National Diabetes Foot Care Audit Report 2014-2016

NHS Digital

England and Wales
14 July 2014 to 8 April 2016

Information and technology
for better health and care

V0.27
7 March 2017

Contents: main body of report

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Introduction

- The National Diabetes Foot Care Audit (NDFA) is a measurement system of care structures, patient management and outcomes of care for people with active diabetic foot disease.
- The NDFA is part of the National Diabetes Audit programme (NDA), commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit Programme (NCA).
- Data on patient care can be submitted from any health care provider treating diabetic foot ulcers. Data on care structures can be submitted from any commissioner.
- Explicit consent to participate is given before any patient data is collected.
- Data is collected on patients and services in England and Wales. Collection started on 14 July 2014.

Prepared in collaboration with:

HQIP
Healthcare Quality Improvement Partnership

NHS Digital

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Why is diabetic foot care important?[1]

- More than 60,000 people with diabetes in England are thought to have foot ulcers at any given time.
- In 2014-15 the annual cost of diabetic foot disease to the NHS in England was estimated at £1 billion, in addition to the personal/social costs of reduced mobility and sickness absence.
- Only around half of people with diabetes who have had a diabetic foot ulcer survive for 5 years.
- Treatment for diabetic foot disease may involve amputation. Around 7,000 people with diabetes undergo leg, foot or toe amputation each year in England.
- The risk of lower extremity amputation for people with diabetes is more than 20 times that of people without diabetes.
- Only half of patients with diabetes who have had an amputation survive for 2 years.

Notes: 1. Adapted from Kerr (2017):
https://www.diabetes.org.uk/Upload/Shared practice/Diabetic footcare in England, An economic case study (January 2017).pdf

Introduction – audit questions

The audit seeks to address three key questions:

1. Are NICE recommended care structures in place for the management of diabetic foot disease[1]?
2. Does treatment of active diabetic foot disease comply with national recommended guidelines?
3. Are the outcomes of diabetic foot disease optimised?

The 2014-2016 audit report:

- Measures against NICE guideline, NG19[1].
- Publishes data at clinical network, commissioner, NHS Trust, Local Health Board and specialist foot care service level[2].
- Includes all ulcer episodes recorded since the audit began (July 2014).
- Reports on outcomes up to 24 weeks for the first time.

Notes: 1. National Institute for Health and Care Excellence (NICE): http://www.nice.org.uk/guidance/ng19
2. Published at http://www.digital.nhs.uk/pubs/ndfa1516. See Glossary (Health Care Providers) for explanation of terms.

Key messages from the 2014-2016 audit

Findings and Recommendations

Key messages

- **Structures**
  - The basic framework for effective prevention and management of diabetic foot disease is often missing.
- **Processes**
  - People with new foot ulcers who get to the specialist foot care service quickly, do best.
- **Outcomes**
  - Six months after first expert assessment one third of people still have unhealed ulcers.

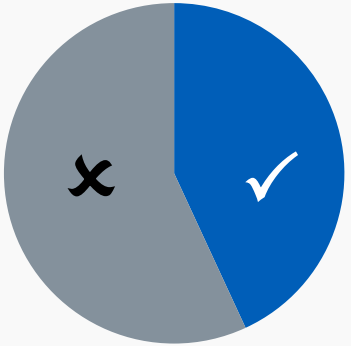
Key findings – Structures

Q. Are the nationally recommended care structures in place for the management of diabetic foot disease[1]?

No: The basic framework for effective prevention and management of diabetic foot disease often seems to be missing.

- Only 54 per cent of commissioners participated in the 2016 NDFA Structures Survey.
- Less than three quarters of responders gave a definitive (yes/no) response to all three survey questions (72 per cent).
- Less than half of responders confirmed that all three care structures were in place (43 per cent).

All 3 structures confirmed?

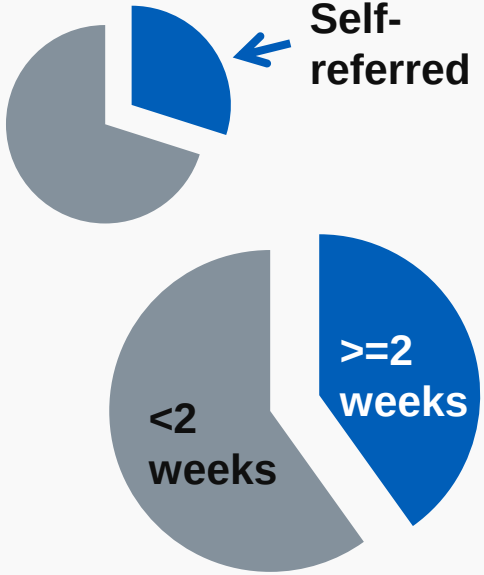


Notes: 1. National Institute for Health and Care Excellence (NICE): http://www.nice.org.uk/guidance/ng19

Key findings – Processes (1)

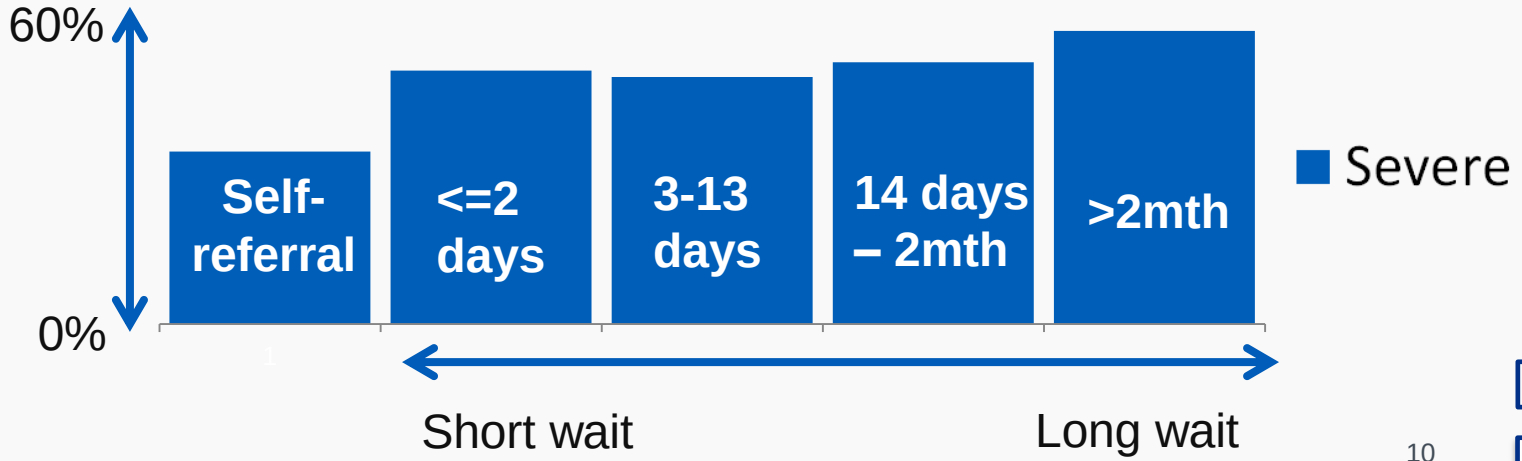
Time to first expert assessment by the specialist foot care service:

- Almost one-third of ulcer episodes were self-referred for expert assessment (30 per cent).
- Excluding self-referral, two fifths of ulcer episodes had an interval of two or more weeks to first expert assessment (40 per cent).



Key findings – Processes (2)

- Self-referring patients[1] were less likely to have severe ulcers (34 per cent).
- Patients not seen for two months or more were most likely to have severe ulcers (58 per cent).

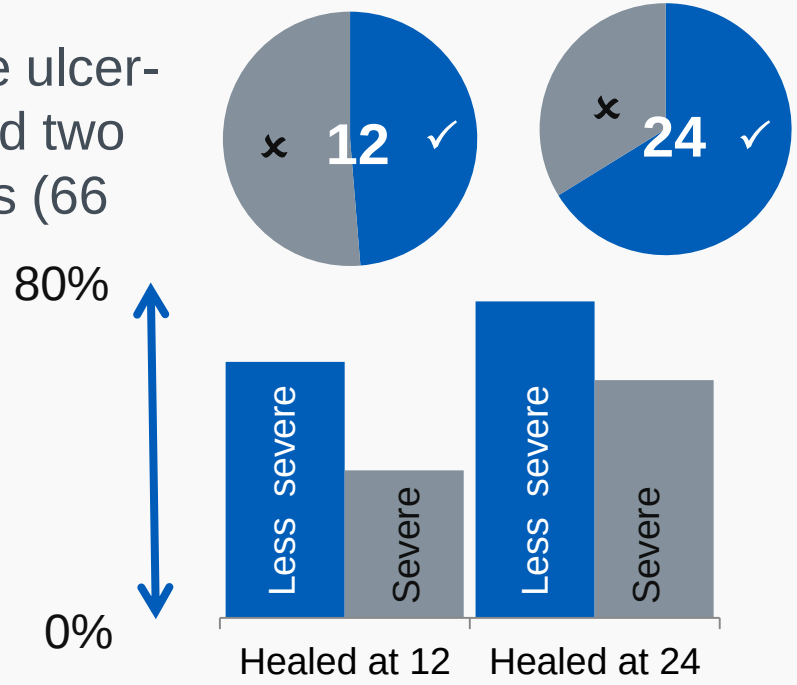


Notes: 1. Caution should be applied when comparing self-referrers against other groups. See slide 37 for further information.

Key findings – Outcomes (1)

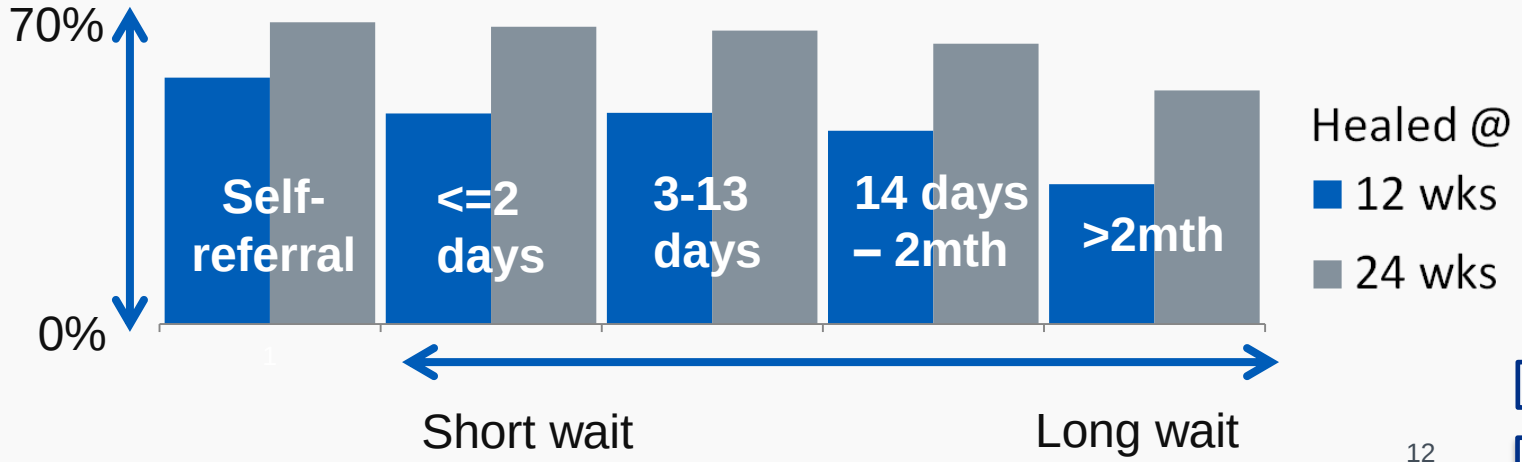
Proportion being ulcer-free at 12 and 24 weeks

- Half of all people with ulcers were ulcer-free at 12 weeks (49 per cent) and two thirds were ulcer-free at 24 weeks (66 per cent).
- People with severe ulcers are less likely to be ulcer-free at both 12 and 24 weeks (35 and 56 per cent).



Key findings – Outcomes (2)

- Patients seen within two weeks had higher rates of ulcer healing than those seen later.
- Self-referring patients[1] had higher healing rates than all other patients after 12 weeks.



Notes: 1. Caution should be applied when comparing self-referrers against other groups. See slide 37 for further information.

Recommendations (1)

For people with diabetes

- If you get loss of feeling (neuropathy) seek advice about how to prevent foot ulcers.
- If you get poor circulation (peripheral artery disease or ischaemia), seek advice about how to prevent foot ulcers.
- If you get a new foot ulcer, seek quick referral to a local specialist diabetes foot care service.

Resources at Diabetes UK will provide you with further information to help with managing your feet and who to contact if you have any of the above concerns: https://www.diabetes.org.uk/Guide-to-diabetes/Complications/Feet/Taking-care-of-your-feet/

Resources for people with diabetes

For people with diabetes: The following resources will provide you with further information to help with managing your feet:

- Taking care of your feet: https://www.diabetes.org.uk/Guide-to-diabetes/Complications/Feet/Taking-care-of-your-feet/
- Everyday foot care: https://www.diabetes.org.uk/Guide-to-diabetes/Complications/Feet/Taking-care-of-your-feet/Everyday-foot-care/
- Foot complications: https://www.diabetes.org.uk/Guide-to-diabetes/Complications/Feet/
- The 'Putting Feet First' campaign: https://www.diabetes.org.uk/putting-feet-first

Recommendations (2)

For healthcare professionals

- Petition Clinical Commissioning Groups and NHS Trust/Local Health Board executives to provide diabetes specialist foot care teams if not already established.
- Create simple and rapid referral pathways.
- Participate in the NDFA to collaborate in this nationwide drive to improve the outcomes for diabetic foot disease.

Recommendations (3)

For commissioners

- Ensure your local services have an easily accessible diabetes specialist foot care team. The South East SCN has prepared commissioning guidance and sample service specification which may help in developing these services[1].
- Ensure that your local diabetes specialist foot care services participate in the NDFA to help improve the disabling, lethal and costly consequences of diabetic foot disease.
- Clinical Commissioning Groups and Local Health Boards should appoint a lead, work with local providers to review services and local care pathways and ensure pathways meet NICE guidelines. They should use the audit findings for the local area to contribute to gap analysis to understand overall NICE compliance across the commissioning area.

Notes: 1. South East Strategic Clinical Networks (2015) Patients with Diabetes Foot Care. Commissioning Guidance and Sample Service Specification: http://www.secn.nhs.uk/files/7414/4127/1172/SE_CVD_SCN_Foot_Care_Commissioning_Guidance_August_2015_v0.5_final.pdf

2016 NDFA Structures Survey

Results and Findings

2016 NDFA Structures Survey – Overview

Audit question: Are the following nationally recommended care structures in place for the management of diabetic foot disease?

- Training for routine diabetic foot examinations[3]
- An established Foot Protection Service Pathway[4]
- An established New Foot Disease Pathway which can allow referral within 24 hours[4]

Why is this important?

"If people with diabetic foot disease are to get the best outcomes, commissioners and service providers[1] should ensure that there are robust protocols and clear local pathways for the prevention and integrated care of all stages of diabetic foot disease."

Stella Vig and Richard Leigh (Co-chairs London Foot Group); Lesley Roberts (Quality & Improvement Manager, Diabetes, London Diabetes Clinical Network)

Key findings

- Only 54 per cent of commissioners participated.
- Only 43 per cent of responders confirmed that all three care structures were in place.
- Only 72 per cent of responders gave a definitive (yes/no) response to all three survey questions.

Recommendation (1)

Commissioners: Participate in the NDFA Structures Survey to collaborate in this nationwide drive to improve the presently dismal outcomes for diabetic foot disease.

Notes:

1. See Glossary (Health Care Providers) for explanation of terms.
2. http://www.nice.org.uk/guidance/ng19
3. Ibid. Recommendation 1.3.3-1.3.7.
4. Ibid. Recommendation 1.2.1

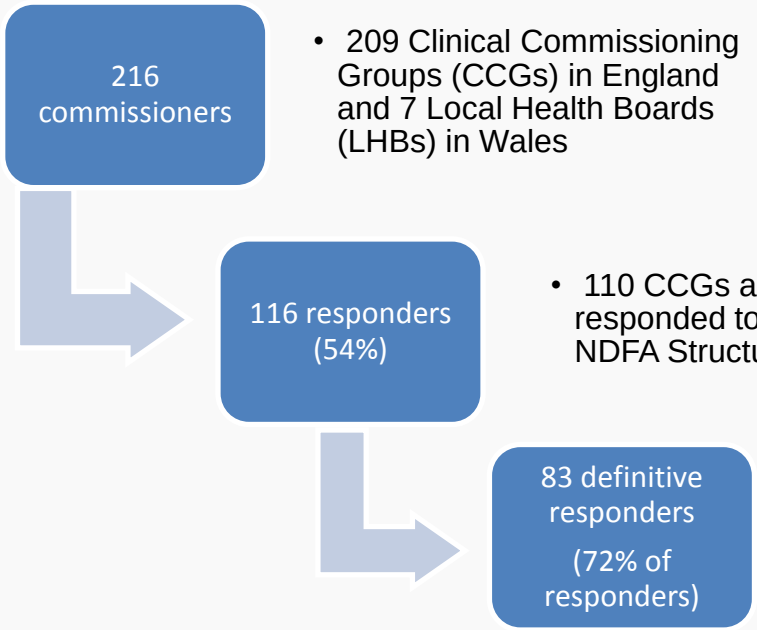
2016 NDFA Structures Survey – Participation

Questions

The 2016 NDFA Structures Survey asked commissioners[1] whether the following NICE recommended care structures were in place:

- A **training** scheme designed to ensure that healthcare professionals have the necessary competence to undertake **routine foot examinations** during annual diabetes reviews[2].
- An established referral **pathway** into a designated **foot protection service** for people identified during annual foot examinations as being at increased risk[2].
- An established **referral pathway** for patients with new, deteriorating or recurrent foot disease to expert assessment **within**, when necessary, **24 hours**[2].

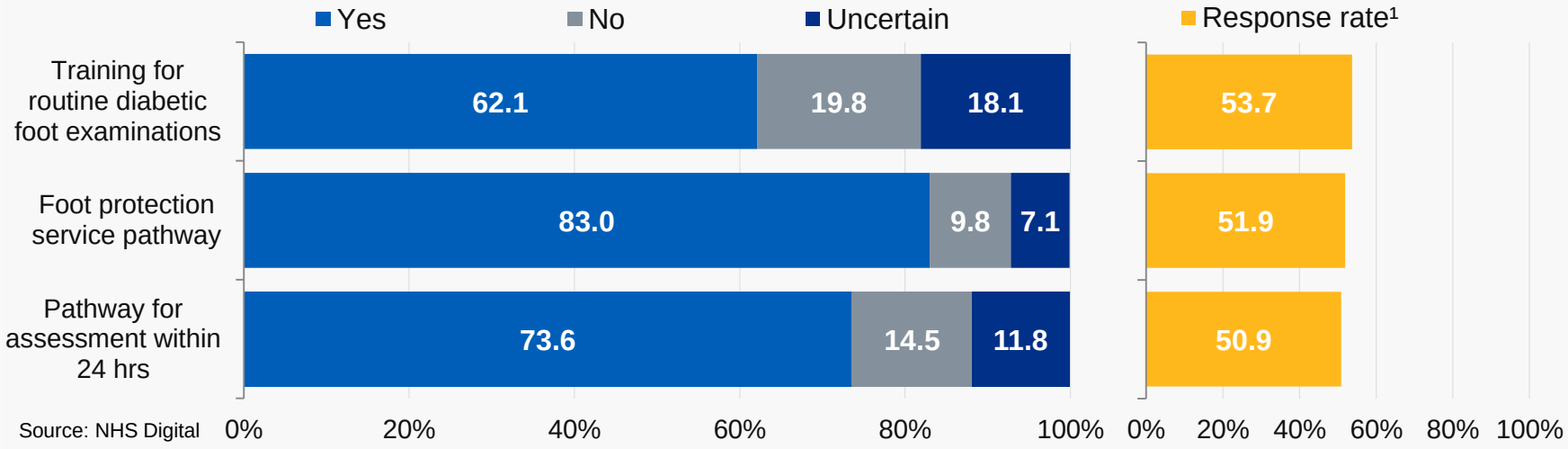
Responses



Notes: 1. See Glossary (Health Care Providers) for explanation of terms.
2. http://www.nice.org.uk/guidance/ng19. Recommendation 1.2.1, 1.3.3-1.3.7.

2016 NDFA Structures Survey – Results (1)

Figure 1: Provision of care structures for the management of diabetic foot disease, England and Wales, 2016



Source: NHS Digital

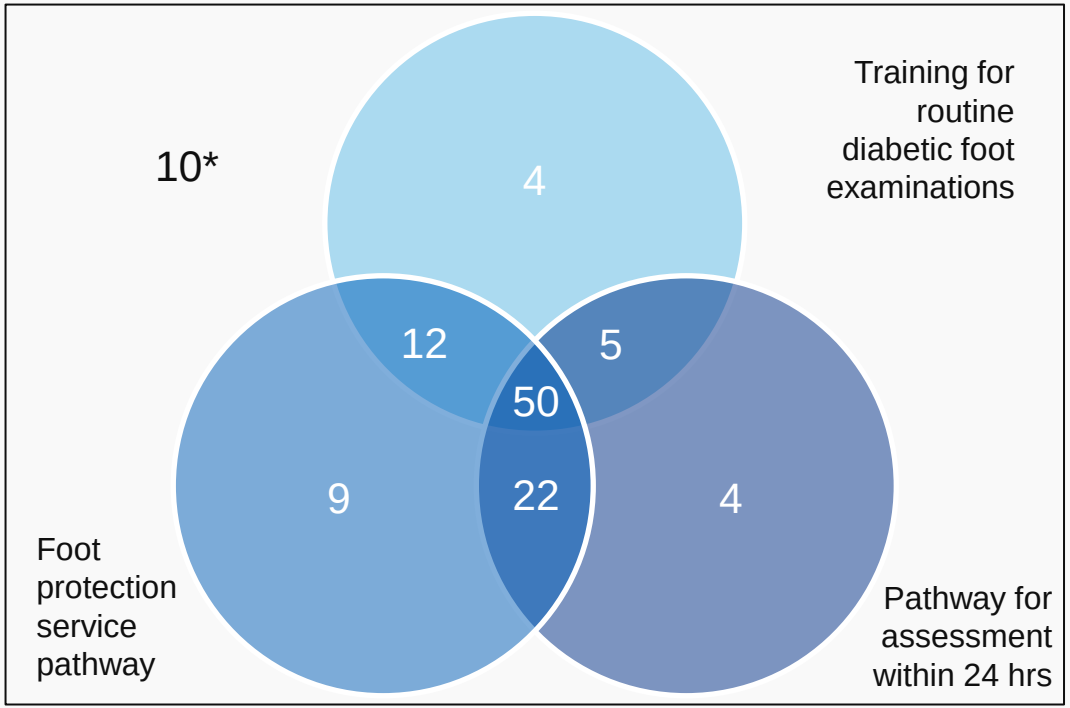
Findings

- The low participation was disappointing and shows a remarkable degree of uncertainty over services provided.

Notes: 1. Responses were provided by commissioners. See Glossary (Health Care Providers) for explanation of terms.

2016 NDFA Structures Survey – Results (2)

Figure 2: Number of commissioners[1] providing care structures for the management of diabetic foot disease, England and Wales, 2016



Findings

- Only 50 commissioners confirmed that all three services were in place (43 per cent of responders).

Notes:
1. See Glossary (Health Care Providers) for explanation of terms.
* 4 commissioners responded but did not confirm that any of the three care structures were in place. 6 commissioners did not provide a response to all of the three questions in the survey.

2016 NDFA Structures Survey – Commentary

Every health commissioner should have a specialist diabetes foot care service. A third of providers (half in England) were unable to say if there was a service in their area. NDFA team

Recommendation (2)

Clinical Commissioning Groups and Local Health Boards should appoint a lead, work with local providers to review services and local care pathways and ensure pathways meet NICE guidelines. They should use the audit findings for the local area to contribute to gap analysis to understand overall NICE compliance across the commissioning area.

"As people with diabetes who have foot disease we are concerned that many commissioners do not see our fearful condition as a priority. How can they be so unsure about what they are delivering?"

Corinne Wykes, Roy Johnson, Sue Brown
Patient Representatives for NDFA

Participation: NDFA processes and outcomes

Results and Findings

Participation – NDFA processes and outcomes

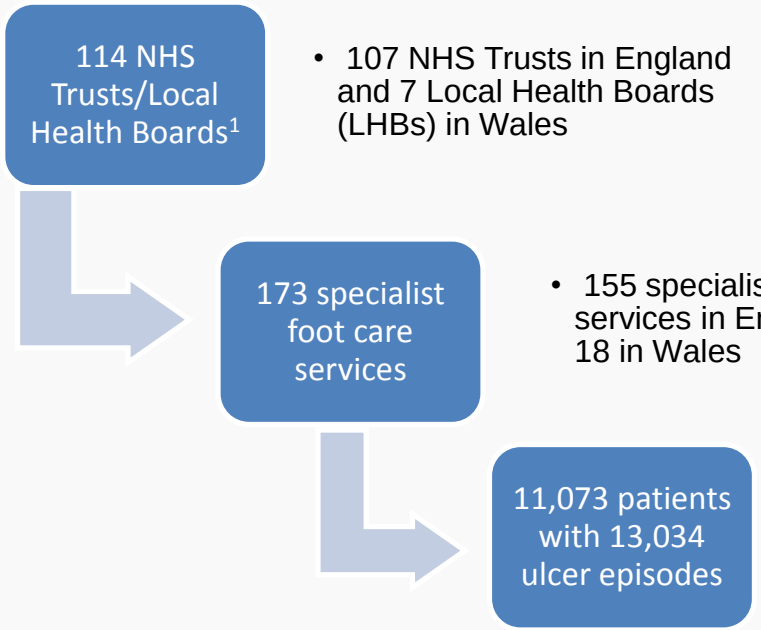
Cohort

The 2014-2016 NDFA report covers patients in England and Wales with ulcers that underwent first expert assessment by a specialist foot care service in the 21 months between 14 July 2014 and 8 April 2016[2].

Case ascertainment

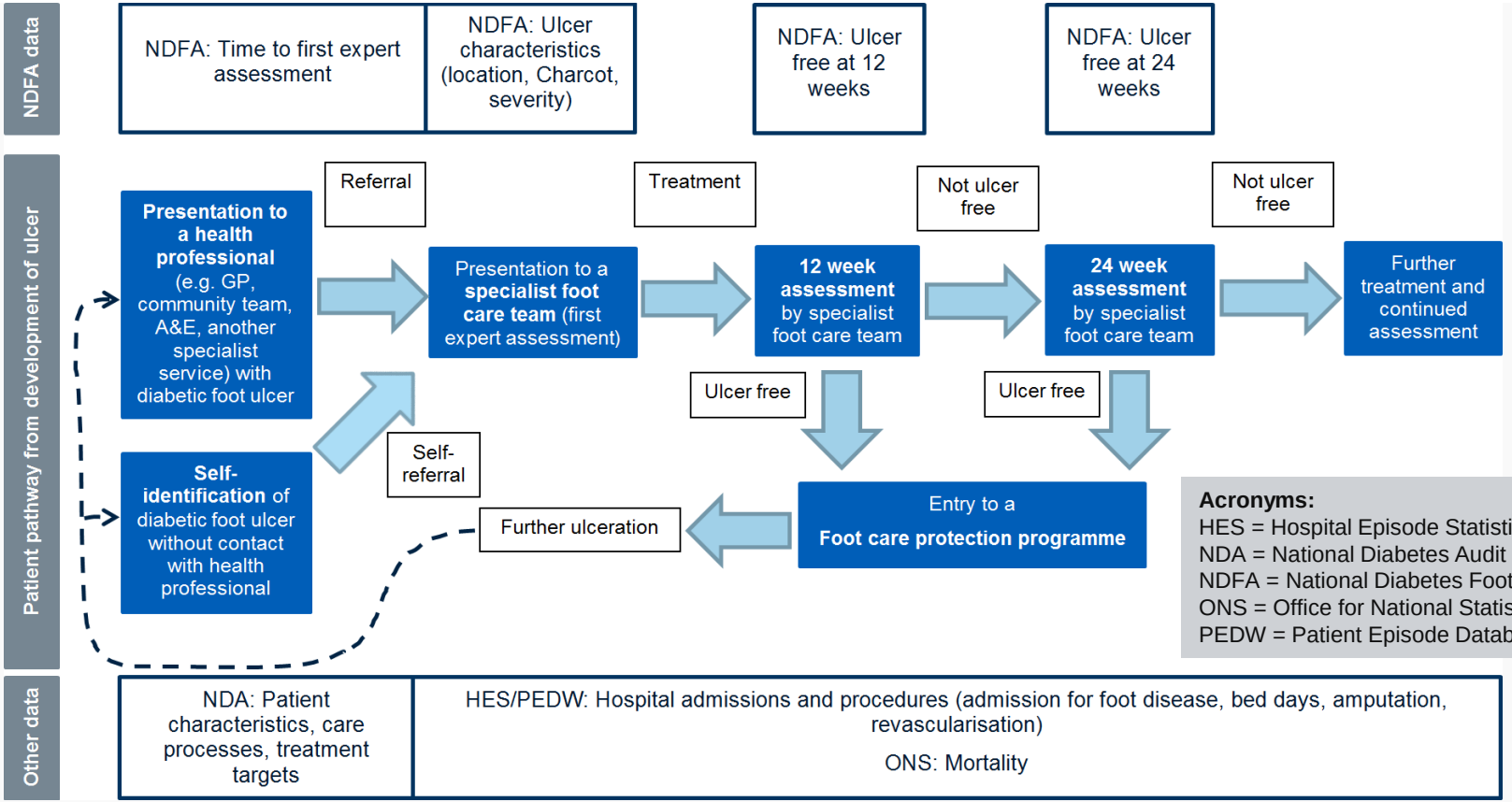
The number of new diabetic foot ulcers in England and Wales each year is not known. A study of people with diabetes in north west England found an annual incidence of 2.2 per cent (Abbott et al 2002), which would put NDFA case ascertainment at around 10 per cent. However, caution should be applied to this estimate due to the study's limited geographic coverage and the length of time since it was undertaken.

Participation



Notes: 1. See Glossary (Health Care Providers) for explanation of terms.
2. The first NDFA report covered the first 9 months of the 2014-2016 cohort (14 July 2014 to 10 April 2015).

Participation – care pathway and data collection



Acronyms:
HES = Hospital Episode Statistics
NDA = National Diabetes Audit
NDFA = National Diabetes Foot Care Audit
ONS = Office for National Statistics
PEDW = Patient Episode Database for Wales

Participation – Recommendations

It is encouraging that a high number of specialist foot care services are participating in NDFA. But it is clear that many find participation onerous, resulting in variable inclusion. Revised approaches are being explored to try and make participation easier and more comprehensive so that improvement can be accelerated.

While every attempt was made to ensure inclusion of all people with new foot ulcers, based on previous research it is likely that a particular group of people under-represented in NDFA are those in care homes[1], because of their lack of easy access to certain health care services.

NDFA team

Recommendations

Commissioners: Encourage your local diabetes foot care services to participate in NDFA and help improve the disabling, lethal and costly consequences of diabetic foot disease.

Healthcare professionals: Participate in NDFA to collaborate in this nationwide drive to improve outcomes for diabetic foot disease.

Notes: 1. NHS England (2016) The framework for enhanced health in care homes.p.7 https://www.england.nhs.uk/wp-content/uploads/2016/09/ehch-framework-v2.pdf

Patient characteristics

Results and Findings

Patient characteristics – Overview

Audit question:
What were the characteristics of NDFA patients at first expert assessment by the specialist foot care service?

Findings
- 87 per cent of people in NDFA were linked to core NDA.

Why is this important?
Patient characteristics such as age, gender, ethnicity and diabetes type may impact on healing outcomes. For example, an elderly person with an ulcer may take longer to heal than a younger person, even if the same quality of care is provided. If a relationship between patient characteristics and outcomes is established, provider results can be adjusted to account for their different patient profiles.

How is this measured? To reduce the burden on data submitters, the NDFA links to the core National Diabetes Audit (NDA) to get patient characteristic data. NDFA patients were linked to the latest three NDA core cohorts (2013-14, 2014-15 and 2015-16) using NHS number, with the latest data items used for the NDFA analysis.

Patient characteristics – Results

NDFA patient profile[1]:

- 13 per cent had Type 1 diabetes; 87 per cent Type 2 diabetes.
- 70 per cent were male.
- Average age at assessment of 67 years.
- Average duration of diabetes of 15 years.
- 92 per cent were white ethnicity.
- 26 per cent were from areas in the most deprived fifth of the country.
- 43 per cent met the NICE HbA1c target (≤58 mmol/mol) before their first ulcer episode[2].

Notes: 1. The previous NDFA report (2016) provides a comparison of the NDFA cohort with the wider diabetic population: http://content.digital.nhs.uk/catalogue/PUB20343/nati-diab-foot-care-audit-14-15-rep.pdf pp. 59-62.
2. NICE recommended care processes: http://pathways.nice.org.uk/pathways/foot-care-for-people-with-diabetes.
The closer HbA1c is to normal (less than 42mmol/mol), the lower the risk of all long term complications of diabetes.

Ulcer characteristics

Results and Findings

Ulcer characteristics – Overview

Audit question: What were the ulcer characteristics of NDFA patients at first expert assessment by the specialist foot care service?

How is this measured? Ulcer severity is recorded using the SINBAD scoring system[1], which scores an ulcer between 0 (least severe) and 6 (most severe) depending on how many of the 6 SINBAD elements[1] are present. An ulcer with a SINBAD score of 3 or above is classed as a severe ulcer. Information was also collected on the presence of possible Charcot foot disease[1].

Why is this important? Knowledge of foot problems associated with ulceration may encourage patients to get help quicker. Charcot disease may delay ulcer healing, and information on ulcer characteristics enables ulcer severity to be factored into audit outcomes. The relationship between ulcer severity and wait for first expert assessment can also be assessed.

Key finding

- Almost half of ulcer episodes were graded severe at first expert assessment.

Recommendations

For people with diabetes:

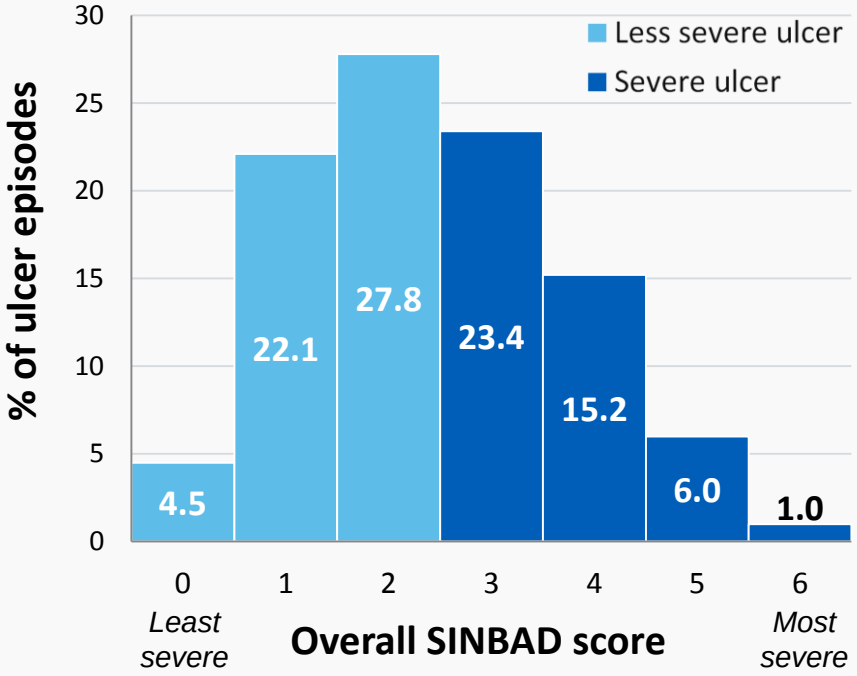
- If you get loss of feeling (neuropathy), seek advice about how to prevent foot ulcers.
- If you have poor circulation (peripheral artery disease or ischaemia) seek advice about how to prevent foot ulcers.
- If you get a foot ulcer seek help from your local expert foot ulcer team without delay.

Resources at Diabetes UK will provide you with further information to help with managing your feet: https://www.diabetes.org.uk/Guide-to-diabetes/Complications/Feet/Taking-care-of-your-feet/

Notes:
1. See Glossary (Ulcer Characteristics) for explanation of terms.

Ulcer characteristics – SINBAD score

Figure 3: Overall SINBAD scores[1], England and Wales, 2014-2016



Findings

- Almost **half** of ulcer episodes were graded **severe** (SINBAD score ≥3) at first expert assessment (46 per cent).

Notes:
1. See Glossary (Ulcer Characteristics) for explanation of terms.

Ulcer characteristics – SINBAD elements

Table 1: Ulcer severity[1], England and Wales, 2014-2016

Ulcer characteristics		All ulcers (13,034 episodes)	
		Number	Per cent
SINBAD element present	**S**ite (on hindfoot)	2,342	18.0
	Ischaemia	4,570	35.1
	Neuropathy	10,744	82.4
	Bacterial infection	5,619	43.1
	Area (≥ 1cm^2)	6,247	47.9
	Depth (to tendon or bone)	2,384	18.3
Severe ulcer		5,947	45.6

Findings

- **43 per cent** of ulcer episodes had **bacterial infection** at first expert assessment.
- **35 per cent** of ulcer episodes affected limbs judged to have some degree of peripheral artery disease (**ischaemia**).

Notes: 1. See Glossary (Ulcer Characteristics) for explanation of terms.

Ulcer characteristics – SINBAD elements by diabetes type

Table 2: Ulcer severity[1] by diabetes type, England and Wales, 2014-2016

Ulcer characteristics		Type 1 diabetes (1,499 episodes)			Type 2 diabetes (9,845 episodes)		
		Number	Per cent		Number	Per cent	
SINBAD element present	**S**ite (on hindfoot)	301	20.1	*	1,706	17.3	*
	Ischaemia	425	28.4	*	3,482	35.4	*
	Neuropathy	1,307	87.2	*	8,086	82.1	*
	Bacterial infection	683	45.6	*	4,216	42.8	*
	Area (≥ 1cm^2)	761	50.8	*	4,663	47.4	*
	Depth (to tendon or bone)	236	15.7	*	1,806	18.3	*
Severe ulcer		699	46.6	n	4,448	45.2	n

Findings

- There is **no difference** in the proportion having severe ulcers between patients with each diabetes type.

Notes: 1. See Glossary (Ulcer Characteristics) for explanation of terms.
* = statistically significant at the 0.05 level (Type 1 vs Type 2).
n = not statistically significant (Type 1 vs Type 2).

Ulcer characteristics – Charcot foot disease

Table 3: Charcot foot disease[1], England and Wales, 2014-2016

Charcot status	All ulcers (13,034 episodes)		
	Number	Per cent	
		All	Known[2]
No Charcot	9,995	76.7	91.4
Inactive Charcot	561	4.3	5.1
Possible Charcot	211	1.6	1.9
Active Charcot	164	1.3	1.5
… confirmed on ulcerated foot	*116*	*0.9*	*1.1*
Not recorded	2,103	16.1	

Findings

- **3 per cent** of all new ulcers were associated with **active** or **possibly active** Charcot foot disease.
- **4 per cent** of all new ulcers were associated with previous, **inactive** Charcot foot disease.

Charcot disease is an uncommon inflammatory disease of the bones of the foot in severe neuropathy and can cause major deformity. It can be difficult to make the diagnosis at first assessment.

Notes: 1. See Glossary (Ulcer Characteristics) and text box above for explanation of terms.
2. The 'Known' denominator excludes ulcers where Charcot status is not recorded.

Processes: Time to first expert assessment

Results and Findings

Time to first expert assessment – Overview

Audit question: Does the length of time to first expert assessment by the specialist foot care service affect ulcer severity?

Why is this important?
It is believed that prompt examination by the specialist foot care service will reduce the likelihood of the patient developing a severe ulcer and improve the prospects of a successful clinical outcome.

Why do some patients self-refer to the foot care service?
People who self-refer may be a sub-group drawn predominantly from people who have had ulcers before. This is supported by the fact that over half of recurrent ulcers in NDFA are self-referrals. Based on their past experience people with previous ulcers may refer themselves when they get a new ulcer.

NICE guidance: People with diabetes who have an active foot problem should be referred to a specialist team within one working day and be triaged within two working days[1].

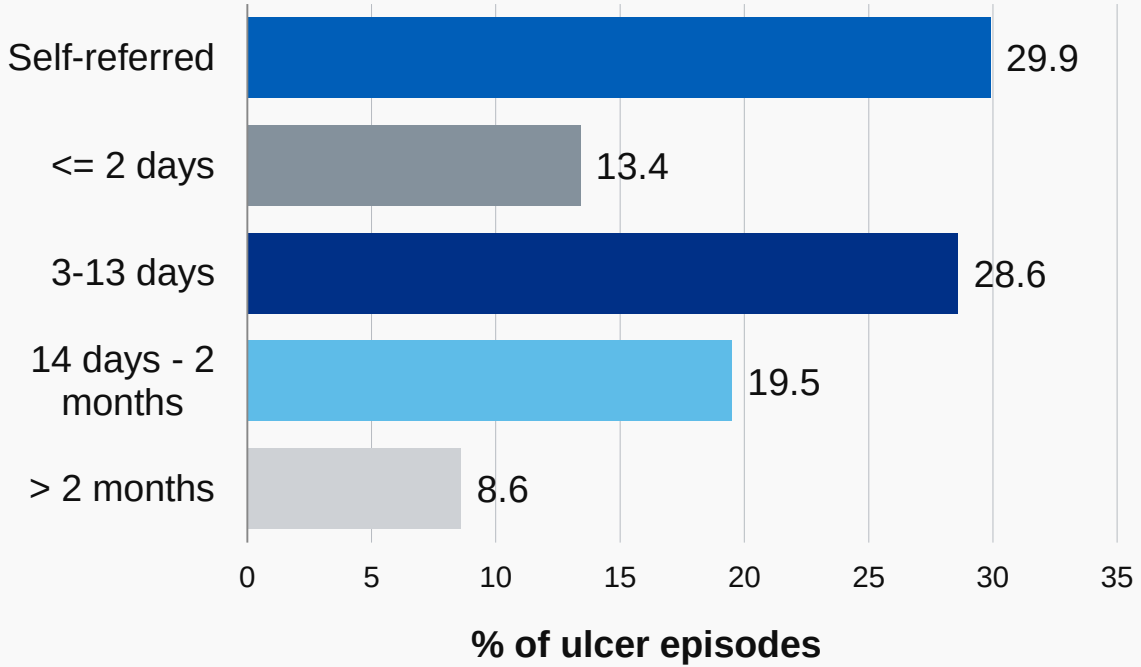
Key findings

- Almost one-third of ulcer episodes were self-referred for expert assessment (30 per cent).
- Where there was an interval of two or more months to first expert assessment the ulcer was more likely to be severe (58 per cent).

Notes:
1. NICE guidelines – Diabetic foot problems: prevention and management. Recommendation 1.4.2 http://www.nice.org.uk/guidance/ng19.

Time to first expert assessment – Results

Figure 4: Time to first expert assessment[1], England and Wales, 2014-2016



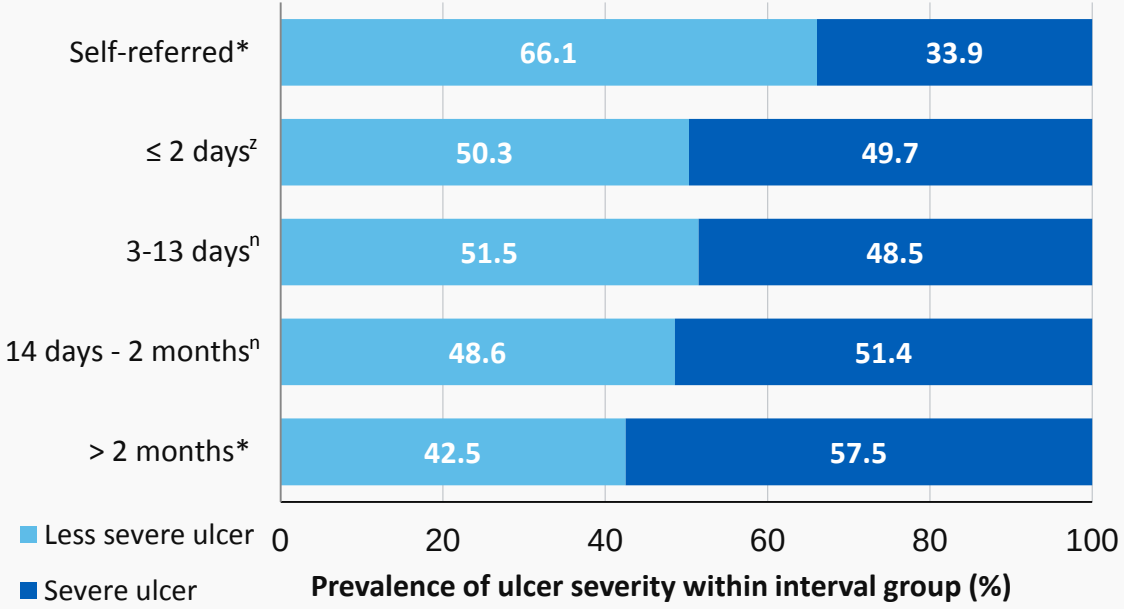
Findings

- Almost **one-third** of ulcer episodes were **self-referred** for expert assessment (30 per cent).
- Excluding self-referral, **two fifths** of ulcer episodes had an interval of **two or more weeks** to first expert assessment (40 per cent).

Notes: 1. See Glossary (Patient pathway) for explanation of terms.
Caution should be applied when comparing self-referrers against other groups. See slide 37 for further information.

Time to first expert assessment – Ulcer severity

Figure 5: Time to first assessment by ulcer severity[1], England and Wales, 2014-2016



Findings

- Ulcer episodes that are **self-referred** are **less likely** to be **severe** (34 per cent vs. 48 to 58 per cent for other categories).
- Ulcer episodes that have an interval of **two or more months** to expert assessment are **more likely** to be **severe** (58 per cent vs. 34 to 51 per cent for other categories).

Notes: 1. See Glossary (Patient pathway and Ulcer characteristics) for explanation of terms. Caution should be applied when comparing self-referrers against other groups. See slide 37 for further information.
* = statistically significant at the 0.05 level (vs ≤2 days). n = not statistically significant (vs ≤2 days).
z = not applicable. Used as comparison group.

Time to first expert assessment – Recommendations

The longer it takes for someone with a new diabetic foot ulcer to reach expert assessment the more likely it is that the ulcer will be severe.

It seems likely that pathways designed to shorten time to expert assessment would reduce the frequency of severe ulcers.

NDFA team

Recommendations

- **People with diabetes**: If you have a new foot ulcer, seek quick referral to a local specialist diabetes foot care service.
- **Healthcare professionals**: Create simple and rapid referral pathways.
- **Commissioners**: Ensure your local services have an easily accessible diabetes specialist foot care team. The South East SCN has prepared a commissioning guidance and sample service specification which may help in developing these services[1].

Notes: 1. South East Strategic Clinical Networks (2015) Patients with Diabetes Foot Care. Commissioning Guidance and Sample Service Specification

Outcomes: Alive and ulcer-free

Results and Findings

Alive and ulcer-free - overview

Audit questions: What proportion of ulcers were healed at 12 and 24 weeks after the first expert assessment by the specialist foot care team?

How do 12 and 24 week outcomes relate to:

- Ulcer severity
- Time to first expert assessment
- NHS Trust and Local Health Board?

Key findings

- Six months after expert assessment one third of people have persistent ulcers and almost one in twenty have died.
- Patients seen within two weeks have higher rates of ulcer healing than those seen later.

How is this assessed? At 12 and 24 weeks the specialist foot care services record whether the patient is alive and whether they are free from active foot disease (i.e. all ulcers present at the start of this episode have fully healed and no other ulcers remain unhealed). Being ‘ulcer-free’ includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed. Patients with an unknown outcome may have been lost to follow-up.

Alive and ulcer-free at 12 weeks

Table 4: 12 week outcome[1], England and Wales, 2014-2016

12 week outcome	All ulcers (13,034 episodes)		
	Number	Per cent	
		All	Known[2]
Alive and ulcer-free[3]	5,833	44.8	48.7
Persistent ulceration	5,849	44.9	48.8
Deceased[4]	304	2.3	2.5
Unknown	1,048	8.0	-

Findings

- Almost **half** of ulcers have **healed at 12 weeks** (49 per cent where the 12 week outcome is known).

Notes: 1. See Glossary (Patient pathway) for explanation of terms.
2. The 'Known' denominator excludes ulcers with an unknown outcome, which may include patients that have been lost to follow-up.
3. This includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed.
4. Crude death rate. Office for National Statistics (ONS) mortality tracing is pending approval, so the number of reported deaths in NDFA may be underestimated.

Alive and ulcer-free at 12 weeks – Ulcer severity

Table 5: 12 week outcome by ulcer severity[1], England and Wales, 2014-2016

12 week outcome	Less severe ulcer (7,087 episodes)					Severe ulcer (5,947 episodes)				
	Number	Per cent				Number	Per cent			
		All		Known[2]			All		Known[2]	
Alive and ulcer-free[3]	3,946	55.7	*	60.3	*	1,887	31.7	*	34.7	*
Persistent ulceration	2,492	35.2	*	38.1	*	3,357	56.4	*	61.7	*
Deceased[4]	107	1.5	*	1.6	*	197	3.3	*	3.6	*
Unknown	542	7.6	n	-	z	506	8.5	n	-	z

Findings

- People with **severe** ulcers are **less likely** to be alive and ulcer-free at 12 weeks than people with less severe ulcers (35 per cent vs. 60 per cent, where the 12 week outcome is known).
- People with **severe** ulcers are **more likely** to have **died** prior to 12 weeks following their first expert assessment than those with less severe ulcers (3.6 per cent vs. 1.6 per cent, where the 12 week outcome is known).

Notes: 1. See Glossary (Patient pathway/Ulcer characteristics) for explanation of terms.
2. The 'Known' denominator excludes ulcers with an unknown outcome, which includes patients that have been lost to follow-up.
3. This includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed.
4. Crude death rate. Office for National Statistics (ONS) mortality tracing is pending approval, so the number of reported deaths in NDFA may be underestimated. * = statistically significant at the 0.05 level (Less severe vs Severe).
n = not statistically significant (Less severe vs Severe). z = not applicable. Not used in cohort.

Alive and ulcer-free at 24 weeks

Table 6: 24 week outcome[1], England and Wales, 2014-2016

24 week outcome	All ulcers in cohort (12,226 episodes)		
	Number	Per cent	
		All	Known[2]
Alive and ulcer-free at 24 weeks[3]	7,123	58.3	66.2
… *Ulcer-free[3] at 12 weeks, no re-ulceration by 24 weeks*	*5,142*	*42.1*	*47.8*
… *Not healed[3] at 12 weeks, but ulcer-free at 24 weeks*	*1,981*	*16.2*	*18.4*
Alive and ulcer-free at 12 weeks[3] further ulceration by 24 weeks	314	2.6	2.9
Persistent ulceration	2,842	23.2	26.4
Deceased[4]	478	3.9	4.4
Unknown	1,469	12.0	

Findings

- Almost **two-thirds** of people are alive and ulcer-free at 24 weeks (66 per cent where the 24 week outcome is known).
- Almost **1 in 20** patients **died** within 24 weeks of first expert assessment (4.4 per cent where the 24 week outcome is known).

Notes: 1. See Glossary (Patient pathway) for explanation of terms.
2. The 'Known' denominator excludes ulcers with an unknown outcome, which includes patients that have been lost to follow-up.
3. This includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed.
4. Crude death rate. Office for National Statistics (ONS) mortality tracing is pending approval, so the number of reported deaths in NDFA may be underestimated.

Alive and ulcer-free at 24 weeks – Ulcer severity

Table 7: 24 week outcome by ulcer severity[1], England and Wales, 2014-2016

24 week outcome	Less severe ulcer (6,631 episodes)					Severe ulcer (5,595 episodes)				
	Number	Per cent				Number	Per cent			
		All		Known[2]			All		Known[2]	
Alive and ulcer-free at 24 weeks[3]	4,425	66.7	*	74.5	*	2,698	48.2	*	56.0	*
… Ulcer-free[3] *at 12 weeks, no re-ulceration by 24 weeks*	*3,483*	*52.5*	*	*58.6*	*	*1,659*	*29.7*	*	*34.5*	*
… *Not healed[3] at 12 weeks, but ulcer-free at 24 weeks*	*942*	*14.2*	*	*15.9*	*	*1,039*	*18.6*	*	*21.6*	*
Alive and ulcer-free at 12 weeks[3] further ulceration by 24 weeks	213	3.2	*	3.6	*	101	1.8	*	2.1	*
Persistent ulceration	1,134	17.1	*	19.1	*	1,708	30.5	*	35.5	*
Deceased[4]	171	2.6	*	2.9	*	307	5.5	*	6.4	*
Unknown	688	10.4	*	-	z	781	14.0	*	-	z

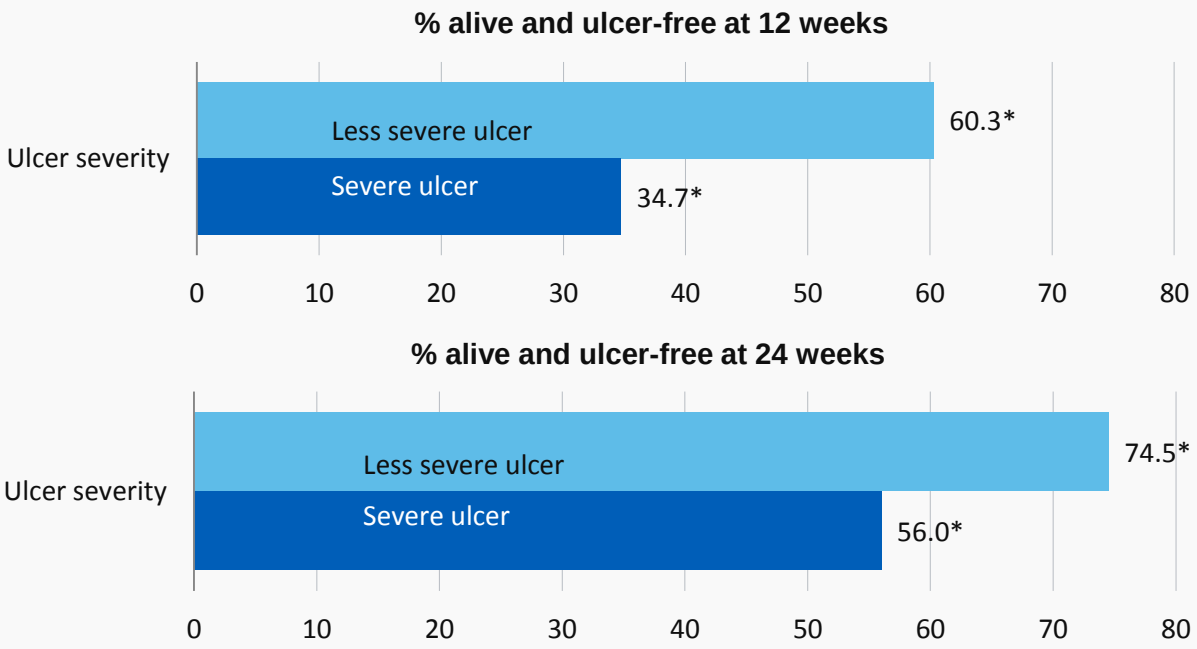
Notes:
1-4. Please see Notes on previous slide. Note that being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed. * = statistically significant at the 0.05 level (Less severe vs Severe). n = not statistically significant (Less severe vs Severe). z = not applicable. Not used in cohort.

Findings

- People with **severe** ulcers are **less likely** to be **alive and ulcer-free** at 24 weeks than people with less severe ulcers (56 per cent vs. 74 per cent, where the outcome is known).
- People with **severe** ulcers are **more likely** to have **died** prior to a 24 week expert assessment than those with less severe ulcers (6.4 per cent vs.2.9 per cent, where the outcome is known).

Alive and ulcer-free – Ulcer severity

Figure 6: Alive and ulcer-free by ulcer severity[1], England and Wales, 2014-2016



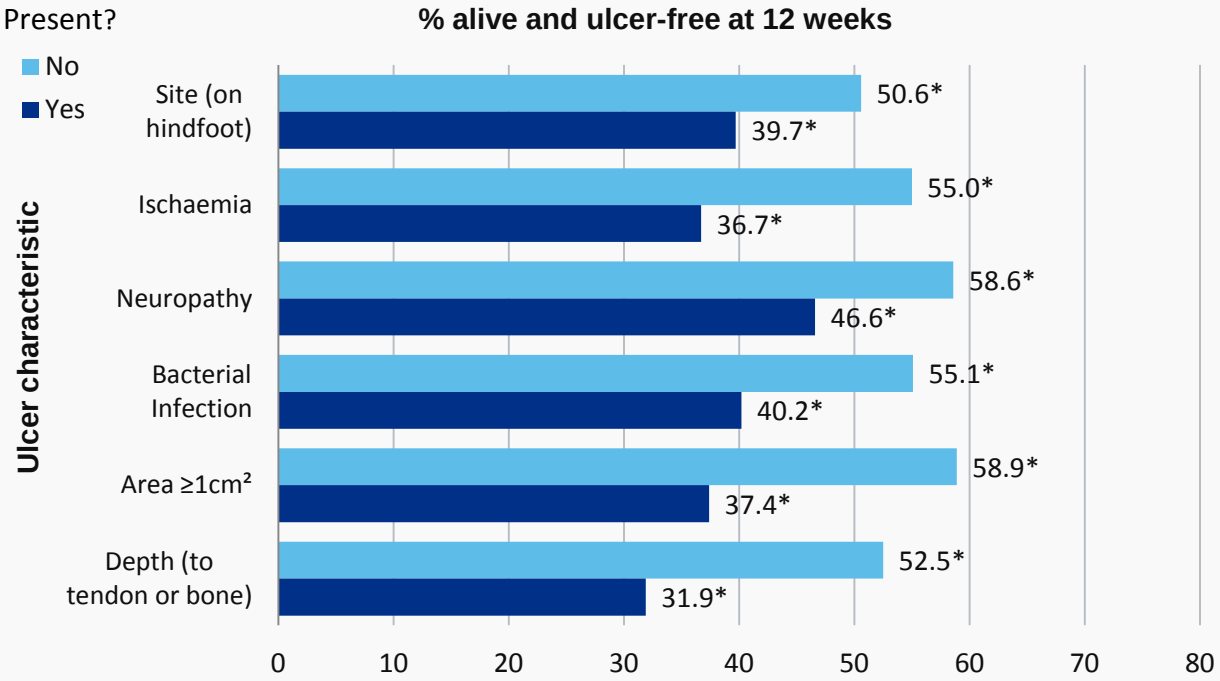
Findings

- People with **less severe** ulcers are almost **twice** as likely to be alive and ulcer-free at 12 weeks as those with **severe** ulcers (60 per cent vs. 35 per cent).
- People with **less severe** ulcers are **more likely** to be alive and ulcer-free at 24 weeks than those with severe ulcers (74 per cent vs. 56 per cent).

Notes: 1. See Glossary (Patient pathway/Ulcer characteristics) for explanation of terms Being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed.
* = statistically significant at the 0.05 level (Less severe vs Severe). n = not statistically significant (Less severe vs Severe).

Alive and ulcer-free at 12 weeks – SINBAD element

Figure 7: Alive and ulcer-free at 12 weeks by ulcer characteristics[1], England and Wales, 2014-2016



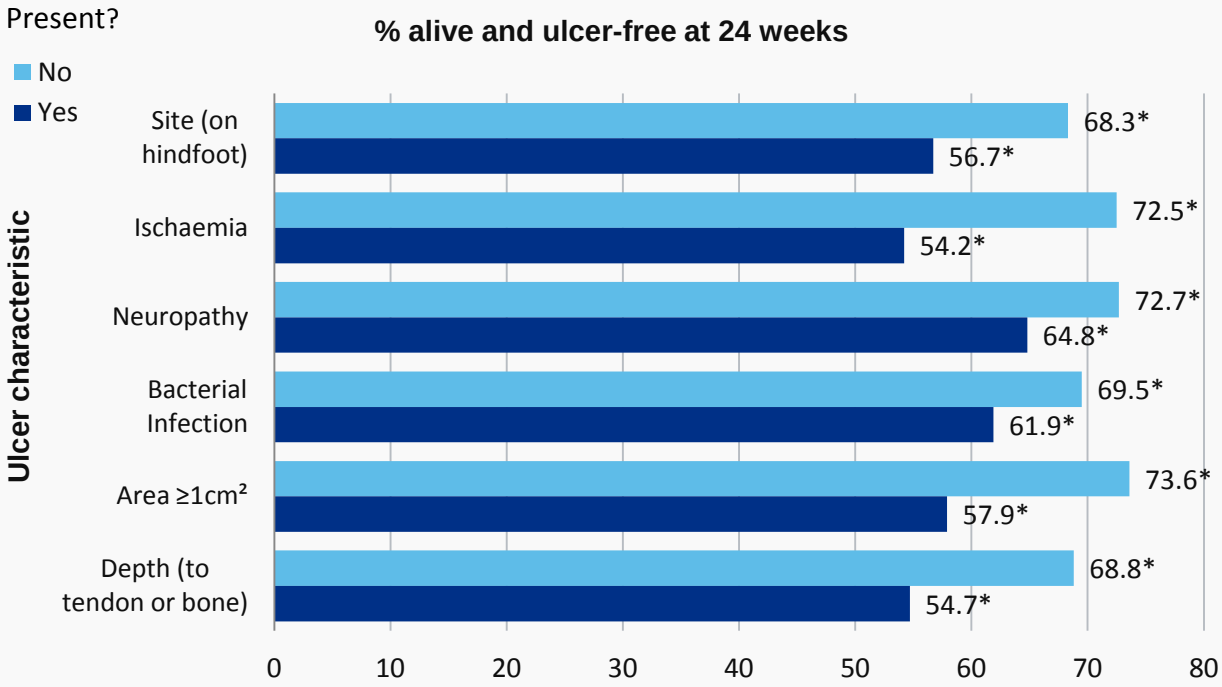
Findings

- The presence of **every** SINBAD element was associated with **reduced healing** at 12 weeks.

Notes: 1. See Glossary (Patient pathway/Ulcer characteristics) for explanation of terms. Being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed.
* = statistically significant at the 0.05 level (Yes vs No). n = not statistically significant (Yes vs No).

Alive and ulcer-free at 24 weeks – SINBAD element

Figure 8: Alive and ulcer-free at 24 weeks by ulcer characteristics[1], England and Wales, 2014-2016



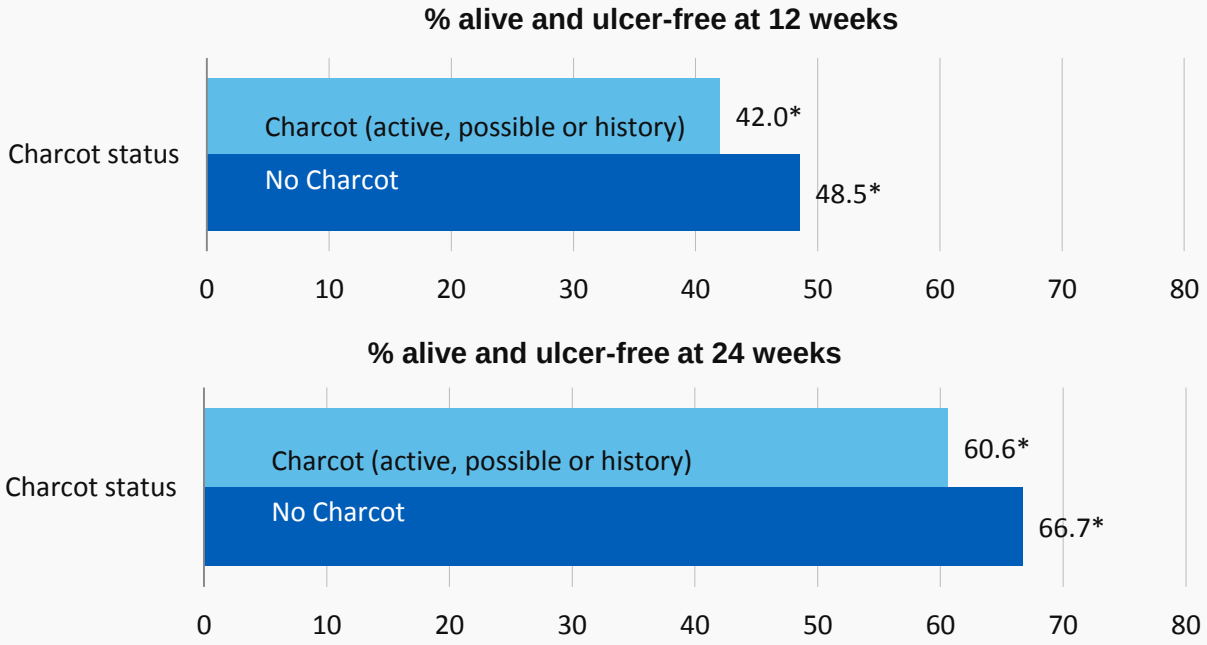
Findings

- The presence of **every** SINBAD element was associated with **reduced healing** at 24 weeks.

Notes: 1. See Glossary (Patient pathway/Ulcer characteristics) for explanation of terms. Being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed.
* = statistically significant at the 0.05 level (Yes vs No). n = not statistically significant (Yes vs No).

Alive and ulcer-free – Charcot foot disease

Figure 9: Alive and ulcer-free by Charcot status[1], England and Wales, 2014-2016



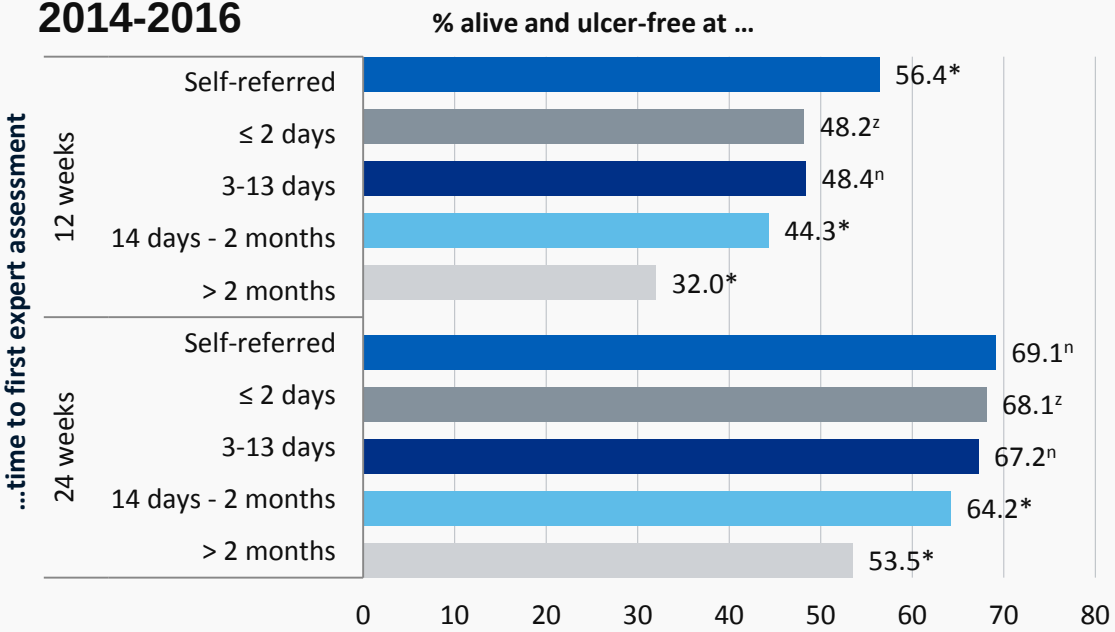
Findings

- Active, possible or a history of **Charcot** is associated with **reduced healing** at 12 and 24 weeks.

Notes: 1. See Glossary (Patient pathway/Ulcer characteristics) for explanation of terms Being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed.
* = statistically significant at the 0.05 level (Charcot vs No Charcot). n = not statistically significant (Charcot vs No Charcot).

Alive and ulcer-free – time to first expert assessment

Figure 10: Alive and ulcer-free by time to first assessment[1], England and Wales, 2014-2016



Findings

- At 12 weeks people who self-referred are **more likely** to be alive and ulcer-free than all other groups. By 24 weeks those who self-referred are **as likely** to be alive and ulcer-free as those seen within two weeks.
- Ulcers that have an expert assessment within **two days** have the **same** healing rate as those seen **3-13 days** after first presentation to a health professional.
- People who have an expert assessment of their ulcer **within two weeks** of their first presentation to a health professional are **more likely** to be alive and ulcer-free than those seen later.

Notes: 1. See Glossary (Patient pathway) for explanation of terms. Being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed. Caution should be applied when comparing self-referrers against other groups. See slide 37 for further information. * = statistically significant at the 0.05 level (vs ≤2 days). n = not statistically significant (vs ≤2 days). z = not applicable. Used as comparison group.

Alive and ulcer-free – Recommendations (1)

The choice of this principal outcome measure was made because it is patient-centred. It must be remembered that the term ‘alive and ulcer-free’ includes those who have had minor or major amputations, provided that all of their wounds have healed.

People were more likely to be alive and ulcer-free at 12 and 24 weeks if the presenting ulcer was less severe. Linked data on admissions, re-vascularisation procedures and amputations will be included in a follow-on report.

NDFA team

Recommendation

People with diabetes:

- If you have a new foot ulcer, seek quick referral to a local specialist diabetes foot care service.

Alive and ulcer-free – Recommendations (2)

An important principle of care is that new foot ulcers should be referred for expert assessment as soon as possible.

When the time to first expert assessment is delayed, ulcers are more likely to be severe. It is therefore believed that overall outcome will be improved if people with new ulcers are referred without delay.

NDFA team

Recommendations

Healthcare professionals: Create simple and rapid referral pathways

Commissioners: Ensure your local services have an easily accessible diabetes specialist foot care team. The South East SCN has prepared a commissioning guidance and sample service specification which may help in developing these services[1].

Notes: 1. South East Strategic Clinical Networks (2015) Patients with Diabetes Foot Care. Commissioning Guidance and Sample Service Specification

Outcomes: Variation between providers

Results and Findings

Variation between providers – Overview

Audit questions:
Does the clinical outcome at 12 and 24 weeks vary by NHS Trust and Local Health Board[1]?

Why is this important?
A worse clinical outcome may be indicative of poorer organisation of care. It is crucial that patients across the whole of England and Wales have access to the same high standards of diabetic foot care.

How is this assessed? Clinical outcomes at 12 and 24 weeks have been compared across NHS Trust and Local Health Boards. Results are split between severe and less severe ulcers. Results have not been case-mix adjusted because the statistical model is not presently strong enough[3].

Caution

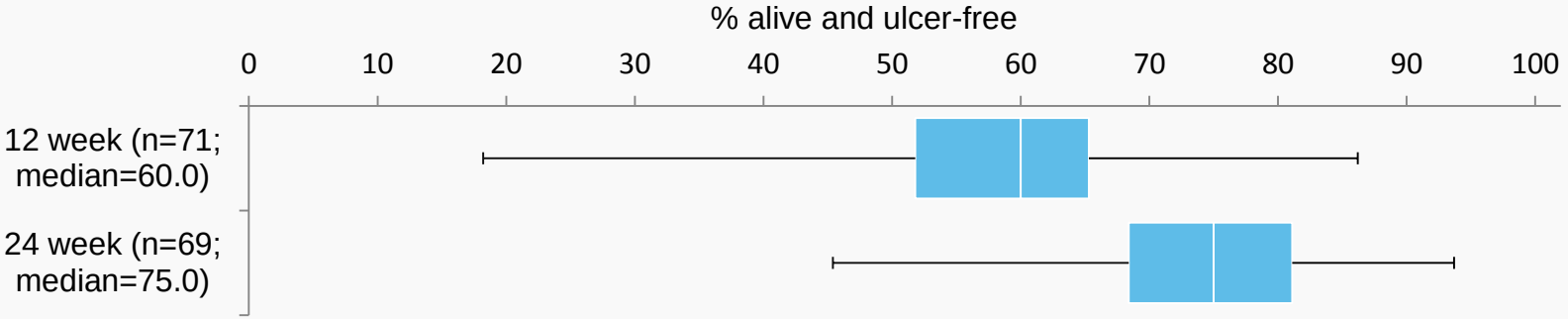
Caution should be applied when reviewing these figures because:

- results have not been case-mix adjusted to account for the patient profile of individual providers[3];
- overall case ascertainment is low (around 10 per cent)[2]; and
- there are regional variations in the quality and quantity of data supplied to the NDFA.

Notes: 1. See Glossary (Health Care Providers) for explanation of terms.
2. See discussion of case ascertainment on slide 24. 3. See discussion of statistical modelling on slide 60.

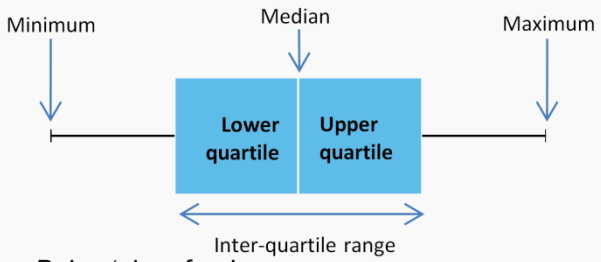
Variation between providers – Less severe ulcers

Figure 11: Range of observed clinical outcomes for <u>less severe</u> ulcers by NHS Trust and Local Health Board[1], England and Wales, 2014-2016



Findings

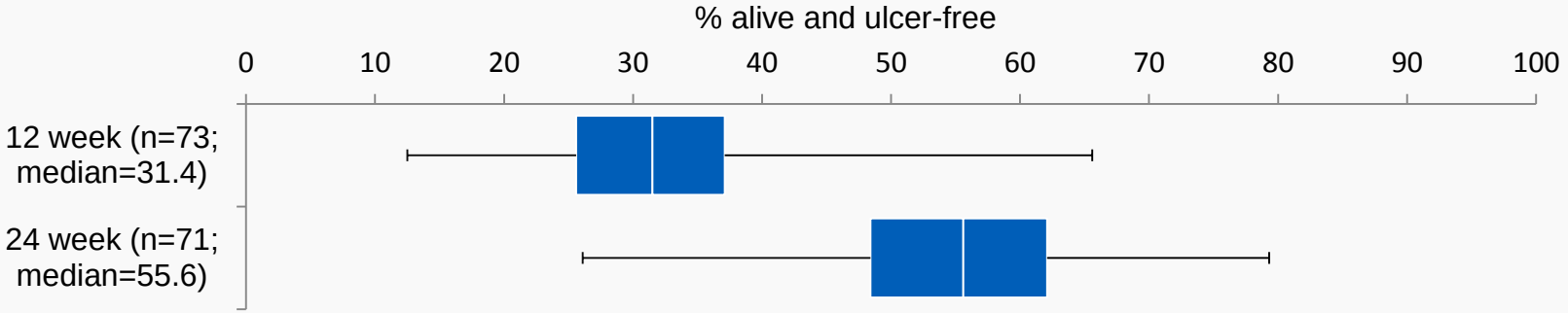
- There is **variation** in observed clinical outcome (within the middle 50 per cent of NHS Trust and Local Health Boards: 52 to 65 per cent at 12 weeks and 68 to 81 per cent at 24 weeks), though more work needs to be done to adjust for the patient profile of each submitter.



Notes: 1. See Glossary (Health Care Providers/Patient pathway/Ulcer characteristics) for explanation of terms. Being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed. Includes NHS Trusts and Local Health Boards >=20 ulcer episodes only.

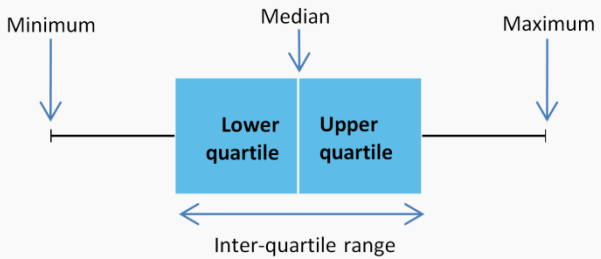
Variation between providers – Severe ulcers

Figure 12: Range of observed clinical outcomes for <u>severe</u> ulcers by NHS Trust and Local Health Board[1], England and Wales, 2014-2016



Findings

- There is **variation** in observed clinical outcome (within the middle 50 per cent of NHS Trust and Local Health Boards: 24 to 46 per cent at 12 weeks and 49 to 63 per cent at 24 weeks), though more work needs to be done to adjust for the patient profile of each submitter.



Notes: 1. See Glossary (Health Care Providers/Patient pathway/Ulcer characteristics) for explanation of terms. Being 'ulcer-free' includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed. Includes NHS Trusts and Local Health Boards >=20 ulcer episodes only.

Variation between providers – Clinical comment

At this stage in development caution should be exercised in the interpretation of variations between services. But local review of any differences from similar services is recommended.

As NDFA matures to include most ulcers from participating services and the numbers from each service cumulate, statistical modeling will reveal any important case-mix adjustments required. Until this point benchmarking in not reliable. However, it seems unlikely that these factors will account for all the variation.

NDFA team

Finding

- There is variation in observed clinical outcomes between NHS Trusts and Local Health Boards, though more work needs to be done to adjust for the patient profile of each submitter.

Outcomes: Factors that predict ulcer healing

Results and Findings

Factors that predict ulcer healing – Overview

Audit question: What characteristics are associated with being alive and ulcer-free at 12 and 24 weeks?

How is this measured? NDFA and National Diabetes Audit (NDA) data is combined in a logistic regression model[1] that looks for factors that are associated with ulcer healing at 12 and 24 weeks.

Why is this important? Outputs from the model help to identify factors that affect a person's outcome. If a strong model is produced, outputs can be used to adjust provider healing rates to account for their unique patient profile. This enables fairer comparison between providers.

Findings

- Characteristics associated with **better healing** include: being female, having self-referred, having Type 1 diabetes, having diabetes for a short duration, being from an Asian or Black ethnic background.
- Characteristics associated with **worse healing** include: being a current smoker, having any of the 6 SINBAD elements, having Charcot foot disease, not having had all 8 NICE recommended annual care processes.

Caution The overall predictive power of the 12 and 24 week ulcer healing models is **poor** (c-statistics <0.7). The factors considered in the model do not explain most of the variation in outcome. Other factors unrelated to the patient may explain some of the outcome variation.

Notes: 1. See Glossary (Statistical terms) for explanation of terms.

Factors that predict ulcer healing – Summary

Table 8: Factors associated with being alive and ulcer-free at 12 and 24 weeks, England and Wales, 2014-2016

		Weeks 12	Weeks 24
Associated with better healing	• Patient is female	▲	▲
	• Patient is from a less deprived area of the country	◀▶	▲
	• Patient has Black or Asian ethnicity	▲	◀▶
	• Patient has Type 1 diabetes	▲	◀▶
	• Patient has had diabetes for less than 5 years	▲	▲
	• Patient has had diabetes at least 5 and less than 10 years	▲	◀▶
	• Patient self-referred to the specialist foot care service	▲	◀▶
Associated with worse healing	• Patient has mixed or 'other' ethnicity	◀▶	▼
	• Patient currently smokes	▼	◀▶
	• Patient presented with Charcot foot disease	▼	▼
	• …with Site/Ischaemia/Neuropathy/Area/Depth	▼	▼
	• …with Bacterial infection	▼	◀▶
	• Patient waited more than 2 months for expert assessment	▼	▼
	• Patient has not had all 8 NICE recommended processes	▼	▼

Key: Strength of models (c-statistic) = **poor**. See Glossary (Statistical terms) for explanation of terms.
▲ = Associated with better healing; ▼ = associated with worse healing; ◀▶ = no association found. Tested at the 0.05 level.

Factors that predict ulcer healing – Findings[1]

12 weeks only

- Patients were **more likely** to be alive and ulcer-free if they had **Type 1** diabetes.
- Patients with **Black** or **Asian** ethnicity are **more likely** to be alive and ulcer-free than those with White ethnicity.
- Patients who **self-referred** to the foot service were **more likely** to be alive and ulcer-free than those seen within 2 days.
- Patients who currently **smoked** were **less likely** to be alive and ulcer-free than those who had never smoked.
- Patients with **bacterial infection** were **less likely** to be alive and ulcer-free than patients without it.

Both 12 and 24 weeks

- Patients were **more likely** to be alive and ulcer-free if they were **female**, or if they had been diagnosed with diabetes in the last **five years**.
- Patients who waited more than **2 months** to be seen be the specialist foot care service were **less likely** to be alive and ulcer-free than those seen within 2 days.
- Patients with any **SINBAD** element – other than bacterial infection – were **less likely** to be alive and ulcer-free than patients without that characteristic.
- Patients that presented with **Charcot** foot disease were **less likely** to be alive and ulcer-free than those without the condition.
- Patients who did not recently have all 8 NICE recommended care processes were **less likely** to be healed than those who did.

24 weeks only

- Patients from **less deprived** areas of England and Wales were **more likely** to be alive and ulcer-free than those from more deprived areas.
- Patients with a **Mixed** ethnic background **less likely** to be alive and ulcer-free than those from a White ethnic background.

Notes: 1. See Glossary (Statistical terms) for explanation of terms. See Appendix 1 for detailed results.

Future plans of the audit

Discussion

Future plans of the audit

Over the next 12 months, the NDFA team will:

- ❑ Work with submitters to encourage participation and improve case ascertainment.
- ❑ Link the NDFA cohort to hospital episode data (HES and PEDW)[1].
- ❑ Produce a second NDFA report focusing on:
  - Hospital admissions for foot disease
  - Major and minor amputation
  - Revascularisation
- ❑ Investigate case-mix adjusted comparisons between care providers.

Notes: 1. HES = Hospital Episode Statistics. PEDW = Patient Episode Database for Wales. ONS = Office for National Statistics

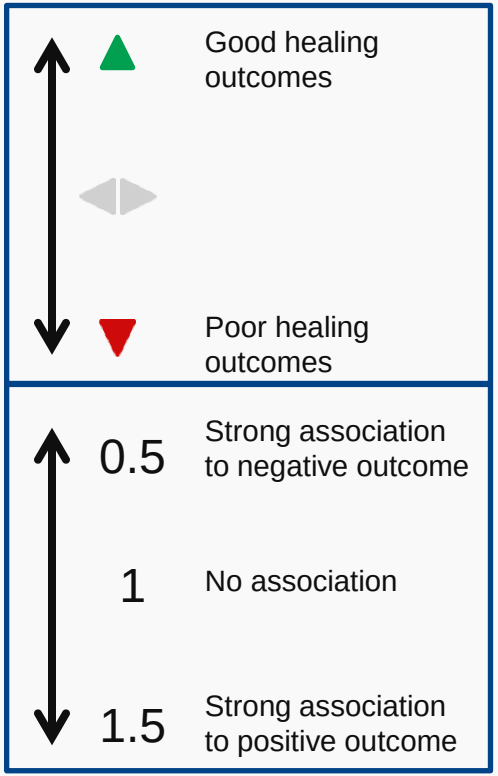
Appendix 1 - Factors that predict ulcer healing

Results and Findings – details

Appendix 1: Modelling healing outcomes – details (1)

Table 9: Patient factors associated with ulcer healing at 12 and 24 weeks, England and Wales, 2014-2016

Patient characteristic	Odds ratios[1]			
	12 Weeks		24 Weeks	
Strength of model (c-statistic)[1]	Poor (0.697)		Poor (0.672)	
Female	▲	1.159	▲	1.233
Asian ethnicity[2]	▲	1.422	◀▶	
Black ethnicity[2]	▲	1.826	◀▶	
Mixed / Other ethnicity[2]	◀▶		▼	0.465
Type 1 diabetes	▲	1.181	◀▶	
Diabetes duration less than 5 years[3]	▲	1.267	▲	1.203
Diabetes duration 5-9 years[3]	▲	1.162	◀▶	
Diabetes duration unknown[3]	▼	0.824	◀▶	
From a less deprived area of the country	◀▶		▲	1.045
Current smoker[4]	▼	0.795	◀▶	
8 NICE recommended care processes = No[5]	▼	0.808	▼	0.810
8 NICE recommended care processes = Unknown[5]	▼	0.757	▼	0.613

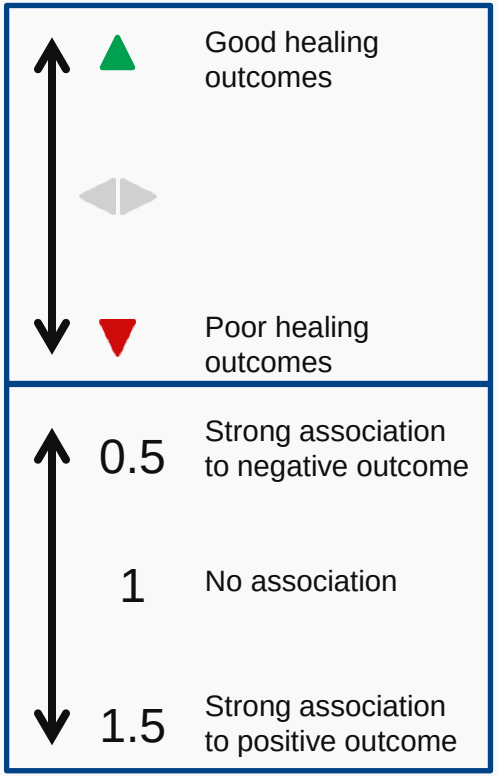


Notes: 1. See Glossary (Statistical terms) for explanation of terms. 2. Vs. White ethnicity. 3. Vs. 10-14 years. 4. Vs. Never smoked. 5. Vs. Yes.

Appendix 1: Modelling healing outcomes – details (2)

Table 10: Ulcer factors associated with ulcer healing at 12 and 24 weeks, England and Wales, 2014-2016

Ulcer characteristic	Odds ratios[1]			
	12 Weeks		24 Weeks	
Strength of model (c-statistic)[1]	Poor	(0.697)	Poor	(0.672)
SINBAD element: Site (on hindfoot)	▼	0.810	▼	0.702
SINBAD element: Ischaemia	▼	0.494	▼	0.482
SINBAD element: Neuropathy	▼	0.637	▼	0.756
SINBAD element: Bacterial infection	▼	0.792	◀▶	
SINBAD element: Area (≥1cm^2)	▼	0.504	▼	0.594
SINBAD element: Depth (to tendon or bone)	▼	0.670	▼	0.684
Charcot foot disease = present[2]	▼	0.722	▼	0.620
Charcot foot disease = possible[2]	▲	1.600	◀▶	
Charcot foot disease = unknown[2]	▲	1.248	◀▶	
Time to expert assessment = self-referred[3]	▲	1.191	◀▶	
Time to expert assessment = >2 months[3]	▼	0.557	▼	0.595



Notes: 1. See Glossary (Statistical terms) for explanation of terms.
2. Vs. Charcot foot disease = not present. 3. Vs. Time to expert assessment = <=2 days.

Glossary

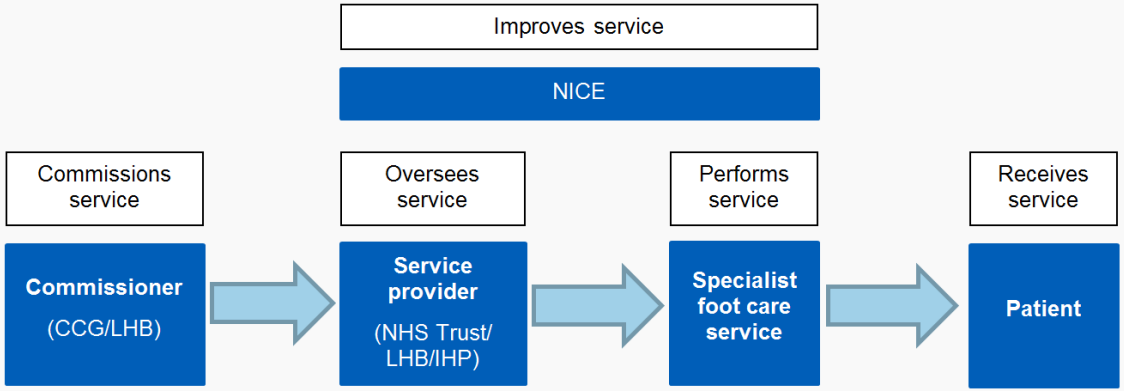
Information and definitions

Glossary – Health Care Providers

NDFA data is submitted by **specialist foot care services** that treat people with diabetic foot ulcers. This includes community and hospital based organisations.

Service providers are the specialist foot care service's parent organisation. This is typically an **NHS Trust** in England or a **Local Health Board** (LHB) in Wales. It may also be an independent healthcare provider (IHP). Each NHS Trust is part of a **Clinical Network** (CN).

Commissioners decide what health services are needed and ensure that they are provided. Clinical Commissioning Groups (CCG) in England and LHBs in Wales are responsible for commissioning healthcare services.



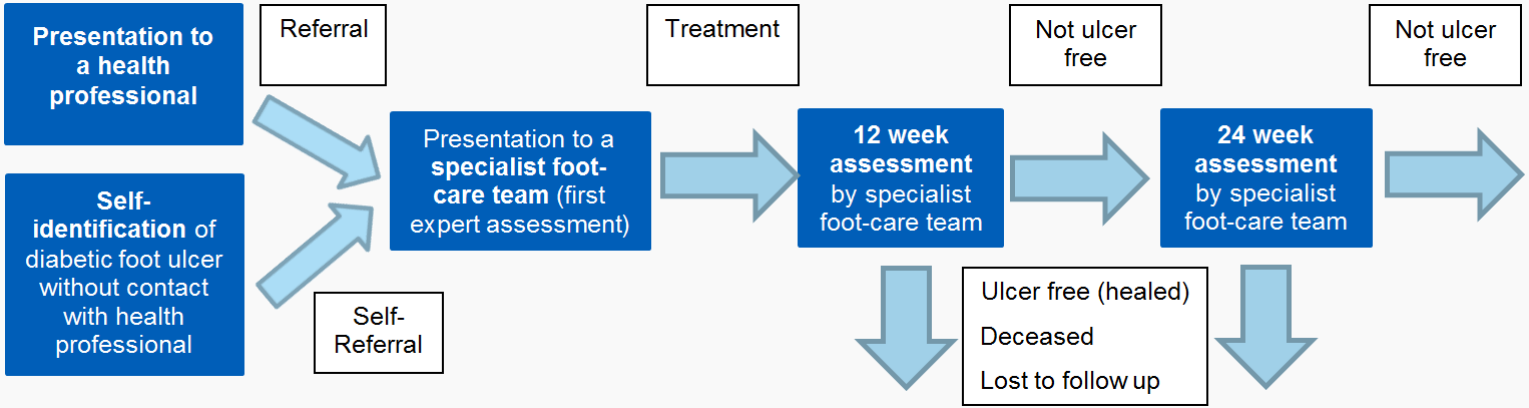
The National Institute for Health and Care Excellence (**NICE**) produces guidelines for the treatment of diabetic foot problems. All diabetes foot care services should follow these guidelines, so that people with diabetes receive the best possible foot care.

Glossary – Patient pathway

The **first expert assessment** of the foot ulcer is undertaken by the specialist foot care service. Patients may self-refer to the specialist foot care service (**self-referral**[1]) or they may be referred following **presentation to a health professional** (e.g. GP community team, Accident and Emergency or another specialist foot care service).

At 12 and 24 weeks following the first expert assessment, the specialist foot care service will record whether the patient is **alive and ulcer-free** (i.e. all ulcers present at the start of this episode have fully healed and no other ulcers remain unhealed). Being ulcer-free also includes those patients who have had surgery (including major and minor amputation), provided all wounds have healed. **Persistent ulcers** are ulcers that have not healed.

Healed at 12 weeks includes all ulcer episodes reported as healed at 12 weeks. **Healed at 24 weeks** includes all ulcer episodes reported as healed at 24 weeks plus those reported as healed at 12 weeks, unless a new ulcer episode occurred within 12 weeks of their 12 week assessment.



Notes: 1. For further information on self-referral see slide 37.

Glossary – Ulcer characteristics

Ulcer characteristics are measured at the first expert assessment by the specialist foot care service. Overall **ulcer severity** is recorded using the **SINBAD** scoring system, which scores an ulcer between 0 (least severe) and 6 (most severe) depending on how many of the 6 SINBAD elements are present. The 6 **SINBAD elements** are:

- ❑ **Site (on hindfoot)** – Ulcer penetrates the hindfoot (rear of the foot).
- ❑ **Ischaemia** – Impaired circulation in the foot.
- ❑ **Neuropathy** – Loss of protective sensation in the foot.
- ❑ **Bacterial infection** – Signs of bacterial infection of the foot

(e.g. redness, swelling, heat, discharge).

- ❑ **Area (≥ 1cm^2)** – Ulcer covers a large surface area (1cm^2 or more).
- ❑ **Depth (to tendon or bone)** – Ulcer penetrates to tendon or bone.

An ulcer with a SINBAD score of 3 or above is classed as a **severe ulcer**.
An ulcer with a SINBAD score of less than 3 is classed as a **less severe ulcer**.

Charcot foot disease is a type of serious bone deformity associated with neuropathy.

Glossary – Statistical terms

Where a result is flagged as **significant at 0.05 level**, there is only a 5 per cent probability that the result is due to chance.

Logistic regression is used to examine the relationship between an outcome (e.g. alive and healed at 12 weeks) and related variables (e.g. ulcer characteristics). Backwards elimination is used to remove variables found not to be significant at 0.05 level, producing a final model that includes variables with significant associations only

Two outputs are particularly useful when interpreting the results of a logistic regression model:

- The **c-statistic** can be used to assess the goodness of fit, with values ranging from 0.5 to 1.0. A value of 0.5 indicates that the model is no better than chance at making a prediction of membership in a group and a value of 1.0 indicates that the model perfectly identifies those within a group and those not. Models are typically considered reasonable when the c-statistic is higher than 0.7 and strong when the c-statistic exceeds 0.8 (Hosmer and Lemeshow, 2000).
- **Odds ratios** (OR) illustrate how strongly a particular value of a variable is associated with the outcome. The further from one the ratio is (either above or below), the stronger the association between it and the outcome. For example, an odds ratio of 0.764 would suggest a stronger association than an odds ratio of 0.830. An odds ratio of one would show that the variable value has no bearing on how likely the outcome is.

  There is always a degree of uncertainty in the calculated odds ratio. This is described by the **confidence interval**. The wider the confidence interval, the less certainty there is in the odds ratio. If the confidence intervals are either side of 1 this indicates that the value taken by the variable has no bearing on how likely the outcome is. Where the confidence interval approaches 1 this indicates that the association with the outcome may be weak.

Further information

Audit references

Further information

- For more information on the National Diabetes Foot Care Audit or access to the Service Level Analysis, please visit the NDFA webpage at http://content.digital.nhs.uk/footcare.
- For further information about this report, please contact NHS Digital's Contact Centre on 0300 303 5678 or email enquiries@nhsdigital.nhs.uk.

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Acknowledgements

The NDFA team would like to thank all the teams who have worked hard to contribute to this unique and valuable insight into the care and outcomes of people with diabetic foot ulcers.

Development and delivery of the NDFA is guided by a multi-professional advisory group of clinicians and patient representatives, chaired by Professor William Jeffcoate. The NDFA Advisory Group members include:

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Prepared in collaboration with:

The Healthcare Quality Improvement Partnership (HQIP). The National Diabetes Foot Care Audit is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit Programme (NCA). HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the NCA Programme, comprising more than 30 clinical audits that cover care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual audits, also funded by the Health Department of the Scottish Government, DHSSPS Northern Ireland and the Channel Islands.

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ISBN 978-1-78386-958-9

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