



Improving Outcomes in Musculoskeletal Disorders

SBRI Healthcare NHS England competition for development contracts

July 2018



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 (AHSNs) 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 runs in two phases (subject to availability of budget in 2019):

- 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 Monday 9th July 2018. The deadline for applications is 1200hrs on Wednesday 22nd August 2018.

Introduction & Background

Musculoskeletal (MSK) conditions are the most common cause of chronic disability and can affect joints, bones and muscles, and also include rarer autoimmune diseases.

According to NHS England, there are more than 200 musculoskeletal conditions, which affecting a quarter of the adult population, equating to 9.6 million adults, and also 12,000 children in the UK.¹

Although the prevalence of major musculoskeletal conditions increases with age, they are not just conditions of older age. Regional pain conditions, low back and neck pain, musculoskeletal injury and inflammatory arthritis commonly affect children, adolescents and middle-aged people.²

Impaired musculoskeletal health is responsible for the greatest loss of productive life years in the workforce compared with other noncommunicable diseases³, commonly resulting in early retirement and reduced financial security². Musculoskeletal disorders account for 10.8m working days lost per year¹. Additionally, more than half of all older people experience multimorbidity and these increase with age and are more common among those in lower socioeconomic groups.⁴ The presence of a musculoskeletal condition significantly reduces physical function, is associated with mental health impairment and increases health-care costs.⁵

Health leaders and epidemiologists predict that over the next thirty years musculoskeletal conditions are set to rise due to an increase in the aging population, increased obesity and physical inactivity.⁶

MSK conditions typically lead to both pain and reduced physical function, often leading to significant mental health decline, together with an elevated risk of developing other chronic health conditions and increased

mortality.⁷ Many musculoskeletal conditions share risk factors common to other chronic health conditions, such as obesity, poor nutrition and a sedentary lifestyle³. Musculoskeletal conditions also account for the greatest proportion of persistent pain across the life course⁸. Back and neck pain, osteoarthritis, rheumatoid arthritis and fractures are among the most disabling musculoskeletal conditions and pose major threats to healthy ageing by limiting physical and mental capacities and functional ability.³

Musculoskeletal pain is predominantly managed in primary care and MSK conditions account for up to a third of GP consultations in England and are also the most common condition that lead to a repeat consultation.⁹

Low back pain is the leading worldwide cause of years lost to disability, yet most low back pain is unrelated to specific identifiable spinal abnormalities, and evidence shows that many people are not receiving the right care, despite international clinical guidelines.^{10,11,12}

Osteoarthritis (OA) is a major contributor to this, with the most common treatment for it being joint replacement or arthroplasty. In England and Wales there were 243,000 joint replacement procedures performed in 2016/17, a 10% increase on the previous year¹³ and the numbers are likely to continue to increase, with increasing longevity and obesity. The more of these procedures that are performed, the greater the number of revision procedures required, which in turn are more costly and less effective than an alternative initial procedure.

The Categories

Under the overall theme of 'Improving Outcomes in MSK Disorders', three categories have been identified via consultation with clinicians and other stakeholders working in MSK. These are outlined in detail below.

Applicants are expected to respond to one of the three categories, 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?
- How will you ensure that the technology will be acceptable to patients (and their families) and to healthcare workers? How could these groups be involved in the development of the innovation?
- 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: Self-Care and Preventative Interventions

Background

A number of clinical practice guidelines, including those produced by the National Institute of Health and Care Excellence (NICE), propose similar approaches for the assessment and management of musculoskeletal conditions such as low back pain. These recommendations have included a non-pharmacological approach

combined with education that supports self-management, including the introduction of exercise and a return to normal activities.⁸

However, there is a gap between what we know and what we do. Given the current challenges in offering optimal care, closing the evidence to practice gap is key and the engagement of all stakeholders (including patients) is essential. Gaps in knowledge are recognized, and yet closing the gap is complex.

Challenges

There are national and international guidelines for the care and management of musculoskeletal conditions in adults, including a combination of both pharmacological and non-pharmacological approaches *i.e.* self-management support.

Delivering this type of care is a challenge and the use of digital platforms to enhance self-management support and service delivery has been variable across the care pathway.

Additionally, these guidelines propose a more prudent use of medication, imaging, and surgery. However, in practice, there has been limited use of recommended first-line treatments and inappropriately high use of imaging, rest, medication, spinal injections, and surgery.⁸

NHS England updated the national pathway for the treatment of low back and radicular pain in Feb 2017 with the aim of involving a specialist triage practitioner (specialist physios or nurses) and the use of a combined physical and psychological programme. Early results from the implementation showed significant improvement in patient management and improved outcomes in pain, disability and mental health outcomes, together with reduced use of MRI scans, radiography and referrals to secondary care.⁸

The NHS England handbook “Transforming musculoskeletal and orthopaedic elective care services”¹⁴ highlights how self-management can support patients to understand and manage their own condition effectively. Additionally, self-management enables patients to understand the variety of options available to them and also encourages and empowers patients to take responsibility for their own health and wellbeing through behavioural change and improve their quality of life.

Additionally, while compliance with self-care regimens tends to be good initially, longer term compliance tends to fall away. Patients’ reasons for reduced compliance are complex and unpredictable, but compliance does reduce once the patient is no longer seeing a physiotherapist.¹⁵

Potential solutions to this challenge include strategies which help to implement this type of best practice, provide occupational interventions in order to reduce work disability and offer both focussed self-care and prevention strategies.

The following “what if’s” are some examples of scenarios that have the potential to help meet unmet needs in this “Self-Care and Preventative Interventions” challenge. The statements are intended as examples only.

What if technology could help prevent or help those with MSK disorders manage their physical function and mental health?

What if we could deliver optimum care by focussing more on prevention rather than treatment?

What if technology could help those with MSK disorders to self manage their condition more effectively?

What if we could use technology to help inform patients and healthcare professionals of current pathways for prevention and treatment?

What if there were better ways of meeting patients' needs and improving outcomes?

What if technology could make physio services more accessible for those with reduced access (e.g. through interactive and virtual services)?

What if digital platforms could enhance the compliance with self care advice on MSK conditions?

What if we could better target technology based self care solutions to employers and their staff and therefore reduce the number of lost working days?

What if technology could help those with Osteoarthritis to manage their condition and therefore reduce the number of lost working days?

Category 2: Efficiencies in Delivering Care

Background

The total annual MSK spend is £10 billion, the third highest behind cardiac and mental health, of which 80% is spent in hospitals¹⁶.

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.¹⁷

Getting It Right First Time (GIRFT) is a national programme designed to improve medical care within the NHS by reducing unwarranted variations. By tackling variations in the way services are delivered across the NHS, and by sharing best practice between trusts, GIRFT identifies changes that will help improve care and patient outcomes, as well as delivering efficiencies such as the reduction of unnecessary procedures and cost

savings. The initial Orthopaedic Surgery review established the GIRFT methodology and became the pilot for the current programme.

Challenges

Post Surgical Rehabilitation

One of the findings from the current GIRFT review¹⁶ describes a lack of emphasis on rehabilitation in the immediate post surgery period for hip fracture patients on acute wards.

Rehabilitation of hip fracture patients aims to return patients to their pre-fracture capabilities and prevent recurrent falls. Current evidence demonstrates that early, intense and frequent rehabilitation results in decreased length of stay and post-operative complications and costs, as well as increases in function and quality of life. However, the report summarises that in the majority of hip fracture services, there appears to be greater focus on improving mobility than rehabilitation and while this is an essential component of rehabilitation, additional time is needed for improving balance, strength, endurance and rebuilding confidence. This would offer longer term improvements, for both independent mobility and help to prevent future falls.¹⁶

A potential contributory factor to this is that the number of physiotherapists is insufficient to meet current demands. Estimates show that an additional 500 physiotherapists need to be trained each year until 2020.¹⁸

Surgical Revisions

While joint replacement offers significant patient benefit, not least reduced pain, improved mobility and potential a return to normal day to day activity, there is an increasing risk of surgical revisions, particularly among younger patients, for all joint replacement procedures.¹³

In 2016, 87,733 hip replacements were carried out, the majority due to osteoarthritis, yet 7933 hip revision procedures were also performed, and the cumulative probability of a hip revision after 13 years is 17%. Revision rates for younger female patients (<55 years) are 2.5 times higher than for those between 65 and 74 years of age. Similarly, 98,147 knee joint replacements and 5,932 knee revisions were performed in 2016 and the cumulative risk of revision after 13 years is 16%.¹³

Revision surgery for total knee arthroplasty (TKA) is more expensive than primary TKA, largely due to an increased length of stay.¹⁹

The following “what if’s” are some examples of scenarios that have the potential to help meet unmet needs in this “Efficiencies in Delivering Care” challenge. The statements are intended as examples only.

What if technology could improve efficiencies in the delivery of care for patients with MSK?

What if new techniques could reduce the length of stay for patients in hospital?

What if technology could improve outcomes for MSK patients?

What if technology could alleviate the shortfall in the number of physiotherapists?

What if we could use technology to improve post-surgery recovery?

What if technology could assist therapists in acute care to deliver rehab to post-op patients?

What if technology could reduce the number of surgical revisions needed?

Category 3: Scaling Up the use of Regenerative Medicine

Background

Until recently, there has been no progress in developing new treatments to alleviate OA as a disease. However, recent evidence presented to NICE has demonstrated that a cell therapy (autologous chondrocyte implantation or ACI) is a cost-effective treatment for treating cartilage defects²⁰. Hence for the first time there is a potential new treatment for early OA using a regenerative medicine approach²¹.

Surgical treatments are offered for progressive pain and disability due to osteoarthritis. However, for patients with no previous history of knee repair surgery, with very minimal OA changes and with cartilage defects over 2 cm², autologous chondrocyte implantation (ACI) may offer a treatment option for those with persistent symptoms.¹³ However, despite approval by NICE, scaling up this treatment method remains a challenge.

Challenges

Evidence given to the House of Commons Select Committee on Regenerative Medicine last year stated that regenerative medicine provides a unique approach to treating diseases by providing the body itself with the means to repair, replace, restore and regenerate damaged tissues. It went on to say that the UK life sciences sector is a pioneer in the clinical development of new regenerative medicine therapies and well-placed to create new high-tech high value manufacturing businesses around them, but that manufacturing support was needed to translate the research to a commercial venture²². ACI finds itself in just such a situation. While it has been approved by NICE, there is little manufacturing capacity currently available.

Added to this, the James Lind Alliance, which prioritises research questions for the benefit of health research funders, identified surgical priorities for treating early OA in the knee and hip. Of the top ten priorities, cell therapies such as ACI could impact on the majority²³. There are in addition, many other areas within the MSK field where regenerative medicine approaches are being trialled, including spinal cord injury. Two main areas of challenge have been identified.

Increase manufacturing capacity within the UK for cell production for treating MSK conditions.

Currently there is only one small scale MHRA-licensed facility within the UK for ACI, demonstrating the need to scale up the manufacturing capacity for producing cells to be used in regenerative medicine for orthopaedics).

Increase the ease of administration and decrease the cost of each treatment: develop allogeneic cell products.

Delivery of the cellular product should be simple, with a cell product available ‘off the shelf’ and applied in a minimally invasive manner. Using ACI and early OA as an exemplar, the most commonly used procedure requires the patients’ own cells (i.e. autologous) to be obtained, cultured for some weeks in a laboratory and then implanted in quite an invasive procedure. If this process could utilise allogeneic cells and be delivered through a needle to the joint, the cost would be greatly reduced, and many more patients treated.

The following “what if’s” are some examples of scenarios that have the potential to help satisfy unmet needs in Scaling up the use of Regenerative Medicine. The statements are intended as examples only.

What if the UK could make wider use of regenerative medicine?

What if technology could support the mass manufacturing of stem cells?

What if technology could support the delivery of cell therapies in more conditions?

What if allogeneic cells could be used and delivered in a less invasive manner?

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.

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 19th July in London. 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 22nd August 2018.

Key dates

Competition launch	9 July 2018
Briefing events	19 July, London
Deadline for applications	22 August 2018 (12:00)
Assessment	September / October 2018
Contracts awarded	November 2018
Feedback provided by	January 2019

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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