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# Diabetes Foot Screening: Challenges and Future Strategies

**Running Title: Diabetes Foot Screening Guidelines**

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## 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

Healthcare options for people with diabetes is still not uniform both within and between countries. This is particularly evident for diabetic foot disease. 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 and new countries or organizations who are in the process of developing local clinical guidelines. This study was aimed at exploring different stakeholder perspectives with a view to develop and introduce culturally competent foot screening guidelines.

## **Methods**

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

## **Findings**

Qualitative analysis identified 3 key themes from the data highlighting barriers to the implementation of diabetes foot screening guidelines. These focused on organizational factors, healthcare professional factors and patient factors.

## **Conclusion**

Current procedures related to diabetes foot screening has shortcomings. The findings of this study clearly highlight the need for change in current practices if effective diabetes foot screening is to be offered. 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 of difference in diabetes foot care.

## **Keywords**

Diabetes, Diabetic Foot, Foot screening guidelines, Health Policy, Foot

## **Introduction**

The number of people living with diabetes is increasing exponentially worldwide [1]. Ministers of Health and other policy makers are looking at directions for solid recommendations to combat diabetes and its complications [2]. Current requirements for better management of this condition

include a set of actions aimed at directing stakeholders in this regard [3] and Malta, a small island in the Mediterranean with a population of 400 000 inhabitants, is no exception. Approximately 10% of the Maltese population is currently living with diabetes, a much higher figure when compared with other European neighbours who report a 2–5% incidence [4]. The increase in prevalence may be due to a combination of factors including changes in lifestyle, aging population and genetic factors [5]. Malta is a small Mediterranean island with a particularly distinct population and culture. It also has one of the highest rates of type 2 diabetes in the world. The increasing number of people living with diabetes is affecting the diabetes services by putting the healthcare sector under considerable strain and prompting the need for a major re-organisation of such services [6].

Health care in Malta is provided both publicly and privately [7] and patients have the right to choose their preferred service. The public healthcare system is free of charge to all Maltese citizens and is financed through state taxation; alternatively, patients can pay for their own care in the private sector. Although, diabetes care in Malta is based on the guidelines of the European Diabetes Policy Group 1998–1999; as such there are no local culturally competent clinical guidelines for the treatment of diabetes. This, however, is not the case for other EU member states [8] since most of them have developed their own local guidelines. These guidelines are devised to define standards for care in those individual countries. They normally use evidence-based interventions 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 and its complications.

Whilst these guidelines focus on general diabetes care, 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 [9]. While some studies report that every 20 seconds, a limb is amputated somewhere in the world [10] other studies highlight that a structured diabetes foot screening program can result in a 75% reduction in amputation rates [11].

Whilst, guidelines define standards for care [12], the number of existing international documents/guidelines, together with discrepancies which exist between different international 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 [13]. In addition, many international diabetes foot screening guidelines propose a variety of different tests and pathways that might be useful to identify the foot at risk. This variability not only creates a confusion amongst different healthcare professionals as to which screening test should be used but also impedes the adoption of these guidelines in clinical practice [14]. 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 [13]. In a recent systematic review conducted by our group which sought to critically 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 [13].

#### *Need for a structured investigation*

The rationale behind this research is that despite the availability 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. In addition, the amputation rates still vary across countries [13]. Variability in recommendations and care is due to geography, differences in healthcare systems, individual clinical specialties and availability of trained healthcare professionals with expertise in the management of diabetic foot problems [9].

From a national perspective, 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 culturally 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 Maltese National Strategy for Diabetes 2016-2020. Although the aim of this strategy is to implement measures to prevent diabetes, expand treatment options and to improve the integrated management of diabetes with a view to prevent or postpone the onset of diabetes-related complications. However, a close look at the strategy does not offer any recommendations with regards to the need of developing comprehensive foot screening and foot care guidelines.. 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 [9].

The aim of this study therefore was to explore different stakeholder perspectives with regards to the possible introduction of culturally competent foot screening guidelines in Malta's healthcare system.

## **Methodology**

A phenomenological method approach was employed to explore the individuals perception with regards to the introduction of culturally-competent foot screening guidelines for individuals with diabetes as recommended by IDF. The goal of qualitative phenomenological research is to describe a 'lived experience' of a phenomenon. It studies structures of conscious experience as experienced from a first-person point of view along with its intentionality. Phenomenology is a design that best fits research problems that are unstructured, and for which there is little or no research or evidence in the literature. Phenomenology involves exploring the lived experiences of individuals, and when these experiences are unique and largely unstudied, this type of approach can generate thick descriptions necessary for the understanding of a problem that has not been explored. The results can be very useful for scoping the dimensions of an unstructured problem, and gaining sufficient knowledge to then structure theory and an understanding of the

problem. Because phenomenology examines the meaning that lived experience has in people's lives, it is a valuable research method.[15]

Information from this type of methodology may give direction to clinical practice, such as, the formulation of other questions or a different way of responding to a health care situation. Above all is the understanding that provides the information with which to build specific plans for future care. The results from such studies may provide information for future interventions and policies, generate further research questions and enhance theory development. Exploring perspectives from different stakeholders, could aid in making generalisations with regards to the current local situation. The reason for choosing a phenomenological approach is normally to aspire pure self-expression, with non-interference from the researcher.

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 since this type of sampling is widely used in qualitative research for the identification and selection of information-rich cases. This involved identifying and selecting individuals who were knowledgeable about or experienced with a phenomenon of interest. In addition to the 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 [15].



The number of participants interviewed was deemed appropriate 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 Service with a focus on diabetes were included in the sample. In this sampling method, the researcher selected participants who have the desired experience in order to obtain maximal accounts of the experience, and increase understanding of some facet of a phenomenon. The adequacy of the sample size was evaluated by the completeness and quality of the information provided by the participants rather than by the number of interviews. This was achieved when the researcher had information redundancy, or the information and understanding was complete in the circular, iterative analysis of the interviews. This type of theoretical sampling maximized access to data that represented the phenomena and contributed to understanding.

Eleven participants, who were identified as the main key stakeholders in diabetes care in the country, ranging from specialist diabetes practitioners to policy makers were interviewed. We aimed to include professionals and policy makers who had a decisive influence on diabetes care. This is not a very large group of people in the Malta. The interviewees represented: key healthcare providers and policy makers. Purposive sampling was used to identify senior staff members who were engaged in quality of care measurement and improvement. For a healthcare provider perspective, we selected active members including diabetes nurses, primary care physicians and medical specialists. For policy makers' perspectives, we contacted the authorities within the Ministry of Health. All participants received an information letter containing information about the aim and methodology of the study in advance and all signed informed consent.

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/her thoughts since it is known that the interview environment could influence the type and amount of data obtained from the participant. Upon informed consent, the participants were interviewed once during this study. Interview duration varied between 45 and 75 minutes. The interviews were conducted in conversational form, beginning with an open question. Follow-up questions were asked to gain deeper insight into the phenomenon. All interviews were audio-taped and later transcribed by the researcher.

#### *Data Analysis*

The analysis began by the researcher listening to the audio-recordings and reading through the transcribed verbatim interviews to become acquainted with the content before trying to identify similarities, differences, and patterns of meaning in the verbatim printed interviews. A verbatim account was recorded to ensure that the content was an accurate reflection of what was said during the interview. Significant statements were highlighted manually and extracted from the text and formulated into clusters of themes.

By observing similarities and differences in what was said a pattern of meanings emerged, transforming the subjective perspective expressed in the individual interviews into a scientific description of the phenomenon under investigation. Thematic analysis is widely used in qualitative

data analysis. It identifies patterns across a dataset to help provide an answer to the research question being posed.

### *Findings*

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 as described below. Verbatim quotes are used within the study findings to increase the trustworthiness of the interpretation and credibility of the study findings. Interview transcriptions and themed data were also discussed with the interviewees in order to verify the reliability of data collection and rigour in the analysis process.

#### *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'*.

#### *Factors relating to Healthcare professionals*

High clinical work load leading to differences in the level of care, power relations at work place, limited communication within the team and a lack of structured and validated 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].

#### *Factors relating to Patients*

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].*

## **Discussion**

Overall, it emerges that, in Malta, 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 to the development of guidelines on foot care for people with diabetes and 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 [16].

### *The way forward*

The Maltese health care system for diabetes, therefore, is in need of radical change with regards to its foot screening strategy. If left unchecked, diabetes and its complications could exceed the capacity of the Maltese health care system in the near future. In response to the need for more consistent foot exams, this study highlights the need for culturally 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 [17]. Databases providing patient and physician reminders and transfer of information are also warranted.

*The Global Context*

National diabetes foot screening guidelines can be described as a formal strategy and implementation plan for improving diabetes policy, services and outcomes that encompass structured and integrated or linked activities which are planned and coordinated 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 means of evaluation. Successful efforts to prevent and treat foot complications depend on 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. Published 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. Audit of all aspects of the service to identify problems and ensuring 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.

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!

Findings and recommendations from this study could all 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. Making changes today and implementing them in the appropriate manner could make a world difference in diabetes foot care.

#### Strengths and limitations

The number of interviews was small, but we included the most relevant health care professionals who participate in diabetes care and we interviewed those employees whose tasks were most closely related to diabetes foot care and screening. As the results indicate, the differences in views even within this small group were substantial. Whilst one could argue that the study should have more participants, our findings do not support it. The inclusion of more health care professionals and policy makers would probably have revealed even more variation than a convergence in views. In addition our study design involved unstructured interview because we hypothesised that only a discussion could help us answer the research question.

## **Conclusion**

This study has found that at present diabetes foot screening in Malta 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.



### Conflict of interest

All authors were fully involved in the study and preparation of the manuscript and declare that there is no conflict of interest.

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