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PROTOCOL

The DEFINITE Audit: a prospective audit of diabetic foot debridement in theatre – a protocol

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Plain English Summary

Why we are undertaking this work: Diabetes foot ulcers often become infected and require operations to treat the infection. The operation can either be to remove unhealthy tissue (debridement) or to remove infected toes (minor amputations). There are guidelines on the best way to perform these operations; however, there is variation in how these operations are performed.

What we will do: This is a worldwide study of patients with a diabetic foot complication who have a debridement or minor amputation. We will collect data on how surgeons treat patients before the operation, how surgeons perform the operation and the treatment patients receive after the operation. We will compare this to the guidelines. We will also collect data on how long wounds take to heal, the number of people who lose their leg (major amputation) and the number of people who died. This is to see if certain treatments result in better outcomes.

What this means: This study will help to identify areas for improvement in the care of diabetic foot complications and help to suggest which treatments result in better healing.

Key words: diabetic foot, wound healing, foot ulcer

Abstract

Background: People with diabetes are commonly affected by foot ulceration (DFU) and subsequent or concurrent infection (DFI). Surgical debridement is often needed to contain infection. Despite international guidelines, there remains significant variation in surgical practice of diabetic foot wound debridement in the operating theatre.

Methods: Diabetic Foot Ulcer Debridement in Theatre Audit (DEFINITE) is a global multicentre, prospective audit of consecutive patients undergoing a debridement or minor amputation in theatre for a diabetic foot complication. DEFINITE is led by the Vascular and Endovascular Research Network (VERN). The primary outcome is adherence to recommended practice as outlined in the International Working Group on the Diabetic Foot and Global Vascular Guidelines. Secondary outcomes are incidence of healing, re-admission, further amputation (minor and major) and mortality at 90 days. Anonymised data will be collected via REDCap. Eligibility and study registration at all hospital institutions performing in-theatre management of diabetic foot complications are eligible to participate after obtaining appropriate institutional level audit approvals. A lead clinician will be responsible for approvals and data management.

Pathway to impact: This audit addresses shared patient-clinician priorities and is supported by the UK Vascular Society multidisciplinary Special Interest Group on the Diabetic Foot. The results will be presented at international scientific meetings and submitted for publication in peer-reviewed publications. The results will also be used to initiate improvement in patient care.

Introduction

People with diabetes are at high risk of developing foot ulceration (DFU). Once established, diabetic foot ulcers are at risk of rapid deterioration and infection which can lead to bacteraemia and sepsis. Infected DFU is associated with high morbidity, limb loss and death.[1–3] The development of severe infection requires emergency hospital admission and surgery to remove necrotic and infected tissue, which is in turn associated with high levels of morbidity and mortality.[4,5] Often multiple episodes of wound debridement, with or without minor amputation, and intravenous antibiotics are required to

eradicate the infection. The economic impact is substantial with 0.9% of the UK National Health Service annual budget dedicated to the management of DFU.[6]

Patients and multidisciplinary clinicians recognise the scale and significance of this problem. Recently borne out in the Priority Setting Partnership led by the Vascular Society of Great Britain and Ireland (VSGBI) in collaboration with the James Lind Alliance (JLA),[7] 'improving outcomes in diabetic foot infections' is a top shared research priority.[8]

There are guidelines available to support practice, primarily aimed at improving healing rates following debridement and reducing the incidence of major lower limb amputation.[9–11] The International Working Group for Diabetic Foot (IWGDF) guidelines[10] and The Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia[11] outline critical recommendations on dealing with infected DFUs. In brief, these guidelines advise removal of all infected and necrotic tissue, drainage of sepsis, effective irrigation, sample collection for microbiological analysis, adequate dressing and sensitivity-driven antimicrobial use.

The Diabetic Foot Ulcer Debridement in Theatre Audit (DEFINITE) aims to assess the current pathways of care for patients with diabetes who undergo a digital amputation and/or foot wound debridement and compare surgical practice with the IWGDF and Global Vascular Guidelines. Secondary aims are to investigate if variations in practice are linked to wound healing rates, reoperation rates (further debridement or minor amputation), 3-month major lower limb amputation rates and 3-month readmission rates. It is hoped that the data gathered will support advances in diabetic foot care addressing a shared patient-clinician research priority.

Methods

Design

This is a multicentre, prospective service evaluation audit conducted in hospitals around the globe. It is delivered through the Vascular and Endovascular Research Network (VERN), a trainee-led national research collaborative that engages with research-active vascular trainees and allied healthcare professionals.

Eligibility criteria

All patients undergoing debridement of a foot wound or minor amputation in the operating theatre with a confirmed diagnosis of diabetes will be included in the audit. A separate record will be created if the patient undergoes debridement or minor amputation in the contralateral limb during the study period.

Patients will be excluded if they have foot wound debridement or minor amputation in a setting other than the operating theatre or if they are younger than 18 years. Patients who have undergone ipsilateral foot debridement or minor amputation in the preceding 6 weeks, and this index event is outside the study period, will also be excluded.

Outcomes measures

The primary outcome is adherence of current practice in debridement and minor amputation of diabetic foot disease to the recommendations outlined in the IWGDF[9] and Global Vascular Guidelines[10] (see Supplementary Information in Appendix 1 online at www.jvsgbi.com). Adherence is defined as the extent to which the procedure undertaken corresponds to the guidance. The audit will report adherence to each item in the guidance as well as overall adherence. Secondary outcomes are the incidence of healing at 3 months, the 3-month reoperation rate, readmission rate, minor and major lower limb amputation rates, the type of microorganisms isolated from diabetic foot tissue samples taken intraoperatively, and the duration and type of antibiotics administered after such procedures.

Recruitment

The DEFINITE audit is open to all centres which provide elective and/or emergency surgical management for diabetic foot infection. One team member acting as site lead clinician will be the point of contact between the DEFINITE audit team and the local audit team. They will register their hospital/site and team members for the audit by completing an online form found on the VERN website, that includes collection of information on existing diabetic foot services in the participating centres. The lead clinician will have overall responsibility for ensuring the audit is conducted according to the standards and methods described in this protocol at their hospital/site, and any instances of non-compliance will be reported by them to the DEFINITE audit team. The anticipated number of audit team members per centre is one lead clinician and five other team members, such as medical trainees, allied healthcare professionals and medical students. If centres include more than five additional team members, it is expected that allied healthcare professionals and/or medical students are included.

Prospective registration of the DEFINITE audit is required prior to data collection. It is the responsibility of the local audit lead to ensure this is complete.

Participant cases will be identified by a member of the DEFINITE team at each centre as per the inclusion/exclusion criteria, using acute admission lists, diabetic foot ward rounds and operating lists (as per local practice). Patient/disease registries will not be screened to identify potential participants. Queries regarding participant eligibility will be directed to the lead clinician, and non-resolution referred to the VERN team.

Data collection

The complete data collection form is available as Supplementary Information in Appendix 2 online at www.jvsgbi.com and at www.vascular-research.net/definite/.

Anonymised data collected will include baseline demographics (age, gender, smoking status), comorbidities, medications, American Society of Anaesthesiologists (ASA) physical status and previous re-vascularisation procedures.

Preoperative data will include COVID-19 status, use of variable rate insulin infusion, medications (regular insulin, steroids and anticoagulants), white cell count, and C-reactive protein, haemoglobin, creatinine and albumin levels. The audit will also collect the indication for the operative procedure, infection status of the contralateral limb, wound ischaemia foot infection (WIfI) stage,[1] whether osteomyelitis was suspected and preoperative antibiotic use. Preoperative antibiotic use will include length of antibiotic course prior to procedure, route of administration, type of antibiotic used and whether any preoperative topical antibiotics were used.

Intraoperatively, the audit will collect data on the speciality which the procedure was performed under, the type of procedure (debridement, digit amputation, both), urgency of the procedure, operative time, skin preparation solution used, irrigation fluid used, packing material choice, local antibiotic use, use of a drain and dressing choice. The audit will also collect data on whether soft tissue and bone samples were sent for microbiology and histology and the method of tissue sample collection.

Postoperative data includes organisms grown from the microbiology samples, antibiotic use (route, length, type, sensitivity to organisms cultured), total length of hospital stay, postoperative morbidity grade (Clavien–Dindo), postoperative mobilisation status, length of drain use (if used), vascular imaging and revascularisation procedures. The audit will also collect data on return to theatre for further debridement or amputation and in-hospital mortality.

The 3-month data collection items are duration of antibiotic therapy, COVID infection status, complete wound healing at 90 days, readmission, further debridement, further amputation (minor/major) and mortality.

Data will be prospectively collected from paper or electronic hospital records. Preoperative data will be collected prior to the procedure, intraoperative data will be collected immediately after the procedure has taken place, postoperative data will be collected when the patient is discharged from hospital and 3-month data will be collected 3 months after the patient underwent the procedure. Data will be entered onto a purpose-built electronic database on the Research Electronic Data Capture (REDCap) platform, hosted by Newcastle Joint Research Office. Data will be collected and uploaded by a member of the audit team with appropriate REDCap training from VERN.

Data management

All audit data will be preferably uploaded directly to REDCap with printable case report forms (CRFs) available if required to facilitate data capture. Oversight of paper CRFs used at centres will be the responsibility of each centre's lead clinician. All CRFs used will be securely stored in an appropriate location onsite until data are uploaded to REDCap, at which point the centre's lead clinician will be responsible for ensuring they are appropriately destroyed.

Through the audit's REDCap database design, no identifiable data can be uploaded. A specific audit identification number will be assigned to each patient to allow anonymised data to be collected. Patients may be enrolled twice if undergoing a procedure for both feet during the study period, and in these cases a unique study ID will be assigned to each procedure. Each centre's lead clinician will be responsible for ensuring a database containing each participant's local hospital ID and corresponding audit ID is maintained to ensure accurate follow-up data and stored securely on an appropriate hospital computer. Data will be kept for two years to allow a possible follow-up audit and will be destroyed thereafter. Data will be available to others. The minimum dataset will be included in the DEFINITE results paper as a supporting information file with fully anonymised patient data.

Data analysis

Descriptive analyses will be performed to describe variations in practice and examine secondary outcomes. Secondary outcomes will be compared between adherent and non-adherent groups. Continuous data will be tested for normality and parametric or non-parametric tests will be used as appropriate. The χ^2 test will be used to analyse for differences in categorical variables.

Missing data will be analysed to determine the pattern of missingness and, if appropriate, multiple imputation will be used using the Markov chain Monte Carlo method. Sensitivity analyses will be conducted to compare the results of imputed data analysis with complete-case analysis.

Univariable and multivariable regression analyses will be used to identify independent predictors of further debridement/minor amputation, major lower limb amputation, and complete wound healing at 3 months following the index procedure. A p value of <0.05 will be used to define statistical significance.

Data quality

Following the initial data collection period, data completeness will be quantified. Patient records with less than 95% completeness of mandatory data points will be returned to the centre for completion and, if not possible, the record will be excluded from analysis. All centres will be required to validate data accuracy. Each centre will identify an additional team member (not involved in initial data collection) to recapture 25% of the data points (at random) for 20% of the cases (at random) for their centre. Any centre reporting less than 95% accuracy will be required to validate a further 20% of their cases, and the lead clinician to investigate and report back to the DEFINITE management team. All centres will be required to assess case ascertainment. The lead at each centre (or delegate of) will be required to review theatre records or registry data (eg, National Vascular Registry) and report the total number of eligible procedures performed during the study period to the DEFINITE management team for comparison with cases submitted to REDCap.

Regulatory approval and research governance

The audit will be conducted in compliance with the principles of Good Clinical Practice (GCP) guidelines and in accordance with all

applicable regulatory guidance, including, but not limited to, the UK Policy Framework for Health and Social Care Research. Ethical approval is not required in the UK as this study is a service evaluation, which does not include any change in routine patient care, and no patient identifiable data will be collected. The lead clinician will be responsible for local audit governance approvals as per their hospital/site policy. Non-UK centres will be required to show evidence of appropriate approvals in accordance with local regulations; this may require institutional review board approval.

The audit departments at the following NHS trusts have approved the project locally: Hull University Teaching Hospital NHS Trust, Leeds Teaching Hospitals NHS Trust, Barts Health NHS Trust, St George's NHS Foundation Trust, Worcester Acute Hospitals NHS Trust, NHS Tayside, Oxford University Hospitals NHS Trust, Manchester University Foundation Trust, London North West University Healthcare NHS Trust, South Tyneside and Sunderland NHS Foundation Trust, NHS Lothian, NHS Greater Glasgow and Clyde, South Tees Hospitals NHS Foundation Trust, Mid and South Essex NHS Foundation Trust, Manchester University NHS Foundation Trust, Nottingham University Hospitals NHS Trust, North Bristol NHS Trust, Shrewsbury and Telford Hospital NHS Trust, Frimley Health NHS Foundation Trust, Imperial College Healthcare NHS Trust, University Hospitals Sussex NHS Foundation Trust, NHS Grampian, Aneurin Bevan University Health Board, Royal Devon and Exeter Hospital, Countess of Chester Hospital NHS Foundation Trust, University Hospitals of Leicester NHS Trust, Cambridge University Hospital NHS Trust, University Hospitals of North Midlands NHS Trust, Belfast Health and Social Care Trust, Nottingham University Hospitals NHS Trust, University Hospitals of Southampton NHS Foundation Trust and Gloucestershire Hospitals NHS Foundation Trust. At international centres the audit has been approved by local boards at: Canberra Health Service, King Saud Medical City, Hippocratio Hospital, Aristotle University of Thessaloniki, Thessaloniki, Greece, University Hospital of Trieste, Dar Al-Elaj Specialized Hospital, Waikato Hospital, Christchurch Hospital, Canterbury District Health Board, University Hospital of Patras, University of Patras and Royal Adelaide Hospital.

Data protection and patient confidentiality

The audit will comply with the Data Protection Act 2018. Participants will be assigned a unique REDCap identifier upon enrolment into the audit to allow pseudonymisation of patient data. Access to patient identifiable information will be restricted to members of the patient's usual clinical team. Hard copies of audit documents will be securely stored in an appropriate location at each centre and will be the responsibility of the lead clinician.

Authorship

A collaborative authorship model will be used for all dissemination methods. To qualify for collaborative authorship, individuals should review and approve any manuscripts for submission to peer-reviewed journals and should either have a significant role in the set-up and management of the DEFINITE audit (including audit department registration/institutional review board approval, creation of a data collection team and engagement with VERN to ensure timely upload of data) or capture sufficient data to warrant authorship. This would be the equivalent of collecting baseline and follow-up data on approximately 10 patients, although it is appreciated that individuals may participate in either baseline data collection or follow-up data capture only.

Current status

The DEFINITE study recruitment of new centres was between 1 December 2021 and 31 March 2022. The expected date of the last patient to be included is 30 June 2022 and data collection will end on 30 September 2022.

Discussion

The DEFINITE audit will capture current worldwide practice on diabetic foot debridement and minor amputation in theatre to identify variations in management and clinical outcomes. This will include information on known patient factors that affect wound healing,[2] preoperative investigations, step-by-step operative details, use of antimicrobials and clinical outcomes to 90 days post-debridement.

Existing global guidelines for the management of at-risk lower limbs in people with diabetes include the IWGDF Guidelines on the diagnosis and treatment of foot infection in persons with diabetes and the Global Vascular Guidelines on the Management of Chronic Limb Threatening Ischaemia.[10,11] There are variable levels of evidence supporting recommendations in these documents. Areas of most uncertainty include microbial sampling,[12,13] wound irrigation,[14,15] choice of dressings,[16–20] ambulation status[21] and use of antimicrobials.[22,23] This audit will demonstrate whether there is significant variation in practice in these key aspects of management.

The guidelines recommend tissue samples should be obtained for isolating micro-organisms. This is supported by the CODIFI study, which also reports that clinicians are more likely to act on results obtained by tissue sampling compared with swabs.[12] However, Travis *et al* reported no difference between tissue samples and swabs on microbial culture results.[13] The ongoing CODIFI2 randomised controlled trial aims to compare the impact of tissue and swab sample results on DFU healing time.[15] This audit will capture the methods used at different centres, will compare microbial growth obtained from different sampling techniques, and determine whether there are geographical differences in microbiological growth.

It is currently unknown whether skin preparation and/or irrigation solution choice impacts upon clinical outcomes for DFU patients undergoing debridement/minor amputation. The current guidelines on managing DFU infections reflect this uncertainty. The National Institute for Health and Care Excellence (NICE) guideline on preventing surgical site infection (NG125) recommends alcohol-based solution of chlorhexidine as first choice skin aseptic

solution.[24] Saline, antibiotic solutions, hydrogen peroxide, chlorhexidine and povidone-iodine solution are commonly used for wound irrigation. There has been no superiority shown between preparations; however, some are associated with severe adverse events.[15,25] The DEFINITE audit will identify the frequency with which these skin preparation and irrigation fluid solutions are used in contemporary practice. The planned regression analyses will determine whether there are associations between skin preparation and irrigation fluid, and key clinical outcomes in this cohort.

Postoperatively, there is limited consensus on appropriate dressings for wound healing by secondary intention. A Cochrane review from 2018 compared negative pressure wound therapy (NPWT) to other dressings for post amputation or debridement in the diabetic foot, finding limited evidence for one dressing type over another in improving time to healing.[16] This finding is not reflected in the IWGDF guidelines, which recommends NPWT post debridement in addition to standard care. The ongoing UK-based SWHSI2 randomised controlled trial aims to address this uncertainty around NPWT in wound healing by secondary intention.[26] This audit will capture use of NPWT immediately post debridement or minor amputation in the diabetic foot.

Guidance on antimicrobial use post debridement recommends that antibiotics should be adjusted to the sensitivity of cultured organisms and given via the oral route. There is ongoing debate regarding the length and route of antibiotic treatment post debridement for the treatment of osteomyelitis in the diabetic foot.[22] A pilot randomised clinical trial comparing 3 weeks to 6 weeks of antibiotics showed no significant difference in remission and adverse events.[23] Antimicrobial prescribing practice will be explored in this audit.

The postoperative mobility status of patients is largely unknown and there is variation in the surgical community on weight-bearing status postoperatively. Offloading and specialist footwear are known to decrease the incidence of recurrence.[21] Ambulation instructions for the immediate postoperative period will be collected in this study, and analysis will determine whether this is associated with clinical outcomes.

The collaborative model of this study is designed to capture practice in a large number of patients in a wide range of healthcare settings over a relatively short period of time. VERN has experience of delivering impactful international studies.[27,28] Outputs from the DEFINITE study will inform future quality improvement and research projects to improve the care of patients with diabetic foot complications. One limitation of this audit will be the inability to determine direct causality between practice and outcome. The study aims to collect data from multiple sites in several countries; however, the results may not necessarily be representative of practice in areas where participation in the audit is low. Despite this, results from this audit will identify areas of variation in practice, identify compliance/non-compliance with international guidelines, and generate hypotheses to guide further research on improving clinical outcomes for this population.

KEY MESSAGES

- There is variation in surgical practice for the management of diabetic foot complications, despite international guidelines.
- DEFINITE is a worldwide prospective audit of patients undergoing debridement or minor amputation in theatre for diabetic foot complications.
- Results from DEFINITE will explore the impact of variation in surgical practices on patient outcomes to help inform and improve patient care in the future.

Pathway to impact

This audit addresses shared patient-clinician priorities and is supported by the UK Vascular Society multidisciplinary special interest group on the diabetic foot. The results presented at national and international scientific meetings and in peer-reviewed publications will be used to initiate improvement in patient level care. A writing team, including those involved with the design, implementation and dissemination of the DEFINITE audit, will be responsible for presentation(s) and submission of manuscript(s) to peer-reviewed journal(s)/publications.

To prompt the results to patients and lay stakeholders, the writing team will work with patients and the public involved in the JLA Priority Setting Partnership to produce a patient-facing lay summary of the results. This will be distributed with support from the audit's charitable supporters. A summary will also be sent to the JLA, Circulation Foundation and Diabetes UK for promotion.

In addition, the results of DEFINITE will be promoted through VERN's Twitter account, newsletter and in dedicated webinars.

Conclusion

The DEFINITE study will provide a comprehensive overview of in-theatre debridement practice of diabetic foot complications worldwide and the associated clinical outcomes. This will identify variation and help target areas of care that can be improved.

Conflict of Interest: None.

Funding: The DEFINITE audit is supported by an Urgo Foundation and Newcastle Hospitals Charity grant. Urgo and Newcastle Hospitals Charity have not been involved in the concept or audit design. Urgo and Newcastle Hospitals Charity will not be involved in the data analysis or interpretation. Urgo and Newcastle Hospitals Charity have not been involved in the drafting of the manuscript or decision to publish.

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Appendix 1 Supplementary File

2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Ulcers

The following recommendations stated the 2012 Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Ulcers[1] will be used:

1. "Clinicians should consider the possibility of infection occurring in any foot wound in a patient with diabetes (strong, low). 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 (eg, nonpurulent secretions, friable or discolored granulation tissue, undermining of wound edges, foul odor) (strong, low)."

Adherence will be assessed by the 'Wound' stage of the Wound Ischaemia foot Infection (WIfI) staging system.[2]

2. "Clinicians should be aware of factors that increase the risk for 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 (strong, low)."

Adherence will be assessed by documentation of baseline demographics, vascular imaging and revascularisation pre-operatively.

3. "Clinicians should select and routinely use a validated classification system, such as that developed by the International Working Group on the Diabetic Foot (IWGDF) (abbreviated with the acronym PEDIS) or IDSA (see below), to classify infections and to help define the mix of types and severity of their cases and their outcomes (strong, high). The DFI Wound Score may provide additional quantitative discrimination for research purposes (weak, low). Other validated diabetic foot classification schemes have limited value for infection, as they describe only its presence or absence (moderate, low)."

Adherence will be assessed by foot infection stage of the WIfI staging system.[2]

4. "Clinicians should 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 (strong, low)."

Adherence will be determined through WIfI stage[2] and blood sampling results.

5. "Clinicians should diagnose infection based on the presence of at least 2 classic symptoms or signs of inflammation (erythema, warmth, tenderness, pain, or induration) or purulent secretions. They should then document and classify the

severity of the infection based on its extent and depth and the presence of any systemic findings of infection (strong, low)."

Adherence will be determined by WIfI stage documentation.[2]

6. "We recommend assessing the affected limb and foot for arterial ischemia (strong, moderate), venous insufficiency, presence of protective sensation, and biomechanical problems (strong, low)."

Adherence will be determined by pre-operative vascular imaging and revascularisation.

7. "Clinicians should debride any wound that has necrotic tissue or surrounding callus; the required procedure may range from minor to extensive (strong, low)."

Adherence will be determined by procedure undertaken.

8. "Diabetic foot care teams can include (or should have ready access to) specialists in various fields; patients with a DFI may especially benefit from consultation with an infectious disease or clinical microbiology specialist and a surgeon with experience and interest in managing DFIs (strong, low)."

Adherence will be determined by the speciality performing the procedure.

9. If there is clinical or imaging evidence of significant ischemia in an infected limb, we recommend the clinician consult a vascular surgeon for consideration of revascularization (strong, moderate).

Adherence will be determined by speciality performing the procedure, prior vascular imaging and revascularisation.

10. "We recommend that prior to being discharged, a patient with a DFI should be clinically stable; have had any urgently needed surgery performed; have achieved acceptable glycemic control; be able to manage (on his/her own or with help) at the designated discharge location; and have 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 (strong, low)."

Adherence will be determined by post-operative antibiotic use, dressing use and weight bearing status.

11. "For clinically uninfected wounds, we recommend <u>not</u> collecting a specimen for culture (strong, low)."

Adherence will be determined by indication for surgery and pre-operative suspicion of osteomyelitis.

12. "For infected wounds, we recommend that clinicians 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 (strong, low)."

Adherence will be determined by whether tissue (soft/bone) samples were sent for microbiology.

13. ”We recommend sending a specimen for culture that is from deep tissue, obtained by biopsy or curettage after the wound has been cleansed and debrided. We suggest avoiding swab specimens, especially of inadequately debrided wounds, as they provide less accurate results (strong, moderate).”

Adherence will be determined by use of clean instruments to take tissue samples.

14. “We recommend that clinically uninfected wounds not be treated with antibiotic therapy (strong, low).”

Adherence will be determined from antibiotic use, WIfI stage,[2] indication for surgery and results from tissue microbiology.

15. ”We recommend prescribing antibiotic therapy for all infected wounds, but caution that this is often insufficient unless combined with appropriate wound care (strong, low).”

Adherence will be determined by WIfI stage[2] and antibiotic use.

16. ”We recommend that clinicians select an empiric antibiotic regimen on the basis of the severity of the infection and the likely etiologic agent(s) (strong, low).

. For mild to moderate infections in patients who have not recently received antibiotic treatment, we suggest that therapy just targeting aerobic GPC is sufficient (weak, low).

a. For most severe infections, we recommend starting broad-spectrum empiric antibiotic therapy, pending culture results and antibiotic susceptibility data (strong, low).

b. Empiric therapy directed at *Pseudomonas aeruginosa* is usually unnecessary except for patients with risk factors for true infection with this organism (strong, low).

c. Consider providing empiric therapy directed against methicillin-resistant *Staphylococcus aureus* (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 (weak, low).”

Adherence will be determined by antibiotic use and tissue microbiology results.

17. ”We recommend that definitive therapy be based on the results of an appropriately obtained culture and sensitivity testing of a wound specimen as well as the patient's clinical response to the empiric regimen (strong, low).”

Adherence will be determined by antibiotic use and tissue microbiology results.

18. ”We suggest basing the route of therapy largely on infection severity. We prefer parenteral therapy for all severe, and some moderate, DFIs, at least initially (weak, low), 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 (strong, moderate).”

Adherence will be determined by antibiotic use (including route), tissue microbiology results and WIfI stage.[2]

19. “We suggest continuing antibiotic therapy until, but not beyond, resolution of findings of infection, but not through complete healing of the wound (weak, low). We suggest 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 (weak, low).”

Adherence will be determine from antibiotic use (duration) and WIfI stage.[2]

20. “Clinicians should consider osteomyelitis as a potential complication of any infected, deep, or large foot ulcer, especially one that is chronic or overlies a bony prominence (strong, moderate).”

Adherence will be determined by pre-operative suspicion of osteomyelitis.

21. “We suggest that the most definitive way to diagnose DFO is by the combined findings on bone culture and histology (strong, moderate). When bone is debrided to treat osteomyelitis, we suggest sending a sample for culture and histology (strong, low).”

Adherence will be determined by bone tissue sampling technique intra-operatively.

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

Adherence will be judged by procedure undertaken, results from clean bone sampling and duration of antibiotics.

23. “For specifically treating DFO, 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) (weak, low).”

Adherence will be determined by dressing choice.

24. “We recommend involving a vascular surgeon early on to consider revascularization whenever ischemia complicates a DFI, but especially in any patient with a critically ischemic limb (strong, moderate).”

Adherence will be determined by vascular imaging and revascularisation.

25. “Diabetic patients with a foot wound should receive appropriate wound care, which usually consists of the following:
    a. Debridement, aimed at removing debris, eschar, and surrounding callus (strong, moderate). Sharp (or surgical) methods are generally best (strong, low), but mechanical, autolytic, or larval debridement techniques may be appropriate for some wounds (weak, low).”

Adherence will be determined by procedure undertaken.

    b. “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 (strong, high).”

Adherence will be determined by post-operative weight bearing status.

    c. “Selection of dressings that allow for moist wound healing and control excess exudation. The choice of dressing should be based on the size, depth, and nature of the ulcer (eg, dry, exudative, purulent) (strong, low).”

Adherence will be determined by dressing choice.

26. “We do not advocate using topical antimicrobials for treating most clinically uninfected wounds.”

Adherence will be determined by use of topical antibiotics and WIfI stage.[2]

Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGFU 2019 Update)

In addition, the following recommendation stated the Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update)[3] will be used:

1.

    a. “Diagnose a soft tissue diabetic foot infection clinically, based on the presence of local or systemic signs and symptoms of inflammation. (Strong; low)”

Adherence will be determined by use of the WIfI stage,[2] white cell count and c-reactive protein levels.

b. "Assess the severity of any diabetic foot infection using the Infectious Diseases Society of America/International Working Group on the Diabetic Foot classification scheme. (Strong, moderate)"

Adherence will be determined using the IWGDF classification system (WIfI foot Infection).[2]

2. "In a person with diabetes and a possible foot infection for whom the clinical examination is equivocal or uninterpretable, consider ordering an inflammatory serum biomarker, such as C-reactive protein, erythrocyte sedimentation rate, and perhaps procalcitonin, as an adjunctive measure for establishing the diagnosis. (Weak; low)"

Adherence will be determined by presence of c-reactive protein result.

3. "In a person with diabetes and suspected osteomyelitis of the foot, in whom making a definitive diagnosis or determining the causative pathogen is necessary for selecting treatment, collect a sample of bone (percutaneously or surgically) to culture clinically relevant bone microorganisms and for histopathology (if possible). (Strong; low)
    a. Collect an appropriate specimen for culture for almost all clinically infected wounds to determine the causative pathogens. (Strong; low)
    b. For a soft tissue diabetic foot infection, obtain a sample for culture by aseptically collecting a tissue specimen (by curettage or biopsy) from the ulcer. (Strong; moderate)"

Adherence will be determined from soft/bone tissue samples sent for microscopy.

4. "Treat a person with a diabetic foot infection with an antibiotic agent that has been shown to be effective in a published randomized controlled trial and is appropriate for the individual patient. Some agents to consider include penicillins, cephalosporins, carbapenems, metronidazole (in combination with other antibiotic[s]), clindamycin, linezolid, dapt)"

Adherence will be determined by antibiotic use (pre- and post-operatively).

5. "Select an antibiotic agent for treating a diabetic foot infection based on: the likely or proven causative pathogen(s) and their antibiotic susceptibilities; the clinical severity of the infection; published evidence of efficacy of the agent for diabetic foot infections; risk of adverse events, including collateral damage to the commensal flora; likelihood of drug interactions; agent availability; and, financial costs. (Strong; moderate)"

Adherence will be determined by antibiotic use (pre- and post-operatively) and tissue sample microscopy and culture results.

6. “Administer antibiotic therapy initially by the parenteral route to any patient with a *severe* diabetic foot infection. Switch to oral therapy if the patient is clinically improving and has no contraindications to oral therapy and if there is an appropriate oral agent available. (Strong; low)”

Adherence will be determined by route of antibiotic delivery.

7. “Treat patients with a mild diabetic foot infection, and most with a moderate diabetic foot infection, with oral antibiotic therapy, either at presentation or when clearly improving with initial intravenous therapy. (Weak; low)”

Adherence will be determined by WIfI stage[2] and antibiotic use.

8. “We suggest not using any currently available topical antimicrobial agent for treating a mild diabetic foot infection. (Weak; moderate)
    a. Administer antibiotic therapy to a patient with a skin or soft tissue diabetic foot infection for a duration of 1 to 2 weeks. (Strong; high)
    b. Consider continuing treatment, perhaps for up to 3 to 4 weeks, if the infection is improving but is extensive and is resolving slower than expected or if the patient has severe peripheral artery disease. (Weak; low)
    c. If evidence of infection has not resolved after 4 weeks of apparently appropriate therapy, re-evaluate the patient, and reconsider the need for further diagnostic studies or alternative treatments. (Strong; low)”

Adherence will be determined by length of antibiotic use and WIfI stage.[2]

9. “For patients who have not recently received antibiotic therapy and who reside in a temperate climate area, target empiric antibiotic therapy at just aerobic gram-positive pathogens (beta-haemolytic streptococci and *Staphylococcus aureus*) in cases of a *mild* diabetic foot infection. (Strong; low)”

Adherence will be determined by antibiotic use pre-operatively and post-operatively.

10. “For patients residing in a tropical/subtropical climate, or who have been treated with antibiotic therapy within a few weeks, have a severely ischemic affected limb, or a moderate or severe infection, we suggest selecting an empiric antibiotic regimen that covers gram-positive pathogens, commonly isolated gram-negative pathogens, and possibly obligate anaerobes in cases of moderate to severe diabetic foot infections. Then, reconsider the antibiotic regimen based on both the clinical response and culture and sensitivity results. (Weak; low)”

Adherence will be determined from location of patient (from the location of the site uploading the data) and antibiotic use.

11. “Empiric treatment aimed at *Pseudomonas aeruginosa* is not usually necessary in temperate climates, but consider it if *P aeruginosa* has been isolated from cultures of the affected site within the previous few weeks, or in tropical/subtropical climates (at least for moderate or severe infection). (Weak; low)”

Adherence will be determined from location of patient (from the location of the site uploading the data) and antibiotic use.

12. “Do not treat clinically uninfected foot ulcers with systemic or local antibiotic therapy with the goal of reducing the risk of infection or promoting ulcer healing. (Strong; low)”

Adherence will be determined by WIfI stage[2] and antibiotic use.

13. “Select antibiotic agents for treating diabetic foot osteomyelitis from among those that have demonstrated efficacy for osteomyelitis in clinical studies. (Strong; low)
    a. Treat diabetic foot osteomyelitis with antibiotic therapy for no longer than 6 weeks. If the infection does not clinically improve within the first 2 to 4 weeks, reconsider the need for collecting a bone specimen for culture, undertaking surgical resection, or selecting an alternative antibiotic regimen. (Strong; moderate)
    b. Treat diabetic foot osteomyelitis with antibiotic therapy for just a few days if there is no soft tissue infection and all the infected bone has been surgically removed. (Weak; low)”

Adherence will be determined by suspicion or proven osteomyelitis and antibiotic duration.

14. “For diabetic foot osteomyelitis cases that initially require parenteral therapy, consider switching to an oral antibiotic regimen that has high bioavailability after perhaps 5 to 7 days, if the likely or proven pathogens are susceptible to an available oral agent and the patient has no clinical condition precluding oral therapy. (Weak; moderate)
    a. During surgery to resect bone for diabetic foot osteomyelitis, consider obtaining a specimen of bone for culture (and, if possible, histopathology) at the stump of the resected bone to identify if there is residual bone infection. (Weak; moderate)
    b. If an aseptically collected culture specimen obtained during the surgery grows pathogen(s), or if the histology demonstrates osteomyelitis, administer appropriate antibiotic therapy for up to 6 weeks. (Strong; moderate)”

Adherence will be determined from intraoperative sampling of bone and tissue and antibiotic use.

15. “To specifically address infection in a diabetic foot ulcer:
    a. do not routinely use topical antiseptics, silver preparations, honey, bacteriophage therapy, or negative pressure wound therapy (with or without instillation). (Weak; low)”

Adherence will be determined by dressing choice.

References

1. Lipsky BA, Berendt AR, Cornia PB, Pile JC, Peters EJ, Armstrong DG, *et al*. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *Clin Infect Dis* 2012;**54**(12):e132-73.
2. Mills JL, Conte MS, Armstrong DG, Pomposelli FB, Schanzer A, Sidawy AN, *et al*. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIfI). *J Vasc Surg* 2014;**59**(1):220-34.e1-2.
3. Lipsky BA, Senneville É, Abbas ZG, Aragón-Sánchez J, Diggle M, Embil JM, *et al*. Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update). *Diabetes Metab Res Rev* 2020;**36**(Suppl 1):e3280.

Baseline Demographics and comorbidities

Record ID	_____
Age at time of procedure	_____ (years)
Gender	◯ Male ◯ Female
Already included for contra-lateral procedure in this audit	◯ Yes ◯ No
If so, what is the REDCap ID?	_____
Ethnicity	◯ White British ◯ White Irish ◯ Any other White background ◯ White and Black Caribbean ◯ White and Black African ◯ White and Asian ◯ Any other mixed background ◯ Indian ◯ Pakistani ◯ Bangladeshi ◯ Any other Asian background ◯ Black Caribbean ◯ Black African ◯ Any other Black background ◯ Chinese ◯ Any other ethnic group
Diabetes	◯ T1DM ◯ T2DM
BMI	_____ (Kg/M2)
Smoking status	◯ Never-smoker ◯ Ex-smoker ◯ Current smoker
ETOH excess	◯ Yes ◯ No
Hypertension	◯ Yes ◯ No
COPD	◯ Yes ◯ No
Ischaemic heart disease	◯ Yes ◯ No

Congestive heart failure	◯ Yes ◯ No
Chronic kidney disease	◯ Yes - no dialysis ◯ Yes - dialysis ◯ No
Neurological disease	◯ Yes ◯ No
ASA	◯ I ◯ II ◯ III ◯ IV ◯ V
Recent imaging to assess need for revascularisation before this admission	◯ Yes ◯ No
Previous ipsilateral revascularisation before this admission	◯ Yes, within the last month ◯ Yes, more than a month ago ◯ No

Medication, bloods, pre-op COVID-19

Variable rate insulin infusion pre-operatively	◯ Yes ◯ No
Insulin (regular)	◯ Yes ◯ No
Steroid (regular)	◯ Yes ◯ No
Anticoagulant (regular)	◯ Yes ◯ No
WCC	_____ (X10(9)/L)
Haemoglobin	_____ (g/dL)
Creatinine	_____ (micromol/L)
Albumin	_____ (g/dL)
CRP	_____
Pre-operative COVID-19 status	◯ Positive (confirmed with COVID-19 test) ◯ Negative (confirmed with COVID-19 test) ◯ Unknown/result awaited

Pre-op infection grade, osteomyelitis and antibiotics

Indication for current procedure	◯ Pain ◯ Non-healing wound (without infection) ◯ Gangrene ◯ Infection
Current infection in contralateral limb	◯ Yes ◯ No
Documented grading of infection using Wifi or IDSA/IWGF	◯ No ◯ Yes (Wifi) ◯ Yes (IDSA/IWGF)
Wifi grading: wound	◯ 0 - No ulcer. No gangrene ◯ 1 - Small, shallow ulcer(s) on distal leg/foot; no exposed bone, unless limited to distal phalanx. No gangrene. ◯ 2 - Deeper ulcer with exposed bone/joint/tendon; shallow heel ulcer, no calcaneal involvement. Gangrene to digits. ◯ 3 - Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer. Extensive gangrene forefoot and/or midfoot; full thickness heel necrosis.
Wifi grading: ischaemia	◯ 0 - ABPI >= 0.8, toe pressure >=60mmHg ◯ 1 - ABPI 0.6 - 0.79, toe pressure 40 - 59mmHg ◯ 2 - ABPI 0.4 - 0.59, toe pressure 30 - 39mmHg ◯ 3 - ABPI < = 0.39, toe pressure < 30mmHg
Wifi grading: infection / equivalent IDSA/IWGDF grade	◯ 0 - No symptoms or signs of infection ◯ 1 - Infection (presence of at least 2 of: local swelling, erythema >0.5 to < =2cm around the ulcer, local tenderness or pain, local warmth, purulent discharge). ◯ 2 - Local infection with erythema >2cm, or involving structures deeper than skin and subcutaneous tissues, and no SIRS. ◯ 3 - Local infection with signs of SIRS (2 or more of: temperature >38° or < 36 ˚C, heart rate >90bpm, respiratory rate >20 breaths/min or PaCO2 < 32mmHg, WBC >12 or < 4 x103cu/mm)
Suspected or confirmed osteomyelitis	◯ Yes ◯ No
Was the patient on antibiotic therapy in the few weeks leading to presentation?	◯ Yes ◯ No
If antibiotics were started in hospital, was pre-operative antibiotic therapy intravenous or oral	◯ Intravenous ◯ Oral ◯ Both

Which antibiotic therapy was initiated?	☐ Penicillins ☐ Cephalosporins ☐ Carbapenems ☐ Metronidazole ☐ Clindamycin ☐ Linezolid ☐ Daptomycin ☐ Fluoroquinolones ☐ Vancomycin ☐ Tigecycline ☐ Gentamycin ☐ Tazocin ☐ Co-trimoxazole ☐ Doxycycline ☐ Teicoplanin ☐ Other
Overall pre-operative antibiotic therapy duration in days (prehospital and in-hospital preoperatively)	_____ (days)
Were topical antibiotics used to treat infection pre-operatively	◯ Yes ◯ No

Procedure

Speciality	◯ Vascular Surgery ◯ Trauma and Orthopaedics
Procedure	◯ Soft tissue debridement ◯ toe amputation+/- debridement
Revascularisation during the same procedure	◯ Yes - Open ◯ Yes - Endovascular ◯ Yes - Hybrid ◯ No
Emergency procedure	◯ Yes ◯ No
Which toes were amputated?	☐ Hallux ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th
Operative time (in minutes)	_____ (minutes)
Skin preparation solution	☐ Alcoholic Chlorhexidine ☐ Aqueous Chlorhexidine ☐ Alcoholic Betadine ☐ Aqueous Betadine
Irrigation fluid used	◯ Saline ◯ Betadine ◯ Hydrogen peroxide ◯ Other _____ ◯ None
Packing material used	◯ Haemostatic (e.g. Kaltostat) ◯ Absorbative (e.g. Aquacel) ◯ Plain gauze or saline soaked gauze ◯ Inadine or betadine soaked gauze ◯ Other _____ ◯ None
Local antibiotic used (e.g. powder, beads, fluid)	◯ Antibiotic sponge/implant (e.g. Collatamp) ◯ Antibiotic beads ◯ Antibiotic powder ◯ Other _____ ◯ None
Was a drain left in the wound?	◯ Yes - open passive system (e.g. corrugated drain) ◯ Yes - closed active system - haemovac drain ◯ No

Which dressing type was used at the end of the procedure?	◯ Absorbent adhesive ◯ Open wound negative pressure therapy ◯ Absorbent pad and tape ◯ Other _____
Soft tissue sample sent for microbiology	◯ Yes ◯ No
Bone sample sent for microbiology	◯ Yes ◯ No
Bone sample sent for histology	◯ Yes ◯ No
Sample of bone from residual stump sent to microbiology to identify residual bone infection	◯ Yes ◯ No
Microbiology samples taken using clean instruments (clean tray)	◯ Yes ◯ No

Post-op

Did the soft tissue/bone sample to microbiology yield growth?	◯ Yes ◯ No ◯ No sample sent
Which organisms were isolated?	☐ Staphylococcus (exc MRSA) ☐ Methicillin Resistant Staphylococcus Aureus (MRSA) ☐ Streptococcus ☐ Campylobacter ☐ Citrobacter ☐ E.Coli ☐ Pseudomonas ☐ Bacteriodes fragilis ☐ Enterobacter ☐ Proteus ☐ Klebsiella ☐ Clostridia ☐ Acinetobacter ☐ Enterococcus (exc VRE) ☐ Vancomycin reseitant enterococcus (VRE) ☐ Mixed flora
All organism(s) identified susceptible to current antibiotic therapy?	◯ Yes ◯ No
Was antibiotic therapy changed to target organisms identified on culture?	◯ Yes ◯ No
Which antibiotic(s) was the patient changed to?	☐ Penicillins ☐ Cephalosporins ☐ Carbapenems ☐ Metronidazole ☐ Clindamycin ☐ Linezolid ☐ Daptomycin ☐ Fluoroquinolones ☐ Vancomycin ☐ Tigecycline ☐ Gentamycin ☐ Tazocin ☐ Co-trimoxazole ☐ Doxycycline ☐ Teicoplanin ☐ Other
Duration of intravenous antibiotic therapy post-operatively (days)	_____ (days (0 if only IV abx was prophylaxis))
Total duration of postoperative in-hospital antibiotic therapy (IV + oral) (days)	_____ (days (0 if only prophylaxis given))
Length of hospital stay (days)	_____ (days)

Post-operative morbidity grade (Clavien-Dindo), select highest that applies	◯ 1 - Any deviation from the normal post-operative course not requiring surgical, endoscopic or radiological intervention. This includes the need for certain drugs (e.g. antiemetics, antipyretics, analgesics, diuretics, and electrolytes), physiotherapy and wound infections opened at the bedside. ◯ 2 - Complications requiring drug treatments other than those allowed for grade I (blood transfusion, antibiotics, TPN) ◯ 3a - Surgical/endoscopic/radiological intervention under regional/local anaesthetic ◯ 3b - Surgical/endoscopic/radiological intervention under general anaesthetic ◯ 4a - Single-organ dysfunction (including dialysis) ◯ 4b - Multi-organ dysfunction ◯ 5 - Death
Post-operative mobilisation?	◯ Full ◯ Partial ◯ Toe touch ◯ None
Duration of post-operative modified weight bearing (ie if toe/partial)	◯ 24 hours ◯ 48 hours ◯ Other _____
How long was the drain left in place (in days)?	_____ (days)
Imaging to assess need for revascularisation during this admission	◯ Yes ◯ No
Ipsilateral revascularisation during this admission	◯ Yes, prior to the toe amputation/debridement ◯ Yes, after the toe amputation/debridement ◯ No
Return to theatre for debridement during this admission	◯ Yes ◯ No
Return to theatre for further amputation of other toe(s) during this admission	◯ Yes ◯ No
Forefoot or ankle-level amputation during this admission	◯ Yes ◯ No
Major lower limb amputation during this admission	◯ Yes ◯ No
In-hospital death	◯ Yes ◯ No
Was the death attributable to COVID-19?	◯ Yes ◯ No

3-month follow up

Duration of postoperative antibiotic therapy within 90 days (in days)	_____ (days (0 if only prophylaxis given))
Positive COVID-19 test within 90 days from the procedure	◯ Yes ◯ No
Complete wound healing by 90 days after the procedure	◯ Yes ◯ No
Re-admission to hospital within 90 days	◯ Yes ◯ No
Further debridement within 90 days	◯ Yes ◯ No
Further amputation of other toe(s) within 90 days	◯ Yes ◯ No
Forefoot or ankle-level amputation within 90 days	◯ Yes ◯ No
Major lower limb amputation within 90 days	◯ Yes ◯ No
Death within 90 days	◯ Yes ◯ No