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National Diabetes Audit Programme Requirement Specification
Document management

Revision History

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<tr>
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Reviewers

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Glossary of Terms

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Introduction

The National Diabetes Audit was established in 2004, initially as a combined adult and paediatric audit, and delivered by NHS Digital (formerly the Health and Social Care Information Centre (HSCIC). It was developed as part of the diabetes National Service Framework (NSF) implementation plan to drive service improvement and monitor the impact of the NSF. In 2011 the adult and paediatric components were tendered separately, the national paediatric diabetes audit (NPDA) was awarded to the Royal College of Paediatric Child Health (RCPCH), whilst the NDA continued to be delivered by the HSCIC (then the Information Centre) as prime contractor and Diabetes UK (DUK) as the subcontractor leading on clinical and patient engagement.

From 2010 new elements were incorporated to include specialised care pathways. Pregnancy in women with diabetes (NPiD), foot ulcer management in people with diabetes (NDFA), and Continuous Subcutaneous Insulin Infusion in people with Type 1 Diabetes were the subjects of new NICE guidelines and care of in-patients with diabetes (NaDIA) arose from a request by the Diabetes National Clinical Director and Department of Health due to concern about the management of people with diabetes admitted to hospital e.g. the post-admission DKA sustained by the index patient in the Mid Staffs enquiry. Transitional care has become a national priority and the NDA has been working with the NPDA to develop measurements relevant to supporting people with diabetes through childhood to adulthood.

The NDA is part of the National Clinical Audit (NCA) Programme, which is commissioned by the Healthcare Quality Improvement Partnership (HQIP) and funded by NHS England. National comparative clinical audit is a data driven improvement approach used to determine if healthcare is being provided in line with nationally agreed standards. It informs care providers and patients of where their service is doing well, and where there could be improvements.

The prevalence of diabetes and associated secondary complications continue to rise nationally, bringing with it a high burden of disease. As such diabetes has been prioritised nationally, forming part of the Department of Health’s 2016/17 mandate to NHS England. In 2015, the NHS England Domain directors, the Welsh Government, HQIP and NAGCAE undertook a prioritisation exercise to review the current NCA Programme to understand their value and benefit and whether they should be re-commissioned. This was to ensure that the NCA programme is current and provides value for money. The decision was made that the NDA Programme should continue.

NHSE and HQIP invited various stakeholders to discuss priorities for the NDA at a Specification Development Meeting in June 2016. Attendees of the meeting included relevant national clinical directors, clinicians and healthcare professionals, representatives of patient bodies, people with diabetes, academia and the Welsh Government. The meeting discussed each of the current audit work-streams and how these could be developed further and any future developments for the audit programme. Based on feedback from the meeting a proposal document was drafted; proposals were prioritised with NHS England and HQIP and the resulting programme of work is detailed within this requirement specification.

From April 2017 NHS England will use their powers under Section 254 of the Health and Social Care Act to direct NHS Digital (formerly the Health and Social Care Information Centre) to collect, analyse and disseminate the NDA Programme of work.

Purpose of Document

This document sets out the requirements for the National Diabetes Audit Programme and should be read alongside the NDA Programme Technical Specification and the Direction issued by NHS England.
Aims of Clinical Audit

The role of a national clinical audit is to support improvement in the quality and outcomes of patient care by benchmarked reporting against national guidance and standards, for example by utilising standards from the National Institute for Clinical Excellence (NICE), and those from other established professional and patient sources. Successful national audits are those where the individuals providing the data are also in a position to improve the system, and there is a shared understanding of what good care looks like.

The overarching aim of the NDA is the collection, analysis and effective reporting of robust comparative data on the quality of diabetes care delivered to people with diabetes to drive improvements in services and outcomes. The audit should at its core be a mechanism to drive improvement within the NHS for the benefit of patients and those working to deliver care. Engagement with clinicians, patients and commissioners (both local and national) and regional networks is essential in order to support improvements and lever change.

This audit programme is expected to:

a. develop a robust, high quality audit designed around key quality indicators likely to best support local and national quality improvement.

b. Achieve, articulate and maintain close alignment with relevant NICE national guidelines and quality standards throughout the audit, as appropriate;

c. enable improvements through the provision of timely, high quality data that explores variation by comparing providers of healthcare, and comprises an integrated mixture of named Trust or Health Board, commissioner, MDT, general practitioner, possibly consultant or clinical team level and other levels of reporting;

d. engage patients, carers and families in a meaningful way, achieving a strong patient voice which informs and contributes to the design, functioning, outputs and direction of the audit;

e. consider the value and feasibility of linking data at an individual patient level to other relevant national datasets

f. ensure robust methodological and statistical input at all stages of the audit;

g. identify full range of audiences for the reports and other audit outputs, and plan and tailor them accordingly

h. provide data in a timely, accessible and meaningful manner to support quality improvements, minimising the reporting delay and providing continual access to each unit for their own data

i. utilise strong and effective project and programme management to deliver audit outputs on time and within budget

j. close engagement with the National Paediatric Diabetes Clinical Audit and to seek opportunities to align scope, methodology and outputs to optimise a whole pathway analysis of diabetes care and outcomes from pregnancy and childhood through to adulthood; and

k. develop and maintain strong engagement with local clinicians, networks, commissioners, patients and their families and carers and charity and community support groups in order to drive improvements in services for patients
National Diabetes Audit Programme Governance

The governance structure should be robust and transparent, and the structure should allow for joint working with the NPDA to ensure opportunities for alignment are maximised.

Clinical Leadership
Effective clinical leadership is integral to the audit delivery. In this context, clinical leadership means that individual(s) with relevant clinical expertise, appropriate experience with national project delivery and demonstrably high professional peer respect and authority are integral to the audit’s governance structure and lead the project. It is essential that clinical leaders represent the specialties responsible for delivery of the care that is being audited as these are the clinicians who will need to accept the findings and lead service improvements.

Strong, effective clinical leadership is a core component, which should help to drive:

a. effective operational delivery of the audit and;
b. successful engagement and influence at local and national levels to maximise the quality improvement impact of the audit (e.g. leading on engagement with local clinicians, commissioners, and networks, patients and carers, whilst aligning and working at a national strategic level in partnership with national clinical directors, clinical reference groups and the equivalent groups in Wales).

Meaningful engagement is integral to the success and utility of the audit. It is essential that the audit continues to successfully engage with primary care, secondary care, CCGs (in England) and Health Boards (in Wales) to promote ownership and drive quality improvement at a local level. It is therefore essential that clinical leadership, engagement and governance continue to be provided effectively and transparently as essential functions either by NHS Digital or subcontracted to a specialist organisation.

Statistical Involvement
Appropriate statistical input is integral to the successful delivery of the audit. Statistician input will be essential to the drafting and delivery of a comprehensive analysis plan which should be developed jointly with the clinical lead(s), the methodologist(s) and other experts on the team. The analysis plan must be designed to support the specific improvement goals and anticipated published comparisons which have been identified for the audit during development.

Methodologist Involvement
Appropriate methodological input must be integral to the planning and delivery from the outset. Audits pose various challenges related to the definition of the patient inclusion criteria, the definition of the dataset and the robust collection of the data, including the linkage of audit data to information from other databases. Methodological input is also required during the analysis and interpretation of the audit findings. These individuals will have a key role in the design of the audit, ensuring that it meets the requirements of the audit aims and objectives.

Patient and Public Involvement
There are seven principles of patient and public involvement (PPI) that should be integrated into the NDA Programme:

- Representation
- Early and continuous involvement
- Clarity of purpose
- Inclusivity
- Transparency
- Cost-effectiveness
- Feedback

Effective and meaningful PPI in the governance structure is required and the above principles should be integrated appropriately throughout every stage of the design and delivery of the work.
Examples that relate to these principles may include:

a. There is appropriate PPI representation on relevant governance groups including the project board
b. Patients are involved when defining specific project improvement goals and audit measures to ensure that they will address issues of importance to patients
c. Patients are clear about their continuing role and purpose in contributing to different stages of the project
d. Information is accessible to facilitate patient engagement with the project throughout its lifetime
e. Patients are included in the development of the National clinical audit report and actively influence the format of the reporting. Patients are involved in developing plain English / patient friendly reports
f. There is transparency about how patient involvement will influence project activity, e.g. there is clear evidence of a collaborative approach to the development of tools and resources that will support the project.

Audit Governance Structure

The audit must be governed by a robust management structure with clearly-defined governance groups, designed to maximise effectiveness. The proposed NDA governance structure is defined in Figure 1. Membership should be reviewed at least on an annual basis and as needed throughout the life cycle of the audit.

Adopting the current approach, each work-stream should have its own Advisory or Working Group that is comprised of a multi-disciplinary team with experience and specialist knowledge of the relevant audit; this should include healthcare professionals, people with diabetes, analysts, and representatives from governing bodies. The Advisory Group will oversee the development of the audit collection and outputs, along with quality improvement initiatives.

In addition to the governance for the individual audits, the NDA should have a governance structure in place that provides responsibility for the delivery of the audits and making executive decisions, along with strategic direction and promotion of the audit. Under the current governance structure this is two governance groups. The NDA Executive Board is responsible for executive decision making and the delivery of the audit against the pre-defined deliverables. The NDA Partnership Board provides Strategic Direction and promotion of the Audit. The group(s) membership should be comprised of relevant professionals e.g. Specialist Clinical Lead, GP Lead, NHS Digital, HQIP, NPDA, NHS England, Welsh Government, Public Health England, people with diabetes.

In addition, any changes to the direction in terms of the requirements or technical specification should be implemented by following the Change Management Process as outlined in this requirement specification.
National Diabetes Audit - Core

The National Diabetes Audit (NDA) started in 2003-4 as part of the Diabetes National Service Framework (NSF) implementation plan to provide reliable measurements for service improvement and monitor the impact of the NSF. The core components of the NDA were designed to align with the Diabetes NSF, NICE guidelines and Quality Standards in respect of achievement rates for annual care process, and treatment targets and disease measure including premature mortality. It integrates data reflecting contributions from all primary and secondary care providers and captures data on over 2 million people with diabetes each year.

The core NDA is designed to answer five key questions:

1. Is everyone with diabetes diagnosed and recorded on a practice diabetes register?
2. What percentage of people registered with diabetes received the nine NICE key processes of diabetes care?
3. What percentage of people registered with diabetes achieved NICE defined treatment targets for glucose control, blood pressure and blood cholesterol?
4. What percentage of people registered with diabetes are offered and attend a structured education course?
5. For people with registered diabetes what are the rates of acute and long-term complications (disease outcomes)?

Inclusion criteria

Services
- NHS funded General Practices in Primary Care.
- Secondary Care Diabetes Services delivering routine Diabetes Care.
- Secondary care diabetes services delivering insulin pump clinics
Geographical coverage

- England and Wales

Patient/population characteristics

a. There are no age limits for patient inclusion
b. Patients with diabetes mellitus (Type 1 and Type 2, Maturity Onset Diabetes of the Young (MODY) and other rare forms)
c. Patients with non-diabetic hyperglycaemia and potentially women with previous gestational diabetes, as guided by the NHS England Diabetes Prevention Programme inclusion criteria (See DPP section).
d. Diabetic patients with learning disability and/or mental health diagnosis.

Dataset design

The NDA dataset should be comprehensive enough to support quality improvement and assurance, allow for adequate risk adjustment, while balancing the need to minimise local burden. To achieve this aim, the existing dataset of the NDA should undergo annual review to ensure all data items collected from providers are directly aligned with the quality improvement questions, and that data linkage opportunities with national data sources (e.g. Hospital episode statistics (HES); Patient Episode Database for Wales (PEDW); Office for National Statistics (ONS)) are maximised. This review should take account of data items that are a priority for stakeholders that are currently not included in the dataset but could become part of the core audit dataset. The review should also be responsive to changes if the dataset requires revision, such as removing data items that are no longer clinically relevant. Any changes to the dataset should go through the appropriate change management process as detailed in this document.

The NDA will be expected to engage in appropriate stakeholder consultations during dataset development and review, including (but not limited to):

a. service users and carers;
b. commissioners (local and national);
c. clinicians (including General Practitioners);
d. third sector organisations; and
e. organisations setting professional standards/users of the data for quality improvement and benchmarking, e.g. National Institute for Clinical Excellence (NICE); Care Quality Commission (CQC).

The dataset should align with current and, where possible, forthcoming national guidance and quality standards of best practice. It is expected that data are collected which directly reflect relevant NICE guidance and quality standards.

Items that should be included in the Core dataset are:

a. measurement of the delivery of NICE recommended care processes;
b. incidence of diabetic complications and mortality using data linkage on an individual patient level with HES, PEDW and Mortality data
c. measurement of NICE recommended treatment target achievement and other meaningful and measurable outcomes at the appropriate care levels, these should align with national best
practice and, where possible, be adaptive to advancements in individualised treatment targets (e.g. collecting drug data);

d. analysis and reporting for learning disability and mental health patient sub groups to support initiatives to reduces health inequalities and support parity of care

e. measurement of the uptake and attendance at structured education programmes

f. The scope of the core dataset should be expanded to include Type 2 diabetes prevention and measure variations by primary care practice and CCG/Health Board in non-diabetic hyperglycaemia, capture uptake and effectiveness of the English Diabetes Prevention Programme lifestyle interventions (utilising specific primary care ‘read codes’, shortly to be replaced by SNOMED codes). Where appropriate it is expected that the NDA explore linkage to the Welsh equivalent cardiovascular prevention programme.

Participation and case ascertainment

It is expected that the audit strives for 100% participation in primary care and the audit engages with key stakeholders, such as clinicians, commissioners and system providers, to influence and enable an increase in participation within secondary care. Case ascertainment should be evaluated and reported, where appropriate this should make use of other national data sources (e.g. hospital episode statistics (HES), Quality Outcomes Framework (QOF) and Patient Episode Database for Wales (PEDW)).

Data collection

The NDA primary care extraction currently takes place annually. Primary Care Extraction will continue as an annual extraction for the 2016-17 audit. For the 2017-18 audit there should be two extractions, followed by the audit moving to quarterly extractions from 2018-19 onwards. This will give more timely reporting to help support local quality improvement.

For secondary care data collection should be continuous whereby service can enter data throughout the year. The online system will be secure, provide data quality checks and completeness functions and validations to help submitters and decrease the burden on services. As part of the continuous collection meaningful information should be able to be extracted by providers, for purposes of local quality improvement, quality assurance and benchmarking. This includes the provision of online reports that present results, in graphical, tabular or another usable format.

Data linkage

The audit should identify and define any potential data linkages which would enhance the data quality, or the impact of the audit or reduce data burden. It is expected that the NDA Core dataset is linked to PDS (Patient demographic service) HES (Hospital Episode Statistics), PEDW (Patient Episode database for Wales) and mortality (Office for National Statistics datasets) on an individual patient level and these data linkages are utilised to best effect, such as collecting data on diabetic complications, admissions or service provision.

It is expected that the NDA Core dataset is linked to the National Paediatric Diabetes Audit (NPDA) dataset to explore the transition of care from paediatric to adult services. The data flow and information governance criteria should be explored, and NHS Digital should work with NPDA and HQIP to address so that data linkage can be undertaken (See Transition Section).

It is additionally expected that the NDA Core dataset is linked to the Diabetes Prevention Programme (DPP) minimum dataset to explore the transition of care from pre-diabetes to post-diabetic diagnosis services. The data flow and information governance criteria should be explored, and NHS Digital should work with NHS England, the DPP and Public Health England to address so that data linkage can be undertaken (See Diabetes Prevention Programme Section).
Other data linkages that would benefit the impact of the audit are linkages with other NCAPOP audits (e.g. national vascular registry, national ophthalmology audit and national cardiac audit programme), and linkage to Improving Access to Psychological Therapies dataset, these should be explored. It is expected that the audit explores the mechanism for linkage with the National Diabetic Eye Screening Programme (DES) in England (https://www.gov.uk/guidance/diabetic-eye-screening-programme-overview) and Diabetic Eye Screening Wales (DESW) (http://www.eyecare.wales.nhs.uk/drssw).

These linkages would reduce the overall collection burden on participating trusts and would improve data completeness and quality, helping to produce a complete picture of diabetes care and comparison of patient outcomes.

**Learning Disability and Mental Health**

The NDA should capture and report meaningful information about the care and outcomes of patients with diabetes who also have a learning disability or a mental health disorder, seeking to answer the following questions:

- **a.** What is the prevalence of learning disability/mental health disorders in people with diabetes and how does this compare with available national prevalence figures?
- **b.** What are the characteristics of diabetic patients with a learning disability/mental health disorder (including BMI index and ethnicity)?
- **c.** How does this reflect on outcomes (e.g. blood sugar control / HbA1C) and complications?
- **d.** Where possible, what proportion of service providers make reasonable adjustments for diabetics with learning disabilities, for instance in relation to structured education programmes, education and awareness for blood sugar control in pregnancy?

**People on Insulin Pumps**

The NDA should capture and report meaningful information about the care of Type 1 patients that are on insulin pumps to help inform services about the care they deliver. The audit should aim to understand the following:

- **a.** The reasons why people are put on pumps
- **b.** How long people have been on pumps
- **c.** Whether their care has improved since they started on a pump
- **d.** Any differences in care process and treatment target achievement for people on pump compared to their peers not on pumps.
- **e.** Whether individual treatment targets are being achieved for those people on pumps

The analysis and data items collected should be considered with relevant stakeholders e.g. Advisory Group, Insulin Pump network. The collection and reporting of data items should be in line with the NDA Core schedule.

**Analysis and audit outputs**

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:
a. For the 2016-17, 2017-18 audit collections care processes and treatment targets should be reported annually. For the 2018-19 audit onwards, an annual report should be produced along with progress reports during the audit year.

b. The annual report should provide details of annual care process completion and treatment target achievement, along with patient demographic information and information for offered and attendance at structured education places. This will help users to identify areas for quality improvement.

c. The progress report should provide an update for how services are performing at meeting the end of audit year annual care processes and treatment targets to help services with local improvements to help improve the variation in completion rates.

d. The content of both the annual report and progress reports should be agreed with stakeholders.

e. Where possible, the data should be linked to PDS data to help improve the quality and data completeness.

f. The data should be linked to HES, PEDW and mortality data and a report for diabetic complications produced every two years. The content of the report should be agreed with stakeholders.

g. The data should be linked to the NPDA dataset, along with linkage to HES and PEDW. A report should be produced as detailed in the Transition section of this requirement.

h. A supplementary annual report for learning disability and mental health should be published that includes information about how well they are performing for care processes and treatment target achievement compared to their peers.

i. A supplementary annual report for insulin pump findings should be reported annually.

National Pregnancy in Diabetes Audit

The National Pregnancy in Diabetes Audit (NPID) launched in March 2013, it is a continuous audit of the care and outcomes of women with diabetes who become pregnant, conducted in secondary care maternity units with a joint maternity and diabetes service.

NPID seeks to answer three key questions:

1. Were women adequately prepared for pregnancy?
2. Were adverse maternal outcomes minimised?
3. Were adverse foetal/infant outcomes minimised?

Inclusion criteria

Services:
• Secondary care maternity units with a joint diabetes and maternity service

Geographical coverage:
• England, Wales and the Isle of Man

Patient/population characteristics:
• Women with pre-existing diabetes who become pregnant
• There is no upper or lower age limit for inclusion
Exclusion criteria

- Gestational diabetes

Dataset design

The dataset should align to current and where possible, forthcoming national guidance (including NICE) and quality standards of best practice. The dataset should consider maternal and foetal process and outcome measures, including:

**Process:**

a. Diabetes treatment prior to pregnancy
b. Treatment and medications before pregnancy
c. Folic acid supplementation
d. Onset of labour and method of delivery
e. Gestation at first contact with specialist antenatal diabetes team
f. Smoking status at booking and delivery

**Maternal outcome:**

g. Diabetes control and complications before pregnancy
h. HbA1C control before, during and where possible extend to post-partum
i. Pregnancy outcomes
j. Adverse outcomes

**Foetal outcome:**

k. special care baby unit/neonatal intensive care unit requirement
l. Gestation length
m. Adverse outcomes

**Participation and case ascertainment**

It is expected that the audit aims to achieve 100% participation of eligible providers and 100% case ascertainment.

**Data collection**

The audit should be a continuous data collection where services can capture pregnancy outcomes throughout the year. The mechanism for data collection should be secure and facilitate data quality and completeness, e.g. built in validations, data completeness reporting.

**Data Linkage**

The NPID dataset should link with other modules of the NDA Programme, particularly the NDA core dataset, to reduce the data collection burden upon participating organisations and maximise opportunities for examination of long term outcomes. It is expected that the audit links to HES and PEDW data for pregnancy and adverse outcome data to decrease burden on services. The audit should explore the opportunity to link with the diabetic eye screening programme to collect the required process and outcome measures.
Analysis and audit outputs

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:

a. As part of the continuous collection improvements meaningful information should be able to be extracted by providers, for purposes of local quality improvement, quality assurance and benchmarking. This includes the provision of online reports that present real time results, in graphical, tabular or another usable format. Services should have input into the design of these reports.

b. National reporting for the NPID audit should occur every two years.

National Diabetes Foot Care Audit

The National Diabetes Foot Care Audit (NDFA) is a continuous prospective audit of diabetic foot disease in England and Wales. The audit aims to examine the care and outcomes of patients with diabetes who develop diabetic foot disease.

The NDFA seeks to address the following key questions:

1. Are the nationally recommended care structures in place for the management of diabetic foot disease?
2. Does the treatment of active diabetic foot disease comply with nationally recommended guidance?
3. Are the outcomes of diabetic foot disease optimised?

Inclusion Criteria

Services:

a. Diabetes specialist foot care services within secondary care, primary care and community care.
b. Inpatient and outpatient services.
c. Commissioners (Clinical Commissioning Groups (CCG) and Local Health Boards (LHB)).

Geographical coverage:

a. England and Wales.

Patient/population characteristics:

a. Health care professional training programme to undertake annual foot checks
b. Referral pathway of those at increased risk to foot protection service (FPS)
c. Referral pathway of those with new foot disease for urgent multidisciplinary foot team (MDFT) assessment
d. All patients with diabetes presenting with a foot ulcer
e. There is no upper or lower age limit for inclusion

Dataset design

The dataset should align to current and where possible, forthcoming national guidance (including NICE) and quality standards of best practice. The dataset should include the following:
Structures Survey:

a. Health care professional training programme to undertake annual foot checks
b. Referral pathway to foot protection service (FPS) and for urgent assessment

Process:

a. Ulcer features and severity at presentation (including SINBAD score)
b. Referral and assessment

Outcome:

a. Foot ulcer status
b. Mortality
c. Hospital admissions and length of stay

Participation and case ascertainment

It is expected that the audit aims to achieve 100% participation of eligible providers and achieves 100% case ascertainment.

Data collection

The audit should be a continuous data collection where services can capture data on foot ulcers throughout the year. The mechanism for data collection should be secure and facilitate data quality and completeness, e.g. built in validations, data completeness reporting.

Data Linkage

It is expected that data linkage (to HES, PEDW, ONS, all relevant modules of the NDA and the national vascular registry) on an individual patient level is utilised to best effect to reduce the data collection burden upon participating care providers and enhance impact.

Analysis and audit outputs

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:

a. As part of the continuous collection improvements meaningful information should be able to be extracted by providers, for purposes of local quality improvement, quality assurance and benchmarking. This includes the provision of online reports that present real time results, in graphical, tabular or another usable format. Services should have input into the design of these reports.
b. National reporting for the NDFA audit should occur every two years.
National Diabetes Inpatient Audit (NaDIA)

Currently the National Diabetes Inpatient Audit (NaDIA) is a bedside ‘snapshot’ audit conducted annually during a specified one-week period. The audit measures the quality of diabetes care provided to people with diabetes while they are admitted to hospital, by answering the following questions:

a. Did diabetes management minimise the risk of avoidable complications?
b. Did harm result from the inpatient stay?
c. Was patient experience of the inpatient stay favourable?
d. Has the quality of care and patient feedback changed since the previous audit years?

Modernised approach to NADIA

It is expected that the audit methodology be adapted to support parity of esteem and reduction in health inequalities between mental and physical health through rotating between secondary care, community care and mental health settings. This should initially be explored through a feasibility study for the ability of community and mental health settings to take part and also case ascertainment for these settings before full implementation.

The approach to all elements of NADIA should be reviewed and modernised where possible. This may include the move to more use of electronic data capture, development of a continuous harms audit and review of the patient experience element.

It is expected that hospital characteristics are collected annually, and two full NADIA audits are collected during the initial three-year period. Work to modernise the audit to be implemented following review and consultation. It is expected that, following review and consultation, a continuous harms collection is developed; this is to be rolled out to all eligible services (including community and mental health setting if appropriate). Following review any electronic data capture for the NaDIA audit week is to be piloted with a subset of hospitals before it is rolled out nationally.

Inclusion criteria

Services:

a. Hospitals that admit people who have diabetes (either for a diabetes related issue or where diabetes is a co-morbidity)
b. Community Hospitals
c. Mental health inpatient facilities

Geographical coverage:

a. England and Wales

Patient/population characteristics:

a. Adults of 18 years and over
b. There is no upper age limit for patient inclusion.
c. Patients with diabetes as a primary diagnosis or comorbidity
d. All patients meeting the eligibility criteria should be included

Dataset Design

The dataset should align with current and forthcoming national guidance and quality standards of best practice, it is expected that relevant NICE guidance and quality standards are incorporated to the dataset. The dataset should also include the following:
Hospital level structures:

- a. Staffing
- b. Training

Process measures:

- a. Blood glucose monitoring
- b. Pharmacological treatment
- c. Involvement of diabetes specialist teams
- d. Using data linkage to reduce the data collection burden and increase the quality of the core dataset

Outcome measures:

- a. Recommended treatment target attainment
- b. Harms: inpatient onset of DKA/HHS, Severe Hypoglycaemia, new foot ulcer
- c. Diabetic complications and mortality

NADIA has a patient experience component this may be retained subject to regular evaluation to ensure it is fit for purpose and meets quality expectations.

Participation and case ascertainment

It is expected that the audit achieves 100% participation of eligible providers and achieves 100% case ascertainment.

Data collection

The data collection should endeavour to move away from a snapshot audit to a continuous collection following review. The mechanism for data collection should be reviewed as part of this development.

Data Linkage

Opportunities for data linkage should be explored as part of the review process. Currently the NaDIA snapshot audit does not contain identifiable data therefore there are no opportunity for data linkage for this audit. The NaDIA harms collection will contain NHS number and it is expected to reduce burden on data collection the data is linked to the NDA Core audit, along with exploring options for linkage to other diabetes audits.

Analysis and audit outputs

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:

1. Detailed national reporting for the NADIA audit week should occur every two years.
2. Reporting should also be provided at a hospital level to ensure meaningful information is available to providers, for purposes of local quality improvement, quality assurance and benchmarking.
3. Hospital characteristics should be reported annually
4. Harms collection should be reported annually

5. On development of a continuous harms collection meaningful information should be able to be extracted by providers, for purposes of local quality improvement, quality assurance and benchmarking. This includes the provision of online reports that present real time results, in graphical, tabular or another usable format. Services should have input into the design of this data collection and outputs.

**Transition**

This is a joint enterprise linking datasets from the adult and paediatric national diabetes audits to evaluate the quality and outcomes of transition care from paediatric to adult diabetes services. Following the completion of the first transition report any lessons learned will be incorporated into the design of future reports.

The audit seeks to investigate if there are changes in the achievement of care standards as children in paediatric diabetes services move to adult diabetes services. It will do this by specifically answering the following questions:

a. Is the transition from paediatric to adult care associated with changes in care process completion rates?

b. Is the transition from paediatric to adult care associated with a change in achievement of treatment targets (specifically HbA1c)?

c. Is the transition from paediatric to adult care associated with changes in episodes of diabetic ketoacidosis (DKA)?

d. Is the transition from paediatric to adult care associated with changes in attendance at clinics?

The NDA will align with the NPDA to capture and share data on processes and outcomes to ensure continuity of excellent care when young people transition into adult diabetes care.

The audit should provide services, commissioners and policy makers with reliable measurements of changes in the achievement of annual care checks and treatment targets along with changes in the experience of outcomes such as DKA and hypoglycaemia. Where possible, the audit should provide measurements for the number of patients lost to follow up from paediatric to adult care (i.e. patients who were engaged and participating in paediatric review and care but then fail to do so when under adult services) and also the number of paediatrics being cared for in primary care only.

Audit results should stimulate and support quality improvements to help improve transitional care particularly for those patients who are lost to follow up (particularly to eye, foot and kidney surveillance) and improvements to care outcomes (such as blood glucose control).

**Inclusion criteria:**

**Services:**
- Paediatric diabetes units
- Primary care
- Specialist secondary care

**Geographical coverage:**
- England and Wales
Patient/population characteristics:
  a. patients with a diagnosis of diabetes mellitus from childhood
  b. patients 24 years or under

Data collection

No additional data is needed for collection for the transition audit. The audit is a data linkage exercise, between the NDA Core dataset and the National Paediatric Diabetes Audit (NPDA). The NDA audit will work with the providers of the NPDA to link the two datasets under the appropriate data sharing agreement. The first transition report linked data for 2003-04 to 2013-14. The Transition audit will add to this linkage by including data for 2014-15 and 2015-16.

Data Linkage

The NDA and NPDA linked dataset should be linked to HES and PEDW data to understand complications during the period before, during and after transition. NHS Digital will work with HQIP and the NPDA to understand data flows and provide the correct information governance framework for the data linkage of these datasets.

Analysis and audit outputs

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:

- Quality improvement activity will be proposed in conjunction with NPDA following on from the reporting.

Diabetes Prevention Programme

- There are currently over 5 million people in England at high risk of developing Type 2 diabetes and if current trends persist, by 2035 one in ten people will develop Type 2 diabetes. People with non-diabetic hyperglycaemia, and therefore at high risk of developing Type 2 diabetes, are being offered an educational Prevention Programme. Following the diabetes prevention programme (DPP) pilot being run by NHS Digital in 2017 the scope of the NDA direction will be updated to include people with non-diabetic hyperglycaemia, impaired glucose tolerance or a pre-diabetes. The aim will be to understand the care that these patients are receiving and to measure over time whether they go on to develop Type 2 diabetes. The audit will also measure whether attending a prevention programme helped to stop/delay the onset of diabetes and any diabetes associated complications.

- The audit will use the findings of the pilot study to understand the best way to update the NDA collection to include the required data, and to work with stakeholders to address the key questions that should be answered as part of the collection. The audit will follow the best process for data linkages to the data collected from DPP education providers supplying the National Prevention Programme and HES and mortality data. The audit will also work with stakeholders, including Public Health England and NHS England to understand roles and responsibilities for analysis and reporting along with mechanisms for any data sharing requirements. The requirements and technical specification will be updated to allow for inclusion of non-diabetic hyperglycaemic patients and recording of prevention programme data along with reporting plans. The specifications will be updated in line with the change management process outlined in this document and the direction.
Inclusion criteria:

Services:
- NHS funded General Practices in Primary Care

Geographical coverage:
- England

Patient/population characteristics:
- Patients with a diagnosis of pre-diabetes, non-diabetic hyperglycaemia or impaired glucose tolerance
- There is no upper or lower age limit for inclusion
- Inclusion of people with learning disability or a severe mental illness

Dataset design

The combined NDA / DPP dataset should be comprehensive enough to support quality improvement and assurance, allow for adequate risk adjustment, while balancing the need to minimise local burden. To achieve this aim, the dataset should undergo annual review to ensure all data items collected from providers are directly aligned with the quality improvement questions, and that data linkage opportunities with national data sources (e.g. DPP minimum dataset, Hospital episode statistics [HES]; Patient Episode Database for Wales [PEDW]; Office for National Statistics [ONS]) are maximised. This review should take account of data items that are a priority for stakeholders that are currently not included in the dataset but could become part of the audit dataset. The review should also be responsive to changes if the dataset requires revision, such as removing data items that are no longer clinically relevant. Any changes to the dataset should go through the appropriate change management process as detailed in this document.

The dataset should align with current and, where possible, forthcoming national guidance and quality standards of best practice. It is expected that data are collected which directly reflect relevant NICE guidance and quality standards.

Items that should be included in the dataset are:

- Measurement of the delivery of care checks and targets for blood glucose levels, cholesterol, blood pressure
- Incidence of complications and mortality using data linkage on an individual patient level with DPP MDS, HES, PEDW and Mortality data
- Inclusion of appropriate drug information, e.g. metformin prescriptions
- Analysis and reporting for learning disability and mental health patient sub groups to support initiatives to reduce health inequalities and support parity of care
- Measurement of the uptake and attendance at the diabetes prevention programme

Participation and case ascertainment

It is expected that the audit strives for 100% participation in primary care. Case ascertainment should be evaluated and reported, where appropriate this should make use of other national data sources (e.g. hospital episode statistics [HES], Quality Outcomes Framework [QOF] and Patient Episode Database for Wales [PEDW]).
Data collection

The first data collection should take place for the audit period 2017-18, there should be two collections during this period, followed by quarterly collections for 2018-19 onwards.

Data linkage

The audit should identify and define any potential data linkages which would enhance the data quality, or the impact of the audit or reduce data burden. It is expected that the DPP dataset is linked to HES (Hospital Episode Statistics), PEDW (Patient Episode database for Wales) and mortality (Office for National Statistics datasets) on an individual patient level and these data linkages are utilised to best effect, such as collecting data on diabetic complications, admissions or service provision. It is expected that the dataset is linked to the prevention programme dataset collected by intervention programme providers, this will improve the quality of the data for referral and attendance for the education programme.

These linkages would reduce the overall collection burden on participating trusts and would improve data completeness and quality, helping to produce a complete picture of care.

The audit should explore the possibility of data dissemination of the DPP dataset linked to the NDA Core dataset, HES, Mortality, and the education provider dataset, to aid evaluation of the DPP.

Analysis and audit outputs

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:

j. For the 2017-18 audit collection an annual report should be produced providing information on the number of people diagnosed, uptake of care checks and uptake of the intervention programme. For the 2018-19 audit onwards, an annual report should be produced along with short progress reports during the audit year.

k. The content of both the annual report and progress reports should be agreed with stakeholders.

Spotlight Audits

A) Provision, attendance, quality and outcomes of structured education for patients and carers

The CCG IAF will measure attendance at structured education programmes for newly diagnosed people within 12 months of diagnosis. Currently the NDA Core collection has highlighted that there are data quality concerns around the recording of attendance at education in primary care clinical systems. The NDA has been working with Diabetes UK, Clinical Networks, CCGs and education providers to highlight a process to help improve data recording. This process has been shared nationally with CCGs and Clinical Networks. The audit will help facilitate the improvement of attendance recording by the following activity during the three years:

- Continue to work with CNs, CCGs, GPs, Specialist services and education providers to support improved data recording for attendance.
- Use results for 17-18 audit to review current approach to data recording, produce case studies for CCGs where improvement shown, publish case studies, and target CCGs where recording still an issue.
- In the 2018-19 annual report 1, if the data supports, include additional analysis for education
• In future years of report 2 measure the impact of attendance on hospital admissions and complications this will need linkage to HES, PEDW and ONS data

• Publicise approach to education recording at Diabetes UK conferences during the 3-year contract, including improvements and case studies, along with results from 18-19 report.

Inclusion criteria:

Services:
  a. NHS funded General Practices in Primary Care
  b. Clinical Commissioning Groups (CCGs)

Geographical coverage:
  a. England and Wales

Patient/population characteristics:
  a. There are no age limits for patient inclusion
  b. Patients with diabetes mellitus (Type 1 and Type 2, Maturity Onset Diabetes of the Young (MODY) and other rare forms)
  c. Diabetic patients with learning disability and/or mental health diagnosis.

Data collection

No additional data collection is needed. This data is already collected as part of the NDA Core dataset. This project is about facilitating the improvement of data recording within GP practices and once improved more in-depth analysis that cannot be currently done due the lack of data completeness.

Data Linkage

In future years of the audit (not within this 3-year contract) it is expected that the audit will link the NDA Core dataset to HES, ONS and PEDW data to look at whether attendance at education helps to reduce the risk of complications.

Analysis and audit outputs

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:

• Case studies will be published and disseminated to CCGs, LHBs and CNs to help facilitate improvements in local data recording for attendance at education programmes

• In the 2018-19 annual NDA Core report 1, if the data supports, include additional analysis for education
  o Measure variation in offering/attendance by practice, specialist service and CCG by type of diabetes, age, sex, ethnicity and IMD
  o Measure the impact of attendance initially on care process completion and treatment target attainment
  o Measure improvement in BMI, blood pressure, blood glucose, cholesterol for before and after the education programme
B) Accessibility and outcomes of treatment using an insulin pump and continuous glucose monitoring

During discussions about the specification for NDA 2017-20 stakeholders articulated the need to measure compliance with NICE TA 151 (Continuous subcutaneous insulin infusion for the treatment of diabetes) and NICE DG21 (Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes)

Specifically, they were concerned to know:

1. Are the recommended services available?
2. Is the infrastructure commissioned to deliver them?
3. Are patients achieving the intended treatment objectives?

To support this, activity will comprise of the following:

- Develop a working group for this spotlight audit collaborating with NPDA (subject to them having resource to do so, and this spotlight being included in their specification) and the Insulin Pump Network.
- Design a ‘structures’ survey to answer questions 1 & 2 and develop a question to add to the insulin pump audit to capture the results for question 3. Alignment would be needed with the NPDA so that the same insulin pump questions are asked from both audits. The methodology for analysis would need to be aligned between the audits so that results are comparable, we will do this through the working group and regular communications.
- Link the insulin pump data collected in Core with the NPID data, to understand if it is feasible to see if insulin pumps helped women with diabetes to achieve target glucose control and also avoid admission with hypoglycaemia.

Inclusion criteria:

Services:
   a. Secondary care diabetes services delivering insulin pump clinics

Geographical coverage:
   a. England and Wales

Patient/population characteristics:
   a. There are no age limits for patient inclusion
   b. Patients with diabetes mellitus (Type 1 and Type 2, Maturity Onset Diabetes of the Young (MODY) and other rare forms) that are on an insulin pump

Data collection

Data is currently collected for insulin pump patients as part of the NDA Core dataset for specialist services. Following the establishment of the Working Group with NPDA and the Insulin Pump Network the group will establish a set of questions for the structures survey that will answer questions 1 and 2. It is expected that this will be developed as an online survey for insulin pump clinics to complete. The working group will also develop additional questions to answer question 3, these will be added to the NDA Core dataset for the 17-18 collection. Whilst designing the questions for the spotlight audit the working group will consider the burden on services and ensure that only the minimum amount of questions are asked to be able to answer the proposed questions to the required amount of detail.
It is expected that the structures survey will only be collected once during the 3-year contract, this will form part of the 17-18 NDA Core collection and will be voluntary for services to participate.

**Analysis and audit outputs**

The analysis and audit outputs should be as specified in the Analysis and Audit Output Section of this requirement document. In addition:

- The current insulin pump report that is published as part of the NDA Core dataset will be updated to include the findings from the structures survey for 17-18

**Other Activities**

The National Diabetes Audit Programme of work also includes a number of other programmes for the 2017-2020 period that will not involve data collection from all services but will form part of either scoping exercises or quality improvement activities. These activities are documented here so that the NDA programme in its entirety can be seen.

**Patient Experience Audit**

Patient Experience is not currently carried out throughout the NDA programme of audits, apart from as part of the inpatient audit. A scoping exercise should be carried out in year 1 which will inform any future work.

The scoping exercise will look at:

- Review the findings from the Pilot study carried out previously
- Review the questions to understand if still relevant and whether new questions need adding, including individualised care planning and dietary advice
- Review feedback from CSQM workshops with people with diabetes
- Review literature and other surveys for questions, uptake, and methodology
- Patient involvement in developing the survey questions and methodology
- Methodology for how we promote to people with diabetes
- Methodology for how we engage GP practices and Specialist Services
- Consideration of the current NaDIA patient experience survey
- Consideration of NPDA approach and whether any joint learning/activity would be possible
- Investigate the use of mobile apps for surveys, how to commission, costs and formats

Following the scoping exercise, we will produce a report for NHS England and HQIP to review and to decide if we proceed.
Quality Improvement

The audit should support a quality improvement programme of work for specialist services. This programme of work should cover NPID, NDFA and NaDIA audits. The programme should be led by an independent person that has relevant experience of quality improvement activities within a healthcare setting. The works should take place between 2017 and 2020, and should use the audit outputs for each audit to help services identify local areas for improvement. The work should capture how services have used the audit outputs, what changes they have identified and any improvements or findings from the processes they have put in place. A report for of the findings should be published for each audit.

Overarching Requirements

Analysis

Strong methodological statistical analysis must be a core component of the audit design and delivery. The analysis should take note of the following:

a. The aim should be to produce data interpretable by all relevant stakeholders, particularly clinicians, commissioners, and service users and carers, to improve the quality of clinical services.

b. The management of missing data or variability in the quality of data submitted to the audit will be explicit.

c. A person or group with appropriate statistical expertise will carry out and supervise the analysis of data.

d. Data will be analysed and presented at general practice, hospital/NHS Trust, Clinical Commissioning Group level subject to NHS Digital disclosure policy and taking into account the views of stakeholders for level of granularity.

e. The interpretation and presentation of the analyses will be a joint enterprise decided by the Advisory Group.

Outlier analyses

- Outliers will be determined in line with national guidance. Outlier analyses should be applied to measures which are robust and have an evidence-based link to patient outcomes.

- The audit will determine with stakeholders, including national commissioners (e.g. NHSE, Welsh Government and HQIP) which measures will be included in the outlier analyses.

Audit outputs

The audit outputs should be developed in such a way that they could be used locally to drive quality improvement e.g. making performance against NICE guidance clear for providers, commissioners and patients; use of interactive tools; bespoke reporting tailored to different audiences (including patient outputs); regional workshops and supporting peer review processes.
The audit is expected to demonstrate an understanding of the audiences for the audit data and tailor the outputs to meet different stakeholder needs and better support local and regional quality improvement. The audit should improve the accessibility of the data, for example through infographics, interactive web tools, run charts.

The level of granularity for reporting should be agreed with stakeholders and in line with NHS Digital disclosure policy, e.g. general practice, trust/health board, clinical commissioning group, local health board.

The audit findings should include a breakdown of analysis by ethnicity and socioeconomic deprivation to support local and national initiatives to reduce health inequalities and promote parity of care.

All reports produced are to be made available in the public domain, at named provider level, excluding any information that might make individual patients identifiable. Data at the level of granularity available in the reports will be made available in .csv format to data.gov.

The audit should engage with other departments to maximise the impact of the audit outputs, this includes working with Public Health England, NHS Choices and MyNHS. Where possible data should be made available on public facing domains to support the transparency agenda.

National and local reports are expected to be made available in a timely manner as soon as possible after data collection and analysis.

**Dissemination**

The audit should report the findings for each work-stream in line with the audit output sections detailed in this document and as agreed with NHS England. The audit should facilitate the need for sharing of audit data with researchers and other organisations. This will follow established NHS Digital governance processes.

**Joint working between NDA and NPDA**

Integral to the success of the national diabetes audit programme is the successful joint working between the NDA and NPDA to optimise a whole pathway analysis of diabetes from pregnancy, to childhood, to adulthood and the complications which can result. It is expected that the NDA proactively seeks opportunities for alignment with the NPDA in governance, scope, methodology and outputs across all elements of the audit such as, but not limited to:

a. Transition from children’s to adult services

b. Spotlight audits

c. The NDA extracts primary care diabetes records for all ages, it is therefore expected that the NDA collect paediatric and adolescent primary care data and through the transition work explores case ascertainment for the NPDA.

d. Reduce duplication of data for CCG level outcomes reporting (CCG OIS and CCG IAF) by working together and alignment.
Synergies between the audits and other national initiatives

During dataset design/review and at key milestones, it is expected that scoping be undertaken to ensure that the audit continues to align and support other national initiatives and priorities. In addition to national clinical guidance and quality standards, it is expected that the national clinical audit design and dataset align with, are responsive to, and can work synergistically with other national policy initiatives and levers to support improvements in services, including (but not limited to):

a. Clinical Outcomes Publication (COP), previously Consultant Outcomes Publication (http://www.hqip.org.uk/national-programmes/clinical-outcomes-publication/)

b. NHS England Seven Day Hospital Services (https://www.england.nhs.uk/ourwork/qual-clin-lead/7-day-week/)


e. CCG Outcome Indicator Set (CCG OIS) (https://www.england.nhs.uk/resources/resources-for-ccgs/ccg-out-tool/ccg-ois/)


g. The NHS Outcomes Framework in Wales (http://llyw.cymru/topics/health/nhswales/circulars/performance-delivery/?skip=1&lang=en)


i. Welsh Diabetes Delivery Plan (http://gov.wales/topics/health/nhswales/plans/diabetes/?lang=en)

j. NHS Rightcare and the Atlas of Variation (http://www.rightcare.nhs.uk/)


l. National Child and Maternal Health Intelligence Network (ChiMat) (http://www.chimat.org.uk/)


o. Best Practice Tariff in England (https://improvement.nhs.uk/resources/developing-201718-national-tariff/)

Alignment with Health Policy Direction

The NDA Programme is part of the National Clinical Audit Programme and therefore the audit design, tools and data items should remain aligned with and responsive to contemporary health policy directives. In particular, the audit must evolve in response to updated NICE guidance and quality standards and should remain responsive to and aligned with other national initiatives (Clinical
Outcomes Publication, BPT, seven-day hospital services, the Rightcare atlas of variation, QOF, NCVIN, ChiMat, Welsh Diabetes Delivery Plan, CSQM and the model hospital).

The audit is also expected to align where appropriate with the NHS Outcomes Framework including the CCG Outcome Indicator Set and Improvement and Assessment Framework. The audit should also contribute to the development of new indicators if required.

### Historical Data

For the audit to be able to provide information about improvements in patient care, and incidence of complications, the NDA will need to follow people over time to understand how their care has changed. This requires the use of historical audit data and linkage from year to year. The direction covers the analysis and reporting of historical audit data for each of the audit workstreams, and from the implementation of the direction all historical audit data will be covered by the direction. NHS Digital are data controllers for the historical data.

### Linkage to other Databases

The audit will consider linkages to other NHS Digital datasets and other national databases including HES, PEDW, ONS, Patient Demographic Service, NPDA, IAPT, DPP minimum dataset, and other national audits, registries and databases to support enhancements of the audits and decrease burden for services. The audit will aim to identify any existing databases for linkages to avoid unnecessary duplication for services, including duplication of data collection platforms. The NDA will work with stakeholders to identify the required information governance frameworks to be able to perform data linkages.

### Data Security

As part of data collection development and maintenance measures will be developed to mitigate the risk of loss of data. The NDA will ensure a full understanding of the Data Protection Act along with other relevant security policies and legislation. The NDA will follow NHS Digital policies for data protection, information security and confidentiality.

### Local Contributor Requirements

The audit design must take into account the workload anticipated locally during participation in the audit and minimise this wherever possible. The dataset size should be the minimum required to effectively meet the requirements of the audit.

The platform supplied for data entry must provide a fast, secure and user-friendly interface, with real-time data entry facilitated wherever possible. Data inputted by each service should be extractible locally and supported by appropriate tools to facilitate its use in relevant local activities such as for presentations or for comparisons with other local data sources. The platform should also supply real-time relevant information such as data completeness.
Communications Plan

Comprehensive information about the audit including the commissioning body, audit aims and objectives, design, geographical cover, timelines, and audit tools / data set (including terms and conditions of their use) must be publically accessible via a dedicated section of the NHS Digital website, with links wherever possible from relevant stakeholders’ websites.

A comprehensive communications plan will form part of the audit delivery. Dissemination of audit results are expected to be to the full range of interested parties including clinical service providers; service commissioners; patients, carers and the public; policymakers and regulators. Dissemination should take place through a variety of formats and activities appropriate to the needs of the target audience. The interpretation of the audit results for all reports must reflect the same integral clinical leadership, methodological/statistical input and patient and public involvement as other stages of the audit to ensure the data can be used by the clinical community for quality improvement and remains grounded in the needs of the patients.

All reports must be publically accessible. Adaptations may be required to remove the risk of patients being individually identifiable and should be aligned to NHS Digital policy for disclosure control.

Change Management

Any changes to the NDA Direction either in terms of requirements and/or in terms of data items will need to be supported by the individual Advisory Groups for the audit and the NDA Executive Board. If the changes are supported the NDA Executive Board will recommend any changes to the NHS England Diabetes Programme Board. The NHS England Diabetes Programme Board will consider the proposals and any financial implications. Following approval from the NHS England Diabetes Programme Board the changes will be considered by the Standardisation Committee for Care Information (SCCI now the Data Co-ordination Board) and the Burden Advice and Assessment Service (BAAS). The requirements and/or technical specification will be updated, with appropriate consideration of whether the direction itself needs to be updated. Once changes have been approved these will be communicated with stakeholders. The approval process is outlined in Figure 2.
Standards and Guidelines

The following tables capture some of the key relevant documents which are likely to underpin the audit, Table 1 relates to NICE publications and Table 2 to other guideline sources and references. It is expected that these and any other relevant standards and guidelines be reviewed at regular intervals during the life cycle of the audits so that the audit’s datasets can be adapted and updated if and when appropriate.
Table 1. NICE guidance, standards and recommendations to inform the National Clinical Audit of Diabetes.

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Title</th>
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<tbody>
<tr>
<td>NICE diagnostics guidance [DG21]</td>
<td>Integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system)</td>
</tr>
<tr>
<td>NICE Guidelines (NG17), August 2015</td>
<td>Type 1 diabetes in adults: diagnosis and management</td>
</tr>
<tr>
<td>NICE Guidelines (NG19), August 2015</td>
<td>Diabetic foot problems: prevention and management</td>
</tr>
<tr>
<td>NICE Guidelines (NG28), December 2015</td>
<td>Type 2 diabetes in adults: management</td>
</tr>
<tr>
<td>NICE Guidelines (NG3), February 2015</td>
<td>Diabetes in pregnancy: management from preconception to the postnatal period</td>
</tr>
<tr>
<td>NICE in development [GID-NG10023] Expected publication TBC</td>
<td>Type 2 diabetes management. Standing committee C update. To update NG28</td>
</tr>
<tr>
<td>NICE in development [GID-NG10024] Expected publication date: March 2017</td>
<td>Type 2 diabetes prevention. Standing committee C update. To update PH38</td>
</tr>
<tr>
<td>NICE guidelines [PH35] Published date: May 2011</td>
<td>Type 2 diabetes prevention: population and community-level interventions</td>
</tr>
<tr>
<td>NICE guidelines [PH38] Published date: July 2012</td>
<td>Type 2 diabetes: prevention in people at high risk</td>
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<th>Standards</th>
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<tbody>
<tr>
<td>NICE quality standard [QS6] Published date: March 2011</td>
<td>Diabetes in adults</td>
</tr>
<tr>
<td>Technical guidance appraisal</td>
<td>Title</td>
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<tr>
<td>NICE quality standard [QS109] Published date: January 2016</td>
<td>Diabetes in pregnancy</td>
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<td><a href="https://www.nice.org.uk/guidance/qs109">QS109</a></td>
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<td>NICE in development [GID-QSD133] Expected publication date: August 2016</td>
<td>Diabetes in adult (update)</td>
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<td><strong>NICE medical technology guidance [MTG22] Published date: December 2014</strong></td>
<td>VibraTip for testing vibration perception to detect diabetic peripheral neuropathy</td>
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<td>Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus</td>
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<td>Ranibizumab for treating diabetic macular oedema</td>
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<td><a href="https://www.nice.org.uk/Guidance/TA274">TA274</a></td>
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<td>Dapagliflozin in combination therapy for treating type 2 diabetes</td>
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<td>Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy</td>
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<td>Canagliflozin in combination therapy for treating type 2 diabetes</td>
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<td><a href="https://www.nice.org.uk/Guidance/TA315">TA315</a></td>
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<td>Aflibercept for treating diabetic macular oedema</td>
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<td><a href="https://www.nice.org.uk/guidance/TA349">TA349</a></td>
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### Table 2. Other Standards, Guidelines, and Useful References

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<td>Action for Diabetes</td>
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<td>Management of Diabetes</td>
<td>Scottish Intercollegiate Guidelines Network (SIGN)</td>
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<tr>
<td>National Service Framework for Diabetes: Standards (NSF)</td>
<td>Department of Health</td>
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<tr>
<td>Together for Health – A Diabetes Delivery Plan</td>
<td>Welsh Government</td>
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<td>2016/17 National Tariff Payment System</td>
<td>NHS England</td>
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<tr>
<td>Lost in transition: moving young people between child and adult health services</td>
<td>Royal College of Nursing - RCN</td>
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<td>Diabetes transition service specification</td>
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<td>ABCD position statement on standards of care for management of adults with type 1 diabetes</td>
<td>Association of British Clinical Diabetologists</td>
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<td>Admissions avoidance and diabetes: guidance for clinical commissioning groups and clinical teams</td>
<td>Association of British Clinical Diabetologists</td>
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<td>Difference intensities of glycaemic control for pregnant women with pre-existing diabetes</td>
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<td>Continuous subcutaneous insulin infusion versus multiple daily injections of insulin for pregnant women with diabetes</td>
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<td>Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus</td>
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<td>Self-management interventions for type 2 diabetes in adult people with severe mental illness</td>
<td>Cochrane Database of Systematic Reviews</td>
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<td>Improving management of type 2 diabetes in South Asian patients: a systematic review of intervention studies</td>
<td>British Medical Journal (BMJ) Open</td>
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<td>Diabetes Eye Health</td>
<td>International Diabetes Federation (IDF)</td>
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<td>Hospital management of hypoglycaemia in adults with diabetes</td>
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<td>Hospital management of hypoglycaemia in adults with diabetes (revised second edition 2013)</td>
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<td>The management of diabetic ketoacidosis (DKA) in adults</td>
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<td>Adult diabetic ketoacidosis emergency care pathway to use in the case notes - accompanies the DKA revised guideline 2013</td>
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<td>Management of Hyperosmolar Hyperglycaemic State (HHS)</td>
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<td>Variable rate insulin infusion (VRII) for medical inpatients with diabetes</td>
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<td>Discharge planning for people with diabetes</td>
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