



Management of Diabetic foot

ICRC's Implementation Plan

for patient education, foot examination with risk stratification, footwear, insoles and off-loading interventions to prevent and heal diabetic foot ulcerations



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Purpose

This implementation plan of the ICRC Physical Rehabilitation Programme (PRP) exists to guide the practice of orthotists within PRP assisted centres in the provision of footwear and insoles to help prevent the occurrence of diabetic foot ulcerations (DFUs) and in the provision of offloading devices to help heal DFUs. It is also for other staff in the care of people with diabetes to know when to refer to a Physical Rehabilitation Centre. This implementation plan is evidence based, consistent with the International Working Group for the Diabetic Foot (IWGDF) Guidance on footwear and offloading and the NICE clinical guideline 19. This ICRC PRP implementation plan and the recommendations contained have been prepared by the PRP Diabetes working group and reviewed by external experts. The aim is to help Physical Rehabilitation Centre (PRC) staff develop a Clinical Pathway as easily as possible.

The document is broken into three sections. 1) Foot assessment, 2) Stratification and 3) Footwear, insoles and offloading implementation. Referrers such as Primary Health Care Clinics (PHCs) or Hospital services will be most interested in the first two sections, while orthotists and PRC staff will need to utilise all three sections.

Introduction

The number of people in the world with diabetes (age standardised) has doubled since 1980 with 422 million people now estimated to be living with diabetes in 2016 and the prevalence of diabetes is growing most rapidly in low and middle income countries (1). Worldwide about 6% of patients with diabetes are suffering from foot problems (2). Peripheral arteriopathy is an increasingly common comorbidity and compromises the healing process of foot ulcers, Therefore, prevention and management of arteriopathy must be emphasized.

Presence of diabetic foot ulceration (DFU) and Charcot foot has been shown to lead to reduced life expectancy (3), and significantly higher rates of lower limb amputation (4) with an 36-fold increased risk (5). Up to 85% of lower limb amputations in people with diabetes follow a DFU (5,6). People with neuropathy in the lower limb often have an absence of protective sensation and impairments to the motor and autonomic nervous system which lead to a reduced physical stress tolerance of the sole of the foot (7).

A loss of protective sensation can lead to insensate areas with higher pressure not being automatically unloaded. Normally people adjust posture to relieve discomfort or pain, but the absence of pain can result in high pressures occurring for longer periods which can lead to, ulcerations, reduced blood flow and eventually may cause cell death, skin breakdown, and the development of an open wound. (8)

For a plantar DFU to heal it requires a mechanical environment that will not disrupt the healing tissue, as it is “a mechanical problem more than a medical problem” (5). To do this, mechanical stress must be removed from the wound and the immediately surrounding tissue. (9)

Offloading and pressure redistribution by appropriately trained professionals is an important part of care given to people with DFUs and for those at increased risk. Pressure redistribution to heal a DFU and prevent its occurrence can reduce the rates of amputation through a reduction of the mechanical disturbance to tissues. (10) Therapeutic shoes and insoles have shown a 2-4 fold reduction in re-ulceration compared with standard shoes (11).

Interdisciplinary Care

It should be realized that offloading to help heal an ulcer and application of preventative measures such as orthotic insoles and footwear is not enough in isolation to bring about good outcomes. The full resources of the physician led multidisciplinary team are necessary to adequately deal with any patient at risk of, or currently experiencing a diabetic foot ulceration. (12)

Whilst the orthotist and physiotherapist may be delegated responsibility for mechanical control of a foot and can have a role to play in education and lifestyle change, the treating physician remains responsible for the overall care with the role of coordinator, including vascular sufficiency, wound, microbiological, and metabolic control of an individual with diabetes. A multidisciplinary comprehensive approach in line with the continuum of care, led by this physician is necessary to obtain good outcomes. (13)

Complications of diabetic foot can be prevented through:

1. Patient education promoting lifestyle changes and adequate self-care
2. Regular foot examination with risk stratification (see hereunder), to evaluate the level of risk
3. Providing appropriate foot wear and, if possible, light coloured socks for monitoring when undressing at night
4. Optimising glycaemic control (to be done at PHC) (for each 1% of HbA1c increase, the risk of arteriopathy rises by 25-30%) (14)

ICRC uses the continuum of care to understand the health system as it relates to people affected by conflict. A liner model does not work well when it comes to Non-Communicable Disease (NCDs) like diabetes. Rather the way the different parts of the health system fit together is better demonstrated by Figure One below:

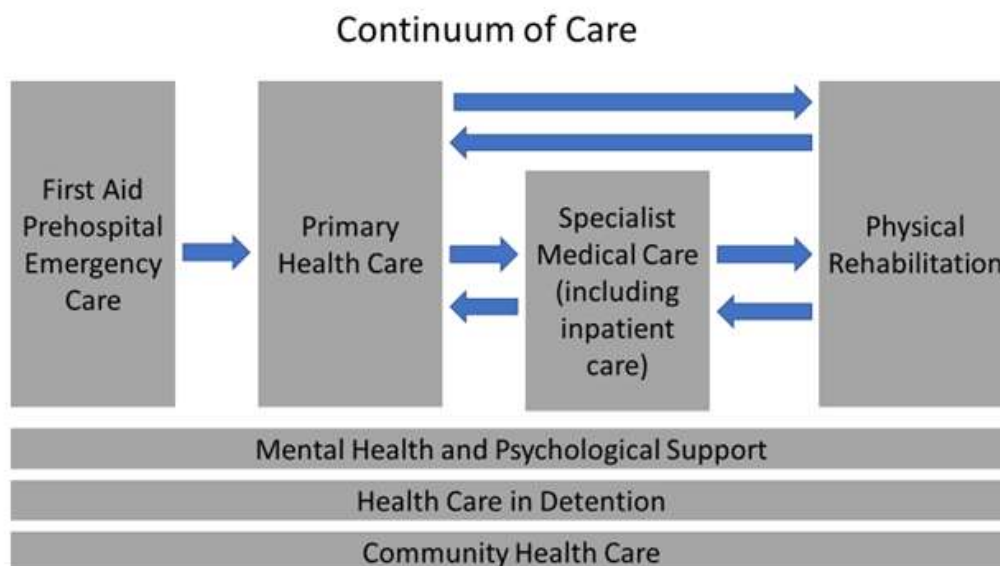


Figure 1: Continuum of care: nonlinear referral pathway for people with diabetes

Referral pathways need to be formally negotiated in each context, respecting the existing structures, relationships between centres and norms. It should be noted that tightening the linkages is an important principle. The point of referral is a time when one part of the system may no longer be following up, but it is unknown if another part of the system has started to engage with the individual in need of care. To ensure that people are not lost at this time of referral, good coordination between centers and individuals is encouraged.

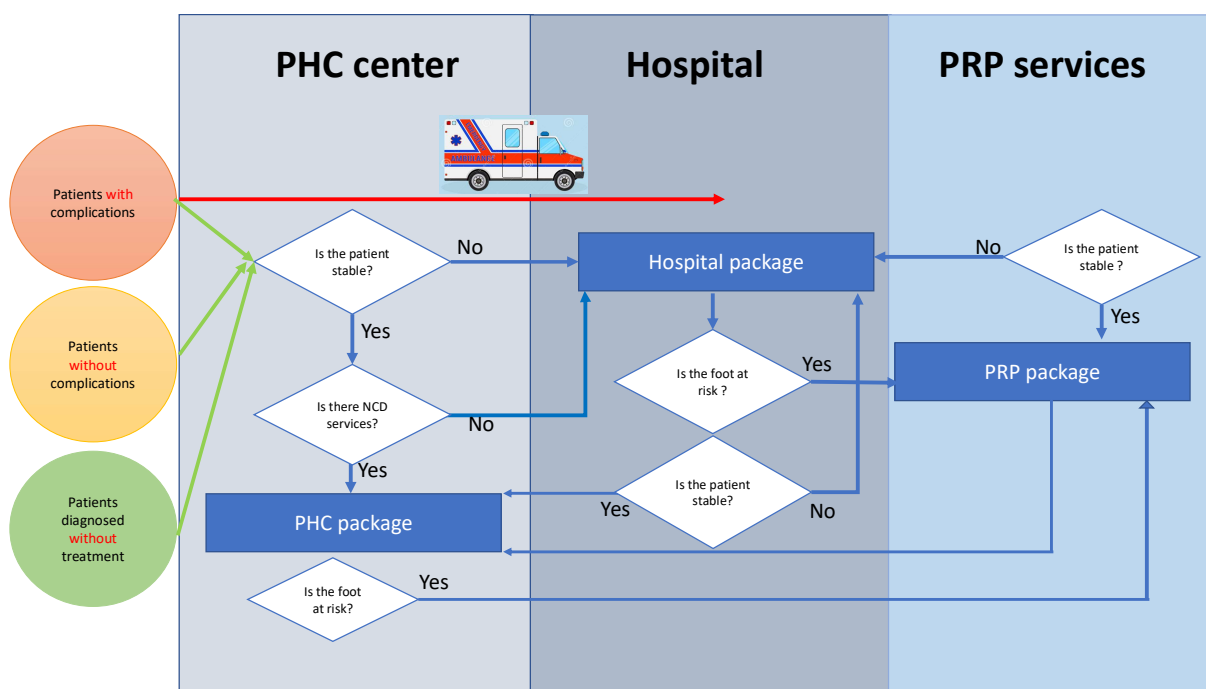


Figure 2: Referral pathway for people with diabetes foot

Commonalities between parts of the health system strengthen linkages. The referral is aided by clear and common assessment and strong understanding of the triggers for referral that are known to both referrer and the part of the health system receiving the referral. Common diagnostic tools, medicines, protocols and patient education should be encouraged as much as possible in order to strengthen the overall response.

ONE: FOOT ASSESSMENT

Regular standardized assessment of feet is important for people with diabetes. Too often the socks and shoes are not even removed in an appointment to check the feet and test the sensibility. Having a documented standard assessment allows for changes over time to be detected.

Foot examination

1. Check for active disease: ulceration, resting pain, gangrene, and cellulitis. If there is a wound, it is very important to find the cause.
2. Check foot temperature and colour:
 - a. Cold (thermal gradient), pale or dusky and hair loss¹, changes in the skin texture², a low systolic blood pressure index; this may indicate ischemia or a low oxygenation
 - b. warm, red or swollen: may indicate infection, acute Charcot foot

¹ Evaluation of the hairiness: where there are hairs, the TCPO2 is good, below the threshold of critical ischemia, the hairs are absent. Sometimes, some of them remain on the dorsal side of the hallux but they do not hold anymore, we can tear them without any pain (even in the absence of neuropathy) ...

² In the case of lower arterial insufficiency, the clinical examination involves placing the dorsal part of the examiner's hand on the hip of the patient and sliding the hand towards the distal end of the lower limb. When it reaches the area where the critical ischemia threshold is located, the skin texture is rougher and the hand slides less well, it is "stumbled". Above this area, the TCPO2 is > 40 mm Hg (therefore with good chances of healing), below the probability of healing is significantly worse. Nevertheless, the TCPO2 at the level of the foot is not significant.

3. Check for lesions and deformities: callus, deformed nails, foot deformities, toe deformity, fungal infection, macerated web spaces, skin fissures

NB: An ulcer can form under the callus and the callused skin can add to the pressure!

4. Check the quality of the footwear
5. Screen for peripheral arterial disease (arteriopathy)
6. Screen for loss of protective sensation (neuropathy) (15)

Testing for Neuropathy with 10g monofilament.

A key element of stratification is testing for sensory neuropathy. Ask the patient to sit or lie down with feet exposed. First explain the test on a non-neuropathic skin area (e.g. the forearm) then ask the service user to close their eyes and respond with a yes when they feel contact of the 10g monofilament on the foot. The monofilament should be pressed at 90 degrees to the skin (but not on areas with thick skin) until it buckles under the force.

Test the following sites with only the monofilament touching the foot (i.e. other hand does not hold feet):



Figure 3-4: Monofilament testing: places to test

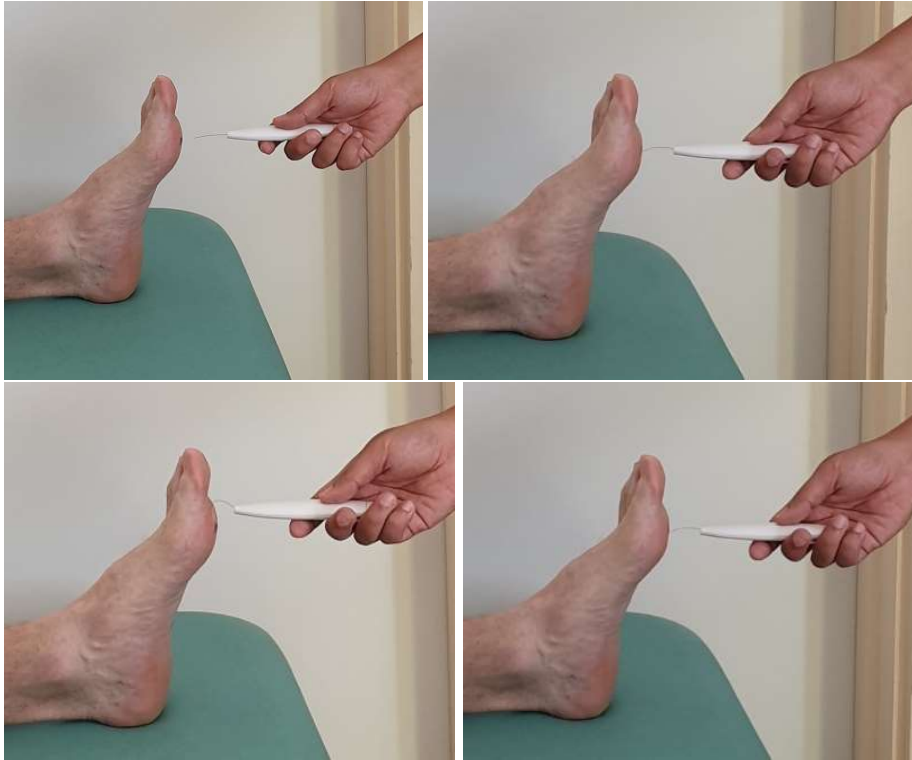


Figure 5-8: Correct use of monofilament

Inability to feel at one site (tested three times) indicates the patient has lost protective sensation. Clean the monofilament after each use and allow a 24hour recovery period after 100 compression cycles. (16)

Testing for Neuropathy with 128 Hz tuning fork

Another way of testing would be with a tuning fork which is applied over the tip of the great toe bilaterally (17). After striking the tuning fork and then pressing it against the toe, if the patient can't feel the vibration they are at high risk. (17)

Signs and Symptoms of diabetes related peripheral neuropathy		
Type of neuropathy	Clinical Sign	Clinical Implications
Sensory neuropathy	Loss of sensation to light touch, pain and temperature.	Loss of pain significantly increases the risk of unnoticed injury or trauma that can lead to tissue breakdown and foot ulceration.
Motor Neuropathy	Poor nerve supply to the muscles in the leg and foot can cause foot deformity.	Foot deformities cause the foot to function abnormally. This can result in high areas of pressure on the foot and can lead to foot ulceration.
Autonomic neuropathy	Absence of sweating (anhidrosis) in the foot can cause dry skin.	Anhidrosis can lead to callus formation and skin fissures (cracks in the skin), which can increase the risk of infection and ulceration in the diabetic foot.

Table 1: Signs and Symptoms of diabetes related peripheral neuropathy. From McIntosh and Halford 2014 Used with permission (18)

Screening for peripheral artery disease

History: intermittent claudication and rest pain, but this pain is not systematic because of the sensory neuropathy.

Palpate: posterior tibial and dorsalis pedis artery in both feet and record as present or absent.

Ankle brachial index ABI: measured using a Doppler device, ratio between highest systolic blood pressure at ankle to the systolic blood pressure in the arm.

Interpretation of severity of arterial disease: with <0.9 considered abnormal; peripheral artery disease excluded if ABI between 0.9 and 1.3 (IWGDF on peripheral arterial disease 2015).

Buerger test

In a limb with a normal circulation the toes and sole of the foot, stay pink, even when the limb is raised by 90 degrees. In an ischemic leg, an elevation to 15 degrees or 30 degrees for 30 to 60 seconds may cause pallor. Elevate both legs to an angle of 60° for 60 seconds. The severity of the arteriopathy can be graduated between 0 and 4, with the score of (0) if the sole remains pink after 60 seconds, (1) if gets pale at 60 seconds, (2) if pallor occurs between 30 and 60 seconds, (3) pallor occurs in less than 30 seconds and (4) pallor in decubitus (lying down) position (19). The time of re-coloration in decubitus (lying down) depends on the level of obstruction.



Figure 9: Buerger test where the pale sole indicates arteriopathy

Ankle range of motion

People with diabetes often have a lack of dorsal flexion of the ankle. This lack of range of motion (less than 5° of dorsal flexion) has a negative effect on forefoot plantar pressures (increase) leading to an increased risk of plantar ulcers. In some cases, the gastrocnemius recession or Achilles tendon lengthening may be required. If not possible, provide a rocker sole under the foot wear / modification of the heel of the shoe.

Venous filling time

Normally in a supine position, a superficial vein of the foot emptied of blood by the examiner's finger fills up almost immediately as soon as the pressure on the vein is released. The longer the venous filling time, the more severe the arterial insufficiency is.

TWO: STRATIFICATION

Information from the assessment is used to group patients together into strata, a process known as stratification. This allows the treatments with the best evidence for these groups of patients to be more easily applied to them.

Risk stratification relates to grouping of patients into categories of similar characteristics so that they can receive a standard treatment that is based on the best evidence. This stratification or grouping allows for simpler and consistent clinical decision making. The ICRC is using the below Stratification Tool of the IWGDF to group patients for people with ulcers or those at risk of ulcers.

For other complications of diabetes not included in this stratification such as rest pain, gangrene, cellulitis, ischemia, fever, if visibly unwell, drowsy, abnormal breathing the patient should be referred to the closest health facility for medical care.

People diagnosed with diabetes should undergo regular foot checks for early signs of foot complications as an important strategy to prevent DFU. These checks should be conducted in primary health care settings and in hospitals. The stratification system uses information from these foot checks to determine treatment modalities and to provide appropriate educational material to prevent and to care. Basic foot checks will also be completed in PRP centres to allow stratification leading to different care pathways depending on the category of severity each service user presents with. It should be noted that someone with an existing amputation secondary to diabetes is automatically in the high-risk category, hence measures to protect their remaining limb are indicated and are important.

The far-left column gives the categories (Low, Moderate, High/in remission and Active). The middle column provides the definition of each category in simple terms to allow people to be categorised. The right column gives a simple action plan that needs to be expanded for each individual. The simple explanation though defines which service categories each patient should be referred to. This standardises the care that people receive based on their clinical presentation.

This stratification system and foot check should be standardised within a health care system as much as possible and if another system is used commonly in the local context, then the characteristics of each category within the traffic light system can be adapted to indicate referral/treatment criteria. The type of stratification system has been shown to be a good predictor of subsequent foot ulceration and so helps direct limited resources to people at greater overall risk. (20)

Category	Characteristics	Frequency and actions
0 – low risk	No Peripheral Neuropathy , no signs of peripheral arterial disease, no other risk factors	Annual review by primary health care team including foot check for deterioration. Footwear advice. Provision of written and verbal education on self-management
1 – medium risk	Peripheral Neuropathy or arteriopathy (without callus or deformity), unable to self-care or on dialysis	Review by primary health care team every six months at minimum, including foot check for deterioration. Footwear/insoles advice and review. Provision of written and verbal education on self-management including emergency contact details
2 – high risk/in remission	Peripheral Neuropathy with Peripheral arterial disease and/ or a foot deformity	Primary health care team review every three to six months. Specialist care review every six months at minimum, check foot-wear and/or insoles, patient education on self-management, provision of written and verbal education including emergency contact details
3 – very high risk	Peripheral Neuropathy and a history of foot ulcer or lower extremity amputation, Charcot foot or kidney failure, active ulceration	In case of active ulcer, Charcot, ischemia, urgent referral to hospital based medical care, ideally an endocrinologist, or diabetes specialist or surgeon or similar. For other patients, primary health care team review everyone to three months , Provision of Irremovable device if available or other offloading devices. Patient education on self-management and provision of written and verbal education including emergency contact details

Table 2: Stratification of foot risk IWGDF table adapted with input of SSGED, SSED Aug 2015

Patient education

When educating a patient, it is essential to assess his or her skills. In addition, if they are unable to see the top and bottom of the foot, identify who else could help to do this kind of assessment (relative).

- Inspect feet daily, including areas between the toes. Use a mirror or ask a family member/care giver if you are unable to do
- Wash feet daily with water at room temperature, including areas between the toes. Don't take foot baths
- Don't use hot water bottles
- Use lubricating oils or creams for dry skin, but not between the toes
- Cut nails straight across, ideally use an emery board to shorten your nails, ask help for it. One mm of nail should stay.
- Do not remove corns and calluses using a chemical agent, plaster or cutting tools (scalpel...). They must be managed by trained staff
- Always wear socks with shoes; ideally white socks to identify traces of blood in case of injury
- Draw around your feet on a piece of cardboard. Cut the shapes out and insert them into your shoes to check that your shoes are long and broad enough
- Before buying new shoes, try them on at the end of the day, as the foot might swell during the day due to oedema
- Check inside the shoes for foreign objects before wearing them
- Avoid walking barefoot
- Ensure qualified health staff examines your foot regularly
- Notify immediately health staff if blister, cut, scratch or sore appears(16)

THREE: FOOTWEAR; INSOLES AND OFFLOADING RECOMMENDATIONS

Active Ulceration

Recommendation for Active Ulceration: Use of a Total Contact Cast if available, this requires specialized training to apply safely. Shown to be just as effective is use of a removable cast walker (known also as a CAM walker) **rendered irremovable** that has an accommodative insole on the plantar aspect of the foot. A regular review mechanism must be in place. Physician must assume overall responsibility for patient care and identify the cause.

The best evidence for healing active ulceration exists for Total Contact Casting (TCC) as the most effective way to offload a DFU. The TCC has been suggested as the 'gold standard' method of off-loading DFU after randomised controlled trials demonstrated 84–92% pressure reduction at the site of ulceration (10). A TCC is difficult to apply and requires a skilled practitioner to do so. There is good evidence that just as effective as the TCC is a well fitted removable cast walker that has been rendered **irremovable** (21). This is likely due to compliance, with one study of removable devices finding that only 29% of all steps were performed in the device (22).



Figure 10: Removable cast boot

Rendering a removable device irremovable can be done through a wrap of fibreglass or similar locally appropriate technique such as the use of plastic cable ties. The advantages of this is that the cast walker itself can be reused for the same patient (with liner replaced or possibly laundered and reused) (8). To protect toes, the cast boot has to be a little bit longer than the foot.

This walker should extend to just below the knee and should be fitted with an appropriate pressure redistributing insole for the plantar aspect of the foot (22). This insole can be used later in footwear also when the healing is achieved. The cast walker can be modified with a heat gun to accommodate deformity before application. A regular review mechanism prescribed by the treating physician should be in place for anyone fitted with any irremovable device.

Offloading occurs through the immobilisation of the ankle and foot which maintains total plantar contact throughout stance phase with pressure distributed over the entire plantar aspect of the foot. The rocker sole can assist with forward progression despite this lack of ankle or foot movement. Offloading also occurs through a firm fit that redistributes load to the device itself (9).

Challenges

Many activities can be challenging in a TCC or Cast walker boot. Driving, sleeping and maintain a normal activity level have been reported as being challenging. Education and explanation are critical to ensure compliance.

Contraindications

In the presence of infection leading to exudate (liquid coming from the ulcer) and/or ischaemia (poor blood perfusion to the foot) irremovable devices are contraindicated (24) and alternative strategies that allow regular visual examination of the DFU should be considered. A simple removable cast walker is a possibility are some other devices below. An inability to ensure proper follow-up and review is a clear contraindication to an irremovable device.

Forefoot and rear foot temporary offloading footwear

As an interim measure or when an irremovable device is contraindicated a forefoot or rear foot offloading temporary footwear can be applied, these shoes move pressure away from the affected area by removal of the sole in this area (23). Angulation through anterior or posterior wedging helps redistribute the weight (13). These temporary shoes should not be continued for long term use as they offer limited protection. When wound healing is achieved definitive protective footwear must be sourced. The sole of this kind of shoes adds to the leg length, while walking, the balance can be disturbed.



Figure 11: Offloading shoes. Pictures used with permission from C. Paoli

To summarize, the likelihood of DFU healing is increased with off-loading adherence, and current evidence favours the use of TCC or removable boots rendered irremovable as optimum off-loading practices. TCC requires skills that will need to be built among rehabilitation professionals. Training with D-Foot incorporates this training and D-Foot is the preferred partner for ICRC.

A next best alternative is for removable cast walker with custom insole, with the patient being encouraged to use it as much as possible. This also might be difficult for many patients.

The next best alternative is offloading shoes, properly fitted and with insoles.

Preventative measures - Footwear

Preventative measures such as footwear and insoles should be applied when service users are found to be in the high-risk category. There is good evidence that appropriate footwear and insoles prescription as part of an outpatient clinic can help prevent diabetic foot ulceration. There is no evidence that footwear heals an active diabetic foot ulcer. At risk service users should never walk in bare feet, in socks or in thin soles standard slippers.

Ill-fitting shoes are a common cause of skin trauma that precedes diabetic foot ulcers (12). Providing appropriate footwear can reduce the risk of DFU by reducing the likelihood of a skin lesion that provides opportunity for infection to occur(5).

Footwear and total contact insoles should be considered in combination, with these two elements together providing a total contact interface for the at-risk foot. This principle of total contact is to reduce both peaks of pressure and the magnitude of sheer forces as both are associated with skin lesions (25)The focus should be on patients obtaining correctly fitting shoes and this is often possible from special footwear shops and should not be automatically borne by the PRC to pay for or supply these shoes. Relationships can be developed with local 'off the shelf' footwear providers to maintain stocks of appropriate footwear. Initially service users in the high-risk category only are being considered for footwear.

Options for appropriate footwear include

- Sensible shoes from normal footwear shops.
- Orthopaedic stock shoes, extra depth or extra width etc. and custom-made insole.
- Customised (modular) or bespoke shoes made to measures or casts.

These shoe options (see picture) need to be provided locally as each patient requires individualised fitting. In terms of stock and bespoke shoes, PRCs can explore local options with shoe makers.



Figure 12: Footwear with flexible forefoot, to accommodate deformity. Used with permission from C. Paoli

Implementation: In Ethiopia and Gaza a range of the above footwear options are available. Finding a suitable footwear provider is the first step, with negotiation of the working relationship with the PRC the next. Arrangements can be made for orthotists to measure and fit with the provider only providing the manufacturing, or the provider can also be utilized for fitting. In house footwear manufacture is a more complicated process, undertaken only if the correct Human Resources are available.

D-Foot International have supported footwear projects such as Flirt Bird and if present in a context would be a good choice of partner.

The functions of footwear for people with diabetic neuropathy should be

1. To protect the foot
2. To relieve areas of excessive pressure
3. To reduce shock
4. To reduce sheer
5. To accommodate deformity
6. To stabilise and support deformity (including immobilisation of appropriate joints)
7. To accommodate insoles or AFO
8. To be cosmetically adequate
9. To be functional
10. Long lasting
11. Should have a rocker bottom in order to decrease plantar pressure/time integral.

Adapted from *Ulbrecht & Cavanagh 2010* and *Janisse & Janisse 2014*

Footwear fitting

The shape and volume of the fitted shoe must be correct to ensure a good fit. Different elements of footwear fitting relevant to people with diabetes will be discussed below. Both feet should be measured as it is common for there to be differences from one side to the other.

Motor neuropathy can cause clawing of toes. This leads to the dorsum of the phalanges pressing against the toe box. Appropriate depth in the area of the toe box is required. This clawing of the toes can make the metatarsal heads more prominent, hence offloading of the metatarsal heads with a total contact insole can be important.

Appropriate width of the toe box prevents toes being crushed together. Presence of bunions (medial) or Taylors bunions (lateral) can lead to excessive pressure from the shoes medially and laterally in the area of the metatarsal heads.

A shoe should be an appropriate length, measuring around 1cm longer than the foot. It should be noted the foot elongates in standing. The widest part of the foot is normally at the 1st metatarsal phalangeal joint (just forward of the 5th MPJ) and this should correspond to the widest part of the shoe.

Depth of the mid foot is important; the shoe should not put pressure over the dorsum of the foot and should accommodate any insoles when achieving this.

Appropriate width and shape of the heel box posteriorly ensures the foot does not slip in the shoe.

Easy to close the footwear: lace or Velcro

Inside the shoe should have smooth lining with stitching and other material not protruding. A strong sole protects the foot from foreign bodies piercing the sole and should have a mild built in rocker sole.

Slip on shoes that sling over the heel should be avoided, in order to fit they are a tight and short fit. (12)

Assessment of Footwear (checklist for patients existing shoes or after a fitting)

At each appointment the following should be checked for all footwear for people with diabetes, as feedback alone is not adequate. This opportunity should be taken to educate the patient.

Subjective	
Ask the client if the footwear is	<ul style="list-style-type: none"> • Comfortable • Being Used • Easy to put on and take off
Objective	
Check fitting for	<ul style="list-style-type: none"> • Firm snug fit throughout that is not tight • Appropriate Length (extends one cm beyond longest toe in standing) • Appropriate width and depth, especially in toe box and MTHs
Check inside the shoe for	<ul style="list-style-type: none"> • Soft intact lining throughout • Foreign bodies
Check the general condition of the footwear	<ul style="list-style-type: none"> • Wear of the sole, especially lateral heel • Condition of the fastener and upper • Hygiene
Determine compliance	<ul style="list-style-type: none"> • Less than expected wear a sign of poor compliance • Orthotic insoles in place (if provided)
For adequate protection	<ul style="list-style-type: none"> • Toes enclosed • Sole adequately firm

Table 3: Assessment of Footwear Adapted from *McIntosh and Halford 2009*

Preventative measures - Footwear modifications

Prevention measures seek to stop ulcers from over occurring. These can be applied to people at high risk of future ulceration.

Rocker Soles

A rocker sole allows movement through stance phase of the foot and shank position without need for the joints of the foot to themselves move. A rocker sole can effectively reduce peak pressures. A rocker sole's apex should be located just posterior to the point of desired offloading. Mild rocker soles are evident in some off the shelf shoes but for feet with deformity a custom rocker sole should be applied to a good quality pair of shoes. The stiffness of the sole is critical to prevent the rocker instead acting as loading of the affected area. (12)



Figure 13: Rocker Sole from McIntosh and Halford 2009 used with permission.

Extended Shank

This is a steel or carbon and is placed within the construction of the sole of the shoe. It stiffens the shoe to prevent it bending during gait. This can be used with a rocker sole. By preventing bending of the shoe, the extended shank ensures the entire plantar aspect of the foot is in contact with the ground during stance phase. This reduces peak and average pressures. (12)

Local relief

Areas of deformity such as claw toes can produce high localised pressures. Pockets of local relief can be added with a leather stretching device and stretching fluid. This can be applied in areas such as claw toes, prominent 1st or 5th Metatarsal heads or other bony prominences. (9)



Figure 14: Leather Stretching Tool. Picture Used with permission G. Halford.

Preventative measures - Foot Orthoses

As above foot orthoses should be considered in combination with the footwear. This combination should **not** be considered as the first choice for healing an active DFU

Foot orthoses are essentially inserts that can be fitted into the shoe. Total Contact Foot Orthoses can prove beneficial particularly in the prevention of ulceration, or in the prevention of ulcer recurrence in those patients with a history of DFU. This effectiveness is due to local peak pressure reductions through spreading pressure more evenly over the entire plantar aspect of the foot.

Orthoses can be designed and manufactured to relieve a specific area on the plantar aspect of the foot, for example, a site of high pressure or previous ulceration, to achieve partial offloading in this area. Such orthoses can be prescribed by an orthotist and/or a podiatrist following a comprehensive assessment of the patient, which should include gait analysis, assessment of the structure and function of the foot, and footwear assessment. When motor neuropathy has left the metatarsal heads more prominent, a metatarsal dome or bar can be effective at reducing pressure in this region. This is often applied with a stiffer soled shoe or a forefoot rocker. This stiffener prevents phalangeal dorsiflexion which is associated with higher pressures in the metatarsal head region. The forefoot rocker allows forward progression despite the limitation to dorsiflexion.

Foot Orthoses can be off the shelf or custom made but of critical importance is that is a good fit for the foot shape of the individual. This appropriate shape reduces pressure and shear forces on the plantar aspect of the foot.

If a patient has a history of Charcot foot, significant deformity, partial foot amputation or neuropathy, custom insoles are more appropriate.

The objectives of a foot orthosis for people with diabetes are

1. Cushion and protect the foot
2. Reduce areas of high pressure through pressure redistribution

3. Provide shock attenuation
4. Support and protect healed fracture sights through immobilisation
5. Reduce sheer forces
6. Control and stabilise flexible deformities
7. Limit motion of affected joints
8. Accommodate fixed deformities
9. To be covered with a thin soft covering material

Adapted from Cavanagh 2010 and Janisse & Janisse 2015

Casting and impressions of feet for custom insoles should be done with care as damage can be caused to feet in various ways. Residual plaster of Paris (POP) left behind between toes can act like gravel and damage neuropathic feet during walking. Firm pressure to push feet into impression boxes or onto a casting bladder can also cause damage to high risk feet. People with active ulcers should also not be asked to walk without shoes or socks for gait analysis. If there is an active ulceration this should be protected during all stages of assessment, casting and fitting to prevent introduction of infection.

Rigid Foot Orthoses are not appropriate (contraindicated) for people with Diabetes (12). Full length semi rigid or accommodative insoles are more appropriate. This can be achieved through ethyl vinyl acetate (EVA) of different densities as it is important that the insole is firm enough to resist structural compression, but the interface should be soft enough to prevent high peak pressures. The soft cover made from soft EVA or shammy leather can be useful for assessing the fit later, as the foot makes an impression. The edges of the insole should be continuous with the footwear, with no ridges resulting in areas of high pressure.



Figure 15: Insole for pressure redistribution. Picture from G. Halford and used with permission

Published literature supports the use of orthotic intervention as an integral aspect of the treatment regime for patients with diabetic foot disease (26) One study found improvements in health status both physically and mentally, for patients who received orthotic intervention (27).

Charcot Foot

Charcot foot (or neuropathic osteoarthropathy) is a serious condition that is characterised by varying degrees of bone and joint disorganisation secondary to underlying neuropathy, trauma and changed bone metabolism. Disorganisation occurs typically in the mid foot but can occur in the fore or hind foot (13).

The classic presentation is a mid-foot collapse that results in a “rocker bottom foot”(28). See Figure 16 below



Figure 16: Rocker bottom foot and plantar hyperkeratosis/callus. Picture used with permission from C. Paoli

The clinical presentation of a Charcot Foot is an acute local inflammation, with warmth (skin 2 °C hotter than contralateral foot) and swelling being often first noticed. A lack of pain due to neuropathy can mean individuals continue to ambulate despite fracture, bone destruction, subluxation, dislocation and deformity (28).

In the case of acute or active Charcot foot, NICE guidelines (2016) advocate immediate offloading through crutches or wheelchair use and application of a TCC to offload the foot and reduce the risk of spontaneous fracture and gross deformity and patients need to be closely followed up at PHC and or specialist/secondary care level. In the absence of a TCC a removable walker can be made non removable and the addition of an insole can make the device total contact to achieve offloading (13). Effort should be made to ensure an intimate total contact fit of the cast walker. Examination should be initially after 3 days and then weekly (28).

Non active Charcot foot is characterised by less than 2 °C skin temperature difference, an X-Ray that shows bone healing and a reduction in redness (13). A Charcot Restraint Orthotic Walker (CROW) is indicated to immobilise and partially unload the foot during early rehabilitation. The CROW walker achieves total contact with a bivalve Ankle Foot Orthosis (AFO) with anterior and posterior sections, with lining in material such as Plastazote™ or soft EVA. It is indicated for a period of 2-3 months (29).



Figure 17: A bivalve custom-made CROW walker

Slow and careful rehabilitation is needed, beginning with just a few short steps per day within parallel bars with partial weight being borne by the upper limbs. A careful and gradual progression of total steps is needed to ensure no relapse. Monitoring for relapse must be undertaken with careful temperature assessment and examination for swelling daily. This should be completed under supervision of a physiotherapist.

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Annexe: Diabetic foot assessment form

DIABETIC FOOT ASSESSMENT

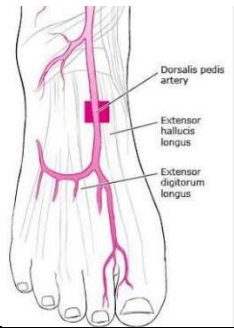
Title	Results	Remark
1- Type of Diabetes	<input type="text" value="Select"/>	
2- History of previous foot ulceration? Healing time Ulcer if known (months)	<input type="radio"/> Yes <input type="radio"/> No <input type="text"/> (from 1 to 24)	
3- Signs of peripheral neuropathy (Ability to feel monofilament test at one of these 4 sites) (picture inserted to help perform test)	<input type="radio"/> Neuropathy <input type="radio"/> Intact sensation 1. <input type="radio"/> Yes <input type="radio"/> No 2. <input type="radio"/> Yes <input type="radio"/> No 3. <input type="radio"/> Yes <input type="radio"/> No 4. <input type="radio"/> Yes <input type="radio"/> No	
4- Foot condition 1. Wound 2. Ulceration 3. Gangrene 4. Rest Pain 5. Cellulitis	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No	
If yes to 2. Ulceration, measure diameter: _____ (numeric field mm)		
Indicate the results regard point 1 to 5 on the drawing using the following abbreviation: W/U/G/RP/C		
Right 	Left 	

If "Yes" to one of the point 1 to 5 in the section "Foot condition", referral to medical care is required if HSU not under care

Select accordingly following information from HSU

☐ HSU under care

☐ Referral

5- Foot Deformity	<div>Select ▼</div>	
6- Temperature:	<input type="radio"/> Cold <input type="radio"/> Hot <input type="radio"/> Normal	
If Cold additional questions - Pale - Dark coloration - Hair loss - Change in skin texture	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No	
If Hot additional questions - Red - Swollen	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No	
7- Dorsalis Pedis Foot Pulse: 	<input type="radio"/> Present <input type="radio"/> Absent <input type="radio"/> Unsure of finding	
8- Footwear Type:	<input type="radio"/> None <input type="radio"/> Open Shoe <input type="radio"/> Closed shoe	
If footwear, check if appropriate Subjective: Ask the user if footwear is - Comfortable - Being used - Easy to put on and take off Objective: 1. Check fitting for - Firm snug fit throughout that is not tight - Appropriate length (1cm beyond longest toe in standing) - Appropriate width and depth 2. Check inside the shoe for - Soft intact lining throughout - Foreign bodies: 3. General condition of the footwear	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Good <input type="radio"/> Acceptable <input type="radio"/> Worn out	

Conclusion:

IWGDF Risk Classification System (table attached)		○ 0 ○ 1 ○ 2 ○ 3	
Category	Characteristics	Frequency of review	
0	No Peripheral Neuropathy, no signs of peripheral arterial disease, no other risk factors	Once a year, patient education on self-management	
1	Peripheral Neuropathy or arteriopathy (without callus or deformity), unable to self-care or on dialysis	Once every 6 months, check foot-wear and/or insoles, patient education on self-management	
2	Peripheral Neuropathy with Peripheral arterial disease and/ or a foot deformity	Once every 3-6 months, check foot-wear and/or insoles, patient education on self-management	
3	Peripheral Neuropathy and a history of foot ulcer or lower extremity amputation	Once every 1-3 months, check foot-wear and/or insoles, patient education on self-management	

Proposed follow up date according to assessment:**Assessment date:****Validated by**

Pictures for drop down list of assessment form

Deformed Nails, Callus, Hallux Valgus, Toe Deformities, Pes Cavus, Foot Deformities, Fungal Infection, Macerated Toe space, Skin Fissures



Hallux valgus, deformed nail, hammer toe



Callus and rocker bottom foot / Charcot foot



Lateral foot ulcer and rocker bottom / Charcot foot



Plantar ulcer



Nail deformation and necrosis