

**A SERVICE EVALUATION OF A DIABETIC FOOT PROTECTION SERVICE:  
PATIENTS' EXPERIENCES AND VIEWS**

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## Abstract

**Background:** Diabetes is an increasingly widespread long-term illness that places a life changing burden on individuals. Foot complications, as a result of diabetes, require a significant amount of healthcare intervention and resource. If not treated effectively foot complications can lead to active foot disease and lower limb amputations which cause disability and suffering. The aim of this service evaluation was to investigate the experiences of people using a new Foot Protection Service (FPS), established in Leeds in 2016, and use the findings to explore ways in which the FPS can be improved.

**Methods:** One-to-one interviews were conducted with a purposive sample of individuals, who were at either moderate or high risk of foot ulceration as a result of diabetes, and had used the FPS. Thematic analysis was used to identify, analyse, code and describe patterns within the data.

**Results:** Seventeen patients who had used the FPS participated in the study. Five key themes were identified: The mechanisms adopted for referral into the FPS and missed opportunities for care, the impact of the FPS as a source of support, increased awareness around self-care, patient views about the service and the accessibility of the FPS. The identification of these themes led to the development of recommendations to support the service in identifying areas for improvement.

**Conclusion:** Health professionals responsible for referring 'at risk' patients need to be fully aware of the risks of a person with diabetes presenting with foot problems, and how to refer to the FPS for assessment. The wider social circumstances of patients should be taken into consideration by Diabetes Specialist Podiatrists (DSPs) to provide effective support whilst patients adjust to this potentially life changing complication, tailoring education and advice to their individual needs. Understanding experience health care services is an invaluable tool in developing quality improvement strategies.

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# Chapter 1 - Introduction

## 1.0 Background

The World Health Organisation (WHO: 2018) states that over 400 million people worldwide live with diabetes and this incidence is predicted to rise if current trends continue. Diabetes is one of the major causes of kidney failure, blindness, stroke, heart attack, lower limb amputation and the seventh leading cause of premature death. In addition to the economic burden on the national economy and health-care systems, diabetes places a heavy socioeconomic burden on people suffering from the disease and their families.

In 2016, based on the findings of four international working groups, the Berlin Declaration was developed to act as a worldwide call to action for healthcare providers to invest in early medical intervention in diabetes. The Berlin Declaration focuses on four elements of early action, these are: early detection, prevention, control and access to the right interventions. Its main purpose is to assist countries to prioritise and focus on policies that are most likely to provide the best outcomes for their population, supporting them to measure improvement as part of an international drive for change which will transform the health and wellbeing of individuals (Ceriello, Gavin, Boulton et al; 2018).

In the United Kingdom (UK) there are an estimated 4.5 million people living with diabetes (DiabetesUK 2016). Kumar, Ashe, Parnell et al. (1994) observed the prevalence of foot ulceration in Type 2 diabetic patients and reported that approximately 6% of people with diabetes currently have, or have previously had foot ulceration.

Diabetes is attributed to more than 80% of limb amputations and is the most common cause of non-traumatic limb amputation (Pecoraro, Reiber and Burgess 1990). Kumar et al; (1994) also found that people with diabetes are 23 times more likely to have a further amputation after their first. Moulik, Mtonga and Gill (2003) found 70% of people died within five years of having an amputation. In addition to the effects on quality of life for people with diabetes, foot complications costs the National Health Service (NHS) an estimated £650 million, which equates to £1 in every £150 of the total NHS expenditure (Kerr, Rayman and Jeffcoate 2014).

The first national guidance recommending that people at moderate, or high risk<sup>1</sup> of developing a foot ulcer, have access to a Foot Protection Service (FPS) was published by

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<sup>1</sup> Moderate risk: Deformity; or neuropathy; or non-critical limb ischaemia. High risk: Previous ulceration; or previous amputation; or on renal replacement therapy; or neuropathy and non-critical limb ischaemi

the National Institute for Health and Care Excellence (NICE) in 2000 (The National Archives 2004). In this guidance moderate and high risk were defined as x and y respectively. The guidance published in 2000 was then superseded in 2015 by new NICE guidance (NG: 19) recommended that people who are at moderate, or high risk, of developing a diabetic foot problem to be referred to the foot protection service.” (NICE 2015). In light of this new NICE guidance, the ‘Operational Delivery of the Multi-Disciplinary Care Pathway for Diabetic Foot Problems’ was published in 2016, developed jointly by leading foot-care organisations in the UK. The contents described how foot protection should be led by specially trained health professionals with the primary aim of establishing the prevention of diabetic foot complications by treating and managing people who are at risk in the community (Diabetes UK 2016).

“If we can ensure patients with diabetes have the appropriate, high quality care they deserve across the country then we can prevent amputations” (Professor Valabhji; NHS England 2016, <https://www.england.nhs.uk/2016/05/diabetic-foot-disease/>).

In order to reduce or prevent foot complications in people with diabetes, NHS England (2016), in line with NICE Guidance, suggest that health service provision should be based on a multi-disciplinary footcare pathway with a primary focus on preventative care. This pathway has three fundamental elements: foot screening, foot protection, and an acute foot care service for those with active diabetic foot complications. However, the National Diabetes Foot Care Audit (NDFCA), that was conducted to enable all diabetes foot care services to measure their performance against NICE clinical guidelines and peer units, found that less than half of local NHS commissioners provide all three care structures recommended by NHS England (NHS Digital 2017). Therefore, in 2016, all three of the Clinical Commissioning Groups (CCGs), who are responsible for the planning and commissioning of health care services in Leeds, acknowledged that the Leeds community podiatrist service was acutely oversubscribed. With approximately 9,600 patients with diabetes on their active caseload it is leading to long waiting lists. In addition to this, an audit, conducted by NHS Leeds West CCG, found that the minor amputation (the removal of toes or feet) rate in Leeds was 7.34%, higher than the national average. Both these factors indicated a clear need for appropriate specialist intervention to prevent further increases in amputation rates as a result of diabetic foot complications. Therefore monies were made available to establish a comprehensive, quality driven diabetes FPS within a robust, multi-disciplinary integrated diabetic foot pathway.

## **1.1 The Meaning of Care Quality**

The World Health Organisation (WHO:2018) define quality as “the degree in which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (p.11). Since the conception of the NHS, quality has played some part in ensuring the effective care of patients. The most recent, and arguably the most significant changes, driving up the quality agenda in health, were set out by the Department of Health’s High Quality Care for All NHS: Next Stage Review Final Report (2008). This review set out a five year programme for improved health and healthcare in the NHS using three quality domains. These domains are described as:

1. Effectiveness; the right treatment is given to the right patient at the right time.
2. Safety; the people using NHS services can be kept safe from harm.
3. Experience; the care received can be responsive to an individual’s needs and values.

These domains should form the basis of all healthcare provision and therefore, it is crucial to develop a robust quality improvement strategy in services. However, before any quality improvement strategies can be developed, data should be gathered to inform where quality improvements can be made. This can be in the form of existing data already available in the service or new data gathered as part of a service evaluation (The Health Foundation 2015).

## **1.2 Service Evaluation to inform Quality Improvement in services**

Service evaluation is described by Shadish, Cook and Leviton (1990) as a study initiated to inform quality improvement initiatives, decision making, discovery and justification. This is supported by Marsh and Glendenning (2005) who suggests that a service evaluation is essentially research and inquiry applied for a purpose. Service evaluation is primarily concerned with judging an activity to assesses its worth or value. Rather than a focus on monitoring or management, service evaluation should focus on unearthing knowledge specific to the environment to support strategic decisions, judgments and decision-making processes. An evaluation should be performed to address specific questions being asked, and the type of programme or initiative being evaluated (The Health Foundation 2015).

However, before starting an evaluation, consideration should be given to establishing whether it is the right tool to support the service in improving quality. Marsh and

Glendenning (2005) suggest reflecting on the following questions to ensure an evaluation will achieve its aims:

1. Is the service meeting the needs of its patients?
2. Can the service be improved to respond to the specific requirements of its patients?
3. After using the service, what are the outcomes for the patients?
4. What is actually happening during consultations?
5. Is the service equitable?

Marsh and Glendenning (2005) also advise that careful consideration should be given to distinguish research from evaluation, as the primary aim of research should be to deliver generalisable knowledge, and should not be based on specific services or areas of service provision. Although Marsh and Glendenning (2005) acknowledged that many of the methods used in evaluation are those used in research, the focus of evaluation should be to support decisions and judgments and decision-making processes around a specific service in order to inform quality improvement initiatives.

Quality improvement is described by The Kings Fund (2017) as “the use of methods and tools to continuously improve quality of care and outcomes for patients”. The Kings Fund goes on to state that quality improvement initiatives should be fundamental to informing local plans for the redesign of NHS services.

This study sought to establish the direct experiences of patients attending a specific service, and how this experience could inform and improve the FPS. The following aims and objectives were developed to support this:

**Aims:**

1. Investigate and evaluate the experiences of people using the FPS in Leeds
2. Explore ways in which FPS can be improved using patient feedback
3. Understand the benefits of the FPS to support future quality improvement initiatives

**Objectives:**

1. Conduct qualitative, semi-structured, face-to-face interviews with people with diabetes who are at moderate or high risk of suffering foot ulceration
2. Evaluate patients’ experiences of using the new FPS in Leeds
3. Feedback findings to contribute in informing future quality improvement initiatives

Although findings of this service evaluation are not generalisable beyond the context of this study, FPS are being established across the UK and therefore this work is important as it will provide an exemplar of context and service specific information generated to inform decision-making processes about this FPS.

This introductory chapter has outlined current understanding and background information about diabetes and its impact on foot health. An overview of relevant health policy has been provided with information on the dimensions of care quality and how these link to service evaluation. The purpose and justification of the proposed service evaluation have been described.

The thesis is comprised of a further four chapters: Chapter Two reviews the current literature available to inform this evaluation and details how the literature was retrieved and reviewed. Chapter Three justifies and describes the methodology used to gather and analyse data. Chapter Four presents the findings and Chapter Five discusses these findings in relation to the literature review and other studies of significance. A conclusion provided in Chapter Six completes the thesis.

## Chapter 2 – Literature Review

### 2.0 Introduction

Although information for when and where studies began on the benefits of FPSs is scant, there is a clear indication that 1996 was the year this thinking came into the forefront of global interest as it saw the formation of the first International Working Group on the Diabetic Foot (IWGDF). The IWGDF's primary objective was to produce international and multidisciplinary guidelines that were based on a thorough scientific process, undertaken by researchers and health professionals from all over the world and had a focus on the prevention and management of diabetic foot disease. The IWGDF Guidelines have been adapted for the healthcare structures of many different countries and been translated into over twenty-five of the major languages of the world (IWGFT 2019). As a result of the IWGFT, NICE produced its first national guidance in 2000 recommending that people at moderate or high risk of developing a foot ulcer, have access to a FPS. However, it could be argued that it was not until March 2012, when Diabetes UK launched its 'Putting Feet First' campaign that the concept of a FPS to support the battle against rising amputation rates as a result of diabetes really came into the forefront of thinking in the UK. The Putting Feet First campaign had a primary aim of improving foot services for people with diabetes to reduce the risk of lower limb amputations by 50% by 2017. Their ambition was to also raise awareness in the importance of taking care of feet, not only amongst people with diabetes, but also those involved in caring for them. The campaign also sought to raise awareness of the service provision that should be offered to all patients regardless of where they live.

The beginning of this service provision is the foot screening of people with diabetes that is described as the 'cornerstone' of effective diabetic foot care and is the foundation on which quality diabetic foot provision is built. When it is established when a patient is identified as being at risk of developing a diabetic foot ulcer which may lead to an amputation, it is vital that they be referred to a specialist podiatry service for an assessment to develop a suitable plan based on the views and needs of the patient (Stang 2015).

This specialist podiatry service, which is referred to as the FPS, should involve the following as part of their role, the education of patient and any other person involved in caring for the patient, an initial assessment, the treatment of people who have developed foot problems, the assessment of footwear including the altering of existing footwear to minimise risk if required and follow-up treatment of high-risk patients (Nazarko 2017). However, although there are significant policy drivers as discussed in

the introduction, to support the implementation of FPSs in all areas of the UK, this section of the thesis will critically explore whether there is evidence to suggest that the implementation of a FPS has any impact on reducing amputations for people with diabetes and therefore reduce costs.

In an initial review of the available literature, it was established that there is evidence to support the implementation of FPSs for people with diabetes and this can be found in a systematic review of interventions to prevent diabetic foot ulcers conducted by Mason, O'Keefe, McIntosh, Hutchinson, Booth, and Young (1999). This review was found that people with diabetes who receive well-organised, regular care with rapid referral to an appropriate specialist team if at a heightened risk of developing foot ulceration can substantially reduce further complications. Although Mason et al; (1999) was unclear about the number of studies included in their review, they did describe the use of meta-analytic techniques where possible or a qualitative overview where this was not possible, to ensure all appropriate studies were considered and gave reasoned evidence to support their conclusions. However, Mason et al; (1999) themselves caution that available studies tended to be of either of inadequate size, insufficient duration of intervention and expressed inappropriate outcomes to address the issues relating to foot ulcer prevention. Despite this they were able to identify two key themes from their review, these being firstly; that trained and vigilant health care professionals could identify risk factors for ulceration earlier at relatively little cost and secondly; well-structured, key complex interventions, such as neurological and vascular assessments, personalised management plans between health professionals and patient and carefully considered educational programmes could support those most risk of ulceration. Mason et al; (1999) go on to state that although the second theme found could be expensive to implement they would be cost-effective in the long term to prevent amputations in people with diabetes.

The results of Mason et al's (1999) review is supported by the systematic review conducted by Li, Zhang, Barker, Chowdhury and Zhang (2010). Although this review did not have a focus on prevention, but rather to assess the cost-effectiveness of interventions to prevent and control diabetes, its complications and comorbidities, Li et al; (2010) did demonstrate a clear reporting methodology of the available literature including a summary of the key features and results for each included study; and the synthesis of interventions based on predefined classification criteria and 'rules' to determine the strength of each study included. In the analysis of the fifty-six studies that met the inclusion criteria, there was strong evidence to suggest that comprehensive foot care intervention to prevent foot ulceration compared with usual care was considered to be cost-effective and that policymakers should consider ensuring the provision of this intervention as a high priority.

However, the results of Mason et al; (1999) and Li et al; (2010) have been contested in later studies and have demonstrated that consistent, focussed evidence to support the hypothesis that a FPS will reduce diabetic related amputations is limited. A comprehensive evidence review that focussed on Cochrane reviews with direct relevance to diabetes-related foot ulceration and also additional information from the International Best Practice Guidelines, Chapman (2017) concludes that studies identified in their review chiefly focussed on single interventions such as education for patient and relatives or local wound treatment. Yet as previously described, preventive foot care for people with diabetes should consist of an integrated approach. Chapman (2017) identifies seven key interventions such as; "relief of pressure and protection of the ulcer, restoration of skin perfusion, treatment of infection, metabolic control and treatment of co-morbidity, local wound care, education for patients and their relatives and prevention of recurrence" (pg 226). However, Chapman (2017) offers a note of caution in this evidence review which was that the lack of evidence should not be confused with evidence that a FPS is not effective but instead highlights the need to for more high quality primary research to be developed to further the evidence base in the field in order to comprehensively establish that the implementation of a FPS will reduce diabetic related amputations.

The findings of Chapman (2017) are supported by the findings of Hoogeveen, Dorresteyjn, Kriegsman and Valk (2015) who undertook a systematic review of complex interventions for the prevention of foot ulceration in people with diabetes to assess their effectiveness. They define complex interventions as combining two or more prevention strategies on at least two different levels of care compared to single interventions. Hoogeveen et al; (2015) found only six Random Controlled Trials (RCTs) that met the criteria for inclusion and the characteristics of each study had substantial differences in terms of healthcare settings, the nature of interventions studied and reported outcomes. Three trials, based around more robust and complex education interventions found little benefit but the other three all reported positive results. However, Hoogeveen et al; (2015) found all the studies were at high risk of bias. The key sources of bias across studies were around a lack of detail of selection, incomplete outcome data, selective reporting and very little predefined quality assessment criteria were met. Therefore concluded that, like Chapman (2017), there is no high-quality evidence assessing the effectiveness of complex interventions for the prevention of diabetic foot ulceration. This is in addition to the insufficient evidence of the benefit of these interventions for people with diabetes at risk of developing foot complications.

It could be argued that the benefits of the implementation of a FPS to reduce amputations in people with diabetes is supported by a very little evidence base. This



being said, a small but robust study conducted by Nason, Strapp, Kiernan, Moore, Gibney, Feeley and Tierney (2013), that aimed to quantify the sustainability and assess the cost-benefit of a multi-disciplinary foot protection clinic in an Irish university hospital, found that investing in a dedicated FPS was directly associated with a 42 % decrease in the number of major amputations, a decreased average length of stay by 2 days and a 13 % decrease in the number of bed days used per year. This resulted in a €114,063 cost benefit savings per year. The study was concluded by stating it demonstrated that a coordinated and assertive approach to diabetic foot care can be both cost-effective and clinically efficient in improving outcomes for people with diabetes at risk of foot problems (Nason et al; 2013). Although this study was conducted in a hospital setting and may not have all the elements of robust research, it does suggest that preventative diabetes services could reduce costs and improve the quality of life for patients. This local study supports a recent report published 'Diabetic foot care in England: an economic study' which aimed to set out a comprehensive analysis of the vast costs associated with diabetes-related foot complications and amputations in the UK (Kerr 2017). This report highlighted in that decision-making on investment in diabetic foot care by budget holders of healthcare has been hindered by an acute lack of knowledge of the cost of foot disease as a result of diabetes, and therefore hinder the proactive commissioning of preventive diabetes care.

The report published by Kerr (2017), which was cited in an article published by Joule (2017) a Policy Manager for Diabetes UK, stated that the NHS could save around £250m if the incidence of foot ulceration in people with diabetes could be decreased by one third if faster healing and fewer recurrent ulcers could be achieved. The article goes on to state the role of a FPS with specially trained podiatrists are integral in the ongoing management of these patients. However, based on the findings of the critical exploration of the research in this area, it could be argued that although there is overwhelming evidence to suggest the huge affliction of foot complications on patients with diabetes and the economic burden on the NHS, there is very little robust evidence to support the drive that the interventions carried out by a FPS will reduce these costs and possibly more importantly, improve the outcomes for patients by reducing foot ulceration incidents.

In reviewing the available evidence on FPSs we can conclude that there is an overall lack of direct evidence to support the theory that the implementation of a FPS will reduce amputations for those people at risk due to diabetes. However, there are some studies, with differing levels of soundness to support the case that specific services to support patients at risk of developing foot ulceration can be cost-effective, Further studies would need to be established to provide a much sounder evidence base.

This chapter has reviewed the current research literature to contextualise the rationale for the implementation of a FPS. It will now review the current research literature on the experiences of people using diabetes-related health services and explain the process adopted in retrieving and reviewing that literature.

### **A literature review of the experiences of people using diabetes-related health services.**

There are multiple approaches that can be used to conduct a literature review. Grant and Booth (2009) published a typology of literature reviews to highlight the most common examples of descriptions used to review research literature in health-related topic areas. After an extensive appraisal, they found fourteen different types of terms, ranging from a critical review to meta-analysis to an umbrella review, but the most generic term used was a 'literature review'. Grant and Booth (2009) describe a literature review as an examination of published, recent or current literature where a thematic synthesis may be applied. Munro, Lewin, Smith et al. (2007) go into more detail, suggesting that a literature review is a systematic process used to access a range of published literature around a particular topic. They recommend that once accessed, a complete and iterative analysis should be undertaken of the literature to support the interpretation of individual studies, assist in clarifying conflicts or differences, develop new theories and identify gaps in knowledge to inform new areas for research.

## **2.1 Methodology**

As this study is a service evaluation, a scoping exercise took place to access the current published service evaluations in the field referred to in this thesis. This scoping exercise found that only two service evaluations could be identified and neither of these was relevant to the experiences of patients using a diabetes foot protection service. Therefore in this literature review, a systematic search was conducted to identify primary research relevant to the experiences of diabetic patients with using footcare health services. Studies that meet pre-set inclusion criteria were assessed, data extracted and synthesised. From this, themes were identified and described in a narrative synthesis that presents current knowledge and understanding around patients' experiences of diabetes related footcare health services.

### **2.1.1 Search Strategy and Study Selection**

An iterative and multistage process was adopted to ensure that all relevant studies were identified to produce a credible and robust literature review. This process involves three stages,

1. Develop a search strategy with key search terms derived from the study question,
2. Develop inclusion and exclusion criteria; and
3. Complete a systematic search of electronic databases, supplemented by hand searching frequently cited journals and reference lists (Aveyard 2014).

The most common tool used to develop key search terms of a literature review is the PICO (Population, Intervention, Comparison, and Outcome) tool. However, Cooke, Smith and Booth (2012) stated that, as the PICO was originally designed to support quantitative research searches, it could often create excessive results in searches for qualitative research. Therefore an alternative search strategy tool for qualitative studies was developed: SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) adapted elements of PICO to make it more suitable for qualitative research. Cooke et al; (2012) found the SPIDER tool enabled a more timely and sensitive search of the literature because of the more appropriate components for qualitative research. However, these findings were contradicted in a study conducted by Methley, Campbell, Chew-Graham, McNally and Cheraghi-Sohi (2014), where results showed, rather than an excessive number of hits as described by Cook et al; (2012), the PICO generated a greater number of relevant hits from searches with greater sensitivity than the SPIDER tool. Methley et al; (2014) went on to recommend the use of the PICO tool for a fully comprehensive qualitative search where time and resources are limited.

Based on this, the PICO framework was used to develop keywords for the literature search (Kiteley and Stogdon 2014). Table 1 is the PICO table used to form the search terms:

Table 1: PICO strategy to support the development of key search terms.

Acronym Meaning	Context with research topic	Key search terms
Population	People with diabetes	Patient, Person, Participant, Individual
		Diabetes, diabetic
Intervention	Foot complication and/or amputation	Foot, feet, lower limb
		Complications, ulcer, wound, injury, infection
Comparison	Views and experiences	Views, opinions, interpretations, Understanding, Beliefs, Perceived, Experience, Knowledge, Feeling
Outcome	Reduced prevalence of lower limb amputation	

Using the key search terms identified by the PICO strategy, key search terms were identified and these were used in conjunction with Boolean operators and phrase searching keywords to support a more effective literature search. Kiteley and Stogdon (2014) describe Boolean operators 'connect' words to assist in achieving specific results from searches. These operators include 'AND'; which narrows the search for example "Diabetes AND Foot complications" and 'OR' which will broaden a search, for example "'Foot complications" OR "Foot amputation". By including quotation marks around words will only generate articles containing an exact phrase, for example "'patient experience'". Also, where possible, an '\*' can be a useful tool for literature searches as this instructs databases to look for articles with all derivatives of that word, for example 'diabet\*' would look for all articles with 'diabetes', and 'diabetic' in them (Kiteley and Stogdon 2014). Aveyard (2014) also suggests checking references of appropriate articles to establish if any publications not already located through searches can be identified.

## 2.1.2 Inclusion and Exclusion Criteria

Hewitt-Taylor (2017) describes the inclusion and exclusion criteria in a literature review as the 'rules' that set out what parameters the studies identified will include.

The inclusion criteria and justification developed for this review were:

- Primary, mixed method research
  - After an initial scope of the literature, there were very few qualitative studies identified, therefore qualitative, quantitative and mixed method research was included
- People with diabetes (both Type 1 and Type 2)
  - People with both Type 1 and Type 2 diabetes can suffer from foot complications (Department of Health 2001)
- People with a history of diabetes related foot complications and/or amputation
- People's experiences of the healthcare they received in relation to foot complications and/or amputation
  - To maximise reach, studies whose primary aim was not to seek patient experience of healthcare, but contained themes around this in their findings were included.
- Published literature only
  - Hewitt-Taylor (2017) suggests that selecting only published literature is a common choice in literature reviews. However, although this option may significantly reduce the evidence to base conclusions for this review, searching and obtaining unpublished literature or 'grey' literature may be very difficult with restricted funding and tight timescales
- Published from 2011 onwards
  - The UK Government outlined a vision for diabetes care in England in the National Service Framework for Diabetes (NSF). Published in 2001, the NSF outlines twelve standards of care to be achieved by health service providers of diabetes care by 2013 (Department of Health 2001). These standards were supported by the introduction of guidance published by the National Institute of Clinical Excellence (NICE) in 2011 (NICE 2011). These publications changed how services provided diabetes related footcare, and therefore only studies after these dates will be included in this review

- Scholarly and peer-reviewed articles only
  - Scholarly and peer-reviewed articles are generally regarded as being of good quality. They give assurance that the review has been through a critical and rigorous process (Hewitt-Taylor 2017)

The exclusion criteria were:

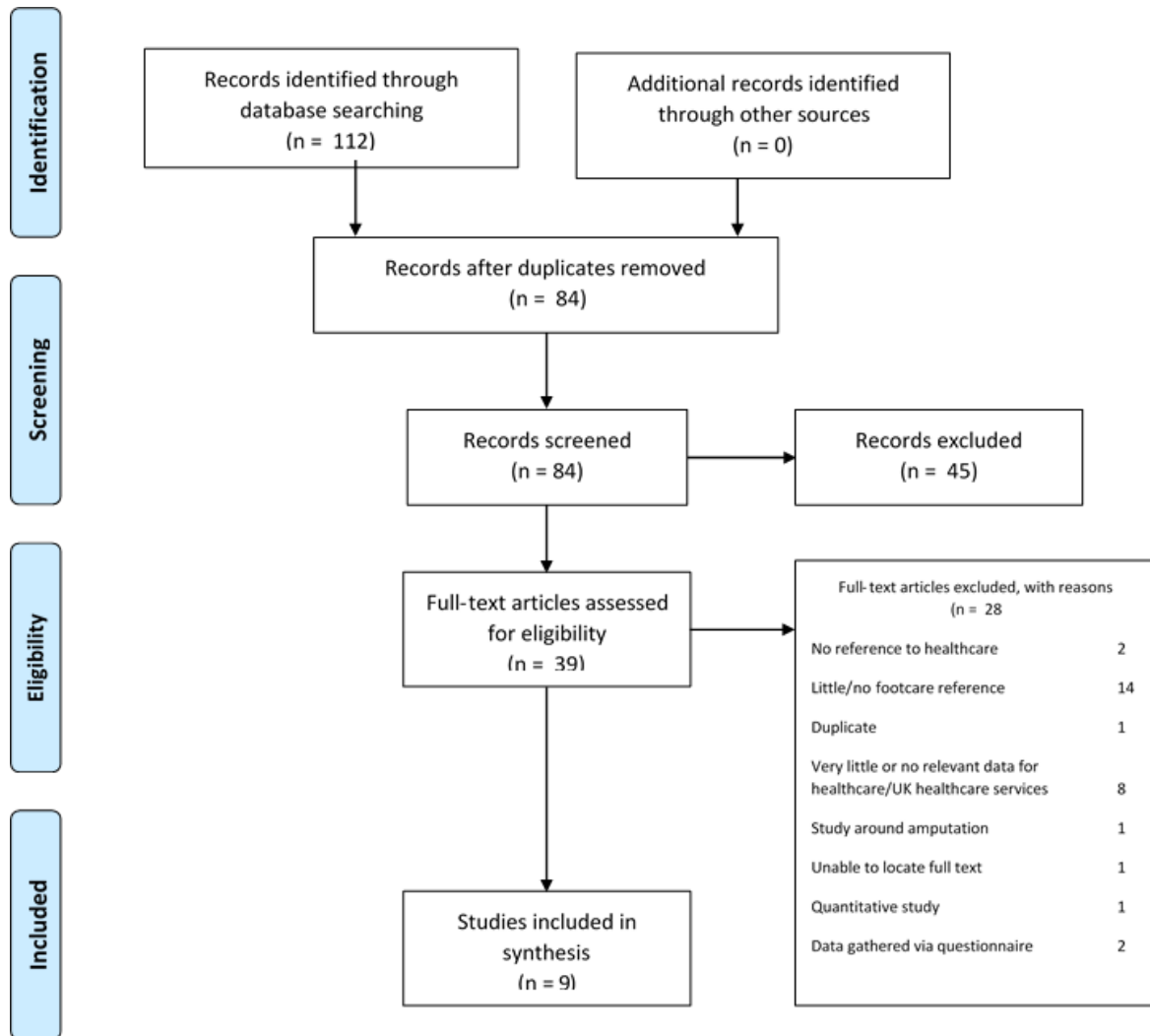
- Studies not connected to people's experiences of healthcare related to diabetic foot complications
- Studies relating to the views of healthcare professionals
- Studies relating to the clinical process of treating diabetes related foot complications

This clear and explicit inclusion and exclusion criteria allowed for a clear framework to be determined, ensuring a systematic search strategy could be applied. This safeguarded the appropriateness of studies selected for further analysis.

Once a clear search strategy had been established, a systematic search of multiple databases was conducted. Identifying the most suitable databases for searching is critical, as searching inappropriate databases will lead to unsuitable findings (Butler, Hall and Copnell 2016). The databases for this literature review were identified using the University of Huddersfield's library guide (University of Huddersfield 2018). Four databases were identified and searched: CINAHL, Cochrane Library, PubMed (was MEDline), and PsycINFO. The search terms used in this literature review can be found in Appendix C

The results of the selection of studies using this search strategy are shown in Figure 1.

Figure 1. PRISMA flowchart for the selection of studies



By developing an effective search strategy as described by Aveyard (2014), nine studies were identified for inclusion in the review.

## 2.2 Results of Search

In summary, nine studies were identified in this review, published between 2011 and 2017. Appendix D details study characteristics. Studies were conducted across nine countries; England (1), Ireland (1), Australia (1), Uganda (1), Iran (1), Canada (1), Sweden (1) Brazil (1) and USA (1). Participants were recruited from either specialist diabetes clinics or hospitals. Five of the studies explored participants' perceptions and/or beliefs about their condition, three detailed information about healthcare provision, and two were connected with participants' feelings and the last concerned patient involvement. All study participants were diagnosed with either type 1 or type 2 diabetes.

### **2.2.1 Quality Assessment**

Hewitt-Taylor (2017) defines a quality assessment as a critical appraisal that comprises of a careful, systematic, reliable and unbiased examination of the strengths and limitations of the literature to determine its 'trustworthiness'.

The term trustworthiness is defined in qualitative studies as "the extent to which the findings are an authentic reflection of the personal or lived experiences of the phenomenon under investigation" (Curtin and Fossey 2007 p. 88). Although determining the trustworthiness of a study should depend on the paradigm of particular disciplines and the research strategy adopted (Morrow 2005), in general terms, the key concepts for assessing the trustworthiness of research focusses on credibility, dependability and transferability, and how these relate to practice is the key in determining whether studies should be included in a literature review (Graneheim, and Lundman 2004).

It is important to understand the meaning of these terms to support a critique of qualitative research literature. The approach used to select the context, participants and techniques to gather and analyse the data will support the credibility, validity, reliability and objectivity of qualitative research. The context or the circumstances in which the study has been set should be relevant to the research question, and ensure an effective environment in which to collect rich data to fully understand the problem under investigation. A clear description of context is important to help the researcher consider the transferability of findings from one study into other contexts and understanding the analytical process of theme development will provide assurance that data was selected to support findings in a credible and reflexive way; this can also assist in establishing the 'dependability' of a study (Graneheim and Lundman 2004).

Dependability, in the context of qualitative studies, is described as an assurance that the process of data analysis and the development of themes remain consistent throughout (Morrow 2005). The degree in which judgements have been made about the differences and similarities of study findings should be rigorous, explicitly described and corroborated with quotes to maintain integrity. This will also enable the 'transferability' of findings in new settings and groups to be established (Graneheim and Lundman 2004).

The term transferability refers to the extent in which study findings can further the knowledge and understanding of future work (Morrow 2005). Studies should be clear and concise in their description of the context, justification of participants,



data collection and the analytical process, with detailed and explicit presentation of the findings (Graneheim and Lundman 2004). When determining if the findings of a qualitative study have relevance to a literature review, Curtin and Fossey (2007) suggest investigators look for evidence of detailed descriptions of the various aspects of the research. Triangulation strategies, participant involvement and the degree of collaboration between the researcher and participants and also the reflexivity and transferability of results, all add to the overall trustworthiness of qualitative research findings.

However, despite the importance of assessing and understanding the trustworthiness and dependability of literature, there is no agreement of set quality criteria in order to make this assessment amongst qualitative researchers. There have been various tools created to assist in this assessment and the Critical Skills Programme (CASP) have developed checklists to enable a systematic assessment of the trustworthiness, relevance and results of published papers. One of the checklists developed by CASP is specific to qualitative studies and therefore used to support the quality assessment of the literature used in this review (CASP. 2018).

Table 2: Results from the quality appraisal using the CASP Qualitative checklists.

Methodological Quality of Included Studies (n=9) Quality Criterion	Agreed Assessment for Each Study		
	Met Criterion	Did Not Meet Criterion	Unclear
Is this study qualitative research?	9	0	0
1. Was there a clear statement of the aims of the research?	9	0	0
2. Is a qualitative methodology appropriate?	9	0	0
3. Was the research design appropriate to address the aims of the research?	5	1	3
4. Was the recruitment strategy appropriate to the aims of the research?	7	1	1
5. Was the data collected in a way that addressed the research issue?	9	0	0
6. Has the relationship between researcher and participants been adequately considered?	4	4	1
7. Have ethical issues been taken into consideration?	8	1	0
8. Was the data analysis sufficiently rigorous?	6	1	1
9. Is there a clear statement of findings?	9	0	0
10. How valuable is the research?	9	0	0

The critical appraisal conducted using the CASP qualitative checklist enabled a thorough evaluation of the studies included in the review. Just over half of the studies justified their research approach (5), but very few specified the underlying

theoretical framework (1). Just over half explained their data analysis process sufficiently to ensure rigour or 'thoroughness' in their analysis strategy (6), they did, however, present sufficient evidence in their findings to ensure trustworthiness, therefore, no studies were excluded on the basis of quality.

## **2.3 Thematic Synthesis**

Synthesising or the "putting together" of studies that have been identified is key to a successful literature review. As each study is appraised it is important to ascertain how they relate to one another. This could be in four different ways; they may find different things, they may find similar things, they may contradict each other or they may contribute to 'building' a particular argument (Noblit and Dwight 1988).

There is no consensus on one approach to synthesising the findings of qualitative studies but rather several. Three common approaches used in health services research are Meta-ethnography, based on the work of Noblit and Hare (1988) in education, Grounded Theory, which was initially developed as a method for studies of social research (Glaser and Strauss 1967) and thematic synthesis, which draws on the principles of these established methods, but simplifies the process (Thomas and Harden 2008). Thematic synthesis using a method described by Thomas and Harden (2008) was the analytical process chosen for synthesising the studies in this focused literature review. This approach was chosen because it provided a pragmatic approach that was broken down into three logical stages:

1. The first stage is manually, line-by-line, coding the findings of the identified studies,
2. The second stage is the organisation of these manual codes into interrelated areas to build up descriptive themes, and
3. The third stage is the development of analytical codes by using the descriptive themes.

Appendix E shows an example of the approach used to the coding process used in the thematic analysis.

## **2.4 Themes**

The findings of the thematic synthesis of data from nine studies were five themes and two sub-themes. In brief, the five themes identified were: (1) health education, (2) patient health literacy, (3) patient health beliefs, (4) depression and diabetes, and, (5) the multi-disciplinary foot team. The two sub-themes were: (1) access to informal education/information, and (2) the accessibility of services.

### **2.4.1 Health Education**

In this theme data is included from studies that include themes or categories about health education. Aliasgharpour and Nayeri (2012) investigated the care process of diabetic foot ulcer patients in Iran and found that many health professionals believed that a patient's lack of understanding or an inability to take care of their feet was the main reason for the worsening of their condition. This finding was supported by Delea, Buckley, Hanrahan, et al. (2015) who reported that information given by healthcare professionals was 'vital' in enabling patients to become aware of the seriousness of foot ulceration and understand effective preventative measures to maintain healthy feet.

"How could I know the possibilities of facing such miseries?...if I had controlled it, this would have been different" (amputee) (Manssoreh et al; 2012).

That being said, it was evident in both studies that some participants were aware of what they needed to do in order to look after their feet, but admitted that they often chose not to follow the instructions given and instead adopted more 'risky' behaviours;

This was supported by the study conducted by Hjelm and Beebwa (2013), which explored the beliefs about health and illness among Ugandans with diabetes related foot ulcers, who found that some patients were aware of the potential problems that diabetes posed to feet, but did not seem able to grasp the severity;

"I am aware of the disease and related complications and consequences. And because of that I don't need to fear anything." (Hjelm and Beebwa 2013)

Delea et al; (2015) also reported that although all of their participants described receiving education around diabetes, some had highlighted they had not been aware of the implications of their illness on their feet until they experienced ulceration. Hill and Dunlop (2015), who conducted a study to explore the perceived impact of education for effective foot-care in patients with diabetes found

that people (regardless of whether they had received structured or formal education around their condition) believed that receiving education around their condition was beneficial. Few participants suggested that education would be of little benefit. This finding was supported by Hjelm and Apelqvist (2016) who conducted a qualitative study using phenomenology to explore the experiences of participants recruited from a single centre in Sweden. They reported that participants said that education was the most essential tool in preventing diabetes related foot complications and that both patients and health professionals agreed that it should include simple advice repeated regularly and aimed at both health professional and patients. A limitation of this study was that the sample was predominantly male (20 males and 6 women).

#### ***2.4.1.1 Access to 'informal' education/advice***

In addition to structured health education, it is important to recognise the theme of accessing 'informal' advice around diabetes related foot-care. Hill and Dunlop (2015) and Hjelm and Beebwa (2013) both reported that structured education was important, but in addition, patient's had access to repeated, informal advice and support was also an important preventative tool.

#### **2.4.2 Patient Health Literacy**

However these findings conflict with the study conducted by Alzubaidi, Mc Narmara, Kilmartin et al; (2015), who compared illness and treatment views between English-speaking people (ESP) and Arabic-speaking immigrants (ASIs) in England with type 2 diabetes, and how these beliefs impact on adherence to self-care behaviours.

Alzubaidi, Mc Narmara, Kilmartin et al; (2015) found that ESP tended to have high levels of health literacy and they linked this with better adherence to their foot-care management. However, ASPs were found to have significantly poorer levels of adherence to their foot-care management and this could be directly related to a lack of ability to access health information in a way that enables them to make good health choices. This shows that UK health services may not be effective in delivering information to those that their first language is not English.

#### **2.4.3 Patient Health Beliefs**

This theme identifies the psychological aspects of a person's beliefs that influence their health behaviour. Alzubaidi, McNarmara, Kilmartin et al; (2015) reported a relationship between participants' perceptions and 'health beliefs' about their illness and their adherence to diabetes self-care activities. Feinglass, Shively, Martin et al. (2012) interviewed participants with diabetes who had undergone a recent amputation. He reported that many participants believed that delays in seeking treatment were, in the main, due to their own personal actions as they believed that they could manage an injury to their foot themselves which led to a worsening of their condition. Hjelm et al; (2016) found that most participants believed that their foot problems could not have been changed or counteracted regardless of what they did, and this belief prevented them from adhering to appropriate self-care practices. This view was reiterated by the views of health professionals:

"The main source of the problem is the patient", "they [patient] do not take care of their feet and also do not control their blood sugar level." (Hjelm et al; 2016)

Alzubaidia, Mc Narmara, Kilmartin et al; (2015) also found in both groups (English and non-English speaking) in their study, that if patients did not believe that their medications were necessary then they were less likely to adhere to their treatment. These studies (Alzubaidia, Mc Narmara, Kilmartin et al; (2015): Hjelm and Apelqvist (2016) both indicated that the health beliefs of people are an important consideration in how people approach their self-care activities in order to prevent foot complications. They suggest that healthcare professionals should incorporate education designed to address inaccurate health beliefs of patients as part of an education programme about routine footcare for all people with diabetes. This is particularly important in the earlier stages of their diagnosis and treatment.

#### **2.4.4 Depression and Diabetes**

This theme identified that diabetes could have an impact on a person's mental health and their feelings about their condition. Almeida, Salome, Dutra et al. (2014) reported that many participants with diabetic foot ulcers reported strong feelings of powerlessness over their disease and many felt depressed. Hjelm and Apelqvist (2016) found that participants who developed a foot ulcer expressed emotions such as worry and fear, which coincided with physical discomfort such as pain and itchiness:

"At first when they were swollen and filled with fluid I had pain, but then ... when treated, it became better ... I was very scared ... that they would have to

amputate a toe or perhaps the foot... And it was mostly my imagination. That made me so worried" (R11) (Hjelm and Apelqvist 2016)

Smith, Gariépy and Schmitz's (2013) explored the impact of depression on the use of, and access to, diabetes healthcare services. They found a trend towards participants with depression identifying issues in accessing diabetes healthcare services. Their results revealed how people with major depression tended to perceive problems with the length of time they have to wait to see a doctor, a lack of specialist care in their area and obstacles getting to the doctor due to transportation and health problems. They also found that often these perceptions were not always factually based, but rather a result of the patient's underlying mood. They therefore, concluded that participants with depression were more likely to develop severe foot complications before seeking medical assistance.

"I'd like to be reassured by the doctor. That we're going to do the best we can here and God forbid if you do have to amputate it, that'd be the last resort totally." (Richard) (Delea et al; 2015)

Delea et al; (2015) found many participants expressed how they valued the communication, understanding, reassurance and empathy from health professionals. They expressed a need for health professionals to not only educate on the physical aspects of diabetes foot-care, but also to support them with the emotional impact of living with the threat or the development of foot ulceration.

#### **2.4.5 The Multi-disciplinary Footcare Team**

One of the themes emerging from the literature review was around the experiences people described of their particular healthcare service. Hjelm and Apelqvist's (2016) explored the beliefs of foreign-born people with diabetic foot ulcer, about health and illness that might affect self-care and the seeking of medical interventions. Almost all study participants stressed the importance of health-care professionals in aiding them to manage their foot health:

"Interviewer: 'What do health-care staff mean for your health?'

'A great deal. They help you to get treatment; you get advice and tips.'"(R16)  
(Hjelm and Apelqvist's 2016)

And;

“...the help I got ... it was 100% ... all kinds of things ... I got help from the diabetes ward, and the nurse who did the wound dressings ... and it was the same with the district nurse, she did all she could ... and I got help from my wife ... she helped if I wasn't able to lift my leg and then she did it.’ (R3).”(Hjelm and Apelqvist's 2016))

Aliasgharpour and Nayeri's (2012) study, that sought to clarify the process of care for Iranian people with diabetes and suffering foot ulceration, implied a lack of education, screening, team work and facilities contributed to the unsatisfactory care of patients suffering from foot ulceration. A lack of visible co-ordination between health care professionals meant the continuity of care for this vulnerable group was, at times, severely lacking, leading to delayed treatment and the increase in the severity of ulcers. Feinglass Shively, Martin et al; (2012) supported these findings as a consistent theme found in their study was the frequent delays in medical care for participants that was often urgently needed. Over half of the study participants described how delays in treatment often led to a deterioration of their symptoms. These delays ranged from hold-ups in primary care referrals, to repeated inaccurate suppositions by health professionals around how quickly symptoms were likely to progress or worsen.

“I was waiting to go in on Wednesday, but I couldn't get in on Wednesday. And that's when I saw the blood. So I finally got to see him (in) his office. And I got to see him and when I came in, my little toe, it was getting a little dark. And he just, got he just panicked. Right away he started calling. He was going to send me to a hospital here in Chicago.” (Patient #8). (Feinglass Shively, Martin et al; 2012)

However, Delea et al's (2015) reported that generally all of the participants had a positive response towards the health care professionals delivering the footcare services which contrasts with the findings of Feinglass Shively, Martin et al; (2012). Participants were keen to emphasise that they felt staff were not to blame for the inadequacies in the system, but rather that issues were a result of the healthcare system itself and the way it was structured.

Throughout all nine studies included in the review, there was an overarching and systematic theme that having a multi-disciplinary, systematic program for the treatment of diabetic foot ulcers, with specially trained health professionals, would lead to the correct management of the disease and engage patients.

#### **2.4.5.1 Access to Services**

This theme concerns access to services and resources. Aliasgharpour and Nayeri (2012) discussed how participants in their study referred to the shortage of specialist diabetes centres or specialist footcare clinics. One patient felt that;

“In case of having no specialist clinic for the diabetic patients, doctors do not see themselves as responsible”. (Aliasgharpour and Nayeri 2012)

Also patients living in rural areas perceived significant difficulties in receiving care due to a lack of services in their local area (Delea et al; 2015). Often the requirement to undertake, sometimes lengthy, travel to specialist centres had implications in terms of time and travel costs. There were also problems identified in more urban areas that related to the lack of wheelchair facilities and numbers of wheelchair parking spaced at hospitals (Delea et al; 2015).

## **2.5 Discussion**

In bringing together the available literature using a systematic search strategy and Thomas and Harden’s (2008) approach to thematic synthesis, five themes were identified. These five themes were found to be intricately linked, describing the effect health care provision had on people’s ability to be able to take care of their feet to prevent foot ulceration, or seek treatment in the early stages should an ulcer develop. It was also identified that there seemed to be a multi-faceted approach to ensure the likelihood of adherence to self-care in people with diabetes. The literature suggests that patients face five key barriers into ensuring good footcare practices, these were: health education, health literacy, patient’s health beliefs and perceptions of their illness, the patient’s emotional needs being met and the quality of the health service provision they received.

Whilst it was argued that comprehensive educational programmes are linked with better outcomes for patients, there were contradictory findings on the effect of education on the prevalence of foot complications (McInnes, Jeffcoate, Vileikyte et al; 2011). The literature review findings suggest that peoples’ level of education and awareness around their diabetes was very diverse. Delea et al; (2015) reported an absence of a comprehensive understanding of diabetes when first diagnosed in people in their study conducted in 2013. This being said, it was also highlighted that, despite people receiving information about how to care for their feet, they sometimes chose not to follow health professional advice. It is important to recognise that many people are unaware they have diabetes until they are in an acute phase of foot ulceration, and sometimes delays in getting a diagnosis can mean that people will not receive the information they need to



ensure they pay extra attention to their feet (Aliasgharpour and Nayeri 2012). Hill and Dunlop (2015) recognise the importance of informal advice to compliment the structured educational programmes and recommend that regular 'top up' educational sessions to strengthen any formal education, preferably soon after diagnosis, would be of considerable benefit. Both studies recognise that any educational sessions should be delivered by health professionals on a regular, or semi-regular, basis to assist in reinforcing key messages about effective foot-care. The results of this literature review suggest that while footcare education is an integral part of helping people manage their diabetes, this should be one part of a much bigger care package.

In their study, Kokoszka, Pouwer, Jodko, et al. (2009) found that negative emotions could often be triggered by specific problems connected with diabetes. One of the most prevalent themes running through the majority of the studies in this literature review was the need expressed by participants for emotional support, in conjunction with the physical treatment of their diabetes. Four of the studies identified in this literature review reported that participants valued supportive, empathic and reassuring interactions with health professionals. Health professionals who were sensitive to patients' differing needs and had an awareness of, not only their condition, but also the psychological factors affecting their ability to manage their condition, were particularly valued. The importance of emotions is supported by the study carried out by Furler, Walker, Blackberry et al; (2008), they reported that many people develop their own self-care plan, based what is important to them on an emotional level. However, the effectiveness of this can be determined by the health professional's ability to support them.

Although the role of the health professional was an important factor in the management of diabetes related footcare other factors were also important. The need for appropriate healthcare systems to be in place to support an individual's ability to manage their condition was another element woven throughout the themes identified in this literature review. Many participants described their experiences of the healthcare system as a whole, and the need for timely access to a multi-disciplinary team was a key theme. Some patients identified that, although on the whole, they had positive experiences with health professionals as individuals, getting access to these professionals in the first instance was the reason for the worsening of their condition. This theme identifies the tension of increased demand and how these are having an impact on the way patients experience using healthcare services.

The terms patient experience, patient perception, patient perspective, patient satisfaction are often used in conjunction with one another and can often cause

misunderstanding and confusion. Ahmed, Burt and Roland (2014) describes patient experience as a person's experience of healthcare and the subsequent feedback received about those experiences. In recent years, the way patient experience health care has become increasingly important in the NHS and in 2012 the National Clinical Guideline Centre (NCGC), commissioned by the National Institute for Health and Clinical Excellence (NICE), developed guidance that focuses on a set of standards to support all people who use adult NHS services in England and Wales. The aim of the NCGC guidance was to provide a clear stance on what the components of good patient experience are that endeavours to generate sustainable change that will result in a truly patient-centred service (NCG 2012).

In developing the "Patient experience in adult NHS services: improving the experience of care for people using adult NHS services" the NCGC set out to explore the frameworks of Patient Experience that are currently used in healthcare in the United Kingdom and internationally (NCGC 2012). After an exhaustive literature review, the NCGC found that there were several frameworks developed around patient experience. The two most commonly quoted frameworks were The Institute of Medicine framework and the Picker Principles. Both of these frameworks adopt the patient perspective as the true approach to patient-centred care (NCGC 2012). Through an amalgamation of these frameworks and other relevant studies, the NCGC describes the best experiences for patients come from those who:

1. Are treated with dignity and respect, those that have comfort,
2. Have had their social, personal and psychological situation taken into account,
3. Have co-ordinated care and have the opportunity to self-care,
4. Are given the opportunity to express their preferences,
5. Have had sufficient information to allow informed choice (NCGC 2012).

In light of this, it could be determined that patients experience could be used in improving the quality of healthcare services to ensure it is safe, effective, patient-centred, timely, efficient and equitable, this, in turn, will lead to patients having good experiences that result in positive outcomes (The Health Foundation 2013).

## ***Conclusion***

The literature review supports the various UK initiatives that emphasise the importance of using patient experiences to inform quality improvement and service design.

Although the studies identified were undertaken in settings around the world, all with differing healthcare structures, patients were united in their views of needing to be informed, and not only have their physical health looked after but also their emotional

wellbeing. This was in conjunction with having access to a multi-disciplinary team of professionals in an accessible, practical and timely way which took into account them as individuals. Evaluating patient experiences of services may provide valuable insight into potential improvements. Understanding the themes identified in published research provides data that will complement the local service evaluation, and contribute to future service improvements in the local Diabetes Foot Protection Service. In Chapter Three the approaches used to collect qualitative participant feedback about the FPS in Leeds is presented.

## **Chapter 3 - Methodology**

### **3.0 Introduction**

This Chapter will describe the actions taken to conduct the service evaluation, including the rationale for the use of particular methodologies, processes and techniques and will describe how data were identified, selected, processed, and analysed to understand patient's views about the FPS.

In the first instance, it was important to understand the differences between formal research, audit and evaluation, and how this impacts on the chosen methodology to gather qualitative data. Twycross and Shorten (2014) describe in their article the difference between research, clinical audit and service evaluation in the following way:

1. Research should be designed and conducted to generate new knowledge and guide practice, however it can take time to get from dissemination of results to practical quality initiatives. Research would also always need NHS ethics approval
2. Audit should be designed to answer whether a service reaches a predetermined standard on 'taking the pulse' of the organisation. An audit can provide quick results to provide assurance quality standards are being met
3. Evaluation should be designed to set a baseline standard, in essence looking at the standard the service is currently achieving and be a tool to capture 'real-time' data to focus quality improvement initiatives

The Health Foundation (2015) suggest undertaking evaluation can be used to achieve a number of objectives:

1. After a change or improvement has been implemented, evaluation can be used to determine whether the desired outcomes have been achieved, whether it has caused or compounded issues, whether patients' best interests have been served and whether what is being evaluated can be sustained
2. If evaluation is undertaken during a change or improvement, as opposed to afterwards, it could provide feedback to allow reflection and review in real time
3. Evaluation can be an opportunity for patients and their representatives to describe their experiences and perspectives and this can then be used to inform future change or improvement

4. Evaluation can provide essential justification for funders and budget holders when making decisions on whether to fund future work

Whatever the reason or justification for undertaking evaluation, Green and South (2006) reiterate that it is an important resource for understanding, learning and sharing knowledge about what does and does not work within a health care setting. This can also be applied in both large and small scale projects which look at full service provision or elements of a service.

There are two of the most commonly used evaluation approaches in healthcare. These are:

1. Summative evaluation is usually carried out at the end of an intervention when all data has been gathered to help determine whether it has been successful. Evaluating in this way can help to establish whether an intervention has met its aims, can assist in determining cost versus benefit analysis and whether changes or improvements need to be implemented. Summative evaluation works at its optimum when the environment in which it is undertaken is unlikely to change during the evaluation period.
2. Formative evaluation is used to assist in the formation and shaping of a particular intervention by providing information about how to modify or revise work as it evolves. This method can be more flexible than a summative evaluation and it can change its methodology to support variation in an intervention. (The Health Foundation 2015)

Taking these definitions into account in relation to the aims of this service evaluation, which was to investigate and evaluate the experiences of people using the FPS in Leeds, a formative evaluation methodology was adopted to assist in the formation and shaping of the FPS as an ongoing service. Using the data gathered in 'real time', information can be gleaned for quality improvement purposes in a meaningful and instantaneous way. This was achieved by gathering and analysing qualitative data in a systematic and methodical way whilst using concepts of reflexivity balanced with transparency and pragmatism.

### **3.1 Design**

Holden and Lynch (2004) describe two basic methods of gathering data; the first a positivistic approach; developing knowledge through objective observation and collating quantitative facts through controlled scientific study. The second, a naturalistic approach; placing an emphasis on words using qualitative data. Sandelowski (2004)

defines the gathering of qualitative data as making an inquiry into an individual's experiences and understanding their interpretation of the world. Although the statistical analysis of quantitative data can provide a thorough assessment of patterns, it may not be able to provide an in-depth understanding of the environmental influences that qualitative data can produce (McCusker and Gunaydin 2014).

Silverman (2013) suggests there are three fundamental questions that should be considered before gathering qualitative data. These are:

1. Why should qualitative methodology be used?
2. Is gathering qualitative data appropriate to the study question and, if so,
3. How should qualitative methodology influence the way the study is defined?

As described in Chapter one, Marsh and Glendenning (2005) suggest using a methods decision tree (Appendix A) to establish what method of data collection would be the most appropriate to support an evaluation. This tool recommended semi-structured interviews as a suitable method when investigating the opinions of a small number of individuals.

With the questions of Silverman (2013) and the recommendations of Marsh and Glendenning (2005) in mind, this service evaluation sets out to explore the perceptions and experiences of a small number of patients who are using a particular health service. These interviews will allow the gathering of quantitative data, which from the patient's perspective, can provide a more in-depth understanding of how successful that service is and also indicate when improvements can be made.

### **3.2 Setting**

The study 'setting' is the physical, cultural and social location in which information is gathered from its participants. In qualitative studies, the focus is on gathering this data in a natural setting where possible; this is in contrast to quantitative study, where participants undertake contextual activities, usually in a laboratory (The SAGE encyclopaedia of qualitative research methods 2008). Understanding the significance of the study setting for interviews is an important aspect of the data gathering process, considering where interviews take place and how this influences power relations between participants and interviewer will assist in creating a more balanced environment, ensuring the credibility of findings (Elwood and Martin 2000). In the two decades prior to their study, Gagnon, Jacob and McCabe (2015) found that, although existing literature gave detailed information for effective interview planning, techniques, styles and the varying methodological approaches, little consideration was given to the interview

location. In a research study cited in their article, Gagnon et al; (2015) describe how a researcher chose community-based organisations to carry out interviews. Taking into account the respective geographical location in relation to participant's homes and the familiarity of surroundings, found this can aid in easing any tension participants may feel. However, the researcher was clear that although community-based organisations could generally be more accessible and inclusive, they may also act as a barrier for the interview process, especially if participants have negative feelings about that particular setting. Therefore, Elwood and Martin (2000) suggest offering participants a choice of locations for conducting interviews. This would assist in alleviating any physical or emotional barriers participants may have, and also allow a more even interaction between interviewer and interviewee.

As this was a service evaluation rather than a research study, participants were recruited from FPS clinics operating from community based health centres throughout Leeds. DSPs see approximately fifty patients per week, and out of these, approximately twenty two are patients attending a review clinic. All patients attending the FPS are deemed as having either a moderate or high risk of developing a foot ulcer. Based on the inclusion criteria, appropriate participants were asked if they were happy for the interview to take place in the health centre in which they received their treatment, or whether they would prefer an alternative venue. All participants taking part in this service evaluation consented to their interview being conducted in their usual treatment site.

### **3.3 Sampling**

'Sampling' can be defined as the method by which participants have been selected to take part in a study. Effective sampling is crucial to the process of qualitative data collection. Robinson (2014) suggests a four-point approach to sampling in qualitative studies to support the validity of the study. This four-point approach is described as the following:

1. Develop a sampling strategy
2. Define participants using inclusion criteria
3. Decide the size of the sample through joint consideration of practical and epistemological factors, and
4. Objective participant recruitment that is effective in considering ethical principles, particularly pertaining to informed consent.

The extent in which these four areas are explored and described in qualitative studies affects the coherence, transparency, impact, and trustworthiness of the overall findings (Robinson 2014).

### 3.3.1 Sampling Strategy

In this service evaluation, it was required that participants describe their experiences of the FPS. Ideally, all patients using the FPS should have been given the opportunity to contribute. However, budget and time constraints meant that this was not possible. Therefore, in conjunction with the FPS clinical lead, the eight FPS clinics held in the Leeds area were divided up into geographical locations (North, East, South, and West) and from each of these locations one clinic was chosen based on the diversity of the people using them. Over a ten week period, patients of these clinics who fulfilled the inclusion criteria (see 'selecting participants' below), were asked if they would agree to take part. Below is a table outlining the numbers of participants agreeing to take part in each clinic.

Table 3 Participant uptake by clinic location

Clinic	Location in Leeds	No. of Participants
One	North	8
Two	West	5
Three	Central	2
Four	South /East	2

Although appropriate participants were asked at each location to take part in the study, uptake in some was very limited. This could have been due to the demographics in each area, Clinic one is an area with a higher number of retired population whereas Clinic four has a higher demographic of working population. Clinics two and three have similar demographics made up of both pockets of affluent and deprived areas. Any future work in this area could consider how to engage more people from the areas where uptake was the lowest.

### 3.3.2 Defining Participants

The selection of participants in qualitative studies should involve the development of set inclusion criteria. These are a set of characteristics that are predefined and used to identify participants who could be included in the study. Inclusion criteria make up the 'eligibility' factors that include or exclude the target population of the study and should incorporate the overall aims and objectives of the study. Establishing appropriate inclusion criteria should improve the validity and feasibility of a study and reduce ethical concerns (The SAGE encyclopaedia of qualitative research methods 2008).



To accurately define an appropriate cohort of participants, a set of inclusion criteria should specify the attributes all participants should possess with a clear rationale for why it should be developed (Hewitt-Taylor 2017) and these principles were used to inform the sample for the service evaluation. The inclusion criteria and justification for patients included in this service evaluation are outlined in table 4:

Table 4: Inclusion Criteria

Criteria	Rationale
The patient was considered at moderate or high risk of active foot ulceration as a result of diabetes	All patients using the FPS service are deemed at either moderate or high risk of developing foot ulceration
18 years or older	The FPS only assess adult patients
Was a current review patient of the FPS	Current review patients of the FPS were the most appropriate cohort of participants as they had already experienced an initial assessment appointment, and had received at least one review appointment.
Be able to read and communicate in English	There was no finance available to support an interpreter to include non-English speaking participants. This is acknowledged as one of the limitations of this study

### 3.3.3 Size of Sample

Marshall, Cardon, Poddar, and Fontenot (2013) suggest that in addition to selecting a study topic and then deciding on the study design, selecting an adequate sample of participants is fundamental to creating credible study findings. Ensuring that there are enough data is the foundation for ensuring trustworthy analysis and reporting. However, it is rare for qualitative researchers to justify the sample size of qualitative interviews, this is compounded by the fact that few qualitative research methodologists stipulate reliable guidelines for estimating sample size. Based on the results of their study, Marshall et al; (2013) recommended that qualitative researchers should involve between 15 and 20 participants. Therefore, these principles were used to decide upon the sample size for this service evaluation.

### **3.4 Participant Recruitment**

Recruitment took place over ten weeks within four clinics. Based on the inclusion criteria, potential participants were identified by the DSPs undertaking a review appointment. Once identified, patients were approached by the researcher, within the clinic waiting area and were invited to participate in this service evaluation. Interested participants were given an information sheet and a consent form and asked to contact the researcher if they wished to take part, however seven participants stated they did not have the time/wanted to come back and requested to be interviewed straight away and this request was actioned. The researcher went through the information sheet and consent form with these patients and reminded them of their right to withdraw if they chose to at a later date. Of those that stated they would like to take part at a later date all requested the researcher contact them to confirm a mutually convenient time to be interviewed.

### **3.5 Qualitative Data Collection Methods**

Interviews are an effective way to explore the views, beliefs, experiences, and motivations of individuals (Chadwick, Gill, Stewart and Treasure 2008) and there are three main types of qualitative interviews, these are:

1. Structured interviews in which set questions are asked with little or no variation. These are relatively quick and easy to administer, but only allow for limited participant response,
2. Semi-structured interviews comprising of key questions that will assist in defining areas to be investigated, whilst allowing the interview to be flexible and explore ideas and responses in more detail,
3. Unstructured interviews are performed with little or no organisation, they are usually very time-consuming and can be difficult to manage, but be useful when there is little or no knowledge around a particular subject (Chadwick et al; 2008).

The format for this service evaluation was semi-structured interviews, as this method provided some guidance on what to discuss, but also allowed for the elaboration of pertinent information.

To assist interviews, a topic guide was drafted by the researcher and modified following feedback from the supervisor and FPS Lead (See Appendix B). The topic guide was also piloted by a patient attending FPS who fulfilled the inclusion criteria. No further revisions were required. To ensure the natural flow of conversation and enable participants to

speak freely about their experiences, the topic guide was used flexibly throughout interviews.

Interviews took place in a private room at health centres with consenting participants to ensure confidentiality. Patients were reminded that they had the right to stop the interview for a break or withdraw entirely at any point. Interviews were audio recorded using an encrypted audio device. At the end of each interview, participants were asked if there was anything else they would like to add to ensure all pertinent aspects of their experience had been included. Interviews lasted between 4:25 and 25:28 minutes with a mean number of 15:35 minutes overall. Recordings were transcribed verbatim and followed all data protection protocols, including the use of pseudonyms.

### **3.6 Data Analysis**

As this service evaluation involved collecting data about the experiences of individuals using the FPS, the use of qualitative data was selected as the most appropriate methodology. To undertake qualitative data collection and its subsequent analysis, an appropriate framework in which to analyse and base findings needed to be established.

Bradley, Curry and Devers (2007) argue that there is no single way to undertake qualitative data analysis. However, there is a general agreement that qualitative data analysis should be an iterative, ongoing process from the early stages of data collection and continued throughout the research. Initial immersion in the data, without coding, enables the comprehension and identification of emergent themes without losing the connections between perceptions and their context. Once there is an understanding of the scope and context of the data, a coding process can begin and giving the analyst a framework to organise data and help to give an accurate assessment of relationships.

An inductive and flexible approach was required for this service evaluation and therefore, Braun and Clarke's (2006) thematic analysis was the primary method used to undertake the analysis of the data gathered. The process for analysis was as follows:

1. Interviews were recorded and transcribed by the researcher to enable familiarisation of the data
2. The systematic generation of preliminary coding commenced on a line-by-line basis.
3. Deeper and focussed coding was then undertaken, using the critical/recurrent initial codes to support the analysis of large amounts of data. This included identifying patterns, trends, distributions and possible contradictions. This comprehensive analysis allowed complete immersion in the data, informing

decisions made about which codes had the most substance to allow simple themes to be identified

4. These simple themes were then reviewed and a search for inconsistent or disconfirming themes was undertaken to combat bias or an overly simplified interpretation of the data
5. Themes were then grouped to create overarching themes
6. Overarching themes were reviewed and checked with a final analysis of extracts to ensure the aims of the service evaluation could be realised
7. In order to assist the thematic analysis required for this study, the software NVivo was used (Appendix G). NVivo is designed to help organize, examine and to find insights in qualitative data and then to identify, analyse and describe themes within that data.

### ***3.7 Trustworthiness and Reflexivity***

It is accepted that in qualitative studies the researcher is central to the influences that will form the basis of data collection, analysis and interpretation. How findings are presented is a joint creation of the relationship between the researcher and the participant (Finlay 2002). The level in which researchers influence qualitative data collection is often described as 'researcher-as-instrument'. This is because of the unique researcher characteristics that will potentially affect the collection of qualitative data. Therefore, it is important for the interviewer to discuss reflexivity and subjectivity during the data collection process (Pezalla, Pettigrew and Miller-Day 2012)

As previously discussed in Chapter two, the trustworthiness of qualitative studies is important in ensuring the validity and reliability of research methodology, data collection and results. "Reflexivity is an attitude of attending systematically to the context of knowledge construction, especially the effect of the researcher, at every step of the research process" (Cohen and Crabtree 2006). With this in mind, consideration was given to the fact that the researcher in this study was evaluating a service in their place of work to provide quality improvement recommendations, as well as developing information for a postgraduate thesis. These factors had the potential to create researcher bias within the results. To prevent this, training provided by the University of Huddersfield around qualitative interview techniques and subsequent analysis was undertaken by the researcher. A pilot interview was conducted to ensure relevant information was gathered to answer the aims of the service evaluation. This also assisted in exploring any bias or assumptions made by the researcher. Using the thematic process of reading, re-reading, coding and re-coding data helped in assuring a subjective approach, and although all interviews were transcribed and analysed by the

researcher, there was support from the research supervisor, who examined sample transcripts along with the coding framework and subsequent themes. Remaining open and transparent with the wider team ensured the researcher could demonstrate the credibility and trustworthiness of this service evaluation, and it remained true to achieving its overall aims and objectives.

### ***3.8 Limitations to Methodology***

There were some limitations to the methodology adopted for this service evaluation. Incorporating participants from all eight clinic sites would have given a broader analysis into the FPS as a whole, however, the availability of the resources required made this unviable. Also interviewing more patients of differing ethnic backgrounds could have provided more insight into the particular barriers these groups may face in getting the most out of the FPS, and should be considered in any future studies.

### ***3.9 Ethics***

The outline for the proposed study was discussed with the Leeds Community NHS Healthcare's Research and Development Department. The Research and Development Manager gave support in principle for the study and confirmed that it was not research but was service evaluation and therefore did not require NHS ethical approval (See Appendix G). To support best practice, the study proposal (See Appendix H) was submitted to the University of Huddersfield's, School of Human and Health Sciences research and ethics committee for their opinion (see Appendix I). They approved the study as a service evaluation providing it had the support of the Research and Development Department within the site where the study was to be conducted.

### ***Conclusion***

This chapter has explained and justified the service evaluation methodology used in this qualitative study. This methodology was chosen to gather data to assist in the exploration into the experiences of people using the FPS in Leeds, to inform possible quality improvement initiatives of the service. Chapter four presents a detailed examination of the results ascertained using a systematic thematic analysis, which will be supported by direct patient quotes.

## Chapter 4 - Findings

As reported in Chapter one, this service evaluation was conducted to investigate the experiences of people using a new FPS in Leeds, and use this knowledge to explore ways in which the FPS could be improved. A formative service evaluation methodology was adopted and by gathering qualitative data in a concise and methodical way and then undertaking a systematic and reflexive thematic analysis of the results, clear and definitive themes could be identified to support this service evaluation of the FPS.

### 4.1 Identification of Themes

There were four main themes to emerge from the thematic analysis of the data provided by the seventeen study participants. These four main themes and their constituent sub-themes are outlined in table 5 below:

Table 5: Themes and Sub-themes of findings

Main Theme	Constituent Sub-themes
Referral Mechanism and Entry into the FPS	Symptoms leading to referral
	Referral Route into FPS
	Missed opportunities for Care
The Impact of the FPS	The FPS as a Source of Support
	Increased Awareness around the Importance of Foot Self-Care
	Supporting Foot Self-Care
	Obstacles to suggested Foot Self-Care Practices
	Diabetes Self-Care Support
	Physical interventions/checks
Views on the FPS	Clinic Location
	Clinic Appointments and waiting times
	FPS Clinicians and Service Provided
Potential Improvements to FPS Provision	Participant Suggested Improvements
	Evaluation Recommendations for Improvements

## 4.2 Demographics of participants

Before discussing the themes identified in this service evaluation in more detail, the demographics of participants are described below. Through effective selection and recruitment, seventeen participants agreed to take part in this service evaluation. Table 6 indicates the demographics of the participants that took part:

Table 6: Participant demographics

ID	Gender	Age	Ethnicity	Total no. of FPS apt.
AA	Female	89	White/British	2
BA	Female	55	Preferred not to say	2
CA	Male	52	White/British	2
DA	Female	76	White/British	2
EA	Male	91	White/British	4
FA	Male	57	White/British	4
GA	Male	83	Indian	5
HA	Female	57	White/British	9
JA	Male	79	White/British	3
KA	Male	69	White/British	3
LA	Male	75	White/British	4
MA	Male	71	White/British	3
NA	Male	61	White/British	2
PA	Male	76	White/British	2
QA	Male	80	White/British	3
RA	Female	51	White/British	2
SA	Female	59	White/British	3

Table 6 shows participants characteristics. There were six females and eleven males, who ranged from 51 to 91 years of age with a mean age of 69, who took part in this service evaluation. Fifteen participants identified as White/British, one as Indian and the other preferred not to say. At the time of the interviews the minimum number of appointments participants had attended at the FPS was two and the maximum was nine, with a mean number of three appointments overall. The initials attributed to participants are used in the results to identify participants but are fictitious.

## 4.3 Themes

The following themes and subthemes were generated from the interview data collected from seventeen participants that took part in this service evaluation.

### **4.3.1 Referral Mechanisms and Entry into the FPS**

When participants were asked how they were referred to the FPS, there were three sub-themes to emerge: (1) symptoms leading to referral, (2) referral route into the FPS, and (3) missed opportunities for care.

#### ***4.3.1.1 Symptoms leading to referral***

Understanding the symptoms that lead people to realise there may be an issue with their feet is important to the service. It can be used to decide whether key health professionals understand the process and referral into the FPS for people with diabetes who may be at a moderate or high risk of developing foot ulceration.

During interviews many participants explained the changes they had experienced in their feet which suggested there may be a problem. Participants described physical changes such as dry/hard skin, ulceration, swelling and changes in foot shape. These physical changes were often accompanied by sensations such as pain "it hurt me" (BA), numbness "Numb...it feels numb now" (EA), burning and pins and needles. Three participants indicated that it was only a diagnosis of diabetes that brought on the realisation that issues they had been experiencing with their feet may be linked:

"I've had some numbness in my feet for about 2 years and I've only recently been diagnosed with diabetes, so...it kind of made sense, once I had the diagnosis for diabetes, that I had some problems with my feet"  
(CA)

#### ***4.3.1.2 Referral route into FPS***

The FPS is a specialist service that patients can access via a referral from another health professional or service.

Participants described four main routes of referral into the FPS, these were (1) a GP, (2) from an acute service (hospital), (3) a Community Podiatrist, or (4) a Diabetes Nurse. This fourth route was identified as the most common route, often via a diabetes review appointment. Many participants suggested that it was only because of this review that they discovered that their feet required medical intervention:



"Maybe I wouldn't have done anything about it, but my time for my diabetes check-up coming round and I told her" (HA)

and;

"No it wasn't painful, still isn't painful, it wasn't stopping me from doing anything and I knew I had the appointment [diabetes review] in like, six or seven weeks' time and I just thought I'd mention it then...or...well it came to light during the examination of my feet" (LA).

Other participants described knowing that the issues with their feet may be related to their diabetes, so they used their diabetes review to express their concern:

"My cousin had diabetes and she lost a toe and now she's lost up to her knee. So I thought 'oh my god', I thought 'I don't want that to happen to me' and so when I went to see the diabetes nurse and I mentioned that I was worried about my toes, and it was her who suggested that I come [to the FPS]" (HA).

Discussing the referral route into the FPS with participants revealed the importance of the diabetes review.

#### ***4.3.1.3 Missed opportunities for Care***

Another sub-theme to emerge, when discussing how participants were referred into the FPS was where opportunities for care were missed. Of the five participants that described their doctor being the first person they contacted about their feet, three claimed that they had been prescribed medication such as painkillers or antibiotics with no further action taken:

"Can't remember that they did much at all. Just gave me painkillers" (EA).

The other missed opportunity for care which was identified was the newly diagnosed diabetes information courses that are widely available to all people recently diagnosed in Leeds. The two participants who stated they had attended this course recalled little or no mention of how diabetes can affect the feet:

“No, it was on foods, recognising foods what foods are good for you, what aren’t good for you. It was more on that” (HA).

These opportunities to give advice or refer for specialist care may have meant participants had a deterioration in their condition before the right intervention was eventually received.

### **4.3.2 The Impact of the FPS**

All participants described how the FPS had positively impacted on them and this impact could be described into six ways (1) a source of support (2) increased awareness around the importance of foot self-care management (3) supporting foot-care self-care (4) diabetes self-care support (5) physical interventions, and (6) obstacles to self-care. These subthemes are described in more below:

#### ***4.3.2.1 A Source of Support***

Having regular access to the FPS was a great source of support and reassurance for some participants. One participant, who had experienced significant foot ulceration and an extended stay in hospital, described his relief at making it to his FPS appointment without his foot “breaking down again” (FA). The participant described how, after being discharged from hospital, he had to wait five weeks for his appointment with the FPS and this was a very anxious time for him:

“...so that was the main feeling, the relief that I’d got to see [DSP] and she said it was doing ok and everything was checked over.” (FA).

Participants also described the positive feelings they had after their FPS assessment:

“...and once I came, oh it was marvellous and right comforting you know” (HA).

Generally, participants who discussed the support of the FPS described how having the support of a DSP helped to alleviate some of their worries and even gave hope for an improved condition:

“the numbness was worse on the day that she tested me...but since then I’ve been back on my bike a bit, lost a bit of weight and so, therefore, I’ve had an increased feeling in my feet again”(CA)

However, not all participants experienced positive emotions during their FPS appointment, one participant described how getting the news that she was at moderate risk of developing an ulcer was difficult for her:

“It’s hard to...just being told that I was at moderate risk...that was the bottom line for me” (LA).

During interviews some participants discussed where they would go to get further support or advice if a problem arose between appointments and responses were mixed, suggesting that this wasn’t clear to patients. Participants generally implied that they contact their GP, while others stated they would contact the FPS or a hospital service.

#### ***4.3.2.2 Increased awareness around the importance of self-care***

When discussing participant’s awareness of foot ulceration as a result of diabetes before they have accessed the FPS, there were several who claimed to be unaware of the risks of having diabetes to the feet:

“It was the Nurse who’d said...and you know, I probably wouldn’t have even realised then had I not had this bad toe. Which wasn’t overly bad, I just mentioned it to her” (HA).

However, some participants described being aware of the effect diabetes can have on feet due, often due to family or friends suffering from diabetes and experienced issues with their feet themselves:

“I knew that I could get problems with my feet, being diagnosed with diabetes because my dad is diabetic as well” (RA).

There were also participants that, although aware that there was a relationship between diabetes and foot complications, did not associate it with themselves when they started to experience foot problems:

“Yeah...well actually I know that the patient, the diabetic patient, when we study...that the blood vessel in the feet, the blood vessel is nearly gone, not active and the patient couldn’t feel the sensation...but I didn’t recognise that I could get the same”. (BA).

Participants described how, through the intervention of the FPS, they now understood that there was a link between diabetes and foot complications and how important this knowledge was in managing the care of their feet:

“My grandson he’s 28 now but he was diagnosed with diabetes 1 when he was four and that is a different type...he’s on a lot of insulin daily. So I had a good idea what it can mean...how it can affect your organs, your limbs...because you don’t really realise, I didn’t realise how important it was to care for your feet with diabetes 2” (DA).

This also suggests that although people may have experienced the risks diabetes poses on feet through others, however, did not instantly recognise the relationship between diabetes and the foot issues they experienced in themselves.

#### **4.3.2.3 Supporting foot self-care**

There were three additional themes to emerge from supporting foot self-care and these were (1) expert advice, (2) adopting foot self-care practices, and (3) obstacles to suggested foot self-care practices and these are described below:

##### **4.3.2.3.1 Expert advice**

Although most participants remembered the physical interventions of their first appointment, once prompted, almost all did recall instructions and advice given by the FPS to help them care for their feet between appointments:

“The information that I was given afterwards for how best to look after my feet in terms of moisturising, massaging, increasing blood flow, exercise” (CA) and also what practices to avoid “don’t wear tight shoes” (BA) and “never walk barefoot” (MA).

Other recollections that participants commented on was around signposting and referrals:

“...he would try [refer] me with physiotherapy. Physiotherapy before do an operation” (BA).

This suggests that signposting people to other services is an important element of the DSP role.

### **4.3.3 Adopting foot self-care practices**

The majority of participants indicated that they had started or increased some self-care routines as a result of advice received from DSPs. Most participants described how they were now applying moisturiser to their feet to decrease dryness and hardness of skin:

“I put the balm on every day and so that’s it” (KA) others described adopting several practices “so moisturising, exercise, using the foot soles” (CA).

Not only do the procedures carried out in clinic help patients, the advice given also enabled participants to develop good self-care practices,

“They [feet] used to be quite dry, not scaly as such, but you could see that it was cracking and it was really dry around the heel...I used to get the build-up of hard skin and things like...but now I'm on top of that as well” (RA).

In addition to adopting practices to improve and maintain healthy feet, some participants also reported that they were advised to stop doing some self-care routines which could be potentially harmful:

“I file them, I don’t cut them like I used to do” (NA) and “You put these blades in this thing and I used to hack at my feet, literally. I would have a towel down on the floor and I would hack away at it and it made it so that when I stood down I didn’t have the pain... so I’ve stopped that” (HA).

Other practices that participants described desisting was the cessation of walking barefoot, putting cream between the toes and wearing tight or unsuitable footwear.

Two participants indicated that they had made no changes to the way they took care of their feet. One participant described how the advice she was given was the same as the self-care practices she already undertook, when asked to describe these she stated and chose not to give more detail:

“As I said, I’ve always looked after my feet, had good shoes. I’ve never worn cheap shoes or anything like that” (AA).

#### **4.4 Obstacles to suggested foot self-care practices**

Several participants described some of the barriers that prevented them from following the advice given by the FPS. The main barrier was centred on the provision of insoles. These participants explained that although insoles had helped them, they were only provided for one pair of shoes and they had several pairs that they often wore:

“In summer I wear these, I like hiking so I have hiking boots on, I like running so I have sort of running shoes...these are now my walkabout trainers. So the insoles are still in my winter shoes, so I will wear them when it’s winter” (KA)

and,

“Yeah. As I say I can’t wear them with these [points to sandals]” (DA).

Another barrier described during interviews was finding the time to moisturise feet due to having to wait for them to dry:

“How can you put cream on your feet? You’re just going to be slippy sliding about in your shoes all the time” (LA).

Other participants had to wear potentially unsuitable footwear due to their occupation:

“The other major problem I have is that I have to wear safety boots at work. Steel-capped safety boots and my big toe has hard skin build up” (LA).

Importantly, when participants were asked whether they had discussed these issues with the DSP, they tended to answer in the negative. One participant stated that although he knew he was referred to the FPS by his Diabetes Nurse, he failed to see that there was an issue with his feet and therefore, felt there was no reason to make any self-care changes.

#### **4.5 Diabetes self-care support**

During interviews participants did not only discuss the self-care of their feet but also about how they managed their diabetes overall, this mainly centred on diet and exercise and could be indicative of the focus of diabetes self-care advice and support:

“So they said, diet and exercise. So that’s why I’ve got an allotment, I just come up most days and work on it. That’s my exercise. Diet, we still have chips and stuff like that but we don’t go mad. They told me, the doctor told me that I can

have anything really, but just don't binge. So it's having a slice of bread instead of half loaf, you know. As you get older you do start feeling twinges and things like that, I just try to keep on top of it" (NA).

However, some participants also discussed some of the difficulties they have with stopping a risky behaviour which then had an impact on other aspects of diabetes self-care, suggesting it can be difficult to balance behaviours and they are intricately linked:

"It's been five years since I stopped smoking, but I'm still eating, compensating for a cigarette. I lost a stone because they used to weigh us at this diabetic meeting, they weighed us and sometimes I lost, sometimes I didn't, but I've put it back on and I don't know why. I still try and eat sensibly, and I'm still walking and...I can't do a lot of exercising because I have COPD, so my breathing is not... it doesn't help me, I try....I mean, touch wood, it doesn't hold me back really, it's just hills I can't walk up" (DA)

Other participants also described some of the 'risky' behaviours they adopted in managing their diabetes, suggesting that although they know there may be risks to not following medical advice they take chances anyway:

"Sometimes I get...if I eat something sweet I...I miss the sweet thing...I take another tablet of insulin. Actually I have to take one tablet of 500 milligram...I have to take another tablet to balance it" (BA)

and;

"I struggle with weight loss, I know there's programmes where you can go, and do twelve weeks of cooking, twelve weeks and learning how to do more...watching what you eat...but the actual diet in itself, don't get me wrong, it's my fault what I put in my mouth" (SA).

This could suggest that the DSP may also be required to reinforce messages around healthy behaviours in relation to diabetes should patients disclose risky behaviour. However, DSPs would need the relevant training in order to do so.

#### ***4.6 Physical interventions/checks***

When participants were asked about their clinic appointments what they tended to remember most was the physical checks and interventions that were performed, suggesting the main objective of bio-medical interventions are achieved:

"There was treatment on my feet...erm...on my toes that was good. Removed some of the hard skin...pieces of skin" (CA) and "All these tests she did...you know checking my feet were still alive...you know with the pulse and things" (DA).

Participants recalled interventions such as removal of a verruca, cutting of toenails and having insoles provided for shoes. This description often came with an acknowledgment that these interventions relieved pain or discomfort. Many described suffering physical symptoms such as pain, numbness, and burning which limited their mobility. Accessing the FPS helped to alleviate many of these symptoms:

"Yes...when I move from the room...when [clinician] cut this...cauterised skin, I feel better...no pain" (BA), "I was trying to keep it as [clinician] had left them, because I was so pleased when I went running, because there was no pain" (KA) and "Like today they feel a little bit numb, but I can live with that. I was worse when they were painful. When they are painful, they're painful" (NA).

However, there were some interventions that two participants revealed caused more discomfort:

"...a toe straightener. Because I've got two toes that are deformed, so it was to try....oh but it killed me you see" (AA)

and,

"The last time I was here, they made me some little prosthetic things to go in between the toes, which I couldn't actually put up with eventually, but I did give them a go" (RA).

It was unclear whether these unsuccessful interventions were discussed in subsequent FPS review meetings.

#### **4.7 Views on the FPS**

Participants expressed their views of the FPS and these fell into three main sub-themes (1) clinical location, (2) clinic appointments and waiting times, and (3) FPS staff and service provided, these sub-themes are detailed below:



### **4.7.1 Clinic location**

Almost all participants expressed their satisfaction at being able to attend clinics locally in their community, suggesting appointments that are easy to get to and near to patient's homes is a positive element of a service:

"So for the [FPS] to come you, I don't mean your home, a surgery near you, it's brilliant" (HA).

Often holding clinics at community-based health centres means that free car parking is available and this was also considered an advantage:

"It's quite relaxing coming here isn't it? We don't have the hassle with the car parking" (AA: R2)

Two participants, who had been referred from acute podiatry services, commented on how it was much easier it was attending the FPS, than attending their hospital appointments:

"It's nothing for me to come here, where it was a half a day's job going to the podiatrist up there [hospital]...half a day's job, but here it's not bad" (MA).

Another two participants discussed having their initial assessment appointment in a clinic that was a significant distance from their home, which caused them a problem. Both requested future appointments are nearer to them and this was actioned by the FPS:

"They [FPS] sent me to [clinic] and it's very far away. I went there once and I contacted them [FPS] and I said I can't come around because my appointment is so far away for me and so they sent me here" (BA).

### **4.7.2 Clinic appointments and waiting times**

Participants also reflected on the clinic waiting times and how they were very rarely left waiting long to go into their appointment, meaning that they could plan how long appointments would take effectively:

"When I come along there's never been a long waiting time or anything like that" (JA)

and,

"I was seen quickly" (KA).

Although, in general people did not discuss how long they had to wait for their first appointment to see a DSP, there were two who discussed having a problem receiving appointments when they were expecting one. One participant was waiting for an assessment appointment after a referral from another service:

"I got a letter from the surgery nurse saying that she'd actually done the referral, and that they would be in touch...I actually rang [the hospital] one day and said, 'I've been referred to the foot clinic, but I've not heard anything' I knew it it's quite a while afterwards that I actually got any communication between the two appointments" (RA).

Another participant explained that she had to ring the FPS for a review appointment that she was expecting but had not received:

"Just this last appointment, I had to ring and get it. I don't know. It was a blip or something..." (QA)

#### **4.7.3 DSPs and service provided**

Almost half of participants made positive comments about the DSP that examined them, suggesting that the clinician's had a positive impact on the experiences of patients:

"[I] saw [DSP] and [clinician] is absolutely fantastic" (HA)

and,

"...efficient I think, very well informed and professional" (LA) and "yes a nice [clinician], professional" (BA).

All participants, in some way, expressed appreciation and praise for the service as a whole using words such as "wonderful", "marvellous" and "amazing". Other participant comments about the service included:

"All I can tell you honestly is that I'm more than happy with the way I've been looked after" (GA), "my feet are fine as far as I'm aware, so I've nothing but praise for the [service]" (KA).

## **4.8 Potential improvements to FPS provision**

Generally, most participants, when asked how the FPS could be improved, repeated or reinforced the positives of the service and believed had nothing they could suggest directly for improvements. However, there were three participants that did have ideas for improvements as part of this service evaluation and these are outlined below.

### **4.8.1 Participant suggested improvements**

Of the three participants that directly offered suggestions for improvements to the provision of the FPS, one participant suggested that information leaflets given during consultations could include links to online resources showing how to put the advice given into practice:

“The paperwork was fine, but I think that I'd have been more likely to search online for additional advice or be directed to that to show me, because I'm a practical learner rather than that necessarily a reader” (CA).

The second suggestion was that people should be given the opportunity to choose and book their next appointment date while still in the clinic:

“The only bad thing is that when I've seen [clinician] she doesn't give me another appointment...because I'm on a timescale I could say like 'could I have ten to two in a months' time or five weeks' time'” (EA).

The third was that the service should be offered to more people:

“Maybe offer the service to more diabetes people because if they've been like me...I mean, I tend to look at people feet more now and I think, they're dry, they're cracked. Just sort of realise how important your feet are” (HA).

These suggested improvements should be considered by the FPS to improve their service.

## **4.9 Unexpected findings - wider service delivery**

Throughout interviews participants referred to their experiences of the diabetes services as a whole and although many of these references were not relevant to this service evaluation, recurrent themes were around (1) the accessibility of other services, (2) comments about appointments in other services, and (3) diabetes support as a whole

suggesting that these elements of healthcare provision is important to patients and getting these elements right will generally improve patient experience of health services.

## ***Conclusion***

This chapter has explained that by undertaking methodical and systematic qualitative data collection in the form of semi-structured interviews and a comprehensive analysis of the data, four clear themes have been identified these were (1) Referral mechanisms into the FPS, (2) The impact of the FPS (3) Views of the FPS, and (4) The potential improvements to the FPS. All these themes describe the experiences of people using the FPS in Leeds and can lead to the development of recommendations for quality improvement initiatives in the service. Chapter five will now interpret the significance of these findings in conjunction with the findings of the literature review, described in Chapter two and in light of what was already known about diabetes foot-care health services, and explain any new understanding or insights about how the current FPS can be improved.

## **Chapter 5 - Discussion**

### ***5.0 Introduction***

This chapter interprets and draws on the findings from the literature review, described in Chapter Two and makes connections with the specific feedback from patients in this service evaluation. This section discusses three main themes which composes of six sub-themes, and then goes on to describe any perceived limitations of this service evaluation:

The themes and sub-themes discussed are:

1. Referral Mechanism and Entry into the FPS
  - a. Specialist care to prevent a worsening condition
  - b. Referrals into specialist service from other care providers
2. The Impact of the FPS
  - a. Education/Advice
  - b. Physiological support
  - c. Supporting self-care management
3. Views on the FPS
  - a. Accessibility of health-care services

### ***5.1 Referral mechanism and entry into the FPS***

Referrals into the FPS can only be conducted by a health professional, usually from primary services such as a GP, practice nurse or a diabetes nurse who is integral to the care of patients with diabetes. Ensuring that these health professionals are aware of the symptoms of people with diabetes at risk of foot ulceration, how to test for the severity of the risk and then how to effectively refer into the FPS is paramount to ensuring the service is utilised to its maximum potential, enabling the service to secure the best outcomes for its patients. There were no themes around this identified in the literature review, however, there were two main themes identified from this service evaluation, which are discussed below:

#### ***5.1.1 Specialist care to prevent a worsening condition***

Foot complications as a result of diabetes, is a widespread issue throughout the world. In most cases, with the right early medical intervention, acute foot ulceration is considered to be eminently preventable (Ceriello, Gavin, Boulton, et al; 2018). However, there is conflicting evidence to support this. In two

systematic reviews conducted by van Netten, Price, Lavery et al (2016) and Hoogeveen, Dorresteijn, Kriegsman et al. (2015), it was found the literature suggested there was very little high quality evidence to support the use of early interventions with an aim to prevent first foot ulceration in risk groups of patient with diabetes. The Berlin Declaration, described in Chapter One, advised that much of early diabetes care should take place in the primary care setting. However, to ensure the best possible outcomes for people, it is essential that primary care is supported by health professionals with specialist knowledge in key diabetes care provision. This specialist care will be fundamental in reducing referrals due to complications, which are continually increasing as the diabetes epidemic grows. The benefits of specialist intervention in the care of diabetes can be seen globally from the many integrated care models that have been developed and successfully implemented. The Berlin Declaration fundamentally supports the case that specialist care, underpinned by an integrated multidisciplinary team, will assist primary care to work effectively with both health professionals and people with diabetes to ensure better outcomes for all (Ceriello, Gavin, Boulton, et al; 2018).

The identification of people with diabetes who are at greatest risk of foot ulceration is relatively straightforward, if it is done by a health professional with training specifically designed for the clinical examination of feet (Boulton, Vileikyte, Ragnarson-Tennvall and Apelqvist 2005). In his article, Kar (2014) builds on the work of Boulton et al; (2005) by discussing the 'super six' model of diabetes care. This super six has a primary aim of identifying areas in the patient diabetes pathway, where the specialist health professional is paramount. It includes antenatal diabetes care, adolescent diabetes care, renal diabetes care and insulin pump and foot diabetes care. Kar (2014) also discusses that the provision of this care may vary depending on local health provision, relationships and the willingness of multiple providers to work together. However, Kar (2014) stresses that the role of the specialist diabetes health professional, in the super six disciplines, is vital in the battle against the life threatening complications linked to diabetes.

As previously described in Chapter one, NICE (2011) published 13 Diabetes Quality Standards (QS) outlining the standards of care people with diabetes should expect to receive. QS10, was specifically around the care of the diabetic foot, proclaiming a significant milestone for the care of people with foot complications as a result of diabetes. QS10 states that "People with diabetes with or at risk of foot ulceration receive regular review by a foot protection team in accordance with NICE

guidance". For QS10 to be fully achieved there must be a sufficiently resourced, accessible and appropriately skilled workforce. The diabetes specialist podiatrist (DSP) is typically the leading figure within the FPS. Yet McInnes and Stuart (2011) argue the DSP role is poorly defined. It refers in particular to the skills and training requirements to undertake their role effectively with under a third of DSPs holding a Master's degree (partially or fully completed) and less than half holding a post-graduate qualification. In their study Bacon and Borthwick (2013) supports these findings. They found that changes to models of health care provision have influenced the development of the DSP as an established specialist in the management of diabetic foot, often in the absence of both the underpinning credentials and a properly defined career pathway.

This being said, it could be argued that regardless of the absence of credible qualifications or career pathways, the evidence suggests the role of DSP does improve the outcomes of people with diabetes. Gibson, Driver, Wrobel et al. (2014) examined whether the interventions of specialist foot care in primary care settings created different outcomes in people who had episodes of hospitalisation and amputation. They found that patients who had received care by a specialist podiatrist in the year prior to a diabetic foot ulcer was linked to a lower risk of amputation. These findings were also supported by the study carried out by Paisey, Abbott, Levenson et al. (2018). They found that the introduction of a DSP led FPS resulted in a significant reduction in major amputation frequency within two years. They also found that failure to improve unsatisfactory FPS provision resulted in continued high amputation rates.

Although it is still too soon to assess the economic impact of the FPS in Leeds due to the short length of time it has been in operation, the evidence suggests that in time, Leeds should start to see a reduction in its lower limb amputation rates due to diabetes. As described, studies consistently find that patients who have access to specialist provision within primary care settings, have better long term outcomes. In addition to this evidence, this service evaluation has allowed for a viewpoint beyond statistics to the real and tangible effect of having a specialist involved in their care has on patients. The participants involved in this evaluation unfailingly reiterated the professionalism and the depth of knowledge of the DSPs to support self-care. The physical interventions often provided relief from pain and psychological support to help alleviate anxieties, reiterating the vital need for specialist care to prevent a worsening condition.

### **5.1.2 Referrals into specialist service from other care providers**

In the UK, referrals into a specialist service tend to come from primary care settings because primary care services tend to provide the first point of contact for people in the healthcare system. Acting as the 'front door' of the NHS, primary care includes general practice, community pharmacy, optometry and dental services. Therefore, when people first start to experience issues with their health and in particular to this study, their feet, primary care or General Practitioners (GPs) will usually be the first point of contact in addressing those concerns.

NICE (2011) states that adults at moderate or high risk of developing diabetic foot problems should be referred to a foot protection service. This will ensure people are assessed at an early stage and then reassessed at regular intervals, which can reduce the likelihood of them getting foot ulcers or other foot problems. In their study, Manu, Lacopi, Bouillet, Vouillarmet, Ahluwalia, Lüdemann and Van Acker (2018) aimed to assess the referral patterns for people presenting with diabetic related foot conditions from primary care to specialised diabetes foot care services in four countries (France, the UK, Germany and Spain). They found that delayed diagnosis and delayed referral for those presenting with foot ailments is common in many countries including the UK, and therefore there is a significant need to improve the management of patients and referral pathways for people with diabetes experiencing foot problems. This is supported by the study conducted by Pankhurst and Edmonds (2018), who found that there were significant delays with referrals from primary care to specialist multidisciplinary diabetes foot clinics. This often resulted in people presenting to secondary services with a worsening or urgent condition. Both studies suggest that this delay in referrals could be due to a poor understanding of the symptoms for referral, the urgency with which some symptoms needed to be treated, a general lack of understanding of who to refer, and when and how to make the referral. It was also identified that there seemed to be a lack of training to help primary care professionals understand the warning signs relating to people with diabetes presenting with foot problems. Delayed referrals could also be attributed to a failure of appreciation for the role of the FPS intervention in preventing diabetic foot ulceration (Pankhurst and Edmonds 2018).

This service evaluation highlighted a particular issue where participants, with a diagnosis of diabetes, described presenting to their GP with foot problems and had not been referred on to the FPS for further investigation and treatment. This led to a worsening condition for two patients and for one patient, hospitalisation for



several months with Charcot Foot and required an intensive treatment regime to prevent full lower limb amputation. It is vital that key primary health care professionals, who are usually the first point of access for people suffering foot complications, understanding the symptoms, triggers and process for referral into the FPS.

This being said, it could be argued that delays inadequate treatment for foot issues the issue could be the result of patients seeking help in the first instance. Individuals, with slight or non-painful symptoms, may not present to their GP at all, therefore, missing the opportunity of getting the right treatment before their condition becomes urgent. This was a finding of the study conducted by Baba, Foley, Davis and Davis (2014), who found that foot abnormalities such as dry skin, callus and fissures were considered normal in many patients with diabetes, and even suggested that these features were often unnoticed, downplayed or disregarded. In addition to this, it was also found that even common observable foot problems such as deformity and infections were not considered by people with diabetes to seek medical intervention, especially if the symptoms remained asymptomatic. These findings were endorsed by the study conducted by Lange and Piette (2005) who found that illness is usually perceived in conjunction with the experiencing of physical symptoms, such as pain, which only then, will lead the patient recognising that medical intervention may be required. Therefore, to support patients in the UK, NICE (2017) recommends that "all people with diabetes should receive annual health checks to monitor and manage their condition, as well as reduce the risk of complications associated with the condition, such as heart disease and amputations". This examination, along with other associated checks, should identify people at moderate or high risk of foot ulceration and should be referred to secondary specialist services (Mayfield, Reiber, Sanders, Janisse and Pogach 2004).

This service evaluation suggests that over two thirds of the participants interviewed indicated the point of referral into the FPS was via their diabetes review appointment, with almost half suggesting that they hadn't realised that their feet were at a moderate or high risk of ulceration. This combined with the fact that all patients had experienced some form of change in their feet, with some not overly worried about this, suggests the enormous importance of regular diabetes reviews that involves a thorough check of the foot health of the patient.

This three faceted approach: (1) GPs and other appropriate primary care professionals adequately trained in identifying people at a moderate or high risk of

foot ulceration (2) clear referrals pathways into the FPS and (3) ensuring people with diabetes receive an annual review, could result in significantly reducing the risk of foot ulceration.

## **5.2 The impact of the FPS**

The evidence to suggest that the FPS had a positive impact on the people within its care for was overwhelming. In this service evaluation, all but one participant described at least one element of the service provision that allowed them to make positive choices in the way they manage their foot health. Several participants also suggesting they had adopted several changes to the way they cared for their feet to reduce the risk of ulceration. The themes around the impact of the FPS are outlined below:

### **5.2.1 Education/Advice**

The Oxford Dictionary (2018) defines education as “the process of receiving or giving systematic instruction” which could suggest that those being educated are passive objects that merely absorb instruction. However, Smith (2015) goes into much more detail. In his analysis he defined education as ‘the wise, hopeful and respectful cultivation of learning, undertaken in the belief that all should have the chance to share in life’ he underpins the principle that education should empower people to make decisions that allow them to flourish and be happy. This definition suggests that people should not be passive in the way they receive education, in fact, the sharing of knowledge should support the vision of the World Health Organisation (WHO 2017). They describe health education as an amalgamation of learning and experiences, which have been designed to assist people and communities to improve their health by increasing knowledge and influencing attitudes.

It has long been considered that health education is an effective way to improve outcomes for patients. Ahmad Sharoni, Minhat, Mohd Zulkefli and Baharom (2016) found that education led to increased effectiveness of the self-care of the feet in people with diabetes and also subsequent follow-ups and evaluations had a significant effect in reducing the risk of developing foot ulceration. This was supported by the findings in van Netten et al’s (2016) study, which revealed a decrease in the risk of ulceration in patients who changed their behaviour after an educational intervention. Interestingly, this contrasts with the findings of the systematic review conducted by Dorresteijn and Valk (2012), who reviewed the evidence of patient education for preventing diabetic foot ulceration. They found

that although education of people with diabetes is widely advocated and implemented as standard practice, there is little scientific evidence that demonstrates that patient education alone is effective in achieving reductions the prevalence of ulceration. However, Dorresteijn and Valk (2012) do suggest that these findings are based on a lack of quality evidence rather than evidence of no effect.

Despite this, it is not a new concept that people living with diabetes should develop a range of knowledge and capabilities to gain an understanding that promotes health and well-being. This will allow them to have greater control over the management and treatment of their disease. However, it could be argued that health professionals are still grappling with how to effectively support patients to attain the skills needed to manage their diabetes. Whilst people can be empowered through education to take responsibility for, and control the management of their disease, and the support of health professionals is integral to the long-term success of patients' achieving their own goals (Cooper, Booth and Gill 2003). Therefore, Cooper et al; (2003) argue that the role of the health professional as an educator demands an understanding of the theories that underpin patient education to promote and encourage autonomy. It could be argued that this provides a case for the integration of medical and social sciences into professional education, in order to ensure the health professional becomes one of supporter and educator rather than a systematic provider of information.

In Chapter 2, the literature review found suggested that peoples' level of education and awareness around their diabetes was varied dramatically. It was also highlighted that, despite people receiving information about how to care for their feet, they sometimes chose not to follow their health professional's advice. The findings also recognised that any educational sessions should be delivered by health professionals on a regular or semi-regular basis in order to assist in reinforcing key messages about effective foot-care.

In their study, Gale, Vedhara, Searle et al. (2008) found that many patients with diabetes hold beliefs about foot complications that are somewhat different from established medical evidence. Significantly, the beliefs held by patients may lead to the adoption of self-care behaviours that could hinder the effective communication between individuals and health professionals and therefore, potentially increase the risk of foot complications and ulceration. Gale et al; (2008) conclude that it is vital for health professionals to create opportunities within clinical appointment to explore patients' beliefs about the causes and

prevention of foot complications and then tailor their advice to take account of these beliefs. The findings of Gale et al; (2008) is supported by the study conducted by Mayfield et al; (2004) who determine that health professionals should undertake an objective assessment of a patient's current knowledge and care practices, using this to tailor advice to help people understand the issues and consequences of not taking appropriate action when certain risk indicators occur, such as the loss of foot sensation and the importance of foot monitoring on a daily basis, including nail and skin care and the selection of appropriate footwear.

During this service evaluation, it became evident that certain elements of the education and advice delivered by DSPs was well received by participants. There was also an acknowledgement by participants that education and advice was a particularly good aspect of the care they received. It was helpful in assisting them to manage their foot health in a pro-active way. However, this evaluation was not able to assess how much of the education and advice given was absorbed by patients, especially around the individual key guidance patients needed in their particular areas of care. In order for the FPS to be really patient centred, the DSPs as supportive educators should have an understanding of the key theories that reinforce the principles of effective patient education, whilst ensuring they recognise patients' self-perceived understanding of their condition. They then should tailor their advice to promote and encourage the patient to become empowered to manage their own diabetes and footcare health.

### **5.2.2 Physiological support**

The FPS, as previously described, is a specialist preventative healthcare service that treats patients who are either at high or moderate risk of getting an ulcer and people that have recently had a foot ulcer and remain at moderate or high risk of suffering another. In this chapter, the emphasis on education and the empowerment of patients to adopt self-care routines has already been described. However, it is still relatively unclear what the emotional impact of being at moderate or high risk of foot ulceration has on patients (Singh, Armstrong and Lipsky 2005).

There remains very limited data on the emotional status of patients with a heightened risk of developing foot ulceration. However, there has been some, limited investigation into the subject. In their study Hagger and Orbell (2003) sought to examine the relationship between a patient's portrayal of illness, their coping behaviours and illness symptoms. They found that if patients perceived

their illness as controllable or curable, there was a significant positive impact on their psychosocial well-being. On the other hand, they found the opposite was true of those patients who believed they were unable to control or cure their illness. In their study Beattie, Campbell and Vedhara (2014) aimed to investigate the emotional and behavioural effects of living with a heightened risk of foot ulceration in people with diabetes. Their findings supported those of Hagger and Orbell (2003) in that a lack of perceived control in maintaining healthy feet, along with the fear of ulceration that may lead to the need for amputation, would increase the prevalence of negative emotions such as anxiety and worry in individuals.

Although limited, this suggests there is some evidence to validate the need for psychological support as an effective method of supporting patients' self-care. However, a lack of mental health provision with specialist diabetes knowledge required to deliver this psychological support means that often there is an expectation for non-mental health professionals to learn and use these practices (Graves, Garrett, Amiel, Ismail and Winkley 2016). In their study Graves et al; (2016) explored the experiences of nurses who had received training in six psychological skills to assist in supporting patients' with their self-care of type 2 diabetes. They found that nurses were concerned about over-stepping the professional boundaries of their role when providing psychological support during consultations. As they were not qualified psychologists, there was a feeling they may be doing more harm than good. However, despite these concerns, the nurses in the study did recognise that having some psychological training was valuable and transferable to better support patients.

Contradictory to the study conducted by Graves et al; (2016), van Dijk-de Vries, van Bokhoven, de Jong, Metsemakers, Verhaak, van der Weijden and van Eijk (2016) argue that patients primarily see health professional as specialists regarding the biomedical management of diabetes and do not expect to have a discussion about their emotional and psychosocial state in their diabetes consultations. The study also found that while younger patients seemed more open to discussing their psychosocial issues, older patients felt that this was not expected or required. This is in contrast to the findings of the literature review described in Chapter two, which found that many patients living with the threat of diabetic foot ulcers had strong feelings of powerlessness over their disease, which often led to feelings of depression. It was also found that many patients expressed how they appreciated the empathy and reassurance from health professionals involved in their care, they felt health professionals should not only educate on the physical aspects of managing their feet, but also provide support around the

psychosocial impact of living with the threat of foot ulceration. This, combined with the study conducted by Graves et al; (2016) suggests that the ability to be able to deliver this kind of psychological support with confidence, could have a positive impact on the care patients receive.

The findings in this service evaluation support the evidence that psychological support during appointments was an important part of the FPS service and a source of reassurance and support for patients. This was especially pertinent to those patients that had previously suffered from foot ulceration and were at a high risk of suffering another. Patients described feelings such as relief, comfort and hope for an improved condition through having the support of the FPS. These findings suggest that there is a need for DSPs to consider the psychological needs of their patients and to support the appropriate interventions to address any anxieties expressed. These interventions should challenge peoples' beliefs around the control they have over their condition, and in so doing, empower them to develop pro-active emotional and behavioural responses in their ability to manage their feet. However, this added element of the DSP role should be limited, as there should be support from mental health services in the wider system which would accept referrals from the FPS where there were more serious concerns about the emotional well-being of an individual.

### **5.2.3 Supporting self-care**

It is widely acknowledged that people diagnosed with long-term conditions often need to make a series of alterations to their lives in order to be able to manage their condition themselves. In their article, Corben, Rosen and The Kings Fund (2005) reviewed the current literature people's self-care of their long-term conditions, with a particular focus on patients' own perspectives about self-care. They found that patients identified a process that they typically needed to go through which allows them to change their self-care behaviours over time. Some people chose not to manage their condition effectively, whilst others found ways to incorporate the self-care of their condition into their lifestyle with varying degrees of success. This indicates that an individual's response to receiving a diagnosis of a long-term condition and how they choose to manage it, is unique to the individual.

This supports the findings from the literature review discussed in Chapter two, where participants described that despite receiving self-care advice around their feet and the ways in which self-care could reduce the ill effects of diabetes, they still chose not to follow health professional advice.

Corben et al; (2005) identified three key themes to emerge from their literature review around what support can be offered by healthcare professionals to enable patients to take control of their diabetes foot care, these were;

1. Developing good patient/health professional relationships,
2. The provision of clear and concise information about their condition and how to self-care and,
3. Flexibility within service provision to allow accessibility.

In this service evaluation almost half of patients described the professionalism and how well informed the DSPs were, and almost all praised the service overall, describing how they felt looked after, suggesting that the DSPs were effective in building up good relationships with their patients. The majority of participants described how they had started or increased some self-care routines as a result of advice received from DSPs, and that the advice given was clear and concise and enabled them to develop good self-care practices to maximise the prevention of a worsening condition.

During interviews, many participants described the self-care routines that they had adopted as a result of the FPS which supported effective foot self-care. These routines included adopting practices such as moisturising and checking feet regularly. However, in van Netten et al's (2016) systematic review, to investigate the effectiveness of interventions to prevent foot ulcers in people with diabetes, found strong evidence to support the self-monitoring of foot skin temperature, with action taken when irregular temperatures are found, could significantly reduce the risk of first foot ulceration. The measurement of foot temperature was not described by participants in this evaluation and therefore, it could be assumed that this is not a self-care process suggested by the FPS.

Another key finding from this service evaluation was the barriers or obstacles reported by participants that prevented them from implementing the advice of the DSPs. It was unclear whether clinicians were aware of such barriers to foot self-care and whether support was provided to overcome them. In their study, Laranjo, Neves, Costa, Ribeiro, Couto and Sá (2015) assessed the perception of facilitators, barriers and expectations in the self-care by patients. Three major themes were identified:

1. Barriers relating to the management of diet, physical exercise and glycaemic control.

2. Barriers related to undertaking physical exercise including tiredness, muscle pain, joint pain and other co-morbidities.
3. Patient's translation of information and knowledge, as well as social and family ties. These often acted as positives in some situations and as barriers in others.

Interestingly the aforementioned barriers to adhering to foot self-care identified were not those most commonly discussed by participants taking part in the service evaluation. Instead, several participants described actual physical barriers that prevented them from taking up self-care advice. These included the provision of insoles or the need to wear risky footwear i.e. safety boots for work that tended to rub the toes. Participants explained that although they wanted to wear insoles as advised by DSPs they were only provided for one pair of shoes and they had several pairs that they often wore. It was unclear whether patients could have more than one set of insoles provided by the FPS.

It is obvious that there is no single approach to supporting patients in self-care, and arguably, neither should there be. Not everyone will choose to be actively involved in managing their condition. However, there are many people that will engage with professionals in order to find solutions for an improved condition. Health professionals that ground their recommendations based on the reality of patients' lives will significantly improve effective patient-centred care.

### **5.3 Views on the FPS**

The primary aim of this service evaluation was to gain an understanding of how patients using the FPS experienced the service. In doing this participants expressed their views on a range of elements. A key factor was the accessibility of the FPS.

#### **5.3.1 Accessibility of health-care services**

Gulliford, Hughes, Gibson, Beech, Hudson, Morgan and Figueroa-Munoz (2002) states access to healthcare "is concerned with helping people to command appropriate health care resources in order to preserve or improve their health". However, the actual facilitation of 'access' is a multifaceted concept. Gulliford et al; (2002) go on to describe that there are at least four aspects to patient perceived access within health care, these are:

1. Services, if they exist, have an adequate supply and therefore, people have the opportunity to 'have access' to them.



2. Services limit the financial, organisational, social and cultural barriers that restrict people to 'gain access' to them.
3. Services are based on affordability, physical accessibility and suitability, not merely adequacy of supply, and therefore, have 'equitable access'.
4. Services are based on relevance and effectiveness to enable people to 'gain access' to satisfactory health outcomes.

The availability, equitability and relevancy of services, in addition to the barriers people may face in trying to access them, have to be considered from differing perspectives based on the services being provided.

In 2006, the UK Government and the Department of Health released a white paper 'Our health, our care, our say: A new direction for community services', outlining their plans to tackle inequalities by improving patient access to community services with a clear focus on those people with long term needs (Department of Health 2006). The paper described how people with long-term conditions would be supported to manage their condition themselves with the right local specialist care. The white paper outlined the need for specialists to be fully engaged locally as partners, with the key feature of providing a patient-centred service from professionals with the right training.

Lawton, Parry, Peel and Douglas (2005) conducted a study to explore the views of newly diagnosed patients with diabetes when services are undergoing a major reorganisation. By doing this they provided recommendations to maximise the opportunities of delivering quality health care. Participants in this study expressed the need to have easy access to healthcare professionals which would allow them to have prompt answers to their questions and concerns. In this service evaluation, several patients expressed confusion about who it was they would contact if they developed a worsening condition between appointments. This suggested that patients were unclear on who to contact with any concerns they might have.

Lawton et al; (2005) also described how convenient to travel to and from appointments is also an important factor for patients, and the evidence suggests that patients are most likely to attend appointments when these are in accessible locations. In Chapter two, the literature review outlined the sub-theme around patient's access to services and resources. Participants perceived a shortage of community based specialist diabetes centres or specialist footcare clinics, especially for those living in rural areas. In this service evaluation the accessibility of the FPS

in terms of being a community based healthcare provision, was also identified as an important theme by attendees. Over half of participants highlighted the delivery of the FPS in a local primary health centre as positive; the environment was quiet, appointment waiting times were short and parking was available. Patients also commented that, when given appointments that were a significant distance from their home, once they had contacted the FPS, they later received appointments that was closer. The only issue, discussed by two patients of the seventeen taking part in this evaluation, was the fact that they had to contact the FPS as they hadn't received an appointment they were expecting. One of these was an initial appointment and the other was for a review appointment.

#### ***5.4 Limitations of study***

This service evaluation has several limitations that warrant consideration. The lack of resource to recruit the services of an interpreter meant that only English-speaking participants could be included and therefore, the views of minority groups have not been included. Consideration should also be given to the 'opt in' process of recruiting participants. This may have biased findings, as participants who consent to take part in studies generally tend to be more compliant than those that decline. This further limitation may have arisen from the local nature of the study and the relatively small sample size. However, these limitations were reduced by recruiting patients from health centres across Leeds, therefore, it was possible to obtain a sample with a diversity of experiences. As also described in Chapter Three, the researcher in this study was evaluating a service in their place of work to prevent any unintended bias, the researcher worked closely with the University supervisor to ensure trustworthy results.

## **Chapter 6 - Conclusion and Implications for Practice**

There can be little debate that a diagnosis of diabetes is a life changing and often, if not managed carefully, painful and debilitating. One of the most important and most common complications of diabetes is the risk of diabetic foot ulceration and if the right medical treatment is not received, can lead to infection, lower limb amputation and even death. In addition to the distress to patients and their families, foot complications, as a result of diabetes, is a huge drain on limited NHS resources. Based on the recommendations of NICE, the Operational Delivery of the Multi-Disciplinary Care Pathway for Diabetic Foot Problems, in 2016, the three CCGs responsible for commissioning healthcare in Leeds, provided the funding to establish a quality driven, specialist led, diabetes FPS within a multi-disciplinary integrated diabetic foot pathway.

In order to evaluate the FPS from the service users perspective, it was determined that an investigation should be undertaken to expressly explore the views and experiences of patients using the service, to determine whether there were any recommendations that could be derived, in which to drive up the quality of the current provision of the FPS. After careful consideration of the various 'tools' that could be used to undertake this investigation, including research and clinical audit, a service evaluation was selected as the most appropriate method in which to effectively achieve the aims of this study. Once this was ascertained, it was then determined that qualitative data would be collected through a series of semi-structured, face-to-face interviews of patients who were at either moderate or high risk of foot ulceration and had received more than one appointment at the FPS. Recruitment then took place over ten weeks in four health centres throughout Leeds. There were seventeen participants interviewed in private rooms within the health centres to ensure confidentiality and privacy. Interviews were audio recorded using an encrypted audio device and transcribed verbatim following all data protection protocols and pseudonyms have been used throughout. A thematic analysis of transcripts was then undertaken, using NVivo software, to develop themes.

In Chapter four, the findings of these themes were described and Chapter five discussed these findings to compare with other studies and literature undertaken in this area. From this discussion, five clear recommendations could be identified in which the service could use to inform quality improvement initiatives of the future; driving up quality as a direct result of the experiences of the people using the service.

These recommendations are detailed below:

### **6.1 Improving referrals into the FPS from other care providers, including primary care:**

The importance of early detection of the groups of people with diabetes at moderate or high risk of ulceration, and then effective referral into the FPS, is imperative in enabling patients to be supported as a preventative measure before developing a worsening condition has been discussed in detail in Chapter Four. This evaluation highlighted that General Practitioners in primary care could be a targeted group of people to receive extra information and support, to ensure they are aware of the risks of people presenting with the recognised early symptoms of foot problems and how and when they should refer to the FPS. This study also identified that the annual diabetes review was instrumental in the early detection of potential foot complications, often when patients were unaware themselves of any issues. Therefore, this group of health professionals should be supported to continue this work, enabling patients to get the specialist care available to them in a timely way. This could be done by educating the workforce, raising the awareness of patients and families of the importance of attending their diabetes review and potentially a change to the patient's record with a flagging system when a patient with diabetes presents with problems with their feet.

### **6.2 The Impact of the FPS - Education/Advice – DSPs as supportive educators**

Many of the participants taking part in this evaluation were particularly positive about the education and advice given to them as part of their care. However, this evaluation was unable to assess how much of the advice given was absorbed by patients, especially around the key messages that were vital to their particular individual needs. A recommendation of this service evaluation would be for a quality improvement initiative to be undertaken in two areas. One would be to support DSP's development to become 'supportive educators' and ingrain the practice of first clarifying their patient's understanding of their condition, whether there are any perceived obstacles in taking advice forward, and then tailor their guidance to re-enforce or even de-bunk perceptions where there may be a detrimental effect to their ongoing foot health. This could be achieved by teaching health professionals more about the principles of self-care support using techniques such as motivational interviewing, with written information provided for patients to take away from their appointment.

### ***6.3 The Impact of the FPS - Education/Advice – Patient information retention***

A key factor is that information alone does not change behaviour, but it is certainly an important factor. Therefore, the second recommendation would be to undertake a further research study to gain an understanding of how much information is retained and understood by patients, in order to establish the best method of ensuring key messages are being absorbed and taken forward to enable the effective management of footcare health.

### ***6.4 The Need for Psychological Support***

Several participants taking part in this evaluation voiced their appreciation of the empathy and reassurance they received from their DSPs, suggesting that the clinician did not only offer bio-medical support, but also support around the psychological elements of living with the threat of foot ulceration. In providing this support, DSPs could help patients react pro-actively in managing their feet, therefore, improving outcomes. Therefore, a recommendation is that DSPs should be supported and possibly receive additional training, to develop their confidence, and a clear referral pathway onto other psychological services, to effectively support the psychological needs of their patients. Alternatively the Improving Access to Psychological Therapies (IAPT) service is being extended to support patients living with long term conditions, so referral to this service may also be an option in the near future.

### ***6.5 Supporting self-care***

In this service evaluation, all participants described how they had developed or desisted self-care practices as a result of the advice given by DSPs, with many describing several changes they had made. However, research evidence suggests that the self-monitoring of foot temperature could be an effective method in decreasing the likelihood of foot ulceration. The FPS could consider piloting this as an additional part of foot self-care support. This could be in addition to ensuring that DSPs discuss with patients any barriers that they may be facing in incorporating the advice given into their self-care routines to enable solutions to these barriers to be identified. More specifically, another recommendation in this area would also be for the FPS to provide more than one set of insoles for the different types of footwear and individual may wear. If this is economically unviable for the FPS, additional sets of insoles could be bought by patients and the DSP could ensure they are fitted correctly.

## ***6.6 Accessibility of health-care services - Patient appointments***

The setting for FPS has a direct impact on accessibility with community settings being favoured. A minority had problems with an expected appointment, and had to ring the service to ensure they had not been missed. Therefore, a recommendation of this service evaluation would be for the FPS to undertake a thorough review of their appointment system to ensure effective processes are in place for both first and follow-up appointments.

## ***6.7 Accessibility of health-care services – Who to contact?***

This service evaluation found patients were confused about who they should contact if they were concerned about their feet between their appointments with the FPS, therefore, the FPS could provide written information to ensure patients are fully aware of who they need to contact and contact details, should a problem occur.

This service evaluation has provided a detailed, systematic and thorough investigation of the views and experiences of people using the FPS in Leeds. From the results, the aims and objective of this study, described in Chapter one, have been achieved. Feeding back the findings and recommendations of this service evaluation will contribute to informing the future provision of the service. This will ensure the FPS continues to strive to be of the highest quality, thereby increasing the likelihood of desired health outcomes of people with diabetes and lowering the financial burden on the NHS by reducing the rates of lower limb amputation in Leeds.

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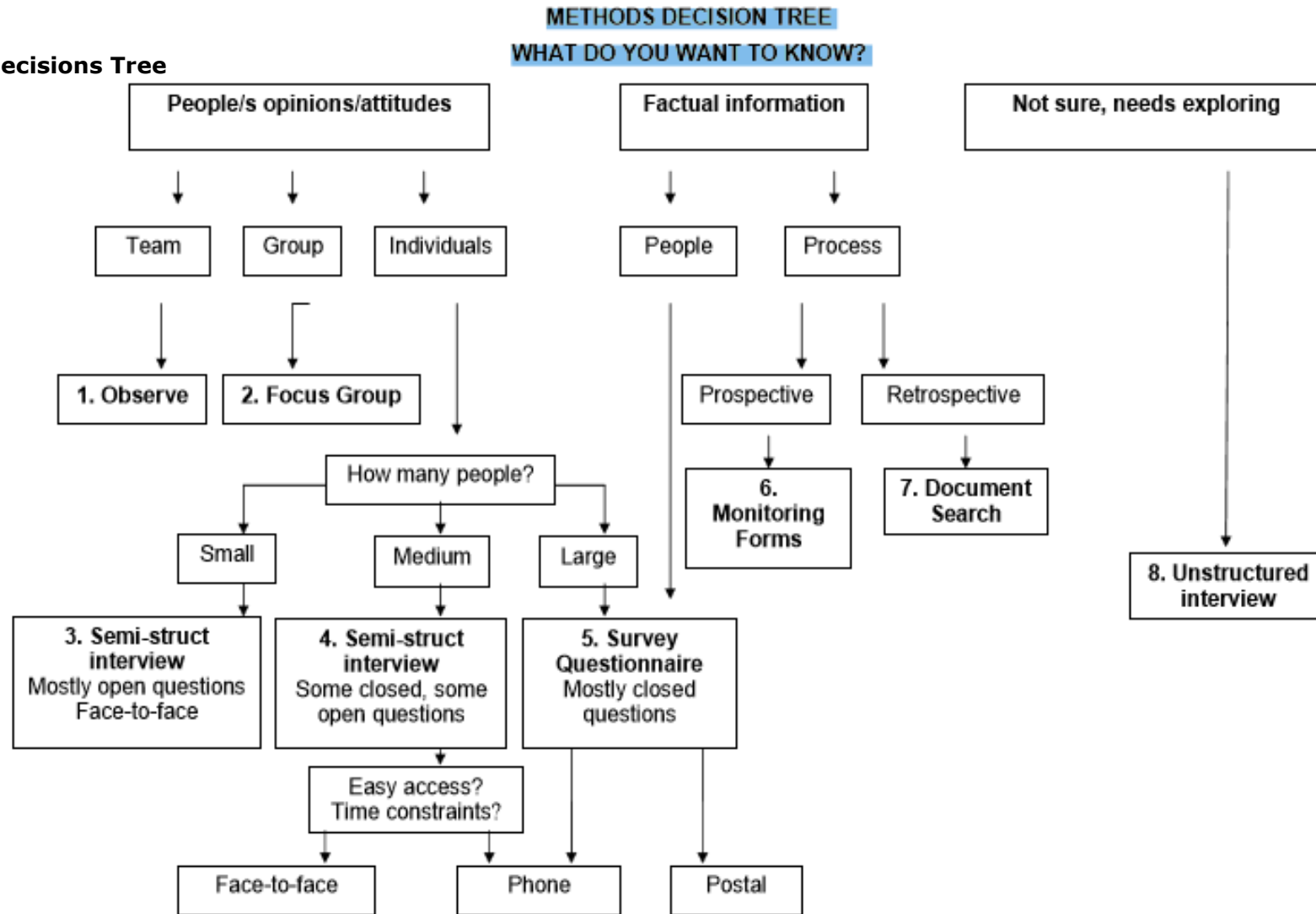
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**Appendix A**

**Method Decisions Tree**



## **Appendix B**

### **Topic Guide**

#### **Introduction**

##### **General background:**

1. When did you first notice a problem with your feet? How did it start?
2. Who was the first health professional you met when you started having problems with your feet?
3. What happened then? Did you see anyone else before you were referred to the Foot Protection Service?

##### **What was the experience of using the FPS service?**

You had an initial appointment with the Foot Protection Service a couple of months ago, and this is now a review visit, can you tell me:

1. What do you remember most about that first visit to the Foot Protection Service?
2. Was there anything you thought was particularly good about that first appointment?
3. Was there anything that was discussed at that first appointment that made you think about how you can care for your feet differently?
4. Are there certain aspects that you feel we should focus on to improve the Foot Protection Service?
5. Thinking about the care you have received as a whole, from the time you first realised you may have a problem with your feet, if you could change one thing what would it be?

## Appendix C

### Literature Review Search Terms

<b>Title</b>	'This is about your feet, this is important'. A Foot Protection Service for Diabetic Patients; a service evaluation of their views and experiences.				
<b>Limits</b>	Set a limit of articles publishes between 2011-2017. English. Only scholarly and peer-reviewed publications.				
<b>Places to search for information:</b>	PUBMED, CINAHL, Cochrane Library, PsycINFO				
Database searched	Search term used	Limits applied	Number of Initial Results	Number of Results after Initial Review	Date
PUBMED	((diabetes OR diabetic) AND (patient OR People) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	21	0	11.01.18
PUBMED	((diabetes OR diabetic) AND (patient OR People) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	243	30	11.01.18
PUBMED	((diabetes OR diabetic) AND (patient OR people) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	446	18	11.01.18
PUBMED	((diabetes OR diabetic) AND (patient OR people) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	157	5	11.01.18
PUBMED	((diabetes OR diabetic) AND (patient OR people) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	76	4	11.01.18

PUBMED	((diabetes OR diabetic) AND (participant OR individual) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	10	0	11.01.18
PUBMED	((diabetes OR diabetic) AND (participant OR individual) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	142	0	11.01.18
PUBMED	((diabetes OR diabetic) AND (participant OR individual) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	273	0	11.01.18
PUBMED	((diabetes OR diabetic) AND (participant OR individual) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	113	0	11.01.18
PUBMED	((diabetes OR diabetic) AND (participant OR individual) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	49	2	11.01.18
CINAHL	((diabetes OR diabetic) AND (patient OR People) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	21	1	11.01.18
CINAHL	((diabetes OR diabetic) AND (patient OR People) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	64	10	11.01.18
CINAHL	((diabetes OR diabetic) AND (patient OR people) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	100	14	11.01.18
CINAHL	((diabetes OR diabetic) AND (patient OR people) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	38	5	11.01.18
CINAHL	((diabetes OR diabetic) AND (patient OR people) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	6	0	11.01.18

CINAHL	((diabetes OR diabetic) AND (participant OR individual) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	6	0	11.01.18
CINAHL	((diabetes OR diabetic) AND (participant OR individual) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	21	0	11.01.18
CINAHL	((diabetes OR diabetic) AND (participant OR individual) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	33	5	11.01.18
CINAHL	((diabetes OR diabetic) AND (participant OR individual) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	17	1	11.01.18
CINAHL	((diabetes OR diabetic) AND (participant OR individual) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	2	0	11.01.18
Cochrane Library	((diabetes OR diabetic) AND (patient OR People) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	13	0	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (patient OR People) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	3	0	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (patient OR people) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	6	0	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (patient OR people) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	31	0	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (patient OR people) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	7	0	18.01.18

Cochrane Library	((diabetes OR diabetic) AND (participant OR individual) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	4	0	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (participant OR individual) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	2	0	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (participant OR individual) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	5	0	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (participant OR individual) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	12	1	18.01.18
Cochrane Library	((diabetes OR diabetic) AND (participant OR individual) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	7	0	18.01.18
PsycINFO	((diabetes OR diabetic) AND (patient OR People) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	4	0	18.01.18
PsycINFO	((diabetes OR diabetic) AND (patient OR People) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	12	3	18.01.18
PsycINFO	((diabetes OR diabetic) AND (patient OR people) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	19	8	18.01.18
PsycINFO	((diabetes OR diabetic) AND (patient OR people) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	7	3	18.01.18
PsycINFO	((diabetes OR diabetic) AND (patient OR people) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	1	0	18.01.18



PsycINFO	((diabetes OR diabetic) AND (participant OR individual) AND (opinions OR views) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	1	0	18.01.18
PsycINFO	((diabetes OR diabetic) AND (participant OR individual) AND (interpretation OR understanding) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	5	0	18.01.18
PsycINFO	((diabetes OR diabetic) AND (participant OR individual) AND (beliefs OR experience) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	12	2	18.01.18
PsycINFO	((diabetes OR diabetic) AND (participant OR individual) AND (perception OR perceive) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	9	0	18.01.18
PsycINFO	((diabetes OR diabetic) AND (participant OR individual) AND (feel OR think) AND (feet OR Foot))	2011-2017. English Only. Peer-reviewed	0	0	18.01.18

## ***Appendix D*** - Literature Review Study Characteristics

**Table 02. Characteristics of Primary Studies Included in this Review**

No.	Author	Year	Title	Design	Population	Aims	Objective
01	Hamzah Alzubaidia, Kevin Mc Narmaraba, Gloria M. Kilmartin, John F. Kilmartin and Jennifer Marriotta	2015	The relationships between illness and treatment perceptions with adherence to diabetes self-care: A comparison between Arabic-speaking migrants and Caucasian English-speaking patients	Cross Sectional Qualitative study	701 participants with type 2 diabetes: 392 Arabic Speaking and 309 English speaking	To identify whether different treatment methods are necessary for English-speaking versus Arabic-speaking people.	Improved adherence to foot treatment and foot ulcer healing rate. Health-related improved quality of life for Arabic-speaking immigrants
02	Andrew Hill and Gloria Dunlop	2015	Determining the patient-perceived impact of foot health education for patients with diabetes mellitus.	Qualitative study with semi-structured interviews	20 participants with either type 1 or type 2 diabetes	Understanding the impact of foot health education for patients with diabetes mellitus	Participant adherence to foot treatment. Foot ulcer healing rate, health-related improved quality of life.
03	Katarina Hjelm, and Esther Beebwa	2013	The influence of beliefs about health and illness on footcare in Ugandan persons with diabetic foot ulcers	Qualitative study with semi-structured interviews	14 Ugandan men and women, aged 40-79, with diabetic foot ulcer.	Understanding how beliefs about health and illness may affect self-care and care seeking behaviour	Improved self-care and care seeking behaviour. Participant adherence to foot treatment. Foot ulcer healing rate and health-related improved quality of life.
04	Mansoor Aliasgharpour and Nahid Dehghan Nayeri	2012	The care process of diabetic foot ulcer patients: a qualitative study in Iran	Qualitative study with semi-structured interviews.	11 patients suffering from foot ulcer disease who were hospitalized in Tehran	Clarify the care process for Iranian patients with diabetic foot ulcer condition.	Improved care processes for diabetic foot ulcer. Participant adherence to foot treatment. Foot ulcer healing rate and health-related improved quality of life.
05	K.J.Smith, G.Gariépy, N.Schmitz	2013	Self-reported use of diabetes healthcare services in a Quebec community-based sample: impact of depression status	Qualitative study with questionnaire at baseline and interviews after one year.	1175 adults with type 2 diabetes.	Ascertain the impact of depression on the use of and access to diabetes healthcare services.	Improved access to diabetes healthcare for people with diabetes and depression. Participant adherence to foot treatment. Foot ulcer healing rate and health-related improved quality of life.
06	Sarah Delea, Claire Buckley, Andrew Hanrahan, Gerald McGreal, Deirdre	2015	Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services	Qualitative study with semi-structured interviews	Ten males recruited from Prosthetic, Orthotic and Limb Absence	Investigate the experiences and attitudes of diabetic patients using footcare with active foot disease or lower limb amputations.	Improved health care model to reduce the prevalence of active foot disease or amputation. Foot ulcer healing rate and health-

	Desmond and Sheena McHugh				Rehabilitation (POLAR) Unit of an Irish hospital		related improved quality of life.
07	K. Hjelm, and J. Apelqvist	2016	Influence of beliefs about health and illness on self-care and care-seeking in foreign-born people with diabetic foot ulcers: dissimilarities related to origin	Qualitative study with semi-structured interviews	People aged 38–86 years; 13 born in European, 13 in non-European countries (all except one in the Middle East). All resident in Sweden for 7–60 years	To explore the beliefs about health and illness among foreign-born people with diabetic foot ulcers that might affect self-care and health-care seeking. To investigate whether there are dissimilarities related to origin	Improved foreign-born participant adherence to foot treatment. Foot ulcer healing rate and health-related improved quality of life.
08	S.A. de Almeida a , Geraldo Magela Salome´ b, *, R.A.A. Dutra b , Lydia Masako Ferreira BRAZIL	2014	Feelings of powerlessness in individuals with either venous or diabetic foot ulcers	Qualitative study with structured interviews	200 adult patients with type 2 diabetes with either venous leg ulcers or diabetic foot ulcers	Explore the feelings of powerlessness in patients with diabetic foot ulcers.	Health-related improved quality of life
09	Joe Feinglass, Vera P. Shively, Gary J. Martin, Mark E. Huang, Rachna H. Soriano, Heron E. Rodriguez, William H. Pearce & Elisa J. Gordon	2012	How 'preventable' are lower extremity amputations? A qualitative study of patient perceptions of precipitating factors.	Qualitative study with semi-structured interviews	22 patients at a rehabilitation hospital 2–6 weeks after a diabetes related amputation	Prevent amputations with coordinated care and motivated patient self-management.	Reduced amputation rates. Participant adherence to foot treatment, foot ulcer healing rate and health-related improved quality of life

## Appendix E

### Literature Review Coding Table

#### Development of analytical themes by using descriptive themes

no	Title	Author and Country	Coded Text	Descriptive Themes	Analytical Themes
1	The relationships between illness and treatment perceptions with adherence to diabetes self-care: A comparison between Arabic-speaking migrants and Caucasian English-speaking patients	Hamzah Alzubaidia, Kevin Mc Narmaraba, Gloria M. Kilmartincd, John F. Kilmartincd, Jennifer Marriotta AUSTRALIA	A substantial difference in the levels of functional health literacy was observed between the two groups. This highlights the need for clinicians to also tailor their communication strategies to the needs of ASPs when addressing the above-mentioned negative perceptions. ASPs might benefit, during medical encounters, from receiving currently available consumer medicine information sheets in Arabic, designed specifically for those with low English-language literacy levels to augment counselling process for those individuals	Differences between the literacy of the two groups highlights the need for clinicians to tailor communication strategies	<b>Health literacy as a barrier</b>
	The relationships between illness and treatment perceptions with adherence to diabetes self-care: A comparison between Arabic-speaking migrants and Caucasian English-speaking patients	Hamzah Alzubaidia, Kevin Mc Narmaraba, Gloria M. Kilmartincd, John F. Kilmartincd, Jennifer Marriotta AUSTRALIA	Conversely, some first-generation ASPs are potentially illiterate in their native language as well as in English. In such cases, encouraging family involvement with care might be more appropriate.	Illiteracy in both English and the patient's native language may act as a barrier to information.	<b>Health literacy as a barrier</b>

The relationships between illness and treatment perceptions with adherence to diabetes self-care: A comparison between Arabic-speaking migrants and Caucasian English-speaking patients

Hamzah Alzubaidia, Kevin Mc Narmaraba, Gloria M. Kilmartincd, John F. Kilmartincd, Jennifer Marriotta AUSTRALIA

There was greater adherence among both participant groups (ASPs and ESPs) when they had a stronger belief in the necessity of diabetes medication. To address patients' intentional non-adherence, a longstanding clinical challenge, healthcare providers should integrate the assessment of patients' perceptions about their prescribed treatment as part of routine care for all individuals with diabetes – particularly at earlier stages of treatment. Healthcare professionals should be aware of the collective cultural and health beliefs, attitudes and assumptions about medicines within Arabic-speaking communities. Our previous research found that ASPs unique collective cultural and health beliefs underlined their pessimistic cognitive appraisal of living with diabetes and embedded lower medication necessity beliefs and higher medication concerns compared with ESPs [45]. ASPs, who were typically diagnosed at a later stage than ESPs

Patient's perceptions about the need to take the prescribed medication should be incorporated into routine assessments to address reasons for non-adherence.

**Beliefs about illness (Reason for disengaging with healthcare professionals)**

The relationships between illness and treatment perceptions with adherence to diabetes self-care: A comparison between Arabic-speaking migrants and Caucasian English-speaking patients

Hamzah Alzubaidia, Kevin Mc Narmaraba, Gloria M. Kilmartincd, John F. Kilmartincd, Jennifer Marriotta AUSTRALIA

The cultural health beliefs of some Arabic communities may have a negative impact on patient's attitude to their condition and therefore their attitude towards managing their condition.

The cultural health beliefs of some Arabic communities may have a negative impact on patient's attitude to their condition and therefore their attitude towards managing their condition.

**Beliefs about illness (Reason for disengaging with healthcare professionals)**

Determining the patient-perceived impact of foot health education for patients with diabetes mellitus.

Andrew Hill, Gloria Dunlop UK

participants (regardless of whether or not they received structured or formal patient education) indicated a belief that structured or formal patient education is/would be beneficial, with very few indicating that they felt it is/would be of little benefit.

Whether or not patient's had already received formal education, almost all agreed that this would be beneficial

**Education around footcare**

Determining the patient-perceived impact of foot health education for patients with diabetes mellitus.

Andrew Hill, Gloria Dunlop UK

Further, regular sessions to reinforce this education would be of significant benefit,

For patient's that had received formal education, patient's requested access to additional regular sessions to reinforce messages

**Education around footcare**

Determining the patient-perceived impact of foot health education for patients with diabetes mellitus.	Andrew Hill, Gloria Dunlop UK	preferred the education to arrive sooner post-diagnosis	patient's wanted educational sessions near to post-diagnosis	<b>Education around footcare</b>
Determining the patient-perceived impact of foot health education for patients with diabetes mellitus.	Andrew Hill, Gloria Dunlop UK	Education, albeit unstructured and/or informal was, and is, being delivered by health professionals on a regular or semi-regular basis.	If formal education sessions had not taken place, patient's indicated that health professionals offered 'informal' advice.	<b>Access to 'informal' advice</b>
The Influence of Beliefs About Health and Illness on Foot Care in Ugandan Persons with Diabetic Foot Ulcers	Katarina Hjelm, and Esther Beebwa UGANDA	Education should be tailored to the patients' beliefs, understanding and social background and aimed at developing awareness of the seriousness of the condition.	Understanding patient's understanding, beliefs and social background of their condition can influence how aware patients are of impact of disease	<b>Beliefs about illness (Reason for disengaging with healthcare professionals)</b>
The Influence of Beliefs About Health and Illness on Foot Care in Ugandan Persons with Diabetic Foot Ulcers	Katarina Hjelm, and Esther Beebwa UGANDA	desired longer opening hours to get health education and help	A need to access help and information out of core hours	<b>Access to services</b>
The Influence of Beliefs About Health and Illness on Foot Care in Ugandan Persons with Diabetic Foot Ulcers	Katarina Hjelm, and Esther Beebwa UGANDA	Many have an underutilised potential for self-care management and need to be supported with diabetes education urgently to become aware of the threat and how to prevent it. Well-organised care, identification of the at-risk foot, and education	The need for timely and well organised education to ensure the awareness of the threat of diabetes to feet and how to prevent ulcers.	<b>Education around footcare</b>
The Influence of Beliefs About Health and Illness on Foot Care in Ugandan Persons with Diabetic Foot Ulcers	Katarina Hjelm, and Esther Beebwa UGANDA	Education is the most important preventive tool in Africa and should include simple and repeated advice targeted at both healthcare workers and patients.	Simple and targeted advice and education is deemed the most important preventative tool.	<b>Education around footcare</b>
The care process of diabetic foot ulcer patients: a qualitative study in Iran	Mansooreh Aliasgharpour and Nahid Dehghan Nayeri	The analysis of the findings in our research indicated that weak performance, lack of a precise screen over education, absence of team work, and lack of facilities lead to weak care	Lack of cross pathway team working to educate and care for patients suffering from a foot ulcer led to	<b>Multi disciplinary team function</b>

techniques of diabetic patients suffering from foot ulcer

weak healthcare performance

The care process of diabetic foot ulcer patients: a qualitative study in Iran

Mansooreh Aliasgharpour and Nahid Dehghan Nayeri

This issue indicates the weak administration of supervisors and the therapeutic team in follow-up contact and appointments, especially after hospitalisation

The ineffective function of administrative and supervisory support can cause issues for patients, especially around follow-up appointments

**Multi disciplinary team function**

The care process of diabetic foot ulcer patients: a qualitative study in Iran

Mansooreh Aliasgharpour and Nahid Dehghan Nayeri

One of the negatively effective shortages that were found through our explorations was the shortage of human resources. The majority of the team members stated that, "lack of availability to a trained individual and a nurse specializing in curing ulcers are among the main reasons for lack of success in curing the diabetic patients".

The lack of suitably trained health professionals is identified as a key issue in the effective treatment of diabetic foot ulcers.

**Shortage of human resources**

The care process of diabetic foot ulcer patients: a qualitative study in Iran

Mansooreh Aliasgharpour and Nahid Dehghan Nayeri

Shortage of specialist centres: another shortage was the lack of specialist centres for curing the diabetic patients. The doctors in the therapeutic team considered having specialist clinics for foot ulcer disease as crucial and some of them believed that, "in case of having no specialist clinic for the diabetic patients, doctors do not see themselves as responsible".

The absence of specialist clinics for the treatment of diabetic foot ulcers seemed to indicate health professionals did not take responsibility for their treatment.

**Access to services**

The care process of diabetic foot ulcer patients: a qualitative study in Iran

Mansooreh Aliasgharpour and Nahid Dehghan Nayeri

The complications resulting from the disease that inflict the patients are due to overlooking the disease and ignoring the therapeutic process since the main role of the team members is the treatment of the patients.

Patient's apathy towards the seriousness of their disease implies health professionals are unable to treat effectively

**Beliefs around illness**



The care process of diabetic foot ulcer patients: a qualitative study in Iran	Mansoorah Aliasgharpour and Nahid Dehghan Nayeri	The team believed that "patients do not have information about their disease or their information is insufficient". They also believed that "patients are unaware of ways to prevent or examine the presence of senses at feet. They do not take care of their feet and also do not control their blood sugar level". The attitude of some of team members was that "the main source of problem is the patient".	Health professionals consider that patient's lack of understanding of their condition or their inability to take care of their feet properly as the main reason for worsening foot ulceration.	<b>Beliefs around illness</b>
Self-reported use of diabetes healthcare services in a Quebec community-based sample: impact of depression status	K.J.Smith, G.Gariépy, N.Schmitz QUEBEC	Results from this study suggest a trend towards people with major depression perceiving access to diabetes healthcare services as being more problematic. The results also show that people with major depression perceive problems with the length of time they have to wait to see a doctor, perceive that there is a lack of specialist care in their area, and are more likely to report having problems getting to the doctor due to transportation and health problems.	People with depression may perceive issues in accessing services to gain information or treat foot complications, whether these issues exist or not.	<b>Patient's mental health status</b>
Self-reported use of diabetes healthcare services in a Quebec community-based sample: impact of depression status	K.J.Smith, G.Gariépy, N.Schmitz QUEBEC	Results from this study suggest a trend towards people with major depression perceiving access to diabetes healthcare services as being more problematic. The results also show that people with major depression perceive problems with the length of time they have to wait to see a doctor, perceive that there is a lack of specialist care in their area, and are more likely to report having problems getting to the doctor due to transportation and health problems.	People with depression may perceive issues in accessing services to gain information or treat foot complications, whether these issues exist or not.	<b>Access to services</b>
Self-reported use of diabetes healthcare services in a Quebec community-based sample: impact of depression status	K.J.Smith, G.Gariépy, N.Schmitz QUEBEC	People with major depression are less likely to use diabetes healthcare services in the absence of diabetes complications (those people with increased complications use more diabetes healthcare services).	Depression may reduce patient's ability to be proactive in their foot care and then overuse series when complications occur	<b>Patient's mental health status</b>
Quality of life in patients with diabetic foot ulcer in Visegrad countries	Jana Nemcova, Edita Hlinkova, Ivan Farsky, Katarina Ziakova, Darja Jarosova, Renata Zelenikov Radka Buzgova, Eva Janikova, Kazimiera Zdzieblo, Grazyna Wiraszka, Renata Stepien,	We found out significant relationship between patients informed about disease and therapy and QoL. The informed patients had statistically significantly higher QoL in physical, psychological and environmental domains of QoL than not informed patients	Information and therapy were found to give patients a better quality of life than those that did not receive information and therapy	<b>Education around footcare</b>

Quality of life in patients with diabetic foot ulcer in Visegrad countries

Grazyna, Nowak-Starz, Mariann Csernus and Zoltan Balogh: Slovak, Czech, Polish and Hungarian

Jana Nemcova, Edita Hlinkova, Ivan Farsky, Katarina Ziakova, Darja Jarosova, Renata Zelenikov Radka Buzgova, Eva Janikova, Kazimiera Zdzieblo, Grazyna Wiraszka, Renata Stepien, Grazyna, Nowak-Starz, Mariann Csernus and Zoltan Balogh: Slovak, Czech, Polish and Hungarian

Quality of life in patients with diabetic foot ulcer in Visegrad countries

Jana Nemcova, Edita Hlinkova, Ivan Farsky, Katarina Ziakova, Darja Jarosova, Renata Zelenikov Radka Buzgova, Eva Janikova, Kazimiera Zdzieblo, Grazyna Wiraszka, Renata Stepien, Grazyna, Nowak-Starz, Mariann Csernus and Zoltan Balogh: Slovak, Czech, Polish and Hungarian

The QoL of patients with DFU is determined by both demographic (age, life alone and dependence in daily activities on others, information about therapy) and clinical characteristics (level of ulceration, length of therapy, pain, ischaemia). We have to orientate our care and therapy towards effective intervention and care strategies which take account of these factors

Diabetes healthcare services should take account of the need of information and therapy to effectively care for patients

**Patient mental health status**

**Multi disciplinary team function**

Quality of life in patients with diabetic foot ulcer in Visegrad countries

Jana Nemcova, Edita Hlinkova, Ivan Farsky, Katarina Ziakova, Darja Jarosova, Renata Zelenikov Radka Buzgova, Eva Janikova, Kazimiera Zdzieblo, Grazyna Wiraszka, Renata Stepien, Grazyna, Nowak-Starz, Mariann Csernus and Zoltan Balogh: Slovak, Czech, Polish and Hungarian

Our study demonstrated the necessity to implement into education for healthcare professionals not only new technical skills, but also a stronger orientation towards healthcare humanisation. This means that we have to consider not only the care of a diabetic ulcer as a wound and ailment but also the care of patients with their specific psychosocial needs and environmental conditions

Not only is education important to support patient's with diabetes but also consideration of their socioeconomical needs as a whole need to be taken into account

**Patient's mental health status**

Quality of life in patients with diabetic foot ulcer in Visegrad countries

Jana Nemcova, Edita Hlinkova, Ivan Farsky, Katarina Ziakova, Darja Jarosova, Renata Zelenikov Radka Buzgova, Eva Janikova, Kazimiera Zdzieblo, Grazyna Wiraszka, Renata Stepien, Grazyna, Nowak-Starz, Mariann Csernus and Zoltan Balogh: Slovak, Czech, Polish and Hungarian

A significantly better QoL was observed in patients with DFU who had the support of their families and information about treatment

Patient's with a diabetic foot ulcer has a better quality of life when they were better informed and had the support of their families.

**Education around footcare**

Quality of life in patients with diabetic foot ulcer in Visegrad countries

Jana Nemcova, Edita Hlinkova, Ivan Farsky, Katarina Ziakova, Darja Jarosova, Renata Zelenikov Radka Buzgova, Eva Janikova, Kazimiera Zdzieblo, Grazyna Wiraszka, Renata Stepien, Grazyna, Nowak-Starz, Mariann Csernus and Zoltan Balogh: Slovak,

**Support of family**

<p>Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services</p>	<p>Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND</p>	<p>Receiving information from health care staff was "vital" for some participants to teach them to be aware of effective preventative measures but also to make them aware of the services available to them which they might not previously have known about.</p>	<p>Education and information self-care was important in prevention and also signposting to other services</p>	<p><b>Education around footcare</b></p>
<p>Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services</p>	<p>Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND</p>	<p>Although all of the participants reported receiving education and information regarding their illness, some indicated that they were not aware of foot problems pertaining diabetes until they were treated for a foot ulcer.</p>	<p>Education not always effective in highlighting need for good foot care practices</p>	<p><b>Education around footcare</b></p>
<p>Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services</p>	<p>Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND</p>	<p>Many participants also explained that they were aware of what they needed to do in order to look after their feet and minimize the negative consequences of diabetes. However, they admitted that they chose not to follow doctors' instructions and many took responsibility for the worsening of their condition.</p>	<p>Patients acknowledge not following instructions causing problems with feet</p>	<p><b>Patient beliefs around illness</b></p>

Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services	Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND	All of the participants generally had a positive attitude towards the health care professionals delivering the services, with few negative incidences reported	Positivity about healthcare professionals	<b>Health professional attitude</b>
Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services	Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND	Participants were keen to stress that staff were not responsible for the weaknesses in the system, as one participant commented "their hands are tied", but rather that problems stemmed from the system itself and the way it was structured	Justification for failings in health professional service, rather problems stemmed from the system	<b>Health professional attitude</b>
Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services	Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND	. Most participants expressed a need for emotional support alongside the medical management of their condition. Their experiences with health care professionals suggested that they valued understanding, empathy, reassurance and communication with health professionals. key theme which emerged in relation to the competing psychological demands was the importance of social support. Most participants were dependent on a family member, spouse or neighbour to attend appointments. Other participants used a private taxi service. One participants emphasized the importance of receiving practical and emotional support immediately after amputation:	In managing their condition patients felt supported by sympathetic and caring health professionals	<b>Patient's mental health status</b>
Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services	Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND	. Most participants expressed a need for emotional support alongside the medical management of their condition. Their experiences with health care professionals suggested that they valued understanding, empathy, reassurance and communication with health professionals. key theme which emerged in relation to the competing psychological demands was the importance of social support. Most participants were dependent on a family member, spouse or neighbour to attend appointments. Other participants used a private taxi service. One participants emphasized the importance of receiving practical and emotional support immediately after amputation:	Social support an important element in supporting self-care and mental wellbeing	<b>Patient's mental health status</b>

<p>Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services</p>	<p>Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND</p>	<p>Those living rurally experienced a number of difficulties stemming from the lack of services in their local areas, the requirement to travel to designated centres and associated time and travel costs.</p>	<p>Lack of service provision in rural areas</p>	<p><b>Access to services</b></p>
<p>Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services</p>	<p>Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND</p>	<p>The problems in urban areas related to the lack of wheelchair facilities and sufficient wheelchair parking in hospitals. These problems in the city provided a double burden for those coming into the city from rural areas.</p>	<p>Lack of parking and wheelchair access to services</p>	<p><b>Access to services</b></p>
<p>Management of diabetic foot disease and amputation in the Irish health system: a qualitative study of patients' attitudes and experiences with health services</p>	<p>Sarah Delea1*, Claire Buckley1,2, Andrew Hanrahan3, Gerald McGreal3, Deirdre Desmond4 and Sheena McHugh1 IRELAND</p>	<p>The issue of transport costs was a bigger problem for participants living in rural areas due to distance to health services.</p>	<p>Lack of service provision in rural areas can be costly to patient</p>	<p><b>Access to services</b></p>

<p>Influence of beliefs about health and illness on self-care and care-seeking in foreign-born people with diabetic foot ulcers: dissimilarities related to origin</p>	<p>K. HjelmSRNT, MScN, PhD, Professor 1J. Apelqvist SWEDEN</p>	<p>Almost all respondents emphasised the importance of health-care staff (professional sector) for their health, as they were a resource for obtaining advice and informative support on how to manage their problems</p>	<p>health professionals seen as main resource for practical information and support</p>	<p><b>Health professional attitude</b></p>
<p>Influence of beliefs about health and illness on self-care and care-seeking in foreign-born people with diabetic foot ulcers: dissimilarities related to origin</p>	<p>K. HjelmSRNT, MScN, PhD, Professor 1J. Apelqvist SWEDEN</p>	<p>in addition to help from health-care staff, and others described them as sources of emotional support by just being there, to care for them or give advice.</p>	<p>Caring health professionals provide emotional support</p>	<p><b>Health professional attitude</b></p>
<p>Feelings of powerlessness in individuals with either venous or diabetic foot ulcers</p>	<p>S.A. de Almeida a , Geraldo Magela Salome´ b, *, R.A.A. Dutra b , Lydia Masako Ferreira BRAZIL</p>	<p>Patients with diabetic foot ulcers had stronger feelings of powerlessness than those with venous leg ulcers.</p>	<p>Feeling of powerlessness were more prevalent in people with foot ulceration</p>	<p><b>Patient's mental health status</b></p>
<p>How 'preventable' are lower extremity amputations? A qualitative study of patient perceptions of precipitating factors.</p>	<p>Joe Feinglass, Vera P. Shively, Gary J. Martin, Mark E. Huang, Rachna H. Soriano, Heron E. Rodriguez, William H. Pearce &amp; Elisa J. Gordon USA</p>	<p>A very consistent interview theme was frequent delays in urgently needed medical care. Over half the patients described delays in treatment that they attributed to the healthcare system. These ranged from delays in primary care referrals to vascular surgery, to frequently inaccurate assumptions by clinicians about how rapidly symptoms were likely to progress.</p>	<p>Frequent delays in accessing services or inaccurate diagnosis contributed to worsening conditions.</p>	<p><b>Access to services</b></p>

How 'preventable' are lower extremity amputations? A qualitative study of patient perceptions of precipitating factors.

Joe Feinglass, Vera P. Shively, Gary J. Martin, Mark E. Huang, Rachna H. Soriano, Heron E. Rodriguez, William H. Pearce & Elisa J. Gordon  
USA

The belief that delays were due to their own care seeking behaviour. Several patients incorrectly thought they could manage traumatic injury on their own.

Worsening condition in Patient's who believed they could manage condition without professionals support

**Beliefs about illness (Reason for disengaging with healthcare professionals)**



# Appendix F

## Nvivo Coding Framework

FPS 2 (NVivo 12).nvp - NVivo 12 Pro

File Home Import Create Explore Share

New Report Output New Extract Output Export Project Project Copy Project Project Page Setup Print Preview Print Print List Export Export List Export Codebook Export Bibliography

Quick Access: Files, Memos, Nodes

Data: Files, File Classifications, Externals

Codes: Nodes, Relationships, Relationship Types

Cases: Cases, Case Classifications

Notes, Search, Maps, Output

**Nodes** Search Project

Name	Files	References	Created On	Created By	Modified On	Modified By	
01 Referral Mechanism and Entry into the FPS		17	87	08/09/2018 10:01	FT	19/01/2019 18:21	FT
Missed Care Opportunities		6	7	10/09/2018 20:03	FT	26/09/2018 09:45	FT
Referral Route into the FPS		1	1	08/09/2018 10:01	FT	19/01/2019 18:22	FT
Symptoms Leading to Referral		17	79	07/09/2018 20:03	FT	19/01/2019 18:23	FT
02 The Impact of the FPS		16	72	08/09/2018 09:51	FT	19/01/2019 18:26	FT
Increased Awareness of the importance of Foot Self-Management		16	39	08/09/2018 09:43	FT	19/01/2019 18:25	FT
Obstacles to suggested Foot Self-management practices		1	1	08/09/2018 09:44	FT	19/01/2019 18:35	FT
Physical interventions - checks		0	0	06/09/2018 21:24	FT	19/09/2018 20:06	FT
Supporting Foot Self-management		13	22	06/09/2018 21:24	FT	19/01/2019 18:27	FT
The FPS as a Source of Support		5	10	06/09/2018 21:24	FT	19/01/2019 18:24	FT
03 Views on the FPS		10	11	10/09/2018 20:09	FT	19/01/2019 18:53	FT
Clinic location, appointments and waiting times		10	13	08/09/2018 09:52	FT	19/01/2019 18:51	FT
FPS Clinicians and Service Provided		9	17	21/09/2018 19:20	FT	19/01/2019 18:46	FT
FPS		7	10	08/09/2018 09:52	FT	19/01/2019 18:55	FT
Specialist Podiatrist		6	7	06/09/2018 21:24	FT	19/09/2018 20:07	FT
04 Potential Improvements to the FPS		6	10	06/09/2018 21:24	FT	19/01/2019 18:47	FT
Evaluation Recommendations for Improvements		2	3	19/09/2018 14:57	FT	19/01/2019 18:49	FT
Participant Suggested Improvements		6	7	10/09/2018 20:16	FT	19/01/2019 18:48	FT
05 Interesting findings that are not relevant to study		9	14	10/09/2018 19:54	FT	19/01/2019 18:50	FT

FPS 2 (NVivo 12).nvp - NVivo 12 Pro

File Home Import Create Explore Share

New Report New Extract Export Project Copy Project Page Setup Print Preview Print List Export Export List Export Codebook Export Bibliography

New Report  
Create a new report using the Report Wizard or the Report Designer.

- Memos
- Nodes

Data

- Files
- File Classifications
- Externals

Codes

- Nodes
- Relationships
- Relationship Types

Cases

- Cases
- Case Classifications

Notes

Search

Maps

Output

Nodes

Search Project

Name	Files	References	Created On	Created By	Modified On	Modified By	
05 Interesting findings that are not relevant to study		9	14	10/09/2018 19:54	FT	19/01/2019 18:50	FT
Access to other services		3	4	05/09/2018 20:59	FT	21/09/2018 20:12	FT
Comments about appointments in the wider service delivery		6	6	08/08/2018 09:13	FT	26/09/2018 09:43	FT
Diabetes support as a whole		4	4	06/09/2018 12:26	FT	21/09/2018 20:12	FT

## **Appendix G**

### **LCH R&D Ethics Approval**

**Telephone enquiries, please contact:**

**Phone:** 0113 8433497

**Email:** [lch.research@nhs.net](mailto:lch.research@nhs.net)



**Leeds Community  
Healthcare**  
NHS Trust

Headingley Office Park

Victoria Road

8/5/18

Ms Frances Tantram

By email

Ref: SE/0100

Dear Frances

### **Re: Translating patients' experiences of a Diabetes Foot Protection Service into Quality Improvement<sup>2</sup>**

Thank you for your application to Leeds Community Healthcare NHS Trust Research Department for approval for service evaluation.

Having read through your project outline and supporting documentation your proposed piece of work fits the National Research Ethics Service definition of service evaluation.

“Designed and conducted solely to judge or define current care...it may involve analysis of existing data but may include administration of interview or questionnaire.”

I can confirm that your project is now approved for conduct within Leeds Community Healthcare NHS Trust based on the following conditions.

1. You adhere to the principals of the Data Protection Act 1998.
2. You have the support and approval from an appropriate manager in the relevant service or department.
3. You also include our Trust's logo on the information sheet (PIS) and consent form

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<sup>2</sup> The title for this thesis was changed in December 2018. There was no change to study protocol approved by LCH R&D.

4. You include details of another person to contact within the Trust on the PIS in case the participant has any concerns about the study. This can be either the relevant service manager or me (using the generic research Dept contact details above).
5. You provide Leeds Community Healthcare NHS Trust Research Department with a report of your findings and any publications.

Please keep in mind the ethical principles of anonymity and confidentiality when conducting your interviews. Should you make changes to project design or documents please get in touch with the research team.

I wish you well with your project. If you have any further questions please do not hesitate to contact the research department on the numbers given above.

Yours sincerely

**Dr Liz Allen**

**Head of Research and Development**

The documents reviewed were:

<i>Document</i>	<i>Version</i>	<i>Date of Document</i>
Service Evaluation plan v2	2	18.4.18
Patient consent form	2	14.2.18
Patient information sheet	3	8.4.18

43.

## Appendix H

### Service Evaluation Proposal Presented to SREP

#### THE UNIVERSITY OF HUDDERSFIELD

#### School of Human and Health Sciences – School Research Ethics Panel

#### APPLICATION FORM

Please complete and return via email to:

**Kirsty Thomson SREP Administrator: [hhs\\_srep@hud.ac.uk](mailto:hhs_srep@hud.ac.uk)**

Name of applicant: Frances Tantram


Title of study: **Translating patients' experiences of a Diabetes Foot Protection Service into Quality Improvement**

Department: School of Health and Human Sciences

Date sent:

Please provide sufficient detail below for SREP to assess the ethical conduct of your research. You should consult the guidance on filling out this form and applying to SREP at <http://www.hud.ac.uk/hhs/research/srep/>.

Researcher(s) details	Frances Tantram Post Graduate- Master in Research – School of Health and Human Sciences
Supervisor(s) details	Professor Felicity Astin School of Human and Health Sciences University of Huddersfield

<p><b>All documentation has been read by supervisor (where applicable)</b></p>	<p>YES / NO / NOT APPLICABLE</p> <p>This proposal will not be considered unless the supervisor has submitted a report confirming that (s)he has read all documents and supports their submission to SREP</p> <div style="text-align: center;">  <p>Supervisor SREP report.html</p> </div>
<p>Aim / objectives</p>	<p><b>Aims:</b></p> <ul style="list-style-type: none"> <li>• Investigate and evaluate the experiences of people using a new Foot Protection Service (FPS) in Leeds</li> <li>• Explore ways in which FPS can be more person-centred using service user feedback.</li> </ul> <p><b>Objectives:</b></p> <ul style="list-style-type: none"> <li>• Conduct qualitative, semi-structured, face-to-face interviews with diabetic patients who are at high risk of suffering active foot disease</li> <li>• Evaluate their experiences of using the new FPS in Leeds</li> <li>• Feedback findings of the evaluation to assist in informing the future provision of the FPS</li> </ul>

Brief overview of research methods

### **Methodology and study design**

High quality health care is defined as healthcare that works in partnership to provide care that is personal, effective and safe to prevent illness, which will help to empower patients have control over their own health and care (Department of Health 2008). A key tool in ensuring high quality care is for providers to undertake Quality Improvement initiatives in their services. Øvretveit (2009) defined quality improvement as achieving better patient experience and outcomes by adopting systematic change methodology and strategies to change provider organisation and behaviours. Improving quality is about making healthcare safe, effective, patient-centred, timely, efficient and equitable and should aim to bring about measurable improvements by applying specific methodology within a healthcare setting (The Health Foundation 2013).

This Quality Improvement (QI) study will explore patient's experiences of a new Leeds Foot Protection Service (FPS) for people with diabetes and use these data to improve the quality of the service by making it more patient-centred. It will be a qualitative study of a purposive sample of individuals, who are at high risk of active foot disease as a result of diabetes, recruited from the FPS.

### **Design and setting**

Qualitative data will be collected through a series of qualitative, semi-structured, face-to-face interviews.

### **Participants/Sample**

All patients with diabetes who are at high risk of active foot disease, using the service, will be eligible to participate. Recruitment will take place over four-eight weeks in six-eight clinics. Participants will be given an information sheet and those who agree to take part will be given a consent form to sign and informed of their rights to withdraw from the QI study.

### **Topic guide**

A semi-structured topic guide will include open-ended questions. The topic guide was developed based on a thematic qualitative review which proposed an overall generic patient experiences framework to assist in QI initiatives (National Clinical Guideline Centre 2012). This was then adapted, working with the Clinical Lead for the FPS, to ensure it was relevant to the proposed QI study.

### **Data collection**

Semi-structured, face-to-face interviews. Interviews will take place in a private room at the FPS clinic to ensure confidentiality and privacy. Patients will be reminded that they have the right to stop the interview for a break or withdraw entirely from the study at any point. Interviews will be audio recorded using an encrypted audio device. The interviews should last around 40 minutes.

Recordings will be transcribed verbatim following all data protection protocols. Pseudonyms will be used throughout the transcripts.

### **Data analysis**

Thematic analysis of transcripts using NVivo software will be used.

### **Prior to interview starting/recruitment:**

- Eligible patient participants attending the FPS clinic, (identified by a clinician from the FPS, but who will not be directly involved in the QI), will be approached in the waiting room by the researcher.
- Researcher will describe what the QI study is about and what it is for, including data protection and the right to withdraw information (see recruitment prompt)
- Patients who are interested in taking part at this point will be given an information sheet to take away and consider (See Information Sheet), and asked to contact the researcher to arrange a mutually convenient time for the interview to take place if they would like to take part. Once an interview time has been agreed a confirmation letter will be sent through the post (See Interview Confirmation letter).

### **During interview:**

- The researcher will start by working through the interview guide, which includes working through the consent form with the participant (see interview prompt and Consent form)
- After consent has been given, the researcher will then work through the topic guide keeping questions open to encourage open dialogue (See Topic Guide)

### **Closing the interview:**

- Researcher will ask if there is anything else the participant would like to know
- Researcher will reiterate who the participant can talk to if any concerns or feel upset
- Participants will be given written information confirming who to contact if feel upset or have any further questions (see Exit Interview Letter)



Project start date	September 2017
Project completion date	March 2019
Permissions for study	Appendix A – Permission to study Leeds Community Healthcare (Research and Development Dept)

<p>Access to participants</p>	<p>Participants will be recruited from the FPS clinics in the city of Leeds.</p> <p>Potential participants will be screened and identified by the FPS Team, who will have set inclusion and exclusion criteria to eliminate clinical bias. The researcher will not have direct access to patient medical records.</p> <p>Recruitment will take place over four to six weeks in six to eight clinics.</p> <p><b>Inclusion Criteria</b></p> <ul style="list-style-type: none"> <li>• The patient is considered high risk of active foot disease as a result of diabetes</li> <li>• Be a current patient of the FPS and attending a review clinic</li> <li>• Be judge to have mental capacity to take part</li> <li>• 18 years or older</li> <li>• Have a good use of English (There is no finance available to support an interpreter to include non-English speaking participants. This is acknowledged as one of the limitations of this study).</li> </ul> <p>Appropriate patients, screened and identified by a FPS clinician, <b>will approached by the researcher in the clinical waiting area</b> and invited to participate in the study. This approach will include:</p> <ul style="list-style-type: none"> <li>• Greeting and researcher's name</li> <li>• Introduction to the QI study – what it is about</li> <li>• Briefly what the QI study involves</li> <li>• If at this point patients are interested give information form with details of who to contact if would like to be involved (See Recruitment Prompt)</li> <li>• Patients will then be given a telephone number and email address to contact the researcher should they wish to be involved.</li> <li>• Patients who contact researcher to be involved, will be given a mutually convenient date, time and place of where interview will take place.</li> <li>• If a patient is interested in taking part and would like to arrange a time during recruitment will be offered a choice of date and time for their interview. They will be given an information sheet (see Information Sheet) that also includes information about their right to withdraw.</li> <li>• A letter will be sent to confirm date, time and place (See Interview Confirmation Letter).</li> </ul>
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Confidentiality

**How will interviews be confidential?**

Interviews will take place in a private room within the FPS clinic. It will be explained to participants that their name and details will only be known by the researcher and as soon as the all the data has been gathered, any documents with their personal details on will be destroyed and pseudonyms will be used.

**Will you provide pseudonyms in the write-up?**

Pseudonyms will always be used on field notes, used when analysing data and in the write up.

**Other considerations:**

As part of the consent (Please see information form, consent form and interview prompt) the participant will be informed that the researcher might need to act to ensure that the participant, or someone identified by them, can access help or support. This may include disclosure of abuse or neglect, or it could relate to serious physical or mental health problems, or it could relate to their support needs (See Interview Prompt and Consent Form). Should this circumstance arise the researcher will alert the Clinical Lead for the service. If the issue involves the service directly then the researcher will follow Leeds Safeguarding Policy, in brief this states:

*“Safeguarding adults refers to the multi-agency procedures for protecting adults at risk from abuse or neglect.*

*If the person you are concerned about is over the age of 18 years of age, they have care and support needs, and you feel they are being abused or at risk of abuse from another person, you can seek help for them using the phone numbers below.*









*Wherever possible involve the person at risk in decisions about reporting a safeguarding concern.*

*Sometimes this may not be possible and sometimes you may need to act in their 'best interests' because they do not have the mental capacity to decide this for themselves. There are also occasions when you may need to report the concern without their permission, for example, it is in their vital interests, or other people are also at risk, or the person is unable to consent because of coercion or duress.*

*Dealing with allegations or concerns about abuse can be very difficult and distressing for everyone involved. Deciding what the right thing to do is can be stressful, particularly if the person you are*

	<p><i>concerned about is reluctant to accept support. If you are not sure what to do you can always seek advice.</i></p> <p><i>How to report a safeguarding adults concern</i></p> <p><i>Report abuse or seek advice</i></p> <p><i>Contact Adult Social Care: 0113 222 4401</i></p> <p><i>Out of hours: 07712 106 378</i></p> <p><i>Inform the Police</i></p> <p><i>In an emergency, contact the police: 999</i></p> <p><i>If the person is not in danger now, contact the police: 101” (Leeds Safeguarding Adults Board 2018).</i></p>
Anonymity	<p><b>Will names be anonymised by the use of pseudonyms or numbers?</b></p> <p>No patient identifier will be used or linked to interview data.</p> <p>The researcher will explain to participants that pseudonyms will be used in order to protect their identity (please see interview prompt sheet).</p> <p>All identifiable information will be removed from any quotes used in the final report, every effort will be made to ensure participants cannot be identified.</p> <p>Participants will be asked if they would like a summary of the results of the QI study sent to them after the analysis has been completed. If so, an appropriate mode of sending this i.e. email address or home address, will be requested.</p>
Right to withdraw	<p><b>Participants will be informed of their right to withdraw from the interviews or withdraw their data from the study in several ways:</b></p> <ul style="list-style-type: none"> <li>• On the information sheet given to patients during recruitment (see information sheet)</li> <li>• Their right to withdraw will be part of the signed consent form (see consent form)</li> <li>• Reminded of their right to withdraw verbally as part of the interview (see interview prompt)</li> <li>• Their right to withdraw will be reiterated on the exit interview letter (See Interview Exit Letter)</li> </ul> <p>It will also be made clear to participants that taking part in this QI study will not adversely affect their relationship with those providing care or the care they receive. Participants will be told however, that they will no longer have the right</p>

	to withdraw once data analysis has commenced (See Information Sheet, Consent Form, Interview Prompt, and Interview Exit Letter).
Data Storage	<p>Transcripts of the interview will be stored on the secure university drives and stored for 10 years</p> <p>All interview data will <b>only</b> be stored in University drives. These will be accessed and worked on remotely (using UniDesktop) and data will never be saved onto a personal lap top or unencrypted data stick.</p> <p>An encrypted mobile audio device will be used to record, carry and access interview data. This device will also be secured with a password or passcode.</p> <p>Remote management tools, which can be used to locate, disable and wipe the data from a device will be used. As soon as data has been saved in the Huddersfield University secure drive, the device will be wiped clean.</p> <p>Transferring data from the university drives will be kept to a minimum. However, if data does need to be transferred, i.e. for transcription purposes, an encrypted data stick will be used, this will not be left unattended unless it is locked in a filing cabinet when not needed. The data stick will be wiped clean as soon as the data on it is no longer needed.</p> <p>All field notes and consent forms will be scanned and saved on university drives as soon as possible after interviews, and only pseudonyms will be used and the paper copies then shredded within 48 hours of the interview taking place. No documents will be left unattended, unless they are locked in a filing cabinet when not needed.</p> <p>Interviews will be transcribed by the researcher via the Huddersfield University Drives. The data will only be shared with the student's supervisor, with identifiers removed, to maintain quality control of analysis interpretation.</p>
Psychological support for participants	<p>As this QI study is asking patients about their experiences of a healthcare service, the researcher is aware that people may have had negative experiences. The interview questions may bring up feelings of worry and concern for participants. Therefore the researcher will be proactive in offering support to participants by undertaking the following actions:</p> <ul style="list-style-type: none"> <li>• <b>If a participant becomes upset during the interview</b> If this circumstance does occur the researcher will immediately ask if the participant would like to take a break or stop the interview. The interviewer will also inform the service lead after the interview has concluded.</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>After the interview</b> The interviewer will make the participant aware of who to contact if they feel upset or have any complaints (see Interview Prompts and Exit Interview Letter)</li> </ul> <p>If the patient does disclose issues with the experience of podiatry they should be given details of how to complain if they wish to. If it psychological support they need then should be referred to own GP to discuss</p> <p>Any concerns the researcher may have will be discussed with the service lead.</p>
Researcher safety / support (attach completed University Risk Analysis and Management form)	 Risk Assessment V1 26.11.17.doc
Information sheet	 Information Sheet V3 08.04.18.doc
Consent form	 Consent Form Frances Tantram V2
Letters / posters / flyers	 Recruitment prompt V2 04.03.18.  Interview confirmation v2 14.C  Interview prompt V2 14.02.18.docx
Questionnaire / Interview guide	 Topic Guide v3 06.04.18.docx
Debrief (if appropriate)	 Exit interview letter V3 08.04.18.docx
Dissemination of results	Findings of the quality improvement Results of this quality improvement will be shared with the following organisations:  Leeds Community Healthcare  Leeds Teaching Hospital Trust  Commissioners

	<p>NHS England</p> <p>A clinical journal</p> <p>Made available to Diabetes UK</p> <p>A summary copy will also be made available to participants if requested.</p>
Identify any potential conflicts of interest	Working for Leeds Community Healthcare within which QI study is taking place.
<p>Does the research involve accessing data or visiting websites that could constitute a legal and/or reputational risk to yourself or the University if misconstrued?</p> <p>Please state Yes/No</p> <p>If Yes, please explain how you will minimise this risk</p>	No
<p>The next four questions in the grey boxes relate to Security Sensitive Information – please read the following guidance before completing these questions:</p> <p><a href="http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/oversight-of-security-sensitive-research-material.pdf">http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/oversight-of-security-sensitive-research-material.pdf</a></p>	
Is the research commissioned by, or on behalf of the military or the intelligence services?	No

<p>Please state Yes/No</p> <p>If Yes, please outline the requirements from the funding body regarding the collection and storage of Security Sensitive Data</p>	
<p>Is the research commissioned under an EU security call</p> <p>Please state Yes/No</p> <p>If Yes, please outline the requirements from the funding body regarding the collection and storage of Security Sensitive Data</p>	<p>No</p>
<p>Does the research involve the acquisition of security clearances?</p> <p>Please state Yes/No</p> <p>If Yes, please outline how your data collection and storages</p>	<p>No</p>



<p>complies with the requirements of these clearances</p>	
<p>Does the research concern terrorist or extreme groups?</p> <p>Please state Yes/No</p> <p>If Yes, please complete a Security Sensitive Information Declaration Form</p>	<p>No</p>
<p>Does the research involve covert information gathering or active deception?</p> <p>Please state Yes/No</p>	<p>No</p>
<p>Does the research involve children under 18 or participants who may be unable to give fully informed consent?</p> <p>Please state Yes/No</p>	<p>No</p>

<p>Does the research involve prisoners or others in custodial care (e.g. young offenders)?</p> <p>Please state Yes/No</p>	<p>No</p>
<p>Does the research involve significantly increased danger of physical or psychological harm or risk of significant discomfort for the researcher(s) and/or the participant(s), either from the research process or from the publication of findings?</p> <p>Please state Yes/No</p>	<p>No</p>
<p>Does the research involve risk of unplanned disclosure of information you would be obliged to act on?</p>	<p>Yes</p>

Please state Yes/No	
Other issues	None
Where application is to be made to NHS Research Ethics Committee / External Agencies	None
<b>Please supply copies of all relevant supporting documentation electronically. If this is not available electronically, please provide explanation and supply hard copy</b>	

All documentation must be submitted to the SREP administrator. All proposals will be reviewed by two members of SREP.

If you have any queries relating to the completion of this form or any other queries relating to SREP's consideration of this proposal, please contact the SREP administrator (Kirsty Thomson) in the first instance – [hhs\\_srep@hud.ac.uk](mailto:hhs_srep@hud.ac.uk)

## References

Department of Health (2008). High Quality Care For All: NHS Next Stage Review Final Report . (CM 7432). Retrieved from <http://webarchive.nationalarchives.gov.uk/20130105061315>

Øvretveit J. (2009). Does improving quality save money? A review of the evidence of which improvements to quality reduce costs to health service providers. London: Health Foundation.

The Health Foundation (2013). Quality improvement made simple: What everyone should know about health care quality improvement. Retrieved from <http://reader.health.org.uk/QualityImprovementMadeSimple>

National Clinical Guideline Centre (2012). Patient Experience in Adult NHS Services: Improving the Experience of Care for People Using Adult NHS Services: Patient Experience in Generic Terms: Appendix BThematic qualitative review: scoping report. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK115230/>

**Delea, S., Buckley, C., Hanrahan, A., McGreal, G., Desmond, D., & McHugh, S. (2015). Management of diabetic foot disease and amputation in the irish health system: A qualitative study of patients' attitudes and experiences with health services. BMC Health Services Research, 15(1), 251. doi:10.1186/s12913-015-0926-9**

## Appendix I

### Huddersfield University Ethics Approval

Appendix I - Huddersfield University Ethics Approval

Fw: SREP Application - Frances Tantram (MSc by Res) - Translating patients' experiences of a Diabetes Foot Protection Service into Quality Improvement (SREP/2018/036)

**From:** SHUM Research Ethics

**Sent:** 03 May 2018 12:05

**To:** Frances Tantram (Researcher) <Frances.Tantram@hud.ac.uk>

**Cc:** Felicity Astin <F.Astin@hud.ac.uk>; Warren Gillibrand <W.P.Gillibrand@hud.ac.uk>

**Subject:** SREP Application - Frances Tantram (MSc by Res) - Translating patients' experiences of a Diabetes Foot Protection Service into Quality Improvement (SREP/2018/036)

Dear Frances,

Dr Warren Gillibrand, Deputy Chair of SREP, has asked me to contact you with regard to your SREP Application as detailed above.

Your Application has been approved **subject to confirmation that either:**

- The study and permission / access has been approved by the NHS Trust concerned as a service evaluation;
- or
- HRA approval is required, in which case, a draft IRAS application form needs to be emailed to SREP as a PDF for review, and processed for sponsorship purposes.

We await your response to the above.

Regards,

Kirsty

(on behalf of Dr Warren Gillibrand, Deputy Chair of SREP)

**Kirsty Thomson**

Research Administrator

☎: 01484 471156

✉: [hhs\\_srep@hud.ac.uk](mailto:hhs_srep@hud.ac.uk)