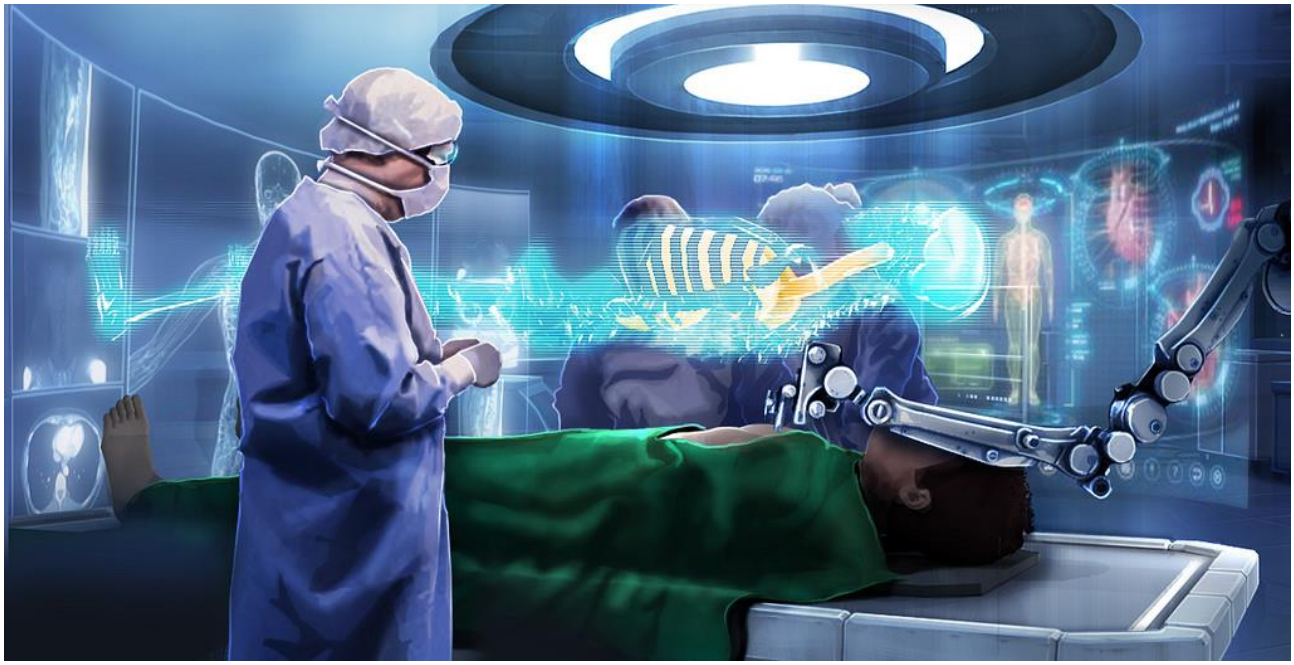

Technology in Surgery

SBRI Healthcare NHS England competition for development contracts

October 2017

Summary

A new national Small Business Research Initiative (SBRI) Healthcare competition is being launched by NHS England in partnership with the Academic Health Science Networks (AHSN's) to find innovative new products and services. The projects will be selected primarily on their potential value to the health service and on the improved outcomes delivered for patients.

The competition is open to single companies or organisations from the private, public and third sectors, including charities. The competition will run in two phases:

- Phase 1 is intended to show the technical feasibility of the proposed concept. The development contracts placed will be for a maximum of 6 months and up to £100,000 (inc. VAT) per project
- Phase 2 contracts are intended to develop and evaluate prototypes or demonstration units from the more promising technologies in Phase 1. Only those projects that have completed Phase 1 successfully will be eligible for Phase 2.

Developments will be 100% funded and suppliers for each project will be selected by an open competition process and retain the intellectual property rights (IPR) generated from the project, with certain rights of use retained by the NHS.

The competition opens on 18th October 2017. The deadline for applications is 1200hrs on 29th November 2017.

Introduction

There is increasing pressure on surgical services, the cost of delivering surgery and patient waiting times.

- Over a ten year period, the number of surgical admissions to secondary care increased by 27%, from 3.7 million in 2003/04 to 4.7 million in 2013/14[1].

- There are over three thousand NHS operating theatres in England, 19% of which are dedicated day case theatres[2] and annual expenditure on surgery in the NHS has been estimated[3] at £4.5 billion (2013).

- Waiting times for non-urgent surgery have been increasing. The 92% target for all patients to be seen within 18 weeks has not been met since February 2016. Furthermore, there was a 39% increase in the total number of patients waiting over 18 weeks for planned treatment in the twelve months to February 2017. In March this year, this target was relaxed, leading to longer waiting times.[4]

[1] Royal College of Surgeons , Surgery and the NHS in numbers. Accessed Sep 2017 https://www.rcseng.ac.uk/news-and-events/media-centre/media-background-briefings-and-statistics/surgery-and-the-nhs-in-numbers/

[2] NHS England, Supporting Facilities Data, 2017 https://www.england.nhs.uk/statistics/statistical-work-areas/cancelled-elective-operations/supporting-facilities-data/

[3] Foundation Trust Network, Operating Theatres - Maximising A Valuable Resource (Royal College of Surgeons estimate), 2013 http://nhsproviders.org/media/1128/operating-theatres-final.pdf

[4] Royal College of Surgeons, RCS response to deteriorating waiting times for planned surgery, Apr 2017

In order to reduce the costs incurred by surgical admissions, there has been a trend towards having both elective and non-elective procedures carried out as day cases, since day case patients incur lower treatment costs, compared to those who stay overnight as inpatients. In 2013–14, the average day case cost was £698 while the average elective inpatient case was £3,375. This increased proportion of day case activity has helped reduce overall costs. Estimates show that by treating more patients as day cases, the NHS had, in effect, saved around £2 billion (2013). [5]

Other examples of reducing length of stay following surgery (as well as patient outcomes) include the use of surgical techniques which are minimally invasive, the deployment of robotic systems and virtual reality based training. However, while robotic systems may ultimately reduce of length of stay[6], they also require significant capital expenditure, potentially restricting adoption and implementation.[7]

Another approach to reducing the costs within surgery is to deploy frugal innovation, which involves taking an established tool or work practice and developing a new and more cost effective way of deploying it.[8]

The recently published Life Sciences Industrial Strategy[9] identifies that gains over the last 30 years in health outcomes and life expectancy can continue and are likely to embrace innovations, such as, digital tools, robotics or artificial intelligence based on machine learning.

The Categories

Under the overall theme of 'Technology in Surgery', two categories have been identified via consultation with clinicians and other relevant stakeholders, they are outlined in detail below.

Applicants are expected to respond to a category whilst being mindful of the broader system.

Companies applying are also asked to consider:

- How will the proposed solution impact on the clinical care pathway, and how will the care pathway need to be changed in order to deliver system-wide benefits?

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https://www.rcseng.ac.uk/news-and-events/media-centre/press-releases/rcs-response-to-deteriorating-waiting-times-for-planned-surgery/

[5] Day case surgery: a good news story for the NHS, The King's Fund July 2015 https://www.kingsfund.org.uk/blog/2015/07/day-case-surgery-good-news-story-nhs

[6] East Kent Hospital University NHS FT, Robotic surgery success recognised, 2014, http://www.ekhuft.nhs.uk/patients-and-visitors/news/news-archive/news-archive-2014/robotic-surgery-success/

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[7] Surgical innovation and regenerative medicine, The King's Fund, Accessed Sep 2017 https://www.kingsfund.org.uk/projects/time-think-differently/trends-medical-advances-surgical-innovation

[8] Call to Action: Frugal Innovation to Improve Surgical Outcomes, Imperial College Health Partners, 2017, http://imperialcollegehealthpartners.com/blog/frugal-news/

[9] Life Sciences Industrial Strategy, Office for Life Sciences, 2017 https://www.gov.uk/government/publications/life-sciences-industrial-strategy

- How will you ensure that the technology will be acceptable to patients (and their families) and to healthcare workers?
- How will you ensure that the technology is affordable to the NHS both immediately and throughout the life of the product ? What health economics evidence will the NHS require before the technology can be adopted?

Category 1: Preoperative Surgical Simulation Technologies

Background

Simulation is a well established tool in many industries, where its use is associated with training, modelling, cost reduction, improved safety and other performance measures.

Within many surgical procedures there is variation in outcomes, this may be due to patient variables but there is also a human element to the surgeon's performance which can vary. The 'preparation phase' for a surgical procedure by the operator is an important step in the overall delivery of a surgical intervention. Surgeons at all levels of experience benefit from mental rehearsal prior to carrying out a procedure. Novices potentially need to do this prior to every procedure, whereas experts rehearse for procedures they have not done for some time, or when the patient's underlying condition, or the complexity of the surgical procedure may present a particular challenge.

The preparation phase for surgery involves imagining and visualizing the relationship of anatomical structures in three dimensions and reflecting on how these influence each step of the procedure. There is also the run through of the various steps of the operation including the anticipation of technical difficulties or unexpected findings.

Simulation can assist the successful preparation for surgical procedures. Simulation technology to aid surgeons has taken many forms during the course of history, including models, cadavers and mannequins. More recently, with the advent and accessibility of high definition imaging, virtual reality platforms and highly accurate 3D printed replicas of body organs are available which allow surgeons to practice and prepare in a safe environment before embarking on the live patient. If surgeons were able to practice on actual patient scenarios using VR, or on models of the actual patient prior to surgery, identical to what they will find when operating on the patient, they could build muscle memory, be faced with fewer decisions to make during surgery and outcomes could be improved.

Whilst robotics are currently used, they tend to be passive and the challenge to utilize robotics in an active way could also reduce variability from human factors. Technologies such as Virtual and Augmented Reality are currently rarely used in a surgical context.

Challenges

A practising colorectal surgeon summaries the current challenge:

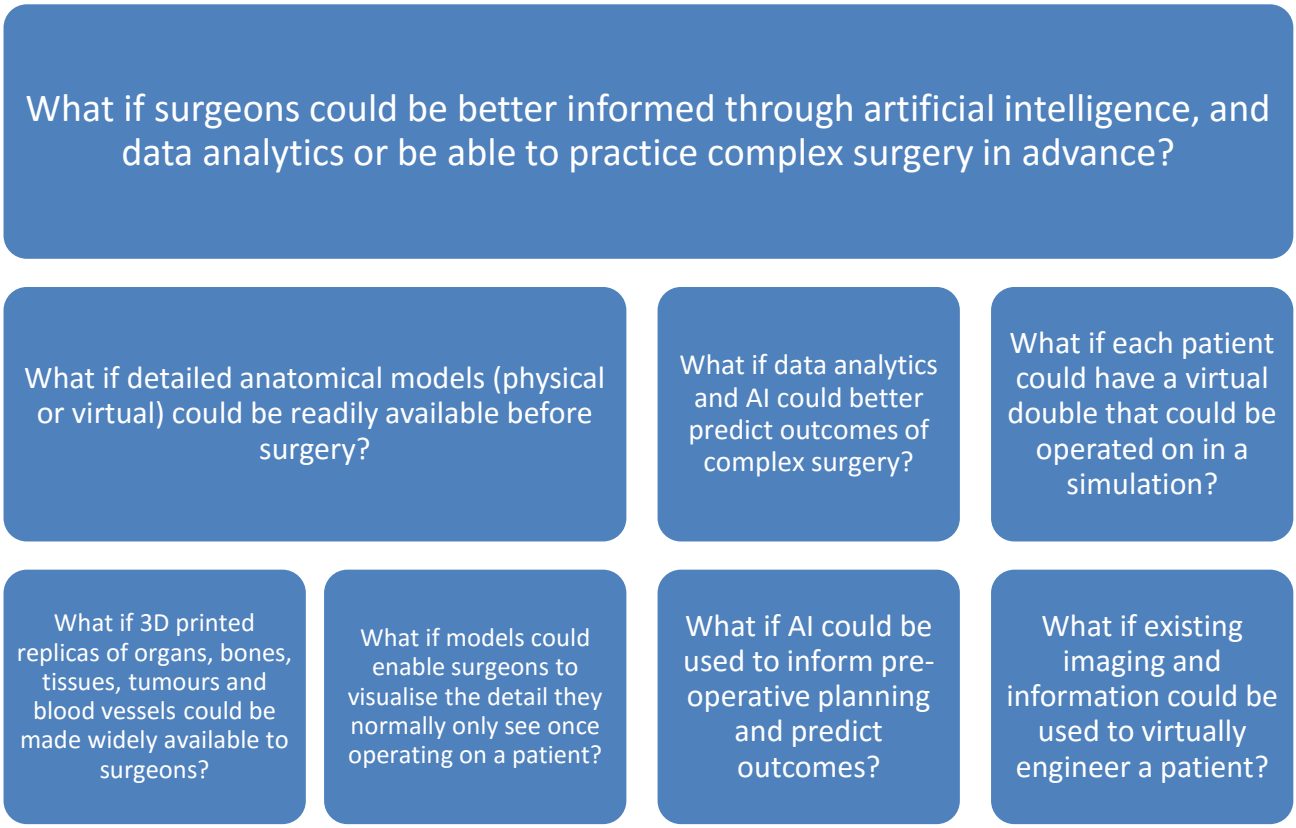
"… currently the best tool we have for helping understand the problem is an MRI scan. These can be difficult for surgeons to interpret and use as a basis for preoperative planning. A more tactile, user friendly representation may help surgeons decide which operation to perform, which platform is most appropriate and whether a more advanced operation is required …"

In order to address this challenge, the proposed solution must be able to create a real or virtual reproduction of actual patient anatomy such that the surgeon can appreciate normal from abnormal, see relationships between organs, blood vessels and other structures and aid in the identification of potential difficulties during the surgery. This should allow the surgery to select the most appropriate procedure and plan for the procedure.

Such a solution would be able to take patient data from existing imaging so as not to introduce an additional cost or delay into treatment.

In order to be adopted, the solution would need to demonstrate cost savings, or be cost neutral through improvements in surgical efficiency, patient outcomes, length of stay and patient safety.

The following "what if's" are some examples of scenarios that have the potential to help meet unmet needs in preparation for surgery and pre-operative planning:



Category 2: Technologies to assist with surgical procedures

Background

The complexity, volume and duration of surgery are continuing to grow. Consequently, more efficient, less labour intensive and more cost effective methods to complete surgical procedures need to be found.

Despite advances in technology, much of the focus of innovation in surgery tends to be on the development and refinement of existing surgical instruments, many of which remain unchanged from the very first instruments used. Ultimately, the skills of the surgeons themselves, their manual dexterity and judgement remain key elements affecting the outcome of procedures.

Surgical staff and their resources account for a substantial proportion of NHS activity and front-line care for patients. Additionally, an increasing number of medical conditions are now being remedied or managed by surgery. In 2014-15 there were 11,341,913 Finished Consultant Episodes (FCEs), 60.5% of which involved some form of procedure or intervention, with 95% of day case episodes involving a procedure or intervention[10].

With outcome data on surgeons and hospitals being published, there is also increasing pressure to increase the quality of outcomes, additionally, patient expectations are also continuing to grow on the treatments that should be available.

Challenges

One of the key challenges in surgery is removing sufficient tissue to address the problem, while ensuring the maximum amount of viable tissue remains for the optimum patient outcome. Ideally, this needs real time, accurate evaluation of the tissue margin to avoid further surgery if insufficient tissues are removed. Currently this is primarily done by the surgeon making a visual judgement and this may lead to incorrect assessments, a technology based testing system could enhance this decision making process.

Despite the improvement in the quality of theatre lighting over the years, issue of shadowing and insufficient light remain, particularly when operating on dark areas, deep in tissues. Headlights are perceived as bulky and uncomfortable when worn for long periods, and to ensure good outcomes, optimal lighting of the surgical site is essential. Enhancing the visibility of surgical sites would allow speedier surgery and reduce the risk of surgical mistakes being made. Potential solutions should not impede or impair the use of instruments, or access in tight areas, neither should they generate heat.

The amount of waste for disposal generated in theatres is high and often not sorted into clinical and non-clinical waste by staff. The cost differential for these is high, so creating an opportunity for potential savings, if correctly sorted[11]. This could become an automated, cost effective, process, using technology to make the sorting decisions.

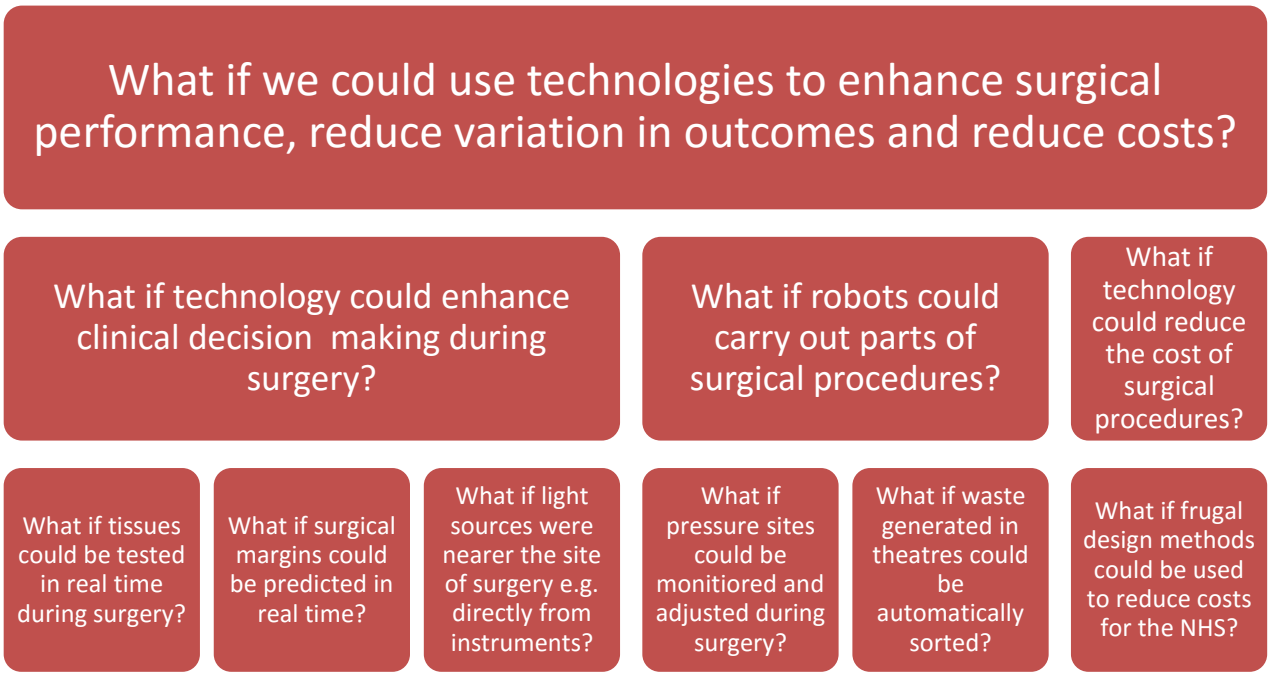
[10] NHS Digital (National Statistics), Hospital Episode Statistics Admitted Patient Care, England - 2014-15 http://content.digital.nhs.uk/catalogue/PUB19124/hosp-epis-stat-admi-summ-rep-2014-15-rep.pdf

[11] The Health Estate Journal, Weight Off Trust's Mind, 2011. https://www.healthestatejournal.com/story/7760/a-weight-

For longer procedures, which can last as long as 8-12 hours, there is still an issue of pressure damage to the patient from extended periods in one position on the operating table. This can lead to the development of pressure ulcers, discomfort and extended hospital stays for the patient post-surgery as well as exacerbating the risks from surgery. To be able to monitor and adjust this in an active way would reduce the risk of tissue damage.

Whilst technology can enhance outcomes it must be cost efficient as budget considerations apply and the cost of purchase can be prohibitive to uptake.

The following "what if's" are some examples of scenarios that have the potential to help satisfy unmet needs during surgery:



Application process

This competition is part of the Small Business Research Initiative (SBRI) programme which aims to bring novel solutions to Government departments' issues by engaging with innovative companies that would not be reached in other ways:

- It enables Government departments and public sector agencies to procure new technologies faster and with managed risk;
- It provides vital funding for a critical stage of technology development through demonstration and trial – especially for early-stage companies.

off-trusts-mind

The SBRI scheme is particularly suited to small and medium-sized businesses, as the contracts are of relatively small value and operate on short timescales for Government departments.

It is an opportunity for new companies to engage a public sector customer pre-procurement. The intellectual property rights are retained by the company, with certain rights of use retained by the NHS and Department of Health.

The competition is designed to show the technical feasibility of the proposed concept, and the development contracts placed will be for a maximum of 6 months and up to £100,000 (incl. VAT) per project.

The application process is managed on behalf of NHS England by the Eastern Academic Health Science Network through its delivery agent Health Enterprise East. All applications should be made using the application portal which can be accessed through the website www.sbrihealthcare.co.uk.

Briefing events for businesses interested in finding out more about these competitions will be held on 24th October in Bristol, 31st October in Nottingham and 3rd November in Liverpool. Please check the SBRI Healthcare Website for confirmation of dates and venues, information on how to register and details of the challenges that will be presented at each event.

Please complete your application using the online portal and submit all relevant forms by 1200hrs on the 29 November 2017.

Key dates

Competition launch	18 October 2017
Briefing events	24 October 2017, Bristol
	31 October 2017, Nottingham
	3 November, Liverpool
Deadline for applications	29 November 2017 (12:00)
Assessment	December 2017 / January 2018
Contracts awarded	March 2018
Feedback provided by	April 2018

More information

For more information on this competition, visit:
www.sbrihealthcare.co.uk

For any enquiries e-mail:
sbrienquiries@hee.co.uk

For more information about the SBRI programme, visit:
https://www.gov.uk/government/collections/sbri-the-small-business-research-initiative

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