Diabetic Foot Infection - Microbiology Full Clinical Guideline

Reference number: CG-ANTI/2023/049

Introduction

- The sensory, motor, and/or autonomic neuropathies of diabetes mellitus predispose people with diabetes to infection.
- The diminished perception of pain, foot deformities, and/or diminished sweat secretion cause traumatic and ulcerative breaches of the skin and enable microbial invasion.
- The host inflammatory responses to the invading pathogen may be blunted by the peripheral arterial disease of diabetes mellitus.
- In people with diabetes, the microbial invasion of tissues inferior to the malleoli, and ensuing destruction, is termed diabetic foot infection (DFI).
- Extension into fascia, muscle, tendons, joints, and bone can cause fasciitis, myositis, tendinitis, septic arthritis, and osteomyelitis variants, respectively, of DFI.

- *Staphylococcus aureus* – methicillin susceptible or resistant *Staphylococcus aureus* (MSSA or MRSA) – and beta-haemolytic streptococci are bacteria commonly associated with DFI.
- Extension from superficial to deep tissue can be associated with polymicrobial invasion: investigation commonly isolates *Staphylococcus aureus*, beta-haemolytic streptococci, enterococci, anaerobes, and/or *Enterobacterales* (e.g. *Escherichia coli*).
- Investigation, especially superficial, also commonly isolates *Pseudomonas aeruginosa*. However, in temperate climates, including the United Kingdom, *Pseudomonas aeruginosa* commonly just colonises diabetic foot ulcers.

Diagnosis

- DFI guidance from the International Working Group on the Diabetic Foot (IWGDF) provides definitions and classification systems.
- DFI is diagnosed with ≥ 2 of:
    - Local swelling or induration
    - Erythema > 0.5 cm* around the wound
    - Local tenderness or pain
    - Local increased warmth
    - Purulent discharge

  without a non-infectious aetiology for the symptoms and/or signs.
- DFI is classified into mild, moderate, or severe:
    - Mild:
        - Infection with no systemic manifestations (see below) involving:
            - Only the skin or subcutaneous tissue (not any deeper tissues); and
            - Any erythema present does not extend > 2 cm** around the wound.
    - Moderate:
        - Infection with no systemic manifestations (see below) involving:
            - Erythema extending ≥ 2 cm* from the wound margin; and/or
            - Tissue deeper than skin and subcutaneous tissues (e.g. tendon, muscle, joint, bone).

    - Severe:
        - Any foot infection with associated systemic manifestations (of the systemic inflammatory response syndrome [SIRS]), as manifested by ≥ 2 of the following:
            - Temperature > 38 ° C or < 36 ° C; and/or
            - Heart rate > 90 beats/minute; and/or
            - Respiratory rate > 20 breaths/minute or $PaCO_2$ < 4.3 kPa (32 mmHg); and/or
            - White blood cells > 12 x 10^9/l or < 4 x 10^9/l.
        - NB Please note, the present definition of sepsis is "life threatening organ dysfunction caused by a dysregulated host immune response to infection". However, past definitions of sepsis have included "Clinical suspicion of, or confirmed, infectious disease plus ≥ 2 of SIRS criteria". Therefore, if severe DFI is diagnosed, consider sepsis and septic shock in the differential diagnosis and 'sepsis six' in management.
- DFI can be subclassified into:
    - Infection involving bone (osteomyelitis), i.e. DFI with osteomyelitis (DFIO).
- * Infection refers to any part of the foot, not just of a wound or an ulcer.
- ** In any direction, from the rim of the wound. The presence of clinically significant foot ischemia makes both diagnosis and treatment of infection considerably more difficult.

- NB Diabetologist review of inpatients diagnosed with DFI is recommended within 24 hours of diagnosis:
    - If diagnosed on presentation:
        - Emergency department, medical assessment unit, etc., to refer the patient to the diabetes team.
    - If diagnosed after admission:
        - Medical/Surgical team to refer the patient to the diabetes team.

Differential diagnosis

- The pain, erythema, warmth, tenderness, and swelling of inflammation can be secondary to non-infectious disease.
- Non-microbial mimickers include acute Charcot neuro-osteoarthropathy, deep venous thrombosis, fracture, gout, limb threatening ischaemia, trauma, and venous stasis.

Investigation

- The management of DFI may include both invasive and non-invasive investigations:
    - If the diagnosis is mild DFI or if there is clinical improvement on empiric antimicrobial chemotherapy:
        - Healthcare professionals may limit their investigations to the non-invasive only.
    - If the diagnosis is moderate/severe DFI or if there is clinical deterioration on empiric antibiotics:
        - Healthcare professionals may extend their investigations to the invasive.
- The investigations outlined herein require tailoring to the patient and the specifics of the DFI.

- NB The provision of clinical details is the duty of the requesting healthcare professional and is integral to best practice. If the healthcare professional has provided robust clinical details, equally, it is the duty of the relevant pathologist to report specialty findings that enable optimal management.

Radiology

- Radiology is recommended for every DFI:
    - First line: X-ray (XR).
    - Second line, if the XR is negative and if clinical suspicions of DFIO, etc.: magnetic resonance imaging (MRI).

Microbiology

- ± Blood cultures (e.g. if episode[s] of fever, or if the differential diagnosis includes bloodstream infection/sepsis/septic shock, or if for initiation of treatment with intravenous antibiotics).

- ± Aspirate/Biopsy:
    - With diabetic foot wounds and ulcers harbouring bacteria capable of both colonisation and invasion, and with the range of bacterial pathogens, variations in resistance and susceptibility profiles, variable antimicrobial bone penetration, contraindications, side-effects, and ± prolonged durations of antimicrobial chemotherapy:
        - Fluid/Pus/Tissue may optimise management.
    - After cleaning with saline (NB cleansing with antiseptic is contraindicated) ± debriding:
        - Aspirate with a needle and syringe through clean, healthy skin adjacent to the lesion; or
        - Biopsy with one set of instrumentation per sample from the resection margins of any bone debrided.
    - NB1 Aspirates of fluid, aspirates of pus, and biopsies of tissue from resection margins with clinical details stating:
        - DFI plus its classification (mild, moderate, or severe); and
        - Cleaned or debrided before sampling; and
        - The location of the sample (resection margin or debrided base)

      will undergo susceptibility testing for *Staphylococcus aureus*, beta-haemolytic streptococci, enterococci, anaerobes, *Enterobacterales* (e.g. *Escherichia coli)*, and *Pseudomonas aeruginosa*, and the microbiology team will release appropriate susceptibilities/resistances, enabling healthcare professionals to optimise management.
    - NB2 Aspirates and biopsies without clinical details stating:
        - DFI plus its classification (mild, moderate, or severe); or
        - The nature of the preparation before sampling; or
        - The location of the sample

      will be processed; however, only cultures, susceptibilities, and resistances for *Staphylococcus aureus* and beta-haemolytic streptococci will be released. Further isolates, in general, will be reported as “mixed colonising flora”.

Histology

- ± Biopsy for histopathology (e.g. if clinical uncertainty regarding diagnosis).

Blood sciences

- ± Bloods (full blood count [FBC], C reactive protein [CRP], urea and electrolytes [U&Es], and liver function tests [LFTs]) (e.g. if admitted for inpatient management).

Management: mild DFI

Diagnosis of DFI with ≥ 2 of:

- Local swelling or induration
- Local increased warmth
- Erythema > 0.5 cm
- Purulent discharge
- Local tenderness or pain

without a non-infectious aetiology for the symptoms and/or signs

PLUS

Infection - with no systemic manifestations (see Management: severe DFI) - involving:

- Only the skin or subcutaneous tissue (not any deeper tissues); and
- Any erythema present does not extend > 2 cm around the wound

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Investigation

- XR
- ± Bloods (FBC, CRP, U&E, LFT); for example, if admitted for inpatient management

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Treatment; empiric, per oral antibiotics

- First line: flucloxacillin 1 g 6 hourly
- Second line, if penicillin allergy: doxycycline 100 mg 12 hourly
- Third line, if penicillin allergy and doxycycline is contraindicated: clarithromycin 500 mg 12 hourly
- Fourth line, if penicillin allergy and doxycycline and clarithromycin are contraindicated: clindamycin 300 mg 6 hourly

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Treatment; directed/targeted, per oral antibiotics (with susceptibilities)

MSSA, according to susceptibilities:	MRSA, according to susceptibilities:	*Streptococcus* groups A/B/C/G, according to susceptibilities:
• First line: flucloxacillin 1 g 6 hourly • Second line, if penicillin allergy: doxycycline 100 mg 12 hourly • Third line, if penicillin allergy and doxycycline is contraindicated: clarithromycin 500 mg 12 hourly	• First line: doxycycline 100 mg 12 hourly • Second line, if doxycycline is contraindicated: clarithromycin 500 mg 12 hourly • Third line, if doxycycline and clarithromycin are contraindicated: clindamycin 300 mg 6 hourly	• First line: amoxicillin 500 mg 8 hourly • Second line, if penicillin allergy: doxycycline 100 mg 12 hourly • Third line, if penicillin allergy and doxycycline is contraindicated: clarithromycin 500 mg 12 hourly

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Total duration of antibiotics: 7-14 days

Management: moderate DFI

Diagnosis of DFI with ≥ 2 of:

- Local swelling or induration
- Erythema > 0.5 cm
- Local tenderness or pain
- Local increased warmth
- Purulent discharge

without a non-infectious aetiology for the symptoms and/or signs

PLUS

Infection - with no systemic manifestations (see Management: severe DFI) - involving:

- Erythema extending ≥ 2 cm from the wound margin; and/or
- Tissue deeper than skin and subcutaneous tissues (e.g. tendon, muscle, joint, bone)

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Investigation

- XR
- ± MRI (e.g. if the XR is negative and if clinical suspicions of DFIO, etc.)
- ± Bloods (FBC, CRP, U&E, LFT); for example, if admitted for inpatient management
- ± Aspirate or biopsy for microbiology (e.g. if there is clinical deterioration on empiric antibiotics)
- ± Biopsy for histopathology (e.g. if clinical uncertainty regarding diagnosis)

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Treatment; empiric, per oral antibiotics

- First line: co-amoxiclav 625 mg 8 hourly plus amoxicillin 500 mg 8 hourly
- Second line, if penicillin allergy:
  - If for inpatient management: metronidazole 400 mg 8 hourly and levofloxacin 500 mg 12 hourly
  - If for outpatient management: ciprofloxacin 500 mg 12 hourly and doxycycline 100 mg 12 hourly (or if doxycycline is contraindicated, ciprofloxacin 500 mg 12 hourly and clindamycin 300 mg 6 hourly)
- Third line, if penicillin allergy and levofloxacin/ciprofloxacin are contraindicated: metronidazole 400 mg 8 hourly and co-trimoxazole 960 mg 12 hourly:
  - With diabetes mellitus sequelae including diabetic nephropathy and with co-trimoxazole risks including electrolyte imbalance, interstitial nephritis, and renal tubular acidosis:
    - If for metronidazole and co-trimoxazole as an inpatient:
      - Monitoring of U&Es 24-48 hourly is mandatory
    - If for metronidazole and co-trimoxazole as an outpatient:
      - Monitoring of U&Es via the complex outpatient antibiotic therapy (COpAT) service is mandatory

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Treatment; directed/targeted antibiotics

- With susceptibilities (please note pages 7 and 8)
- Total duration: without surgical intervention, 2-6 weeks

Management: severe DFI

Diagnosis of DFI with ≥ 2 of:

- Local swelling or induration
- Erythema > 0.5 cm
- Local tenderness or pain
- Local increased warmth
- Purulent discharge

without a non-infectious aetiology for the symptoms and/or signs

PLUS

Any foot infection with associated systemic manifestations (of SIRS), as manifested by ≥ 2 of the following:

- Temperature > 38 ° C or < 36 ° C
- Heart rate > 90 beats/minute
- Respiratory rate > 20 breaths/minute or PaCO2 < 4.3 kPa (32 mmHg)
- White blood cells > 12 x 10^9/l or < 4 x 10^9/l

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Investigation

- XR
- ± MRI (e.g. if the XR is negative and if clinical suspicions of DFIO, etc.)
- Bloods (FBC, CRP, U&E, LFT, lactate)
- Blood cultures
- Aspirate or biopsy for microbiology
- ± Biopsy for histopathology (e.g. if clinical uncertainty regarding diagnosis)

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Treatment; empiric, intravenous antibiotics

If the patient is clinically stable, post aspirate or biopsy:

- First line: co-amoxiclav 1.2 g 8 hourly
- Second line, if non-immediate without systemic involvement penicillin allergy: metronidazole 500 mg 8 hourly and cefuroxime 1.5 g 8 hourly
- Third line, if immediate rapidly evolving or non-immediate with systemic involvement penicillin allergy: metronidazole 500 mg 8 hourly and levofloxacin 500 mg 12 hourly

NB If clinical concerns regarding the risk of MRSA, add teicoplanin or vancomycin, dose as per hospital guidelines, teicoplanin target pre dose level 20-40 mg/l, vancomycin target pre dose level 15-20 mg/l

If the patient is clinically unstable (haemodynamic instability, sepsis, septic shock), preferably post aspirate or biopsy:

- First line: piperacillin tazobactam dose as per hospital guidelines; if clinical concerns re the risk of MRSA, add teicoplanin or vancomycin
- Second line, if non-immediate without systemic involvement penicillin allergy: metronidazole 500 mg 8 hourly and ceftazidime dose as per hospital guidelines and teicoplanin or vancomycin
- Third line, if immediate rapidly evolving or non-immediate with systemic involvement penicillin allergy: metronidazole 500 mg 8 hourly and ciprofloxacin dose as per hospital guidelines and teicoplanin or vancomycin

Teicoplanin or vancomycin, dose as per hospital guidelines, vancomycin target pre dose level 15-20 mg/l, teicoplanin target pre dose level 20-40 mg/l

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Treatment; directed/targeted antibiotics

- With susceptibilities (please note pages 7 and 8)
- Total duration: without surgical intervention, in general, 6 weeks

Management: moderate and severe DFI; directed/targeted antibiotics

methicillin susceptible *Staphylococcus aureus* (MSSA), according to susceptibilities		
Intravenous	Per oral, excluding osteomyelitis and septic arthritis	Per oral, involving bone and joint
First line: **flucloxacillin** 2 g 6 hourly Second line, if non-immediate without systemic involvement penicillin allergy: **cefuroxime** 1.5 g 8 hourly Third line, if immediate rapidly evolving or non-immediate with systemic involvement penicillin allergy: **vancomycin or teicoplanin**, dose as per hospital guidelines, vancomycin target pre dose level 15-20 mg/l, teicoplanin target pre dose level 20-40 mg/l	First line: **flucloxacillin** 1 g 6 hourly Second line, if penicillin allergy: **doxycycline** 100 mg 12 hourly Third line, if penicillin allergy and doxycycline is contraindicated: **clarithromycin** 500 mg 12 hourly	Please liaise with the diabetologist first ± the microbiology consultant second, or collaborate and discuss within the DFI multi-disciplinary meeting, regarding *Staphylococcus aureus* DFI involving bone and joint

methicillin resistant *Staphylococcus aureus* (MRSA), according to susceptibilities		
Intravenous	Per oral, excluding osteomyelitis and septic arthritis	Per oral, involving bone and joint
First line: **vancomycin or teicoplanin**, dose as per hospital guidelines, vancomycin target pre dose level 15-20 mg/l, teicoplanin target pre dose level 20-40 mg/l Second line, if vancomycin or teicoplanin are contraindicated: **clindamycin** 600 mg 6 hourly Third line, if vancomycin/teicoplanin and clindamycin are contraindicated: **linezolid** 600 mg 12 hourly (NB or per oral [absorption 100%])	First line: **doxycycline** 100 mg 12 hourly Second line, if doxycycline is contraindicated: **clarithromycin** 500 mg 12 hourly Third line, if doxycycline and clarithromycin are contraindicated: **clindamycin** 300 mg 6 hourly	Please liaise with the diabetologist first ± the microbiology consultant second, or collaborate and discuss within the DFI multi-disciplinary meeting, regarding *Staphylococcus aureus* DFI involving bone and joint

Streptococcus groups A/B/C/G, according to susceptibilities		
Intravenous	Per oral, excluding osteomyelitis and septic arthritis	Per oral, involving bone and joint
First line: **benzylpenicillin** 1.2-2.4 g 6 hourly Second line, if non-immediate without systemic involvement penicillin allergy: **ceftriaxone** 2 g 24 hourly Third line, if immediate rapidly evolving or non-immediate with systemic involvement penicillin allergy: **vancomycin or teicoplanin**, dose as per hospital guidelines, vancomycin target pre dose level 15-20 mg/l, teicoplanin target pre dose level 20-40 mg/l	First line: **amoxicillin** 500 mg 8 hourly Second line, if penicillin allergy: **doxycycline** 100 mg 12 hourly Third line, if penicillin allergy and doxycycline is contraindicated: **clarithromycin** 500 mg 12 hourly	First line: **amoxicillin** 500 mg - 1 g 8 hourly Second line, if penicillin allergy: **doxycycline** 100 mg 12 hourly Third line, if penicillin allergy and doxycycline is contraindicated: **clindamycin** 300-450 mg 6 hourly

Enterobacterales (e.g. *Escherichia coli*), according to susceptibilities		
Intravenous	Per oral options, excluding osteomyelitis and septic arthritis	Per oral options, involving bone and joint
First line: penicillin; narrowest spectrum of **amoxicillin** or **co-amoxiclav** or **piperacillin tazobactam** standard dosage Second line, if non-immediate without systemic involvement penicillin allergy: cephalosporin; narrowest spectrum of **cefuroxime** or **ceftriaxone** standard dosage Third line, if immediate rapidly evolving or non-immediate with systemic involvement penicillin allergy: **ciprofloxacin** 400 mg 12 hourly (consider 500 mg per oral 12 hourly [absorption 60-80%])	Penicillin (narrowest spectrum of **amoxicillin** 1 g 8 hourly; or **co-amoxiclav** 625 mg 8 hourly **plus amoxicillin** 500 mg 8 hourly) **Ciprofloxacin** 500 mg 12 hourly **Co-trimoxazole*** 960 mg 12 hourly	Penicillin (narrowest spectrum of **amoxicillin** 1 g 8 hourly; or **co-amoxiclav** 625 mg 8 hourly **plus amoxicillin** 500 mg 8 hourly) **Ciprofloxacin** 500 mg 12 hourly **Co-trimoxazole*** 960 mg 12 hourly
* With diabetes mellitus sequelae including diabetic nephropathy and with co-trimoxazole risks including electrolyte imbalance, interstitial nephritis, and renal tubular acidosis: • If for co-trimoxazole as an inpatient: monitoring of U&Es 24-48 hourly is mandatory • If for co-trimoxazole as an outpatient: monitoring of U&Es via the COpAT service is mandatory		

Enterococcus species, according to susceptibilities		
Intravenous	Per oral, excluding osteomyelitis and septic arthritis	Per oral, involving bone and joint
First line: **amoxicillin** 1 g 8 hourly Second line, if penicillin allergy: **vancomycin or teicoplanin**, dose as per hospital guidelines, vancomycin target pre dose level 15-20 mg/l, teicoplanin target pre dose level 20-40 mg/l	First line: **amoxicillin** 1 g 8 hourly Second line, if penicillin allergy: **linezolid*** 600 mg 12 hourly (NB maximum of 4 weeks)	First line: **amoxicillin** 1 g 8 hourly Second line, if penicillin allergy: **linezolid*** 600 mg 12 hourly (NB maximum of 4 weeks)
* With linezolid risks including optic neuropathy and blood disorders: • If for linezolid as an outpatient: monitoring of FBC via the COpAT service is mandatory		

Pseudomonas aeruginosa, according to susceptibilities		
Intravenous	Per oral, excluding osteomyelitis and septic arthritis	Per oral, involving bone and joint
First line: **piperacillin tazobactam** 4.5 g 6 hourly Second line: if non-immediate without systemic involvement penicillin allergy: **ceftazidime** 2 g 8 hourly Third line: if immediate rapidly evolving or non-immediate with systemic involvement penicillin allergy: **ciprofloxacin** 400 mg 8 hourly	**Ciprofloxacin** 750 mg 12 hourly	**Ciprofloxacin** 750 mg 12 hourly

Appendix 1: diabetic foot team

- The Royal Derby Hospital (RDH) diabetic foot team is comprised of:
    - Diabetes consultants; and
    - ≥ 1 of the podiatry team; and
    - ≥ 1 of the orthopaedic surgeons; and
    - ≥ 1 of the vascular surgeons; and
    - ≥ 1 of the microbiology/OPAT consultants; and
    - ≥ 1 of the antimicrobial/OPAT pharmacists.
- The RDH team convenes - via Microsoft Teams, 1500-, every Tuesday - to review the inpatients and outpatients with DFI.

Appendix 2: susceptibilities

- *Streptococcus* groups A/B/C/G, MSSA, and MRSA that are tetracycline S are also doxycycline S.
- *Streptococcus* groups A/B/C/G, MSSA, and MRSA that are erythromycin S are also clarithromycin S.
- Susceptibility of *Streptococcus* groups A/B/C/G, MSSA, and MRSA to clindamycin is, in general, inferred from macrolide (e.g. erythromycin) S.
- *Streptococcus* groups A/B/C/G that are penicillin S are also amoxicillin S.
- *Streptococcus* groups A/C/G that are penicillin S are also flucloxacillin S.

Appendix 3: dalbavancin

- Periodically, the management of DFI sub-populations can prove challenging.
- If intravenous, OPAT, and/or per oral antimicrobial chemotherapy options have been exhausted, the DFI team may consider dalbavancin therapy.
- Dalbavancin indications are limited, presently, to superficial, soft tissue infections. Medical literature is only beginning to emerge regarding dalbavancin usage beyond the skin. Reflecting this, recommendations and prescriptions of this antibiotic – in the context of DFIO – require the input of the DFI team.

Appendix 4: surgical intervention

- The pathology of chronic osteomyelitis is complex:
    - Bacteria transition from planktonic to sessile states. Active bacterial metabolism is integral to the mechanism of action for antibiotics; slow growing bacteria are less susceptible to antimicrobial chemotherapy.
    - Biofilm forms. The matrix secreted by the microbial pathogen restricts antibiotic diffusion, impeding antimicrobial chemotherapy delivery.
    - Bacterial-coated sequestra form. Detachment from the body of the bone detaches the bony fragment from the vasculature, further impeding antibiotic delivery.

  Therefore, physicians and microbiologists commonly advocate surgical intervention to remove infective foci, biofilm, and restore perfusion.

- The clinical decision for surgical intervention is also complex, involving patient background and prognosis. Ultimately, the clinical decision for surgery remains the responsibility of the surgeon, in collaboration with the anaesthetist.
- With the benefits and risks of operating, a surgical consultant opinion on intervention is recommended.

- NB If vascular and/or orthopaedic teams intervene, debridement before sampling and biopsies from resection margins are recommended.

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Document control

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Version:	5
Approval date:	Antimicrobial Stewardship Group - 12/09/2023 Medicine Division - 22/09/2023
Changes from previous version:	Introduction: reworded (minor). Diagnosis: reworded (minor). Investigation: reworded (minor) and reformatted (minor). Treatment/Management (Mild/Moderate/Severe DFI): reformatted (major). Management (moderate and severe DFI; directed/targeted antibiotics): reworded (minor). Appendices: deletion of appendix re Penicillin Allergy; insertion of appendix re susceptibilities; insertion of appendix re surgical intervention. References: updated (minor).
Date uploaded:	29/9/2023
Next review date:	September 2026
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