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About the Audit

What is the National Pregnancy in Diabetes (NPID) audit?

The NPID audit measures the quality of pre-gestational diabetes care in pregnancy against National Institute for Health and Care Excellence (NICE) guideline based criteria and the outcomes of pre-gestational diabetic pregnancy. The NPID audit is part of the National Diabetes Audit (NDA) programme commissioned by the Healthcare Quality Improvement Partnership (HQIP) and managed by NHS Digital (formerly known as the Health and Social Care Information Centre (HSCIC)), in collaboration with Diabetes UK.

What does it measure?

The audit aims to answer the following questions:

- Were women adequately prepared for pregnancy?
- Were adverse maternal outcomes during pregnancy minimised?
- Were adverse fetal/infant outcomes minimised?

Which patients should be included in the NPID audit?

The NPID audit includes data from all consenting pregnant women with pre-gestational diabetes. As well as patients with Type 1 or Type 2 diabetes, the audit also includes women with Maturity Onset Diabetes of the Young (MODY) or Glucokinase deficiency whose diabetes outside of pregnancy can normally be managed with lifestyle adjustments alone.

The NPID audit excludes women with gestational diabetes.

Who is expected to participate in the audit?

All trusts and local health boards with joint diabetes and obstetric services in England and Wales are expected to participate in the audit.

Where can I obtain all the necessary documentation to take part in the audit?

All documentation required to take part in the audit can be downloaded from the NPID website at http://content.digital.nhs.uk/npid
**When should I enter data?**

The audit is continuous, you can enter data throughout the year. The audit team report on pregnancies with an outcome in the calendar year, and will announce a deadline for when data needs to be entered into the online tool for it to be included in the next report. However this does not stop you entering data into the online tool, if you miss the deadline your data will be included in the next report.

**Where can I find the reports?**

The first report was published in October 2014, based on pregnancies with a recorded outcome before 31 December 2013 and submitted by 7 February 2014. The report is available here.

The second report was published in November 2015, based on pregnancies with a recorded outcome before 31 December 2014 and submitted by 12 February 2015. The report is available here.

The third annual report was published in October 2016; based on pregnancies with a recorded outcome before 31 December 2015 and submitted by 12 February 2016. For the first time we also published Service level data alongside the annual report. These reports are available here.

The next annual report will be based on pregnancies with an outcome prior to 31 December 2016 and submitted by 10 February 2017. This report will be published in October 2017.

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

Yes, NPID is an NCAPOP audit and is listed in the Quality Accounts Resource 2010-2016:

- Category – Long term Condition
- NCAPOP code – LTC002

The audit forms part of the mandated Quality Accounts, there is no funding available for units taking part.

**Has the audit been approved by an NHS Research Ethics Committee (REC)?**

NPID is an audit; therefore it does not require NHS 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 the Health Research Authority (HRA) framework which includes ethics and confidentiality. The NPID information leaflet and consent form have undergone the Information Governance Assurance process and meet the HRA requirements for clinical audit.

All Trusts and Local Health Boards with joint diabetes and obstetric services in England and Wales are expected to participate in the audit.
About Patient Consent

What information about the audit is available for participants?
The audit provides an information leaflet for participants along with an information sheet containing the data items collected. These are available to download from our website http://content.digital.nhs.uk/npid. All participants should be given a copy of the Participant Information Leaflet before they are asked to consent to taking part in the audit.

Who can record participant consent?
All healthcare professionals who are involved in managing the antenatal care of pregnant women with pre-gestational diabetes can obtain consent from the patient. The person taking consent should print their name, sign and date the relevant section of the Participant Consent Form once it has been completed by the patient.

The consent form asks women to consent to their anonymised NPID information being used for research purposes. What kind of research is this likely to be?
All research being conducted using NPID audit data will fall in line with the aims of the audit. For example, research may look at how services can be improved in order to better the care received by women with pre-gestational diabetes during pregnancy. All applications for data are assessed by the National Diabetes Audit Executive Board and need to go through the HQIP data access process to ensure that the research aims and methodology are clinically and statistically sound, and that the correct legal permissions are in place before permission is given to share the data.

What happens if a participant refuses consent?
Only data from consented women should be included in the audit. Do not enter data into the online submission tool for women that have not consented to be part of the audit. You do not need to record the number of women who refused to give their consent. The audit is not collecting or publishing data on the number of women who refused to give their consent. However we may ask at certain times for an estimate of the number that have refused, only so that we can understand any barriers to participating and how to improve the audit.

Do we need to obtain the women’s consent before submitting the data?
Yes, informed consent must be obtained from all women before data on their pregnancy can be entered on to the clinical audit platform. Data cannot be submitted to the audit for any woman who has not given their consent. All participants must be provided with a Participant Information Leaflet.
and have signed the Participant Consent Form before data is entered on to the clinical audit platform. The informed consent provides NHS Digital with the required legal basis to obtain the NHS number of the mother and baby for the audit.

**Our Trust has a local policy in place for consent. Can this be used instead of obtaining specific NPID audit consent?**

Unfortunately, local consent policies are not sufficient for data to be submitted to the NPID audit. All women eligible for taking part in the audit need to provide their specific, informed consent using the audit documents available from the NPID website. It is important that the audit has a consistent approach to obtaining consent and that all women agreeing to take part in the audit have the same level of understanding before consenting (i.e. they are all given the NPID audit information leaflet. NHS Digital, also has a duty to be confident that the women included in the audit have been fully informed about the audit and have provided informed consent for their data to be submitted to the audit. The audit documentation satisfies this requirement.

**Why does the NPID audit need to obtain consent when other audits, such as the National Diabetes Audit, do not?**

The Health Research Authority (HRA) is responsible for governing clinical audits and granting Section 251 approval (which exempts audits from obtaining individual informed consent from patients). Section 251 is only granted where it is not deemed feasible to ask all eligible patients for their consent, for example the core National Diabetes Audit where data is collected on approximately 3 million patients each year. The NPID audit has not been granted the exception and therefore must obtain informed consent because of the low volumes of eligible patients (approximately 3,500 people each year) and the fact that there is an appropriate setting in which the consent may be obtained.

**What happens if a participant consented but has since said they would like to withdraw their consent from the audit?**

Participants may choose to withdraw their consent from the audit at any time. If a participant who has previously consented wished to withdraw, any data manually recorded, including their consent form should be destroyed securely in line with Caldicott and Data Protection principles. If you have already entered data into the NPID online tool for a participant who withdraws consent, you will also need to inform NHS Digital that this person has withdrawn consent to ensure all records are destroyed. Please contact the NPID team at npid@nhs.net if you need to inform the team of withdrawn consent.

**Do participants need to complete a consent form for each pregnancy?**

There is no need for participants to complete the Participant Consent Form for each pregnancy, however, before data on any new pregnancy is collected, it is essential to check that a signed consent form is held on record and ask the woman if she would like to continue to participate in the NPID audit.
**What happens if a participant submitted data for previous pregnancies but does not want to submit data for subsequent pregnancy(ies)?**

If the patient is happy for data on their original pregnancy to continue to be used within the audit then that information will remain within the secure system. Do not enter data into the online submission tool for the subsequent pregnancies unless the patient agrees. If the patient wishes to withdraw their consent form the initial pregnancy then please inform the NPID team at npid@nhs.net

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**About Data Collection**

**What data items are collected?**

For a full list of data items collected for the audit, please refer to the NPID data Items and Sources Sheet available on the NPID website. The NPID audit requires a small number of data items to be collected manually using the Data Collection Form in addition to data items obtained from linkage to other data sources.

The data items collected will allow the NPID audit to look at the standards of care provided to women with pre-gestational diabetes who are pregnant as well as maternal outcomes, obstetric outcomes and neonatal outcomes.

**How is data collected?**

Data for each pregnancy should be collected by completing an NPID Data Collection Form from preferably the first antenatal appointment onwards. Data Collection Forms are available to download from the NPID website.

Once the final section has been completed, the form will need to be submitted online using the NPID secure web portal at [https://clinicalaudit.hscic.gov.uk/](https://clinicalaudit.hscic.gov.uk/)

**When will data be collected?**

Manual data collection began 11th March 2013 for all eligible pregnancies where the first contact with the antenatal clinic was no earlier than 1st July 2012. However local units should decide on their own start date for data collection and can join the audit at anytime during the calendar year if they are not yet registered. Information on all consenting patients whose first contact with the antenatal clinic is on or after this start date must be included.

All pregnancies from consented patients should be entered into the clinical audit platform by a specified date each year to be included in the next annual report. The latest cut off point was the 10 February 2017, for all pregnancies with an outcome before 31 December 2016.
Who can fill in the Data Collection Form?
All healthcare professionals who are involved in managing the antenatal care of pregnant women with pre-gestational diabetes can fill in the Data Collection Form. Whoever completed the form should record their name in the relevant section to ensure you can follow up any queries with the right person locally as you are entering the data online.

Where can I obtain guidance for completing the Data Collection Form?
For help completing the Data Collection Form, please refer to the data definitions section of the Implementation Guidance document which is available to download from the NPID website at http://content.digital.nhs.uk/npid

How should data be stored?
The Patient Consent Form and Data Collection Form(s) should be kept securely in line with Caldicott principles. Please contact your local Caldicott Guardian or information governance team for further information on secure data storage and time periods for keeping.

Can NHS Digital use the data collected for the NPID audit for other purposes?
NHS Digital will only use the NPID data for audit purposes to look at improving care for women with diabetes when they are pregnant or considering pregnancy. Anonymised information about pregnant women with pre-gestational diabetes and their babies collected by the NPID audit and held securely by NHS Digital may be used for research to improve NHS healthcare delivery. There are strict data confidentiality controls in place to protect participant data and any research must be in line with the audit aims and have been through HQIPs data access process to ensure that the legal permissions are in place to allow the sharing of the data.
About Data Submissions

How is data submitted?

Once you have collected all the data and completed the Data Collection Form, you will need to submit the data online using the NPID secure web portal at: https://clinicalaudit.hscic.gov.uk/

Data Linkage

All data must be submitted using the online portal. Once submitted, the data will be linked with data from the core National Diabetes Audit (NDA), Hospital Episode Statistic (HES) data and Patient Episode Database for Wales (PEDW). This combined data will be used to produce the reports. Linkage is undertaken to help reduce the burden on data collection of services. The data linkage is in line with audit aims to improve pregnancy outcomes for women.

When should I enter the data into the secure web system?

Certain elements of information from the NPID audit data collection form need to be entered together so that you can save a record. In particular

- All of the information in Section A of the form needs to be entered together
- All of the information in Section C of the form needs to be entered in one visit, apart from the ‘Alive at 28 days’ response for live births – this can be entered later.
- The answer ‘Yes’ to the ‘Alive at 28 days’ question can only be entered at least 28 days after the Pregnancy End Date. The record will only be treated as complete once this has been completed.

When should the data be submitted?

The latest submission deadline is 10 February 2017 (for all pregnancies ending on or before 31 December 2016).

However the audit is continuous and you can enter data throughout the year at any point, therefore you may find it easier to submit the data soon after the pregnancy ends so that you have access to the patient records should you need to refer to these.

Does data need to be submitted for all consenting diabetes pregnancies or can a sample be submitted?

All information on all consenting patients whose first contact with the antenatal clinic is on or after the audit start date you have chosen locally must be included.
What happens if the booking and delivery hospital are different? Who is responsible for completing the record if a participant delivers their baby at a different hospital?

If the booking hospital has created the patient record but a different hospital is the delivering hospital, and they also participate in NPID, then the delivering hospital can complete the pregnancy record by searching for the NHS number of the patient and adding the required information. If the delivering hospital does not participate in the audit but provides you with the details, you can complete the pregnancy record.

For pregnancies ending on or after 1 January 2015, you will need to record the delivery hospital for live and stillbirths - if the delivering hospital is not available to select in the drop down list please contact the audit team by emailing Enquiries@nhsdigital.nhs.uk to request that the delivering hospital is added. Please include ‘NPID audit’ in the title of your email.

What happens if a patient moves hospitals during their pregnancy?

If the first hospital participates in the audit and has created the patient record the second hospital can add to that record by searching for the NHS number and adding the required information. If the delivering hospital is not available to select in the drop down list please contact the audit team by emailing Enquiries@nhsdigital.nhs.uk to request that the delivering hospital is added. Please include ‘NPID audit’ in the title of your email.

What if the mother has more than one baby in a single pregnancy? How should I record this?

If a woman has more than one baby in any single pregnancy e.g. twins, the additional baby form should be completed. In the online tool a second “Add baby” record should be completed for the second baby.

What if the mother has an additional pregnancy and has already participated in NPID?

If a woman that has already participated in NPID has an additional pregnancy then an additional “Add pregnancy” record should be created for the patient in the online tool, therefore creating two (or more) pregnancies for the patient. The “add baby” tab should not be used to record additional babies that were not from the same single pregnancy.

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

The NPID audit team will run data quality checks after the submission deadline and contact you if there are any issues to be resolved. Once the inputter is confident that there are no data quality issues then the Data Collection forms should be securely destroyed in line with the hospital disposal and destruction policy. This should ensure that the forms are destroyed confidentially and
assurances that this has taken place need to be in place. The consent forms should be kept securely in line with your hospital governance policy.

**How do I view my hospital’s audit data**

Registered users of the secure web data entry system can download a csv file containing all the completed audit records entered for their hospital.

If you are unsure of the registered users within your organisation please contact the audit team for more information.

Please note that this includes only the NPID data entered using the secure web system - it does not include any data that will be obtained by linking to other datasets (NDA, HES).

**How can I check my hospital’s audit data?**

The secure web entry system includes several reports that you can use to review your hospital’s submitted data:

**Patient View** – a list of records submitted by users at your hospital providing quick access to updating records

**Data Quality Checks** – a small number of checks for inconsistent/unlikely date combinations

**Incomplete Records** – a list of partially completed records showing which sections are still to be completed.

**Completed Record Extract** - You can also download a csv file of your hospital’s completed records

**Count of submitted records** – Number of pregnancies for this hospital with a pregnancy outcome completed.

**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 NPID Team at NPID@nhs.net or 0300 303 5678