

HOW TO GUIDE #4

How to: Use root cause analysis to reduce diabetes related amputations

USE THIS GUIDE TO:

- identify who to involve in a root cause analysis and how to involve them
- gather the right data to support a root cause analysis
- learn how to use different techniques to identify the causal factors and root causes of diabetes related amputations
- develop solutions and share your findings.

What is root cause analysis?

Root causes are the most basic, underlying causes of an event that can be reasonably identified.

Root cause analysis (RCA) is the method used to identify root causes. It is a process used to identify what happened, how something happened, and why it happened. By understanding why an event occurred, it is possible to identify areas for change to prevent or significantly reduce the chance that the same event will reoccur for the same reasons.

Why use root cause analysis for diabetes related amputations?

80% of diabetes related amputations are avoidable¹. RCAs can help reduce future amputations by determining to what extent an amputation was avoidable or unavoidable, and whether or not it was the best possible outcome for the person with diabetes. If avoidable, completing an RCA will help identify what changes are required to reduce the likelihood of the same event happening again.

Approaches for root cause analysis

Contemporary² Analysis of lower limb amputations as they occur. Reviews are ongoing and take place in 'real-time'		Retrospective A review of lower limb amputations that occurred during a specific period	
Advantages	Limitations	Advantages	Limitations
Smaller number of cases to review at a time	Necessary to collate results from all reviews annually (at least), and to consider findings of previous RCAs in reviews, to identify recurring themes and identify new solutions	Comprehensive – assessing all amputations at the same time allows for recurring themes to be easily identified	Depending on the number of amputations during the review period, likely to be very time consuming
Less time intensive compared to retrospective approach as less cases to review at one time	Requires ongoing commitment from RCA stakeholder group		Potential difficulties accessing old patient records and other historical data
Easier to access data and overcome any gaps in knowledge or records			Significant amount of time will be spent accessing, collating and analysing data

1 Diabetes UK State of the Nation 2014 report available at: <https://www.diabetes.org.uk/Documents/About%20Us/What%20we%20say/State%20of%20the%20nation%202014.pdf>

2 You may already be conducting RCAs contemporarily as part of Serious Untoward Incident (SUI) or Significant Event Analysis (SEA) reporting processes.

Before starting a RCA

- Discuss your plans with local footcare networks.** These networks can provide support and help share lessons learned from the RCA³.
- Engage commissioners.** Discuss whether any support or funding is available, such as administration or analyst support to help with data collection and analysis.
- Identify the current information reporting system for amputations.** For community and acute care, this is likely to be as part of the incident reporting system. In primary care, this is likely to be reported as part of practice level data. If there is no system in place, encourage commissioners to ask Trusts and practices to report all diabetes related amputations as an incident or adverse event. This will provide the list of amputations to review.
- Engage the Trust's Clinical Governance team.** Discuss how they can support the RCA, for example by monitoring RCA recommendations as part of the Trust's risk management procedures.
- Agree how to report the findings back to the Trust and CCG.** It is likely this will be via the local incident reporting system.



Duty of candour

All providers have responsibility to follow duty of candour regulations, as per the Health and Social Care Act 2008⁴. This includes having a method to notify patients about any investigations to their care and if the outcome was avoidable or unavoidable. It is good practice to involve the patient in an RCA to get their opinion about the experience and care given, and for the person leading the investigation to lead correspondence with the patient⁵.

Who to involve in a RCA?

To get a full picture of what led to the amputation, involve primary, secondary and community services. If any of these services are not involved, you are less likely to understand all the events that led to the amputation.

Before starting, form a group to oversee the RCA process. Seek support from the different services and get key individuals to commit to becoming members of the RCA group. It is likely that most members of the RCA group will be members of the multidisciplinary foot care service (MDFS)⁶.

³ More information on how to deliver successful local networks is available at: www.diabetes.org.uk/Professionals/Resources/shared-practice/Networks/

⁴ Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.

More information is available at: www.cqc.org.uk/content/regulation-20-duty-candour#guidance.

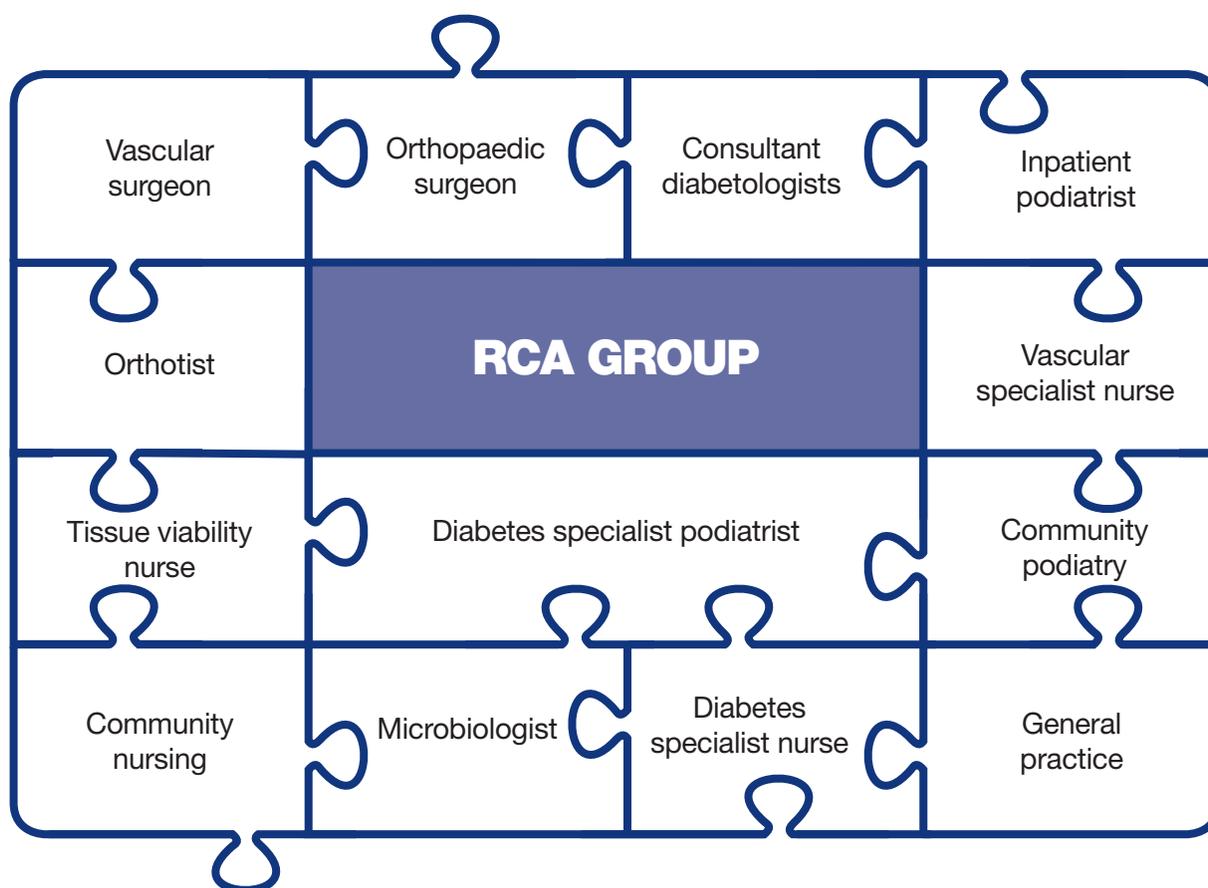
⁵ An example patient information sheet and consent form can be found in the South West Cardiovascular Strategic Clinical Network Diabetes Foot Care Resource Pack available at: www.swscn.org.uk/wp/wp-content/uploads/2016/04/Diabetes-Foot-Care-Resource-Pack-April-2016.pdf.

⁶ See glossary on page 11 for a definition.

Ensure people in the RCA group:

- have prior knowledge of diabetic foot disease
- understand what good referral pathways look like⁷
- can determine if the patient followed the appropriate pathway and received the correct intervention at the right time
- have knowledge of the factors that can contribute to an amputation
- are aware of the available interventions for the different complications that may arise.

Once you have formed the RCA group, agree who will lead the RCA process. It is useful if this person has clinical authority, for example the clinical lead, so they can drive the RCA forward, lead the delivery of recommendations and hold people to account for agreed actions.



⁷ See NICE Guideline 19: Diabetic foot problems: prevention and management available at: <https://www.nice.org.uk/guidance/ng19>. Also refer to local pathway documents and the multi-disciplinary care pathway for diabetic foot problems: www.diabetes.org.uk/Upload/030416%20DiabeticFoot%20FINAL%20pdf.pdf.

Completing an RCA

Step 1: Plan

Meet with the RCA group and agree:

- The type of amputations to review – major, minor, or both.
- Whether to conduct RCAs contemporarily or retrospectively.
 - If retrospective, the period to cover.
 - If contemporary, how often and when reviews will take place. Monthly reviews will help limit RCA workload from building up too much.
- Who will be responsible for collecting the data – will one person collect all the data, or will members of the RCA group collect the data relevant to their service?
- The fields or questions you want to include in the data collection form (see step 2). It is recommended that, as a minimum, the RCA is able to answer the following:
 - If the patient was known to be high risk.
 - Whether the patient was known by the community podiatry service, foot protection service⁸, or footcare provider.
 - The initial cause of the problem that led to the amputation.
 - If NICE Guideline 19 was followed.
 - If the patient received prompt offloading.
 - Whether the patient received prompt and appropriate antibiotics therapy for any infected wounds.
 - If there was prompt MDFT referral.
 - If the patient received timely vascular intervention.
- How progress and learning will be shared across services. Consider existing and new communication channels (e.g. GP bulletins, staff bulletins, staff engagement events).
- How often the group will meet and how RCA members will communicate between meetings.
- How patients, carers and/or families will be involved in reviews.

TOP TIP
If conducting contemporary RCAs, review and refine the questions in the data collection form annually to ensure only necessary data is being collected.

TOP TIP
If using a contemporary approach, hold the review meeting in the same place at the same time each month so it becomes routine.

⁸ See glossary on page 11 for a definition.

Step 2: Collect data

When completing an RCA, the majority of time is spent collecting data⁹. Create a form or template to guide data collection using the questions the RCA group agreed on in Step 1. See Appendix 1 for an example template for secondary care reviews and Appendix 2 for an example template for primary care reviews. For a list of points and questions to investigate across each service visit: www.diabetes.org.uk/shared-practice-footcare.

Data can come from:

- GP
- Practice records
- Community podiatry records
- Community nursing
- Hot foot clinics, or podiatry clinics within hospital setting
- Inpatient records
- Orthotist records
- Outpatient records
- Clinical codes
- National Diabetes Foot Audit (NDFA)

There may be barriers to accessing data from different services, particularly if different IT systems are used. If this occurs, discuss issues and potential solutions with the RCA group and commissioners, if involved.



CASE STUDY

In Torbay, the RCA group are unable to access patients' primary care records. To overcome this, they call the relevant GP to get a personal account of a patient's history to ensure this part of the pathway can be considered in their analysis.

Compare local amputation lists to the national vascular registry¹⁰. This will allow you to identify any amputations missed on local amputation lists and help ensure RCAs are being conducted on all diabetes related amputations.

TOP TIP



RCAs and primary care

In Bristol, the CCG funded a practice nurse clinical lead to conduct primary care based RCAs. This involved reviewing the GP electronic records of patients to understand the footcare procedures followed prior to secondary care presentation. This allowed for system gaps to be identified and solutions to these gaps to be developed with the goal of reducing footcare emergencies and amputations. By clearly communicating the benefits of the reviews before and during meetings, all practices were fully engaged with the reviews. Individual practices were provided with the findings of their review, and a general report was submitted for wider public circulation.

⁹ James J. Rooney and Lee N. Vanden Heuvel. (2004). Root Cause Analysis for beginners. Available at: <http://asq.org/quality-progress/2004/07/quality-tools/root-cause-analysis-for-beginners.html>

¹⁰ For more information visit: www.vsqip.org.uk

FOCUS POINT

National Diabetes Foot Audit (NDFA)

Participating in the NDFA will help make the RCA process less time consuming, as much of the RCA data will already be collected as part of the NDFA. The NDFA will also allow you to measure whether there are improvements year on year. The current NDFA gives you a baseline of ulcers and by monitoring these it will be possible to see if the changes made as a result from the findings of the RCA are having a positive impact on patient outcomes. All clinical outcomes will be included in the next round of NDFA analysis. Analysis on minor and major amputations will form part of this.

Step 3: Chart causal factors

As soon as you start collecting data, begin mapping the sequence of events leading to the amputation (see chronology template in Appendix 3). This will allow you to organise the information to understand what happened and when. Review this information to identify the causal factors – the factors or events that, if improved or eliminated, would have prevented, delayed or reduced the likelihood of the diabetes related amputation occurring.

Example causal factors

<p>Patient factors</p> <ul style="list-style-type: none"> Non-compliance with smoking advice Poor compliance with foot wear Compliance with treatment plan Other disease factors impacting their diabetes Failure to attend appointments 	<p>Task factors</p> <ul style="list-style-type: none"> Staff did not have the right skills Services were not accessible or at the right time and place Standards of GP practice foot checks Too many people involved in the care of the patient causing conflicting opinions 	<p>Communication factors</p> <ul style="list-style-type: none"> Poor records of shared care plan Poor communication of best practice pathway Care or discharge plans did not include appropriate referrals to services Accessibility and integration of IT systems Communication between different members of MDFS
<p>Team and social factors</p> <ul style="list-style-type: none"> MDFS skill mix Capacity of community services Patients not referred in timely manner Understanding the chronicity of wound Onward referral in timely fashion Delay from referral to being seen 	<p>Education and training factors</p> <ul style="list-style-type: none"> Patients unaware of facts about risk Wider team's knowledge of pathways, foot classification, and when to escalate Skills and competency of teams involved in the care Availability of education resources Knowledge of deteriorating wounds Pathway compliance 	<p>Equipment and resource factors</p> <ul style="list-style-type: none"> Capacity of community services Availability and suitability of dressings Access to offloading devices and orthotic services Availability of staff to treat high risk within 24 to 48 hours
<p>Working condition factors</p> <ul style="list-style-type: none"> Compliance with inpatient pathways IT systems Having members of the MDFS available when needed Timely pathways Protocols for interventions, such as antibiotics, imaging, casting and swabs 	<p>Organisational and management factors</p> <ul style="list-style-type: none"> MDFS skill mix – representation of suitable areas Availability and accessibility of inpatient services across acute and community orthotics services 	

Step 4: Identify the root cause

Identifying causal factors is a great start. But to understand what improvements can be made to reduce the likelihood of another amputation occurring for the same reasons, it is essential to find the underlying reason (root cause) for each casual factor.

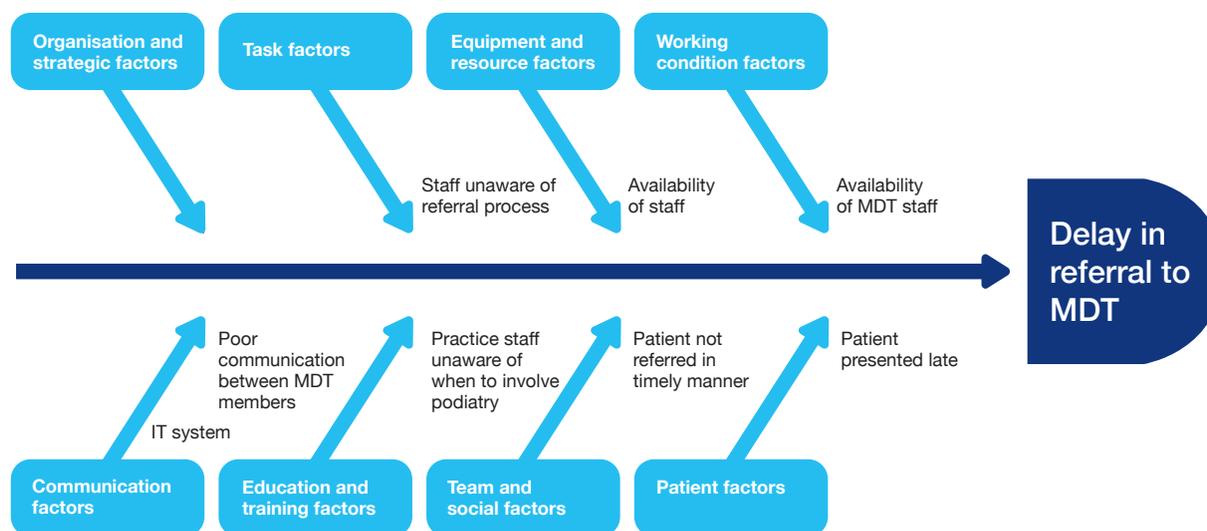
There are various root cause analysis techniques available¹¹. Some examples include:

Cause and effect (fishbone) technique

The cause and effect technique explores the problem or issue by breaking it down to identify all possible causal factors that relate to it. To complete this process:

1. Draw a skeleton of a fish and write the problem to be analysed in the head of the fish.
2. Label each branch of the spine with a broad theme that causal factors are likely to fall in. The example below gives the themes developed by National Patient Safety Agency (NPSA) for healthcare organisations. Alternatively, ask the RCA group to label the branches with themes relevant to the problem.
3. As a group, review each theme and identify all causes that led to the problem. Plot these causes on the branches of the spine. Use the information from the previous steps to help identify causes. Focus on one theme before moving on.
4. Analyse the fishbone diagram and identify the theme with the most causal factors. This theme is likely to be the root cause as it is likely to have more impact than the other themes.

Example cause and effect diagram



¹¹ For more tools and techniques see the Healthcare Quality Improvement Partnership guide 'Using root cause analysis techniques in clinical audit' available at: www.hqip.org.uk/resources/using-root-cause-analysis-techniques-in-clinical-audit/

Change analysis technique

This process identifies divergence from best practice by comparing what did happen against what should have happened. To complete this process:

1. Map the best practice process using local pathways models and NICE guidelines.
2. Compare what actually happened against the best practice model. Identify and list the areas where best practice was not followed (divergence).
3. If more than one divergence exists, prioritise them so that the one that had the greatest impact is focussed on first.
4. Assess the divergence to understand why best practice was not followed. Identify what changes or new procedures need to put in place to ensure similar divergences do not occur again.

Example change analysis table

Process under review: Patient presents late with foot ulcer						
	Best practice	Actual practice	Was there divergence (y/n)	Did the divergence lead to sub-standard care (y/n)	Priority to address	Changes required
Step 1	Annual foot check completed	Last foot check missed as didn't receive reminder	Yes	Yes	3	Send appointment reminder via letter and text message
Step 2	Patient checks feet and shoes outside of annual foot check	Patient has family member check feet, but socks not removed	Yes	Yes	2	Information packs on how to complete foot checks provided at annual checks
Step 3	Patient knows to take notice of any loss of feeling in feet	Patient did not notice loss of feeling in feet	Yes	Yes	1	Review patient education at annual foot checks to ensure this is discussed. Ensure local diabetes education programmes include a section on looking after your feet.

Five whys technique

The basic premise of this simple technique is to ask 'why?' enough times to get to the root cause. It may take more or less than five whys to get to the root cause.



Step 5: Develop solutions and an action plan

Once you have identified the root cause, work with the RCA group to identify suitable solutions and actions to prevent this from happening again. As a group, agree who will be responsible for taking ownership of relevant actions.

In the previous five whys example, solutions could include reviewing locally offered training, or requesting all practice nurses completing foot checks to undertake foot check training as part of their annual Continuing Professional Development (CPD).

The person leading the RCA group is responsible for monitoring actions to ensure they are implemented as agreed. Having actions as a fixed agenda item for RCA meetings can help support this monitoring process.

Step 6: Report

The purpose of reporting is to share the findings of the RCA with all services who were involved in the lead up to the amputation, as well as commissioners, if involved. Include in the report a description of the incident, a summary of how patients, carers or families were involved in the review, the causal factors, root cause, lessons learned, and actions needed to prevent similar incidents.

Reporting can include traditional formal reports and presentations, or informal channels such as staff bulletins. See Appendix 4 for an example reporting and action plan template.

Do's and Don'ts of RCA for diabetes related amputations

- ✓ **DO** involve the person who has had a diabetes related amputation, and their carer or family, wherever possible.

- ✓ **DO** inform commissioners and seek their involvement and support.

- ✓ **DO** monitor agreed actions.

- ✓ **DO** start completing RCAs as soon as possible. They will help identify areas for improvement that will help reduce diabetes related amputations.

- ✗ **DON'T** conduct an RCA in isolation. Involve primary, secondary and community services to get a full picture of the events that led to the amputation.

- ✗ **DON'T** focus the RCA on one service. Areas for improvement will be identified in each service at different times.

- ✗ **DON'T** underestimate the support local foot care and diabetes networks can provide. Link with these networks to share learning, problem solve, identify trends and support each other to improve services across regions.

Glossary

The multidisciplinary foot care service (MDFS) – sometimes referred to as the multidisciplinary footcare team (MDFT), should be led by a named healthcare professional, and consist of specialists with skills in the following areas:

- Diabetology
- Podiatry
- Diabetes specialist nursing
- Vascular surgery
- Microbiology
- Orthopaedic surgery
- Biomechanics and orthoses
- Interventional radiology
- Casting
- Wound care

The MDFS should have access to rehabilitation services, plastic surgery, psychological services and nutritional services.

Foot protection service – this service should be led by a podiatrist with specialist training in diabetic foot problems, and should have access to healthcare professionals with skills in the following areas:

- Diabetology
- Biomechanics and orthoses
- Wound care

Appendix 1: Data collection template¹²

Hospital number	
Postcode	
Gender	M F
GP practice	
Date and type of admission	
Date of discharge	
Date of amputation	
Type of amputation	BKA TKA AKA Other:
Left or right limb amputated?	
Time interval (days) between foot problem developing and major amputation	
What was the site of the index/ main ulcer?	Digit Forefoot Midfoot Heel
Was a SINBAD score assigned to the ulcer when it was first identified?	Yes / No
If yes, what was the score?	

¹² This example data collection form has been provided by the Northern Diabetes Footcare Network.

Dialysis	Yes / No
Is neuropathy present?	Yes / No / Unsure
Charcot disease	Yes / No
Was the patient seen by the diabetes foot care service within six months prior to major amputation?	Yes / No
Were foot pulses examined and the result recorded within 24 hrs?	Yes / No
Was there at least one palpable foot pulse in the affected limb?	Yes / No
Was a foot x-ray performed within 24h of admission?	
If no, indicate reason	Foot not clinically infected Recent x-ray (within one week) Non-viable foot needing amputation Other (please specify):
Were antibiotics given according to Trust protocol, appropriate cultures or microbiological advice?	Yes / No
Did the patient have any revascularisation during this episode?	Yes (give date): No Angioplasty Bypass Stent

Was the patient seen by a member of the MDFS within 24 hours of presenting with the foot problem?	Yes / No
Which member of the MDFS saw the patient within 24hrs?	Vascular General orthopaedics Foot and ankle surgery Podiatrist Diabetes Consultant MDT N/A
Date, or estimate of time, between patient-reported start of symptoms and first MDFS review (in days)	
First debridement	Date: Service: Vascular/ Foot and ankle surgery/ General orthopaedics Grade: Consistent/ Registrar Procedure: Surgical debridement/ Minor amputation
Second debridement	Date: Service: Vascular/ Foot and ankle surgery/ General orthopaedics Grade: Consistent/ Registrar Procedure: Surgical debridement/ Minor amputation

List any reasonable steps you would have expected but that have not been taken, or any other areas in which care could have been improved	
Did the patient contribute to poor compliance?	Yes / No
Any areas where the footcare pathway or other recommendations were not followed?	
Death in hospital or discharged alive?	
In the view of the multidisciplinary foot care service, could the amputation have been prevented?	Yes / No / Don't know
If yes, how?	
If no, what were the causes of the amputation?	<ul style="list-style-type: none"> Non-reconstruct able arterial disease Patient concordance Overwhelming sepsis Non-viable foot
Additional comments	

Appendix 2: Primary care data collection tool

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 Type 2
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 moderate or 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?

Appendix 3: 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	

(Table continued overleaf)

Appendix 4: Reporting template

REPORT AND ACTION PLAN				
<ul style="list-style-type: none"> • 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

Further resources

- Download example data collection and reporting templates at: www.diabetes.org.uk/shared-practice-footcare
- National Patient Safety Agency training course presentations: www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/rca-training-course-overview/
- NPSA templates and RCA tools and forms: www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/
- Healthcare Quality Improvement Partnership 'Using root cause analysis techniques in clinical audit' guide: www.hqip.org.uk/resources/using-root-cause-analysis-techniques-in-clinical-audit/

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The Resource Pack is available at: www.swscn.org.uk/wp/wp-content/uploads/2016/04/Diabetes-Foot-Care-Resource-Pack-April-2016.pdf.

Some of the information from this guide has been adapted from the following resources:

National Patient Safety Agency. (2011). Root Cause Analysis (RCA) investigation resources. Available at: www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/.

James J. Rooney and Lee N. Vanden Heuvel. (2004). Root Cause Analysis for beginners. Available at: <http://asq.org/quality-progress/2004/07/quality-tools/root-cause-analysis-for-beginners.html>.