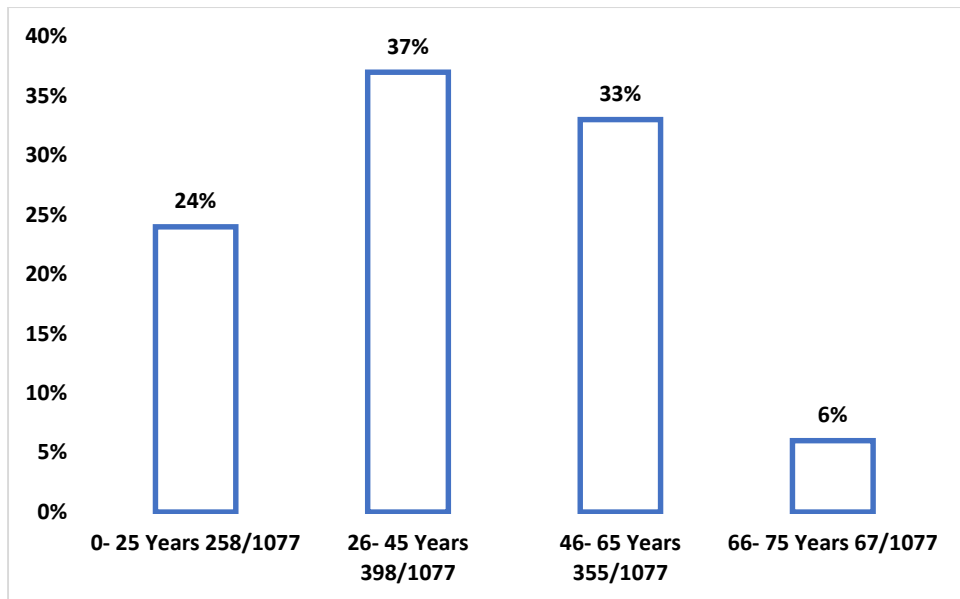


# South African Journal of Diabetes and Vascular Disease

## Risk Factors for Diabetic Foot Ulceration in Diabetic Patients Presenting At Primary Healthcare Clinics in South Africa

--Manuscript Draft--

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<b>Order of Authors Secondary Information:</b>	
<b>Manuscript Region of Origin:</b>	SOUTH AFRICA
<b>Abstract:</b>	<p><b>Abstract</b></p> <p><b>Objective:</b> The main purpose of the study was to investigate the need for podiatrists as members of the primary healthcare team. One of the objectives of the study was to determine the percentage of patients presenting at the two Primary Healthcare clinics who are at risk of developing foot complications as a result of an underlying concomitant systemic disease.</p> <p><b>Research design and methods:</b> A descriptive cross-sectional study in which data was collected from patients presenting at two homogeneously selected Primary Healthcare (PHC) clinics in Johannesburg. Nursing staff assisted by a final year podiatry student collected data using a self-constructed data collection form (DCF) from each consenting patients as part of their routine patient consultation. Simple descriptive statistics were used for data analysis.</p> <p><b>Results:</b> Data was collected and analysed from 1077 patients and showed that 29% of the patients had diabetes. Diabetic foot ulceration risk factors that were recorded included peripheral neuropathy in 74% of diabetic patients, structural foot deformities in 47%, peripheral vascular symptoms in 39% and foot ulcer in 28% of the diabetic patients.</p> <p><b>Conclusion:</b> Early identification of diabetic patients who are at high risk of diabetic foot ulceration is important and can be achieved via a mandatory diabetic foot screening with subsequent multidisciplinary foot-care interventions. Understanding the factors that place patients with diabetes at high risk of ulceration, together with an appreciation of the links between different aspects of the disease process and foot function, is essential to the prevention and management of diabetic foot complications.</p>



**Figure 1. Age spread.**

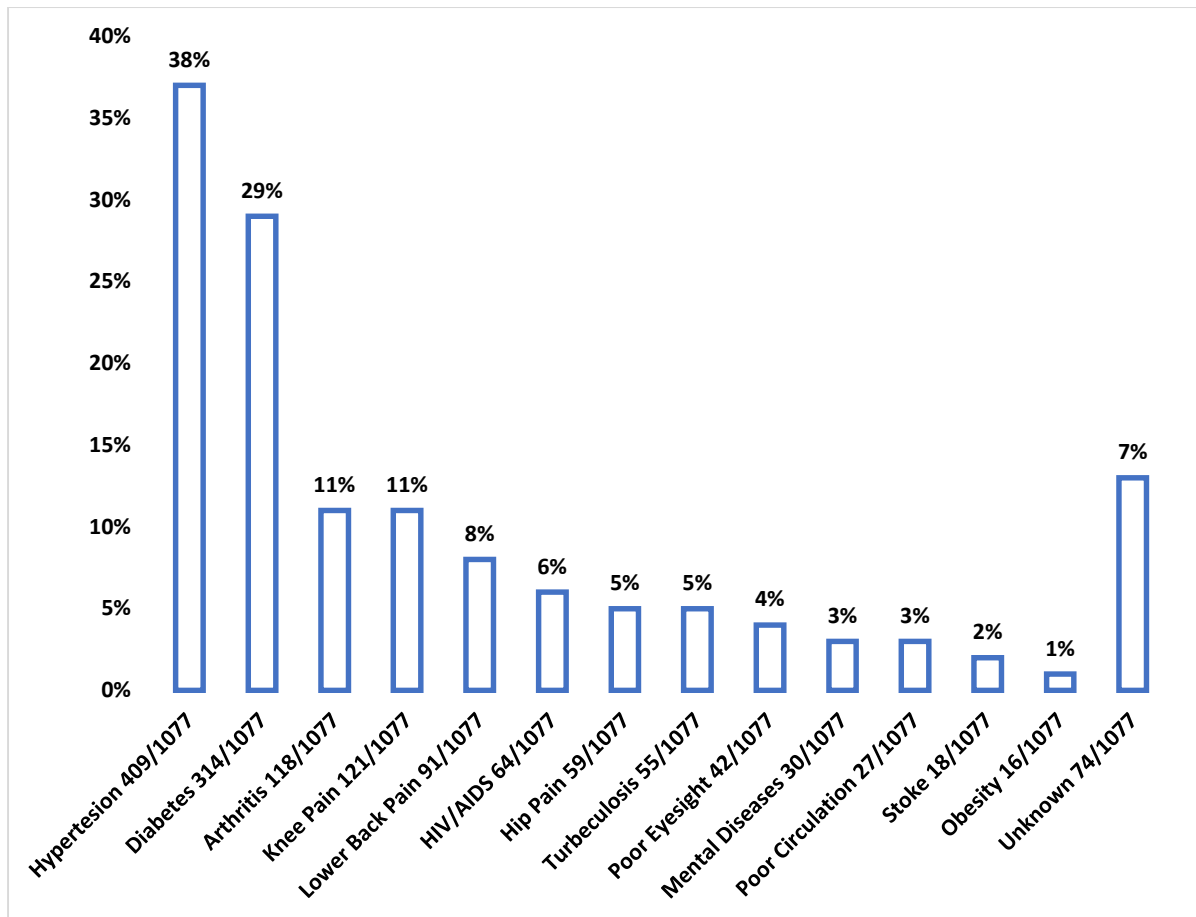


Figure 2. Systemic disease or joint condition.

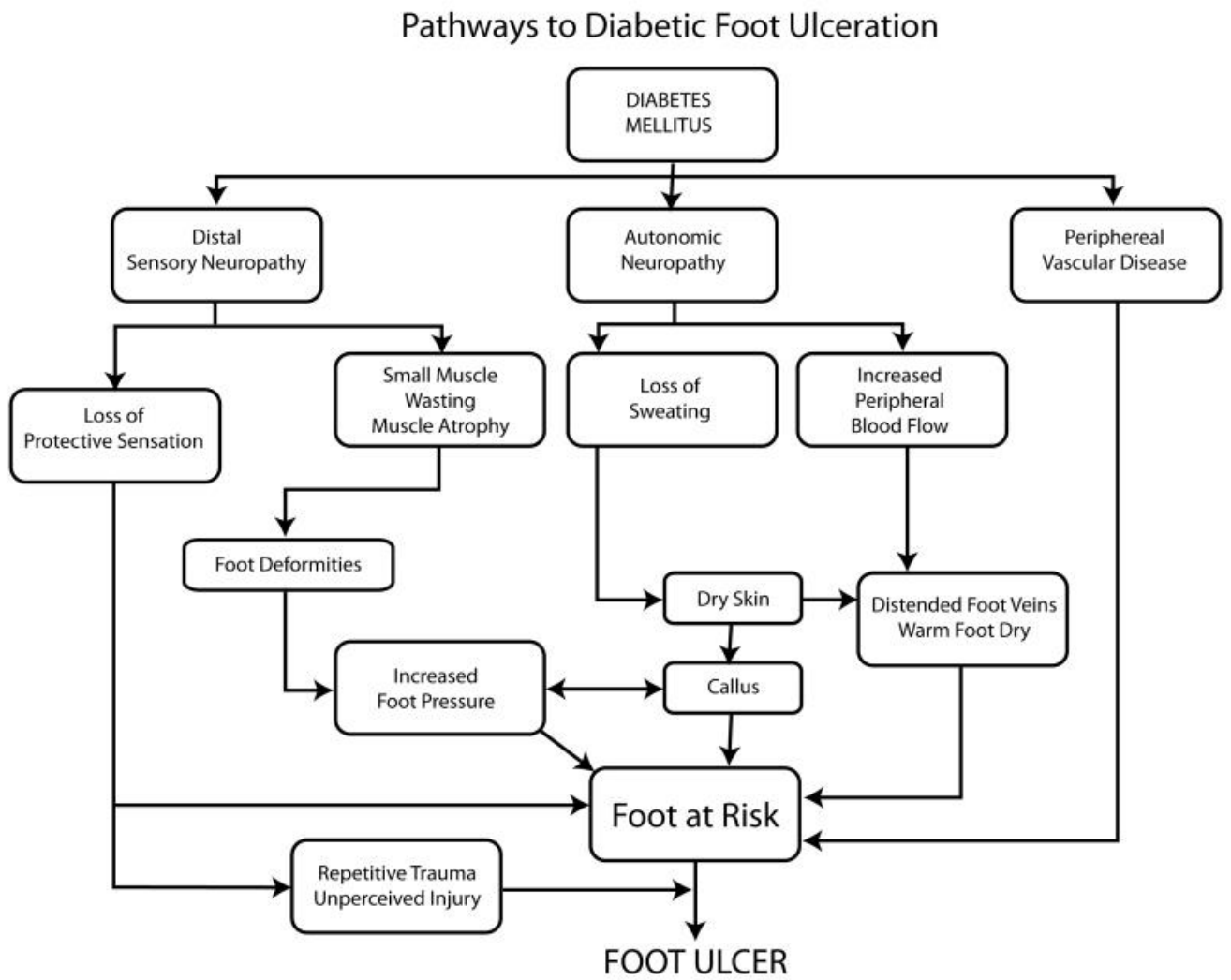


Figure 3. The pathway to foot ulceration in diabetes Boulton AJM [35].

**Table 1. Diabetic Foot Risk Factors.**

<b>Risk Factor</b>	<b>Prevalence</b>
<b>Neuropathy</b>	<b>75 % (n=236)</b>
<b>Structural Deformities</b>	<b>47% (n=147)</b>
<b>Peripheral Vascular Disease Symptoms</b>	<b>39% (n=124)</b>
<b>Foot Ulcers</b>	<b>28% (n=87)</b>

**Table 2 Foot pathologies and symptoms recorded in diabetic patients.**

<b>Foot Pathology/ Complaint</b>	<b>Prevalence (%)</b>
<b>Corns</b>	<b>26% (n=82)</b>
<b>Calluses</b>	<b>40%(n=125)</b>
<b>Ulcers/Wounds</b>	<b>28% (n=87)</b>
<b>Infections</b>	<b>25% (n=79)</b>
<b>Thick nails</b>	<b>4% (n=13)</b>
<b>Ingrown nail</b>	<b>21% (n=66)</b>
<b>Fissures/Cracks</b>	<b>32% (n=102)</b>
<b>Interdigital Maceration</b>	<b>21% (n=67)</b>
<b>Burning feet</b>	<b>16% (n=50)</b>
<b>Tingling</b>	<b>31% (n=97)</b>
<b>Numbness</b>	<b>28% (n=89)</b>
<b>Cold feet</b>	<b>22% (n=70)</b>
<b>Intermittent Claudication</b>	<b>17% (n=54)</b>
<b>Pes Planus (Flat feet)</b>	<b>31% (n=98)</b>
<b>Hammer toes</b>	<b>2% (n=7)</b>
<b>Bunions</b>	<b>7% (n=22)</b>
<b>Overlapping toes</b>	<b>1% (n=5)</b>
<b>Pes Cavus (High arches)</b>	<b>5% (n=15)</b>

Table 3. Components of the diabetic foot exam. Adapted from Boulton AJM, et al. [35]

Inspection	Neurological	Vascular
<ul style="list-style-type: none"> <li>• Evidence of past/present ulcers?</li> <li>• Foot shape?</li> <li>• Prominent metatarsal heads /claw toes</li> <li>• Hallux valgus</li> <li>• Muscle wasting</li> <li>• Charcot deformity</li> <li>• Dermatological</li> <li>• skin status: colour, thickness, dryness, cracking</li> <li>• Sweating</li> <li>• Infection: check between toes for fungal infection</li> <li>• Ulceration</li> <li>• Calluses/blistering: haemorrhage into callus?</li> <li>• Erythema</li> <li>• Dystrophic nails</li> </ul>	<ul style="list-style-type: none"> <li>• 10g monofilament at 4 sites on each foot + 1 of the following:</li> <li>• Vibration using 128 Hz tuning fork</li> <li>• Pinprick sensation</li> <li>• Ankle reflexes</li> <li>• Vibration perception threshold</li> </ul>	<ul style="list-style-type: none"> <li>• Foot pulses</li> <li>• Ankle Brachial Index, if indicated</li> <li>• Doppler wave forms, if indicated</li> </ul>

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## **Risk Factors for Diabetic Foot Ulceration**

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## **Key Words**

Diabetic Foot Ulceration, Diabetic Foot Risk Factors, Primary Healthcare, Podiatry Services, Diabetic Foot Assessment

## **Abstract**

**Objective:** The main purpose of the study was to investigate the need for podiatrists as members of the primary healthcare team. One of the objectives of the study was to determine the percentage of patients presenting at the two Primary Healthcare clinics who are at risk of developing foot complications as a result of an underlying concomitant systemic disease.

**Research design and methods:** A descriptive cross-sectional study in which data was collected from patients presenting at two homogeneously selected Primary Healthcare (PHC) clinics in Johannesburg. Nursing staff assisted by a final year podiatry student collected data using a self-constructed data collection form (DCF) from each consenting patients as part of their routine patient consultation. Simple descriptive statistics were used for data analysis.

**Results:** Data was collected and analysed from 1077 patients and showed that 29% of the patients had diabetes. Diabetic foot ulceration risk factors that were recorded included peripheral neuropathy in 74% of diabetic patients, structural foot deformities in 47%, peripheral vascular symptoms in 39% and foot ulcer in 28% of the diabetic patients.

**Conclusion:** Early identification of diabetic patients who are at high risk of diabetic foot ulceration is important and can be achieved via a mandatory diabetic foot screening with subsequent multidisciplinary foot-care interventions. Understanding the factors that place patients with diabetes at high risk of ulceration, together with an appreciation of the links between different aspects of the disease process and foot function, is essential to the prevention and management of diabetic foot complications.

## **Significance of the study**

- There is limited data available on diabetic foot risk factors across all levels of care in South Africa.
- The study found that up to 74% of patients presenting at PHC facilities in this study had symptoms of diabetic peripheral neuropathy and 28% had foot ulcers.
- The findings are suggestive of a need for diabetic foot assessment to be mandated at PHC level as part of the routine diabetic patient assessment and for Podiatrists to be involved at this level of care.

## **Introduction**

Diabetes mellitus is a multi-system disease affecting many systems and tissues and foot problems, including foot ulcerations, are common in patients with diabetes. In 2015, there were 2.8 million diabetics in South African [1]. The majority of diabetic patients in South Africa (SA) are most likely seen at Primary Healthcare clinics. These PHC clinics brings health care as close as possible to where people live and work, are the first line of access for people needing healthcare services and in some cases are the only available platform for delivery of healthcare for most of the population [2,3]. In Gauteng province where this study was done 740 118 diabetic patients presented at various PHC clinics for routine diabetic follow up visits in 2012/13 [4].

Foot problems are an associated complication and are an increasing problem among individuals with diabetes. Risk factors such as peripheral neuropathy, peripheral arterial disease, and structural foot deformities put the foot at risk of ulceration. Healthcare professionals at PHC level are mandated and are accountable for screening, early identification, and referral to more advanced levels of sophisticated care and or treatment if the need arises [5-7 ]. However, with regard to patients at risk of diabetic foot ulcerations, it remains unclear if this is done as there is no data on the diabetic risk factors recorded in patients presenting at various PHC clinics in SA. Diabetic foot ulceration (DFU) develop as a result of a combination of factors that together lead to tissue breakdown. The most frequently occurring causal pathways to the development of foot ulcers include peripheral neuropathy, vascular disease, foot deformity and trauma.

Early identification of patients with diabetes mellitus who are at high risk of DFU is important. This, as between 10-25% of diabetic patients are likely to develop DFUs at some stage of their lives which may lead to foot or leg amputations in 25-50% of these patients [8,9]. Available data in SA suggest that 60.2% of all non-traumatic lower limb amputations in public hospitals in SA are accountable to diabetes, with unpublished data from two separate public hospitals showing an amputation rate of 78.5% with 85% of these beginning with a foot ulcer [10,11]. In most cases by the time patients with diabetic foot ulcerations are referred it is often too late to save foot [12].

Currently, the PHC clinics provide an ideal setting for early diabetic foot risk identification, as these facilities are primarily focused on preventative care and early risk identification rather than curative approach [13-15]. However, nurses who are at the coalface of primary healthcare delivery are overworked and do not have time to provide comprehensive care in all consultations [16]. This may lead to diabetic foot assessment being omitted as part of diabetic patient routine assessment. This assertion is supported by the lack of data on diabetic foot risk factors emanating from PHC clinics.

There is, therefore, a need to look at including other healthcare cadres to ensure delivery essential foot health services including to the diabetic patients. A multidisciplinary approach underscoring a comprehensive preventive strategy, including early risk detection via mandatory foot assessment,

patient and staff education, and multi-factorial treatment of diabetic foot ulcers is needed. Literature shows that in some cases, such approaches have reduced amputations by more than 50% [17-20]. Such interventions will ensure good outcomes for diabetic patients, as well as prompt treatment and or referral where needed. This may be difficult to realise immediately as currently, foot health service guidelines or policies are unclear. In fact, the current PHC package of services available at PHC level and the Human Resources for Health plans do not mention foot health services or integration of (podiatric) such services as part of services to be offered at PHC level of care [21,22].

There is, however, a need to understanding and document the factors that predisposes diabetic patients to risk of ulceration, together with an appreciation of the links between different aspects of the disease processes and foot function. This is needed for the prevention and management of diabetic foot complications. Thus, this article focuses on the risk factors for diabetic foot ulceration recorded in patients presenting at PHC clinics.

### **Research design and methods**

A descriptive cross-sectional, study was conducted over a period of fourteen weeks between June and September 2013 at two primary health care clinics in Johannesburg. The participating clinics were selected using homogeneous sampling method with one clinic located in the inner city and the other in a township. Patients presenting at the participating clinics were asked to participate in the study and 1077 patients consented to taking part in the study. Those patients who agreed to participate had their medical data recorded and their feet inspected by a clinic nurse assisted by a final year podiatry student. Data was collected as part of routine patient consultation and was captured on a self-constructed data collection form (DCF).

The data collection form had four sections which dealt with demographics, the presence of foot related complaints, presenting systemic or joint condition and current management of patients with foot complaints presenting at PHC clinics. The data collection form was pretested at another primary healthcare clinic in Johannesburg before being used for data collection in the study. Simple descriptive statistics were undertaken to analyse data which included performing basic frequencies, inferential method for comparing groups and a comparative analysis of demographics was completed using comparative inferential statistics.

### **Ethical approval**

Ethical clearance for the study was obtained from the University of Johannesburg, Faculty of Health Sciences, Research Ethics Committees (REC-241112-035). Permission to access the selected clinics for data collection purposes was granted by the Executive Director of the City of Johannesburg Health Department.

## Results

Data was analysed from the 1077 completed data collection forms, 442 from one clinic and 635 from the other. No patient identifying data was collected as part of the study, only gender, population group and age were collected as part of the demographic data for this study. Three hundred and fourteen patients were confirmed as having diabetes based on their medical records.

### Gender.

Overall analysis of the 1077 DCFs gathered showed that 33% (n=356) were male patients, and 62% (n=672) were female patients. The gender of the remaining 5% (n=49) could not be decided as the forms were not properly completed concerning this question.

### Age.

The mean age was between 46 and 49 years for the two clinics respectively. The age spread of patients in this study is presented in Figure 1.

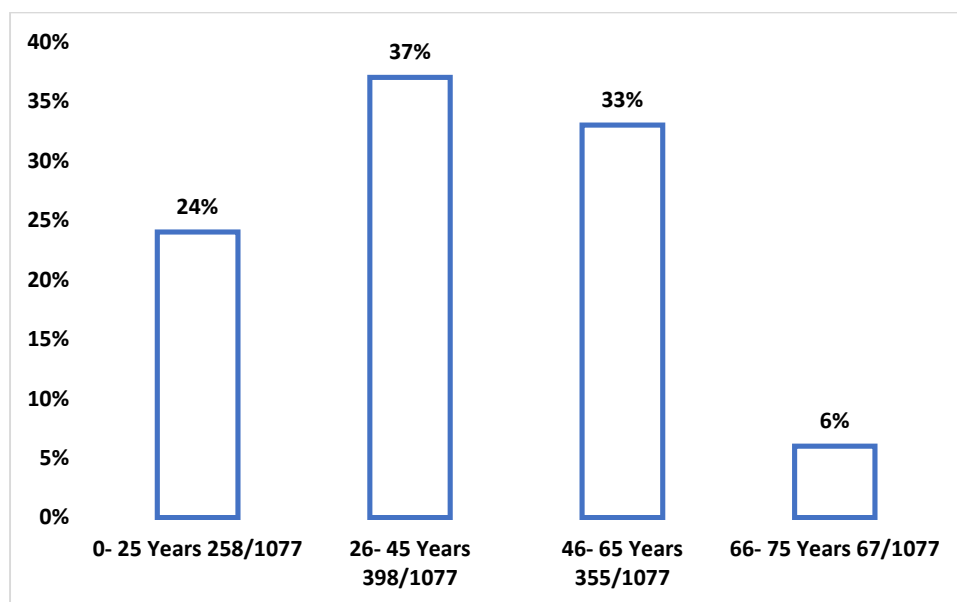


Figure 1. Age spread.

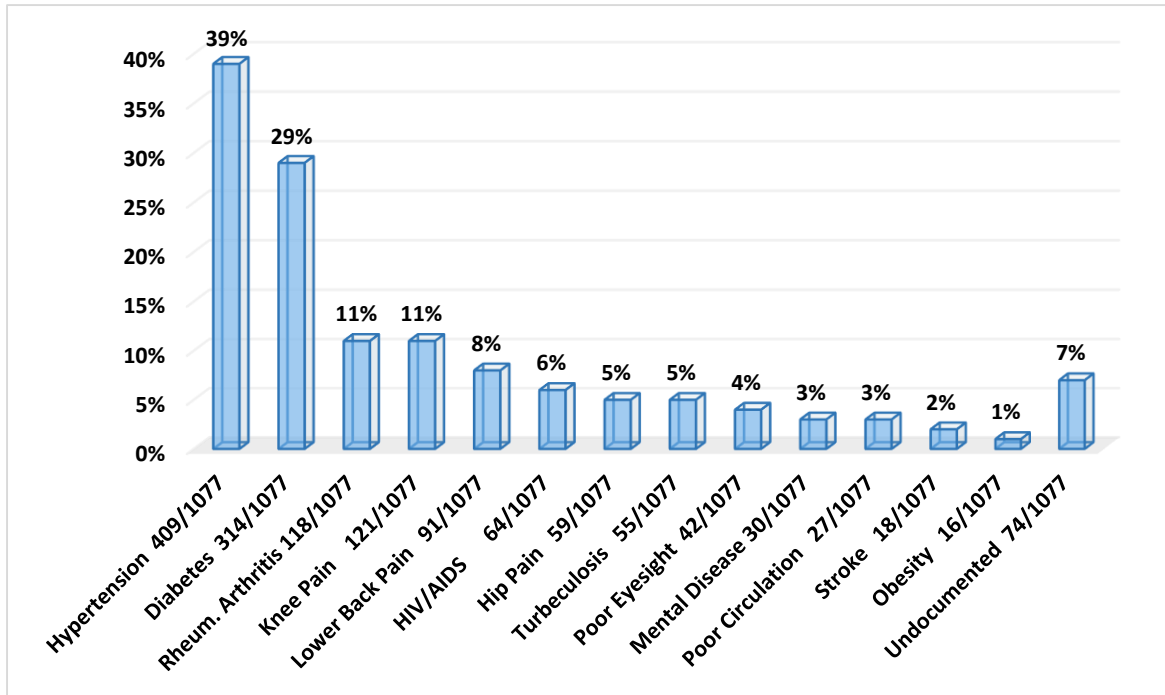
### Population group.

Black Africans were the majority population group in this study at 51% followed by coloureds (mixed ancestry) at 25%. Whites and Indians made up 3% and 9% respectively and in 12% of the DCFs, the population group was not documented.



**Presenting chronic systemic disease/condition.**

In total 54% (n=583) patients presenting at the two PHC clinics had a systemic disease or a joint condition. Diabetes was recorded in 29% (n=314) of the patients whose data was collected in this study. Systemic conditions recorded in this study are presented in Figure 2.



**Figure 2. Systemic disease or joint condition.**

**Recorded Risk factors for diabetic foot ulcerations.**

The risk factors for diabetic foot ulcerations recorded in this study are presented in Table 1.

**Table 1. Diabetic Foot Risk Factors.**

Risk Factor	Prevalence
Neuropathy	75 % (n=236)
Structural Deformities	47% (n=147)
Peripheral Vascular Disease Symptoms	39% (n=124)
Foot Ulcers	28% (n=87)

**Foot pathologies or symptoms recorded in diabetic patients.**

Foot pathologies and or symptoms that were recorded in diabetic patients in this study are presented Table 2.

**Table 2 Foot pathologies and symptoms recorded in diabetic patients.**

Foot Pathology/ Complaint	Prevalence (%)
Corns	26% (n=82)
Calluses	40%(n=125)
Ulcers/Wounds	28% (n=87)
Infections (Tinea)	25% (n=79)
Thick nails	4% (n=13)
Ingrown nail	21% (n=66)
Fissures/Cracks	32% (n=102)
Interdigital Maceration	21% (n=67)
Burning feet	16% (n=50)
Tingling	31% (n=97)
Numbness	28% (n=89)
Cold feet	22% (n=70)
Intermittent Claudication (Cramping)	17% (n=54)
Pes Planus (Flat feet)	31% (n=98)
Hammer toes	2% (n=7)
Bunions	7% (n=22)
Overlapping toes	1% (n=5)
Pes Cavus (High arches)	5% (n=15)

## Discussion

Primary health care facilities may in most cases be the only available or accessible form of healthcare for the majority of the population [2,3]. This can be seen in the 128 million people who were seen or visited a PHC clinic in 2013/2014 [23]. It is very likely that a significant number of these patients were diabetic, we know that in Gauteng alone 740 118 diabetic patients were seen at various PHC clinics for routine diabetic follow up visits in 2012/13 [4]. However, to date, there is no data available on the number of diabetic patients who had a diabetic foot assessment as part of their routine diabetic care coming from PHC clinics.

Our study has provided evidence of diabetic patients presenting at PHC clinics who are at a real risk of developing diabetic foot ulceration. Diabetic foot ulcerations develop as a consequence of a combination of risk factors, most commonly peripheral neuropathy, peripheral vascular disease, foot deformity and (unperceived) trauma. In our study, we recorded all these risk factors in the diabetic patients. The life time risk of a diabetic patient developing a DFU is estimated to be as high as 25% [24]. Thus early identification of risk factors that may lead to tissue breakdown is important as potential DFU sites are often not diagnosed in diabetic patients until tissue loss is evident, usually in the form of a nonhealing ulcer. Though, diabetic foot ulceration pathway (**Figure 3**) is complex multifactorial

process involving interactions between numerous risk factors leading to skin breakdown, up to 85% of amputations can be prevented via routine diabetic foot assessment and early identification of risk factors [25,26].

Thus foot assessment and resultant early identification of those patients who are at risk for foot ulceration is paramount in the prevention of DFUs. Early risk identification and regular inspection of the feet (by podiatrists) has been identified as the cornerstone in the prevention and management of diabetic foot complications [27]. The annual diabetic foot inspection has been identified as probably the single most important tool available in the prevention of diabetic foot ulcerations [28]. The aim of such assessment is to identify those with early signs of complications and institute appropriate interventions such as determining the frequency of clinic visits and actions to be taken to prevent progression of risk factors into DFUs. Thus, the characteristics of such foot assessment would include the removal of shoes and socks for a careful inspection of both feet including between the toes to be undertaken (**Table 3**)

Ideally, every diabetic patient should be screened for evidence of diabetic foot ulceration risk factors at least annually at their PHC clinic.

For example, diabetic peripheral neuropathy (DPN) risk factors which are associated with a seven-fold increase in risk of ulceration [29,30], which was recorded in patients in this study, can be identified by simple clinical observation. Such an observation would include looking for features such as small muscle wasting, clawing of the toes, prominence of the metatarsal heads, distended dorsal foot pains (a sign of sympathetic autonomic neuropathy), dry skin and callus formation. Additional test may include a vibrating 128 Hz tuning fork, the 10g monofilament to be used at specific sites of the foot. Assessment of the actual foot structure or deformity should also be undertaken. Structural foot deformities when combined with neuropathy and ensuing altered biomechanics may lead to abnormal loading of the foot or abnormal plantar pressure leading to ulcer formation [24]. Foot deformities were noted on patients in this study as well as actual foot ulcers in diabetic patients. Patients, in this study, were at an increased risk of amputation as 28% had foot ulcers and 39% had symptoms of peripheral arterial disease (PAD) [31,32].

Studies done on the diabetic population in SA suggest that foot health at PHC level is ranges from non-existent, to mostly ignored or disorganised at best. One study done at an outpatient department of a district hospital in found that 67.5% of diabetic patients had never had their feet examined by either a doctor or a nurse at a PHC Clinic [33]. Other studies have found that primary and secondary prevention were not prioritised in routine diabetic patient clinical care and that foot screening is often neglected at PHC level [34,35].

Though, our findings are suggestive of the need for preventative measures, including having diabetic foot assessment included as mandatory item of routine diabetic patient care at PHC clinics. Poor diabetic foot care at PHC level is understandable. Nurses at PHC clinics have a heavy patient load which may limit patient consultation times and getting through their patient load may lead to a situation where possibly, foot assessment may be the last thing on both the nurses' and patients' minds during consultation [16,36]. Therefore, there is a need to consider the involvement of podiatrists at PHC clinics to undertake diabetic foot assessment and risk stratify patients as well as provide treatment for some of the foot pathologies at this level of care [37].

Podiatrists play a key role in the prevention (includes regular foot examinations, risk stratification, and appropriate footwear recommendations) and treatment of foot deformities and complications related to diabetes at PHC level. Podiatry approach to diabetic foot ulceration is distinctive in that the diabetic foot ulceration is not viewed in isolation but rather in the perspective of the overall structure and function of the foot, ankle and lower limb. Therefore, podiatric treatment of DFUs includes a focus on biomechanical anomalies that often precede ulcer formation. Further, simple interventions like regular callus debridement to prevent increases in focal pressures can reduce the likelihood of ulcer formation.

## **Conclusions**

We have provided some evidence of patients presenting at PHC clinics with risk factors for diabetic foot ulcerations. Our findings should be used as an indicator of a silent, but imminent, public health problem that is likely to impose significant challenges on the South African healthcare systems in the near future. Thus, indicative of a need for effective, early preventative approaches, primarily the early identification of at risk patients at PHC level.

Based on our healthcare delivery structures a substantial number of diabetic patients are likely seen at PHC facilities across South Africa and a considerable number of them may be at risk of diabetic foot ulcerations. Early identification of at risk patients can prevent or delay development of DFUs and in cases where patients already have DFUs prompt management or referral with subsequent multidisciplinary foot-care intervention can be assured.

Therefore, there is a need for diabetic foot assessment to be (mandated) a part of routine diabetic patients care at PHC level.

## **Acknowledgements**

I am grateful to the nurses (especially the clinic managers) and the patients from the two clinics who took part in this study as well as the two final year podiatry students who assisted with data collection. Thanks also to the Dr R. Bismilla Executive Director, City of Johannesburg Health Department for allowing me to conduct this study in their facilities.

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**Authors' contributions**

S. Ntuli—concept, data collection, analysis and interpretation, initial draft, and revisions.

C. Vincent-Lambert—concept and study design development, supervision, draft revision.

A. Swart—concept and study design development, supervision, draft revision.

**Competing interests**

The authors declare no conflicts of interest in relation to this work.

**Consent for publication**

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the study. Thus, consent for publication is not required.

**Ethics approval and consent to participate**

Ethical approval for the study was obtained from the University of Johannesburg, Faculty of Health Sciences, Research Ethics Committees (REC-241112-035). Permission to access the selected clinics for data collection purposes was granted by the Executive Director of the City of Johannesburg Health Department.

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