VERN
Vascular and Endovascular Research Network

DEFINITE
diabetic foot debridement in theatre

The DEFINITE Audit – Prospective Audit of Diabetic Foot Debridement in Theatre

A VERN collaborative project

Protocol

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Contents

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Collaborators	VSGBI Diabetic Foot Specialist Interest Group (DF SIG)
Sponsors	Urgo medical (£6500) Newcastle Hospitals Charity (£4000)

Summary

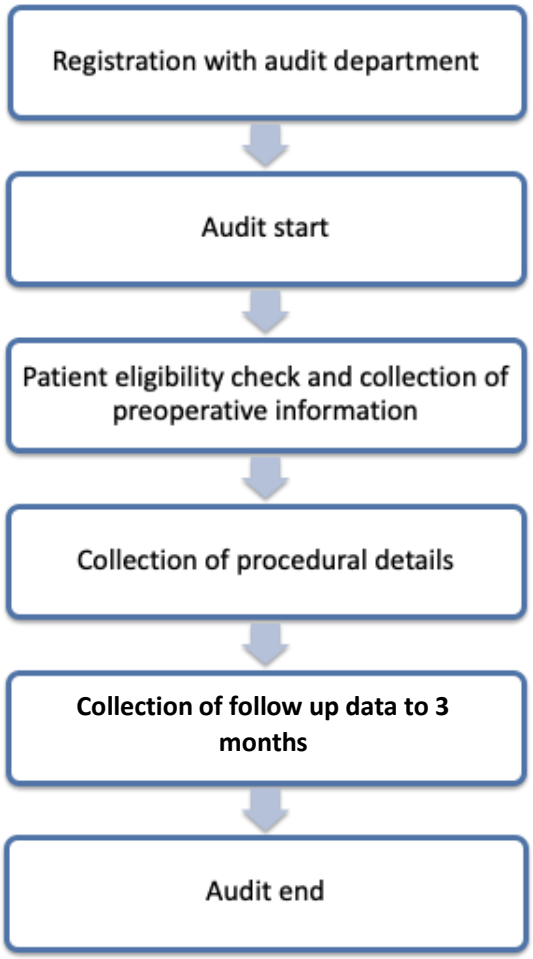
Full title	The DEFINITE Audit: Management of Diabetic Foot Debridement In Theatre	
Short title	DEFINITE	
Aim	To audit national practice in operative debridement of diabetic foot wounds and correlate variation with healing rates and international guidelines.	
Design	Prospective multi-centre international Audit	
Audit participants	Patients undergoing elective or emergency surgery for debridement or digital amputation of the foot under a vascular team with a confirmed diagnosis of Diabetes	
Planned audit period	Each site will have a 3-month recruitment period and a 3-month follow-up period.	
Planned audit start date	1st December 2021	
Planned audit end date	April 2022	
	Objectives	Outcome Measures
Primary	Map international practice of diabetic foot debridement and/or minor amputation in theatre against current international standards	Centre debridement or minor amputation practice of diabetic foot in theatre
Secondary	1) Measure incidence of healed wounds at 3 months after index procedure 2) Assess rate of further intervention (including major amputation) after the index procedure 3) Assess readmission rate 4) Collect information on length of antibiotic course and type of antibiotics used after the index procedure 5) Review micro-organisms seen in diabetic foot wounds	1) Incidence of healed wounds at 3 months 2) 3-month reoperation rate 3) 3-month readmission rate 4) 3-month major lower limb amputation rate 5) Duration and type of anti-biotics after index procedure 6) Results of tissue cultures

Schedule of Events

Table 1: Schedule of Events

	Before Surgery	During Surgery	Day of Discharge	3 months
Eligibility check	X			
Baseline demographics and comorbidities	X			
Medication, bloods, pre-op COVID-19	X			
Infection grade and wound grade	X			
Results of Microbiology	X	X	X	X
Antibiotics	X	X	X	X
Procedure details		X		
Complications			X	X
Further debridement or amputation			X	X
Readmission, death				X

Audit Flow Chart



List of definitions

NHSN Operative Procedure: a procedure that
· is included in the ICD-10-PCS or CPT NHSN operative procedure code mapping
And
· takes place during an operation where at least one incision is made through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure
And
· takes place in an operating room.

Diabetes: The NHSN SSI surveillance definition of diabetes indicates that the patient has a diagnosis of diabetes requiring management with insulin or a non-insulin anti-diabetic agent. This includes patients with "insulin resistance" who are on management with anti-diabetic agents. This also includes patients with a diagnosis of diabetes who are non-compliant with their diabetes medications.

Emergency operative procedure: A procedure that is documented per the facilities protocol to be an Emergency or Urgent procedure.

Non-primary Closure: closure of the surgical wound in a way which leaves the skin level completely open following the surgery.

Wound class: The WIfI score is used to objectively grade wound severity [1]. This is the Wound, Ischemia, and foot Infection score from the Society for Vascular Surgery.

Return to theatre: Any procedure to the same surgical site that occurs after the index procedure, that takes place in an operating theatre. Minor debridement that takes place on the ward is not included.

Healed wound: Complete epithelisation without discharge for 2 weeks [2]

Separate courses of antibiotics: A separate course of antibiotics refers to a course that is started at least 14 days after the previous course of anti-biotics.

AUDIT PROTOCOL

The DEFINITE Audit: Prospective Audit of Diabetic Foot Debridement In Theatre

1. INTRODUCTION

People with diabetes are at high risk of developing foot ulceration (DFU) and wound infection. Diabetic foot wounds are at high risk of rapid deterioration and can lead to bacteraemia and sepsis which is associated with high morbidity, risk of limb loss and death [3]. The development of severe infection requires emergency hospital admission and surgery to remove dead and infected tissue, which are 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 National Health Service annual budget dedicated to management of DFU [6].

Guidelines have been designed to improve healing rates following debridement and reduce the incidence of major lower limb amputation (MLLA) [7,8,9]. There are two major international guidelines that will be used:

1. The International Working Group for Diabetic Foot (IWGDF) guidelines [8]
2. The Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia [9]

Guidelines advise:

1. Removal of all infected and necrotic tissue
2. Drainage of sepsis
3. Effective irrigation
4. Sample collection for microbiological analysis
5. Adequate dressing
6. Sensitivity-driven antimicrobial use [8].

However, there is significant variation in surgical management of the diabetic foot wound. The irrigation fluid, dressings used, number of samples sent for microbiological analysis and first line antibiotic choice is up to the individual surgeon or based on local microbiology policies. It is unknown how each of the elements influence the chance of wound healing, the risk of needing further debridement or amputation, or the length of antibiotics required after surgery.

The Vascular Society of Great Britain and Ireland recently completed the final stages of the Vascular Research Priority Setting Partnership, in collaboration with the James Lind Alliance. The results support the 2017 Delphi consensus of UK vascular healthcare professionals, who identified ‘improving outcomes in diabetic foot infections’ as a top research priority. The debridement of diabetic foot sepsis is most commonly performed by trainees, with or without direct senior oversight. Therefore, this topic is an ideal one for a trainee led audit of practice.

2.RATIONALE

2.1 Aims and Hypothesis

The primary aim of this prospective audit is to assess the pathway 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. Specific standards to be audited are detailed in Appendix 1.

Secondary aims are to investigate if variation in practice is linked to:

1. wound healing rates
2. reoperation rates (further debridement or minor amputation)
3. 3-month major amputation rates
4. 3-month readmission rates

2.2 Justification

Diabetic foot complications cause significant morbidity and mortality. Prolonged healing time results in a great risk of infection, hospitalisation, cost, patient distress and limb loss. Variation in practice and non-adherence to guidelines may lead to poorer outcomes.

3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

Primary objective:

To audit practice of the index* minor amputation or debridement to manage diabetic foot infection against current international standards and explore any variation in management.

Secondary objectives:

1. To compare current practice to recommendations from global guidelines [8][9]
    a. Specific standards are shown in Appendix 1.
2. To determine the rate of further debridement and minor amputation at 3-months following the index procedure*.
3. To determine the rate of major lower limb amputation at 3-months following the index procedure.
4. To determine the rate of wound healing at 3-months following the index procedure.
5. To determine the frequency with which causative organisms are identified from microbiological samples taken during the index and subsequent procedures.
6. To identify predictors of:
    a. Subsequent debridement and/or minor amputation(s) at 3-months following the index procedure.
    b. Subsequent major lower limb amputation at 3-months following the index procedure.
    c. Complete wound healing at 3-months following the index procedure.

*Index defined as no previous amputation or debridement within the last 6 weeks.

4. AUDIT DESIGN

This is a multicentre, prospective audit including adult patients undergoing a wound debridement or minor amputation of the foot in theatre to treat a complication of diabetes. The audit will be delivered through the Vascular and Endovascular Research Network (VERN). VERN is a trainee-led national research collaborative that is run by, and engages with, research-active vascular trainees and allied healthcare professionals.

We will be open to any centre who wishes to join for the duration of the audit. We estimate that at least 30 centres will be enrolled.

5.ELIGIBILITY CRITERIA

Inclusion criteria

- Patients undergoing debridement of a foot wound or minor amputation in a theatre environment to treat a complication of diabetes.
- Patients already included in the audit who undergo debridement of a foot wound or minor amputation of the contralateral limb in a theatre environment to treat a complication of diabetes.

Exclusion criteria

- Patients who have undergone a debridement of the wound in theatre within the last 6 weeks of the index foot*. If the previous procedure has not been used as the index procedure, the patient should not be included in the audit.
- Patients having debridement of a foot wound or minor amputation in a setting other than the operating theatre.
- Patients under 18 years of age.

*Time period based on the recommended maximum duration of antibiotic therapy for osteomyelitis in the context of a diabetic foot infection (Item 25b of IWGDF 2019 guideline).

6.AUDIT PROCEDURES

6.1 Registration

The DEFINITE audit is open to all centres which provide elective and/or emergency surgical management for diabetic foot infection. Centres can register to participate by completing the online DEFINITE registration form, that includes collection of information on existing diabetic foot services in the participating centres. The audit is also required to be registered in each site prospectively, prior to data collection. It is the responsibility of the local audit lead to ensure this is complete prior to starting data collection.

Participants will be identified and recruited as per the inclusion/exclusion criteria. Potential participants will be identified by a member of the surgical team at each centre. Healthcare professionals identifying patients will be members of the patient's normal clinical team and as such there should be no issues surrounding patient confidentiality. The resources used to identify potential participants will be acute admission lists, diabetic foot ward rounds and operating lists. 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.

6.2 Baseline Data

Included data points (see CRF for complete list):
Baseline assessments will include: Demographics (age group, gender, smoking habits), medical history, previous surgery to the affected foot, concomitant medication, wound classification, routine laboratory tests (all part of routine care), radiology investigations (imaging used to diagnose infection, imaging to assess/plan revascularisation), and anti-biotic use at the time of index procedure.

6.3 Peri-operative data

This will include details of specific steps of the procedure, including irrigation fluid used, micro-biological samples, and materials used to dress the wound.

6.4 Subsequent assessments

Following the index procedure, the patient will remain in the audit for 3 months. Information on antibiotic usage and wound healing will be gathered up until discharge, and then again at 3-month follow up. No additional tests or investigations will be required beyond standard care.

6.5 End of audit definition

The end of audit is defined as being after the 90th day since the index operation of the last patient recruited into the audit.

7. DATA ANALYSIS

Descriptive analyses will be performed to describe variation in practice nationally. Statistical analyses will be used to examine secondary outcomes. Continuous data will be tested for normality and parametric or non-parametric tests used as appropriate. The Chi-squared 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. Subsequent analyses conducted on imputed data will be compared to sensitivity analyses using 'complete-case analysis'.

Univariate and multivariate regression analyses will be used to identify independent predictors of: further debridement/minor amputation, major lower limb amputation, and complete wound healing (all at 3 months following the index procedure). Variable reaching threshold of $p<0.10$ on univariate analysis will be put forward to the multivariate regression analysis. $P<0.05$ will be used to define statistical significance.

8. DATA MANAGEMENT

8.1 Data collection tools and source document identification

All data will be collected prospectively using a purpose-built electronic database known as the Research Electronic Data Capture (REDCap) platform, which is overseen by Bristol University. Data

will be collected and uploaded by a member of the audit team with appropriate REDCap training from VERN.

8.2 Data handling and record keeping

All audit data will be preferably uploaded directly to REDCap, however, all centres will be provided with printable case report forms (CRFs) to be used at their discretion where access to REDCap may be limited (e.g. in operating theatres). Oversight of paper CRFs used at centres will be the responsibility of the centre's PI. All CRFs used will be securely stored in an appropriate location on-site until data is uploaded to REDCap, at which point the centre's lead clinician will be responsible for ensuring they are appropriately destroyed.

A specific audit identification number will be assigned to each patient to allow anonymised data to be collected prospectively using a purpose-built REDCap database that will be accessible at each centre. Patients may be enrolled twice if undergoing a procedure for both feet during the study period, a unique study ID will be assigned to each procedure in these cases. Each centre's lead clinician will be responsible for ensuring a database containing each participants' local hospital ID and corresponding audit ID is maintained to ensure accurate follow-up data is uploaded. The lead clinician at each centre is responsible for ensuring this database is stored securely on an appropriate hospital computer. Data should be kept for two years – to allow a possible follow-up study- and get destroyed thereafter. Through this audit's REDCap database design, no identifiable data can be uploaded.

8.3 Source Data

Source documents are original documents, data, and records from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF/REDCap database), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence.

8.4 Participant Confidentiality

The audit staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant's ID number on the REDCap database. The audit will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

8.5 Data completeness and accuracy

Following the initial data collection period, data completeness will be quantified. Patient records with less than 95% completeness of mandatory datapoints 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 re-capture 25% of the datapoints (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 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 (e.g 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.

9. ETHICAL AND REGULATORY CONSIDERATIONS

9.1 Ethical approval and research governance

The audit will be conducted in compliance the principles of the ICH 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 will not be sought as no patient identifiable data will be available to VERN. There will also be no change to routine patient care. Local audit approval will be sought from the Research and Development department at each participating centre, this will be the responsibility of the local PI at each centre.

9.2 Data protection and patient confidentiality

The audit will comply with the Data Protection Act 2008. Participants will be assigned a unique REDCap identifier upon enrolment into the audit to allow pseudonymisation of patient-identifiable data. Access to patient identifiable data will be restricted to members of the patient's usual clinical team. Hard copies of audit documents will be stored in locked filing cabinets in secure entry-card protected sites only and will be the responsibility of the PI at each centre.

9.3 Centre set-up and pre-audit questionnaire

Healthcare professionals or medical students interested in contributing to the audit may contact the DEFINITE audit team through a dedicated email address: DEFINITE.audit@gmail.com. One team member from each centre will act as PI and will be the point of contact between the DEFINITE audit team and the local audit team. They will have the responsibility to register their centre and team members for the audit by filling in an online form found on the VERN website.

Each PI will have overall responsibility for ensuring the audit is conducted according to the standards and methods described in this protocol at their site. Any instances of protocol non-compliance will be reported to the local PI, who in turn will report to the DEFINITE audit team.

A questionnaire briefly exploring current local practice will be completed by the local PI of each participating centre prior to their data collection period.

10. FUNDING

The funding bodies had no involvement in the audit design, and will not be involved in data collection and analysis, preparation of manuscripts or decision to publish.

11. DISSEMINATION AND AUTHORSHIP POLICY

Data will be submitted for presentation at national and international academic conferences. Further, a manuscript will be prepared for peer reviewed publication. Data will be presented to the diabetes specialist interest group.

A writing team, including those involved with the design, implementation and dissemination of the DEFINITE audit and those contributing to data analysis will be responsible for both presentation(s)

and publication(s). For both presentation(s) and publication(s) a collaborative authorship model will be used. Criteria to qualify for collaborative authorship are defined as:

1. Had a significant role in the set up and management of the DEFINITE audit; including audit department registration/ethical approval, creation of a data collection team and engagement with VERN to ensure timely upload of data (with validation as required)

OR

2. Captured 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 individuals may participate in only baseline data collection or only follow up data capture. Data collection is expected to be complete (>95% variables completed) and submitted within 7 months of starting data collection

OR

3. (for principal investigators) provide oversight and support as detailed in sections 8 and 9.

AND

4. Review and approve any resultant manuscript(s) for submission to a peer-reviewed journal.

The corresponding author will take primary responsibility for communication with the journal throughout the submission process.

Anticipated number of audit team members per centre is: 1 PI + 5 other team members (medical trainees, allied healthcare professionals, medical students). If centres include more than 5 additional team members, it is expected that allied healthcare professionals and/or medical students are included.

12. REFERENCES

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13. APPENDIX

Selected specific standards to measure, based on:

- **Guidelines on the diagnosis and treatment of foot infection in persons with diabetes (IWGDF 2019 update) [8]**
- **The Global Vascular Guidelines on the management of chronic limb-threatening ischaemia [9]**

1. 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) [8][9]
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) [8]
3. In a person with diabetes and suspected osteomyelitis of the foot, we recommend using a combination of the probe-to-bone test, the erythrocyte sedimentation rate (or C-reactive protein and/or procalcitonin), and plain X-rays as the initial studies to diagnose osteomyelitis. (Strong; moderate) [8]
4. 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) [8]
5. Collect an appropriate specimen for culture for almost all clinically infected wounds to determine the causative pathogens. (Strong; low) [8]
6. 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) [8]
7. 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, daptomycin, fluoroquinolones, or vancomycin, but not tigecycline. (Strong; high) [8]
8. 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) [8]
9. 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) [8]
10. 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) [8]
11. We suggest not using any currently available topical antimicrobial agent for treating a mild diabetic foot infection. (Weak; moderate) [8]
12. 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) 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) [8]

13. 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 (betahaemolytic streptococci and Staphylococcus aureus) in cases of a mild diabetic foot infection. (Strong; low) [8]
14. 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) [8]
15. 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) [8]
16. 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) [8]
17. 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) [8]