National Diabetes Footcare Audit
Frequently Asked Questions
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What data items are being collected?

For every new diabetic foot ulcer episode:

- The clinic will record six items at the first expert assessment of a person with a newly presenting lesion:
  1. NHS Number and date of birth
  2. Organisation code
  3. Consent obtained (tick to indicate yes)
  4. Date
  5. Interval between first presentation to a health professional and first assessment by your team (tick one of 5 options)
  6. Presenting features (tick one or more of 9 options)
  7. SINBAD score (tick yes/no to 6 choices; SINBAD is a simple validated ulcer severity scoring system; the yes and no definitions are listed on the Data Collection Form)
  8. Lost to follow-up at either 12 weeks or 24 weeks. For patients no longer under your care at week 12 or week 24

At 12 and 24 weeks following the initial expert assessment, the clinic will record whether the participant is alive and whether they are free from active foot disease.

What other data sources will the NDFA link to?

NHS Digital (formerly the Health and Social Care Information Centre (HSCIC)) will link the locally recorded data (using NHS number) with data items from the Core National Diabetes Audit and with HES (Hospital Episode Statistics) for England and PEDW (Participant Episode Database for Wales) for Wales and with ONS (Office for National Statistics) mortality data. The following data items will be collected via linkage work:

<table>
<thead>
<tr>
<th>Data item</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Sex</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Social Deprivation Score</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Diabetes type</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Year of diagnosis</td>
<td>NDA Core</td>
</tr>
<tr>
<td>BMI</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Smoking history</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Last creatinine level</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Last UACR</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Last foot exam</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Last HbA1c</td>
<td>NDA Core</td>
</tr>
<tr>
<td>Last BP systolic</td>
<td>NDA Core</td>
</tr>
</tbody>
</table>
Has ethical approval been sought?

NDFA is an audit; therefore it does not require NHS Research Ethics Committee (REC) approval. Section 2.3.12 of the DH document ‘Governance Arrangements for Research Ethics Committees Document (Harmonised Version)’ excludes clinical audit from REC approval. Data collected for clinical audit must adhere to Health Research Authority (HRA) framework which includes ethics and confidentiality. The NDFA patient information leaflet and consent form have been developed through consultation with the NHS Digital Information Governance team and people with diabetes.

Is NDFA an National Clinical Audit and Patient Outcomes Programme (NCAPOP) audit?

Yes. Further information about NCAPOP audits can be found here http://www.hqip.org.uk/national-programmes/

Which organisations is the audit applicable to?

The audit is applicable to all NHS Funded diabetes specialist foot care services within secondary care, primary care and community care. If you are unsure if your hospital/service is eligible please contact the audit team at ndfa@nhs.net

I work for a GP practice; can the practice participate in the audit?

If you provide a diabetic foot treatment service then you should participate. To check your eligibility for this audit please contact the audit team by emailing ndfa@nhs.net
Is the audit open to other countries other than England and Wales?

Due to the current commissioning arrangements, the audit is open to England and Wales services only. However, countries who wish to use the audit tools published on the NDFA website (http://content.digital.nhs.uk/footcare) to conduct a local audit may do so.

Does the audit cover inpatients too?

The audit covers the work of foot care teams both outpatient and inpatient. It is designed to audit foot ulcer care from the point of presentation to the foot care specialist team.

Do we need to obtain the patient’s consent before collecting data?

For health care services in England:

No. From May 2017 the legal basis for collecting, processing and holding data within the National Diabetes Audit Programme changed. Since then NHS England has directed NHS Digital to collect patient identifiable data for the audits from providers in England. Due to how the contract for the NDFA and collection/submission deadlines fall, it was decided to implement the changeover in August 2017. The new legal basis for data to be collected by the NDFA (Direction under section 254 of the Health and Social Care Act 2012) will mean the submission of data for the NDFA audit will be mandated for NHS footcare clinics and specialist MDFT services in England. Therefore, primary and secondary health services which deal with diabetic footcare in England will need to work with NHS Digital to supply data from the treatment of their patients.

For health care services in Wales:

Yes, The NHS England direction only covers service providers in England. For Wales, the legal basis for the collection of data will remain as Section 251 and patients will still need to be consented. There will be no change for how organisations participate in the audit for Wales. Informed consent must be obtained from all patients before data on their foot ulcer can be collected for the purpose of the audit. Data cannot be submitted to the audit for any patient who has not given their consent. All potential patients must first be provided with a Patient Information Leaflet and then provide their signed consent by completing the Patient Consent Form. The informed consent provides NHS Digital with the required legal basis to obtain the NHS number of the participant.

Both the Patient Information Leaflet and the Patient Consent Form can be found on our website: http://content.digital.nhs.uk/footcare
Do patients need to complete a consent form for each new foot ulcer?

This answer applies to Welsh health care services only – see above.

There is no need for patients to complete the patient consent form for each new foot ulcer. However, before data on any foot ulcer is collected, it is essential to check that a signed consent form is held on record and ask the participant if they would like to continue to participate in the NDFA.

What do I do if a patient withdraws consent or dissents after their details are entered into the online tool?

This answer applies to English and Welsh health care services.

If you are registered to enter data on the Clinical Audit Platform (CAP) system then you are able to delete episode records and patients for your service. If this is a new patient then do not start a record for them. If the patient has historic records then delete these and the patient from the system.

If clinics in other locations have been visited then the patient will need to contact them directly or inform NHS Digital:

Email: enquiries@nhsdigital.nhs.uk
Telephone: 0300 303 5678
Address:
Clinical Audit and Registry Management Service
NHS Digital
1 Trevelyan Square
Boar Lane
Leeds LS1 6AE

What counts as a ‘new’ patient for this audit?

Any diabetic patient is eligible who presents with a foot ulcer having had a preceding period, however short, without any foot ulcer.

If a patient is discharged from the service and returns with a new foot ulcer should we record these?

If the patient had a period, however short, without ulcers this would be a new episode.
Which patients should be excluded from the audit?

- People without diabetes
- People with diabetes who have foot pathology but no ulcer

Where do I enter the information?

Once you have collected all the data you will need to ensure the data is submitted online using the NDFA secure web portal at:

https://clinicalaudit.hscic.gov.uk/

All data must be submitted using this online portal. The NDFA cannot receive or process paper records. The people who submit data do not need to be the same people who recorded it. Everyone who submits data must be formally registered to do so. To register, users complete a NDFA registration form available from http://content.digital.nhs.uk/footcare, which needs to be signed off by the registering organisation’s Caldicott Guardian to approve the users’ access to the online portal.

I have submitted my data online. What should I do with the Data Collection Forms?

Once the NDFA has completed it’s data quality round and the submitter is confident that there are no data quality issues then the data collection should be securely destroyed in line with the hospital disposal and destruction policy. Assurances that this has happened need to be in place.

I am leaving the organisation; can I transfer my registration to a colleague?

No, anyone wishing to access the online system will require a new registration form signed by their organisation’s Caldicott guardian. The registration form is available from http://content.digital.nhs.uk/footcare
I am leaving the organisation, is there anything I need to do?

Yes, please notify the NHS Digital that you are leaving the organisation and no longer require access to the audit on your organisation’s behalf. Please do this by emailing ndfa@nhs.net. To ensure that your organisation can continue to participate in the audit please make sure someone else within your organisation has access.

I can’t remember my registration details to access the online system?

Please contact the NHS Digital Contact Centre team on 0300 303 5678 or email: enquiries@nhsdigital.nhs.uk.

Do I need to enter the data by a certain date?

The NDFA is a continuous data collection, with an annual data submission deadline.

The audit is now collecting data for the fourth annual report of the NDFA. Data for patients seen on or after 1 April 2017 for their first assessment need to be entered into the online tool before 31 March 2018. After the submission deadline there will be a data quality period. Participating organisations will be provided with information about data quality issues in their submitted data. The submission deadline for the data quality period will be 31 July 2018.

When will the reports be published?

The first annual and local reports for the NDFA were published in March 2016. These are available from our website: http://content.digital.nhs.uk/article/7037

The second annual report and local reports for the NDFA were published in March 2017.

The Hospital Treatment report which combines data from English and Welsh hospital treatment will be published in October 2017.

The third annual report and local reports for the NDFA will be published in March 2018.

Are there a minimum number of records which must be submitted to receive a report?

For services to receive a statistically significant comparison, a minimum of 100 patients will need to have been treated during the audit year. Participating centres should attempt to record data on ALL new referrals to their service.
Further Information

Who do I contact for further information about the audit?

For further information or general enquiries, including queries regarding data collection and submission, please contact the NDFA Team at NDFA@nhs.net or 0300 303 5678