PATHWAYS FOR INNOVATION (P4I)
for the Prevention, Diagnosis and Treatment of the Diabetic Foot Ulcer

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Knowledge Transfer Network

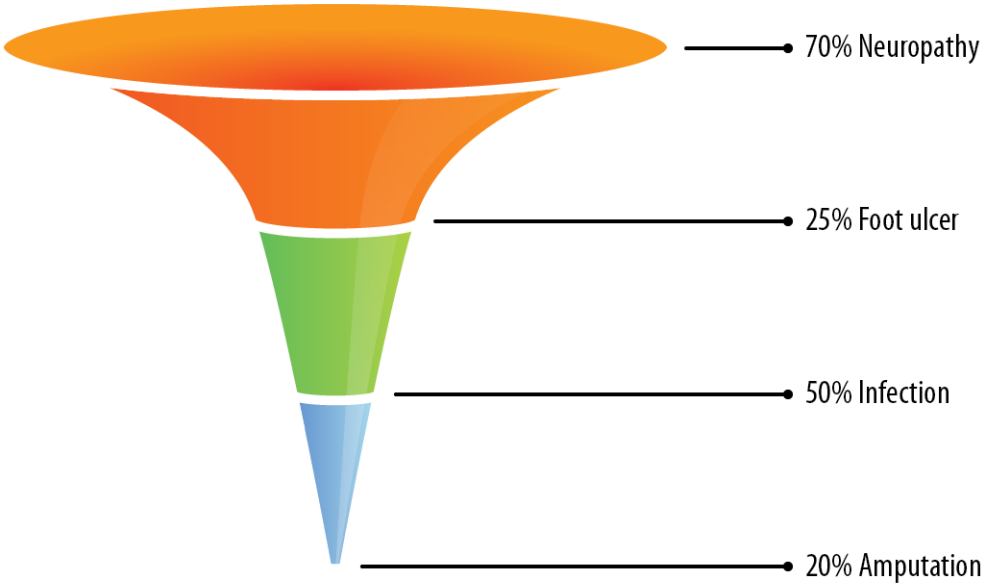
Medical Technologies

P4I SUMMARY

- **Pathways for Innovation** is an **innovation process** that brings medical technology experts together with healthcare and creative industry professionals through facilitated engagement to create a vision into future healthcare scenarios to provide a stimulus for medical innovation.
- **The P4I process** is able to explore how new interventions could radically change patient pathways and thereby achieve cost savings for the NHS.
- This process should provide a means to **inform clinical commissioning** of the value of innovative medical technologies
- This process offers **opportunities for funding bodies** to help direct their funding to areas to where it has most impact.
- We welcome feedback on how effective is the P4I process in providing a context **to inspire clinically effective medical technology innovation.**

THE CLINICAL NEED

- Diabetic foot disease is an increasing global health problem. Diabetes currently affects 26 million people in the US and more than 366 million people worldwide. By 2030, at least 550 million people will have diabetes - approximately 10% of the world's adult population.

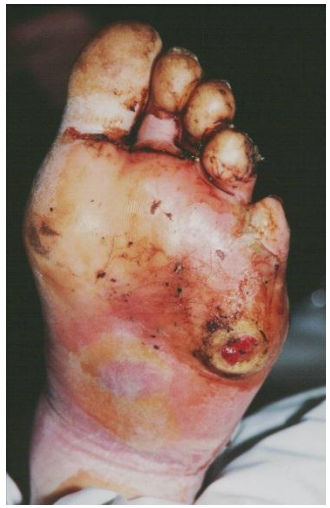


- 60-70% of those with diabetes will develop peripheral neuropathy - loss of sensation in their feet - and up to 25% of those with diabetes will develop a foot ulcer. More than half of all foot ulcers become infected, requiring hospitalisation, and 20% of infections result in amputation.
- Diabetes contributes to approximately 80% of non-traumatic amputations performed yearly in the developed world.

Clinical Presentation of the Diabetic Foot Ulcer











Background: High morbidity, mortality and cost to the NHS of the diabetic foot ulcer

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

Figure 5. Five-year relative survival rates for the four most common cancers (Source: ONS) and estimated 5-year relative survival rate for patients with diabetic foot ulcer (Estimate derived from: Moulik P.K et al.[42])

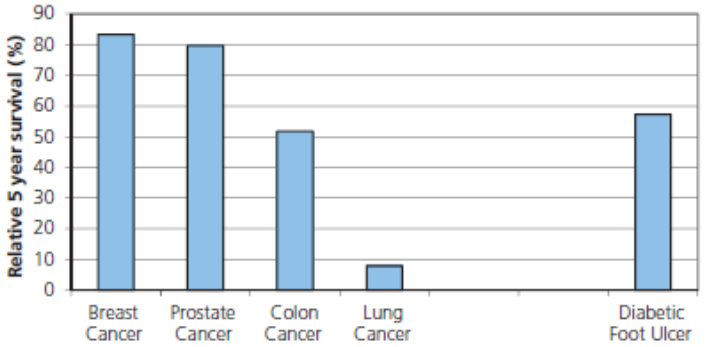
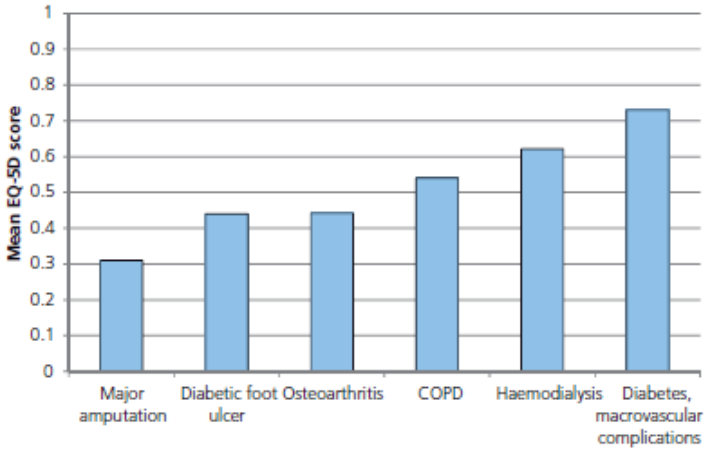
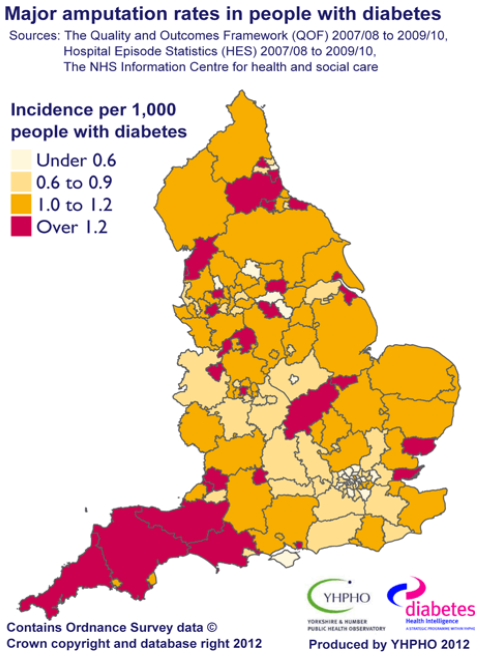


Figure 3. Health-related quality of life (EQ-5D) scores for people with diabetic foot ulcers and other long-term conditions (Sources: Ragnarson Tennvall et al,[25] U.K. Prospective Diabetes Study Group,[28] Brazier et al,[23] Wasserfallen et al.[27])





Source: Footcare for People with Diabetes: The Economic Case for Change
Produced for NHS Diabetes by Marion Kerr, Insight Health Economics
https://www.diabetes.org.uk/Documents/nhs-diabetes/footcare/footcare-for-people-with-diabetes.pdf

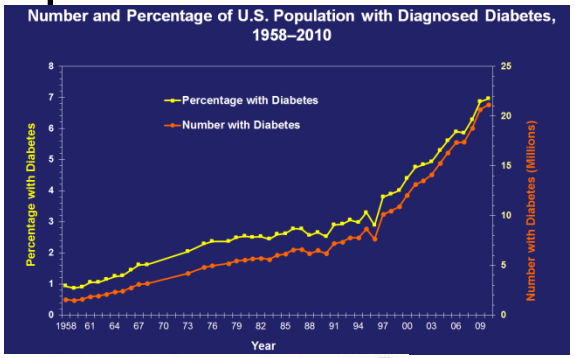
Background: Key Points on the Diabetic Foot Ulcer

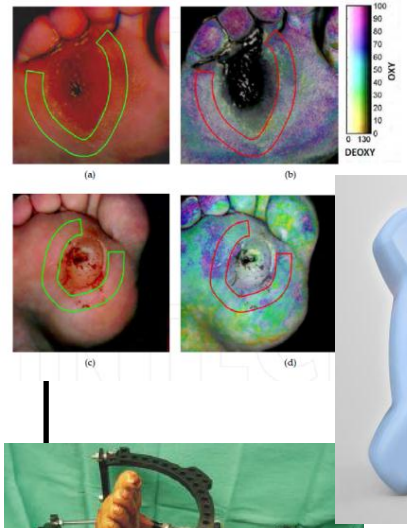
- **Diabetic wounds are highly variable**
  - due to individual lifestyle
  - due to the heterogeneous nature of DFUs (diabetic foot ulcers), e.g. the location of the wound on the foot, the type of skin affected
- **Diabetic wounds have multiple causes**
  - caused by muscle contractures and foot deformity due to neuropathy
  - associated with the breaking of weakened skin
  - caused by ill-fitting footware
  - caused by sharp trauma, often in the home
- **Diabetic wounds may be avoided if footcare is more effective**
  - patients need to recognise early-on the seriousness of complications
  - patients need to regularly monitor their feet so they see issues early

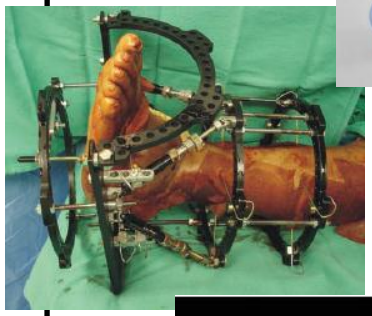
HORIZON scanning

New developments that may be effective in the **prevention, diagnosis and treatment** of diabetic foot ulcers include:-

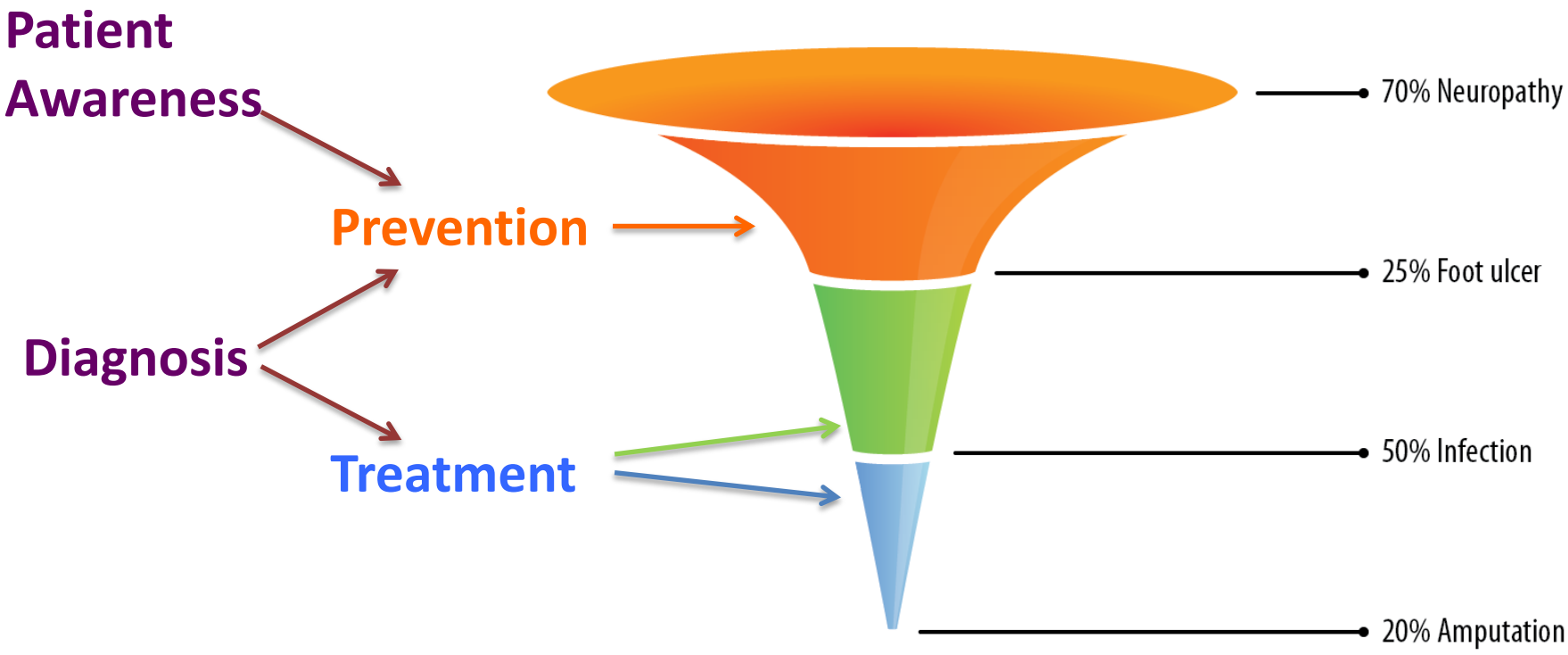
- tissue perfusion assessment
- off-loading and active footwear
- external stimulation (e.g. ultrasound, shockwave, electrical, laser, phototherapy)
- infection control
- wound bed preparation
- dressings
- surgery (e.g. Charcot osteoarthropathy, revascularisation, skin grafts)
- stem cells, artificial skin, topical oxygen, negative pressure, prostaglandins
- behavioural change models







Therapeutic Objectives



Prevention: What Ifs

What if patients wore well fitting footwear?

Footwear tailored to the foot of the patient?

More appealing off-loaders?

'Smart' footwear to obtain information to assist management decisions?

What if we had an objective assessment tool for pressure?

Could 3D scanning give an accurate model of the foot for offloading, and a tailored insole to fit inside a shoe to better distribute weight?

Would attractive off-loaders that could be worn without being conspicuous, e.g. Gucci-style, increase compliance?

What if patients could wear pressure sensitive socks?

What if a sock could be heat sensitive?

What if the sensation of trauma or high pressure lost through neuropathy could be restored or simulated?

Diagnosis: What Ifs

What if we had effective diagnosis of poor blood flow at the bedside?

Could ankle:brachial pressure index as a marker of arterial disease be improved for use in diabetic patients?

Could there be an accurate prediction of which patients may benefit from early revascularisation?

Arterial deposits in diabetic patients affect accurate measure of arterial pressure

Pressure measurement can be time consuming and difficult to reproduce

What if it is possible to discriminate between neuropathy and PAD as primary cause of DFU?

Treatment: What Ifs (1)

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?

Treatment: What Ifs (2)

What if clinicians could better attend to the wound base?

Dressings for pressure bearing wounds

- 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?

Dressings with better absorbancy

Dressings for infection

- 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?

Checklist: A Context for Use

To enhance clinical utility and facilitate early adoption, ideally a treatment should meet the following criteria:-

- ❑ A treatment that is scalable to general practice
- ❑ A treatment that doesn't require a system change
- ❑ A treatment that can be rapidly adopted
- ❑ A treatment that is acceptable to patients
- ❑ A treatment that can be used by patients themselves
- ❑ A treatment that requires minimum training

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