iDEAL
Insights for Diabetes Excellence, Access and Learning

iDEAL Group Position Statement

ACT NOW!
Diabetes and Foot Care Assessment and Referral

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The iDEAL Group (Insights for Diabetes Excellence, Access and Learning are a dynamic multidisciplinary team of diabetes specialists with expertise that spans across diabetes management, medicine, pharmacy, dietetics, technology, nursing, psychology, commissioning and the perspective of living with diabetes. Their focus is to build consensus, network, research, share knowledge and collectively seek to make things better; both for practitioners working in partnership with and for people living with diabetes.

In keeping with its ethos of encouraging the implementation of the best evidence and clinical opinion iDEAL would like to recognise the significant contribution to this Position Statement from Chris Aldred (aka The Grumpy Pumper).

KEY RECOMMENDATIONS

- Increased awareness of the risks to all people living with diabetes (PLwD) to promote foot health and avoid delays in seeking help when facing any difficulties.
- Establish a national education programme with practical information in an illustrated practical handout for all PLwD about foot self-care and checks from diagnosis onwards.
- Increased access to education in foot assessment and urgent referral for ALL Health Care Professionals (HCPs) working with PLwD.
- Adoption of the 'ACT NOW' acronym, detailed at the end of this paper, in urgent foot care referrals for every PLwD by all HCPs.
- Clarity of referral pathways is essential for all HCPs to avoid unnecessary delays and LEAN thinking techniques to facilitate and enable clarity of pathways for easy referral.
- For all NHS Trusts to enable PLwD to self-refer as required to Multidisciplinary Foot Care Teams (MDFT) to avoid unnecessary delays.
- NHS Standardisation of evidence based provision of MDFT in all NHS Trusts and referral criteria to reduce postcode lottery and fragmented services across the NHS and to comply with the guidance from The International Working Group of the Diabetic Foot (IWGDF) (2019).
- Regular audit to assess the impact on services and demonstrate the need to increase access to MDFT.
- Call upon professional bodies to review the annual data from NHS England and the National Diabetes Audits to assess the training and support needs for HCPs to have the necessary capabilities to address prioritised unmet needs.
- All Clinical Commissioning Groups and Primary Care Networks provide all three care structures of care for PLwD with diabetes and foot disease, as recommended by NICE Guideline, NG19 (2019).
  1. Training for healthcare staff to carry out routine foot examinations
  2. A clear pathway for assessment if someone has new, worsening or re-occurring foot ulcers (within 24 hours if needed)
  3. A clear pathway for referral into a specialist foot protection service if someone is assessed as being at increased risk of developing foot ulcers

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THE SITUATION - THE UNMET NEED

During their lifetime, one in three PLwD may develop foot ulcers (Armstrong et al, 2017). These are highly susceptible to infection which can spread rapidly causing overwhelming tissue destruction or gangrene necessitating major amputation. The progression from an initial "scratch" to gangrene can take as little as 48 hours. People may also lose a leg because of a reduction in blood supply to the foot which leads to gangrene as well (National Diabetes Footcare Audit, (NDFA), 2019).

There were 7,545 major amputations in people with diabetes in England between 2015 to 2018 (Public Health England, 2019). The age and ethnicity standardised major amputation rate of for PLwD per 10,000 population-years in England was 8.2 and has been essentially static from 2013. Furthermore, in England, there is an unacceptable 7 fold countrywide variation in the major amputation rate even after correcting for age and ethnicity with the incidence (annualised over 3 years) ranging from 3 to 21 major amputations per 10 000 population-years (Holman et al, 2012; Jeffcoate et al, 2017). After major amputation of one limb, over 50% of people with diabetes have an amputation either major or minor in the contralateral limb (Izumi Y 2006).

As well as amputation being a personal life-changing event, the financial burden of diabetes foot care is immense. The cost of health care for ulceration and amputation in diabetes in 2014–2015 was estimated at between £837 million and £962 million; 0.8% to 0.9% of the National Health Service (NHS) budget for England (Kerr et al, 2019).

With national difficulties in GP appointments wait time, delay in PLwD being able to access assessment or treatment is not their fault.

This iDEAL position paper seeks to reduce the stigma often experienced by PLwD regarding complications and remove any blame or shame associated with diabetes complications. This includes not using the terms 'Diabetic Foot or Diabetic Ulcer' as these add to the stigma experienced by PLwD. These changes can be created through encouraging and enabling an environment of education, knowledge and trust using language that enables and not disadvantages PLwD (Cooper et al, 2018).

A lack of knowledge leads to a lack of urgency, which creates negative outcomes by both HCPs and PLwD who may not recognise that they have a foot related problem requiring urgent referral or care interventions (Pankhurst and Edmonds, 2018). A temperature change can indicate infection or the development of Charcot arthropathy. However, Charcot arthropathy can be easily missed without access to an x-ray or MRI and thus may not receive a necessary urgent referral to the MDFT (Vopat et al, 2018).

The National Diabetes Footcare Audit (NDFA) (2019) reported that 54.5% of PLwD who self referred were alive and ulcer free at 12 weeks compared with 49.0% in whom there was a 3-13 days interval before first expert assessment ($p<0.05$). Furthermore, 64.5% who self referred had less severe ulcers compared with 53.3% in whom there was a 3-13 days interval before the first expert assessment) ($p<0.05$). Kerr et al (2019) suggested if the NHS were to reduce the prevalence of foot ulceration in England by one third, the suggested gross annual saving would be in excess of £250 million.

This position statement advocates the development of MDFTs and improved education in foot care for both PLwD and HCPs to make these savings achievable. However, since the removal of NHS student bursaries in 2017 in England and Wales, the Council of Deans of Health (2019) have identified that programmes for podiatry and prosthetics are struggling to attract and retain enough students to enter the profession for succession planning to meet the needs of PLwD in the future.

iDEAL recommend that PLwD should be able to self refer to a specialist multidisciplinary diabetes foot care team (MDFT) to avoid unnecessary delays if worried with their first concerns about diabetes related foot problems. The 2019 NDFA reports that PLwD who self refer have usually had a previous foot ulcer and know the foot care team, or may have been identified as high risk and have attended a Foot Protection Service. However, this should be enabled for every PLwD to avoid delays and potential deterioration. iDEAL acknowledges too that PLwD who have experienced foot related problems can experience significant psychological distress, even if the outcome is positive, so increasing access to psychological and emotional health in these circumstances is also recommended (Vileikyte et al, 2019).

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THE WAY FORWARD

TREATMENT OF ULCERS

84% of major amputations are preceded by an ulcer (Pecoraro et al, 1990). Thus, when ulcers do develop, there is an urgent need for rapid healing which can be achieved if the ulcer is treated optimally. An infection will then not have the opportunity to arise and amputation will be avoided. If an infection does occur, the urgent need is, again, for rapid treatment as promoted by the acronym ACT NOW! Also, if there is a severe reduction in blood supply to the foot (ischaemia) which prevents the healing of an ulcer, the urgent need is also for rapid treatment of ischaemia to prevent amputation. Healing of ulcers, treatment of ischaemia and prevention of amputations can best be achieved by the MDFT (NDFA, 2019).

PREVENTION OF ULCERS

The way forward in the medium term is to avoid the development of ulcers in the first place or at least prevent the recurrence after an initial ulcer is healed. However, at present, the recurrence rates of foot ulcers of PLwD after successful healing are 40% within a year and 65% within 3 years (Armstrong et al, 2017). The NDFA report (2019) indicated that 9 in 10 providers of foot care have a Foot Protection Service which has primary responsibility for the care of people at high risk of new ulceration and thus for the prevention of ulcers.

BARRIERS TO THE OPTIMAL TREATMENT OF ULCERS

1. The delay at various stages in the patient pathway to access specialist care in the MDFT.
2. The unavailability of such optimal specialist care because of the absence of an MDFT in the local acute hospital or community

DELAY IN THE PATIENT PATHWAY

In a systematic review investigating the identification, causes, and outcomes of delays in the management of chronic limb-threatening ischemia and foot ulceration in PLwD, Nickinson et al (2019) reported that "*median times from symptom onset to specialist health care assessment ranged from 15 to 126 days, with subsequent median times from assessment to treatment ranging from 1 to 91 days*". A number of reasons were put forward for the delays including "*poor symptom recognition by the patient, inaccurate health care assessment, and difficulties in accessing specialist services*" (Nickinson et al, 2019).

Delay can take place at three stages:

1. Delay by the PLwD in seeking and reaching care
2. Delay by HCPs in referring to specialist care
3. Once a referral is made, delay in actually accessing care in the MDFT.

DELAY REGARDING PLwD

The initial decision to seek care must be prompted by the PLwD who should be alert to untoward events such as a break in the skin, discharge, redness, swelling or the new onset of pain. Even before skin breakdown, the foot may develop an abnormal shape related to current or previous trauma, comprising Charcot arthropathy. PLwD should be warned that such deformities may lead to high pressures on the foot which can result in skin breakdown.

iDEAL proposes the establishment of a national education programme with practical information in an illustrated practical handout for all PLwD about foot self care and checks from diagnosis onwards are needed.

This information must be made easily accessible in national diabetes related websites (for example Diabetes UK, JDRF, NHS, TREND as examples) and in all GP surgeries and all pharmacies.

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Delay occurs because of the failure to recognise the seriousness of a break in the skin, discharge, redness or swelling. Feinglass et al. (2012) identified both misunderstandings of the condition and confusion about the need for specialist care when reporting interviews with PLwD: Feinglass (2012) commented that "*Patients reported unexpected onset and rapid progression of ulceration, infection, progressive vascular disease, foot trauma and complications of comorbid illness as precipitating events. Fateful delays of care were common. Many had long histories of painful prior treatments. A fatalistic approach to self-management, difficulties with access and communication with providers and poor understanding of medical conditions were common themes. Few patients seemed aware of the role of smoking as an amputation risk factor.*"

It was concluded that most PLwD felt out of control and had a poor understanding of the events leading to their initial amputations. In addition to this, concurrent retinopathy and neuropathy prevented PLwD appreciating the seriousness of their symptoms.

Macfarlane and Jeffcoate (1997) previously reported that only 53% of foot ulcers were actually identified by the PLwD themselves. At masterclass foot health conferences in 2015 and 2016, UK based diabetes HCPs perceived sub-optimal patient education on the risks of foot ulcers to be the critical barrier to a PLwD in accessing professional care. (Pankhurst & Edmonds, 2018) and this was also recognised in the root cause analysis of delays by Canavan and Martin (2015). Furthermore, in a study of pre hospital delay in 270 patients admitted to hospital with diabetic foot problems, there was a statistical association between "long delays" (>30 days from symptom onset to specialist care) and both a lack of diabetes related foot education (odds ratio [*OR*], 2.70; 95% confidence interval [*CI*], 1.03-7.06;*P*=0.043) and a lack of PLwD knowledge of foot danger signs (*OR*, 2.14; 95% *CI*, 1.16-3.94;*P*=0.015) (Yan et al, 2014). Spanos et al (2017) reported that for each additional day of delay until referral, the odds risk for major amputation increased by 3.5% (95% *CI*, 1%-6%;*P*= .011).

DELAY REGARDING HCPs

When a PLwD seeks advice from an HCP, there is sometimes a delay because of failure of the HCP to recognise or make a diagnosis or, even after making the correct diagnosis, to appreciate the seriousness of the condition and to make the appropriate referral to the MDFT. Normahani et al. (2018) reported that 17% of podiatrists would refer a PLwD for a vascular opinion if an ulcer remained unhealed after 42 days of conservative management as indicated within the 2019 IWGDF guidelines. An association has been noted between the number of HCPs in the referral pathway and increased delays in reaching specialist hospital care: the more complex the referral pathway, the greater the delay (Sanders et al, 2013). Furthermore, Pankhurst and Edmonds (2018) reported that HCPs identified difficulties in accessing specialist diabetes foot services, citing funding constraints, lack of staffing and centralisation of services.

DELAY OF ACCESS TO THE MDFT

Faglia et al. (2006) previously reported a better outcome in PLwD referred for emergency surgical debridement directly from a specialist outpatient (MDFT) clinic in his own hospital compared with those referred from another hospital in which they had a mean stay of 6.2+/-7.5 days without any debridement. A delay in the surgical debridement of a deep space abscess increased the amputation level. Regression logistic analysis showed a significant relationship between the amputation level and the number of days elapsed before debridement (*OR*, 1.61; 95% *CI*, 1.10-2.36;*P*=0015).

DELAY FROM SYMPTOM ONSET TO SPECIALISED CARE AFFECTS WOUND HEALING

The longer the time from symptom onset to specialised care the slower the rate of wound healing.

The NDFA (2019) has shown that when early referral to specialist care is made, ulcers are less severe on arriving at the MDFT (compared with delayed referral) and this is associated with better outcomes at 12 weeks .

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OVERALL REASONS FOR A DELAY

When HCPs were asked as to what they perceived as barriers to care, they reported:

- the suboptimal or poor recognition and diagnosis of foot problems;
- lack of awareness of the need for referral both by the PLwD and HCPs;
- difficulties in the referral pathway;
- lack of access to multidisciplinary care;
- shortage of resources; and
- lack of education of both PLwD and HCPs.
- These barriers contributed to the delay in PLwD receiving specialist help (Pankhurst & Edmonds, 2018).

A root cause analysis of the overall PLwD pathway identified four areas contributing to a delay in referral to a clinic;

- PLwD education,
- HCP education,
- Community foot care services
- Problems surrounding communication amongst the diabetes multidisciplinary team (Canavan & Martin, 2015)

THE UNAVAILABILITY OF OPTIMAL SPECIALIST CARE

The National Diabetes Inpatient Audit (NaDIA) of 2018 which covered the structures of care that are fundamental to achieving the standards of safe effective inpatient diabetes care reported that one sixth of hospital sites (17.3%) did not have an MDFT (NaDIA, 2018).

BARRIERS TO THE PREVENTION OF ULCERS

Prevention of ulcers both primary and recurrent is very difficult. There is no definitive evidence on the effect of screening for preventing foot ulceration in PLwD. Despite many forms of education being available, research on its effectiveness is limited. The evidence to support the use of any educational intervention for the primary prevention of ulcers is not strong: Jeffcoate et al (2018) reported that there are a small number of randomised controlled trials but those that claimed benefit were not of high quality. Although foot care knowledge and self-reported PLwD behaviour seem to be positively influenced by education in the short term, there is insufficient evidence that PLwD education alone is effective in achieving clinically relevant ulcer risk reduction.

In a Cochrane Review, Dorresteijn et al (2014) concluded that there was insufficient robust evidence that patient education albeit limited is effective alone in achieving clinically relevant reductions in ulcer and amputation incidence. This was based on two studies which were sufficiently powered in the Review, reporting the effect of patient education on the primary endpoint of ulcer prevention one by Malone et al (1989) and the other by Lincoln et al (2008). However, in these studies, the educational programme was very limited, comprising only a single one hour educational session, reinforced by handouts, compared with either routine patient education or written instructions only. The conclusions of these studies were conflicting, (the Malone et al (1989) study was positive, the Lincoln et al (2008) study was negative) but because the risk of bias was lower in the Lincoln et al study, more weight has been given to the negative outcome of this study. Although these studies had very limited education, this does not rule out the effectiveness of more comprehensive and/or more intensive educational strategies.

Indeed, an evidence based national programme of education for PLwD with accessible information is urgently required.

WHAT DO THE GUIDELINES SAY?

NICE Guidelines NG19 2015, updated in 2019 indicated that there should be a multidisciplinary foot care service specifically for PLwD. This is to manage their foot problems in hospital and in the community that cannot be managed by the general Foot Protection Service. NICE NG19 also advocated that a PLwD who has a limb threatening or life threatening foot problems such as ulceration with limb ischaemia or with fever or any signs of sepsis or a deep-seated soft tissue or bone infection or gangrene should be referred immediately to the acute services and the multidisciplinary foot care service be informed.

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For all other active diabetes related foot problems, the PLwD should be referred within one working day to the MDFT or Foot Protection Service (according to local protocols and pathways) for triage within one further working day. Delays in accessing GP appointments for assessment and referral, underpin the requirement for PLwD to be able to self-refer.

The IWGDF, (2019) suggests that PLwD with a foot ulcer and peripheral arterial disease should be referred for vascular imaging and revascularization if the ulcer does not heal within 4-6 weeks despite good standard of care. Urgent vascular imaging and revascularisation should always be considered in a PLwD with a foot ulcer and an ankle pressure <50 mmHg, an ankle brachial pressure index <0.5, a toe pressure <30 mmHg or a foot transcutaneous oxygen tension <25 mmHg.

RECOMMENDATIONS

- **The short term aim should be to ensure that PLwD with a foot ulcer attends the MDFT as quickly as possible for treatment.**
- **The medium term aim should be to prevent the development of ulcers.**
- **Once an ulcer has developed, the proposed intervention must empower the PLwD and the HCP to enable them to rapidly get the individual to specialist care. Improving PLwD knowledge of their conditions seems a reasonable method of reducing delays (Nickinson et al, 2019).**
- **PLwD and their HCPs should be capable of recognising problems in the foot and then be able to rapidly access expert care from the MDFT.** Manu et al (2018) in a study of health care systems in Europe, concluded *"Despite differences in healthcare structures across Europe, delays in referral to specialist foot care teams seems to be a common theme. There is an ongoing need to educate GP's, nurses and patients to be more aware of the risk of DFU (diabetic foot ulcer), and the need for prompt referral to specialist diabetic foot teams."*
- **Health Commissioners and Providers should facilitate the option of self referral by PLwD directly into their local MDFT.** This is likely to increase the total number of referrals into the MDFT. Although this will facilitate more rapid assessment and treatment of foot ulcers with subsequent greater and prompter ulcer healing it will increase demand for podiatrists within the diabetes foot service.
- **The government needs to urgently review the decision to remove the NHS student bursaries into podiatry to improve recruitment into this discipline.**
- **A national campaign similar to the campaigns that informed heart attack and stroke (which had the acronym STOP and FAST) is required.** Such a mnemonic campaign should help detect and enhance the responsiveness to the warning signs displayed by a PLwD. The iDEAL Group suggest **"ACT NOW".**

A

Accident?
Recent or history of an accident, injury or trauma?

C

Change?
Is there any new swelling, redness or change of shape of the foot?

T

Temperature?
If there is a change in temperature present? Could this be an infection or possible Charcot?

N

New Pain?
Is there pain present? Is it localised or generalised throughout the foot?

O

Oozing?
What colour is any exudate? Is there an odour?

W

Wound?
Can you document the size, shape and position of the wound in the foot affected?

Any of which would activate a referral to specialist care in the MDFT.

This presupposes that an MDFT is available in each NHS trust hospital. However as reported in the NaDIA (2018) this is still absent in 17% of NHS trusts.

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- **There should be MDFT provision in every acute hospital and a supplementary part of the Diabetes transformational campaign would be to make sure that there is an active credible MDFT in each NHS trust, to which there is ready access by PLwD with foot problems.**

As previously noted, the NDFA (2019) has indicated that 9 in 10 providers have a Foot Protection Service which has primary responsibility for the PLwD at high risk of new ulceration and has the difficult task of preventing initial ulcers and also recurrent ulcers.

Although specific education programmes may improve knowledge and foot self-care behaviour they have generally not resulted in better outcomes. However, Adiewere et al. (2018) in a systematic review and meta-analysis of patient education in preventing and reducing the incidence or recurrence of adult diabetes foot ulcers, concluded that an intensive educational approach, as opposed to a brief educational approach, showed a statistically reduced incidence of foot ulcers. It has been suggested that continuous education throughout a PLwD's care, with teaching being reinforced at each clinical encounter is a possible solution (Nickinson et al, 2019). Also, The IWGDF (2019) recommends that structured education should be provided to all PLwD who can be at risk of foot ulceration about appropriate foot self-care for preventing a foot ulcer. This is coupled with the need for continuous CPD for all HCPs also who work with PLwD or who have any contact with PLwD to ensure their care is evidence based, current and effective, as advocated by iDEAL (Phillips et al, 2019).

As well as structured education, the IWGDF (2019) has encouraged foot self management which involves advanced interventions specifically designed for ulcer prevention. The IWGDF (2019) report that home monitoring of plantar foot skin temperature once per day with an infrared thermometer, combined with subsequent preventative action when elevated temperatures were noted for two consecutive days, was more effective than standard treatment for preventing foot ulcers in high risk-PLwD (Armstrong et al, 2007).

It has been estimated that such integrated foot care including professional foot care, adequate footwear and structured education about self-care may reduce the recurrence of ulceration by 75% (Bus & van Netten, 2016).

- **PLwD are recommended by guidelines in the IWGDF (2019) to have a footwear assessment such that people who are moderate-high risk are advised to wear accommodative properly fitting therapeutic footwear.**
- **In PLwD patients that fail non-surgical treatment for deformity which leads to an active or imminent ulcer, surgical intervention may be considered.**

IMPACT: THE POTENTIAL TO HALVE THE NUMBER OF AMPUTATIONS

It is hoped the impact would be to accelerate the healing of ulcers in PLwD and hence reduce the number of foot infections, hospital admissions and major amputations. When ulcers develop, there should be fast access to the MDFT. PLwD who were referred to specialist health care by a general practitioner ≥ 52 days after ulcer onset had a 58% (Sub distribution Hazard Ratio (SHR) 0.42, CI 0.18-0.98) decreased healing rate compared to PLwD who were referred earlier (Smith-Strøm et al, 2017).

Once a PLwD gets into the MDFT, individual outcomes are expected to improve, the number of major amputations should be reduced and savings should be generated for the NHS.

In 2012 the National Audit Office estimated that by reducing the late referrals to specialist foot teams by 50%, the resulting reduced number of amputations could save £34 million a year (National Audit Office 2012).

Our campaign has a target to reduce the number of major amputations by at least 50% over 5 years. The cost of inpatient care for major amputations in 2014-2015 was £24.8 million (Kerr et al, 2019) and achieving this target would save over £12 million.

Education is vital for all PLwD regarding their own daily foot assessments and how and when to seek advice and help from HCPs. Additionally education on effective foot assessment and referral criteria is vital for all HCPs who work alongside PLwD at potential or actual risk of a foot ulcer. Clarity of referral pathways is also essential for all HCPs to avoid unnecessary delays and LEAN thinking techniques (NHS Confederation, 2006) to facilitate and enable clarity of pathways for easy referral to include PLwD to self-refer as required should be enabled within all NHS Trusts.

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ACT NOW!

Tool for all NHS Primary and Secondary Care services to promote prompt and rapid referral to the MDFT (Multidisciplinary Foot Care Team) (Edmonds et al, 2020).

Refer the PLwD (Person/People Living with Diabetes) if they present with any of the following to their foot/feet:

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ACT NOW! Checklist

ASSESSMENT OF FOOT	Tick if present	Digital photo taken to include with referral	Date referred	Document referral to Specialist MDFT
A - ACCIDENT? Recent or history of an accident or trauma?				
C - CHANGE? Is there any new swelling, redness or change of shape of the foot?				
T - TEMPERATURE? If there is a change in temperature present? Could this be an infection or possible Charcot?				
N - NEW PAIN? Is there pain present? Is it localised or generalised throughout the foot?				
O - OOZING? What colour is any exudate? Is there an odour?				
W - WOUND? Can you document the size, shape and position of the wound in the foot affected?				

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