STANDARD TREATMENT GUIDELINES

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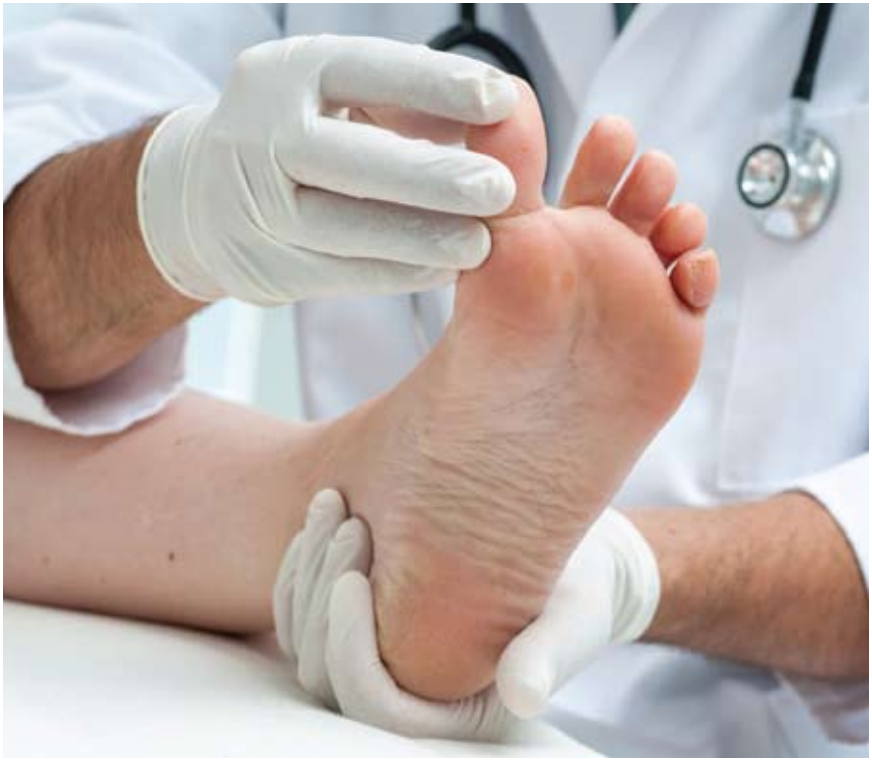
THE DIABETIC FOOT

PREVENTION AND MANAGEMENT IN INDIA



AUGUST 2017

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

Ministry of Health & Family Welfare
Government of India

NHSRC

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THE DIABETIC FOOT

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Ministry of Health & Family Welfare
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INTRODUCTION

India is set to become the diabetes capital of the world with a projected 109 million individuals with diabetes by 2035. India ranks second (after China) with more than 66.8 million diabetics in the age group of 20-70. The prevalence of Diabetes in India is 8.6% and, as of 2013, more than 1 million Indians die each year due to diabetes related causes.

Diabetic foot care is one of the most ignored aspects of diabetes care in India. Due to social, religious, and economic compulsions, many people walk barefoot. Poverty and lack of education lead to usage of inappropriate footwear and late presentation of foot lesions. Many non-medically qualified persons are interfering in the treatment of diseases, including diabetes. Patients also try home remedies before visiting their physicians. It estimated that 90% of diabetic patients in India do not see a specialist in their lifetime. Problem is further worsened by a delay in accessing healthcare due to patient approaching informal care providers and alternative medicine prescribers.

There is a lack of a good evidence-based standard guideline on Diabetic foot care in India. Currently, diabetic feet are treated by individual practitioners. Physicians, General surgeons, or thopaedic surgeons, primary care physicians, endocrinologists and podiatrists all look after the diabetic feet. But neither their roles, responsibilities nor the protocols are clearly defined in the public domain. Moreover, in the Indian context, due to the pronounced variability in the health care system, a common national guidance for providing curative as well as preventive methods to curb the growth of diabetic foot in the future is essential. Hence, it is a public health imperative to create an integrated framework for comprehensive management of diabetic foot.

CASE DEFINITION

Diabetic foot as defined by the World Health Organization is, “The foot of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and/or destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease, and/or metabolic complications of diabetes in the lower limb”.

INCIDENCE OF DIABETIC FOOT IN INDIA

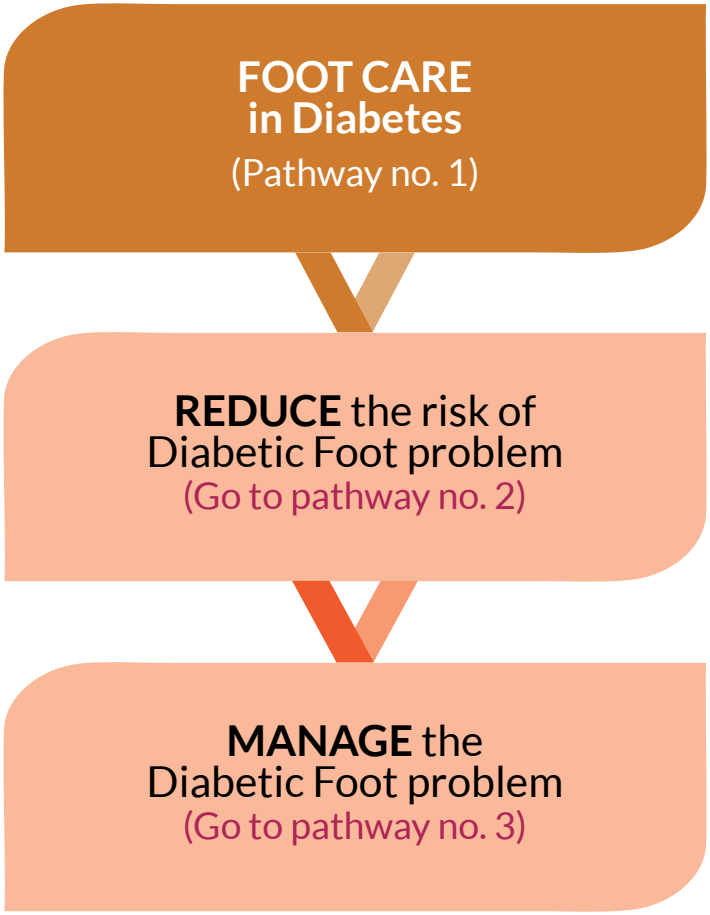
Diabetic Foot (DF) is one of the most common complications for admissions imposing tremendous medical and financial burden on our healthcare system. The lifetime risk of a person with diabetes having a foot ulcer could be as high as 25% and is the commonest reason for hospitalization of diabetic patients (about 30%) and absorbs about 20% of the total health-care costs, more than all other diabetic complications. The prevalence of foot ulcers in diabetics attending a centre managing diabetic foot (both indoor and outdoor setup) in India is 3%. Foot ulcers among outpatient and inpatient diabetics attending hospitals in rural India was found to be 10.4%.

Peripheral Vascular Disease (PVD) occurs in about 3.2% diabetics below 50 years of age and rises to 55% in those above 80 years of age. 15% of those with diabetes for a decade suffer from diabetic foot, where as it increases to almost 50% by another decade.

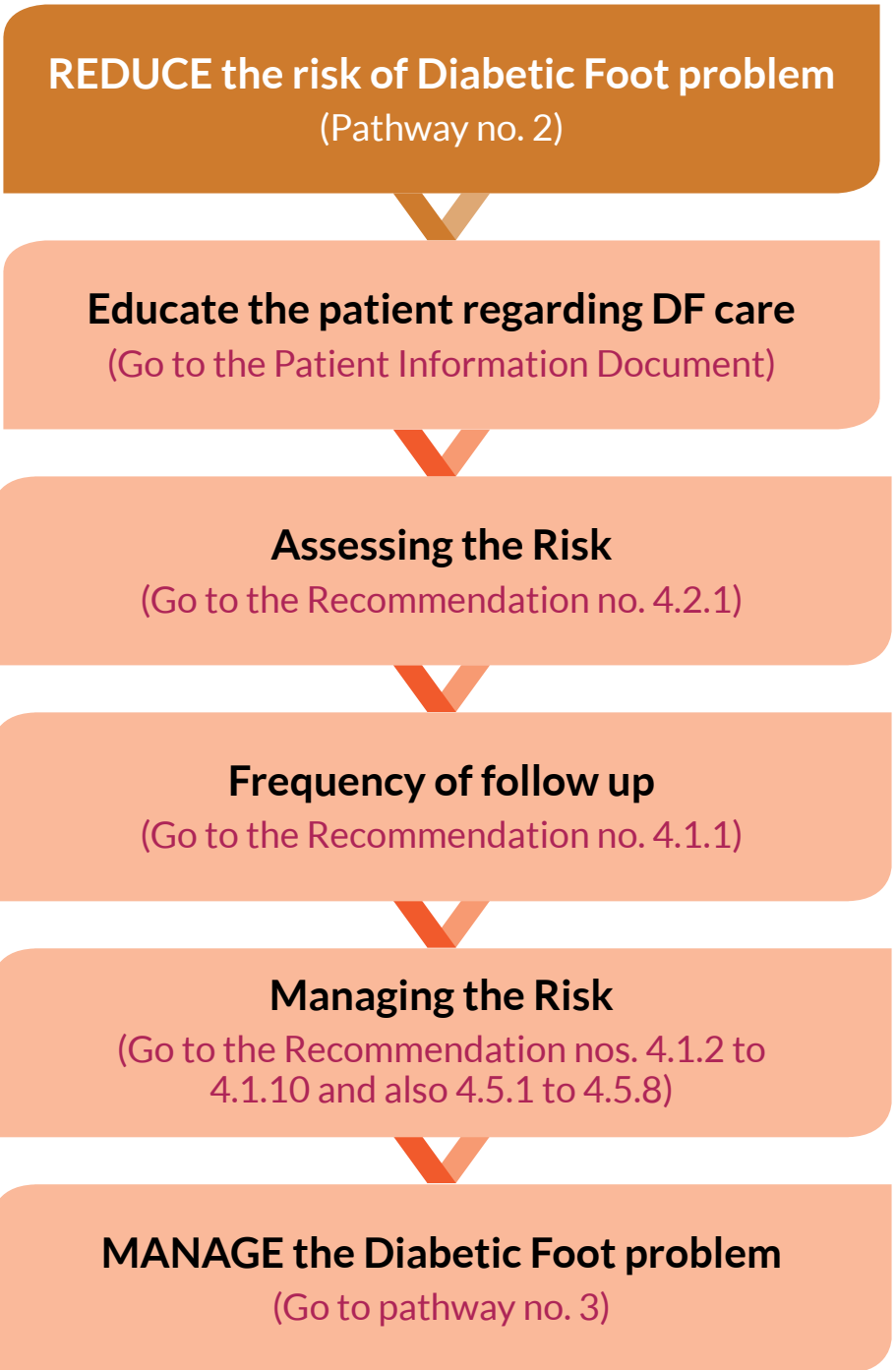
Approximately, 85% of non-traumatic lower limb amputations are seen in patients with prior history of diabetic foot ulcer. Each year, more than 1 million people with diabetes lose at least a part of their leg due to diabetic foot. It shows that every 20 seconds a limb is lost in the world somewhere. In India, though recent population based data is not available, it is estimated that approximately 45,000 legs are amputated every year in India. The vast majority (75%) of these are probably preventable because the amputation often results from an infected neuropathic foot. More than half of all foot ulcers become infected, requiring hospitalization, while 20% of infections result in amputation. After a major amputation, 50% of people will have the other limb amputated within two years' time. People with a history of diabetic foot ulcer have a 40% greater 10-year death rate than people with diabetes alone.

RECOMMENDATIONS

CLINICAL PATHWAY 1: OVERVIEW OF FOOT CARE IN DIABETES



CLINICAL PATHWAY 2 : PREVENTION OF DIABETIC FOOT



4.1 PREVENTION

Overview

- Identification of the at-risk foot
- Regular inspection and examination of the at-risk foot
- Education of patient, family and healthcare providers
- Routine wearing of appropriate footwear
- Treatment of pre-ulcerative signs

Prevention of Diabetic foot problems

4.1.1 To identify a person with diabetes at risk for foot ulceration, examine the feet annually / six monthly / quarterly / monthly (depending on patient's risk category) to seek evidence for signs or symptoms of peripheral neuropathy and peripheral artery disease.

Risk Classification System and preventive screening frequency

Category	Characteristic	Frequency
0	No peripheral neuropathy	Once a year
1	Peripheral neuropathy	Once every six months
2	Peripheral neuropathy with peripheral artery disease and/or a foot deformity	Once every 3-6 months
3	Peripheral neuropathy and a history of foot ulcer or lower-extremity amputation	Once every 1-3 months

Source : The IWGDF guidelines 2015.

4.1.2 In a person with diabetes who has peripheral neuropathy, screen for: a history of foot ulceration or lower-extremity amputation; peripheral artery disease; foot deformity; pre-ulcerative signs on the foot; poor foot hygiene; and ill-fitting or inadequate footwear.

4.1.3 Treat any pre-ulcerative sign on the foot of a patient with diabetes. This includes: removing callus; protecting blisters and draining when necessary; treating ingrown or thickened toe nails; treating haemorrhage when necessary; and prescribing antifungal treatment for fungal infections.

4.1.4 To protect their feet, instruct an at-risk patient with diabetes not to walk barefoot, in socks, or in thin-soled standard slippers, whether at home or when outside.

4.1.5 Instruct an at-risk patient with diabetes to: daily inspect their feet and the inside of their shoes; daily wash their feet (with careful drying particularly between the toes); avoid using chemical agents or plasters to remove callus or corns; use emollients to lubricate dry skin; and cut toe nails straight across.

4.1.6 Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles, or toe orthosis.

4.1.7 Instruct a high-risk patient with diabetes to monitor foot skin temperature at home to prevent a first or recurrent plantar foot ulcer. This aims at identifying the early signs of inflammation, followed by action taken by the patient and care provider to resolve the cause of inflammation.

4.1.8 To prevent a first foot ulcer in an at-risk patient with diabetes, provide education aimed at improving foot care knowledge and behaviour, as well as encouraging the patient to adhere to this foot care advice.

4.1.9 To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking and encourage the patient to wear this footwear.

4.1.10 To prevent a recurrent foot ulcer in an at-risk patient with diabetes, provide integrated foot care, which includes professional foot treatment, adequate footwear and education. This should be repeated or re-evaluated once every one to three months as necessary.

4.2 ASSESSMENT, CLASSIFICATION AND REFERRAL

4.2.1 Assessing the risk of developing a diabetic foot problem:

4.2.1a. Evaluate a diabetic patient presenting with a foot wound at 3 levels: the patient as a whole, the affected foot or limb, and the infected wound.

4.2.1 b. Assess the affected limb and foot for arterial ischemia, venous insufficiency, presence of protective sensation, and biomechanical problems.

Explanatory note: Biomechanical problems means anatomical and physiological disturbances of the foot, i.e., structural changes which happen in the bones, joints and muscles of the foot of diabetics and the changes in the blood circulation and nerve sensation of the foot of diabetics.

Table 1: Infectious Diseases Society of America and International Working Group on the Diabetic Foot Classifications of Diabetic Foot Infection

Clinical Manifestation of Infection	PEDIS Grade	IDSA Infection
Uninfected: No symptoms or signs of infection	1	Uninfected
Infected: At least two of the following items are present: • Local swelling or induration • Erythema >0.5cm around the wound • Local tenderness or pain • Local warmth • Purulent discharge (thick, opaque to white or sanguineous secretion) Exclude other causes of an inflammatory response of the skin (eg, trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis, venous stasis). Local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). An erythema, must be </=2 cm around the ulcer.	2	Mild
Local infection (as described above) with erythema > 2 cm, or involving structures deeper than skin and subcutaneous tissues (eg, abscess, osteomyelitis, septic arthritis, fasciitis), and No systemic inflammatory response signs (as described below)	3	Moderate
Local infection (as described above) with the signs of SIRS, as manifested by ≥2 of the following: • Temperature >38°C or <36°C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min or PaCO2 <32 mm Hg • White blood cell count >12,000 or <4000 cells/μL or ≥10% immature (band) forms	3	Severe[a]

4.2.2 Classification of Diabetic foot:

4.2.2a. Assess the severity of any diabetic foot infection using the Infectious Diseases Society of America/ International Working Group on the Diabetic Foot Classification system.

Abbreviations: IDSA, Infectious Diseases Society of America; PaCO2, partial pressure of arterial carbon dioxide; PEDIS, perfusion, extent/size, depth/tissue loss, infection, and sensation; SIRS, systemic inflammatory response syndrome.

4.2.2 b. Do not use the Wagner classification system to assess the severity of a diabetic foot ulcer.

4.2.3 Referral for Diabetic foot problems

4.2.2a. Initially hospitalize all patients with a severe infection, selected patients with a moderate infection with complicating features (eg, severe peripheral arterial disease [PAD] or lack of home support), and any patient unable to comply with the required outpatient treatment regimen for psychological or social reasons. Also hospitalize patients who do not meet any of these criteria, but are failing to improve with outpatient therapy.

(Also refer to Table 3 and 4 for explanatory notes.)

Table 3: Characteristics suggesting a more serious diabetic foot infection

A - Findings suggesting a more serious diabetic foot infection	
Wound specific	
Wound	Penetrates to subcutaneous tissues, (e.g., fascia, tendon, muscle, joint, bone)
Cellulitis	Extensive (>2 cm), distance from ulceration or rapidly progressive
Local signs	Severe inflammation or induration, crepitus, bullae, discoloration, necrosis or gangrene, ecchymoses or petechiae, new anaesthesia
General	
Presentation	Acute onset/worsening or rapidly progressive
Systemic signs	Fever, chills, hypotension, confusion, volume depletion
Laboratory tests	Leukocytosis, very high C-reactive protein or erythrocyte sedimentation rate, severe/worsening hyperglycemia, acidosis, new/worsening azotaemia, electrolyte abnormalities
Complicating features	Presence of a foreign body (accidental or surgically implanted), puncture wound, deep abscess, arterial or venous insufficiency, lymphedema, immunosuppressive illness or treatment
Current treatment	Progression while on apparently appropriate antibiotic and supportive therapy

Source : From the IWGDF guidelines 2015

Table 4: Factors indicating that hospitalization may be necessary

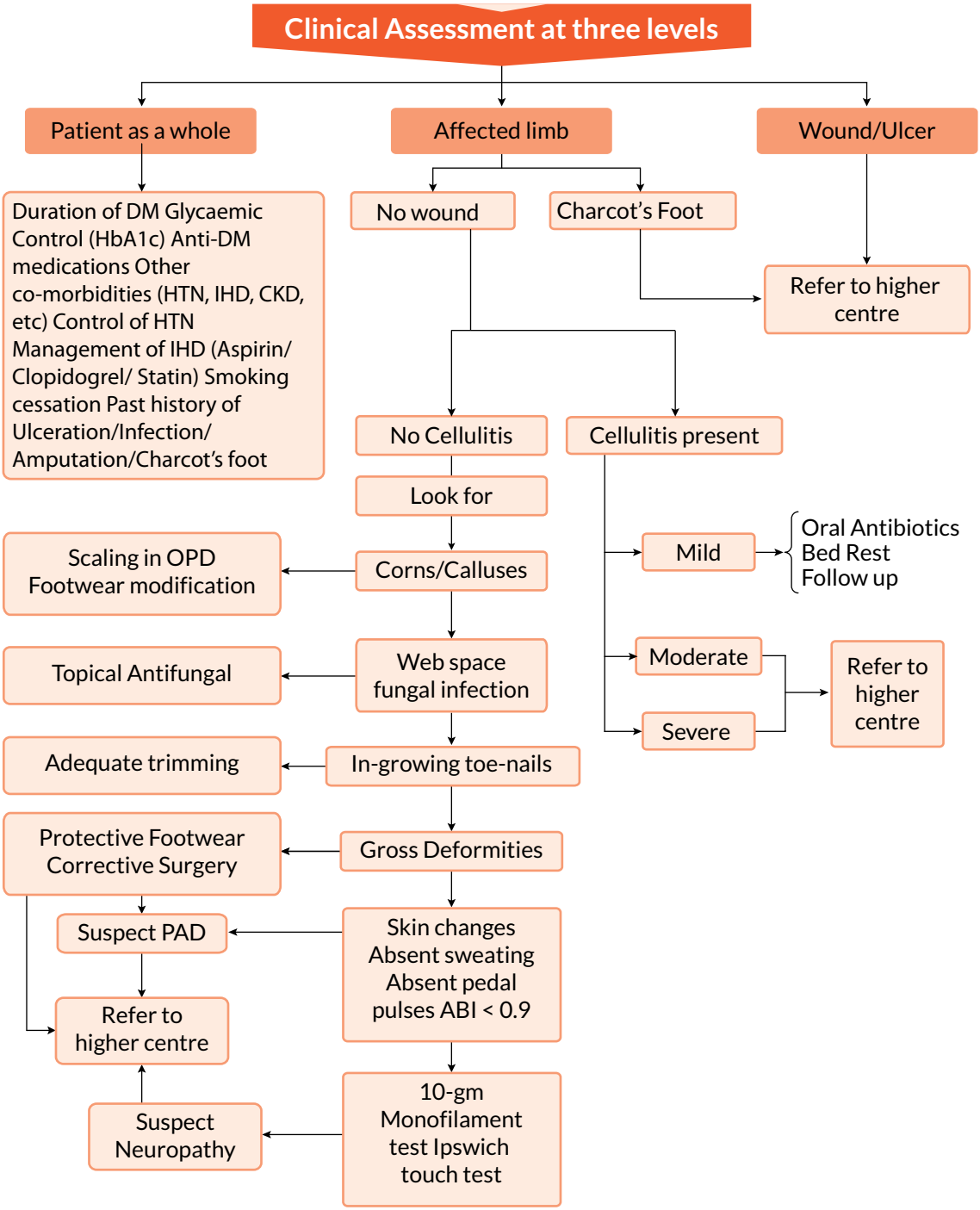
B - Factors suggesting hospitalization may be necessary
• Severe infection (See Table 4A)
• Metabolic or hemodynamic instability
• Intravenous therapy needed (and not available/appropriate as outpatient)
• Diagnostic tests needed that are not available as outpatient
• Critical foot ischemia present
• Surgical procedures (more than minor) required
• Failure of outpatient management
• Patient unable or unwilling to comply with outpatient-based treatment
• Need for more complex dressing changes than patient/caregivers can provide
• Need for careful, continuous observation

Note: A deep space infection may have deceptively few superficial signs, but clinicians should consider this possibility in a patient with evidence of systemic toxicity, inflammation distant from the skin wound, persistent infection or elevated inflammatory markers despite apparently appropriate therapy, deterioration of previously controlled glycaemia or pain in a previously insensate foot (21, 47, 125). The presence of foot ischemia is of particular concern, as it can both diminish clinical findings and worsen prognosis. if in doubt, consider seeking consultation from an experienced surgeon and evaluating with ultrasound, MRI or potentially other imaging techniques.

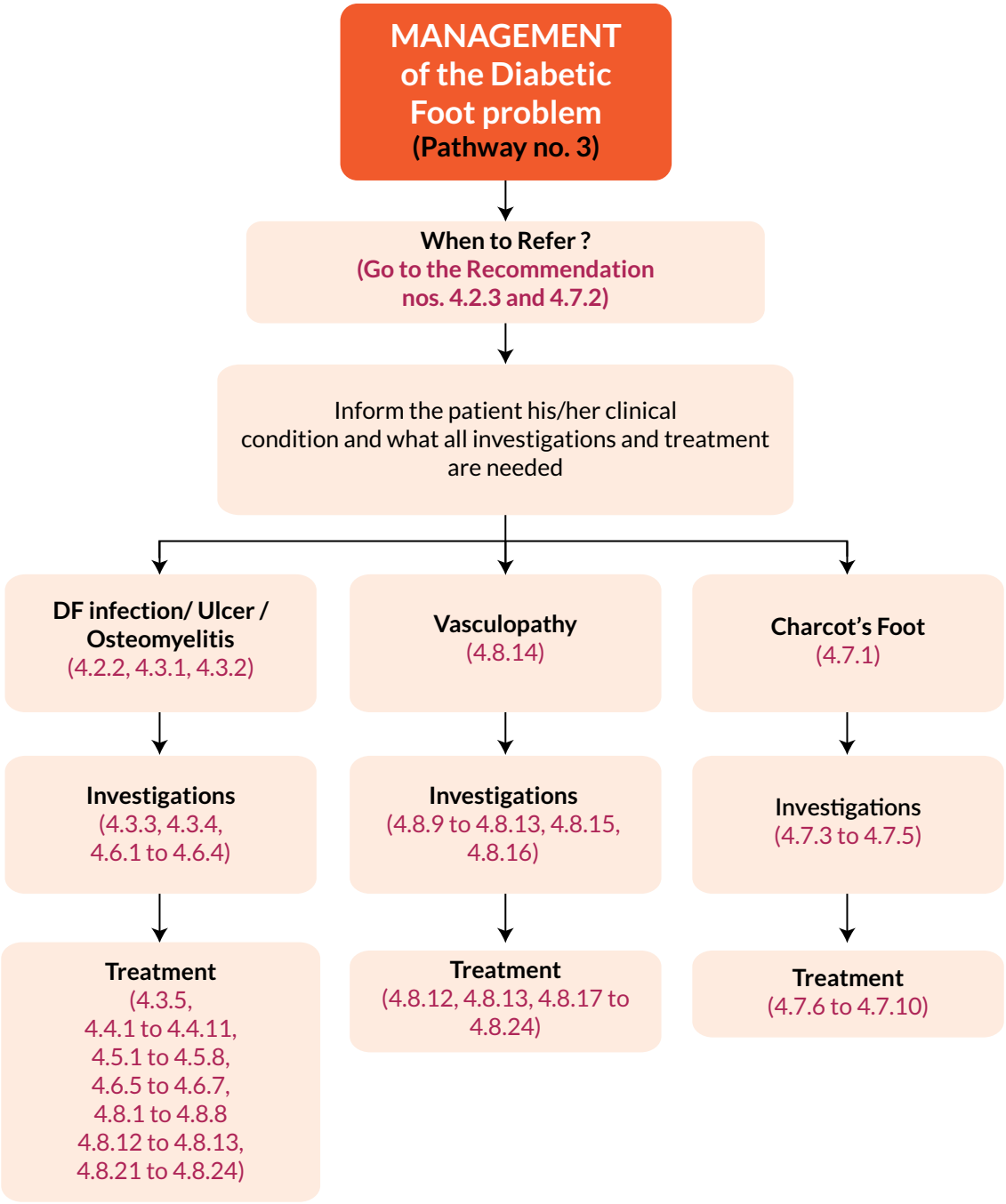
Source : From the IWGDF guidelines 2015.

4.2.2 b. Prior to being discharged, make sure that a patient with a DFI (Diabetic Foot Infection) is clinically stable; has had any urgently needed surgery performed; has achieved acceptable glycemic control; is able to manage (on his/her own or with help) at the designated discharge location; and has a well defined plan that includes an appropriate antibiotic regimen to which he/she will adhere, an off-loading scheme (if needed), specific wound care instructions, and appropriate outpatient follow-up.

CLINICAL PATHWAY 2.1: ASSESSMENT OF PATIENTS



CLINICAL PATHWAY 3:
OVERVIEW OF MANAGEMENT OF DIABETIC FOOT



4.3 DIABETIC FOOT INFECTIONS

4.3.1 Consider the possibility of infection occurring in any foot wound in a patient with diabetes. Evidence of infection generally includes classic signs of inflammation (redness, warmth, swelling, tenderness, or pain) or purulent secretions, but may also include additional or secondary signs (e.g., non-purulent secretions, friable or discolored granulation tissue, undermining of wound edges, foul odor).

4.3.2 Be aware of factors that increase the risk for diabetic foot infections (DFI) and especially consider infection when these factors are present; these include a wound for which the probe-to-bone (PTB) test is positive; an ulceration present for >30 days; a history of recurrent foot ulcers; a traumatic foot wound; the presence of peripheral vascular disease in the affected limb; a previous lower extremity amputation; loss of protective sensation; the presence of renal insufficiency; or a history of walking barefoot.

4.3.3 Take plain radiographs of the affected foot of all patients presenting with a new Diabetic Foot Infection to look for bony abnormalities (deformity, destruction) as well as for soft tissue gas and radio-opaque foreign bodies.

4.3.4 **When and how to obtain culture from Diabetic foot patients?**

4.3.4a. For clinically uninfected wounds, do not collect a specimen for culture.

4.3.4 b. Send a specimen for culture that is from deep tissue, obtained by biopsy or curettage and after the wound has been cleansed and debrided. Avoid swab specimens, especially of inadequately debrided wounds, as they provide less accurate results.

Explanatory note: Wash the wound with saline and the surrounding skin with antiseptic solution before taking culture to avoid contamination of the specimen obtained for culture.

4.3.4c. Do not obtain repeat cultures unless the patient is not clinically responding to treatment.

Explanatory note - Expert consensus says that if the signs of inflammation do not subside even after 72 hours of starting treatment, then it should be considered that patient is not responding.

4.3.4d. For infected wounds, clinicians should send appropriately obtained specimens for culture prior to starting empiric antibiotic therapy, if

possible. Cultures may be unnecessary for a mild infection in a patient who has not recently received antibiotic therapy.

4.3.5 Selection of Antibiotic **and when should it be modified?**

4.3.5a. Do not treat clinically uninfected wounds with antibiotic therapy.

4.3.5b. Prescribe antibiotic therapy for all infected wounds but caution that this is often insufficient unless combined with appropriate wound care.

4.3.5 c. Base the route of therapy largely on infection severity. Prefer parenteral therapy for all severe, and some moderate DFIs, at least initially with a switch to oral agents when the patient is systemically well and culture results are available. Clinicians can probably use highly bioavailable oral antibiotics alone in most mild, and in many moderate infections and topical therapy for selected mild superficial infections.

4.3.5d. Select an empiric antibiotic regimen on the basis of the severity of the infection and the likely etiologic agent (s):

a. For mild to moderate infections in patients who have not recently received antibiotic treatment, therapy just targeting aerobic gram-positive cocci (GPC) is sufficient

b. For most severe infections, start broad-spectrum empiric antibiotic therapy, pending culture results and antibiotic susceptibility data.

c. Empiric therapy directed at P. aeruginosa is usually unnecessary except for patients with risk factors* for true infection with this organism.

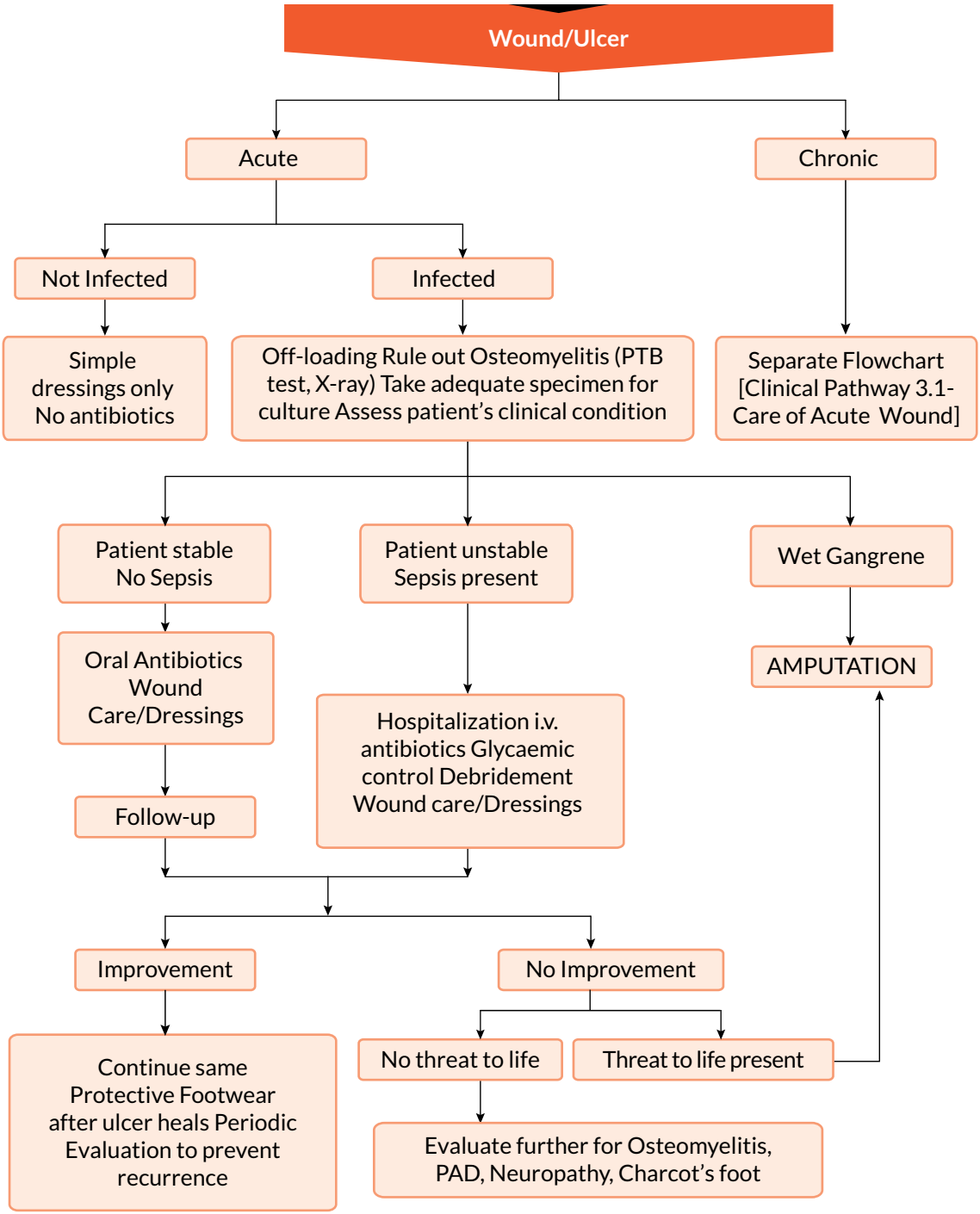
d. Consider providing empiric therapy directed against MRSA in a patient with a prior history of MRSA infection; when the local prevalence** of MRSA colonization or infection is high; or if the infection is clinically severe.

Explanatory notes

**Risk factors for true infection with Pseudomonas aeruginosa include Immunocompromised status, Chronic Kidney Disease, warm climate and frequent exposure of foot to water.*

***The local prevalence of MRSA (i.e., percentage of all S. aureus clinical isolates in that locale that are methicillin resistant) is high enough (perhaps 50% for a mild and 30% for a moderate soft tissue infection) that there is a reasonable probability of MRSA infection.*

CLINICAL PATHWAY 3: CARE OF ACUTE WOUND



4.3.5e. Give an initial antibiotic course for a soft tissue infection of about 1–2 weeks for mild infections and 2–3 weeks for moderate to severe infections.

4.3.5f. Continue antibiotic therapy until, but not beyond, resolution of findings of infection, but not through complete healing of the wound.

4.3.5g Administer parenteral therapy initially for most severe infections and some moderate infections, with a switch to oral therapy when the infection is responding.

4.1 WOUND CARE

4.4.1 Clean ulcers regularly with clean water or saline*, debride them when possible in order to remove debris from the wound surface and dress them with a sterile, inert dressing in order to control excessive exudate and maintain a warm, moist environment in order to promote healing**.

Explanatory note:

**Clean water is boiled cooled water (distilled water)*

*** Do not use H2O2, EUSOL, etc*

4.4.2 Select dressings principally on the basis of exudate control, comfort and cost.

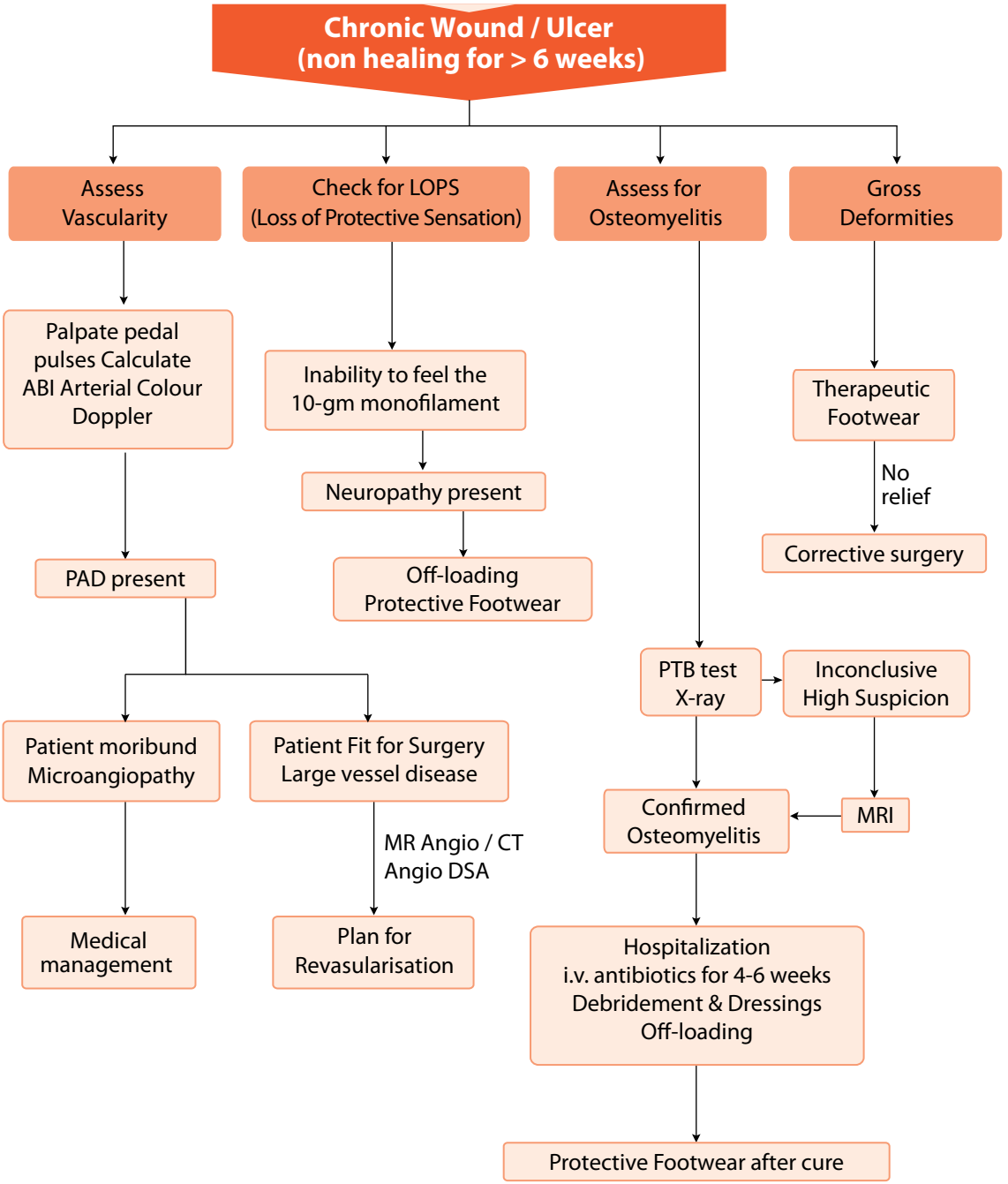
4.4.3 Do not use antimicrobial dressings with the goal of improving wound healing or preventing secondary infection.

4.4.4 Do not offer the following to treat diabetic foot ulcers, unless as part of a clinical trial:

- Electrical stimulation therapy, autologous platelet-rich plasma gel, regenerative wound matrices and dalteparin.
- Growth factors (granulocyte colony-stimulating factor [G-CSF], platelet-derived growth factor [PDGF], epidermal growth factor [EGF] and transforming growth factor beta [TGF-β]).
- Hyperbaric oxygen therapy.

4.4.5 Consider dermal or skin substitutes as an adjunct to standard care when treating diabetic foot ulcers, only when healing has not progressed and on the advice of the multidisciplinary foot care service.

CLINICAL PATHWAY 3.2: CARE OF CHRONIC WOUND



4.4.6 Consider negative pressure wound therapy after surgical debridement for diabetic foot ulcers, on the advice of the multidisciplinary foot care service.

4.4.7 Do not select agents reported to improve wound healing by altering the biology of the wound, including growth factors, bioengineered skin products and gases, in preference to accepted standards of good quality care.

4.4.8 Do not select agents reported to have an impact on wound healing through alteration of the physical environment, including through the use of electricity, magnetism, ultrasound and shockwaves, in preference to accepted standards of good quality care.

4.4.9 Do not select systemic treatments reported to improve wound healing, including drugs and herbal therapies, in preference to accepted standards of good quality care. Redistribution of pressure off the wound to the entire weight-bearing surface of the foot ("off-loading"). While particularly important for plantar wounds, this is also necessary to relieve pressure caused by dressings, footwear, or ambulation to any surface of the wound.

4.4.11 When deciding about wound dressings and offloading when treating diabetic foot ulcers, take into account the clinical assessment of the wound and the person's preference, and use devices and dressings with the lowest acquisition cost appropriate to the clinical circumstances.

4.5 FOOTWEAR

4.5.1 To heal a neuropathic plantar forefoot ulcer without ischemia or uncontrolled infection in a patient with diabetes, offload with a non-removable knee-high device with an appropriate foot-device interface.

Non-removable (cast) walker: Same as removable (cast) boot/walker but then with a layer (s) of fibreglass cast material circumferentially wrapped around it rendering it irremovable (also known as "instant total contact cast")

4.5.2 When a non-removable knee-high device is contraindicated or not tolerated by the patient, consider off loading with a removable knee-high walker with an appropriate foot-device interface to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only when the patient can be expected to be adherent to wearing the device.

Removable (cast) boot/walker: Prefabricated removable knee-high boot with a rocker or roller outsole configuration, padded interior, and an insertable and adjustable insole which may be total contact.

4.5.3 When a knee-high device is contraindicated or cannot be tolerated by the patient, consider offloading with a forefoot offloading shoe, cast shoe, or custom-made temporary shoe to heal a neuropathic plantar forefoot ulcer in a patient with diabetes, but only and when the patient can be expected to be adherent to wearing the shoes.

4.5.4 Instruct an at-risk patient with diabetes to wear properly fitting footwear to prevent a first foot ulcer, either plantar or non-plantar, or a recurrent non-plantar ulcer. When a foot deformity or a pre-ulcerative sign is present, consider prescribing therapeutic shoes, custom-made insoles, or toe orthosis*.

**Toe orthosis:- An in-shoe orthosis to achieve some alteration in the function of the toe.*

4.5.5 To prevent a recurrent plantar foot ulcer in an at-risk patient with diabetes, prescribe therapeutic footwear that has a demonstrated plantar pressure relieving effect during walking and encourage the patient to wear this footwear.

4.5.6 Instruct a patient with diabetes not to use conventional or standard therapeutic footwear to heal a plantar foot ulcer.

Explanatory note: Use footwear with following features:

Sandals: Should have adjustable straps, insole, full heel counter and rigid outsole.

Shoes: Should have wide toe box extra depth and without laces.

4.5.7 Consider using shoe modifications, temporary footwear, toe spacers or orthoses to offload and heal a non-plantar foot ulcer without ischemia or uncontrolled infection in a patient with diabetes. The specific modality will depend on the type and location of the foot ulcer.

4.5.8 If other forms of biomechanical relief are not available, consider using felted foam* in combination with appropriate footwear to offload and heal a neuropathic foot ulcer without ischemia or uncontrolled infection in a patient with diabetes.

Felted foam - A fibrous, unwoven material backed by foam with absorbing and cushioning characteristics. The foam is generally 'rubber foam' or 'PU foam' which is formed by either a polyester or polyether polyol resin, in conjunction with water

and Toluene di Isocyanate, along with various catalysts and blowing agents and colouring pigments to give the desired compression.

4.6 TREATMENT OF DIABETIC FOOT WITH OSTEOMYELITIS

4.6.1 For an infected open wound, perform a probe-to-bone test; in a patient at low risk for osteomyelitis a negative test largely rules out the diagnosis, while in a high risk patient a positive test is largely diagnostic.

4.6.2 Markedly elevated ESR is suggestive of osteomyelitis in suspected cases.

Explanatory note: Tests for serum inflammatory markers are costly and not widely available, except ESR. Also these tests are not diagnostic of DFO .

4.6.3 If osteomyelitis is suspected in a person with diabetes but is not confirmed by initial X-ray, consider an MRI to confirm the diagnosis. In places where MRI is unavailable, diagnose osteomyelitis by the PTB test (clinically) and/or taking a Bone biopsy and culture.

Explanatory note: "Expert Consensus says that as availability of MRI is limited across the country, it is recommended to use MRI wherever available." At the primary and secondary health centre levels, the PTB test and bone biopsy and culture are more feasible and economical and reasonably accurate.

4.6.4 A definite diagnosis of bone infection usually requires positive results on both histological and microbiological examinations of an aseptically obtained bone sample, but this is usually required only when the diagnosis is in doubt or determining the causative pathogen's antibiotic susceptibility is crucial.

4.6.5 Avoid using results of soft tissue or sinus tract specimens for selecting antibiotic therapy for osteomyelitis as they do not accurately reflect bone culture results.

4.6.6 When a radical resection leaves no remaining infected tissue*, we suggest prescribing antibiotic therapy for only a short duration (2–5 days). When there is persistent infected or necrotic bone, we suggest prolonged (≥4 weeks) antibiotic treatment.

*Explanatory note: *A proximal bone histopath to be done if available to get a clear margin and confirm that no infected bone remains.*

4.6.7 For specifically treating Diabetic foot osteomyelitis, we do not currently support using adjunctive treatments such as hyperbaric oxygen therapy, growth factors (including granulocyte colony stimulating factor), maggots (larvae), or topical negative pressure therapy (eg, vacuum-assisted closure).

4.7 CHARCOT'S FOOT

4.7.1 Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present or pain is not reported.

4.7.2 Refer the person with suspected charcot's foot early (within one week) to the "Diabetic Foot Care Center" to confirm the diagnosis, and offer non-weight-bearing treatment until definitive treatment can be started.

Diabetic Foot care centre:- In India, since there are no minimum standards of services offered to the diabetic foot patients, in our recommendations we have used this term to denote this facility, which may exist at the General Practitioner's office, Primary health centre, Secondary care centre or at a tertiary care centre. Preferably, the diabetic foot care centre should consist of atleast a surgeon, a physician, and an orthotist.

4.7.3 If acute Charcot arthropathy is suspected, X-ray the affected foot. Consider an MRI if the X-ray is normal but clinical suspicion still remains.

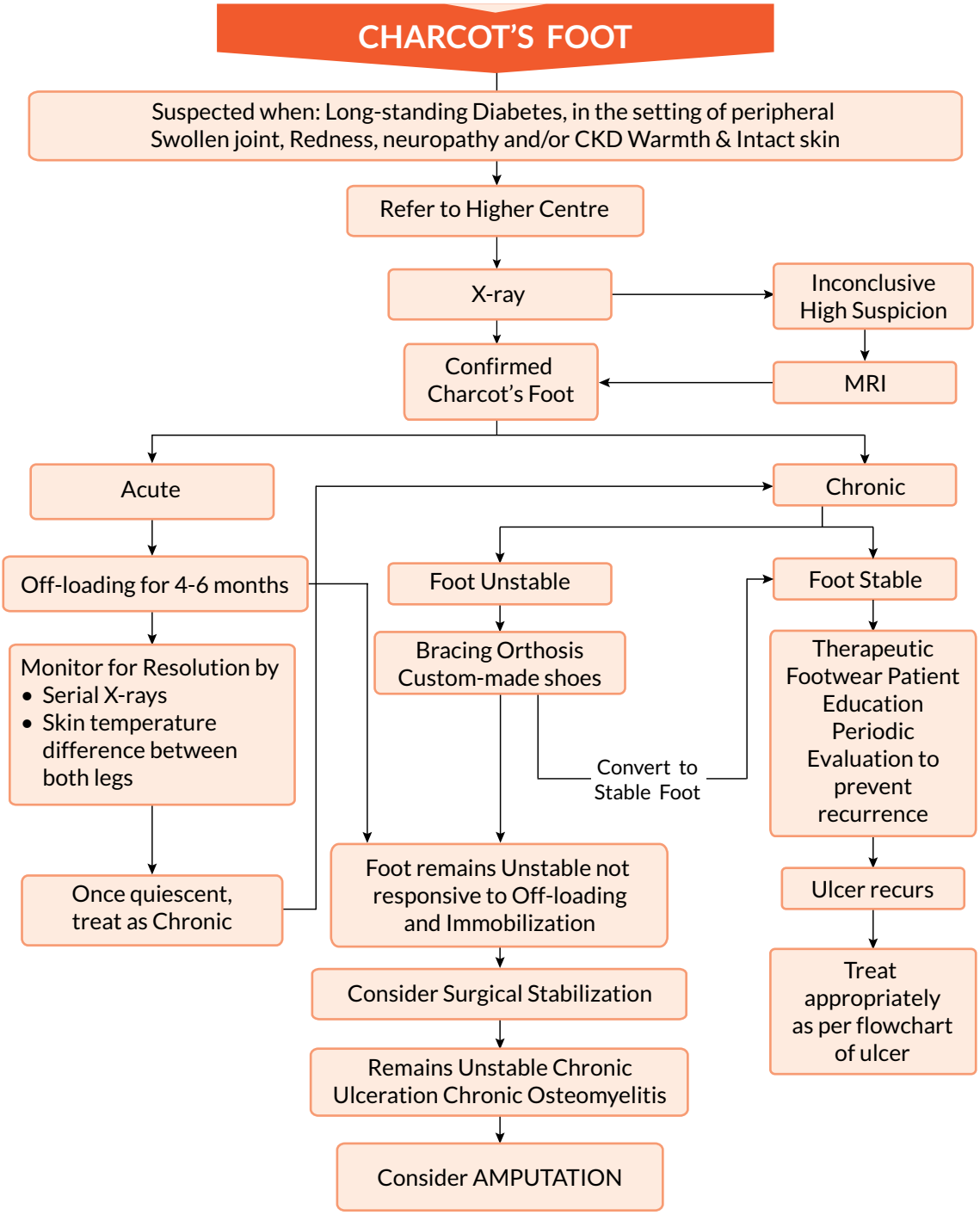
4.7.4 Distinguishing the bony changes of osteomyelitis from those of the less common entity of diabetic neuro-osteoarthropathy (Charcot foot) may be particularly challenging and requires considering clinical information in conjunction with imaging.

4.7.5 Clinical clues supporting neuro-osteoarthropathy in this context include midfoot location and absence of a soft tissue wound, whereas those favoring osteomyelitis include presence of an overlying ulcer (especially of the forefoot or heel), either alone or superimposed on Charcot changes.

4.7.6 If the films show classic changes suggestive of osteomyelitis (cortical erosion, periosteal reaction, mixed lucency, and sclerosis), and if there is little likelihood of neuro-osteoarthropathy, it is reasonable to initiate treatment for presumptive osteomyelitis, preferably after obtaining appropriate specimens for culture.

4.7.7 If the Diabetic Foot Care Center suspects acute Charcot arthropathy, offer treatment with a non-removable off-loading device. Only consider treatment with a removable off-loading device if a non-removable device is not advisable because of the clinical or the person's circumstances.

CLINICAL PATHWAY 3.3: MANAGEMENT OF CHARCOT'S FOOT



4.7.8 Do not offer bisphosphonates to treat acute Charcot arthropathy, unless as part of a clinical trial.

4.7.9 Monitor the treatment of acute Charcot arthropathy using clinical assessment. This should include measuring foot–skin temperature difference and taking serial X-rays until the acute Charcot arthropathy resolves. Acute Charcot arthropathy is likely to resolve when there is a sustained temperature difference of less than 2˚ centigrade between both feet and when X-ray changes show no further progression.

4.7.10 The Diabetic Foot care centre should care for people who have a foot deformity resulting from a previous Charcot's arthropathy as they are at high risk of ulceration.

4.8 SURGICAL INTERVENTIONS AND REVASCULARIZATION

4.8.1 Consult a surgical specialist in all cases of diabetic foot infections that are moderate or severe.

4.8.2 Perform urgent surgical intervention in most cases of deep abscesses, compartment syndrome and virtually all necrotizing soft tissue infections.

4.8.3 Debride any wound that has necrotic tissue or surrounding callus; the required procedure may range from minor to extensive.

4.8.4 Perform urgent surgical intervention for most foot infections accompanied by gas in the deeper tissues, an abscess, or necrotizing fasciitis, and less urgent surgery for wounds with substantial nonviable tissue or extensive bone or joint involvement.

Additional note: In those with a non-severe infection, carefully observing the effectiveness of medical therapy and the demarcation line between necrotic and viable tissue before operating may be prudent.

4.8.5 Consider surgical intervention in cases of osteomyelitis accompanied by: spreading soft tissue infection; destroyed soft tissue envelope; progressive bone destruction on X-ray; or, bone protruding through the ulcer.

4.8.6 Remove slough, necrotic tissue & surrounding callus with sharp debridement in preference to other methods, taking relative contraindications such as severe ischemia into account.

4.8.7 Consider digital flexor tenotomy to prevent a toe ulcer when conservative treatment fails in a high-risk patient with diabetes, hammer toes and either a pre-ulcerative sign or an ulcer on the toe.

4.8.8 Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar foot ulcer.

Management of Peripheral Artery Disease **in patients with Diabetic foot problems**

4.8.9 Examine a patient with diabetes annually for the presence of peripheral artery disease (PAD); this should include, at a minimum, taking a history and palpating foot pulses.

4.8.10 Evaluate a patient with diabetes and a foot ulcer for the presence of PAD. Determine, as part of this examination, ankle or pedal Doppler arterial waveforms; measure both ankle systolic pressure and systolic Ankle Brachial Index (ABI).

4.8.11 Use bedside non-invasive tests to exclude PAD. No single modality has been shown to be optimal. Measuring ABI (with <0.9 considered abnormal) is useful for the detection of PAD. Tests that largely exclude PAD are the presence of ABI 0.9-1.3, Toe Brachial Index (TBI) ≥0.75 and the presence of triphasic pedal Doppler arterial waveforms.

4.8.12 In patients with a non-healing ulcer with either an ankle pressure <50mmHg or ABI <0.5 consider urgent vascular imaging and revascularisation.

4.8.13 Consider vascular imaging and revascularisation in all patients with a foot ulcer in diabetes and PAD, irrespective of the results of bedside tests, when the ulcer does not improve within 6 weeks despite optimal management.

4.8.14 Do not consider Diabetic microangiopathy to be the cause of poor wound healing in patients with a foot ulcer.

4.8.15 To obtain anatomical information when revascularisation is being considered, use one of these tests - Colour Doppler ultrasound, CT-angiography, MR-angiography or intra-arterial digital subtraction angiography. Evaluate the entire lower extremity arterial circulation, with detailed visualization of below-the-knee and pedal arteries.

4.8.16 Offer duplex ultrasound as first-line imaging to all people with peripheral arterial disease for whom revascularization is being considered. Take the decision of revascularisation on the basis of colour doppler findings and use DSA for defining the vascular anatomy prior to the procedure.

4.8.17 The aim of revascularisation is to restore direct flow to at least one of the foot arteries, preferably the artery that supplies the anatomical region of the wound, and adequate revascularization should be assessed post-operatively with colour Doppler wave-fronts (preferable) or a hand held Doppler probe used bedside.

4.8.18 A centre treating patients with a foot ulcer in diabetes should have liaison / association with a centre having the expertise necessary to diagnose and treat PAD; both endovascular techniques and bypass surgery should be available.

4.8.19 The multidisciplinary team should treat the patient after a revascularisation procedure for a foot ulcer in diabetes, as part of a comprehensive care plan.

4.8.20 There is inadequate evidence to establish which revascularisation technique is superior and a multidisciplinary team should decide the technique of revascularization for a patient based on a number of individual factors, such as morphological distribution of PAD, availability of autogenous vein, patient co-morbidities and local expertise.

4.8.21 Give emergency treatment to patients with signs of PAD and a foot infection as they are at particularly high risk for major limb amputation.

4.8.22 Avoid revascularisation in patients in whom, from the patient perspective, the risk-benefit ratio for the probability of success is unfavourable*.

**Explanatory note: Unfavorable risk benefit ratio would indicate those patients who are frail, elderly, bed ridden, having low life expectancy, multiple co-morbidities imposing high risk for surgical intervention, etc.*

4.8.23 All patients with diabetes and an ischemic foot ulcer should receive aggressive cardiovascular risk management including support for cessation of smoking, treatment of hypertension and prescription of a statin as well as low-dose aspirin or clopidogrel.

4.8.24 Do not offer major amputation to people with critical limb ischaemia unless all options for revascularisation have been considered by a vascular multidisciplinary team. Major amputation without giving a chance for revascularization is indicated only in lifesaving situations like foot causing septicemia, wet gangrene, or completely destroyed foot (post charcot's or osteomyelitis etc).

GUIDELINE DEVELOPMENT PROCESS

BACKGROUND

A Task Force was constituted in December 2014 to guide the development of Standard Treatment Guidelines (STG) in India. The Task Force subsequently approved the draft STG development manual of India (Part 1) for development of adapted guidelines. A subgroup of the task force was appointed to select prioritized topics for STG development and it recommended a list of 14 topics which were then approved by the Task Force." These 14 topics are from 10 clinical specialties for which the first set of STGs will be developed. The topic diabetic foot is included in this first list and was ealt with by the General Surgery clinical subgroup.

OVERVIEW

The STG on Diabetic foot management, was developed by a team of experts and relevant stakeholders. The recommendations in the STG were adopted/adapted from four source guidelines which are the IWGDF (2015), IDSA (2012) and NICE guideline (26th August, 2015) on diabetic foot, and the NICE guidelines on PAD (Peripheral Arterial Disease) November 2014.

Available from and full reference below:

http://www.iwgdf.org/files/2015/

http://www.idsociety.org

https://www.nice.org.uk/guidance/NG19

https://www.nice.org.uk/guidance/cg147

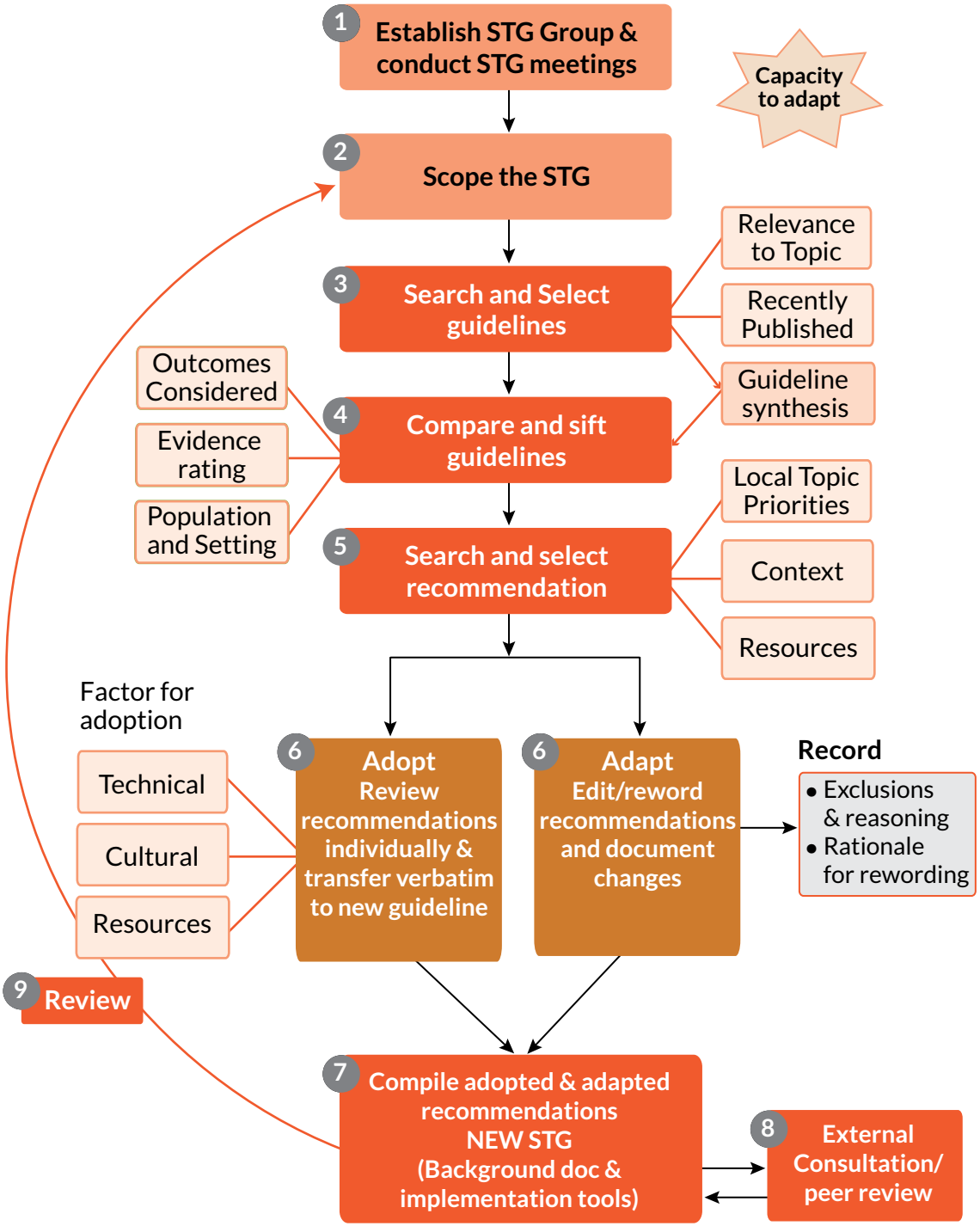
1. 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections
2. The National Institute for Health and Care Excellence (NICE) guidelines- Diabetic foot problems: prevention and management (NG19) (Published: 26 August 2015)
3. International Working Group on the Diabetic Foot (IWGDF) 2015 - Prevention and Management of Foot Problems in Diabetes Guidance Documents and Recommendations
4. NICE guideline- Lower limb peripheral arterial disease: diagnosis and management (NICE clinical guideline 147) (Issued: August 2012 last modified: August 2015)

The processes and methods used in developing this STG draw on those outlined in the STG development manual of India (Part 1) for development of adapted guidelines and summarized in the Stepwise guide on STG development. The figure below contains a schematic of the process followed and each of the steps are detailed in subsequent sections below.

The NHSRC with technical support from NICE Iternational carried out a training workshop in May 2015 to guide the STG group members and chairs on the methodology to follow in developing adapted STGs suitable for the Indian context. This workshop was conducted on 29th & 30th May, 2015 and two members (NR, MK) of the surgery STG team attended. Subsequently, NHSRC facilitated the STG development process by providing resources approved by the Ministry of Health &Family Wlfare to the expert group.

To assist widespread implementation of the diabetic foot STG, three implementation tools have been developed in addition to the STG document. They include:

- The Quick Reference Guide to help the clinical practitioner (Clinical pathways)
- “A Patient Information Document to create awareness among the patients and their caregivers.
- The Quality Standards developed from key priority recommendations.


1 Establish STG Group & conduct STG meetings
Capacity to adapt
2 Scope the STG
3 Search and Select guidelines
Relevance to Topic
Recently Published
Guideline synthesis
Outcomes Considered
Evidence rating
Population and Setting
4 Compare and sift guidelines
5 Search and select recommendation
Local Topic Priorities
Context
Resources
Factor for adoption
Technical
Cultural
Resources
6 Adopt
Review recommendations individually & transfer verbatim to new guideline
6 Adapt
Edit/reword recommendations and document changes
Record
• Exclusions & reasoning
• Rationale for rewording
9 Review
7 Compile adopted & adapted recommendations NEW STG (Background doc & implementation tools)
8 External Consultation/ peer review

Steps followed during the development of the STG on diabetic foot are as follows:

Diabetic foot STG Subgroup established

A multi-disciplinary group consisting of health professionals, subject matter experts in various fields and a patient representative undertook the development of this evidence-based STG on diabetic foot. Official letters of invitation were sent from the NHSRC head office. The members of the task force who worked for the Government experienced delays and difficulties in procuring permissions from their respective departments for this work. Subsequently, there were drop outs and new experts invited. The names of the 14 group members in the STG sub-group on diabetic foot, their specialities and organization affiliation are listed here:

Task Force: The STG Subgroup on Diabetic foot

None of the members report any conflict of interest in the development of this guideline and all have signed their declarations.

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Private Practitioner	Sanjay Vaidya, Plastic surgeon, Hinduja Hospital DFSI Exec committee member

Paramedic /Nurse/ Rehabilitation Experts	GauthamGopalakrishna,Principal senior Scientist & Head, Footwear Design and Development, Central Leather Institute, Chennai
Primary Care Practitioners	TruptiPatil, Chembur CHSS dispensary, Chembur, Mumbai
Patient Right Group/NGO	Raman Kataria, Surgery, Jan SwasthyaSahyog, Ganiyari Village, Bilaspur District, Chhattisgarh Nandakumar M, Senior secondary care surgeon, Ashwini, Gudalur, Tamil Nadu SushilPatil, JSS, Ganyari, Chattisgarh

Expert Adviser

Dr. Raghuram Sekhar, Vascular surgeon, Kokilaben Dhirubhai Ambani Hospital, Mumbai Dr Abha Mehndiratta was the technical person providing oversight and guidelines in the meetings. Satish Mishra and Sushil Patil were the patient right representatives in the group.

The STG Subgroup met twice face-to-face and all meetings (including the smaller weekly ones were quorate (50%=7 members). The working group met every tuesday evening, before and after each of these meetings over a period of two months. Some of the members joined the small group meetings via video-conference. In the induction and orientation session held on 21st July 2015, the facilitator (Chair) welcomed all the members of the subgroup, and set up the rules of operation based on the STG development manual, on the consistent use of terminology and definitions, using the structured powerpoint presentation provided by NHSRC/NICE.

The induction and orientation session was held on 21st July 2015 in which the facilitator (Chair) welcomed all the members of the subgroup, and set up the rules of operation based on the STG development manual, on the consistent use of terminology and definitions, using the structured power-point presentation provided by NHSRC/NICE.The STG Subgroup met face-to-face twice between July 2015 to November 2015. The writing team met every week, on Tuesday evening during the same time period. All these meetings were quorate (50% = 7 members). Those who could not attend physically joined in via video conferencing (Skype). Also, the individual members in the writing team kept in touch via

e-mails and Whatsapp. In the initial few meetings the recommendations were drafted, and in the subsequent meetings, the recommendations were edited as per the peer review comments from the NHSRC/NICE.

NOTE

NOTE

MINISTRY OF HEALTH AND FAMILY WELFARE
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