NHS England

South West Cardiovascular Clinical Network

Diabetes Foot Care Resource Pack

January 2016

Contents

Provider Resources

Commissioner Resources

Overview

Diabetes accounts for around 10 per cent of the annual NHS budget. This is nearly £10 billion a year, or £1 million every hour.

80% of NHS spending on diabetes goes on managing complications, most of which could be prevented.

Around 6,000 people with diabetes have leg, foot or toe amputations each year in England – up to 80 per cent of people die within five years of having an amputation.

People with diabetes are more likely to be admitted to hospital with a foot ulcer than with any other complication of diabetes. Foot ulcers and amputations account for around £1 in every £150 the NHS spends each year.

Up to 80% of amputations are avoidable through early diagnosis of risk and complications, good preventative foot care in the community and fast access to a specialist multidisciplinary team when needed.

[The above data has been extracted from: Diabetes UK – 'State of the Nation (England): Challenges for 2015 and beyond' document]

The All Party Report on Vascular Disease https://appgvascular.org.uk/reports has shown persistently high minor and major lower extremity amputation rates in those with diabetes in the South West. The publication informed that '**Amputation is TWICE AS LIKELY for patients in the South West as in London'.**

The South West (SW) Cardiovascular (CV) Clinical Network supported by NHS England commissioned a formal peer review programme of diabetic foot care services across all 14 acute trusts and 11 CCGs within the South West. The aim of the review was to understand the variation in practice, establish compliance with NICE CG119, identify and share good practice and make recommendations for change and improvement.

Evidence from the foot care reviews demonstrated that in order to improve outcomes for patients and prevent amputations, current processes should be examined across the whole pathway to:

- understand reasons leading to amputations,
- act upon lessons learnt
- identify opportunities to develop services.

To support this, the SW CV Clinical Network has developed a Diabetes Foot Care Resource Pack which includes information on performing a Root Cause Analysis (RCA) and Significant Event Audit (SEA). The enclosed documents have been produced *as a reference tool* to assist healthcare professionals in implementing the RCA and SEA processes. The introduction of a SW approach will ensure that all care providers are reviewing and assessing pathways of care, consistently enabling benchmarking and the sharing of best practice.

PDF copies can also be found on our website at: www.swscn.nhs.uk and may be used by any clinical staff member who cares for a Diabetic patient.

Should you have any queries or require additional information, please contact:
Michelle Roe, Cardiovascular Network Manager
South West Strategic Clinical Network
NHS England South (South West), Peninsula House,
Tamar View Industrial Estate, Saltash, Cornwall PL12 6LE
Email: michelle.roe@nhs.net or phone: 07876 546422

Rachel Levenson, Cardiovascular Programme Manager
South West Strategic Clinical Network
NHS England South (South West), 4th Floor, South Plaza,
Marlborough Street, Bristol BS1 3NX
Email: r.levenson@nhs.net or phone: 07760 501971

Useful links:

1. **Public Health England / NHS England 'Atlas of Variation – September 2015':**

   Map 30: Percentage of people in the National Diabetes Audit (NDA) with Type 1 and Type 2 diabetes who received NICE-recommended care processes (excluding eye screening) by CCG

   Map 35: Relative risk of major lower limb amputation among people in the National Diabetes Audit (NDA) with Type 1 and Type 2 diabetes compared with people without diabetes by CCG (Indirectly standardised rate, adjusted for age and sex, 2010/11–2012/2013)

   (to download:
   http://www.rightcare.nhs.uk/index.php/atlas/nhs-atlas-of-variation-in-healthcare-2015)

2. **Public Health England GP Practice Profiles (per CCG in SW Peninsula):**

   Summary analysis of Diabetes Neuropathy Indicator (DM012) for 2014/15
   (to download: http://fingertips.phe.org.uk/profile/general-practice)

3. **National Diabetes Audit (NDA)**

   For more NDA information and the accompanying excel documents and data please visit the HSCIC website via: http://www.hscic.gov.uk/pubs/ndauditcorerep1415

4. **National Diabetes Footcare Audit (NDFA)**

   Further information and all NDFA documentation are available at: www.hscic.gov.uk/NDFA.
   The NDFA team can be contacted directly via email at: NDFA@hscic.gov.uk.

   Note: *PHE news: The first year of NDFA data will be published at the end of March 2016, and will be available to download at www.hscic.gov.uk/footcare*

South West Cardiovascular Clinical Network

Guide to undertaking

A

Root Cause Analysis

Authors:

Angie Abbott

Head of Podiatry and Orthotics, Torbay and South Devon NHS Foundation Trust

Dr Richard Paisey

South West Cardiovascular Strategic Clinical Network

Contents

1 Introduction- What is Root Cause Analysis (RCA)

A root cause analysis is a process to identify what happened, how something happened and potentially why it happened.

The RCA is undertaken by gathering information from a range of sources charting the information and making recommendations. The process involves data collection, root cause identification and then the creation of recommendations to address the cause. Once the investigation into the event has occurred and the information has been charted steps need to be put in place to prevent the incident happening again. This can be undertaken by creating an action plan to address the key learning points.

The root cause analysis into lower limb amputations need to involve a range of services from the start of the patient journey, to the amputation and then on to the process of putting together the recommendations and the ownership of the action plan.

This guidance has been drawn up with some useful tools to help with the process of undertaking the data collection; in addition it makes suggestions for the level of detail that is required to undertake a root cause analysis into diabetic lower limb amputations.

This is a guide that aims to demonstrate how to undertake a root cause anlaysis into diabetic lower limb amputations based on the learning from undertaking RCA's in one NHS provider area. There are likely to be a range of different methodologies that can be tried and tested.

Some key points are described so that the investigator can understand if the patient's journey followed best practice. What we are trying to ascertain is if; the right pathways were in place, staff had the right skills and referred in a timely fashion, so that the patient received the right intervention, at the right time and patients were educated to the risk. In summary the following are **"key avoidable factors"**

Patient unaware of foot risk

Practice referral to podiatry of high risk or ulcerated foot patient not made

Absence of foot protection team

Delay more than 2 weeks in referral of deteriorating ulcer to MDT

Delay of more than 48hrs before review by one member of MDT in case of hot foot.

Absence of care plan shared with patient and all professionals

2 Definition of a diabetic lower limb amputation

For the purpose of the RCA described a diabetic lower limb amputation is determined as:

Major amputation
Above ankle, above knee, through knee, below knee.

Minor amputations
Below ankle, toe amputation, ray amputation, mid-foot amputation, excision of osteomyelitis calcaneal excision.

The guidance has been designed to look at an RCA process for major amputations however this could be used for minor amputations.

3 Who should undertake the RCA?

It is recommended that the team, people or person that undertakes the RCA has prior knowledge of diabetic foot. They need to have an understanding of what good referral pathways should look like to ensure patients are seen in a timely manner by the most appropriately trained person(s). They should be able to determine if the patient followed an appropriate pathway or journey and received the correct interventions at the right time to prevent limb loss. It is helpful to have some knowledge of the factors that contribute to an amputation. It is also helpful to understand what necessary interventions should occur for each of the complications that arise in terms of diabetic foot disease.

They investigator needs to be able to articulate what the findings prove. They also need to be able to make recommendations to improve diabetic foot services in order that there is seamless and timely delivery of diabetic foot care.

4 Steps to undertaking an RCA

Step one—data collection. The first step in the analysis is to gather data. It is suggested that data is obtained from:

- GP practice
- Community podiatry records
- Community nursing
- Hot foot clinics, or podiatry clinics within hospital setting
- Inpatient records
- Orthotist records

- Hospital records for inpatient and outpatient care for the time leading up to the amputation.

Without the complete set of information and an understanding of the event, the causal factors and root causes associated with the incident/amputation cannot be identified. The majority of time spent analysing an event is spent in gathering the data.

Step two—Causal factor charting. Causal factor charting of the data can be undertaken using a range of tools from flow charts to chronology timelines. These provide a structure for investigators to organize and analyse the information gathered during the investigation and identify gaps and deficiencies

Step 3 -Root cause identification. After all the causal factors have been identified, the investigators begin root cause identification.

Step 4.—Recommendation generation and implementation. The next step is the generation of recommendations. Following identification of the root causes for a particular causal factor, achievable recommendations for preventing its recurrence are then generated.

5 Key points to look for when undertaking and RCA

Prospective or retrospective investigation of major amputations is seen as a necessary to understand how patient came undergo either an above or below amputations and whether this was an avoidable or unavoidable procedure. Not all amputations are deemed a poor outcome for patients. However by undertaking root cause analysis only then can we determine the factors that contribute to the lower limb amputation and decide if this was avoidable or unavoidable or if this was a good outcome for the patient?

It is recommended the following areas are the focus of the root cause analysis.

- ***Was the patient known to be high risk?***
- ***Where they known to community podiatry service or foot care provider?***
- ***What was the initial causative problem?***
- ***Was NICE CG10 Followed?***
- ***Did the patient receive prompt offloading?***
- ***Did the patient receive prompt and appropriate antibiotics therapy for any infected wounds?***
- ***Was there a prompt MDT referral?***
- ***Did the patient receive timely vascular intervention?***
- ***Outcome?***

This information can be gathered retrospectively or prospectively

6 Who should be collecting information on amputations and reporting mechanisms (Support for the RCA process)

In order that the RCA process is effective and a valuable use of time it is necessary to determine who is going to commission the RCA process and take ownership for any actions or recommendations.

A reporting system needs to be agreed for recording the amputations.

Most provider services use an incident reporting system. This reporting can be undertaken by the community service or reported by the acute hospital. GP practice data can be obtained to determine practice level data on amputations.

Commissioners should be encouraged to request numbers of lower limb amputations as an incident or adverse event.

It is advised that RCA investigations are reported to commissioners of services. Some commissioning organisations are willing to hold the incident on their STEIS reporting system. Some agreement needs to be reached as to who will report the amputations and who takes ownership of sharing the learning and creating action plans to address any necessary learning/recommendations.

7 What should a good diabetic foot service look like?

Understanding what a diabetic foot service should look like can help in determining if a patient followed an appropriate pathway, if they had timely access to care and if they were offered preventative advice or education.

There is commissioning guidance that indicates what a good diabetic foot service should look like in terms of best practice

Ref NICE CG10 /CG119/ NG19.

GP practice level investigation

Diabetic foot checks at practice level- were foot checks undertaken at practice level and was any information offered to the patient on risk status of the foot and appropriate education.

- Was the patient told of their risk classification?
- Is there a standard operating procedure for diabetic foot examination at annual diabetic review?
- Are all members of staff undertaking the diabetes annual foot check trained to examine and record risk status?
- Is each patient advised about foot care at each annual review?

- Does the practice have written foot care information for patients at diabetic annual review?
- Is every patient at increased or high risk of diabetic foot ulceration referred to community podiatry for regular review?
- Is everyone at the practice (including nurses involved with wound care) conversant with pathways for referral of increased, or high risk and ulcer patients to podiatry and secondary care?
- Were signs of deteriorating foot ulcers recognised and onward referrals made promptly?

Podiatry level investigation/community nursing

If a patient was referred to, or under the care of a foot protection team the communication and appropriate onward referral needs to be mapped to determine if this was timely, appropriate and followed NICE guidance.

- Are communications from community podiatry and secondary care for diabetic foot patients adequate i.e. detailed care plan, identification or risk?
- What was the referral to treatment times within podiatry, 24 to 48 hours for a wound or longer?
- In this specific case: what was the foot risk score at the last routine foot check prior to this episode?
- Was preventative provision of nail cutting and debridement of callus for those with diabetic risk provided before the ulceration occurred and were risk factors assessed and documented and acted on when they were identified.
- Was this individual known to podiatry prior to this episode?
- If so were they under regular podiatry review?
- When this individual first presented with a foot wound how long until presentation to foot team?
- Did referral on classification of an increased risk foot occur?
- Did the patient get referred quickly when they were determined to be at risk of diabetic foot ulceration?
- When a patient presents with corns/ callus was appropriate treatment offered and was the advice/care appropriate in terms of frequency.
- Were prevention strategies employed to prevent ulceration?
- Was there the provision of insole/ orthotic provision and return times?
- Was vascular and neurological status checked at visit and was the patient educated about risk factors such as smoking etc.
- Did the patient receive education on risk of developing foot ulcers?
- Had podiatry undertaken vascular assessments and neurological assessments according to NICE guidance?
- Was the patient seen with a frequency appropriate to need?
- Had the patient been offered diabetic foot education or advice?

- Were signs of deteriorating foot ulcers recognised and onward referrals made promptly

Hospital level investigation

Once a patient developed foot ulceration or foot problems did the patient receive appropriate and timely interventions to address vascular factors, infection, offloading appropriate debridement, dressings and care. Did this comply with NICE compliant services and recommended NICE guidance?

- If the patient was not under the care of the foot protection team and they ulcerated or developed a wound was the patient then referred promptly within 24 hours to a member of the foot protection team?
- Is there a summary sheet with care plan in the hospital/podiatry notes which has been shared with the patient and all professionals involved?
- If the patient was referred, were they then seen promptly by a member of the multidisciplinary foot protection team?
- Were this referral reviewed and the patient seen within a timely manner i.e. 24 to 48 hours?
- On referral with a wound was blood supply assessed, and were ischemic factors explored further with imaging, duplex, angiogram, angioplasty etc., was there timely and appropriate vascular intervention?
- Were debridement strategies used to reduce bacterial burden of wounds
- Were signs of deteriorating foot ulcers recognised and onward referrals made promptly
- After vascular intervention were discharge pathways appropriate?
- Did the patient receive onward referral to foot protection team for continued monitoring for deterioration of the foot /limb?
- Was offloading provided for the patient when ulceration occurred to facilitate wound healing?
- Did the patient get referrals for orthotics intervention/footwear to prevent ulceration or foot health deterioration?
- Was this pathway for offloading intervention smooth and timely?
- Did the patient receive education on risk to foot health and how to prevent foot problems and how to access help if needed?
- Were risk factors documented such as blood supply to foot and neurological status
- On development of ulceration did a prompt referral to a member of the foot protection team occur?
- What was the measurements of time to referral.
- Was infection recognised and did the patient receive appropriate antibiotics?
- Time to receipt of antibiotics.

- Were X rays undertaken to look for bone infection osteomyelitis and charcot-arthropathy in chronic wounds or wounds that probed to bone or delayed healing occurred?
- If the patient had neuropathy was this recorded and risk of Charcot foot addressed to prevent injury and foot deformity.
- Did the patient have vascular investigations, where foot pulses checked? Time to vascular referral for duplex, angiogram and time to vascular for interventions.
- Post-surgical management of the wounds. Was this by a member of the foot protection team and was post-surgical management timely and appropriately delivered by staff with relevant knowledge and skills in the treatment of diabetic foot.
- Was the patient seen by a member of the foot protection team with appropriate skills for the care of the reaming limb post amputation.
- Was the amputation avoidable/ unavoidable?

8 How to gather the information

Data base

There are some benefits from holding a data base of all diabetic foot ulcerations however if a patient touches a range of different providers this can be challenging to maintain.

Participation in the national diabetes foot audit should address this issue and we would encourage all organisations to participate in this national audit as the preferred data collection.

http://www.hscic.gov.uk/footcare

A data base can make the data gathering for an RCA easier however this is time consuming to maintain when large volumes of ulcerations occur. Appendix A contains some suggested headers for the data collection.

Retrospective data collection.

This information can be obtained once the patient's amputation has been reported and the RCA is undertaken as an alternative to continuous data collection. The headings (see Appendix 1) can be used to create continuous record of learning from the RCA's.

Determining the chronology of events leading up to the amputation is a good way of mapping the patient journey in terms of time frames when there are multiple agencies involved in the patient's journey.

As part of the chronology there is some benefit to mapping the post amputation care, this can help ensure that post amputation pathways are followed. These are designed to protect the remaining, limb which will now be at increased risk of ulceration

A chronology template can be found in ***Appendix 2***

Table of where to look for the necessary information and what information is needed can be found in the documentation table in ***Appendix 3***

9 Duty of Candour

Organisations have responsibility to ensure duty of candour and patient views are sought when undertaking an investigation.

Regulation 20: Duty of candour Categories: Organisations we regulate Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20

The intention of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

Organisations should have in place a method for notifying patients about any investigations relating to their care and to notify the patient if this was potentially avoidable or unavoidable. Good practice would be to also obtain the patients opinion about their experience of the care given.

10 What Next? Learning and action planning

It is recommended that the investigating team or person, presents and discusses their findings with the range of services providers from the GP practice, community services, and hospital service providers involved in the care leading up to the amputations. The report should ideally be forwarded to commissioners of services if they are involved in commissioning the RCA's.

Aim is to:

- Share learning
- Undertake a risk analysis
- Action plan – learning
- Prevention of future incidents

Once the RCA has been undertaken reviewing the findings will then assist in the creation of a summary report that should help determines the following causative factors:

- Patient Factors
- Task Factors (adequacy of care provision)
- Communication Factors
- Team & Social factors
- Education & Training
- Equipment and resource factors
- Working condition factors
- Organisational & Management factors

Below are some examples of relevant contributing factors;

Patient Factors – noncompliance with smoking advice, poor compliance with foot wear, concordance with treatment plan, other disease factors, failure to attend appointments

Task Factors – staff did not have the right skills, services were not accessible or at the right time and place, standards of GP practice foot checks. Number of people involved in the care of the patient, and skills competencies/training.

Communication Factors – poor records of shared care, poor communication of plan, pathway compliance, Care plans, discharge plans that included appropriate referrals to services

Team & Social factors – MDT skill mix, capacity in community services, patients not referred in timely manner. Chronicity of wound and onward referral in timely fashion

Education & Training – patients not in receipt of facts about risk. Wider team knowledge of pathways and foot classification, when to escalate. Skills of teams involved in the care, education resources. Knowledge of deteriorating wounds, pathway compliance/ knowledge

Equipment and resource factors – Capacity in community teams, dressings etc, access to offloading devices and orthotic services. Availability of staff to treat within 24 to 48 hours,

Working condition factors – Concordance with inpatient pathways, IT Systems, having members of the MDT available when needed, timely pathways, Protocols for interventions such as antibiotics etc.

Organisational & Management factors – MDT skill mix, inpatient services across acute and community, orthotics services.

An action plan should then be completed to address any causative factors and to share the learning so that services can be improved or lessons learned.

An example of a summary template and action plan can be found in **Appendix 4**

Appendix 1

Database – header information

NHS Number	Type DM	Gender	age yrs	Smoker	Occupation	where and when presented with defining problem	Time GP referral to pod appointment	practice ann rev	pod referral when high risk

where and when presented with defining problem	Time GP referral to pod appointment	summary sheet	mobility	position	sensation	pulses	HbA1c	CRP	egfr

date presentation of ulcer	date healed	classification	time present to MDT	time present to offloading	time present to antibiotics	xray	duplex	angiogram	angioplasty

Vascular surgery involvement	Orthopaedic surgery involvement	Comments	comments

Appendix 2 - Chronology Template

Incident Number.	
STEIS Reference Number.	
NHS or ID number, if available, of person who the Incident relates.	
Patient's GP Practice.	
Date/Time/Location of the incident.	
Date patient admitted to ward/ onto district caseload.	
Incident Type.	
Diagnosis if relevant to the Incident.	
Name and job role of person completing the Chronology.	

Event date & Time	**Event- what actually happened**	**Missing information/gaps**	**Good practice identified**	**Problems identified**
Additional Comments and Information.				

Summarise by looking at the Possible Causative Factors

Patient Factors –
Task Factors –
Communication Factors –
Team & Social factors –
Education & Training –
Equipment and resource factors –
Working condition factors –
Organisational & Management factors-

Appendix 3

Documentation table

Outcome measure	Evidence of documentation		
Time onset ulcer to presentation with HCP	**Patient report, GP or carer referral**	**Podiatry notes**	**Hospital notes**
Quality of assessment at presentation	Patient status i.e. neuropathy	Pulses (Hand held Doppler ideal)	ulcer score/photo
Time presentation to initial therapy	offloading	antibiotics	referral to MDT
Time to arrange investigations	radiology	vascular	bloods
Time to intervention	debridement	revascularisation	amputation
Summary of presentation and care plan	Full letter	Summary sheet in notes	Patient and carers copied in
Evidence of integrated care pathway	GP letter	Referral to podiatry	referral to MDT

Appendix 4

Action plan

Action plan				
• **Brief incident description:** • **Incident date:** • **Incident type:** • **Healthcare Specialty:** • **Actual effect on patient and/or service:** • **Actual severity of incident:**				
Level of investigation conducted				
Involvement and support of the patient and/or relatives				
Detection of the incident				
Care and service delivery problems				
Contributory factors				
Root causes				
Lessons learned				
Recommendations				
Arrangements for sharing learning				
Recommendation	**Action**	**By When**	**By who**	**How we will know improvements have been made**

Root Cause Analysis (RCA) into Lower Limb Amputation
Steps to undertaking an RCA

Patient undergone a diabetic lower limb amputation

Major: Above ankle, above knee, through knee, below knee

Minor: Below ankle, toe amputation, ray amputation, mid-foot amputation, excision of osteomyelitis calcaneal excision.

Step 1-data collection obtained from:

- GP practice level Investigation
- Community podiatry records
- Community nursing
- Hot foot clinics, or podiatry clinics within hospital setting
- Inpatient records
- Orthotist records
- Hospital records for inpatient and outpatient care for the time leading up to the amputation.

Step 2- Causal factor charting of the data.
This can be undertaken using a range of tools from flow charts to chronology timelines. These provide a structure for investigators to organize and analyse the information gathered during the investigation and identify gaps and deficiencies.
Please see Appendix 2 for tools including:

A) Data collection headers
B) Chronological template
C) Documentation table

Step 3- Root cause identification.
After all the causal factors have been identified, the investigators begin root cause identification. Outcomes presents and discusses their findings with the range of services providers from the GP practice, community services, and hospital service providers involved in the care leading up to the amputations. The report should ideally be forwarded to commissioners of services if they are involved in commissioning the RCA's.

Step 4 - Recommendation generation and implementation.
The next step is the generation of recommendations. Following identification of the root causes for a particular causal factor, achievable recommendations for preventing its recurrence are then generated.
Please see Appendix 3 for example of summary template and action plan

Appendix 1 (related to step 1)

GP practice level investigation

Diabetic foot checks at practice level - were foot checks undertaken at practice level and was any information offered to the patient on risk status of the foot and appropriate education.

- Was the patient told of their risk classification?
- Is there a standard operating procedure for diabetic foot examination at annual diabetic review?
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- Was this individual known to podiatry prior to this episode?
- If so were they under regular podiatry review?
- When this individual first presented with a foot wound how long until presentation to foot team?
- Did referral on classification of an increased risk foot occur?
- Did the patient get referred quickly when they were determined to be at risk of diabetic foot ulceration?
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- Were prevention strategies employed to prevent ulceration?
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- Was vascular and neurological status checked at visit and was the patient educated about risk factors such as smoking etc.
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- Had podiatry undertaken vascular assessments and neurological assessments according to NICE guidance?
- Was the patient seen with a frequency appropriate to need?
- Had the patient been offered diabetic foot education or advice?
- Were signs of deteriorating foot ulcers recognised and onward referrals made promptly

Hospital level investigation

Once a patient developed foot ulceration or foot problems did the patient receive appropriate and timely interventions to address vascular factors, infection, offloading appropriate debridement, dressings and care. Did this comply with NICE compliant services and recommended NICE guidance?

- If the patient was not under the care of the foot protection team and they ulcerated or developed a wound was the patient then referred promptly within 24 hours to a member of the foot protection team?
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- Was this pathway for offloading intervention smooth and timely?
- Did the patient receive education on risk to foot health and how to prevent foot problems and how to access help if needed?
- Were risk factors documented such as blood supply to foot and neurological status
- On development of ulceration did a prompt referral to a member of the foot protection team occur?
- What were the measurements of time to referral?
- Was infection recognised and did the patient receive appropriate antibiotics?
- Time to receipt of antibiotics.
- Were X-rays undertaken to look for bone infection osteomyelitis and charcot-arthropathy in chronic wounds or wounds that probed to bone or delayed healing occurred?
- If the patient had neuropathy was this recorded and risk of Charcot foot addressed to prevent injury and foot deformity.
- Did the patient have vascular investigations, where foot pulses checked? Time to vascular referral for duplex, angiogram and time to vascular for interventions.
- Post-surgical management of the wounds. Was this by a member of the foot protection team and was post-surgical management timely and appropriately delivered by staff with relevant knowledge and skills in the treatment of diabetic foot.
- Was the patient seen by a member of the foot protection team with appropriate skills for the care of the reaming limb post amputation?
- Was the amputation avoidable/ unavoidable?

Appendix 2- related to step 2

A) Data base headers

NHS Number Gender Age Type DM Smoker Occupation
Where and when presented with defining problem Time GP referral to podiatrist appointment practice annual review pod referral when high risk
Mobility position sensation pulses HbA1c CRP Egfr
date presentation of ulcer date healed classification time present to MDT time present to offloading time present to antibiotics x-ray duplex angiogram angioplasty Vascular surgery involvement Orthopaedic surgery involvement

B) Chronology Template

Incident Number.	
STEIS Reference Number.	
NHS or ID number, if available, of person who the Incident relates.	

Patient's GP Practice.	
Date/Time/Location of the incident.	
Date patient admitted to ward/ onto district caseload.	
Incident Type.	
Diagnosis if relevant to the Incident.	
Name and job role of person completing the Chronology.	

Event date & Time	**Event- what actually happened**	**Missing information/gaps**	**Good practice identified**	**Problems identified**
Additional Comments and Information.				

Summarise by looking at the Possible Causative Factors

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Task Factors –
Communication Factors –
Team & Social factors –
Education & Training –
Equipment and resource factors –
Working condition factors –
Organisational & Management factors-

C) Documentation table

Outcome measure	**Evidence of documentation**		
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Time to arrange investigations	radiology	vascular	bloods
Time to intervention	debridement	revascularisation	amputation
Summary of presentation and care plan	Full letter	Summary sheet in notes	Patient and carers copied in
Evidence of integrated care pathway	GP letter	Referral to podiatry	referral to MDT

Appendix 3- related to step 4

Action plan
• **Brief incident description:** • **Incident date:** • **Incident type:** • **Healthcare Specialty:** • **Actual effect on patient and/or service:** • **Actual severity of incident:**
Level of investigation conducted
Involvement and support of the patient and/or relatives
Detection of the incident
Care and service delivery problems
Contributory factors
Root causes
Lessons learned
Recommendations
Arrangements for sharing learning

Recommendation	Action	By When	By who	How we will know improvements have been made

NHS England

South West Cardiovascular Clinical Network

DEPARTMENT OF ORTHOTICS AND PODIATRY
FOOT ULCER CARE PATHWAY

Please use the foot ulcer care pathway for every patient that presents with a new foot ulcer with or without diabetes.

Attach PAS label (or fill in patient details)
Name: _____
NHS No: _____
Date of Birth: _____/_____/_____

Date:
Date of ulcer presentation:

Location:

Classification:

Neuropathic	
Ischaemic	
Neuro-ischaemic	
Pressure sore	
Surgical wound	
Other	


Right Foot Dorsum


Right Foot Plantar


Left Foot Plantar


Left Foot Dorsum

MEDICAL HISTORY

Diabetes	Type 1		Type 2		Years since diagnosis		
Angina			Asthma/COPD		Previous CVA		
Heart Failure			Hypertension		PVD		
Retinopathy			Renal Impairment		Rh A		

MEDICATION LIST- *Please include current and previously prescribed and non-prescribed medicines, supplements and complimentary remedies, and allergies and intolerances*

Allergies:

Name:…………………………………………………NHS No:…………………………………….

Haemoglobin A1c:		**eGFR:**		**Cholesterol:**	

NEUROVASCULAR ASSESSMENT

Smoking History:				
Palpable	RIGHT		LEFT	
	Dorsalis pedis	Posterior tibial	Dorsalis pedis	Posterior tibial
Doppler	Monophasic	Monophasic	Monophasic	Monophasic
	Biphasic	Biphasic	Biphasic	Biphasic
ABPI	Brachial		Brachial	
	DP		DP	
	ABPI		ABPI	

Name: _____ NHS No: _____

10g Monofilament	/ 5	/ 5

TEXAS WOUND SCORE

	0	1	2	3
A	Pre or post ulcerative lesion completely epithelialized	Superficial wound, not involving tendon, capsule or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	Infection	Infection	Infection	Infection
C	Ischaemia	Ischaemia	Ischaemia	Ischaemia
D	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia	Infection and ischaemia

If a heel pressure sore: SSKIN:

EPUAP Grade:		Waterlow Score:	Surface:	MUST Score:	
Wound measurements:			Skin:		
Wound bed:			Keep the patient moving:		
			Nutrition and hydration:		

INVESTIGATIONS

Swab for C + S:		Bloods:	
X-ray:		Photograph:	

ANTIBIOTICS *(Please detail the name, duration and strength of antibiotics prescribed)*

OFFLOADING

CURRENTLY USING PRESCRIPTION FOOTWEAR YES / NO

SHORT TERM TREATMENT PLAN TO INCLUDE RATIONALE FOR DRESSING CHOICE

Shared care with district nursing team: Yes/No (*If yes, ask patient to bring in folder)*

LONG TERM TREATMENT PLAN

Name: _____ NHS No: _____

At every visit consider if the wound is improving or deteriorating and take appropriate action. Review the **SHORT TERM** and **LONG TERM TREATMENT PLAN** every three months.

Northern, Eastern and Western Devon
Clinical Commissioning Group

Healthcare Associated Infections Team
Northern, Eastern and Western Devon Clinical Commissioning Group
Crown Yealm House
Pathfields Business Park
South Molton
Devon
EX36 3LH

Dear Patient

Diabetic Foot Amputation Review

We are writing to you from the Healthcare Associated Infections team at Northern, Eastern and Western Devon Clinical Commissioning Group. The Clinical Commissioning Group is responsible for buying healthcare services on behalf of the population of the local area.

We are sorry to hear you have recently undergone an amputation. The Clinical Commissioning Group is currently investigating the pathways of care that patients with diabetes like you have to an outcome of amputation. We are trying to understand if there is anything we can change in the future to reduce the chances of this happening to others.

In order to carry out the investigation we would like to look at your medical records. Although we are part of the NHS we do not automatically have the right to access your records and therefore we are requesting your consent for this purpose. We would like to assure you that we treat all communication into the organisation in a confidential and sensitive manner and in line with the Data Protection Act 1998. If you have any concerns about how we may use your information please do not hesitate to contact us for a copy of our ***Your information: patient information leaflet***, which is also available to download from our website http://www.newdevonccg.nhs.uk/who-we-are/information-gove+rnance/100094

If you agree to the Clinical Commisioning Group looking at your records for the purpose of investigation of this amputation please complete and return the consent slip below in the envelope provided.

Please do not hesitate to contact us on 01769 575161 or 01392 267873.

Andrew Kingsley & Alastair Harlow
Healthcare Associated Infections Team

Express Consent for the purpose of Post Infection Review investigations

…… (patient name in BLOCK CAPITALS) give express consent for Northern, Eastern and Western Devon Clinical Commissioning Group to access my medical records for the purpose of investigating amputation. I understand the information will be treated in the strictest confidence and in accordance with the Data Protection Act 1998.

Signed: ……..

Date: ……..

Chair: Dr Tim Burke
Chief Officer: Rebecca Harriott

Newcourt House, Newcourt Drive, Old Rydon Lane, Exeter, EX2 7JQ
Tel. 01392 205205
www.newdevonccg.nhs.uk

Northern, Eastern and Western Devon Clinical Commissioning Group

Healthcare Associated Infections Team
Northern, Eastern and Western Devon Clinical Commissioning Group
Crown Yealm House
Pathfields Business Park
South Molton
Devon
EX36 3LH

GP Name
Address

Dear Colleague

Re: Diabetic Foot Amputation case review
Name of Patient – DOB of patient – NHS No of patient

As you may be aware, there is currently a CQUIN active in NEW Devon CCG regarding diabetic foot amputations. These need to be investigated to determine root causes and identify actions to reduce the risk of further cases happening.

In order to undertake the investigation we will require access to your patient's medical records. To comply with Information Governance principles we have produced the enclosed pro forma which we would be grateful if you could forward to your patient for completion and return.

Once we have received consent we will forward a copy to you and arrange for access to the medical records.

If you have any questions, please do not hesitate to contact us.

Yours sincerely

Andrew Kingsley
HCAI Lead Nurse
andrew.kingsley@nhs.net
01769 575161

Alastair Harlow
HCAI Support Officer
aharlow1@nhs.net
01392 267873

South West Cardiovascular Clinical Network

Significant Event Audit checklist for diabetic foot amputations

Major amputations

Patient factors:-

Arterial disease history – patient or family?

Neuropathic disease history?

Were blood pressure and cholesterol well controlled in the recent preceding years?

Was medication required?

Smoking history?

If yes were there any attempts at smoking cessation?

Was weight within acceptable BMI range?

If no were any control interventions attempted?

Diabetes history – type 1 or 2?

If yes:-

how long has the patient been diabetic?

was blood sugar control effective in the recent preceding years?

had the annual foot checks been undertaken and were any abnormalities identified?

If yes had there been any specialist referrals, such as podiatry, vascular etc?

How was concordance with treatments?

Had there been any prior minor amputations?

System factors

1. Is there a standard operating procedure for diabetic foot examination at annual diabetic review?
2. Are all members of staff undertaking the diabetes annual foot check trained to examine and record risk status?
3. Is each patient advised about foot care at each annual review?
4. Does the practice have written foot care information for patients at diabetic annual review?
5. Is every patient at high risk of diabetic foot ulceration referred to community podiatry for regular review?
6. Is the practice conversant with pathways for referral of high risk and ulcer patients to podiatry and secondary care?
7. Are communications from community podiatry and secondary care for diabetic foot patients adequate?

NHS England South – South West

Primary Care Serious Incident 48 Hour Notification Form

(this form may also be used to report SEAs)

The purpose of this form is to comply with national guidance and enable timely information sharing and facilitate learning from Serious Incidents Requiring Investigation and Significant Event Audits in Primary Care. Please complete this form with as much detail as possible.

Please email your form to england.devcorn-incidents@nhs.net , **or for non NHS email accounts fax to: Safe Haven Fax - 01752 841589.**

DO NOT INCLUDE PATIENT IDENTIFIABLE INFORMATION OR THAT OF INDIVIDUALS OTHER THAN THOSE OF THE REPORTER FOR COMMUNICATION PURPOSES.

After reading the 'How to' guide, in your opinion is this incident a Significant Incident Requiring Investigation (SIRI) or a Significant Event Audit (SEA)?

SIRI ☐ **SEA** ☐

When, Where and Your Details

Type of Incident: *(Please see appendix for list of Incident types)* **If Other, please specify:**	**Reporting Organisation:**
Date of Incident:	**Reporter Name:**
Time of Incident:	**Reporter Job title/Role:**
Location of Incident:	**Reporter Tel No:**
Date Incident Identified:	**Reporter Email:**
Name of other Organisations Involved (where relevant): *eg: Hospital, Ambulance Service, OoH, Care Homes, Mental Health Services, Police, etc.*	
Care Sector: *eg: General Practice, Dentistry, Pharmacy, Optometrists, Other. If Other please specify.*	

Patient Details *This information should only be supplied if this form is transmitted via a secure transmission – NHS.Net email account or a safe haven fax – please do not include patient name or other patient identifier.*

Patient Date of Birth:	**Patient Gender:**
Patient Registered GP Practice:	**Patient Ethnic Group:**
Patient NHS Number:	

What Happened?

Description of What Happened including how the SI/SEA was identified:
Immediate Action Taken:
Any Further Information:
Details of any Police, Media Involvement/Interest:
Please indicate which other organisations have been notified? ☐ **CQC** ☐ **IG Toolkit** ☐ **HSE** ☐ **MHRA** ☐ **NRLS** ☐ **CCG**
Details of contact with or planned contact with patient/family or carers:

Learning Outcomes:

What lessons might be learned and shared with others?
Have you identified any factors you are not in a position to change?

ACTION POINT	WHO	BY WHEN

What impact or potential impact did the event have on the patient?

Apparent Outcome of Incident: *Please describe:* *Please categorise significance/potential significance (tick A for actual harm and P for potential harm) Definitions of harm can be found in the National Framework.*				
None	**Low Harm**	**Moderate Harm**	**Severe Harm**	**Death**
P **A**	**P** **A**	**P** **A**	**P** **A**	**P** **A**
Likelihood of Reoccurrence: ***Before reviewing this event*** **–** *Please attempt to assess the likelihood of a similar event happening again.*				
Almost certain	**Likely**	**Don't know**	**Unlikely**	**Rare**

This form should be completed and sent to us within 48 hours of first identification of the incident. Email your form to england.devcorn-incidents@nhs.net**, or for non NHS email accounts fax to: Safe Haven Fax - 01752 841589.**

Appendix

Type of Incident List

- Access, admission, transfer, discharge
- Adverse media coverage or public concern about the organization or the wider NHS
- Bogus health workers
- Clinical assessment (including diagnosis, scans, tests, assessments)
- Consent, communication, confidentiality
- Death on GP premises
- Delayed Diagnosis
- Disruptive, aggressive behavior
- Documentation (including records, identification)
- Environment and Infrastructure
- Infection control incident
- Medical device/equipment

- Medication
- Patient abuse (by staff/third party)
- Patient accident
- Pressure Ulcer Grade 3 or 4
- Safeguarding issues (including Child Abuse, Child Death & Safeguarding Vulnerable Adult)
- Self-harming behavior (including Suicides)
- Surgical Error (including Wrong site surgery)
- Treatment, procedure
- Unexpected Death
- Other

Northern, Eastern and Western Devon
Clinical Commissioning Group

GP SEA lower limb major amputations proforma

The definition of a lower limb major amputation is a below knee or above knee amputation. People with diabetes are likely to feature strongly in this group but will not be alone.

The All Party Parliamentary Group on Vascular Disease in their 2014 report Tackling Peripheral Arterial Disease More Effectively: Saving Limbs, Saving Lives note that '*in 2012-2013, there were almost 12,000 lower limb amputations in England, a figure that remains stubbornly high year on year. The vast bulk of these lost limbs were related to Peripheral Arterial Disease and Diabetic Foot Disease. Amputation is TWICE AS LIKELY for patients in the South West as in London.*'

http://appgvascular.org.uk/media/reports/2014-03-tackling_peripheral_arterial_disease_more_effectively__saving_limbs__saving_lives.pdf

It is likely that some of these major amputations are 'avoidable' and therefore to reduce their number across the whole healthcare system, investigation to identify root causes and learn lessons is necessary.

NICE guidance relating to this issue is:

1. Type 2 diabetes foot problems: Prevention and management of foot problems; Issued: January 2004 last modified: December 2014; NICE clinical guideline 10; guidance.nice.org.uk/cg10

2. Peripheral arterial disease: Issued: January 2014. NICE quality standard 52; guidance.nice.org.uk/qs52

3. Diabetic foot problems: Inpatient management of diabetic foot problems; Issued: March 2011; NICE clinical guideline 119; guidance.nice.org.uk/cg119

Notes

- *Please indicate answer by circling, underlining, bolding or deleting as appropriate*

SEA Reporter Name, Job Title & Phone Number		**Patient's Registered GP Practice**	
Patient NHS number (*not* *name*)		**Patient Gender**	
Date Patient added to		**Date SEA**	

Practice Register		**conducted**	

Arterial disease history				
Patient:				
Family:				
Neuropathic disease history				
Physiological controls – blood pressure and statins				
BP	Range	Management	Cholesterol	Statins prescribed
3rd year before amputation				Yes / No
2nd year before amputation				Yes / No
the year before amputation				Yes / No
Smoking				
3rd year before amputation	Yes / No	Quantity: >20 cigs per day/ <20 >5 / <5 / Other (specify):		
2nd year before amputation	Yes / No	Quantity: >20 cigs per day/ <20 >5 / <5 / Other (specify):		
the year before amputation	Yes / No	Quantity: >20 cigs per day/ <20 >5 / <5 / Other (specify):		
Diet				
3rd year before amputation	BMI:	Weight loss advice: Yes / No Other details:		
2nd year before amputation	BMI:	Weight loss advice: Yes / No Other details:		
the year before amputation	BMI:	Weight loss advice: Yes / No Other details:		
Diabetes history				

Type: Type – 1 / Type - 2	**Date of diabetes onset:**
Date of first presentation to General Practice with a diabetic foot problem:	

Physiological controls – blood sugar *(in 3 years preceding amputation)*	
HbA1c – range in the 3rd year before amputation	
HbA1c – range in the 2nd year before amputation	
HbA1c – range in the year before amputation	

Diabetes complications	
Retinopathy	
Renal disease	
Other (specify)	

Diabetes foot check *(in 3 years preceding major amputation)*

Date of check	**Abnormalities detected**	**Foot risk score recorded**	**Referral made** *(state if refused)*	**Foot care advice documented**
	Yes / No – *If yes* pulse / sensation / deformity	Yes / No – *if yes* score was:	Podiatry/Vascular /Diabetologist Date:	Yes / No
	Yes / No – *If yes* pulse / sensation / deformity	Yes / No – if yes score was:	Podiatry/Vascular /Diabetologist Date:	Yes / No
	Yes / No – *If yes* pulse / sensation / deformity	Yes / No – if yes score was:	Podiatry/Vascular /Diabetologist Date:	Yes / No

Patient focussed issues (concordance with management plan/social isolation/ cognitive impairment etc)

Amputation history

Minor amputations (prior to major) – *specify*:	**Date:**
Major amputations - Below knee / Above knee	**Date:**

Root Cause		
Was this amputation avoidable?		
Yes	No	**Comment:**
Learning from this case (can it be applied to other patients on practice list?)		

Action Plan		
Action	**Action Owner**	**Completion Date**