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National Diabetes Audit Programme Requirement Specification 2022-2025

Document management

Revision History

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3.1	19/04/2024	Updated to include the collection of gestational diabetes and triglyceride testing data from GPs, and linkage of England NPDA data to NDA Core for measuring glucose technology uptake and effectiveness
4.0	04/07/2024	Uplifted to version 4.0 for publication

Approved by

This document must be approved by the following people:

Name	Signature	Title	Date	Version
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Contents

1. Introduction

The National Diabetes Audit (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 and NHS Wales. 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 National Diabetes Audit was established in 2004, initially as a combined adult and paediatric audit. In 2011 the adult and paediatric components were separated; 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 NHS England (formerly NHS Digital) as prime contractor and Diabetes UK (DUK) as the subcontractor leading on clinical and patient engagement. Since this point, several new elements have been incorporated into the audit including pregnancy in women with diabetes (NPID), foot ulcer management in people with diabetes (NDFA), inpatient safety (NDISA) and the transition between paediatric and adult services (AYA). In 2017, the NDA scope was expanded to allow for inclusion of non-diabetic hyperglycaemic patients and linkage to the National Diabetes Prevention Programme (DPP) education providers data.

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 and a decision was made that the NDA audit programme should continue until 2025.

The Secretary of State for Health and Social Care has directed[1] NHS England under section 254 of the Health and Social Care Act 2012 to establish and operate the National Diabetes Audit Information System for the collection and analysis of information in accordance with the NDA Requirements Specification.

2. Purpose of this document

This document sets out the requirements for the NDA Programme and should be read alongside the NDA Programme Technical Specification and the National Diabetes Audit Directions 2017.

3. 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 Health and Care 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. This includes people at risk of all types of diabetes mellitus (this includes type 1 diabetes, type 2 diabetes and other rarer forms of diabetes, such as monogenic diabetes and diabetes secondary to cystic fibrosis and pancreatitis). 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

[1] National Diabetes Audit Directions 2017

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 aims 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 GIRFT (Getting It Right First Time) standards for specialist diabetes care and quality standards throughout the audit, as appropriate

c. enable improvements through the provision of timely, high quality data that compares providers of healthcare, and comprises an integrated mixture of named trust or health board, commissioner, integrated care system (ICS), primary care network (PCN), multi-disciplinary team, 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 either from the outset or in the future, and plan for these linkages from the inception of the contract

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

g. identify from the outset a 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 commissioning and 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. 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; and

k. enable delivery and analysis of the National Diabetes Experience Survey.

4. National Diabetes Audit Programme Governance

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

1.1 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
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, ICSs (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 England or subcontracted to a specialist organisation.

It is also important that there is direct reporting at clinical lead level to the NHSE National Clinical Director for Diabetes and Obesity to ensure alignment with national clinical and policy initiatives. Replacement of clinical leadership roles within the NDA should be undertaken via a process of succession planning, with NHSE involved in recruitment processes.

1.2 Analytical Involvement

Appropriate analytical input, covering data management, statistical and methodological expertise, is integral to the successful planning and delivery of the audit. Audits pose various challenges related to the definition of the patient inclusion criteria, the definition of the dataset, the robust collection of the data and how it is managed after collection, including the linkage of audit data to information from other databases. Analytical input is essential to the drafting and delivery of a comprehensive analysis plan which is developed jointly with the clinical lead(s) and other experts on the team. The analysis plan will be designed to support the specific improvement goals and anticipated published comparisons which have been identified for the audit during development.

1.3 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 are integrated appropriately throughout every stage of the design and delivery of the work.

Within the NDA, the term ‘experts by experience’ is used to encompass the input of patients with diabetes on the various engagement groups.

Examples that relate to these principles may include:

a. appropriate PPI representation on relevant governance groups including the project board

b. patient involvement when defining specific project improvement goals and audit measures to ensure that they will address issues of importance to patients and carers
c. patients and carers being clear about their continuing role and purpose in contributing to different stages of the project
d. information being accessible (via a project website) to facilitate patient and carer engagement with the project throughout its lifetime
e. patient and carer inclusion in the development of the project outputs and active influence over the format of the reporting, working towards achieving co-production and co-design of outputs and recommendations that are aimed at patients
f. appropriate communication and effort made to reach the seldom-heard population; patients and carers are involved in developing dissemination plans to support patient and public outputs
g. transparency about how patient and carer 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
h. planning is in place to measure the impact of PPI

1.4 Audit Governance Structure

The audit is governed by a robust management structure with clearly defined governance groups, designed to maximise effectiveness. The decision making, reporting and accountability hierarchies are defined in Figure 1. Membership is reviewed at least on an annual basis and as needed throughout the life cycle of the audit. Each group has a terms of reference which sets out the purpose, scope and authority of the group and a process for managing declarations of conflicts of interest.

Each work-stream has its own Advisory Group (AG) that is comprised of a multi-disciplinary team with experience and specialist knowledge of the relevant audit; this includes healthcare professionals, people with diabetes, analysts, and representatives from governing bodies. These groups provide advice and guidance to the NDA, but are non-decision making and mechanisms must be in place to permit effective reporting to the Executive Board and NHSE. It is anticipated that the NDA advisory groups will be expanded to include a research advisory group which will oversee and support access of NDA data to embedded researchers / analysts (through honorary contracts) for the purpose of collaborative projects. A new approach to the Advisory Groups is being piloted for NDISA. This approach includes a data AG which defines the analysis plan and reviews the findings from analysis and also an Implementation AG which focuses on taking findings from the report to develop strategies to maximise their impact in the clinical setting. Should this new approach be successful, it will be rolled out across all NDA workstreams during the period of this contract.

In addition to the governance for the individual workstreams, the NDA has a two-tier 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. 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 Partnership Board's membership is comprised of relevant professionals e.g. Specialist Clinical Lead, GP Lead, HQIP, NPDA, NHS England, Welsh Government, the Office for Health Improvement and Disparities (OHID) and people with diabetes. HQIP and NHSE are included in the membership of the supplier's highest level project governance group, normally the Programme Board.

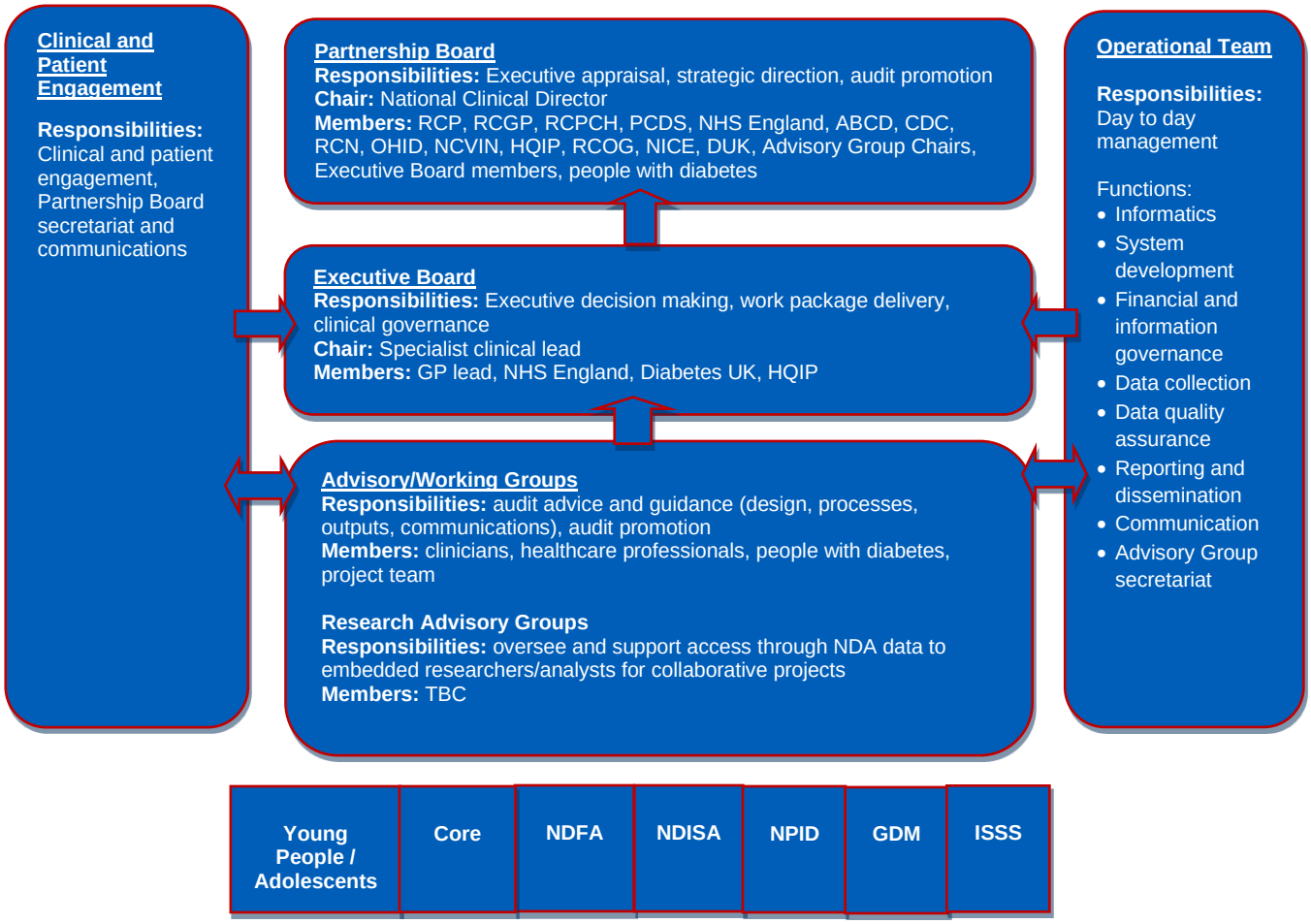

Figure 1: NDA Governance structure

5. National Diabetes Audit overview

The NDA dataset is comprehensive enough to support quality improvement and assurance and allows for adequate risk adjustment, whilst balancing the need to minimise local burden. To achieve this aim, the existing dataset of the NDA undergoes 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); civil registration data are maximised). This review takes 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 is responsive to changes if the dataset requires revision, such as removing data items that are no longer clinically relevant. Any changes to the dataset go through an appropriate change management process.

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

a. professionals working in the NHS

b. care organisations (such as general practices, trusts, Health Boards, Integrated Care Systems (ICS) and Sustainability and Transformation Partnerships (STPs) and Primary Care Networks (PCNs))
c. people who are affected by diabetes and their carers, relatives and friends
d. care commissioners (e.g. Integrated Care Boards (ICBs)) and regulators (e.g. Care Quality Commission (CQC), Healthcare Inspectorate Wales (HIW)) and organisations setting professional standards (e.g. NICE and the Professional Record Standards Body (PRSB)).
e. national bodies such as NHSE, the Welsh Government, Department of Health and Social Care and UK Government

The dataset aims to align with current and, where possible, forthcoming national guidance and quality standards of best practice. It is expected that data collected directly reflects relevant NICE guidance and quality standards. Consideration will be given to the feasible collection of Continuous Glucose Monitors (CGM)/flash/technology data (to determine time in range) once the PRSB diabetes information standard is in place. This would apply across all elements of the NDA.

Throughout all workstreams, the datasets will be regularly reviewed to ensure they remain relevant to the guidelines / metrics being measured and that where possible linkage will be used to reduce burden on service providers. Where metrics are static, there is no improvement intent or there is no link to national policy initiatives, discussion at an Advisory Group will be made to determine if they need to be retired.

6. NDA 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 the number of people living with diabetes each year.

The core NDA is designed to answer four key questions:

1. What percentage of people registered with diabetes received the nine NICE key processes of diabetes care?
2. What percentage of people registered with diabetes achieved NICE defined treatment targets for glucose control and blood pressure and what percentage are on statin treatment for primary and/or secondary prevention of cardiovascular disease?
3. What percentage of people registered with diabetes are offered and attend a structured education course?
4. For people with registered diabetes what are the rates of acute and long-term complications (disease outcomes)?

6.1 Inclusion criteria

<u>Services</u>

- NHS funded General Practices in Primary Care
- Secondary Care Diabetes Services delivering routine diabetes care
- NHS funded diabetic eye screening services
- NHS funded services delivering diabetes structured patient education

- NHS funded services delivering Diabetes Prevention Programme (DPP)
- NHS funded services delivering other aspects of the NHS Long Term Plan, such as the low calorie diet (LCD) programme
- NHS funded monogenic diabetes testing services
- Health services in prisons (adult and young offender) providing diabetes care

Geographical coverage

- England and Wales
- Prisons (England only)
- Monogenic (England only)

Patient/population characteristics

a. There is no age limit for patient inclusion

b. People living with all types of diabetes mellitus referred to throughout as ‘diabetes’

c. People living with a diagnosis of pre-diabetes and non-diabetic hyperglycaemia

The Core dataset covers:

a. the validation of diabetes diagnosis through the capture and analysis of relevant data such as recorded diagnosis, HbA1c and medication

b. measurement of the delivery of NICE recommended care processes

c. the rates (and longitudinal changes) of acute and long-term complications of diabetes and mortality

d. measurement of NICE recommended treatment target achievement for glucose control, blood pressure, statins and cardiovascular risk reduction (measured using data on lipid testing (including cholesterol and triglycerides) and medications)

e. an evaluation of access to services and health inequalities, including but not limited to age, sex, patient protected characteristics (e.g. ethnicity and disability), socioeconomic deprivation, mental health and learning disability

f. use of the frailty index to identify patients living with mild, moderate or severe frailty, so they can be separately analysed since some treatment targets may be hazardous in this group

g. measurement of the uptake and attendance at nationally commissioned structured education programmes (including Healthy Living and My Type 1). Given the introduction of universal digital programmes, analysis of “attendance” should not be limited to within 12 months of diagnosis

h. Type 2 diabetes prevention and measure variations by primary care practice and commissioners/Health Board in non-diabetic hyperglycaemia, capture uptake and effectiveness of the English Diabetes Prevention Programme lifestyle interventions. It is expected that the NDA will explore linkage to the Welsh equivalent cardiovascular prevention programme

i. retinopathy screening and outcomes

j. activity and outcomes of patients referred to / attending the NHS low calorie diet programme

k. a comprehensive evaluation of the care, use of technology (including flash glucose monitoring, continuous subcutaneous insulin infusion (CSII), real time Continuous Glucose Monitors (CGMs), closed loop and other technologies for people with type 1 diabetes) and glucose control (including the Gold and Clarke score for people with type 1 diabetes to enable reporting of impaired awareness of hypoglycaemia) covering secondary care, primary care and an evaluation of those patients not attending any care services

l. development of a mechanism for capturing and evaluating Type 2 diabetes remission, establishing:
    - a retrospective baseline of incidence, on-going care and outcomes
    - inclusion of biochemical and diagnosis data
    - the impact of NICE guided care (including bariatric surgery)

m. an evaluation of care within prisons, following the expansion of the audit into these settings from 2023 onwards

6.2 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), Digital Health Care Wales (DHCW) practice data and Patient Episode Database for Wales (PEDW)).

A report into the feasibility of collecting data from prisons was compiled in 2021, and it was agreed that adult and young offender prisons in England should be included in the NDA Core audit. The data will begin to be collected quarterly from August 2023. The NDA will therefore start to incorporate suitable analysis for the care and outcomes of patients treated within prison settings into the audit outputs once this collection starts.

6.3 Data collection

Since 2018 primary care collection within England has occurred via GPES (General Practice Extraction Service) and extraction within England has occurred every three months (quarterly) to enable timelier reporting to support local quality improvement.
Primary care data collection is undertaken annually in Wales.

GPES will also extract data, on a quarterly basis, from adult and young offender prisons in England from August 2023.

For secondary care data, collection should be continuous whereby services can enter data throughout the year. The online system is secure, provides data quality checks and completeness functions and validations to decrease the burden on submitting services. As part of the continuous collection online reports can be extracted by providers, for purposes of local quality improvement, quality assurance and benchmarking.

Diabetic eye screening data for England from Diabetic Eye Screening Programme (DESP) services and Monogenic Diabetes data for England from the Royal Devon University Healthcare NHS Foundation Trust are sent annually to NHS England via Secure Electronic File Transfer (SEFT). National Paediatric Diabetes Audit (NPDA) data for England and Wales from the Royal College of Paediatrics and Child Health (RCPCH) is also sent to NHS England via SEFT annually. A subset of this data for England (relating to hybrid closed loop technologies) is to be sent on a quarterly basis from 2024.

6.4 Data linkage

The audit aims to identify and define any potential data linkages which would enhance the data quality, or the impact of the audit or reduce data burden. The NDA Core dataset is linked to the Personal Demographics Service (PDS), Hospital Episode Statistics (HES), Digital Health Care Wales (DHCW) primary care data, Patient Episode Database for Wales (PEDW), mortality (civil registration datasets) and Improving Access to Psychological Therapies (IAPT) data on an individual patient level. The audit

aims to use these data linkages to best effect, such as collecting data on diabetic complications, admissions, or service provision.

The NDA Core dataset will be analysed and linked to the PDS to identify patients eligible to participate in the National Diabetes Experience Survey and invite them to take part. For more information, see Section 13.2.

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 and for validation of diagnostic categories in children living with diabetes. From 2024, NPDA data for England will also be linked to the NDA Core dataset to measure uptake, equitable access and effectiveness of hybrid closed loop (HCL) devices as part of NHS England's Hybrid closed loop technologies: 5-year implementation strategy. This strategy was developed following the publication of NICE's technical appraisal guidance, TA943.

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.

In addition, data is linked with data from nationally commissioned structured education programmes (including Healthy Living and My Type 1 resources) and to the minimum dataset from NHS commissioned providers delivering low calorie diets. This aims to evaluate whether attendance at education helps to reduce the risk of complications (by linking the NDA core dataset to HES, PEDW and civil registration (mortality) data).

Other data linkages that would benefit the impact of the audit are linkages with other National Clinical Audit and Patient Outcomes Programme (NCAPOP) audits (e.g. National Vascular Registry, National Ophthalmology Audit and National Cardiac Audit Programme). Future potential linkages include to the CVDPREVENT Audit, the National Obesity Audit, the MODY (Maturity Onset Diabetes of the Young) register and any other NCAPOP projects as required.

The audit explored linkage with the National Diabetic Eye Screening Programme (DESP) in England (https://www.gov.uk/guidance/diabetic-eye-screening-programme-overview) and received the first data from Eye Screening Programmes in 2020. Similarly, the programme is exploring linkage with the Diabetic Eye Screening Wales (DESW) service (http://www.eyecare.wales.nhs.uk/drssw). The linkage to the eye screening data has been agreed and the data will be reported in the workstream reports across the NDA.

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

6.5 Learning Disability and Mental Health

The NDA captures and reports within all core annual reports 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 people with diabetes 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?

6.5.1 Analysis and audit outputs

The analysis and audit outputs are as specified in section 14 ‘Overarching Requirements’ of this document. In addition:

a. an annual report will be produced along with progress reports during the audit year

b. the annual report will 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. interactive dynamic reports and tools (updated annually)

d. the content of reports will be agreed with stakeholders

e. where possible, the data will be linked to PDS data to help improve the quality and data completeness

f. the data will be linked to HES, DHCW primary care data, PEDW and civil registration (mortality) data and a report for diabetic complications produced every two years. The content of the report will be agreed with stakeholders

g. annual reporting for learning disability and mental health will be published that includes information about how well they are performing for care processes and treatment target achievement compared to their peers

h. measurement of variation in offering/attendance at structured education by practice, Primary Care Network (PCN), specialist service, region and ICS

i. measurement of the impact of attendance at structured education on care process completion, treatment target attainment and improvement in outcomes (BMI, blood pressure, blood glucose and cholesterol)

j. evaluation of whether attendance at structured education helps to reduce the risk of complications (by linking the NDA core dataset to HES, PEDW and civil registration (mortality) data

k. in consultation with key stakeholders, suitable analysis and outputs will be developed for the prisons data. It is envisaged these outputs will be available during 2024

6.6 Type 1 Audit

The NDA will produce a comprehensive evaluation of the care and outcomes of Type 1 diabetes services within secondary care, primary care and an evaluation of those patients not attending any care services at all. This report will utilise existing NDA core audit data amalgamated with additional data on the care of patients affected by Type 1 diabetes and the range of available technologies to help inform services about the care they deliver. The audit aims to understand the following:

a. what are the characteristics of people diagnosed with Type 1 diabetes?

b. what care structures are in place to look after people diagnosed with Type 1 diabetes? This information should be collected within the Integrated Specialist Services Survey.

c. how can quality of care between specialist centres and equality of access to care processes and technology be benchmarked?

d. how many people receive the care processes that are recommended to manage their Type 1 diabetes?

e. how many people are offered and attend structured education?

f. how many people with Type 1 diabetes meet their recommended treatment targets? This should include information on insulin treatment regimes, the use of insulin pumps and other technologies and treatment for primary/secondary prevention of complications.

g. what is the uptake and effectiveness of glucose technologies for people with Type 1 diabetes? This will include linkage of the National Paediatric Diabetes Audit (NPDA) dataset to the NDA Core dataset for England to allow measurement of people seen across paediatric and adult diabetes services.

6.6.1 Analysis and audit outputs

National reporting for the Type 1 service report will include:

a. interactive dynamic reports and tools
b. an annual 'state of the nation' summary report
c. a summary infographic to accompany 'state of the nation' report
d. outputs which provide information for the public and people affected by diabetes

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

6.7 Diabetes Prevention Programme

It is estimated that 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. The NHS DPP is a joint commitment from NHS England and DUK to deliver, at scale, evidence based behavioural interventions that can prevent or delay the onset of Type 2 diabetes in adults who have been identified as having non-diabetic hyperglycaemia. Following the diabetes prevention programme (DPP) pilot being run by NHS England (formerly NHS Digital) in 2017 the scope of the NDA direction was updated to include people with non-diabetic hyperglycaemia, impaired glucose tolerance or pre-diabetes. The aim is 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.

As there is a new prevention programme being rolled out across Wales (the All Wales Diabetes Prevention Programme (AWDPP)), the NDA will explore and submit proposals for how the DPP element of the NDA could be expanded to incorporate requirements for Wales.

6.7.1 Inclusion criteria:

Services:

a. NHS funded General Practices in Primary Care
b. DPP education providers
c. Health services in prisons (adult and young offender) providing diabetes care

Geographical coverage:

a. England
b. Wales (the AWDPP is now being rolled out across Wales)

Patient/population characteristics:

a. patients with a diagnosis of pre-diabetes, non-diabetic hyperglycaemia, or impaired glucose tolerance
b. there is no upper or lower age limit for inclusion

6.7.2 Dataset design

The combined NDA / DPP dataset is 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 undergoes 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 (DPP MDS), Hospital Episode Statistics (HES), DHCW practice data, Patient Episode Database for Wales (PEDW); civil registration (mortality) data are maximised. This review takes 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 reviews will 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 will go through the appropriate change management process.

The dataset aligns with current and, where possible, forthcoming national guidance and quality standards of best practice. It is expected that data collected directly reflects relevant NICE guidance and quality standards.

Items that are included in the dataset are:

a. measurement of the delivery of care checks and treatment relating to blood glucose levels, cholesterol (including triglyceride testing), blood pressure and Body Mass Index (BMI)

b. incidence of complications and mortality using data linkage on an individual patient level with DPP MDS, HES, PEDW and civil registration (mortality) data

c. inclusion of appropriate drug information and medications prescribed, e.g. metformin prescriptions

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

e. measurement of the uptake and attendance at the diabetes prevention programme

f. incidence of Type 2 diabetes, and in the longer term incidence of diabetes complications and mortality

g. the audit will build a mechanism which enables the tracking of rates of progression from ‘at risk’ to ‘diagnosed with’ Type 2 diabetes to aid longer term evaluation

6.7.3 Participation and case ascertainment

The audit strives for 100% participation in primary care. Case ascertainment is evaluated and reported; where appropriate this makes use of other national data sources (e.g., Hospital Episode Statistics (HES), Quality Outcomes Framework (QOF) and Patient Episode Database for Wales (PEDW)).

6.7.4 Data collection

Data collection is undertaken on a quarterly basis.

6.7.5 Data linkage

The audit will identify and define any potential data linkages which would enhance the data quality, or the impact of the audit or reduce data burden. The DPP dataset is linked to HES (Hospital Episode Statistics), PEDW (Patient Episode database for Wales), the DPP minimum dataset (DPP MDS) and mortality (civil registration) datasets on an individual patient level. 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 will reduce the overall collection burden on participating trusts and will improve data completeness and quality, helping to produce a complete picture of care.

6.7.6 Analysis and audit outputs

The analysis and audit outputs are specified in section 14 'Overarching Requirements' of this document. In addition, there will be:

a. an annual 'state of the nation' summary report

b. interactive dynamic reports and tools (updated quarterly but the NDA programme will propose if and when more frequent reporting is possible):

- Summarising registration and demographic information on people who have non-diabetic hyperglycaemia
- Numbers of people recorded as having been offered, declined and attend DPP behavioural change courses.

c. a summary infographic to accompany 'state of the nation' report

d. outputs which provide information for the public and people affected by diabetes

6.8 Adolescents and Young Adults (AYA) and Young Type 2 audit

Since 2017 the NDA has delivered the Adolescents and Young Adults (AYA) (formerly known as the Transition Audit) which involves the linkage of NPDA data to NDA adult data to evaluate the care of patients with Type 1 diabetes who transition from paediatric to adult diabetes services. The NPDA is managed by the RCPCH. In 2020, the scope of this audit was refined to incorporate a separate young Type 2 audit, which utilises existing data and linkage of both the NPDA and NDA datasets to examine the care and outcomes of young people with Type 2 diabetes. This report focuses on care processes and treatment targets, as previously set out in the Transition Audit, as well as demographic information relating to where these patients are being seen and how many are being diagnosed with Type 2 diabetes.

The audit will 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 will 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).
The AYA and young Type 2 audits will be delivered in alternate years.

6.8.1 AYA Dataset design

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? To date it has not been possible to answer this question since the relevant data relating to video and telephone consultations (commonly used in this age group) is not captured within the NHS, but it is to remain within scope until feasible to address.

e. are any patients lost to follow up who disappear from both the NDA and NPDA datasets?

6.8.2 Young Type 2 Dataset design

The audit seeks to investigate the cohort of young people with Type 2 diabetes under the age of 40 years. It includes a focus on mental health and learning difficulties. It will do this by specifically answering the following questions:

a. where are young people with Type 2 diabetes being seen?

b. what are the characteristics of young people diagnosed with Type 2 diabetes?

c. are young people with Type 2 diabetes having NICE recommended, age-related, care process checks and achieving treatment targets?

d. what are the interventions/medications being used in young people with Type 2 diabetes?

e. what are the complications and mortality for young people with Type 2 diabetes?

6.8.3 Inclusion criteria:

Services:

a. Paediatric diabetes units
b. Primary care
c. Specialist secondary care
d. Community services.

Geographical coverage:

a. England and Wales

Patient/population characteristics:

Adolescent and Young Adults:

a. Patients with diabetes diagnosed under the age of 18 whose initial treatment involves paediatric specialist services
b. Patients 25 years or under

Young Type 2:

a. Patients with Type 2 diabetes
b. Patients 40 years or under

6.8.4 Data collection

No additional data is needed for collection for the AYA/young Type 2 audits. The audits are data linkage exercises between the NDA Core dataset and the National Paediatric Diabetes Audit (NPDA).

6.8.5 Data Linkage

The NDA and NPDA linked dataset will be linked to HES, DHCW practice data, PEDW and retinopathy data to understand complications during the period before, during and after transition. NHS England 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.

6.8.6 Analysis and audit outputs

The analysis and audit outputs are specified in section 14 'Overarching Requirements' of this document. In addition, outputs include:

- quality improvement activity will be proposed in conjunction with NPDA, following on from reporting
- interactive dynamic reports and tools (updated for both adolescents and young adults and young Type 2 annually)
- annual 'state of the nation' summary reports which alternate between adolescents and young adults and young Type 2
- summary infographic to accompany 'state of the nation' report
- outputs which provide information for the public and people affected by diabetes. This will be suitable for young people and present information in a clear, concise and accessible format. The NDA will work with stakeholders and young people to investigate an appropriate format

7. 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?

7.1 Inclusion criteria

Services:

- Secondary care maternity units with a joint diabetes and maternity service

Geographical coverage:

- England, Wales

Patient/population characteristics:

- Women with pre-existing diabetes who become pregnant
- There is no upper or lower age limit for inclusion

7.2 Exclusion criteria

- Gestational diabetes

7.3 Dataset design

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

The care received by women affected by diabetes who become pregnant including:

a. diabetes control and complications before pregnancy (incl. previous gestational diabetes)
b. treatment and medications and medications in the period leading up to and including conception
c. Continuous Glucose Monitoring (CGM) at booking and 28 weeks (including whether patients have been offered/have accepted CGMs and the type of CGMs)
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
g. HbA1c control before, during and where possible extend to post-partum

The outcomes of women affected by diabetes who become pregnant:

a. Onset of labour and method of delivery
b. Adverse maternal outcomes

The outcomes for babies of women affected by diabetes including:

a. special care baby unit/neonatal intensive care unit requirement
b. gestation length
c. adverse foetal outcomes

7.4 Participation and case ascertainment

The audit aims to achieve 100% participation of eligible providers and 100% case ascertainment.

7.5 Data collection

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

7.6 Data Linkage

The NPID dataset is linked 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. The audit links to HES and PEDW data for pregnancy and adverse outcome data to decrease burden on services. The audit will link with the diabetic eye screening programme to collect the required process and outcome measures and also the Maternity Services Data Set (MSDS). The NPID team will continue to monitor data completeness of this dataset and alter our data collection and specification as and when we can collect full data from MSDS. From 2021 the audit is linked with the Neonatal Research Database (NNRD) which is managed by The Imperial College, London. This data is used to collect and report on Neonatal Intensive Care length of stay and outcomes (this linkage is covered by S251 and does not form part of the Direction).

7.7 Analysis and audit outputs

The analysis and audit outputs are specified in section 14 ‘Overarching Requirements’ of this document. In addition, outputs include:

a. management reports made available to participating units and data quality is checked annually
b. a ‘state of the nation’ summary report for the NPID audit occurs every two years
c. summary infographic to accompany ‘state of the nation’ report

d. interactive dynamic reports and tools (updated as real time as possible)

e. pseudonymised CGM data should be made available to NHS England analysts, updated as frequently as possible, including relevant information on protected characteristics to assess equality of access

8. 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?

8.1 Inclusion Criteria

Services:

a. Diabetes specialist foot care services within secondary care, primary care and community care.
b. Inpatient and outpatient services.

Geographical coverage:

a. England and Wales.

Patient/population characteristics:

a. All patients with diabetes presenting with a foot ulcer
b. There is no upper or lower age limit for inclusion

8.2 Dataset design

The dataset aligns to current and where possible, forthcoming national guidance (including NICE) and quality standards of best practice. The dataset includes the following:

Structures (this information is collected within the Integrated Specialist Services Structures Survey):

An annual survey to understand what structures are in place to provide services and care to patients

a. Health care professional training programme to undertake annual foot checks
b. Referral pathway of those at increased risk to foot protection service (FPS)

Process:

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

b. Referral and assessment

Outcome:

a. Foot ulcer status (alive and ulcer free at 12 weeks after first expert assessment and re-ulceration after healing)
b. Mortality
c. Amputations (major and minor)
d. Hospital admissions and length of stay

8.3 Participation and case ascertainment

The audit is striving to achieve 100% participation of eligible providers (specialist foot services with a multidisciplinary foot care team) and 100% case ascertainment (of the ulcers referred to specialist services).

8.4 Data collection

The audit is a continuous data collection where services can capture data on foot ulcers throughout the year. The mechanism for data collection is secure and facilitates data quality and completeness, e.g. built in validations, data completeness reporting. In order to improve the capture of foot ulcer information it is proposed that the NDA explore the feasibility of collecting relevant data from the primary care dataset and the community services dataset (CSDS).

8.5 Data Linkage

Data linkage (to HES, PEDW, Civil Registration data, all relevant modules of the NDA and if required 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. In addition, analysis may be undertaken using data linked to NHS England data on the use of electrocardiograms within foot care settings.

8.6 Analysis and audit outputs

The analysis and audit outputs are specified in section 14 ‘Overarching Requirements’ of this 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 results, in graphical, tabular or another usable format. Management reports are made available to participating units and data quality is checked annually
b. a ‘state of the nation’ summary every two years
c. summary infographic to accompany ‘state of the nation’ report
d. outputs which provide information for the public and people living with diabetes

9. National Diabetes Inpatient Safety Audit (NDISA)

The National Diabetes Inpatient Audit (NaDIA) has been superseded by NDISA, to enable continuous measurement of 4 harms that can occur whilst a patient with diabetes is in inpatient care.

9.1 Dataset Design

The 4 harms being collected are:

- hypoglycaemia
- diabetic Ketoacidosis (DKA)

- hyperosmolar hyperglycaemic state (HHS)
- foot ulcers

In addition to measuring the above harms, NDISA will measure compliance against the national Getting It Right First Time (GIRFT) standards and develop a number of measures using activity data such as length of stay, readmissions. The GIRFT standards will be measured using the Integrated Specialist Services Structures Survey (ISSSS).

9.2 Data Linkage

The audit will link data from the harms collection with ONS, HES and PEDW as well as other elements of the NDA as required to fulfil the aims of the NDISA and to reduce burden on the service.

9.3 Inclusion Criteria

Data will be collected from acute trusts and Health Boards in Wales for patients aged 16 and over who are living with diabetes.

9.4 Participation and case ascertainment

The audit will develop strategies to increase participation to 100%. Case ascertainment is difficult to measure due to absence of data to establish the denominator, but strategies will be developed to encourage trusts and Local Health Boards to submit all cases.

9.5 Analysis and audit outputs

The analysis and audit outputs are specified in section 14 ‘Overarching Requirements’ of this 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 results, in graphical, tabular or another usable format. Management reports should be made available to participating units which include data quality reports

b. a ‘state of the nation’ summary every two years

c. summary infographic to accompany ‘state of the nation’ report

d. outputs which provide information for the public and people living with diabetes

10. Gestational Diabetes Mellitus (GDM) Audit

Following a feasibility study, a new audit on the care and outcomes of women who develop gestational diabetes during pregnancy is being developed.

The 2021 feasibility study demonstrated that it is possible to provide data on key maternal and neonatal outcomes using the Maternity Services Dataset (MSDS).

There are three key questions based on NICE Guidance NG3 that the audit is aiming to answer:

1) **Diagnosis (1.2.8)**
    a. How many women are diagnosed with GDM in England and what are their healthcare inequalities?

2) **Key maternal and neonatal outcomes (1.2.10)**
    a. What impact does diagnosis and management of GDM have on key obstetric and neonatal outcomes?
3) **Postnatal follow up (1.6.8-1.6.15)**
    a. How many women go on to develop type 2 diabetes and what are we doing to prevent this happening?

10.1 Inclusion criteria

Services:

a. Secondary care maternity units with a joint diabetes and maternity service
b. NHS funded General Practices in Primary Care

Geographical coverage:

a. England

Patient/population characteristics:

- Women who develop diabetes during pregnancy
- There is no upper or lower age limit for inclusion
- Women with a history of gestational diabetes, as guided by the NHS England Diabetes Prevention Programme inclusion criteria (See DPP section).

10.2 Exclusion criteria

Women with pre-existing diabetes who become pregnant.

10.3 Dataset design

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

a. the number of women being diagnosed with GDM
b. key maternal and neonatal outcomes
c. demographic data on ethnicity and deprivation
d. postnatal GP follow up and subsequent risk of developing Type 2 diabetes
e. measurement of the delivery of care checks and treatment for blood glucose levels, cholesterol (including triglyceride testing), blood pressure and Body Mass Index (BMI)
f. inclusion of appropriate drug information and medications prescribed, e.g. metformin prescriptions
g. analysis and reporting for learning disability and mental health patient subgroups to support initiatives to reduces health inequalities and support parity of care
h. measurement of the uptake and attendance at the diabetes prevention programme
i. incidence of Type 2 diabetes, and in the longer-term incidence of diabetes complications and mortality using data linkage on an individual patient level with DPP MDS, HES and civil registration (mortality) data
j. the audit will build a mechanism which enables the tracking of rates of progression from ‘at risk’ to ‘diagnosed with’ Type 2 diabetes to aid longer term evaluation

10.4 Participation and case ascertainment

The audit aims to achieve 100% participation of eligible providers and 100% case ascertainment.

10.5 Data collection

MSDS will be used for the data items required for this workstream from secondary care. The full details of the collection will be defined by the Advisory Group that will be established for GDM.

From 2024, primary care collection within England will occur via the General Practice Extraction Service (GPES) every three months (quarterly) to measure postnatal GP follow up and support local quality improvement.

10.6 Data Linkage

The audit will link collected data with Civil Registration data, HES and DPP MDS as well as other elements of the NDA as required to fulfil the aims that are established for GDM and to reduce burden on services.

10.7 Analysis and audit outputs

The analysis and audit outputs will include:

a. 'State of the Nation' summary reporting for the GDM audit is expected to take place every two years
b. summary infographic to accompany 'state of the nation' report
c. interactive dynamic reports and tools (updated as real time as possible)

11. Integrated Specialist Services Survey (ISS)

This is an integrated organisational survey which incorporates and replaces the separate specialist surveys required for the Type 1 service, NPID, NDFA and NDISA elements of the NDA. It is intended that structural data requirements for any component of the NDA from specialist services be incorporated within this annual survey to reduce burden upon participating providers.

11.1 Inclusion criteria

Services:

a. Specialised diabetes services

Geographical coverage:

a. England and Wales

11.2 Data collection

The ISS survey is sent out annually to all registered Trusts and services in England and Wales delivering diabetes care. Submitters need to complete an Excel template and upload it to the Strategic Data Collection Service (SDCS) platform. The mechanism for data collection is secure and facilitates data quality and completeness, e.g. built in validations and data completeness reporting.

11.3 Analysis and audit outputs

The data collected in the survey will be published in an aggregate form in each of the national audit reports for each workstream. When each report is published, they will indicate resource levels, staffing levels and availability of clinics at trust level.

12. Transition and Young Adult Care (TYA) Pilots

This collection seeks to inform an evaluation of the impact of an enhanced model of care on engagement, care and outcomes for people with diabetes aged 16-25 yrs.

12.1 Inclusion criteria

Services

a. Diabetes specialist services providing care for young adults.

Geographical coverage

a. 15 NHS Trust pilot site locations in England who have agreed to take part

Patient population characteristics

a. People with diabetes aged 16-25 years.

12.2 Dataset Design

This collection seeks to inform an evaluation of the impact of an enhanced model of care for people with diabetes aged 16-25 yrs.

It will do this by answering the following specific questions:

Is the enhanced model of young adult care associated with changes in;

a. service engagement?
b. achievement of treatment targets (specifically HbA1c and blood pressure)?
c. care process completion rates (specifically HbA1c, BMI and blood pressure)?
d. in diabetes related admissions (such as diabetic ketoacidosis (DKA))?

The model specification aligns to existing quality standards of best practice and the dataset was developed with national and local stakeholders to ensure it covers what is required for the evaluation while balancing the need to minimise local burden.

12.3 Data collection

NHS Trusts will source data from their patient administration systems collected as part of the direct care of the patient and submit the agreed dataset specification, on a 6 monthly basis, via the national data landing portal (DLP) platform.

The data will then be loaded and processed by AGEM CSU's Regional Processing Centre (RPC), who will perform data validation checks for data quality purposes, pseudonymise the NHS Numbers and conduct derivations of a few key fields, such as changing full date of birth to age.

The pseudonymised data will then be made available for onward analysis and linkage by NHS England within the National Commissioning Data Repository (NCDR) and the Unified Data Access Layer (UDAL).

12.4 Linkage

Within the National Commissioning Data Repository (NCDR) and the Unified Data Access Layer (UDAL), the TYA pilot data will be linked to the Secondary Uses Services (SUS) datasets as well as other elements of the NDA as required to fulfil the aims of the pilot evaluation and to reduce burden on

the services. A common pseudo key will be used, to compare the pilot sites to a like group comparator in order to assess the impact of the pilot interventions.

12.5 Analysis and audit outputs

NHS England will compare the pilot sites to a like group comparator, this will be a randomised group of individuals from the NDA who share similar characteristics to the treatment group, to assess the impact of the pilot intervention.

The analysis and audit outputs take the form of interim and final analytical reports, containing fully anonymous data. Summaries tailored to different audiences (including commissioning bodies, people with diabetes and clinicians) will also be produced.

13. Other Activities

The National Diabetes Audit Programme of work also includes a number of other programmes for the 2022-2025 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.

13.1 Quality Improvement

The audit will support a quality improvement programme of work for primary care and specialist services delivered to date by Quality Improvement Collaboratives (QIC). This programme of work will cover the NPID, NDFA and NDISA audits. The programme will continue to be led by an independent person who has relevant experience of quality improvement activities within a healthcare setting. The works will take place between 2022 and 2025 and will use the audit outputs for each audit to help services identify local areas for improvement. The work will 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 of the findings should be published for each audit.

The quality improvement programme of work will:

a. disseminate learning from the first phase of QIC delivery and explore new learning within second phase collaboratives
b. deliver activities orientated around evaluation of the effectiveness in improving key metrics of new technologies (e.g. Continuous Glucose Monitors (CGMs) for pregnancy) and other new technologies, patient education initiatives, changes in pathways or service organisation and medications.
c. use the outputs for each audit to help services identify local priorities for improvement
d. 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 of the findings should be published for each element of the NDA
e. make recommendations for how audit outputs could be adapted to better stimulate local quality improvement activities.

13.2 National Diabetes Experience Survey

As part of the Diabetes Patient Insight Programme (DPIP), NHS England is conducting the National Diabetes Experience Survey to measure perceptions, expectations and experiences of diabetes care in order to support the development of a more person-centred policy for delivering healthcare

services for people with diabetes. The survey is voluntary and will be sent to a representative sample of the patient population recorded as living with type 1 or type 2 diabetes, aged 18 or over, diagnosed at least 12 months ago and registered with a General Practice in England.

Under section 251 of the NHS Act 2006 and Regulation 5 of The Health Service (Control of Patient Information) Regulations 2002, NHS England has conditional support from the Secretary of State to temporarily lift the common law duty of confidentiality to enable NHS England to:

- analyse and link data from the NDA Core and the PDS to identify patients eligible to participate in the survey
- share confidential patient information with the survey provider, Ipsos Mori (NHS England's processor), so that they can contact the eligible patients to invite them to participate in the survey

The survey responses will be anonymised and linked using a pseudonymised NHS number to other de-identified datasets held in the Unified Data Access Layer (UDAL) such as the Diabetes Prevention Programme (DPP), Low Calorie Diet (LCD), Healthy Living (HL), Type 1 Diabetes with Disordered Eating (T1DE)), and hospital activity data (for example Secondary Uses Services (SUS) or Hospital Episode Statistics (HES)). This is to support the understanding of any divergence of perceptions and experience of care that diabetes patients have from the achievement of good clinical outcomes.

The survey results will be published in aggregate, anonymous form so that no individual can be identified.

14. Overarching Requirements

14.1 Analysis

Strong methodological statistical analysis is a core component of the audit design and delivery. The analysis takes 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, Integrated Care Board level subject to NHS England 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

<u>Outlier analyses</u>

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

b. 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.

14.2 Internal Access

Data obtained under this Direction may be analysed under the NHS England De-Identified Data Analytics and Publication Directions 2023 (Data Analytics Direction). Any analysis under the Data Analytics Direction will be subject to the conditions set out in Paragraphs 4.2 and 4.3 of those Directions and having regard to the statutory guidance issued by the Secretary of State under s274A of the 2012 Act including, so far as is applicable under that guidance, obtaining advice from the NHS England Advisory Group for Data.

14.3 Audit outputs / Publications

The audit outputs will be developed in such a way that they can 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 commissioning bodies, people with diabetes and clinicians); regional workshops and supporting peer review processes. Outputs will include:

- Dashboards
- State of the nation reports
- Outputs for patients
- Summary infographics

The audit expects 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 aims to improve the accessibility of the data, for example through infographics, interactive web tools, run charts.

The level of granularity for reporting is agreed with stakeholders and in line with NHS England disclosure policy, e.g. general practice, trust/health board, integrated care board, local health board. Producing appropriate information for ICSs to use will be a new focus for the audit. The levels of granularity of reporting include:

a. General practice and prisons in England (Core NDA care processes and treatment targets only). Currently, there is no approval in place to publicly present data at GP practice level in Wales, until that approval is gained, data should be presented at health board and anonymised GP practice level
b. Specialist service (may be more than one per trust/local health board (LHB))
c. Trust/LHB
d. Commissioner (regional and national)
e. Integrated Care System (ICS)
f. Sustainability and Transformation Partnerships (STPs)
g. Primary Care Network (PCN)
h. National (England and Wales separately)

The audit findings 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 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 published in .csv format and linked to from data.gov.uk.

The audit engages with other organisations to maximise the impact of the audit outputs, this includes working with the Office for Health Improvement and Disparities (OHID), HQIP and Diabetes UK. Where possible data will be made available on public facing domains to support the transparency agenda.

The audit aims that national and local reports are made available in a timely manner as soon as possible after data collection and analysis. Producing appropriate information for ICSs to use will be a new focus for the audit.

14.4 Interactive dynamic reports

Data dashboards have been published for most elements of the NDA programme, with more to follow. These are published on the NDA Dashboard Hub. The design and development of these dashboards will continue based on feedback from users and stakeholders.

14.5 Dissemination

NHS England may use its discretionary powers under section 261 of the Health and Social Care Act 2012 to disseminate National Diabetes Audit data, including to Digital Health and Care Wales, researchers and other organisations to support wider service evaluation, quality assurance and research. This will include establishing and maintaining an embedded researcher process.

All dissemination will follow established NHS England governance processes through the Data Access Request Service (DARS) including advice from the Advisory Group for Data (AGD) in accordance with the statutory guidance published by the Secretary of State for Health and Social Care under Section 274A of the Health and Social Care Act 2012.

14.6 Synergies between the audits and other national initiatives

During dataset design/review and at key milestones, scoping will 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. Getting It Right First Time (GIRFT): http://gettingitrightfirsttime.co.uk/
b. National Clinical Project Benchmarking (NCAB): http://www.hqip.org.uk/national-programmes/clinical-project-benchmarking/

And where requested and agreed:

c. NHSEI RightCare programme: https://www.england.nhs.uk/rightcare/
d. Model Health System (Model Hospital): https://model.nhs.uk

14.7 Historical Data

For the audit to be able to provide information about improvements in patient care, and incidence of complications, the NDA needs 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 is covered. NHS England are data controllers for the historical data.

14.8 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 UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 along with other relevant security policies and legislation. The NDA follows NHS England policies for data protection, information security and confidentiality.

14.9 Local Contributor Requirements

The audit design must continue to 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 provides a fast, secure, and user-friendly interface, with real-time data entry facilitated wherever possible. Data inputted by each service is extractible locally and is 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 also supplies real-time relevant information such as data completeness.

14.10 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) are publicly accessible via a dedicated section of the NHS England website, with links wherever possible from relevant stakeholders' websites.

A comprehensive communications plan forms part of the audit delivery. Dissemination of audit results are to the full range of interested parties including clinical service providers; service commissioners; patients, carers, and the public; policymakers and regulators. Dissemination takes 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 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 are publicly accessible. Adaptations may be required to remove the risk of patients being individually identifiable and are aligned to NHS England policy for disclosure control.

15. 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 but have additional financial implications, the NDA Executive Board will recommend any changes to the NHS England Diabetes Programme Directors Group. If necessary, the change will then be escalated to the NHS England Diabetes Programme Board to consider the proposals and any financial implications. 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.

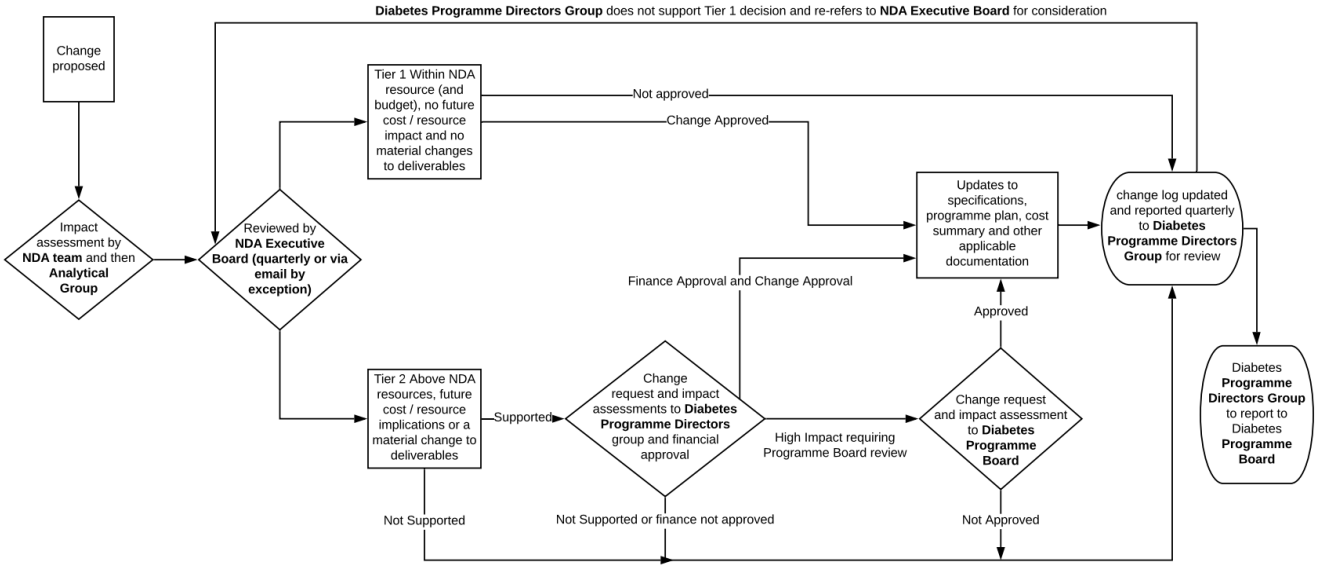

Figure 2: Change Management Process for the National Diabetes Audit Programme

16. 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. These and any other relevant standards and guidelines are reviewed at regular intervals during the life cycle of the audits so that the 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.

Guidelines	**Title**
NG17, published: 26 August 2015 (Last updated: 17 August 2022)	Type 1 diabetes in adults: diagnosis and management- https://www.nice.org.uk/guidance/ng17
NG28, published: 02 December 2015 (Last updated: 29 June 2022)	Type 2 diabetes in adults: management - https://www.nice.org.uk/guidance/ng28
NG3, published: 25 February 2015 (Last updated: 16 December 2020)	Diabetes in pregnancy: management from preconception to the postnatal period - https://www.nice.org.uk/guidance/ng3
NG18, published: 01 August 2015 (Last updated: 29 June 2022)	Diabetes (type 1 and type 2) in children and young people: diagnosis and management - https://www.nice.org.uk/guidance/ng18
NG19, published: 26 August 2015 (Last updated: 11 October 2019)	Diabetic foot problems: prevention and management - https://www.nice.org.uk/guidance/ng19
PH38, published 12 July 2012 (Last updated: 15 September 2017)	Type 2 diabetes: prevention in people at high risk - https://www.nice.org.uk/guidance/ph38
TA943, published 19 December 2023	Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes - https://www.nice.org.uk/guidance/ta943
Standards	**Title**
QS6, published; 30 March 2011 (Last updated: 18 August 2016)	Diabetes in adults - https://www.nice.org.uk/guidance/qs6
QS167, published: 11 May 2018	Promoting health and preventing premature mortality in black, Asian and other minority ethnic groups - https://www.nice.org.uk/guidance/qs167

QS109, published: 19 January 2016	Diabetes in pregnancy - https://www.nice.org.uk/guidance/qs109
QS125, published: 14 July 2016 (Last updated: 31 March 2022)	Diabetes in children and young people - https://www.nice.org.uk/guidance/qs125

Table 2. Other Standards, Guidelines, and Useful References

Other Standards, Guidelines, and Useful References	Link
All relevant standards from the PRSB	https://theprsb.org/
GIRFT diabetes	https://www.gettingitrightfirsttime.co.uk/medical-specialties/diabetes/