved by NICE for the functional assessment of coronary lesions found on CT. This combined CT assessment of coronary anatomy, and the functional significance of selected coronary lesions by FFRCT, provides valuable diagnostic and therapeutic information and may reduce the need for more invasive investigations. Based on NICE's Medical Technology Guidance (2017) there is an estimated potential net saving of £214 per patient for HeartFlow FFRCT compared with the current treatment pathway.[5] As the cost of HeartFlow FFRCT is lower than in the NICE guidance, savings will be expected to be even greater.

7.5 Scope

Aims and objectives of product

This innovation must aim to improve the diagnosis of coronary artery disease and improve the patient experience by avoiding the need for invasive coronary angiography and revascularisation.

This innovation must:

- Be a coronary physiology simulation software package and service used for the qualitative and quantitative analysis of previously acquired computerised tomography (Digital Imaging and Communications in Medicine data)
- Improve patient care by avoiding the need for invasive coronary angiography and revascularisation

This innovation must be appropriate for use in:

- Adult patients with stable, recent onset chest pain who are offered a coronary CT angiography (CCTA) as a part of the NICE pathway on chest pain

4 https://www.nice.org.uk/guidance/mtg32

7.6 Clinical Standards

This innovation must:

- Be CE marked as a Class IIa software solution
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in MTG32[6]

7.7 NHS Site Criteria

NHS sites implementing HeartFlow must meet the following criteria.

CT Data Format and Quality Requirements:

- Requirements for HeartFlow are consistent with the Society of Coronary Computed Tomography (SCCT) Performance of Cardiac CT Guidance Document
- 64 or greater slice CT scanner with cardiac gating capability
- Dual syringe injector for 2 phase injection
- Access to scheduled time on the scanner for CCTA
- Experience, willingness, and staffing to use Glyceryl Trinitrate (GTN) and beta blockers (BB) (oral or IV) for proper vessel visualisation and heart rate control, respectively
- Accredited CCTA reader (or equivalent experience of >150 cardiac CTs) - may be SCCT Level 1+ or accredited through other organisations/fellowship
- At least 1 radiographer trained in CCTA and experienced with cardiac reconstructions
- Ability to meet minimum quality requirements for HeartFlow process (minimum 8/10 consecutive cases pass initial quality acceptance)
- HeartFlow on-site 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

6 https://www.nice.org.uk/guidance/mtg32

7.8 Site-specific Criteria

Additional site-specific criteria to ensure broad evaluation of HeartFlow in England

- Imaging team with CCTA expertise meeting recommendations set by Royal College of Radiology and Society of Coronary Computed Tomography as well as a demonstrated ability to meet minimum CT quality requirements
- Annual CCTA volume of > 300 scans or prior experience with HeartFlow

If your site currently has an annual CCTA volume of >300 scans and you would like to be considered for this programme contact england.innovation@nhs.net

NHS sites are required to:

- Have broad support across radiology, cardiology, and site administration with ability and commitment to enable and educate physicians to follow a CT±FFRCT pathway
- Provide health economic data to NHS England and NHS Improvement/HeartFlow

Applicable Service Standards:

- HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography: Medical technologies guidance [MTG32]

Applicable standards set out in Guidance and/or issued by a competent body:

- Consistent with standards set by Royal College of Radiology and Society of Coronary Computed Tomography (SCCT). [7]

[7] https://www.rcr.ac.uk/publication/standards-practice-computed-tomography-coronary-angiography-ctca-adult-patients

7.9 Reporting

At the end of each quarter, providers must report back on the following minimum data set:

Report for previous financial year:

- Number of patients scanned with a 64-slide (or above) coronary CT angiography during each quarter of the previous financial year
- A list of the different pathways the site has used for patients presenting with new onset chest pain suggestive of stable angina

Report for each quarter of the current financial year:

- The number of patients scanned with a 64-slice (or above) coronary CT angiography.
- The number of patients receiving a HeartFlow Analysis.
- The number of patients receiving an angiography after a HeartFlow Analysis.

Payment is contingent on reporting complete data by the 20th of the month following each quarter. If you have any questions about the required data, contact england.innovation@nhs.net

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings: Year_Quarter_Site name_HeartFlow_Submission date

8. Innovation Specification: Endocuff Vision® - to improve visualisation of the bowel during colonoscopy by increasing the total surface area of the visual field

8.1 Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is included in the Innovation and Technology Payment (ITP) with respect to improved colorectal examination for patients.

8.2 Expected Outcome

The expected outcome is an increase in the adenoma detection rate (ADR) of up to 21% based on the findings from the ADENOMA study[8]. Improved visualisation will enhance the identification of colonic polyps, specifically adenomas and adenocarcinomas, and increase the likelihood of complete excision as well as aiding post-excision scar examination. This will be achieved through improved stability and visualisation provided by Endocuff Vision® during colonoscopy.

8.3 Payment / price detail

The ITP agreed price for Endocuff Vision® is £12.05 ex VAT per device ordered from Norgine Pharmaceuticals via Olympus under the zero-cost model. Providers can email info@olympus.co.uk or call 01702 616 333 to order this product. There is a minimum order of three boxes of Endocuff Vision®. More information about Endocuff Vision® is available from: http://endocuff.com/products/endocuff-vision.

8.4 Population Needs

National/local context and evidence base

Earlier cancer detection is a priority for the NHS in England. Bowel cancer is the fourth most common cancer in the UK, after breast, prostate and lung cancers. Over 41,000 people are diagnosed with bowel cancer each year. Early diagnosis improves

[8] Ngu WS, Bevan R, Tsiamoulos ZP, et al. Improved adenoma detection with Endocuff Vision: the ADENOMA randomised controlled trial. Gut Published Online First: 23 January 2018. doi: 10.1136/gutjnl-2017-314889

prognosis. Approximately 16,000 people die as a result of bowel cancer in the UK each year, meaning it is the second highest cause of deaths from cancer.[9]

8.5 Scope

This innovation aims to:

- Improve patient care by improving visualisation to enhance the identification of colonic polyps, specifically adenomas and adenocarcinomas, and increase the likelihood of complete excision as well as aiding post-excision scar examination. Earlier diagnosis of bowel cancer leads to better patient outcomes and potentially less intensive or invasive management.

This innovation must:

- Be a distal device that fits onto the end of a colonoscope, providing improved visualisation and stability during colonoscopy to improve ADR
- Have a Class II CE Mark

This innovation must be appropriate for use in:

- Patients undergoing colonoscopies who meet the acceptance and exclusion criteria outlined below. It is expected that decisions on use with individual patients are based on the healthcare quality criteria outlined in section 8.6.

8.6 Clinical Standards /acceptance and exclusion criteria and thresholds

NHS sites adopting this technology must:

- Only use Endocuff Vision® attachments with compatible colonoscopes;
- Ensure staff are trained in the correct use of Endocuff Vision®
- Follow instructions for use and use correct Endocuff Vision® size in accordance with the scope being used
- Should not be used for complex sub-mucosal dissection where a separate distal attachment is required

[9] https://www.bowelcanceruk.org.uk/about-bowel-cancer/bowel-cancer/

Sites should be aware that:

- The Endocuff Vision® is not intended for deep ileal intubation
- Should not be used in cases with acute, severe colitis or where there is known colonic stricture

Applicable Service Standards

- Must be consistent with standards set by the Royal College of Physicians Joint Advisory Group on GI Endoscopy
- Be supported by an appropriate clinical evidence-base and be compliant with NICE guidance set out in MTG45.

8.7 Reporting

- No reporting requirements have currently been stipulated.

9. Innovation Specification: SecurAcath - Improved stability / securement and reduced infection risk for patients with a peripherally inserted central catheter

9.1 Purpose

This specification gives NHS providers and commissioners information on SecurAcath, a product included in the Innovation and Technology Payment programme, to secure peripherally inserted central catheters (PICCs).

9.2 Expected Outcome

The expected outcomes from using SecurAcath are a reduction in the number of securement device replacements required and the number of catheter replacement procedures required. This is associated with a lower incidence of catheter-associated complications, such as migration, dislodgement, occlusion, thrombosis and infection. SecurAcath is designed to remain in place as long as the catheter is in place.

9.3 Payment / price detail

The ITP agreed price for SecurAcath is £18 ex VAT per device and is available under the zero-cost model. NHS Trusts can order SecurAcath directly from the supplier: contactus@aquilantservices.com or call 01256 365 490.

9.4 Population Needs

National/local context and evidence base

NICE states that SecurAcath is more effective than adhesive securement devices when a PICC is anticipated to stay in place for 15 days or more.[10]

Their analysis suggests that around 128,000 people are eligible for SecurAcath, based on the approximate number of people having PICCs each year. They estimate that uptake will be steady from year 5 after implementation, with around 121,000 people having SecurAcath with a saving for England of £4.2m.[11]

[10] https://www.nice.org.uk/guidance/mtg34/chapter/6-Conclusions
[11] https://www.nice.org.uk/guidance/mtg34/resources/resource-impact-report-pdf-4481645725

Estimated cost savings range from £9 to £95 per patient for dwell times of 25 days and 120 days, respectively. Cost savings result from shorter maintenance times and less need for device replacement with SecurAcath.[12]

9.5 Scope

Aims and objectives of product

This innovation aims to:

- Reduce the number of securement device replacements required and lower the number of catheter-associated complications
- Reduce the number of catheter replacement procedures required due to migration or dislodgement

This innovation is:

- a device which allows subcutaneous attachment of peripherally inserted central catheters (PICC) lines leading to improved stability and reduced infection risk for patients with a PICC
- be supported by an appropriate clinical evidence-base and be compliant with NICE guidance MTG34

This innovation must be appropriate for use in:

- Patients who have an anticipated medium-to long-term dwell time of 15 days or more with a peripherally inserted central catheter, in line with NICE guidance.[13] Through the scope of the ITP, SecurAcath is only funded for PICC lines, not centrally inserted central venous catheters

Applicable Service Standards:

- SecurAcath for securing percutaneous catheters: see NICE guidance MTG34

[12] https://www.nice.org.uk/guidance/mtg34/chapter/5-Cost-considerations
[13] https://www.nice.org.uk/guidance/mtg34

9.6 Clinical Standards

Acceptance and exclusion criteria and thresholds and site-specific criteria:

- Patients who have an anticipated medium-to long-term dwell time of 15 days or more with a PICC, in line with NICE guidance.[14]
- Through the scope of the ITP, SecurAcath is only funded for PICC lines, not centrally inserted central venous catheters
- Follow the supplier's recommended training plan and available online resources so that all frontline staff are properly trained to be able to correctly insert, maintain and remove SecurAcath, as recommended by NICE
- It should not be used for anyone with a clinically documented nickel allergy
- Pain may be experienced on removal of the device and local anaesthetic may be needed, particularly until staff are fully familiar with the technique
- Infection rates may be increased if the device and catheter are not maintained and dressed according to protocol
- If a surgical 'nick' in the skin is used to aid catheter insertion, the risk of bleeding post-insertion related to this 'nick' can be managed with pressure until haemostasis is achieved or a haemostatic patch and dressing
- Initial adverse events may occur, such as skin indentation and anchor migration, until staff becomes familiar with the correct insertion and care techniques

Aquilant provides a range of free of charge training platforms, and participation is highly recommended. The training platforms include guidance on correct insertion, care and maintenance and removal of the SecurAcath stabilisation device.

To access these training programs please contact your local Territory Manager or email contactus@aquilantservices.com or T 01256 365490.

[14] https://www.nice.org.uk/guidance/mtg34

9.7 Reporting

At the end of each quarter, providers must report back on the following minimum data set:

Report for previous financial year:

- Number of patients who have PICC lines for more than fifteen days in each quarter of the previous financial year. This is only required for the first report
- Number of complications resulting from catheter dislodgements in each quarter of the previous financial year for patients who had PICC lines for more than fifteen days. This is only required for the first report

Report for each quarter of the current financial year:

- Number of patients who have used SecurAcath during this period of reporting
- Number of complications resulting from catheter dislodgements for patients who have PICC lines for more than fifteen days from this period of reporting

Payment is contingent on reporting complete data by the 20th of the month following each quarter. If you have any questions about the required data, please contact england.innovation@nhs.net.

Reports should be returned to Arden GEM CSU using the following email address agem.innovation@nhs.net.

CCGs and Providers can also obtain a copy of the reporting template from Arden GEM using the same email address. Reports should be returned using the following subject headings: Year_Quarter_Site name_SecurAcath_ Submission date

10. Innovation Specification: Plus Sutures - Reduction of Surgical Site Infection (SSI) through the use of antimicrobial sutures

10.1 Purpose

The purpose of this specification is to give providers and commissioners of NHS services specific details as to the basis on which this product is covered under the Innovation and Technology Payment (ITP) with respect to Triclosan-coated absorbable sutures which are designed to reduce the incidence of surgical site infection (SSIs).

10.2 Expected Outcome

Complications arising from SSIs cost the NHS £700m a year, with a longer expected length of stay putting additional burden on NHS Trusts.[15]

It is anticipated that there will be considerable cost savings as a result of the anticipated reduction in SSIs by up to 30 per cent through using the Plus Sutures. In part this will be realised through a reduction in length of stay by using the sutures. The reported average savings from using antimicrobial sutures is £91.25 per procedure across all wound types.[16]

NHS England and NHS Improvement has identified Plus Sutures as Triclosan-coated absorbable sutures which currently meets the specification set out in this document. Plus Sutures are an effective way of cutting the incidence of SSIs.

Plus Sutures alone may be expected to reduce infection rates, but they may be more effective when introduced into a specific bundle of measures designed to prevent SSI occurrence.

10.3 Payment / price detail

NHS England and NHS Improvement will reimburse designated NHS Trusts that transition from standard to Plus Sutures in designated specialties for the 30% premium cost of Plus Sutures, compared to the standard Ethicon sutures. This

[15] https://www.nice.org.uk/guidance/qs49/resources/support-for-commissioning-for-surgical-site-infection-253715293

[16] Wang Z, Jiang C, Cao Y and Ding Y (2012) Systematic review and meta-analysis of triclosan-coated sutures for the prevention of surgical-site infection. British Journal of Surgery 100: 465-473.

central reimbursement will be paid on the increased adoption from the initial baseline level at the start of the period. Reimbursement will be made eligible to NHS Trusts which have a baseline SSI rate of 4 per cent or higher, further detail around the baseline criteria is included below.

If the NHS Trusts that adopt Plus Sutures under this ITP programme collectively do not realise a significant reduction in their SSI rate that offsets the additional costs associated with the product then Johnson and Johnson Medical Ltd will reimburse NHS England and NHS Improvement the difference between the SSI saving achieved and the premium up to a maximum of the total premium incurred by NHS England and NHS Improvement. This ensures that an NHS Trust which has a baseline SSI rate of 4 per cent and above should not have to pay any more for sutures in the specialities set about below than their current Ethicon baseline price or the equivalent baseline price if they are using alternative suture supplier.

Availability: Only sites which meet the 'Site Specification' outlined below will be eligible to have this premium cost covered. Forward enquires to Luke Evans, Platform Manager for Wound Closure, phone 07825 843020 or email levans13@ITS.JNJ.com

10.4 Population Needs

National/local context and evidence base

Surgical site infections cost the NHS £700m a year. SSIs lead to an increased length of stay for patients in hospital. NICE have estimated that the average cost of treating one SSI is £4,300, made up of drugs, dressings, interventions and professional time.[17] NICE estimate that the cost of surgical site infection ranges from £2,100 to £10,500 per infection.[18] Experts have estimated that the cost for complex surgery could be as high as £20,000 per SSI and up to £14,000 for general surgery.[19]

10.5 Site Specification

The following criteria must be met for NHS hospital sites to be funded to purchase Plus Sutures through the ITP. NHS Trusts must have a baseline Surgical Site Infection rate of 4 per cent or above. This is based on data from Hospital Episode

[17] https://publications.parliament.uk/pa/cm200809/cmselect/cmpubacc/812/812.pdf
[18] https://www.nice.org.uk/guidance/qs49/resources/support-for-commissioning-for-surgical-site-infection-253715293
[19] https://www.nice.org.uk/guidance/qs49/resources/support-for-commissioning-for-surgical-site-infection-253715293

Statistics for 2016/2017 for the following specialties: Bariatrics, Breast augmentation, Breast reconstruction, Coronary artery bypass grafting (CABG), Caesarean Section, Cardiac, Colorectal, General Surgery, Gynaecology (not including Hysterectomy), Head and Neck, Hernia, Hepatopancreatobiliary (HPB), Hysterectomy, Neuro, Oncological ablations, Thoracic, Upper Gastrointestinal (UGI), Urology and Vascular.

By targeting NHS Trusts with higher than expected SSIs, the ITP will make the biggest meaningful impact on overall SSI rates which will enable better patient outcomes and cost savings to be realised in the Trusts.

10.6 Scope

Aims and objectives of the innovation

This innovation must:

- Reduce the incidence of Surgical Site Infections using Triclosan-coated absorbable sutures

This innovation must:

- Be Triclosan-coated absorbable sutures which are designed to reduce incidence of surgical site infection
- Improve patient care by reducing the incidence of Surgical Site Infections (SSIs)

This innovation must be appropriate for use in:

- Patients undergoing the surgical procedures set out in the ‘Clinical Standards’ section of this guidance document below.

10.7 Clinical Standards

NHS England and NHS Improvement will only reimburse trusts the premium cost of plus sutures when used in the following areas of surgery:

- Bariatrics, Breast augmentation, Breast reconstruction, CABG, Caesarean Section, Cardiac, Colorectal, General Surgery, Gynaecology (not including Hysterectomy), Head and Neck, Hernia, HPB, Hysterectomy, Neuro, Oncological ablations, Thoracic, UGI, Urology and Vascular.

10.8 Reporting

A baseline SSI rate for participating Trusts (those with a 4 per cent SSI rate or above) was produced, based on the procedure and diagnosis codes and specialities as set out above for the 2017/2018 financial year

NHS England and NHS Improvement will track the progress of SSI rates based on the procedure and diagnosis codes and specialities set out above on a quarterly basis to track the expected outcomes listed. Trusts should return their SSI rates monthly.

Appendix A: Academic Health Science Network (AHSN) contacts

Location	Contact Name	Email/Telephone
Eastern	Helen Oliver Chief Operating Officer	E: helen.oliver@eahsn.org T: 01223 661 493
East Midlands	Tim Robinson Commercial Director	E: tim.robinson@nottingham.ac.uk T: 0115 7484244
Health Innovation Network	Anna King Commercial Director	E: anna.king1@nhs.net T: 0207 188 9805
Health Innovation Manchester	Arjun Sikand Associate Director Commercial Partnerships	E: Arjun.Sikand@healthinnovationmanchester.com T: 0161 206 7978
Imperial College Health Partners	Shirlene Oh Director of Commerce, Innovation and Capability Building	E: Shirlene.oh@imperialcollegehealthpartners.com T: 0333 077 1707
Innovation Agency	Carole Spencer Transformation Director	E: Carole.Spencer@innovationagencynwc.nhs.uk T: 0177 520260
Kent, Surrey and Sussex	Charlotte Roberts Senior Programme Manager	E: charlotte.roberts18@nhs.net T: 0300 303 8660 M: 07818580404
North East and North Cumbria	Nicola Wesley Chief Executive Officer	E: Nicola.Wesley@ahsn-nenc.org.uk T: 0191 208 1239 M: 07834307906
Oxford	Julie Hart Director of Strategic and Industry Partnerships	E: Julie.hart@oxfordahsn.org T: 07766 775553
South West	Stuart Monk Director of Delivery	E: Stuart.Monk@swahsn.com T: 0139 224 7903
UCL Partners	Suzanne Ali-Hassan Head of Commercial Engagement	E: innovationteam@uclpartners.com T: 0203 108 2321
Wessex	Joe Sladen Associate Director Strategic Programmes	E: joe.sladen@wessexahsn.net T: 07736 896545
West Midlands	Tony Davis	E: tony.davis@wmahsn.org

Location	Contact Name	Email/Telephone
	Commercial Director	T: 0121 371 8061
West of England	Kay Haughton Director of Service and System Transformation	E: Kay.haughton@weahsn.net T: 0117 900 2192 M: 07557 800886
Yorkshire and Humber	Neville Young Head of Commercial Development	E: neville.young@yhahsn.com T: 0192 466 4506

Appendix B: Innovations funded under the ITP and ITT

Funding mechanism	Description	Benefit	Example Product	Nature of funding
ITP 2019/20	A device to allow non-invasive vagus nerve stimulation for the treatment of cluster headaches.	Reduction in cluster headache severity and frequency and improvement in patient quality of life.	gammaCore™	Being funded for national spread
ITP 2019/20	Absorbable spacer to reduce rectum radiation exposure during prostate radiation therapy	Reduction in complications arising from rectal toxicity. Reduced demand across the health system.	SpaceOAR™	Being funded for national spread
ITP 2019/20	A diagnostic placental growth factor test for the rule out of preeclampsia in pregnant women	Improved risk assessment for pregnant women with suspected pre-eclampsia. Cost savings through a reduction in bed days and increased clinical staff time.	Roche Elecsys sFlt-1/PlGF ratio test and Quidel Triage PlGF Test - Preeclampsia	Being funded for national spread
ITP 2018/19	Fractional flow reserve from coronary CT angiography	Rapid diagnosis of patients with suspected Coronary Heart Disease (CAD) using advance image analysis	HeartFlow	Being funded for national spread
ITP 2018/19	Device to allow subcutaneous attachment of PICC lines	Improved stability and reduced infection risk for patients with a peripherally inserted central catheter	SecurAcath	Being funded for national spread
ITP 2018/19	Triclosan-coated absorbable sutures to reduce incidence of surgical site	Reduction of Surgical Site Infection (SSI) through the use of antimicrobial suture packs	Plus Sutures	Uplift cost funded for sites which have a baseline Surgical Site Infection rate of 4 per cent and above.
ITT 2017/18	Needle free arterial connecting system with one-way valve	Designed to reduce bacterial contamination and the accidental administration of medication, additionally making blood sampling simple for staff and improving arterial line safety	Non-injectable arterial connector (NIC)	Being funded for national spread

Appendix C – General Requirements

All innovations must be governed by criteria similar to the Institute of Medicine's six dimensions of healthcare quality[20]. This means that products or services are:

- Safe – avoiding harm to patients wherever possible
- Effective – providing support based on clear benefit to patients
- Efficient – avoiding waste
- Person centred – accepting patient's needs and preferences
- Timely – reduces waits and harmful delays
- Equitable – care does not vary in quality due to patient characteristics

Infection Control

Appropriate infection control measures must be in place and must comply with The Health & Social Care Act 2012 and follow current guidance from the Department of Health and the National Institute for Health & Clinical Excellence.

Safeguarding Children & Vulnerable Adults

Hospitals should have appropriate policies and processes in place to ensure the safeguarding of children & vulnerable adults in compliance with National & local policies and statutory requirements.

Patient records and reporting of episode of care

All clinical records will be clear concise, accurate and legible.

Systems should be set up within the service so that patients should only need to repeat their registration and case history details for safety and clinical reasons and not because the information cannot be transferred

Clinical discharge summaries should include:

- The patient's demographic details and NHS number
- The patient's presenting condition and diagnosis
- Details of any diagnostics conducted and where possible, their results
- Any treatments provided, management plans followed, and any medications prescribed

[20] Institute of Medicine: Crossing the quality chasm: a new health system for the 21st century. Washington DC: National Academy Press, 1990, p244.

- Clinical outcomes
- Details of any referrals to specialist services to address the patient's immediate needs
- Any recommendations made to the patient for services to which they might self-refer
- Any recommendations about appropriate services (including social services) that the GP might wish to refer the patient for their ongoing needs.

Governance

Hospitals will be expected to maintain appropriate operational governance arrangements and to undertake regular reviews of operational processes and resolve any problems or issues that arise.

Hospitals will be expected to demonstrate that robust clinical governance arrangements are in place. The Trust are expected to maintain registration with the Care Quality Commission and comply with all appropriate national regulatory requirements.

Hospitals will be expected to comply with locally agreed clinical standards.

Hospitals will be expected to comply with all local & National Information Governance regulations.

Hospitals must operate a complaints procedure which is consistent with the principles of the NHS complaints procedure.

Hospitals must demonstrate robust arrangements for recording and investigating Serious Incidents Requiring Investigations SIRIs. All SIRIs involving patients must be reported to the relevant Clinical Commissioning Group.

The service provider must demonstrate that they are appropriately indemnified to meet the costs of any legal claim by having full indemnity and liability insurances in place.