Prevention Of primary Foot Ulcers in high-risk Diabetes patients (PrOFoUnD): A cluster randomised trial of 3D printed Insoles Versus Standard Care

North West Coast Clinical Network

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Emergent ICS CM Transformation Funding for programme

- Top sliced from CCG baselines
- All programmes encouraged to bid to develop improvements that could be scaled up
- 20 programmes competed
- Strong logic and evidence but smaller funding offer
- Decision to conduct RCT
- STP agreement
Diabetic Foot Ulcers

- 3.7m People have diabetes in England
- 10% will develop a foot ulcer at some time in their lives
- 85% of amputations begin with a foot ulcer
- The 5-year mortality rate after a major amputation is 70%
- Annually in England 58,000 patients with diabetes have an ulcer
- Estimates that foot ulcer incidence is around 2% per year
- Once a patient develops a primary ulcer they are twice as likely to develop further ulcer

The cost and burden of diabetes foot ulcers to the NHS

• Annual cost of healthcare for foot ulcer and amputation in 2014/15 estimated to be between £837 million to £962 million\(^1\)
• Accounts for 1% spend of national NHS Budget and 90% of the foot care budget was spent on ulcer management\(^1\)
• Footcare expenditure greater than combined breast, prostate and lung cancer
• Reducing the prevalence of foot ulcers by a 1/3 would save the NHS £230 million\(^1\)

SUMMARY OF DIABETIC FOOT CARE IN CHESHIRE AND MERSEY SIDE STP

Diabetic foot disease affects a large number of people and imposes a high cost on sufferers and NHS budgets. Experienced by 1 in 15 people with diabetes, foot ulcers have a severe effect on quality of life and are often prolonged. They can lead to lengthy spells in hospital and ultimately amputation. The longer patients wait for treatment, the longer and more severe the condition is likely to be and the higher the cost of treatment. Better care can improve outcomes and reduce costs.

There were 144,020 patients registered with diabetes in your STP population in 2016/17, and it is estimated that, at any given time, 3,240 of these had diabetic foot ulcers.

The cost of caring for these patients in primary, community and outpatient settings across your CCGs is estimated to be £36,965,000 in 2017/18.

NICE recommends that all adult diabetes patients receive a foot assessment at least once a year. The percentage for your STP is 81%.

However, a foot check is only useful if action is taken when risk is found. In many parts of the country there are no appropriate follow-on services to deliver this.

NICE recommends that patients with active diabetic foot problems are referred within one working day to a specialist foot care service for triage within one further working day.

In the most recent National Diabetes Foot Care Audit, 92% of patients in your STP footprint waited more than 2 days and 58% of your patients waited at least 14 days.

49% of ulcers were rated as severe and at least 30% were unhealed after 12 weeks. At least 15% had still not healed after 24 weeks.

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Hospital data for the three year period to March 2016 shows there were 5,988 spells with diabetic foot disease across your CCGs during this time, and patients stayed in hospital for an average of 16 nights. 1,349 amputations were undertaken in this period. 425 of these were major amputations.

Based on this level of activity, we estimate that hospital care on ulcers and amputations together with post amputation care will cost the CCGs in your STP footprint £19,774,000 in 2017/18.

So that gives an estimated total annual cost to your CCGs for diabetic foot care of £56,459,000.

There is strong clinical evidence that good foot care services can reduce the duration of ulcers and the rates of amputations and hospitalisations, thereby improving lives and saving money.

A reduction of 10% across your CCGs would mean savings in the region of £5,644,000 in 2017/18. And UK experience shows that improvements and savings can start to be seen within the year changes are implemented.

With the expected increase in the prevalence of diabetes, these savings could be worth £6,446,000 by 2030/31.
• Annual cost of approximately £1.17 Billion. Hospital based care £370 million and £800 million for community based footcare

• Based upon 2016/17 data estimation of 70,535 ulcers annually

• Number of amputations over a 3 year period 25,535. Major amputations 7,133 and Minor 18,461

**Data Sources**

OOF 2015/16, National Diabetes Footcare Data2014-16, Diabetes Footcare profiles 2017 NCVIN,HES data 2015/16, Diabetes prevalence models PHE.

4 College of Podiatry Diabetes Commissioning Toolkit: Insight Health Improvement
Total costs of Ulcer & Amputation Management PA

Hospital costs £370 Million PA

Community Costs £800 Million PA

10% ROI Cost saving if NICE practice adoption £117 Million

Total Cost to NHS £1.17 Billion PA
Diabetes Foot Ulcers in Cheshire & Merseyside HCP

• 3,240 ulcers at any one time
• £56.4 Million per year on amputations and foot ulcers
• £36.5m for community based care and £19.7m for hospital care (14% national expenditure on footcare in NW)
• Ulcers cost on average £214 per person per week
• Potential reduction in costs NICE costing model of 10% but could be as high as 40% in high risk groups
• Only 20% High risk patients receive any plantar pressure relief
• Estimated annual savings of £5.5 million each year if 10% reduction for C&M
3D Imprints orthotics

Bespoke, 3D Printed

- Inputs: 3D foot scan & patient weight
- Captures **foot shape** and **load zones**
- Auto-design patient specific orthotic
- Variable density zones, form fitting
- Patient-specific pressure reduction (~21%)
- Manufactured using rubber material in 1-2hrs

» 10x lower cost
Primary objective

• To compare the rates of primary diabetic foot ulcers (DFUs) in high-risk diabetic feet using 3D printed insoles compared to standard care

Primary endpoint/outcome

• The incidence of DFU in patients with high-risk diabetic feet
Definition of Standard Care (at baseline, 12, 26, 38 and 52 weeks)

- Foot examination
- Routine podiatry treatment including debridement of callus
- Consider simple insoles or footwear referral as required
- DFU prevention education including footwear advice
The F-Scan: Ultra-thin, in-shoe sensors capture timing & pressure information for foot function & gait analysis

Feet pressure measurement substudy in a cohort of intervention patients
Secondary objectives

• Compare plantar foot pressures at baseline and 52 weeks of 3D insole use in patients who consent in one intervention site
• Compare patient satisfaction at baseline, 26, and 52 weeks
• Evaluate quality of life using NeuroQoL, EQ-5D-3L, and Quebec questionnaire
• Incidence of adverse events relating in the 3D insole group
• Assess protocol adherence with 3D insoles
• Determine cost-effectiveness over 52 weeks
Study Design

• Prospective cluster randomised study

• We will recruit 900 adults with diabetes and high risk of foot ulcers
900 patients
25% drop out rate should result in 450 patients per cohort meeting study power requirement (360)

Intervention Group
Control Group
Total subject per area
Total Cohort size
25%+ drop out
Inclusion criteria

• Adults with a diagnosis of diabetes
• Peripheral sensory neuropathy

with (one of the three)

1. Signs of abnormal loading as indicated by callus formation or hyperaemia

   Or

2. limb ischaemia as evidenced by intermittent claudication / non-palpable pulses / history of vascular intervention

   Or

3. On renal replacement therapy
**Exclusion criteria**

- Currently prescribed with or in need of therapeutic footwear
- Active or history of foot ulcer
- Active Charcot’s neuroarthropathy
- History of major operation in the foot including amputation
- Local / systemic symptoms of infection, severe illness that would make 12-month survival unlikely
- Unable to provide informed consent
- Inability to follow the study instructions (as judged by the recruiting clinician)
PROFOUND Study Flow Chart

Foot prevention service; podiatry units recruited & randomised

**Control Group**
- Patients screened & invited to participate in research Trial
- Patient agrees to participate in research?
  - Yes
    - Screening patient visit Informed consent and clinical features
    - Baseline patient visit - QOL questionnaires & baseline measurements completed. Data recorded
    - 3 month visit, data recording
    - 6 month visit data recording, QoL questionnaire
    - 9 month visit, data recording

  - No
    - Standard care by Foot Protection Service
    - 12 month visit & Outcome data collection

**Intervention Group**
- Patients screened & invited to participate
- Patient agrees to participate in research?
  - Yes
    - Screening patient visit Informed consent and clinical features
    - Baseline patient visit QOL questionnaires & baseline measurements & Foot scanning. Data recorded
    - Visit for insole fitting within 2 weeks
    - 3 month visit, data recording
    - 6 month visit data recording, QoL questionnaire & foot scan
    - Visit for insole fitting within 2 weeks
    - 9 month visit, data recording

  - No
    - Standard care by Foot Protection Service
    - 12 month visit, assessment & Outcome data collection
Progress to Date RCT

• Sponsor - Countess of Chester Trust R&D

• Co-Investigators agreed

• Health Research Authority – achieved Ethics Approval

• Adopted National Institute of Health Research (NIHR) portfolio

• Agreed Research Nurse & Administration support from Clinical Research Network

• Capacity & Capability R&D approved

• Identified Lead investigators at all sites – Senior podiatrists

• Established Operational group/ Research Advisory Group

• Site Visits undertaken – Site initiation calls in October
Timeline

- **Q2 2019**
  - Sites chosen
  - Pathways Developed
  - Documentation Created

- **Q3 2019**
  - Developmental Workshop
  - NIHR Approval
  - Site visits undertaken
  - Ethics Approval
  - Printing/creation of patient files
  - Site initiation calls
  - Staff Training
  - Capability & Capacity Agreements

- **December 2019**
  - Remaining sites begin recruiting patients

- **Q1 2020**
  - Two front runner sites begin recruiting patients
  - Printing/creation of patient files
  - Site initiation calls
  - Staff Training
  - Capability & Capacity Agreements

- **Q1 2021**
  - All patient data captured from front runners
  - Data analysis by statistician
  - Conclusion of study

- **Q1 2021**
  - All patients recruited onto study
  - Intervention group begins to receive 2nd set of insoles

- **November 2019**
  - All patients recruited onto study
  - Intervention group begins to receive 2nd set of insoles