



Improving the Care of the Diabetic Foot Ulcer – Better prevention, diagnosis, treatment

SBRI Healthcare NHS England competition for development contracts

October 2014

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 20th October 2014. The deadline for applications is 1200hrs on 09th December 2014.

Background

Diabetes is a major public health challenge on a global scale. In the UK, the latest "State of the Nation" statistics prepared by Diabetes UK shows an alarming growth in the demand on healthcare services¹. Diabetes is associated with disability and death through its associated complications involving blindness, cardiovascular and kidney disease and through the development of chronic wounds, notably the Diabetic Foot Ulcer (DFU). This new SBRI competition specifically targets the prevention, diagnosis and treatment of the DFU.

An initiating factor of the DFU is neuropathy or nerve damage that often accompanies patients who have long-standing diabetes. Whilst some neuropathies are painful, more problems arise when the nerve damage leads to a loss of sensation in the feet of a patient with diabetes, so that injuries due to trauma or the damage caused by ill-fitting footwear that would normally be painful, go unnoticed. The loss of sensation can lead to a psychological disconnect with the affected limb to which the patient with diabetes can become indifferent and which may reduce compliance with preventative or therapeutic regimens. Furthermore, a secondary complication of the neuropathy is abnormal and persistent muscular contractures in the feet that cause deformities and high pressure zones in footwear, affecting the individual's gait and resulting in a greater risk of trauma and chronic ulceration.

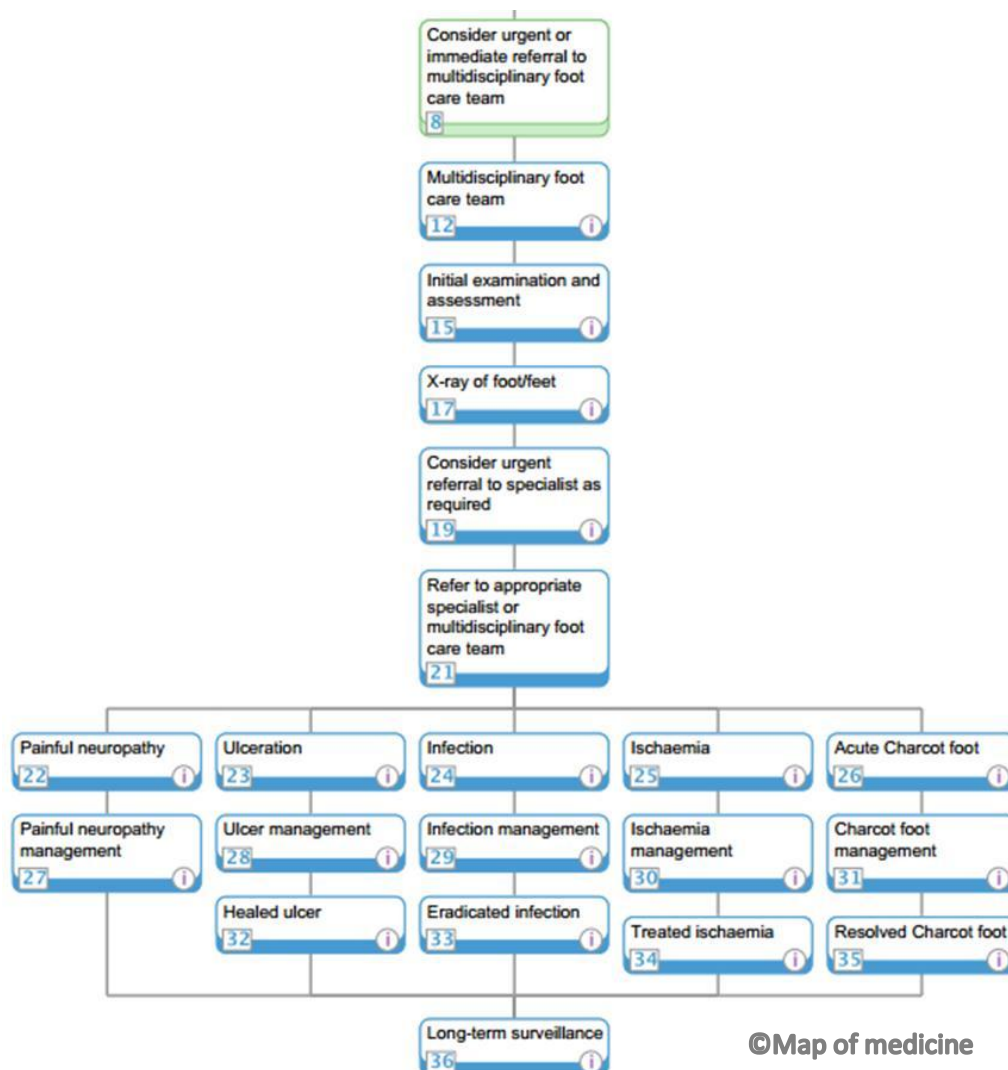
Once a DFU appears it can go unnoticed due to the lack of sensation, and the wound can deepen and become infected. Healing is inhibited because the originating cause of the DFU remains and infection has serious consequences for limb survival and can be life threatening.

¹ <http://www.diabetes.org.uk/Documents/About%20Us/What%20we%20say/0160b-state-nation-2013-england-1213.pdf>

A wide variety of wound care dressings are available for the treatment of DFUs. However, their selection for individual patients involves a significant element of trial and error. A contributing factor to this uncertainty is the difficulty in assessing the blood circulation in the lower limb. Peripheral vascular changes that are an additional complication of diabetes may reduce the blood flow and tissue perfusion which affects normal wound healing processes. The standard assessment of blood flow that works well at other sites in the body can be unreliable in the lower limb of the patient with diabetes. The effectiveness of revascularisation therapies are therefore difficult to predict. These uncertainties on the nature of the presenting wound, possible infection and limited blood flow combine to complicate the treatment of the DFU.

Current care pathway

A patient with diabetes will enter the care pathway through primary care contact with their GP, followed by risk identification and a consequent management plan. High risk patients or those presenting with a DFU can be referred to a secondary care centre, in most cases to be treated by a multi-disciplinary team of clinicians, specialist nurses, podiatrists and other allied health professionals to cover the multifactorial causes of the DFU.



In England, over 6,000 foot or toe amputations are carried out each year on people with diabetes. Up to 80 per cent of these are preventable with the correct management.

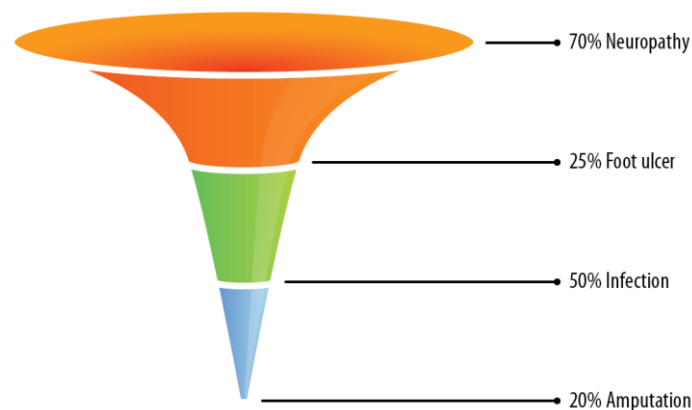
Amputation rates vary widely across England – in the worst area a person with diabetes is eight times more likely to have a major amputation than in the best.

Amputations and foot ulcers have a huge impact on quality of life. Up to 80 per cent of people die within five years of having an amputation. If current rates continue, the amputation rate will rise to more than 7,000 in 2015/16 in England

There is evidence that providing an integrated foot care pathway, with trained staff in foot protection services in the community and speedy access to multi-disciplinary teams has been shown to reduce amputations by over 50 per cent

From State of the Nation 2013, Diabetes UK

A multi-disciplinary team of diabetes, wound care, vascular and musculoskeletal specialists cover the diverse treatment options and match these to the specific needs of individual patients. However, within this patient pathway DFUs can worsen, become infected and this infection can lead to amputation. Typically, of the 70% of patients that present to the multi-disciplinary clinic with neuropathy, 25% of these will go on to develop a foot ulcer. Of these foot ulcers, around 50% will become infected and 20% of these infected ulcers will lead to varying degrees of amputation.



New products and services that improve these statistics will have a major impact on quality of life and also alleviate the financial burden the DFU places on healthcare systems. A comprehensive report on the health economics of DFUs shows that treatment costs the NHS in England alone around £650 million per annum (Table A)².

² Kerr M. 2012 Foot Care for people with diabetes: the economic Case for Change. NHS Diabetes and Kidney Care. <http://www.diabetes.org.uk/Documents/nhs-diabetes/footcare/footcare-for-people-with-diabetes.pdf>

Table A Estimated cost of ulceration and amputation in people with diabetes, England, 2010–11

	Lower estimate	Upper estimate
Primary, community and outpatient care	£306,508,970	£323,062,601
Accident and emergency		£849,278
Inpatient care – ulceration	£213,151,916	£213,151,916
Inpatient care – amputation	£43,546,901	£48,896,735
Post-amputation care	£75,807,423	£75,807,423
Total	£639,015,210	£661,767,953

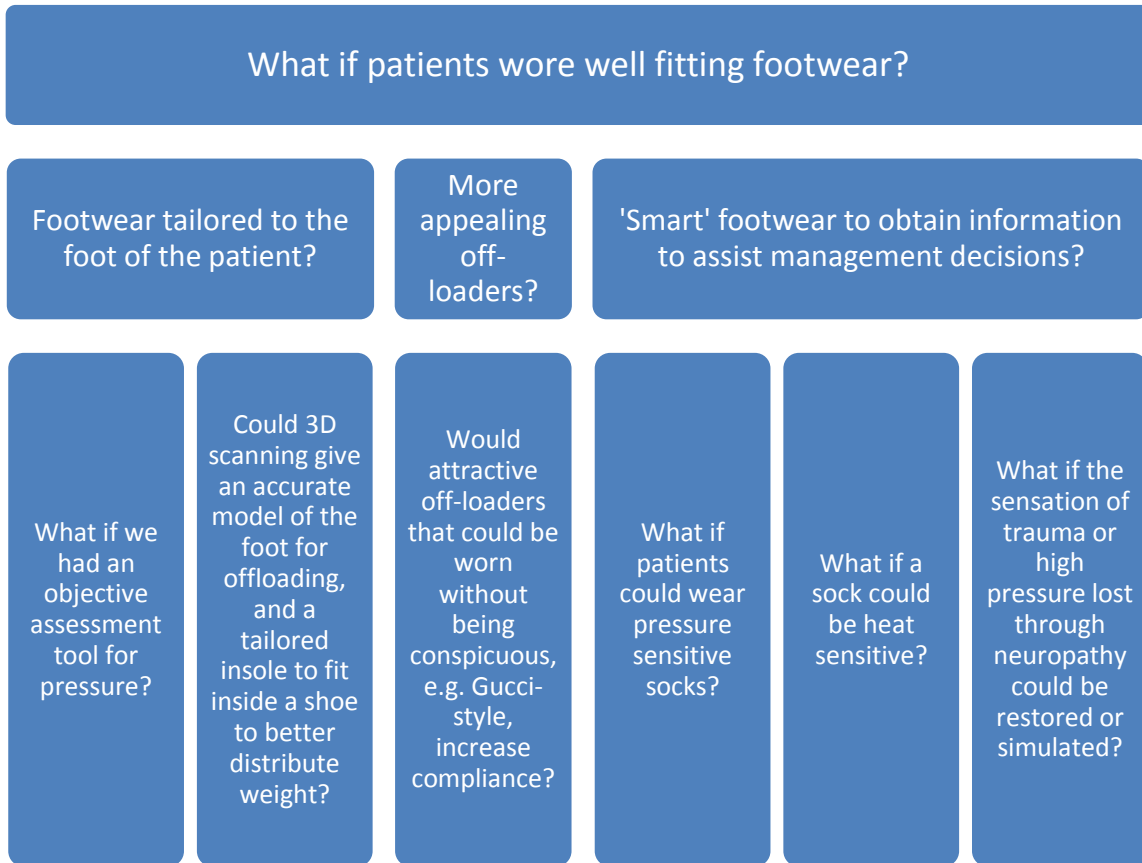
Key Information about the Diabetic Foot Ulcer

- **Diabetic wounds are highly variable**
 - due to individual lifestyle
 - due to the heterogeneous nature of DFUs, e.g. the location of the wound on the foot, the type of skin affected
- **Diabetic wounds have multiple causes**
 - muscle contractures and foot deformity due to neuropathy
 - poor blood flow due to reduced peripheral circulation (ischaemia)
 - associated with the breaking of weakened skin
 - ill-fitting footwear
 - sharp trauma, often in the home
- **Diabetic wounds may be avoided if foot care is more effective**
 - patients often do not recognise when complications develop

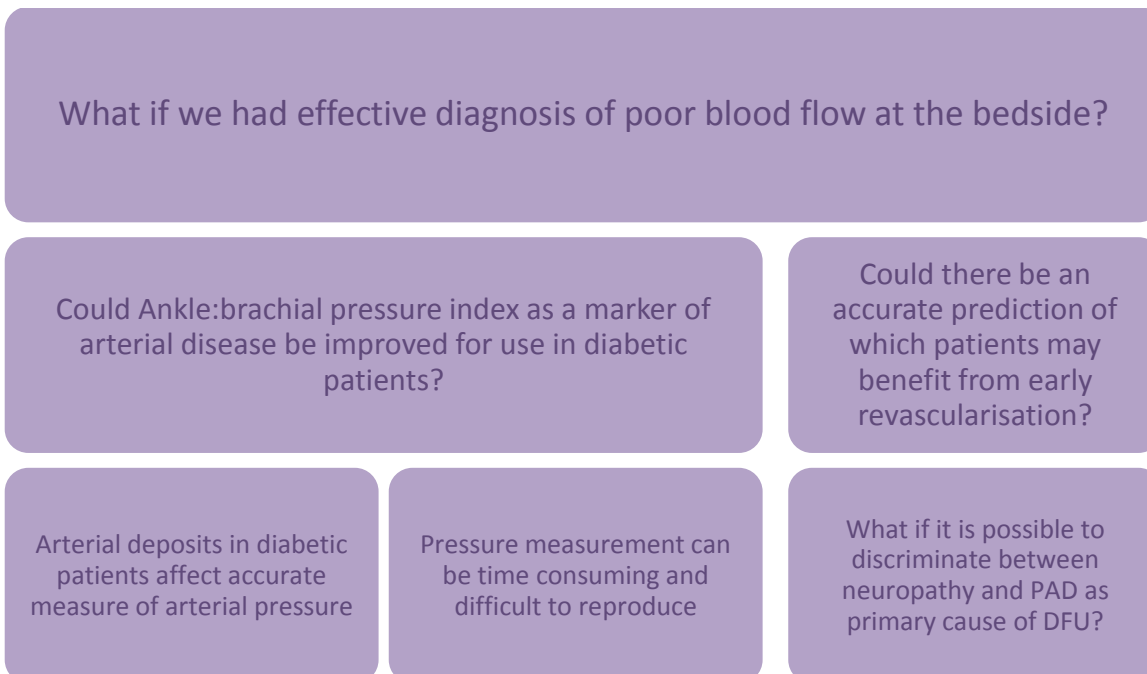
Challenges

Clinical panels that reflect the composition of the DFU multi-disciplinary teams have expressed a series of scenarios that could improve the care they are able to offer to patients. Below, these “What If” scenarios, that could have the greatest impact, have been prioritised to identify opportunities for new products and services, which may be supported through SBRI funding. The scenarios listed below not exhaustive. They should only be used as a guideline for the sort of solutions that may be of interest.

Prevention:



Diagnosis:



Treatment:

What if there was better infection control?

What if there was a bedside POC test that could identify active infection within minutes for appropriate DFU treatment with antibiotics?

What if clinicians knew whether there were resistant organisms (e.g. MRSA) present so they could use the correct antibiotics?

What if there was a bedside test to identify antibiotic sensitivities?

What if clinicians could better attend to the wound base?

Dressings for pressure bearing wounds

Dressings with better absorbancy

Dressings for infection

What if a dressing could modulate the wound healing pathway to promote healing or prevent biofilm production?

What if the dressing could also provide pressure relief?

What if the dressing was able to provide targeted antibiotic therapy to the wound?

What if the dressing was able to detect markers of early infection?

New products and services that may be effective in the **prevention, diagnosis and treatment** of diabetic foot ulcers and which may address the above challenges include:-

- off-loading and active footwear
- tissue perfusion assessment systems
- infection control
- wound bed preparation
- dressings with the stratification and selection of patients for the most appropriate dressing

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 forms which can be accessed through the website www.sbrihealthcare.co.uk.

Briefing events for businesses interested in finding out more about the competition will be held on the 11th and 13th of November in London and Leeds respectively. Please check the website for confirmation of dates and venues, information on how to register and details of the categories that will be presented at each event.

Please complete your forms using the online application process and submit them by 1200hrs on the 09th December 2014.

Key dates

Competition launch	20 October 2014
Briefing events	11 & 13 November
Deadline for applications	09 December 2014
Assessment	January / February 2015
Contracts awarded	March 2015
Feedback provided by	April 2015

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:

www.innovateuk.org/SBRI

Acknowledgements

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