**Highlights:**

A phenomenological study to explore the stakeholder perspectives on diabetic foot screening.

Current diabetes foot screening is inadequate and has shortcomings.

National cultures and local practices have a detrimental influence on diabetes foot care.

**Abstract**

**Background**

Clinical management of foot related complications resulting from diabetes is still not uniform both within and between countries. The number of existing documents/guidelines, together with discrepancies which exist between different organizations or countries can lead to confusion for both practicing health care professionals, new countries or organizations who are in the process of developing local clinical guidelines. The purpose of this study is to explore different stakeholder perspectives on foot screening guidelines and to explore whether there is a need for culturally competent foot screening guidelines.

**Methods**

A phenomenological study which incorporated non-structured interviews with eleven local stakeholders and experts in the field were held to explore interviewees’ perspectives regarding foot screening guidelines for Malta.

**Findings**

National culture and local practices may have a detrimental influence on the management of diabetes foot care. The findings highlight the need for change in current practices if effective diabetes foot screening is to be offered.

**Conclusion**

Current diabetes foot screening is inadequate and has shortcomings. Findings and recommendations from this study are relevant to other countries especially those who share same cultures and practices. Making changes today and implementing them in the appropriate manner could make a world difference in diabetes foot care.

**Keywords**

Diabetes, Foot screening, guidelines, practices, management

**Introduction**

The number of people living with diabetes is increasing exponentially. Various stakeholders including government and health officials, policy makers and politicians look for directions and solid recommendations to combat diabetes related complications. Current requirements for better management of this condition include a set of actions aimed at directing stakeholders in this regard [1] and Malta, a small island in the Mediterranean with a population of 400 000 inhabitants, is no exception. Currently, approximately 10% of the Maltese population is living with diabetes, compared with 2–5% of its European neighbours [2]. The increase in prevalence may be due to a combination of factors including changes in lifestyle, aging populations and genetic factors [3]. Malta is a small Mediterranean island with particularly distinct population and culture. It also has one of the highest rates of type 2 diabetes in the world. As a result it provides a unique microcosm of problems in diabetes care common across Europe. Nevertheless, the increasing number of people living with diabetes is affecting the diabetes services, putting it under considerable strain and prompting the need for a major reorganisation of services [4].

Health care in Malta is provided both publically and privately [5] and patients have the right to choose their preferred service. The public health care system is free of charge to all Maltese citizens and is publicly financed through taxation; alternatively, patients can pay for their own care in the private sector. Diabetes care in Malta is currently based on the guidelines of the European Diabetes Policy Group 1998–1999. There are currently no local clinical guidelines for the treatment of diabetes for Malta to date including culturally competent foot screening guidelines. This, however, is not the case for other EU Member States [6].

Foot complications are common in people with diabetes. It is estimated that 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives. After a first amputation, people with diabetes are twice as likely to have a subsequent amputation as people without diabetes. Mortality rates after diabetic foot ulceration and amputation are high, with up to 70% of people dying within 5 years of having an amputation and around 50% dying within 5 years of developing a diabetic foot ulcer [7]. While some studies report that every 20 seconds, a limb is amputated somewhere in the world [8] other studies highlight that a structured diabetes foot screening program can result in a 75% reduction in amputation rates [9].

Guidelines are devised to define standards for care and should use evidence-based interventions in order to provide health care professionals, policy makers, administrators and people living with diabetes with a set of recommendations for prevention, diagnosis and management of type 2 diabetes [10]. The number of existing documents/guidelines, together with discrepancies which exist between different organizations or countries on the same issue can lead to confusion for both practicing health care professionals or new countries or organizations which are in the process of developing local clinical guidelines. Many diabetes foot screening guidelines and studies have been published proposing a range of different tests and pathways that might be useful to identify the high risk foot, creating confusion amongst different healthcare professionals as to which screening test should be adopted in clinical practice [11]. Furthermore, with changes in the pattern of disease progression and its outcome, environmental changes, anthropometric changes and new developments in technology for both measurement and treatment of this condition advocates for more accurate diabetes foot screening guidelines. A recent systematic review which sought to evaluate the current foot screening guidelines and to examine their relevance in terms of advancement in clinical practice, improvement in technology and change in socio-cultural structure, concluded that future research with regards to diabetes foot screening using high-quality evidence is urgently needed should the risks of foot ulceration and its devastating consequences be reduced [12].

*Need for a structured investigation*

The rationale behind this research is that despite the publication of several diabetes foot screening guidelines across Europe and America for preventing and managing diabetic foot problems, there is variation in practice in preventing and managing diabetic foot problems across different settings, and amputation rates still vary across countries [12]. The practice of diabetes care is still not uniform both within and between countries. These variations in practice result from a range of factors including the different levels of organization of care for people with diabetes and diabetic foot problems. This variability depends on geography, individual trusts, individual specialties and availability of healthcare professionals with expertise in the management of diabetic foot problems [7].

There is a need for a comprehensive guideline on foot care for people with diabetes in Malta. In 2008, the IDF had called for the need for Malta to develop cultural competent foot screening guidelines in order to help reduce the number of foot complications and amputations in this country. To date this has not yet materialized despite the recent launch of a National Strategy for Diabetes 2016-2020. Although the aim of this strategy is to implement measures aimed at preventing diabetes, expanding treatment options and improving the integrated management of diabetes so as to prevent or postpone the onset of diabetes-related complications, a close look at the strategy does not offer a comprehensive guideline on foot care for people with diabetes addressing all settings inside Malta’s health care system. Robust protocols and clear local pathways for the continued and integrated care of people across all settings, including emergency care and general practice is missing. Ensuring that all assessments and, where necessary, referrals to foot care services, are undertaken by skilled and trained healthcare professionals will reduce the risk of complications associated with diabetic foot problems (such as ulceration, infection, amputation and death) and their associated costs [7].

The aim of this study was to explore different stakeholder perspectives with regards to diabetes foot screening guidelines and to explore whether there is a need for cultural competent foot screening guidelines. Our pragmatic approach for developing foot screening guidelines for people living with diabetes required interviews with local stakeholders and experts in the field. Findings and recommendations from this study could be relevant to other countries especially those who share same cultures or are trying to implement culturally-competent diabetes foot screening guidelines in their country as recommended by IDF and WHO themselves. Making changes today and implementing them in the appropriate manner could make a world difference in diabetes foot care.

**Methodology**

Due to the nature of the subject area, a phenomenological approach was employed to explore the individuals understanding of the current practice and their opinion. This approach attempted to understand participants’ perceptions, perspectives and understandings with regards to diabetes foot screening.

By looking at multiple perspectives from different stakeholders of the same situation, the researcher could start to make some generalisations of what the current local situation is like as an experience from the 'insider's' perspective. The aim of choosing a phenomenological research is normally to aspire to pure self-expression, with non-interference from the researcher. To achieve this aim a series of non-structured interviews were conducted. Field notes were also made which detailed the environment in which the interview occurred and the interviewees' reactions to the questions. A reflective journal was also kept to help the researcher to identify her own prejudices and so enable a development of an understanding of the current local care provision.

Purposive sampling was used in this study. This technique is widely used in qualitative research for the identification and selection of information-rich cases. This involves identifying and selecting individuals who are knowledgeable about or experienced with a phenomenon of interest. In addition to knowledge and experience the importance of availability and willingness to participate in the study, and the ability to communicate experiences was considered an essential aspect in this study to assure collection of rich data. This sample size was determined when saturation point was reached and the collection of new data did not shed any further light on the topic under investigation. This helped to ensure that people with a range of experiences in Malta's national health diabetes service were included in the sample. Eleven participants, identified as the main key stakeholders, ranging from specialist diabetes practitioners to policy makers were interviewed. Ethical approval was sought and obtained from the University Research Ethics Board. Informed consent was obtained from the individual interviewees before any data collection. Data were collected by way of participant observation and in-depth unstructured interviews. The interviews were conducted in English. The place and time of the interview was decided by the interviewee, so that the latter could feel more at ease whilst sharing his thoughts as it is known that the interview environment might influence the type and amount of data obtained from the participant. Upon informed consent, the participants were interviewed once during this study. All interviews were audio-taped and later transcribed.

#### Analysis and Results

For the purpose of analysis an interactive mode of analysis was chosen as the phenomenon under investigation was explored by means of interviews and their transcribing. This was done by the researcher getting accustomed to the data by listening to the transcripts and looking for patterns in the data. A verbatim account was recorded to ensure that the content was an accurate reflection of the interview.

Three key categories emerged from the data all highlighting barriers to diabetes foot care relating to: organisational factors, health care professional factors and patient factors. Tables [1–3](http://onlinelibrary.wiley.com/doi/10.1002/pdi.1549/full#tbl1) summarise categories and themes that emerged from the analysis of interviews conducted.

*Insert tables here*

|  |
| --- |
|  |

**Discussion**

The reported results suggest that, currently, diabetes foot screening is being managed neither effectively nor efficiently. Overall, it is clear that the organization and management of the diabetes services do not meet the needs of their users. Furthermore, the current National Strategy for Diabetes 2016-2020 does not offer comprehensive evidence-based recommendations/guidelines on foot care for people with diabetes for healthcare professionals to consider in the prevention and management of diabetes foot care. Failure to carry out comprehensive diabetes foot screening at a national level has been reported to have detrimental consequences for those with diabetes [13]. This article summarizes specific barriers to diabetes foot screening which emerged from this study relating to organizational factors, healthcare professional factors and patient factors.

*Organisational Factors*

The lack of local uniform foot screening guidelines for diabetes between different clinics/settings has been highlighted as a barrier in diabetes care – ‘*We need proper local policies for diabetic foot screening, we need also care pathways for ourselves because our health care system might be different from other countries’* [Interviewee 2]. Poor human and financial resources, the lack of a diabetes register to identify all patients living with diabetes in Malta and the need to improve the current IT system in this country and to make patient medical information accessible and transferable for all healthcare professionals were highlighted as major organizational barriers to improved care. Findings highlight a huge diversity in how patients living with diabetes are currently being screened and a diversity of standards of clinical practice. Furthermore it seems that foot screening is not reaching many, perhaps the majority of people who could mostly benefit from early comprehensive foot screening as highlighted by interviewee 2 ‘*I think the main concern is where the patient who is diabetic, who is potentially developing both arterial disease and neuropathy has no contact with either his own doctor and in our particular context this is important because most of our patients do not have a GP, so it actually only a minority of patients who have a doctor, so having a point of contact for diabetes screening and management’.*

*Healthcare professional factors*

High clinical work load leading to improper care, power relations, limited team communication and a lack of structured foot screening clinical guidelines made effective working difficult. It was reported that routine foot examination and rapid risk stratification is often difficult to incorporate into busy primary care settings. ‘*the screening has to be done in a very busy clinic so it had to be something which is quick and easy to use….. the chances are that due to time constraints they have never been screened appropriately, not with a Doppler or for neuropathy, no education is given*.’ [Interviewee 1].

*Patient factors*

The third category included patient concordance issues, lack of patient motivation, lack of patient education and cultural traditions were identified as potential barriers to current care. ‘*We meet patients who have had diabetes for years, come to check their feet, but they barely know what diabetes is about…... we encourage them to attend the educational classes and send them to make an appointment, we do make the effort…..but sadly only a few patients listen to our advice and actually attend diabetes educational classes provided’ [*Interviewee 4].

**The way forward**

The Maltese diabetes health care system is, therefore, in need of radical change with regards to its foot screening strategy. If left unchecked, diabetes and its complications could exceed the Maltese health care system capacity in the near future. In response to the need for more consistent foot exams this study highlights the need for cultural competent foot screening guidelines and pathways. To achieve this, an inter-professional team with the appropriate expertise is required and the system needs to support and allow for sharing and collaboration between primary care and specialist care as needed [14]. Databases providing patient and physician reminders and transfer of information are also warranted.

**The Global Context**

National diabetes foot screening guidelines can be defined as formal strategies for improving diabetes policy, services and outcomes that encompass structured and integrated or linked activities which are planned and co-ordinated nationally and conducted at the national, state or district, and local level. The guidelines must include stated goals and objectives, supported by a strategic plan, specified timeframes and milestones and dedicated funding, and a means of evaluation. Successful efforts to prevent and treat foot complications depend upon a well-organised team, that uses a holistic approach and that integrates the various disciplines involved. Effective organization requires systems and guidelines for education, screening, risk reduction, treatment, and auditing [8].

The over-arching goal of a structured framework is to ensure that people with diabetes have their feet cared for, based on their level of risk, by healthcare professionals with the appropriate skills. The literature suggests that local variations in resources and staffing often dictate how care is provided. A system to detect all people who are at risk is necessary, with an annual foot examination of all persons with diabetes. Auditing of all aspects of the service to identify problems and ensure that local practice meets accepted standards of care is warranted. Improved care would mean better quality of life for all those living with type 2 diabetes, improved outcomes, fewer diabetes-related complications and limb loss prevention contributing to cost-effective health care.

From the international perspective, the findings reported within this study highlight the need for more competent foot screening guidelines since as discussed earlier to date every 20 seconds a limb is amputated somewhere in the world despite the existing guidelines and care provided implying that something is not right.

The authors advocate that when formulating screening policies, the aims and objectives of any screening policy should be clearly stated. Epidemiological considerations, considerations of health system capacity, economic considerations, the judgement of tests taking into account sensitivity and specificity together with their cost, competing priorities and ethical and political considerations need to be considered. Evidence needs to be reviewed from time to time as new evidence accumulates [12]. A paradigm shift on how to screen for risk factors in the high risk foot using high quality evidence is urgently required if the risk of foot ulceration and its devastating consequences are to be improved. This will have a clear socio economic impact by improving management of diabetes foot complications and compliance facilitating effective clinical management. The next step is to develop diabetes foot screening guidelines that will truly translate into effective diabetes foot care as recommended by IDF and WHO. The overall goal of screening guidelines is to prevent diabetic foot complications or at least to halt or decelerate their development. Guidelines which could possibly make a world difference in foot care and help save limbs.

**1.6 Conclusion**

This study has found that at present diabetes foot screening is inadequate and has many shortcomings. There is evidence of power imbalances and poor channels of communication that prevail in a dated and hierarchical structure. It is hoped that the findings from this study have highlighted the necessity for change and will have the potential to make a change in the current way in which diabetes foot screening is managed, leading to improved patient care. This study recommends that policy makers, managers and health care professionals should take these findings into consideration in order to develop and implement culturally appropriate foot screening guidelines with relevant pathways of care to improve diabetes foot care.

**Declaration of Interests**

The authors have no financial or personal interests to disclose.

**References**

1.Del Prato S. A call to action – the UN Resolution on diabetes. *Int J Clin Pract*.2007; 61(157):1–4.

2.Rocchiccioli TJet al. Diabetes in Malta: Current findings and future trends. *Malta Med J*.2005; 17(01):16–9.

3. Formosa C et al. Influence of national culture on diabetes education in Malta: A case example. *Diabetes & Primary Care*.2008;10(2):109–16.

4. Lawton J et al. Lay perceptions of type 2 diabetes in Scotland: bringing health services back in. *SocSciMed*. 2005; 60:1423–35.

5. Ministry of Health, the Elderly and Community Care. ‘Together for a Healthy Community’ Community and Primary Health Care Working Document. Malta: 2007.Available from: [health.gov.mt/en/hcs/Documents/dhcssannualreport2007](https://health.gov.mt/en/hcs/Documents/dhcssannualreport2007).pdf

6.European Commission Health & Consumer Protection Directorate-General. Accessed 20 December 2008. Source: Diabetes: the Policy Puzzle – towards Benchmarking in the EU25, FEND 2005. Available from: ec.europa.eu/health/major\_chronic\_diseases/docs/policy\_puzz le\_2008.pdf

7.NICE (2015). Diabetic foot problems: prevention and management. Available from: [http://www.nice.org.uk/guidance/ng19/resources/diabetic- foot-problems-prevention-and-management-1837279828933](http://www.nice.org.uk/guidance/ng19/resources/diabetic-%09foot-problems-prevention-and-management-1837279828933)

8.International Diabetes Federation and International Working Group of the Diabetic Foot. 2005. Time to Act. WH, Riley P, The Netherlands. International Working Group on the Diabetic Foot. Prevention and management of foot problems in diabetes: a Summary Guidance for daily practice 2015, based on the IWGDF Guidance documents. <http://www.iwgdf.org/files/2015/website_summary.pdf>

9. Weck M, Slesaczeck T, Paetzold H. Structured health care for subjects with diabetic foot ulcers results in a reduction of major amputation rates. *Cardiovascular Diabetology*. 2013;12:45.

10. Ryden L, Standl E, Bartnik M. Guidelines on diabetes, pre- diabetes, and cardiovascular diseases: executive summary. The Task Force on Diabetes and Cardiovascular Diseases of the European Society of Cardiology (ESC) and of the European Association for the Study of Diabetes (EASD). *EurHeart J.* 2007;28(1):88-130.

11 .Boulton AJM, Armstrong DG, Albert SF et al. Comprehensive Foot Examination and Risk Assessment. A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. Diabetes Care.2008; 31(8): 1679-1685.

12. Formosa C, Gatt A, Chockalingam N. A Critical Evaluation of Existing Diabetic Foot Screening Guidelines. Rev Diabet Stud 2016; 13:158-186.

13. Kuhnke J, Botros M, Elliot J et al. The case for diabetic foot screening. Diabetic Foot Canada.2013;1(2):8-14.

14. Cheng A (2013). Clinical Practice Guidelines: Introduction. Canadian Diabetes Association.2013. Available from:guidelines.diabetes.ca/browse/Chapter 1.

|  |  |
| --- | --- |
| **Table 1 Organisational factors** | |
| * Diabetes national health problem * Power hierarchy * Primary prevention and educational campaigns * Primary prevention more important than current care * No ongoing diabetes education available * Lack of planning and decision making * Lack of communication * Long waiting lists/time to see specialists * Power relations | * Lack of human and financial resources * No national diabetes foot screening guidelines * Bureaucratic system * Mismanaged system * Need for more organisational support for both professionals and health service users * Crisis management * Breaching of patients’ rights * Poor IT service * Need for a diabetes register |

|  |  |
| --- | --- |
| **Table 2 - Health care professional factors** | |
| * Lack of human and financial resources * Shortage of specialists with particular expertise * Lack of communication between stakeholders * Clinician workload * Work practice * Reluctance to introduce new measures or guidelines * Power relations * Need for recruiting and retaining of staff * Crisis management | * Long waiting lists/time to see specialists * No formal structure or forum between stakeholders * No teamwork * Lack of health care professional training * Lack of ongoing education * Very little current support given to patients * No standardised approach for foot screening between clinics |

|  |
| --- |
| **Table 3 - Patient factors** |
| * Power relations * Lack of compliance with advice * Lack of knowledge of diabetes care * Lack of communication between patients and doctors * De-motivation * Financial constraints * Culture and traditional roots |