### **ABHI**





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### INTRODUCTION

One in two people in this country will be told they have cancer at some point in their lives. Early diagnosis and rapid, effective intervention are vital to survival and quality of life.

The NHS Long Term Plan (LTP) was published in January 2019, with an ambitious plan to improve a number cancer outcomes, and stating specifically that:

- by 2028, 55,000 more people each year will survive their cancer for five years or more; and
- by 2028, 75% of people with cancer will be diagnosed at an early stage (stage one or two).

The <u>NHS Cancer Programme</u> is responsible for delivering the LTP for cancer and should deliver these commitments in a manner that:

- improves quality of life
- · improves patient experience
- reduces variation
- · reduces inequalities.

The plan is, to a large extent, predicated on better and faster adoption of technology to improve national screening programmes and give people faster access to diagnostic tests, as well as cutting-edge treatments and technologies. Many of the changes recommended by the LTP and the Prevention Green Paper are underpinned by a need for faster, more accurate technology enabled diagnosis.

Historically, annualised, silo budgets have made investment in technology that produces savings over a number of years problematic. The NHS now has the opportunity to fundamentally change its approach to technology procurement, working with industry to develop more flexible payment models focused on patient outcomes.

The LTP sets out some important changes to make it easier to carry out more research in the NHS, and hence speed up the time it takes for new innovations to get to NHS patients:

- making it easier for patients to register to participate in research, with a target of one million people registering their interest by 2023/24
- creating simpler standardised clinical trial processes and prices.

The LTP also focus on giving people with cancer more say over care that suits their needs with personalised care packages. Industry will seek to work with the health system and charities to ensure that the full benefits of all types of technology are communicated and made available to patients, ensuring access to the most effective, appropriate interventions.

The coronavirus pandemic has significantly impacted the delivery of care to NHS patients. Whilst urgent cancer cases have continued to be treated , the suspension of screening programmes, the reluctance of citizens to interact with the health system and bottlenecks in the diagnostic pathways, have led leading clinicians to highlight the potential, long-term consequences on the outcomes for cancer patients.

The following case studies have been provided by ABHI members, offering examples of practice which could further improve the delivery of screening programmes, enable access to rapid diagnosis and provide effective, personalised approaches to treatment consistent with the ambitions in the LTP.

All of these, we believe, can play a crucial role in addressing the backlog of cases arising from the coronavirus pandemic.

Macmillan Cancer Support has reported that cancer is going undiagnosed for up to 2,000 people a week due to the coronavirus pandemic, whilst the Institute of Cancer Research suggests putting-off cancer surgeries for three months could lead to almost 5,000 excess deaths in England alone.

It is, therefore, vital for tackling the backlog caused by coronavirus, and the longer-term ambitions of the NHS, that both diagnosis and treatment makes the best use of technology.

### TRANS ARTERIAL CHEMO EMBOLISATION - TACE

#### **Technology Name**

Trans Arterial Chemo Embolisation - TACE

#### **NHS Reset Aim**

NHS England issued guidance on the management of non-COVID patients requiring systemic anti-cancer treatments. Clinicians are advised to consider alternative and less resource-intensive treatment regimens<sup>(1)</sup>. Alternative solution, that shorten patient hospital stay and require less patient hospitalisation/consultation should be favoured.

#### **The Current Situation**

New figures from University College London suggest there could be 18,000 more cancer deaths in England because of the coronavirus pandemic. Cancer Research UK reports, that despite national guidelines stating that urgent and essential cancer treatments must continue, unfortunately this is not the case in some hospitals across the UK. Surgery has been worst hit, and clinicians are needing to have very difficult conversations with patients to explain risks vs benefits. Chemotherapy and palliative care have also been affected by COVID-19<sup>(2)</sup>.

### Transarterial Chemoembolisation (TACE) as an alternative to systemic therapy

TACE is the most widely used primary treatment for unresectable Hepatocellular carcinoma (HCC). TACE is recommend for patients with BCLC stage B by The European Society for Medical Oncology (ESMO) and The European Association for the Study of the Liver (EASL 2018) (3). TACE is also an efficient treatment option in patient with colorectal cancer metastases as an alternative to systemic treatment in patients that have failed previous systemic treatment<sup>(4)</sup>.

#### **Technology Overview of TACE with Drug eluting beads**

Transarterial Chemoembolisation (TACE) can be performed using either Doxorubicin and Lipiodol, known more commonly as cTACE (Conventional Transarterial Chemoembolisation) or with microscopic beads loaded with chemotherapy, known commonly as TACE or DEB-TACE (Drug Eluting Bead Chemo-Embolisation).

They are both performed using angiographic techniques in Interventional Radiology and could be repeated on demand depending on tumour type and the extent of disease within the liver<sup>(3,4)</sup>. TACE is an intra-arterial, intrahepatic injection into the tumour which cause a local effect of ischaemic tumour embolisation, and release chemotherapy directly into the tumour. Drug eluting beads can be loaded with Irinotecan (for colon cancer liver metastases) or Doxorubicin, Epirubicin or idarubicin (for hepatocellular carcinoma) chemotherapy and is an established method of treatment for primary and secondary hepatic tumours including HCC, and Colorectal<sup>(3-9)</sup>.

This treatment has proven high response rates and a lower complication profile than other types of transarterial liver directed therapy<sup>(10:11)</sup>. At present there is no alternative funded treatment for liver dominant or liver only disease in the UK for HCC patients.

Since the treatment is delivered directly to the tumour site, the patient is spared many of the systemic effects of intravenous chemotherapy such as bone marrow suppression, neutropenic sepsis, anaemia and thrombocytopaenia and hair loss which are distressing for patients. Consequently, the treatment is not only effective, but less toxic in general than the equivalent systemic therapy.

It is a minimally invasive treatment not requiring general anaesthetics and is minimally aerosol generating. This treatment reduces in-patient hospitalisation as it can be done in a day case setting and helps alleviate waiting lists for surgery. It provides an alternative option to systemic treatment in patient with localised liver cancer<sup>(12-17)</sup>. TACE is fully reimbursed and in the NHS.

#### **How Technology Can Help**

This treatment is a cost-effective option that supports the NHS Reset aims. The treatment reduces bed stay and number of hospital stays compared to repeated cycles of chemotherapy. It is a safe way for patient's to be either treated for their disease or to be sued during periods where patients cannot take systemic therapy to hold the disease state<sup>(3.4:10:17)</sup>. It is also not performed in surgery keeping theatre and aneasthetic cover available for those who need it. The treatment is non aerosol generating and does not limit the patient's future treatment options.

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# **CASE STUDY 2**SELECTIVE INTERNAL RADIATION THERAPY - SIRT

#### **Technology Name**

Selective Internal Radiation Therapy (SIRT)

#### **NHS Reset Aim**

NHSE issued guidance on the management of non-COVID patients requiring systemic anti-cancer treatments. Clinicians are advised to consider alternative and less resource-intensive treatment regimes <sup>(1)</sup>.

#### **The Current Situation**

New figures from University College London suggest there could be 18,000 more cancer deaths in England because of the coronavirus pandemic. Cancer Research UK reports, that despite national guidelines stating that urgent and essential cancer treatments must continue, unfortunately this is not the case in some hospitals across the UK. Surgery has been worst hit, and clinicians are needing to have very difficult conversations with patients to explain risks vs benefits. Chemotherapy and palliative care have also been affected by COVID-19<sup>(2)</sup>.

#### **Technology Overview**

Selective internal radiation therapy (SIRT) is used for the treatment of hepatic neoplasia. SIRT is an internal radiation treatment, in which radioactive beads are infused into the hepatic artery, become lodged in capillaries and radiation is emitted to destroy cancer cells<sup>(3,4)</sup>. The goal for the SIRT procedure is to deliver an absorbed dose of radiation to the lesions greater than the tumouricidal threshold, while ensuring that the dose to the surrounding non-targeted tissue is limited. SIRT is approved in Europe for the treatment of hepatic neoplasia. In the UK current funding is only for a specific group of metastatic colorectal cancer (mCRC) patients who have failed second line systemic treatment.

#### **How Technology Can Help**

SIRT are used to treat both primary and secondary Liver cancer. In HCC It can be used as a bridge to liver transplantation downstage to curative surgery and as a palliative treatment option in patients with disease localised to the liver who are not a candidate for either a curative treatment option or systemic treatment. It is a minimally invasive treatment not requiring general anesthetics, performed as an outpatient procedure reducing infection risks and is minimally aerosol generating. In mCRC it could be used to downstage to curative surgery and as a palliative treatment option in patients with disease localised to the liver for patients who are not candidates for either curative treatment options or systemic treatment.

This treatment is a safe and effective way for patient's to be treated for their disease it is cost effective, reduces bed stay and waiting times. It is not performed in surgery keeping theatre and anesthetic cover available for those who need it. The treatment is non aerosol generating and does not limit the patient's future treatment options. It can offer both curative and palliative options for patients<sup>(5.6.7)</sup>.

SIRT is currently reimbursed by NHS England in a specific subset of patients with metastatic colorectal cancer (mCRC) confined to the liver<sup>(8)</sup>. SIRT is currently being appraised under the NICE Multiple Technology Appraisal process for HCC.

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# CASE STUDY 3 CRYOBLATION THERAPY

#### **Technology Name**

Cryoablation Therapy

#### **NHS Reset Aim**

NHSE issued guidance on the management of non-COVID patients requiring systemic anti-cancer treatments. Clinicians are advised to consider alternative and less resource-intensive treatment regimens<sup>(1)</sup>.

#### **The Current Situation**

New figures from University College London suggest there could be 18,000 more cancer deaths in England because of the coronavirus pandemic. Cancer Research UK reports, that despite national guidelines stating that urgent and essential cancer treatments must continue, unfortunately this is not the case in some hospitals across the UK. Surgery has been worst hit, and clinicians are needing to have very difficult conversations with patients to explain risks vs benefits. Chemotherapy and palliative care have also been affected by COVID-19<sup>(2)</sup>.

#### **Technology Overview**

Cryoablation (also known as cryosurgery and cryotherapy) is a minimally invasive cancer treatment<sup>(3)</sup>. Where extreme cold is applied<sup>(4)</sup> using high pressure argon gas, to destroy abnormal or diseased tissue<sup>(3)</sup>. The number and duration of freeze cycles may vary due to tissue type, however, typically a procedure consists of 2 freeze cycles separated by a single thaw cycle<sup>(3)</sup>.

Freezing is achieved by utilising the Joule Thomson effect (compressed gases) using high-pressure argon gas that circulates through closed tip cryoablation needles to induce tissue freezing<sup>(3)</sup>. Active tissue thawing is achieved by circulating helium gas through the needles. In addition to the helium thawing, an electrical thawing is also available facilitating additional fast thawing and track ablation capabilities.

Two cryoablation methods exist: laparoscopic cryoablation (LCA) and Percutaneous Cryoablation (PCA). PCA is more commonly used, as LCA is more invasive<sup>(5)</sup>. PCA is typically performed with the patient under local anesthesia. It utilises CT or MRI to place cryoprobes into the targeted tissue, while LCA uses ultrasound.

#### **How Technology Can Help**

Cryoablation therapy can be used for treatments of multiple cancers, such as kidney, prostate, Musculoskeletal and lung, as both a curative treatment option and a palliative option<sup>(6;7)</sup> and to successfully bridge or downstage a patient until further treatment is available. This treatment is minimally invasive, limiting infection rates and is not performed in theatre which opens space up for other treatment. Many studies reported on PCA systems as a safe and effective treatment option with low rate of complications, fast recovery time, short procedure time, short length of stay in hospital, minimal sedation required, improved oncologic outcomes, low recurrence rate, good cryoprobe utilisation and economic advantages (versus PN and LCA).<sup>(8-12)</sup>

Cryoablation for Renal Cell Carcinoma (RCC) can be done under Conscious Sedation<sup>(13)</sup>, without the need for GA making it minimally aerosol generating and reducing the burden on Anaesthetics cover.

The benefits of cryotherapy are well established in RCC. These benefits include reduce local recurrence rates and complications (including bleeding), reduce procedure and recovery time, and length of stay in hospital. In addition, it can be safely used in older patients or in patients with comorbidities not fit for surgery, reduce pain and use of sedation, reduce the number of computerized tomography (CT) scans during surveillance periods, be cost saving<sup>(13-16)</sup>.

Cryoablation is indicated in the European Society for Medical Oncology (ESMO) and British Association Urological of Surgeons (BAUS) guidelines and European Association of Urology (EAU) guidelines<sup>(12)</sup>.

NICE has produced several interventional procedure guidance on Cryoablation therapy as a cancer treatment<sup>(16)</sup>. Cryoablation is a fully funded procedure as an excluded device and is a treatment option in most major Cancer sites.

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# DIGITAL PATHOLOGY SOLUTION FOR REMOTE REPORTING OF CANCER CASES

#### **Technology Name**

Digital pathology solution for remote reporting of cancer cases

#### **Long Term Plan Aim**

Digital pathology is a dynamic, image-based environment that enables the acquisition, management, sharing and interpretation of pathology information generated from a digitised glass slide. This enables pathologists to work flexibly and to securely read digital cases remotely by using an internet browser. Access to digital images during urgent or unusual circumstances offers significant clinical value e.g. providing a second opinion or a primary diagnosis for cancer cases.

#### **The Current Situation**

Digital pathology is gaining momentum as a proven technology, supporting education, drug development, and the practice of human pathology throughout the world. Adoption of digital pathology for clinical use has been slow, with only a handful of departments across the UK currently using this for primary diagnosis, and five centres of excellence to enable digitisation.

The Coronavirus pandemic served to further highlight the chronic workforce issue with 97% pathology departments reporting a shortage of pathologists. Digital pathology enables flexible working with cancer cases being reviewed remotely and sent to specific cancer pathology specialists as needed.

The technology is primed to make an important contribution to telehealth now and in the future, enabling the potential for pathologists to collaborate from wherever they are in the world.

#### **Technology Overview**

Digital pathology empowers pathologists to provide precise diagnosis and supports the future of personalised healthcare by delivering innovative digital pathology solutions. Combining precision scanners, software and clinical algorithms into a seamless digital pathology solution that offers a complete and fully integrated acquisition, management and analysis system. Developed in partnership with expert pathologists, this solution enables pathologists to maximise their capabilities and evolve their practices. Brightfield scanners are designed for a variety of applications. Fast and simple technology offering a no-touch start process and intuitive user experience.

Software provides pathologists, histotechnicians and administrators a universal platform to manage cases, view, organise, retrieve and annotate digital tissue slide images. Image analysis software are specifically designed to aid pathologists in the assessment, measurement and diagnosis of cancer cases. Producing consistent and objective interpretations through semi-quantitative score to improve diagnostic consistency and confidence.

#### **How Technology Can Help**

Digital pathology is a rapidly growing area that has the potential to transform how pathology is practised. The potential benefits, enabled by the electronic transfer of slides from the laboratory to the pathologist, include:

- Enabling the rapid referral of cases between organisations or across pathology networks, enhancing access to expert advice and opinion on diagnoses.
- Improving laboratory workflow and connectivity and increasing flexibility and efficiency of the workforce, helping create digital training resources that support the development of specialists.
- Increasing the power to share slides, making it easier to access remote expertise and enabling extension and reorganisation of subspecialist reporting.
- Enabling the use of artificial intelligence, which can bring advances to pathology services.

These factors offer potential solutions for local shortages of pathologists, enable remote working and may help to improve the overall quality of services.

### DIGITAL IMAGE ANALYSIS SOLUTION FOR CANCER CASES

#### **Technology Name**

Digital image analysis solution for cancer cases

#### **Long Term Plan Aim**

Digitisation of glass pathology slides, in combination with the development of specialised software, has given pathologists the ability to utilise digital image analysis on tissue sections. Tissue image analysis, when performed correctly, results in the generation of tissue-derived readouts that are precise and reproducible.

#### **The Current Situation**

Digital pathology is gaining momentum as a proven technology, supporting education, drug development, and the practice of human pathology throughout the world. Adoption of digital pathology for clinical use is slow, with only a handful of departments across the UK using this for primary diagnosis. Pathologists play a key role in the data generation via the use of image analysis algorithms.

Whole-slide images of tissue samples are rich in information, only accessible visually by a trained pathologist whose expertise was based on previous experience and training.

When undertaking assessment and quantification of biomarkers, image analysis tools are of great value in standardising analysis, minimising bias and the variability of generated data. Assessments can be tuned to:

- limit the quantification of the present biomarker to tissue compartments and subcellular compartments;
- consider variable staining thresholds; and/or
- enable more global biomarker data collection that then can be interrogated in post processing steps.

#### **Technology Overview**

Digital pathology combines hardware, software and image analysis applications to offer a complete and fully integrated system. Developed in partnership with expert pathologists, to provide precise diagnosis and supports the future of personalised healthcare by delivering innovative digital pathology solutions.

Image analysis software or clinical decision support tools are specifically designed to aid pathologists in the assessment, measurement and diagnosis of cancer. Producing consistent and objective interpretations through semi-quantitative scores can improve diagnostic consistency and confidence. Image analysis algorithms are an aid to the pathologist in the determination of a biomarker's status in formalin-fixed, paraffin-embedded normal and neoplastic tissue specimens. Exact tumour and immune cell counts are especially important in certain diseases - including HER2 positive breast cancer, where each tumour cell is critical in determining if a patient is eligible for targeted treatment treatment.

Nowadays we have more complex testing and more options for treating cancer, digital pathology offers oncology a fundamental tool to help ensure that the right patient gets the right diagnosis and that the right diagnosis leads to the right

#### **How Technology Can Help**

The combination of image analysis software and pathology expertise provides an opportunity to transform a traditionally qualitative assessment towards a more quantitative approach, analysing complex biomarker expression, patterns, and tissue phenotypes. Image analysis and machine learning algorithms can automatically identify tissue compartments of interest, segment individual cells, or anatomical features and categorise these features based on biomarker expression levels and localisation.

Image analysis tools not only reduce bias introduced by both visual limitations and cognitive traps, they also enable the capture of data from tissue slides that may not be accessible via routine microscopy. They equip pathologists with tools that can improve accuracy, precision, and reproducibility in the interpretation of biomarkers using image analysis.



# CASE STUDY 6 COMMUNITY DIAGNOSTICS CENTRES

#### **Technology Name**

Community Diagnostic Centres

#### **Long Term Plan Aim**

The LTP outlines its ambition that by 2028, the proportion of cancers diagnosed at stages 1 and 2 will rise from one half to three quarters of all cancer patients<sup>(1)</sup>. These ambitions are underpinned by plans to radically overhaul diagnostic and screening services through the roll-out of new local diagnostic centres across the United Kingdom, which upgrade and bring together latest diagnostic equipment and expertise<sup>(1)</sup>.

#### **The Current Situation**

Cancer survival is currently at its highest ever level – in 2015, one-year survival was 72% over 11 percentage points higher than in 2000. Despite strong progress, the NHS plans to continue to focus on improving cancer survival rate through increasing early diagnosis, with patients at stages 1 and 2 having the most likely chance of curative treatment and long-term survival (2)

The impact of the COVID-19 pandemic has created further delays in cancer diagnosis and treatment in the United Kingdom. According to recent research, concerns around access to routine screenings, urgent referrals and treatments could lead to a potential 7,000 excess deaths – rising to a worst-case scenario of 35,000<sup>(3)</sup>.

#### **Solution Overview**

In order to achieve LTP ambitions to accelerate early cancer diagnosis and screening, the NHS are partnering with likeminded independent healthcare providers, who access external investment in order to realise Community Diagnostic Centres (CDC).

Independent healthcare providers partner with leading health technology companies on CDC construction, to provide infrastructure, state of the art medical technologies including MRI, CT, Ultrasound, integrated information systems and enabling solutions, packaged in Managed Services, aimed at delivering clinical, experiential, operational and financial outcomes

#### **How Solution Can Help**

CDCs have the ability to transform current models of care delivery by providing rapid access to "right first time" diagnostics and treatment services, closer to patient's homes.

A first CDC is planned to open in Taunton, Somerset in  $2021^{(4)}$ .

## ACCELERATING HEAD AND NECK CANCER DIAGNOSES: A PATIENT-CENTRIC APPROACH

#### **NHS Cancer Priorities**

The Long Term Plan has targeted the introduction of a new Faster Diagnosis Standard from 2020 to ensure most patients receive a definitive diagnosis or ruling out of cancer within 28 days of referral from a GP or screening. The new Faster Diagnosis Standard will be underpinned by a radical overhaul of the way diagnostic services are delivered for patients with suspected cancer<sup>1</sup>.

#### **The Current Situation**

The current Head and Neck cancer pathway includes the provision to biopsy an area of concern following consultation, though this traditionally happens within the theatre setting. Due to the undertaking of more complex surgery within the Head and Neck service and increased time pressure on theatre availability, the scheduling of these cases can be a challenge. Patients can sometimes wait three to four weeks for an available theatre slot. This is an anxious wait for patients and presents a challenge to hospitals striving to meet cancer waiting targets. For hospitals that do breach waiting list targets, this can carry hefty fines.

The National Institute for Health and Care Excellence (NICE) recommend<sup>2</sup> considering a suspected cancer pathway referral (for an appointment within two weeks) for laryngeal cancer in people aged 45 and over with:

- persistent unexplained hoarseness, or
- an unexplained lump in the neck

Given the requirement to adhere to existing cancer wait targets; Two-week wait (2WW), 31 day and 62 day<sup>3</sup>, and the introduction of the Faster Diagnosis Standard, the pressures on the Head and Neck service will only become greater.

#### **Technology Overview**

One method to reduce the diagnostic delay and ease the burden on theatre time is to perform a biopsy during the initial consultation in the Outpatient setting. This can be achieved by using a video-nasoendoscope which includes a therapeutic channel. The endoscope is inserted through the nose to the area of concern and the appropriate biopsy forceps are passed down the channel to take a tissue sample which can then be sent to Histopathology.

#### **How Technology Can Help**

This less invasive approach to taking biopsies in the Outpatient department requires only the administration of local anaesthesia. By comparison, a full general anaesthetic is required for those patients that have their biopsy taken in theatre. The Outpatient approach allows patients to attend clinic and return home shortly after, reducing the duration of stay in hospital. In addition, the time taken to take a biopsy in the Outpatient setting is significantly shorter than that in theatre. This ensures that valuable theatre capacity is utilised for more complex surgical procedures that cannot be performed under local anaesthetic.

"Intervention in the outpatient setting reduces hospital and releases theatre capacity."

Suspected Head and Neck cancer patients that undergo biopsy in the Outpatient department face a significantly shorter wait for confirmation of their diagnosis. By removing the need to wait for an available theatre slot, patients need only to wait for the result of the biopsy from Histopathology following their initial consultation. This eliminates a significant proportion of time from the patient pathway, three to four weeks in some instances. This optimisation of the diagnostic pathway will ensure that hospitals can meet the Faster Diagnosis Standard.

"Eliminates a significant proportion of time from the patient pathway, three to four weeks in some instances."

A further benefit of Outpatient biopsy is the creation of a 'see and do' approach where the clinician can react immediately to viewing an area of concern and taking a biopsy. Biopsies are just the beginning of therapeutic procedures that can be delivered by the Head and Neck service in the Outpatient setting. Emerging technologies, growing pressure on theatre time and new clinical guidelines continue to question the most effective provision of Head and Neck services.



# PROSTATE RECTUM HYDROGEL SPACING & RADIOTHERAPY TREATMENT

#### **Technology Name**

Prostate rectum hydrogel spacing & radiotherapy treatment

#### **Long Term Plan Aim**

NHS England issued guidance on the management of non-COVID patients requiring Radiation Therapy. Clinicians are advised to consider alternative and less resource-intensive treatment regimens<sup>1</sup>.

#### **The Current Situation**

Approximately 36,280 cancer surgeries have been cancelled in the UK, with a 12-week cancellation rate of 28.8%². Approximately 43,000 men are diagnosed every year with prostate cancer(3.4), with approximately 16% (7,018) receiving cancer surgeries and 30% (13,891) radical radiotherapy treatment⁴. Currently 10% of men treated with radiotherapy have a severe gastrointestinal complication within 2 years, requiring surgical intervention⁴. Cancer Research UK state due to COVID-19 as many as 2.1 million people in Britain have been affected by the backlog in cancer care, waiting for screening, further tests or treatment⁵. Since the lockdown began 12,750 fewer patients have had surgery, 6,000 fewer have had chemotherapy and 2,800 fewer have had radiotherapy⁵.

One of the first line treatments for localised prostate cancer is radiation therapy<sup>6</sup>. Stereotactic body radiotherapy (SABR/SBRT) is a highly targeted radiation therapy which offers the potential for dose escalation and delivers ultrahypofractionation treatments usually in five fractions/visits or less (instead of 20 or more fraction/visits) for the treatment of prostate cancer<sup>7</sup>. Every UK cancer centre can provide SABR but only 26 out of England's 52 centres are permitted to offer it<sup>8</sup>. The treatment has been recommended by the Royal College of Radiologists and National Institute for Health and Care Excellence<sup>7,8</sup> but NHS England has indicated that the national expansion would not be completed until 2022<sup>8</sup>.

#### **Technology Overview**

SpaceOAR Hydrogel is an option for men undergoing radiotherapy for prostate cancer, acting as a spacer to temporarily position the rectum away from the high dose radiation during treatment for the preservation of healthy tissue and reducing potential side-effects from radiation exposure<sup>9</sup>. The rectum is anatomically in close proximity to the radiation target area and at risk of being exposed to an unintended radiation dose.

SpaceOAR Hydrogel is a unique, soft, gel-like material (an absorbable hydrogel) and remains in place for about three months and is naturally absorbed in the body after approximately six months<sup>10</sup>.

SpaceOAR Hydrogel is clinically shown to reduce radiation exposure related side-effects such as rectal urgency, urinary incontinence and sexual dysfunction<sup>9-12</sup>.

#### **How Solution Can Help**

- 1. Reducing post treatment complications and follow up For men receiving prostate radiotherapy, injection of a hydrogel spacer was safe, provided prostate-rectum separation sufficient to reduce v70 rectal irradiation, and was associated with fewer rectal toxic effects and higher bowel-related quality of life in late follow-up<sup>9</sup>. SpaceOAR Hydrogel is a minimally invasive procedure which can be implanted under local anaesthetic<sup>10</sup>.
- 2. Supporting reduced radiotherapy hospital sessions
  Recent evidence has now shown the benefits of a
  hydrogel spacer are maintained during SABR/SBRT
  treatments<sup>13-16</sup>. When compared to no spacer SABR/
  SBRT treatment, hydrogel spacer is significantly
  associated with reduced late GI toxicity and lower odds
  of developing late GU toxicity<sup>14</sup>. Results from case
  studies are not necessarily predictive of results in other
  cases. Results in other cases may vary.

## SUPERPARAMAGNETIC IRON OXIDE (SPIO) FOR BREAST CANCER SENTINEL NODE MAPPING

#### **Technology Name**

Magnetic Lymphatic Tracer (also known as SPIO)

#### **Long Term Plan Aim**

A key ambition in the NHS Long Term Plan for cancer is to ensure that 75% of people with cancer will be diagnosed at an early stage (stage one or two) by 2028, delivered in a way that improves patient experience outcomes<sup>1</sup>.

#### **The Current Situation**

The coronavirus pandemic has taken the lives of over 50,000 people in the UK<sup>2</sup>. When the pandemic relents, many will continue to be affected by the disruption that COVID-19 has caused in the coming years, including those in need of cancer services

There is now a backlog of over 2 million people awaiting cancer screening, testing and treatment<sup>3</sup>. Compounding this issue, the number of urgent cancer referrals in England alone has dropped by approximately 75% compared to the start of the pandemic, with 290,000 fewer patients being referred for further testing<sup>3</sup>. Now more than ever, cancer patients need access to the highest standard in diagnostic and staging technology.

#### **Technology Overview**

SPIO is a non-radioactive dark liquid tracer, developed for sentinel node biopsy staging procedures, currently in use in 27 NHS trusts across the UK. When injected, the tiny magnetic particles of SPIO are optimised to follow the path a spreading cancer cell would through the lymphatic system to the sentinel lymph nodes, those most likely to contain cancer  $^{4,5}$ .

Having successfully migrated up to the axilla, SPIO is detected by a localisation system, which picks up the magnetic signal. This, alongside the visual staining from the tracer, directs surgeons to the potentially affected nodes. By removing these nodes, surgeons are able to determine if cancer has spread beyond the breast and into the lymphatic system<sup>5</sup>.

#### **How Technology Can Help**

SPIO is administered to patients in a single injection, up to seven days or as little as 20 minutes before surgery<sup>6</sup>, giving patients, radiologists and surgeons flexibility: an important asset during scheduling disruption. Improvements in patient recovery time when using the technology has already been noted, with women receiving a less-invasive and less painful breast cancer staging procedure than with Tc-99m<sup>7</sup>.

It is not radioactive, unlike the current standard of care, Tc-99m, which delivers a radioactive signal that decays quickly. Tc-99m cannot be stockpiled due to its short shelf-life and is only available for use in nuclear medicine facilities<sup>8</sup>. The magnetic alternative avoids these significant barriers.

Furthermore, disruption in access to nuclear medicines is a significant concern with radioactive solutions for healthcare professionals. Without alternatives to Tc-99m like SPIO, difficulties may arise in staging breast cancer.

During the coronavirus pandemic, many breast surgeons moved surgical procedures to 'cold sites' - smaller breast clinics, created to free up space for COVID-19 patients at larger UK hospitals<sup>9</sup>. Smaller clinics often have limited access to nuclear medicine facilities, making non-nuclear technologies, like SPIO, essential to performing sentinel lymph node biopsies.

"We pushed for SPIO at our Winchester site because we had no nuclear medicine and the patients had to go to another hospital to be injected (with Tc-99m). That's something we really wanted to avoid during the pandemic, so SPIO has been really helpful in developing that<sup>10</sup>."

Ms. Siobhan Laws, Consultant Breast and Reconstructive Surgeon at Hampshire Hospitals NHS Foundation Trust



# AUTOANTIBODY ELISA PANEL FOR THE EARLIER DETECTION OF LUNG CANCER

#### **Technology Name**

Autoantibody ELISA panel for the earlier detection of lung cancer

#### **Long Term Plan Aim**

The importance of early-stage diagnosis of lung cancer is evident when looking at the current five-year survival rates of the disease by stage-at-diagnosis<sup>1</sup>:

Stage 1: 56.6% Stage 2: 34.1% Stage 3: 12.6% Stage 4: 2.9%

To support the NHS' long term plan of detecting 75% of all cancers early (at stages I & II) and thereby saving 55,000 lives in the UK, the autoantibody ELISA panel can be used in two applications:

- 1. A tool that enables the triage of patients at-risk into CT-scanning to make at-scale screening more efficient in finding cancers and hence more feasibly deployed at scale.
- 2. For patients with a CT-scan or X-ray detected indeterminate pulmonary nodule (IPN), to better characterise and therefore better manage the risk of nodule malignancy.

#### **The Current Situation**

#### Screening:

Imaging, particularly CT-scanning sits at the center of any lung cancer screening programme in the UK. CT-scanning is a capital and labour intensive practice, and one that is already operating beyond capacity in the NHS. Of the approximate £2 billion² spent annually to deliver imaging services today, more than 2/3 are spent on staffing the services. The NHS has stated that "with rising activity, this level of funding is not likely to be sustainable neither financially nor in terms of delivering a sustainable service."  $^{\rm 3}$ 

#### IPN management:

The pandemic has led to a backlog of suspected cancers that are not receiving the follow-up they require. Urgent suspected lung cancer referrals have been the slowest to recover since April, with numbers at the end of September still only at 60% of pre-COVID-19 levels<sup>4</sup>. Prior to the pandemic, IPN management was a large component of care in the NHS.

Approximately 611,000 chest and abdomen CTs are performed annually in the NHS<sup>5</sup> with the British Thoracic Society estimating that 13%<sup>6</sup> of these CTs result in approximately 80,000 lung nodules being detected each year.

#### **Technology Overview**

The technology measures autoantibodies raised in response to lung cancer associated antigens. Autoantibodies, or tumour related antibodies, are an amplified proxy of the disease and are known to be present in the earliest stages of lung cancer allowing for early detection of the disease. The test has been shown to detect lung cancer on average four years before current standard of care in a cohort of NHS patients.<sup>7</sup>

The test is thought to be the world's most validated blood-based test for the detection of lung cancer and has been shown to shift the stage-at-detection in a population of at-risk screening participants when used to triage patients into CT-scanning. The test demonstrated a 36% reduction in late-stage presentations in the Early detection of Cancer of the Lung Scotland trial (ECLS).

#### **How Solution Can Help**

#### Screening:

The autoantibody ELISA panel can be used as a tool that enables the triage of patients into CT-scanning to make atscale screening more efficient in finding cancers and hence more feasibly deployed at scale. When used in this way, this technology has been shown to reduce late-stage presentation of lung cancer by 36% in at-risk individuals.<sup>9</sup>

#### IPN management:

The technology can support nodule management to re-classify malignant nodules that would otherwise be triaged to CT-surveillance ensuring that more lung cancers can be found and treated earlier. This improved triage will also decrease the volume of CT scans required in CT-surveillance.

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