

What are we learning from the National Diabetes Foot Care Audit?



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The National Diabetes Foot Care Audit of England and Wales (N DFA) started in 2014 and published its third Annual Review on March 14, 2018 (NHS Digital, 2018). This included data from all episodes of diabetic foot ulcers (DFUs) registered up to March 31, 2017 including the results of 6 months' follow up.

What is the N DFA designed to do?

The aims of the N DFA are to obtain detail of the outcome of as many as possible of all new DFUs and to try to find reasons for the very wide variation, which is known to exist in outcome across the two countries (England and Wales). The latest data from England, for example, show that the incidence of major amputation varies over seven-fold between the highest and the lowest Care Commissioning Groups (CCGs), even after adjustment for age and ethnicity (Jeffcoate et al, 2017). The intention is to identify patterns of working that are most closely associated with either better or worse outcomes and it is hoped that this will trigger changes, which lead to greater consistency of care with overall improvement.

What the N DFA is not designed to do

The N DFA is not a mechanism for assessing the performance of professionals caring for people with DFUs. It is not a ranking tool. It is inevitable that it will identify variation due to differences in the organisation and resourcing of care, but the primary aim is to assess the effectiveness of the services available to people with DFUs in each part of the two countries.

Who runs the N DFA?

The N DFA is funded by central health departments through the agency of the Health Care Quality Improvement Partnership (HQIP). It is coordinated by NHS Digital in collaboration with Diabetes UK. The design, conduct and reporting of the audit is guided by an N DFA advisory group, which includes

healthcare professionals with a special interest in the field, people with diabetes and representatives of NHS Digital and Diabetes UK.

Participation in the audit was individually consented and voluntary up until August 2017 when the framework changed to a 'Direction' from NHS England, under which all NHS providers are expected to participate and while people with DFUs should be aware that the audit is being undertaken, it is no longer necessary to obtain informed consent in England (although it is still a requirement in Wales).

What information does the N DFA collect?

Data were collected from commissioners (CCGs in England and Local Health Boards in Wales). Every CCG/LHB is sent a questionnaire once a year and asked to answer three questions about the structure of the service they commission. Specifically, they are asked whether they are compliant (yes or no answer) with three aspects of NICE guidance:

- 1) Whether there is a training scheme available for all professionals who undertake annual screening to detect feet at risk
- 2) Whether there is a system available to ensure that all people with diabetes who are defined as being at risk can be assessed by a member of a local Foot Protection Service with the aim that they receive further expert input or surveillance, and
- 3) Whether there is a defined pathway to ensure that anyone with a new or deteriorating DFU can be assessed as an emergency if necessary.

Care process and outcome: data on individual cases referred for specialist assessment

Most readers will be familiar with the information gathered on each new case. It is submitted online by whoever is assuming care of the DFU and is reduced to an absolute minimum — i.e., documentation of the NHS number plus the following clinical details:

Table 1. The SINBAD measure of ulcer severity for use in comparative audit.

Detail of ulcer/foot	Item scores			
Site — forefoot or hindfoot	Forefoot	0	Hindfoot	1
Ischaemia	PAD absent	0	PAD present	1
Neuropathy	Absent	0	Present	1
Bacterial infection	Absent	0	Present	1
Area of ulcer	<1cm ²	0	>1cm ²	1
Depth	¹ More superficial	0	² Periosteum/ bone	1
Total score	0–6			
¹ equivalent to University of Texas grades 1,2 ² equivalent to University of Texas grade 3				

- a) How long the DFU has been present (using time categories designed to make data entry simpler and more reliable)
- b) How severe it is (using the SINBAD grading system, which is based entirely on clinical assessment, *Table 1*) and
- c) Outcome at 12 and 24 weeks, with outcome for this purpose being limited to whether a person is alive and ulcer-free at each time point.

The SINBAD system was designed to characterise populations of ulcers to allow comparison of outcome between different services (*Table 1*). A total score of 3 or more has been shown to equate with an ulcer being ‘more severe’ and associated with worse outcome in a number of different countries (Ince et al, 2008).

Detail obtained by linkage with other databases

The NDFA is one of the family of audits run under the umbrella of the National Diabetes Audit (NDA). As the NDA ensures near completeness of demographic and basic diabetes-related information on nearly every person with diabetes in England and Wales (95.3% in 2016), this information does not need to be re-collected for people registered in the NDFA because it can be cross-linked by NHS Digital using the NHS number. In the same way, it is possible to link with data derived from hospital episode statistics (HES in England; PEDW in Wales) and soon also with the Office of National

Statistics and the National Vascular Registry run by the Royal College of Surgeons. The use of the NHS number for these linkages greatly reduces the burden of data collection imposed on clinicians and it also eliminates the possibility of duplicate entry.

Latest results available following analysis of data on 22,653 ulcer episodes in 19,453 people between 2014 and 2017

The full details from 22,653 ulcer episodes (in 19,453 people) registered between 2014 and March 2017 and followed for 24 weeks is available on www.content.digital.nhs.uk/footcare.

Structure audit

The audit reveals that participation by CCGs and LHBs has been far from complete — presumably reflecting the generally limited attention paid to the problem of DFUs by commissioners, despite the suffering caused, as well as the enormous cost to the NHS. Less than 50% of all commissioning groups were able to answer ‘yes’ to all three questions.

**Care process and clinical outcome
Time elapsed to first expert assessment and ulcer severity**

Approximately 54% of all ulcers were judged less severe and 46% were severe using the SINBAD criteria. There was a very strong statistical relationship between time elapsed before first expert assessment and ulcer severity.

Alive and ulcer-free at 12 and 24 weeks

Not surprisingly, there was a strong association also between severity at presentation and outcome. Approximately 50% and 74% of people with less severe ulcers were alive and ulcer-free at 12 and 24 weeks respectively, compared with 34% and 56% respectively for severe ulcers. There was also a strong statistical relationship between the existence of a designated care pathway and a person being alive and ulcer-free at 12 and 24 weeks.

Amputation and hospital admissions

Amputation is a treatment, and not always a precise measure of either disease outcome or the quality of clinical care, but it is the outcome that is most feared. The incidences of both major and minor amputation

were, not surprisingly, higher in people with severe ulcers (3.5% and 11.6%, respectively) than in people with less severe ulcers (0.7% and 2.8%). Once again, there was a strong statistical relationship between the incidences of both major and minor amputation and the existence of a care pathway between community and specialist services. Similar relationships were apparent for hospital admissions (total or primarily for foot disease) in the six months after presentation, as well as for total lengths of hospital stay.

Variation between providers

Preliminary analysis reveals the considerable variation between localities in England and Wales, which is dismaying, but not unexpected. Thus, while 59% of people with a less severe ulcer might expect to be alive and ulcer-free at 12 weeks after first expert assessment the actual figure varied from 32% and 86%, depending on where they lived. Similarly, a median 33% people with a severe ulcer could expect to be alive and ulcer-free at 12 weeks, but the range across localities was from 13% to 62%.

Discussion

The NDFA has been very successful in its first 3 years and has generated an enormous amount of valuable information. Specifically, these data indicate the likelihood of a very strong causative relationship between compliance with NICE guidance and clinical outcomes. The observation of such a close relationship with the care structures adopted by commissioners echoes the findings from the south-west region of England where the incidence of major amputation has recently been shown to have dropped abruptly in those CCGs that adopted new care plans, while it remained unchanged in those that did not (Paisey et al, 2018).

The NDFA does, however, have some limitations. Dominant among these is the likelihood that the study population is quite highly selected — by their referral to a specialist service, by the interest in the NDFA of those caring for them, by time pressures in a busy clinical service impacting on completeness of patient recruitment and by the earlier need for each

participant to provide informed consent. A variety of pointers suggest that the selected population represents between 10–20% of the total ulcers that arose during the study period to date. The situation should be greatly improved, in England at least, by participation being made a Direction by the NHS. Accumulation of greater numbers of participants will enable more sophisticated analysis in the future.

The next stage will, however, also include an initiative designed to document change in response to the evidence gathered. This quality improvement programme is scheduled to commence early in 2019.

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The National Diabetes Foot Care Advisory Group 2014-2017

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