Professional Record Standards Body

Better records for better care

Diabetes information standards

FINAL REPORT

March 2022

Document Management

Revision History

Version	Date	Summary of Changes
0.1	2/2/22	First draft created.
0.2	28/4/22	Updates following project board and assurance committee review
1.0	6/6/22	Version uplift following signoff by project board
1.1	4/8/22	Updated following endorsement to include standard name changes revised for ISN.

Reviewers

Reviewer name	Title / Responsibility	Date	Version
Ben McGough	Digital Lead NHS Diabetes Programme, NHS England and NHS Improvement		0.1
Prof. Partha Kar	SRO, National Specialty Advisor, Diabetes with NHS England and co-lead of Diabetes GIRFT with NHS Improvement.		0.1
Mark Brodigan	NHS England		0.1
Lorraine Foley	CEO, PRSB		0.1
Dr Iain Cranston	Consultant Physician, Diabetes and Endocrinology Portsmouth Hospitals NHS Trust		0.1
Dr Neel Basudev	GP, Lambeth CCG		0.1
Ojaih Willow	Citizen Lead		0.1
Helene Feger	Director of strategy, communications and engagement		0.1

Approved by

Name	Title/Responsibility	Date	Version
PRSB Assurance Committee		4/5/22	0.1
Project Board		6/6/22	1.0

Glossary of Terms

Term / Abbreviation	What it stands for
ACR	Albumin to Creatinine Ratio
AGP	Ambulatory Glucose Profile
API	Application Programming Interface
ATTD	Advanced Technologies & Treatments for Diabetes
BG	Blood Glucose
BP	Blood Pressure
CCG	Clinical Commissioning Group
CGM	Continuous Glucose Monitor
CIS	Core Information Standard
COVID-19	Coronavirus Disease 2019
DAPB	Data Alliance Partnership Board
DIY	Do It Yourself
dm+d	NHS Dictionary of Medicines and Devices
DPS	Dynamic Purchasing System
EMIS	Egton Medical Information Systems
EPR	Electronic Patient Record
FHIR	Fast Healthcare Interoperability Resources
GIRFT	Get It Right First Time
GP	General Practitioner
HbA1c	Glycated Haemoglobin A1C
HCP	Healthcare Professional
HL7	Health Level Seven® International
HSSF	Health Systems Support Framework
IDDM	Insulin Dependent Diabetes Mellitus
ISCE	Information Standards, Data Collections and Data Extractions
ICS	Integrated Care Systems
IG	Information Governance
isCGM	Intermittently Scanned CGM
LMP	Last Menstrual Period
LPP	London Procurement Partnership
MHRA	Medicines and Healthcare Products Regulatory Agency
NDA	National Diabetes Audit
NHSE/I	NHS England and NHS Improvement
NICE	National Institute of Health and Care Excellence

NPDA	National Paediatrics Diabetes Audit
NPID	National Pregnancy in Diabetes Audit
PwD, T1 or T2	Person with Diabetes (Type 1 or Type 2)
PRSB	Professional Record Standards Body
QOF	Quality and Outcomes Framework
rtCGM	Real Time CGM
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
STP	Sustainability and Transformation Partnership
TPP	The Phoenix Partnership
UCUM	Unified Code for Units of Measure

Planned Review Date and Route for User Feedback

The next maintenance review of this document is planned for February 2025, subject to agreement with NHS England and NHS Improvement as the commissioning body.

Please direct any comments or enquiries related to the project report and implementation of the standard to support@theprsb.org

Contents

1 Executive Summary

"Diabetes care is multi-professional and multi-location [and] is centrally dependent on personal understanding and application. Diabetes is lifelong. Shared electronic records (between people with diabetes and their disparate care team) has long been recognised as the ideal. Detaching services from their established record systems would in my view be formidably difficult. So, for me, record architecture and interoperability are the key challenges." **Consultant Diabetologist**

There are approximately 4.8 million people living with diabetes in the UK and this is expected to rise to 5.3 million by 2025. It is a condition that is predominately self-managed therefore education of people with diabetes, agreed care plans and support play an important role in a person's ability to self-manage their condition and interactions with health and care professionals can be delivered across multiple care settings, primary, secondary and community. In consultations health and care professionals need access to information about the person such as their medications, information about eye screening and foot checks as well as test results. Currently not all this information is being digitally shared between the different clinical systems in use in different settings.

Digital and technological innovations are delivering tools and devices to help people better self-manage their diabetes – significant advances have been made in medical devices that can be transformative for people who use them.

The cohort of people with diabetes being offered medical devices for glucose monitoring and delivering insulin to self-manage their condition is growing. From March 2019, NHS England set out that all people with type 1 diabetes in England would be offered intermittently scanned continuous glucose monitors and from March 2021 all pregnant women with type 1 diabetes in England will be offered ambulatory continuous glucose monitoring. It is likely that those being offered and using medical devices for monitoring and delivery of insulin will increase over the coming years.

Using a continuous glucose monitor (that uses a sensor worn just under the skin) to self-manage diabetes requires an ability to understand and interpret the data from the device, which is generally accessed via an app on the person's mobile phone. Some people with diabetes also need to use the data and apply it to insulin mealtime bolus calculations to control their sugar levels. Some people with diabetes are now using hybrid closed loop systems to assist their self-management of their insulin dosing. These use real-time data from a continuous glucose monitor and apply a dosing algorithm to adjust the automated delivery of basal insulin from the person's insulin pump. These aspects can be complex, and people may need support to help them with this.

People can give healthcare professionals access to their personal data recorded by their medical device, but often the professional will need to access to the data in proprietary systems and is unable to bring together data from different devices to have a complete view of the data with which to advise the person with diabetes. This information cannot currently be included in a person's health and care record in a structured way meaning that the information being used by the person to self-manage is not the information that the professional team is using to help advise, thus creating a clinical maelstrom. This information needs a standard for its routine collection so that a uniform approach can be developed across differing systems to allow device and system interoperability.

To address these issues NHS England commissioned the PRSB to work with professionals, people with diabetes and suppliers to produce two information standards – a definition of the structure and content of information for, firstly, a diabetes record and, secondly, for sharing information that a person with diabetes collects and records at home and wants to share with their health and care team.

Information that is collected and recorded in a consistent way can be shared between multiple systems across different care settings. This information can then be used to support population health management, to enable population-level trends and characteristics to be identified and targeted interventions planned. Another biproduct of the consistent recording of information for the purposes of direct care is that it supports the world class national diabetes audits enabling local services to identify where they are performing well and improve the quality of treatment and care they provide to people with diabetes.

The development of the standards involved a consultation with many health and care professionals, people with diabetes and clinical systems and medical device suppliers through online focus groups and workshops, surveys and discussions.

The key findings from the consultation were:

1. **Diabetes management requires information from many different sources across the health and care system and currently it is not all being effectively shared**. Examples cited where information sharing is not effective were between the eye screening programme and the hospital, from external providers of structured education on attendance and outcomes, information recorded by podiatrists and community nurses and more generally between GPs and hospital teams. Use of a standard for the consistent recording and structuring of information is an enabler of better information sharing for example in an ideal world, outcome information like retinopathy grading and structured education attendance would be coded and shared between hospital, community systems and GP systems.

2. **Better education and on-going support are needed to empower people to self-manage.** There are often vast amounts of data and information available to people with diabetes particularly if they are using devices to help them manage their condition. Interpreting the data and applying it can be complicated and some people need more support with this. There also needs to be a consistent focus on primary support staff, privately employed carers or carers commissioned from private and sometime very small providers as well as staff in care homes. Their understanding, skills and abilities and ability to input to and access systems is fundamental. People said they wanted more help in understanding what causes changes in the measurements, for example, blood sugars and they wanted education refreshers. Uptake of structured education is quite low, with key concerns being time taken and having to miss work. A form of continuing education and advice online may have more impact than structured education. Although annual reviews and care planning are helpful, people wanted these to be more holistic and not just focused on targets and goals that they may feel are not achievable, and standards can support bringing together information from different sources supporting more holistic conversations.

3. **With the rise in use of medical devices for self-monitoring and self-management it is important to consider digital poverty and not exacerbate inequalities.** While the digital world becomes stronger there are still weak spots with 1.5 million across the UK with no internet access. Use of digital devices to manage diabetes in children and young people is lowest in ethnic minority groups and the areas of highest deprivation. The ability to use digital tech by those who were once able to, does, for some, diminish with age e.g. dementia, the ability to physically and accurately use touch screens and buttons and even the ability to clearly articulate for speech recognition. Although these standards are for sharing of digital information, it is important that there remains a process for people to

share information by other means and there is support for those that wish to move to the use of digital tools to manage their diabetes.

4. **People want to be able to control who has access to the information that they have recorded at home either using medical devices or in apps.** Currently, people can give access to hospitals or individuals to data collected using medical devices and it is accessed through applications not linked to GP or hospital record systems. The intention is that the data could eventually be part of shared care records and would then be available to anyone with a legitimate reason for accessing the shared care record. Not all people want to share every part of their personal health with every health and care professional involved in their care. Continuous Glucose Monitors, for example, collect data continuously while the person is at home and going about their daily life and could be shared with health and care professionals between appointments to support remote monitoring rather than at an appointment. People want to be the gatekeeper for this information, in the same way as they are if they agree to have a test or answer a particular question. However, there are risks if people do not share the information, or share partial information, as it means that health and care professionals cannot provide advice based on accurate information about a person and it can lead to poorer decisions and on occasions to incorrect diagnoses especially for patients with complex multi-system disorders. Being in control of one's own information is important, as is knowing what has been shared and with whom and why. Clear communication about who will be able to access the information and how they will use it is paramount. In addition, some children and people with learning disabilities may not have the capacity to record or decide what information to share with health and care professionals therefore support from a carer or family member may be required and it would need to be clear where this had happened.

5. **Concerns were raised about the potential volume of data from devices that could be shared with clinical systems across health and social care and the expectations of people with diabetes that health and care professionals will review and act on the data and lack of clarity on liabilities if an adverse event occurred resulting from inaction. Possible benefits of access to the data enabling predictions using machine learning were also identified.** Continuous glucose monitors can take between 96 and 1040 glucose readings in a day and if this data is shared with the person's record it may result in network and storage implications. There is also potentially a workload and capacity issue in terms of managing data and potentially adding it to records. Concerns were raised about reviewing vast quantities of data. Individual readings are generally less important than trends and summary metrics and how the data is displayed will aid faster review and interpretation (for example through graphing and use of summary statistics).

   The volume of information and the potential numbers of individuals who would be able to share information from their medical devices means that this information could not be monitored and reviewed on a regular basis by health and care professionals. There is a general lack of clarity of where liability would sit in a scenario where an individual develops complications or an urgent clinical issue which could potentially have been identified from the data that has been made available to health and care professionals but had not been reviewed and/or acted upon. There may be different triggers for a person to share information that may complicate the liability issue. For example, if the

person with diabetes is given a device by a healthcare professional and asked to share the information with them compared with the situation where the person bought a device off the shelf and chose to share information with the healthcare professional. Advice received suggests that this can be mitigated through clear, evidenced, communication at the point at which the person is initially given the device.

6. **Validated information recorded and shared by a person with diabetes is important in day-to-day condition management and should not be disregarded by healthcare professionals.** People with diabetes are experts in their condition. They collect and use many different types of information in the daily management of their condition and want to be able to share that information with healthcare professionals to inform their consultations. As long as the provenance of the information is clear, for example was it from a device, if so what type of device (e.g. continuous glucose monitor, Fitbit), was it manually entered, if so by whom, where was the measurement taken (e.g. was blood pressure or weight measured at home) healthcare professionals should not disregard the information but should apply clinical judgement on the validity of the information for clinical decision-making in the same way that they treat information recorded by any healthcare professional. In incorporating information collected by people with diabetes into their electronic health records, consideration needs to be given to the impact on incentives (particularly for GPs and the data extracted for QOF). Existing collections and extractions that pull information from clinical systems about, for example, glucose and blood pressure monitoring may need to be modified to exclude the person's self-monitoring information.

7. **The medical devices market for diabetes management is global and dynamic due to increasing demand for monitoring products because of innovation and price, increasing awareness and increasing need for self-monitoring and management.** Next generation technologies include smart pens, hybrid closed loop (combining monitoring with insulin delivery) and next generation continuous glucose monitors are being launched. Their use will increase, and product innovation will continue. This is a changing global market and therefore data sharing from devices needs to meet international standards, where possible to avoid the need for reengineering to meet the individual demands of each country and whilst the diabetes standards use SNOMED CT[1] and Unified Code for Units of Measure (UCUM), international standards for clinical terminology and units of measure respectively and adhere to the international consensus on glucose monitoring, the structure of the information is not necessarily aligned to other international standards as it is derived from the Core Information Standard, developed in the UK for information sharing.

8. **There is a complex environment of systems and technology to support diabetes that need to share information and will need to conform with the information and technical standards to do so.** There are four broad groups of systems and technology increasing from the micro to macro level for example an app, a device, a local management system at ICS level though to a regional or national system:

[1] SNOMED CT - NHS Digital

a. lifestyle apps for supported self-management.
b. medical devices (including self-monitoring and insulin delivery devices, Point of Care systems in hospitals and systems integrating data from devices)
c. specialist diabetes management systems
d. non-diabetes specific health and care record and electronic prescribing and medications administration systems

In order for information to be shared between these systems they may need to be adapted to ensure that the information is structured and coded in alignment with the standards. The diabetes standards were developed based on the Core Information Standard which sets out the structure of information that can be shared across the system between health and social care but the level of conformance with the Core Information Standard of non-diabetes specific health and care systems is currently unclear so too, therefore, is the amount of adaptation required to support the diabetes standards. However, it should be noted that having implemented the Core Information Standard is not a dependency for implementing the diabetes standards but it would make implementation of the diabetes standard easier in those systems that have done so. Work is starting on blockers to implementation and measurement and quantification of uptake which should conclude in the summer and will assist the adoption of the diabetes standards. Groups a-c will not have implemented the Core Information Standard and will only need to implement a subset of the standards that are relevant to their products, so for example, an app used to display and share glucose measurements from a CGM device will only need to implement the sections in the standard relevant to glucose information.

National technical messaging standards are based on Fast Healthcare Interoperability Resources (FHIR). FHIR UK core is in development and is unlikely to cover all information that is required in the diabetes standards so a pragmatic approach to rapidly develop technical standards for immediate implementation is required.

Point of care glucose and ketone testing in hospitals were not explicitly considered in the development of the standards so it is unclear whether the metrics defined for glucose measurements and insulin administration would be appropriate for point of care systems.

9. **Clarity on how SNOMED CT should be used to support diabetes coding requirements is needed particularly in relation to use of qualifier values for indeterminate diagnoses and in summary metrics. Codes do not currently exist for non-prescribed devices to support information sharing from devices.**

a. Not all clinical data items have SNOMED CT codes, such as Time in Range or codes to support NICE guidelines for the categorisation of risk of foot disease
b. There is confusion about which diabetes diagnosis codes to use (including if the type of diabetes is indeterminate).
c. It is not clear how and when to use qualifier values such as for ‘suspected’ diagnoses or ‘standard deviation’ for mean values
d. The NHS Dictionary of Medicines and Devices (dm+d) does not currently include non-prescribed medical devices.

SNOMED CT is the information standard for clinical terminology; it is an international standard and it applies to data that relates to clinically relevant information, for example symptoms, diagnoses, interventions and observations. The NHS dictionary of medicines and devices (dm+d) is a dictionary for use in the NHS of medicines licensed in the UK. The UK Drug Extension links SNOMED CT and dm+d codes. SNOMED CT and dm+d

are fundamental standards supporting information sharing and systems and applications that support the direct management of the health and care of a person are required to adhere to them.

The diabetes standards include key metrics increasingly used by people with diabetes and health and care professionals in the management of diabetes (some of which have international consensus), for example Time in Range (percentage of time spent within a normal glucose range). SNOMED CT codes for these metrics do not currently exist.

There are a number of codes for diabetes diagnoses, and we have been told that it is not clear which codes should be used, and in particular which codes to use when the type of diabetes is indeterminate. We heard an example of diagnoses being coded and 'suspected' included as a supplementary comment that when shared with other systems was not reliably included in the message which is a clinical risk.

Currently dm+d, and by extension SNOMED CT, does not include codes for medical devices because the dm+d scope is limited to prescribed products (on the drug tariff) and devices are not prescribed. In reviewing information collected and shared by the person with diabetes the healthcare professional needs to know the type of device and the make and model that was used for self-monitoring of glucose or insulin delivery. In addition, information about a person's device use is needed in their record to support the following circumstances: in the event of safety notices or product recalls; if the person is using an older version of a device and could upgrade to a later version; if a person is not using a device but qualifies for one to help them better manage their diabetes; or if the person is using a device that is not recommended in particular circumstances.

10. **The diabetes standards are designed to support the management of a person's diabetes. They include the information needed by endocrinologists about pregnancy to manage the diabetes but not everything needed to manage the pregnancy.** The key information needed is whether the woman has plans to become pregnant, contraceptive use and whether they are actively pregnant. Pregnancy affects how a woman manages her diabetes but also hyperglycaemia causes a risk of harm to the baby and other complications. A woman can also develop gestational diabetes during pregnancy. This is not an enduring condition but should be recorded in systems. Maternity teams supporting a person with diabetes during their pregnancy would require much more information about the pregnancy itself and the outcomes of previous pregnancies than is set out in the Diabetes Record Information Standard. They would require the full maternity record and a pragmatic decision was taken not to replicate the information structure and content from the maternity record in the development of the Diabetes Record Information Standard. This would mean that for the team supporting a pregnant woman with diabetes, the information content set out in both the maternity and Diabetes Record Information Standards would be required.

11. **The procurement frameworks in use in the NHS can be used to encourage suppliers to conform with mandated standards.** One lever to help to drive conformance with standards is by obtaining approval of the information standard from the Data Alliance Partnership Board (DAPB) via the Data Standards Assurance Service as providers must comply with these standards and will therefore seek to procure systems that are compliant. To assist this procurement frameworks can require suppliers to provide evidence to demonstrate compliance with these standards. In addition, the framework owners provide procurement guidance to buyers looking to procure from the frameworks setting out what they could include in their specifications about conformance

with standards. Not all procurement activity goes through frameworks so reaching buyers purchasing using other routes to make them aware of the standards will also be important. A self-assessment process is typically used to demonstrate conformance with standards, but consideration should be given to the level of evidence required and whether more formal assessment processes should be put in place. This applies to all standards, not just the diabetes standards. PRSB has a conformance assessment framework that could support this and would support buyers not using procurement frameworks as well as those using procurement frameworks. It should be noted that compliance with information standards is the first step in interoperability. Technical messaging standards and data sharing arrangements need to be in place to support sharing across primary, community, secondary and social care.

Recommendations:

- Consider the approach to education and support for both people with diabetes and healthcare professionals. Both will need education and support to manage complex data visuals and clinical management. Consider offering continuing education and advice online, signposting to quality information, education and peer support as part of regular reviews, to people with diabetes. Knowing the outcome of structured education is important to healthcare professionals in consultation with people with diabetes. Encourage commissioners to reflect this in contracts with structured education providers.

- Summary metrics and trends should be used to present large volumes of data. Data visualisation in systems should be aligned with the international consensus where possible, for example, glucose data are often visualised as an ambulatory glucose profile (AGP).

- Establish a programme of work to support the implementation of the standards nationwide and accelerate adoption. This should cover two broad areas:

    a. Further work on the standards to support implementation:

        i. Work with NHS Digital to ensure that the SNOMED CT codes required for the diabetes standards are included (summary metrics, devices and care planning goals and actions) and provide clarity on coding of diabetes diagnoses (including suspected but not confirmed diagnoses).
        ii. NHS Digital, supported by PRSB, to develop technical messaging standards aligned to the information standards. This will include:
            - Mapping the two diabetes standards to the existing national messaging standards (FHIR UK Core) and, where they do not map, working with the ICS community to develop solutions for early use to drive consistency.
            - Mapping the two standards to GP Connect to demonstrate how information could be pulled from, and pushed into, GP systems.
            - Undertaking a discovery piece of work to determine to what extent GP systems comply with the standards and develop a proposal for incremental conformance.
        iii. Work with 1 or 2 early implementers in a clinical context to undertake first of type testing and piloting. Base this on areas that would add most value, for

example sharing between GP, hospital systems and eye screening services and sharing of a person's self-monitoring data from devices with clinical systems. As well as enabling the standards to be tested and refined, this would enable the development of support materials (in addition to technical specifications, lessons learnt and case studies could be captured to support implementation in other areas). In addition, it would enable the testing of both the technical aspects of interoperability (architecture, impact on networks etc.) and also the impact and benefits for health and care professionals including in relation to workload and capacity.

iv. Work with NHS Digital and NHSX architecture teams and local ICSs to develop a cookbook for how the standards can be implemented in event driven architecture and a shared care record architecture, ensuring this supports the national data architecture strategy and local ICS implementation.
v. Undertake a short piece of work to test the applicability of the standards to Point of Care systems in hospitals.

b. Activation – make it easy for standards to be adopted:

i. Publish implementation support materials, developed in (a) above, as part of an online implementation toolkit with the ability to provide feedback and get support. Make it easy to find. Promote it with suppliers and local IT teams in addition to professionals.
ii. Continue engagement and collaboration with systems and tech suppliers including a targeted engagement campaign to inform, encourage and support with systems and tech suppliers on their journey towards conformance.
iii. Build a coalition of the willing to promote the standards, for example, Diabetes UK, HL7, Association of British Healthtech Industries, NICE.
iv. Continue to identify and address the barriers to implementation.
v. Identify and enact levers and incentives to support implementation:

- Seek Data Alliance Partnership Board (DAPB) assurance for the two diabetes standards. DAPB assurance would require providers to comply with the standards and to comply they will require systems that conform to the standards.
- Ensure that the standards are included in the NHSX standards register.
- Consider the use of other incentives for example incorporating the diabetes standards into the What Good Looks Like framework, the ICS mandates and the NICE guidelines.
- Ensure that the information and technical standards are referenced in the relevant procurement frameworks (as a package) where possible and, if not immediately possible, develop guidance for buyers setting out the benefits of the standards. As not all procurement activity will be through procurement frameworks, write out to Integrated Care Systems setting out what they should ask for from their suppliers in relation to compliance with diabetes standards and the benefits of doing so.
- Consider how conformance with standards should be assessed and work with procurement framework leads to agree and implement an approach. Consider the use of the PRSB conformance assessment

framework as it is complementary to driving conformance through procurement frameworks to support providers when not procuring from a procurement framework and where a framework refresh is not imminent.

- The upcoming review of the maternity standard should explicitly consider gestational diabetes and whether components of the diabetes standard should also be available in a maternity record standard such as summary glucose or insulin metrics.

In conclusion, there was broad support for the development of these standards throughout the consultation process across professionals, people with diabetes and clinical systems and medtech suppliers. We now need to build on that support to make it easy to adopt the standards by developing the technical components needed to support the sharing of information, activating a community of willing participants to promote the standards, continue to identify and address perceived barriers to implementation and identify and activate levers and incentives to drive adoption.

3 Introduction

The number of people living with diabetes in the UK is estimated at 4.8 million (including approximately 1 million that do not know they have it) and is expected to rise to 5.3 million by 2025. Ninety percent of those are living with type 2.[2] In England there are about 3.4 million people living with diabetes.[3] Nearly two-thirds of adults in England and a third of children leaving primary school are overweight or obese and the risk of developing type 2 diabetes is up to six times higher in certain Black, Asian and Minority Ethnic groups. [4] Five million people have high blood sugar (pre-diabetes).[5] Uncontrolled diabetes can lead to serious health complications like heart disease, stroke and kidney failure.

As the number of people with diabetes is so large and expected to rise rapidly, the NHS Long term plan (January 2019) sets out that it will accelerate support for people to manage their own health and will roll out the NHS Personalised Care model to reach 2.5 million people by 2023/24. For people newly diagnosed this means structured education and digital self-management support tools. There is also an important role for informal carers such as parents of children with diabetes and family members of older people living with diabetes and other long-term conditions.

In the UK, there are approximately 400,000 people currently living with type 1 diabetes, including around 29,000 children, with the number of new diagnoses in children under 5 rising by 5% each year.[6]

In March 2019, NHS England published national arrangements outlining that all patients with type 1 diabetes in England would be offered flash glucose monitors and at least 34% of the type 1 population now have one.[7] In March 2021, NHS England released funding to support the aim that all pregnant women with type 1 diabetes in England will be offered continuous glucose monitoring, helping to improve neonatal outcomes.[8]

Supporting people to manage their own health requires healthcare professionals to have access to accurate and up to date (and potentially real-time) information about the person with diabetes so that they are able to make sure that the person receives the care and support they need. For example, they need to know whether and when a person received structured education and whether a refresher course is needed, whether diabetic retinal screening is due, when the feet were last examined, what the latest urine ACR test results are. For those using continuous or flash glucose monitors and insulin pumps, they may require help in using the technology and interpreting the data which can be better provided if they are able to share the data with the healthcare professionals involved in their care.

The diabetes standards support the digital sharing of this information to help to support the policy driver of accelerating support for people to manage their own health.

This work is addressing two key problems:

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[2] Diabetes UK. [Accessed June 2021]

[3] NHS. NHS Diabetes Prevention Programme (NHS DPP) [Accessed January 2022]

[4] NHS. The NHS Long Term Plan [Accessed June 2021]

[5] NHS. NHS RightCare Pathway: Diabetes [Accessed June 2021]

[6] JDRF. Type 1 diabetes facts and figures [Accessed January 2022]

[7] NHS. 'Glucose monitoring for patients living with diabetes.' [Accessed August 2021]

[8] NHS Supply Chain. 'Continuous glucose monitors available for all pregnant women with type 1 diabetes.' [Accessed August 2021]

1. With increased self-management of diabetes (and other long-term conditions) and increasing use of devices and apps (such as flash glucose monitors and continuous glucose monitors (CGMs) to monitor glucose levels and pumps or connected pens to administer insulin) to support self-management, the data generated can be shared with clinicians and used in clinic or during remote consultations. However, there is currently no information standard for self-management data related to diabetes, which means that different devices and apps cannot always share data with clinical systems so clinicians often have to access the data via third-party (proprietary) software meaning they may have to access multiple platforms to view the data they need to help a person manage their diabetes. Clinicians are not always able to access the proprietary software (because of local restrictions) and information cannot be brought together for comparison if, for example a person is using a pump by one manufacturer and a CGM device from another manufacturer. The information cannot be easily imported in a structured way into the person's electronic health record.

2. It is also difficult to digitally share diabetes information about a person (e.g., care plans) between professionals across different settings and within multidisciplinary teams, leading to a risk of harm. This may also lead to patients having to tell their story more than once and duplication of clinical effort or investigations, for example patients under consultant-led care may have blood tests performed in the hospital setting but because the information is not shared with the GP the blood tests are repeated, if a person is admitted to hospital, information about the latest foot check is not always available in the hospital setting. In addition, the National Diabetes Audit[9] and National Paediatric Diabetes Audits are important for quality improvement of diabetes services, however a lack of information sharing between systems contributes to labour intensive manual data collection and variable response rates across settings. Population health management, a technique to help find and support vulnerable patients to improve their health, environment, and lifestyles, relies on data collected as part of routine care to inform interventions and sharing information digitally will help to support this. There is no nationally agreed information standard for the information structure and content for a diabetes record in England.

PRSB was commissioned by NHS England and NHS Improvement to address these two challenges. This follows a discovery phase of work that took place in November 2020 (a separate discovery report is available) which validated the need for a Diabetes Record Information Standard to support the sharing of information between patients, their carers and professionals.

Two information standards have been developed:

i. Diabetes Record Information Standard (for adults and children covering all types of diabetes, type 1, type 2, gestational, monogenic, Latent autoimmune diabetes in adults etc.)
ii. Diabetes Self-Management Information Standard (information from devices such as Flash, CGM and insulin pumps and other person-generated self-management data relevant to the management of diabetes such as blood pressure, exercise etc.)

These standards are based on the existing PRSB standards (in particular the Core Information Standard[10] which sets out how information should be structured and coded in a

[9] National Diabetes Audit Programme - NHS Digital

[10] Core information standard v2.0 – PRSB (theprsb.org)

shared care record). The Diabetes Record Information Standard is a version of the Core Information Standard tailored for a person with diabetes. It includes extensions specifically for diabetes for insulin dosing, glucose metrics, structured education and eye screening and sets out how the key information should be coded for diabetes. This will support interoperability between diabetes management systems, shared care records, GP records, electronic patient records and person held records.

4 Methodology and consultation approach

4.1 Methodology

4.1.1 Aims and objectives

The overarching aims of this project were:

1. to enable key information about a person with diabetes to be shared between themselves, their carer and professionals to support self-management and to enable the best care to be delivered by professionals.
2. to enable information collected as part of routine care to be used once anonymised, for audit and population health management purposes.

The objectives were to:

- Develop an information standard for recording information relating to a person's diabetes that can be shared between the professionals, informal carers and care and support workers involved in the care of that person.
- Develop an information standard for sharing person-generated self-management data from the person with diabetes related to the 9 care processes, glucose monitoring and insulin dosing.
- Update the existing Core Information Standard (for a shared care record) and the Personalised Care and Support Plan standard[11] with key information related to a person's diabetes.
- Facilitate pilots to test the standards.
- Facilitate adoption of the standards by:
    - working with NHS England and Improvement and NHSX commercial teams to identify and make recommendations on the procurement frameworks that should reference the standards.
    - working with key stakeholders including the Association of British HealthTech Industries to make recommendations on the implementation and deployment of the standards and how they can support population health management.
    - supporting the application for DAPB approval for the standards.

4.1.2 Project phases

The project was delivered across the following phases

1. Scoping
    a. Review of published literature

[11] Personalised care and support plan: v2.0 – PRSB (theprsb.org)

    b. Mapping of existing diabetes standards, the National Diabetes Audit (and associated audits), the National Paediatric Diabetes Audit and NICE guidelines for diabetes against PRSB standards
    c. Interviews with stakeholders
    d. Focus groups
2. Development of draft standards
3. Consultation
    a. Two webinars focused on people with diabetes
    b. Two webinars focused on professionals and suppliers
    c. Two surveys (one easy to read shared with the learning disabilities community)
    d. Engagement with medtech and clinical systems suppliers
4. Finalisation of standards and drafting of supporting materials
    a. Implementation guidance
    b. Clinical safety report and hazard log
    c. Submission of requests for new SNOMED CT codes
5. Prototyping and simulation
    a. Mini workshops for development of personae
    b. Prototyping report and outputs
6. Procurement
    a. Discussions with procurement framework leads and NHSX commercial leads
    b. Recommendations on approach and materials to support procurement frameworks
7. Deployment and population health management
    a. Round table event on how the standards can support population health management
    b. Recommendations on deployment

4.1.3 Scope

The scope of this project was defined based on a review of key literature, conversations with professionals and people with diabetes and two focus groups, one for professionals and one for people with diabetes. The key themes from the literature and scoping discussions, which informed the scope, are set out in Appendix 1 and the use cases identified to inform the development and testing (through consultation and prototyping) of the standards are set out in Appendix 2.

In scope

1. The development of a Diabetes Record Information Standard based on a review of existing diabetes datasets, standards, audits and care plans and requirements to support the 9 care processes[12], glucose monitoring and insulin dosing (and other medications). It includes the summary metrics for self-management data. It reuses components already defined in existing PRSB standards where possible.
2. The development of an information standard to support sharing of person-generated of self-management information from person-held devices and apps used to support glucose monitoring, insulin dosing and the nine care processes for self-management and remote monitoring. The standard supports devices and apps, where data is entered manually and directly from devices.
3. Updates to the Core Information Standard and Personalised Care and Support Plan standard where necessary to include proportionate, summary information from the Diabetes Record Information Standard in a shared care record and holistic care and

[12] See NICE (footnote 4)

support plan in line with the maintenance and update schedules for these published standards.

The two new diabetes standards:

- had four nations input.
- supports all types of diabetes including type 1, type 2, gestational, latent autoimmune diabetes in adults and monogenic diabetes.
- supports the 9 care processes defined by NICE for diabetes management (and the SIGN guidelines). The 9 care processes are:
    - Glycated haemoglobin (HbA1c) measurement
    - Blood pressure (BP) measurement
    - Cholesterol level measurement
    - Diabetic eye screening
    - Foot checks
    - Urinary albumin testing
    - Serum creatinine testing
    - Weight check
    - Smoking status check
- supports regular glucose monitoring and insulin dosing (outside the 9 care processes).
- supports children and adults (note: the Core Information Standard and Personalised Care and Support Plan standard have been tested for adults only).
- considered the information requirements of people with diabetes and professionals and staff working in primary, community, mental health and secondary care services and in council provided and independent residential care homes and support workers providing to support to people in shared lives / supported accommodation, domiciliary care and informal carers.
- were designed to support information required for the National Diabetes Audit and National Paediatric Diabetes Audit where the information can be collected as part of routine care (for England and Wales).
- were designed to support the information requirements for population health management of diabetes, where it is collected as part of routine direct care.

The summary metrics for information from glucose monitoring devices were based on the international standard for metrics agreed at the Advanced Technologies & Treatments for Diabetes (ATTD) congress in February 2019.[13]

Out of scope

- Information sharing with schools, police, armed forces/defence and prisons.
- Specific information requirements relating to pre-diabetes.
- Development of the technical messaging standard (such as Fast Healthcare Interoperability Resources (FHIR) message standards or Application Programming Interfaces (APIs) which are to be commissioned via NHSX.

4.1.4 Project team

The project team is set out in Appendix 3 and consisted of NHS England representatives, two clinical leads and a citizen lead and the PRSB team.

[13] See Battelino and others above.

4.2 Consultation Approach

Evidence review

The aim of the evidence review was to identify the information that was relevant for inclusion in the draft standards.

The evidence review included identifying relevant standards (and datasets including the national diabetes audits) and NICE guidelines. The existing standards and audits were mapped against the PRSB Core Information Standard together to identify areas of commonality and gaps (these are set out in Appendix 4). The relevant NICE guidelines were also mapped against the PRSB's Core Information Standard to identify where the standards support the NICE guidelines and to identify gaps (these are set out in Appendix 5). The mapping for the Diabetes Record Information Standard is set out in Appendix 18.

A systematic and pragmatic approach was used to conduct the literature review. After discussions, two key consensus papers were identified which were reviewed to identify themes. Screening (by title and abstract) of approximately 700 further papers took place identified by citation chaining using Google Scholar®. The two key documents were:

1. 'Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range.' Battelino and others, 2019
2. 'International consensus on use of continuous glucose monitoring.' Danne and others, 2017

Of the screened papers, 25 were used in the development of the standards and tested in the webinars (these are set out in Appendix 6). Throughout the project other relevant papers were identified through discussions and were used in the development of the implementation guidance and are referenced separately in the implementation guidance.

Mapping of the literature against data items in the Diabetes Self-Management Information Standard is set out in Appendix 19 – Appendix 23.

Initial scoping interviews and focus groups

Interviews were held with a range of professionals, people with diabetes and medtech and clinical systems suppliers (see Appendix 7). Two focus groups were also held on 22nd June 2021, one for professionals and suppliers with 16 attendees (see Appendix 8) and one for people with diabetes with 13 attendees (covering people with Type 1, Type 2 and one person with pre-diabetes) (see Appendix 9).

A combination of the interviews and focus group covered professionals involved in audit and population health management as well as professionals involved in the care of people with diabetes as well including care of children and adults), medtech suppliers and representatives from Scotland and Wales.

The aims of the focus groups were to agree the areas of focus for the project and to test the draft use cases identified during the discussions to support the development and testing of the standards (the use cases were refined after the focus groups and are set out in Appendix 2. The approach tested at the focus groups was:

1. To define who needs what information for diabetes management (person with diabetes, professional) – focusing on the nine care processes and insulin dosing.
2. To identify the key components of the shared care record (Core Information Standard) that supports diabetes management.

3. To identify and fill any gaps in the shared care record.
4. To define a standard for sharing data (that affects glucose) to support insulin dosing (e.g., from pumps, continuous glucose monitoring, flash glucose monitoring, apps etc.)
5. Test and refine the Personalised Care and Support Plan standard for diabetes management

The focus groups were recorded, and the transcript and chat analysed for themes.

There was general support for the scope and approach proposed. The detailed findings are included in Appendix 1.

Development of the draft standards

The diabetes standards are based on PRSB's Core Information Standard which sets out the structure and content of information that should be shared about a person in a shared care record. The Core Information Standard is made up of information components such as medications, investigation results, examination findings and assessments. Different standards can have different combinations of components identified through consultation. Where a component is included in a standard it is structured in the same way across all the standards so that the information can move between systems.

The Core Information Standard is currently being implemented in Integrated Care Systems. Reusing the components from the Core Information Standard in the diabetes standards means that information needed to support a person with diabetes such as foot examination results and HbA1c and cholesterol test results would be structured and coded in the same way as other examinations and test results making it easier to share the information between systems.

Where an information need was identified but a component did not already exist in the Core Information Standard, other PRSB standards were used, for example the Healthy Child standard and Maternity standard.

Where an information need was identified but a component did not exist in any existing PRSB standards, new definitions for the structure and content were created, for example for summary glucose and insulin metrics.

The draft standards were iteratively developed following review and mapping of existing standards, the literature, discussions, webinars and surveys.

Webinars

Wide ranging discussions took place over the course of the project with professionals, clinical systems and medtech suppliers and commercial teams (Appendix 10).

Four webinars took place during September 2021. The webinars were recorded, and the transcript and chat analysed for themes. The questions asked and key findings are set out in Appendix 11.

- **Webinar 1** for people with diabetes focused on care planning – 20th September 2021 (23 attendees, see Appendix 12)
- **Webinar 2** for people with diabetes on data they collect and use at home to manage their diabetes – 21st September 2021 (26 attendees, see Appendix 13)
- **Webinar 3** for healthcare professionals and medtech suppliers on the information needed in a diabetes record about a person with diabetes – 27th September 2021 (84 attendees, see Appendix 14)

- **Webinar 4** for healthcare professionals and medtech suppliers on what data people with diabetes collect and use at home would is helpful for healthcare professionals to have access to – 30th September 2021 (54 attendees, see Appendix 15)

Surveys

Following the webinars, two online surveys were conducted (including a main survey and an easy-to-read version). The questionnaires were intended to gather qualitative and quantitative data to inform the further development of the standards. The surveys ran from 11 September 2021 – 11 December 2021. The main survey generated 511 responses and the easy-to-read survey 41 responses. Following cleaning of the dataset (involving removal of duplicate and inadequately completed entries) a total of 280 responses were included in the final analysis. The surveys were aimed at testing the content of the diabetes standards with the people who will use them and better understanding issues that may affect the implementation of the standards in the real world and the potential impact on people who will use them. The survey findings can be found in Appendix 16 (separate document).

Supplier engagement

Individual discussions with suppliers took place during January and February 2022 to review the updated standards. The discussions that took place are set out in Appendix 17.

Throughout the project weekly team meetings and regular discussions took place with the clinical and citizen leads to agree changes to the standards.

5 Findings and recommendations

The overall findings and recommendations across all the consultation activities are set out below

Diabetes management requires information from many different sources across the health and care system and currently it is not all being effectively shared	
Findings	• Clinicians need better access to all relevant information (information is not always shared between primary and secondary care). This results in people with diabetes being called for duplicate appointments, tests and reviews. • People with diabetes are not always receiving their investigation results in sufficient time to act on them – to mitigate the risk. • Information about eye screening and treatment is not always shared across the system. • There is limited feedback from external providers of education on whether the person partially or fully attended the education. This information is helpful for professionals.

	• Lack of access to information recorded by community nurses, podiatrists and district was highlighted. • Information is not always being shared between primary and secondary care. • Information is not always shared between maternity and diabetes teams.
Rationale	**From webinars:** "...really resent having to take a half a day off work for all the foot checks and the blood tests and then another half day off work to actually attend the GP appointment when they might have already seen their consultant three weeks beforehand. And the GP also has to do the tests again, even though those tests were done at the hospital." **PwD, T1** “I get frustrated between the link between primary and secondary care ... my GP should have a holistic view of my care; they should know more about me than my consultant does.” **PwD, T1** "Is there a way to mitigate risks...I would like to know my results long before we get into red, because in red, it's too late. I need to know a lot earlier, but I find it very difficult to get test results from a GP." **PwD, T1** "In my opinion, all medical, physical and social services should be able to access the data so a holistic approach is made, and the patient should have access as should ambulance etc." **PwD, T2** "The issue with eye screening in Wales particularly was [if] retinopathy [was detected] under onward referral into secondary care … the current feedback loop … only included primary care. So, … patients … would be treated, would be discharged, and only the GP was notified. And … eye screening Wales were … waiting to find out when they could start the clock again and get them back on the retinal screening programme." **Digital Architect** "As soon as people get out of the screening programme into secondary care, those are the ones that you really want the data from. And we're not getting the information from the ophthalmology clinics back into diabetes." **Senior Lecturer and Consultant** "... it is helpful to [information about whether structured education was] completed or not, because then [you can consider] outcomes...for local [courses] we never see any outcomes so … it's really difficult to know if [the person has] the skills [to self-manage]. What we can do then is look at associations e.g. time and range, admissions..." **Senior Lecturer and Consultant**

"We have some largish collaborative education courses, both in Type 1 and Type 2 diabetes. But we also have a plethora of much smaller and usually much more localised education. And of course, at some level we have one to one education in every clinical contact. So, the question is what sort of information and how would we want to create a data record around someone's structured educational needs, provision and outcomes?" **Professional Lead**

"A really important improvement would be mandation [sic] of all education providers to share completion reports." **Consultant Diabetologist**

"Technology and accessing information are a challenge I have seen in community nursing/primary care." **Community Staff Nurse**

'One of the main problems we have is if [as a clinician you] don't have access [to the right information]. Approximately one in four women will have a miscarriage or a pregnancy loss. A number will have terminations. And we have just no good sharing of data between maternity and diabetes services. So, we may see these women and have no idea that they've just had a loss or a seriously bad pregnancy outcome.' **Clinical lead for diabetes and pregnancy audit**

'One of the biggest disconnects we have is the data being shared from district nursing and that is a huge implication, not just for the patient themselves, but also for quality of the service for the teams and risk. So, there'll be blood glucose monitoring undertaken, but because the systems, are not interoperable [it is not] shared. So therefore, we are sometimes called by [someone who] could be a carer, could be a family member, discussing about their loved one and what's happened [regarding] some of their signs and symptoms and we have no understanding of what their blood glucose levels are. And even worse, I'm afraid to say in some circumstances these patients are on insulin. And it's just a huge risk that's not shared in real time.' **Diabetes Specialist Nurse**

‘[One issue is the] … lack of information between primary and acute care. But there's an intermediate step in community care. Similar to the district nursing issue in the sense that podiatrists are often managing patients in community care and foot protection teams, are in primary care networks. And that information isn't really shared between the acute care and the primary care. So, there's a sort of missing loop. So often you get that jump straight to acute and missing out the middle bit where a lot of the preventative footcare happens.' **Podiatrist**

From survey:

The most highly cited themes in the comments indicated that information sharing breaks down between the GP and hospital teams (n=65), between hospital teams within a trust (n=9), between hospital trusts (n=10), between the hospital teams and

	community care (n=11), between diabetic eye screening services and hospital teams (n=11) and between the podiatrist in the community and others (n=18). Several respondents said that information sharing breakdown was systemwide (n=21) although some PwDs said they had no experience of this (n=10).
Recommendations	• Review information flows from eye screening and ophthalmology services. • Information on attendance and outcome of structured education courses should be shared. Encourage commissioners to reflect this in contracts with structured education providers. • Test the standards in the scenarios where information sharing breaks down and develop guidance to support providers in implementing information sharing.

Better education and on-going support are needed to empower people to self-manage

Findings	• Some people with diabetes need more support with understanding the technology and data. • People want clinicians to support them by educating them and giving them the tools to self-manage, but some clinicians need more help with understanding technology and data. • Peer support can be beneficial in helping people take control of and understand their diabetes. • Education may be undertaken at diagnosis and not repeated. People with diabetes felt that regular education refreshers are important. • There is a need to ensure that people with diabetes have the right information to be able to self-care, for example to check their feet regularly, or help to understand what causes a change in blood glucose. • The language used in sharing results with people with diabetes may need review. • People like to view the information in different ways, and it is important that they can choose how they want to do it. • People want a more holistic approach to reviewing their diabetes at their annual review. • There was a mixed response to goal setting. Some thought achievable personalised goals help with self-management; others find goals unhelpful.
Rationale	**From webinars:**

"Just giving people their results without any kind of information to them or schooling or opportunity for them to go through and make sure they've understood what those things mean. And I don't think you can necessarily expect people to then arrive at a doctor's appointment if it's needed, with the questions that they've got, because not everybody is able to do that." **PwD, T2**

"The analysis [of the data from devices] is something completely different. And I think that's potentially a gap where perhaps people are able to get the most out of the data that's being presented to you." **PwD, T1**

"Where I can't, I want [my healthcare professional] to work with me and to give me the responsibility by empowering me and teaching me and educating me how to use [data and devices] now to look after myself." **PwD, T1**

"There is a fantastic community who use DIY diabetes technologies (artificial pancreas systems, Nightscout etc). Community guides have been collaboratively written to enable us to get started on each of the technologies and large support groups exist on Facebook etc for help." **PwD, T1**

"Peer support is less frightening for newly diagnosed patients." **PwD, T2**

"Helping people learn and get support as it's become (even more) clear since COVID-19 that GP services don't have the capacity to meet all the needs of the [person with diabetes]." **Carer**

"I have type one. I've had it for many, many decades. And it's just hugely frustrating that actually my GP doesn't understand the data. I want him to know my CGM charts. I printed them all off and took him because he can't access them." **PwD, T1**

"The data is one thing, the REASONS behind low and high blood glucose are not available via the electronic platforms. Hence face to face discussions and time is needed for the patient and the doctor to work through together the reasons for fluctuation and see what steps can be taken to avoid hikes and drops." **PwD, T1**

"The other thing is understanding exactly how many carbohydrates are in the various foods, because without that, you're not going to be able to manage your insulin levels properly." **PwD, T1**

"The education and ongoing education are part of the process. In Scotland, we only had one education session and that's when we got diagnosed. Nothing after that." **PwD, T2**

"One-off education may not be enduring - I can remember very little 'O' level maths." **Endocrinologist and Diabetes Specialist Physician**

"Supporting the patient, around inspection of their own feet, because we're only doing this once a year. How do we ensure

that people that we are seeing with diabetes actually have the right information to be able to self-care and make it a person-centred care?" **Nurse Consultant**

Discussing feedback from eye screening: "wording to patients and children should be reviewed." **Consultant Physician**

"I love the pie charts for time in range - quick and easy to understand BUT important to know the period being measured...Need to allow patients to choose what method they find most useful, so the standards and the clinicians need to allow an element of choice." **PwD, T2**

"Access to choice of technology is an important part of this work…one size does not fit all." **Parent**

"... holistic care should be a model taking into account other conditions like mental ill-health, medical conditions etc." **PwD, T2**

"Mental health for example has an effect on a person's ability to manage physical health. Need for whole person to be considered in diabetes management." **PwD, T2**

"I get really motivated and I think I'm going to do this, and sometimes I just think ... I just can't do any more than I'm doing. Maybe targets is the word. Maybe that's a trigger." **PwD, T1**

"I don't really relate well to the term targets because it makes me feel that I'm going to fail rather than what is achievable." **PwD, T2**

"What is important to me might not be what is important to someone else. Sometimes targets/goals are a good idea and I'm fully supportive of that, sometimes I don't want any targets, I just need to stay alive a little bit longer**." PwD, T1**

"I think people will develop their own goals, but I think … there's a philosophical decision that we need to make about whether the purpose of the consultation is to support someone to live well with a condition or to manage their condition well, which is not quite the same thing. And they affect what we want to record. So, if we want to help people to live well with their diabetes, then we should be thinking about what is it that helps you to live well with your diabetes, which may not be about a numerical target at all." **Endocrinologist and Diabetes Specialist Physician**

"Re: goal setting - quite often patients present during a significant crisis (bereavement, job loss etc), need to have an option to 'just get through' or 'stay safe' etc rather than continually pushing them to improve which may not be appropriate in the circumstances." **Psychologist**

"Must have ongoing joint planning through self-reporting on goals/targets if not achieving in set time frame and becoming anxious and low mood." **Nurse Consultant**

Recommendations	• Consider the approach to education and support for both people with diabetes and clinicians. Both will need education and support to manage complex data visuals and clinical management. • Consider the need to offer continuing education and advice online (as structured education uptake is generally quite low) and signposting to quality information, education and peer support to people with diabetes as part of regular reviews. • Knowing the outcome of structured education is important to healthcare professionals in consultation with people with diabetes. Encourage commissioners to reflect this in contracts with education providers.

With the rise in use of medical devices for self-monitoring and self-management it is important to consider digital poverty and not exacerbate inequalities

Findings	• It is important to consider digital poverty and digital exclusion and not exacerbate health inequalities.
Rationale	About 1.5 million households have no access to the internet (March 2021).[14] Those least likely to have internet access are those aged 65+, lower income households and those most financially vulnerable. However, the number of people with internet access is increasing the ONS reported that "in January to February 2020, 96% of households in Great Britain had internet access, up from 93% in 2019 and 57% in 2006".[15] Digital capability is also increasing rapidly. Between 2016 and 2020 1/3 of the population used digital tools and websites in the management of physical and mental health and in the last year this has risen to 49% (UK Consumer Digital Index 2021).[16] However, the UK CDI found that 2.6 million people remain completely offline and an additional 20.5 million adults have Low or Very Low digital engagement. Digital poverty is exacerbated by existing vulnerabilities.[17] The NHS Race and Health Observatory's review into ethnic inequalities in health care found that there are ethnic

[14] Digital divide narrowed by pandemic, but around 1.5m homes remain offline - Ofcom

[15] Internet access – households and individuals, Great Britain - Office for National Statistics (ons.gov.uk)

[16] 210513-lloyds-consumer-digital-index-2021-report.pdf (lloydsbank.com)

[17] 210513-lloyds-consumer-digital-index-2021-report.pdf (lloydsbank.com)

	inequalities in digital inclusion “affecting older ethnic minority people due to a lack of access to digital devices, a lack of digital literacy or due to digital applications not being made available in languages other than English” The National Paediatric Diabetes Audit Report for 2020/21 reported an overall increase in the use of Continuous Glucose Monitors across all deprivation and ethnic groups of children and young people. The highest increase in use was in black children and young people but this was still the lowest usage across all ethnic groups. The audit report states that black children and young people having the lowest use of insulin pumps (27.4%) compared with white children (40.2%). Higher use of insulin pumps was associated with living in a less deprived area, with 44.0% of those in the least deprived areas using a pump compared with 32.5% in the most deprived areas.[18] **From webinars:** “…If they don't have a computer, then they need to go and bang on that on the door of the diabetes educators and ensure that they get regular and ongoing support so that they understand how to manage the diabetes themselves.” **PwD, T1** “In terms of inequalities, in terms of the digital aspect, you know, there are so many people with English as a second language and digital poverty.” **PwD, T2** Where self-reporting is reliant on digital devices is there a risk of creating a cohort of data rich patients vs those living in "digital poverty"? **Medtech supplier** "It is well reported that DFUs (Diabetes Foot Ulcers) are in low income/educational families." **Medtech supplier** "Digital poverty is something that our American colleagues are now referring to as the sixth key health indicator or observation in terms of things like pulse, heart rate. That's why heart rate, temperature, respiratory rate and connectivity or digital connectivity, simply because they're seeing so much adverse outcome-based event for people who don't have digital connectivity, because so much is being developed as digital first." **Professional Lead**
Recommendations	• These standards enable sharing of information digitally. There is a need to maintain the ability to share information through non-digital means. Consider how people who wish to move to the use of digital devices to manage their diabetes can be supported to do so.

[18] National NPDA report 2020-21 Summary Report.pdf (rcpch.ac.uk)

People want to be able to control who has access to the information that they have recorded at home either using medical devices or in apps	
Findings	• Some people are happy to share all information with their clinician. Others are more wary; the relationship between patient and clinician is important. • There is a lack of clarity about how a person with diabetes consents to share their information and with whom. When using a device people with diabetes are often required to give access to a hospital but if the information from the device is shared with a shared care record the data may be shared wider than the hospital setting. • There is appetite within the medtech community for sharing information from devices with electronic patient records, but historically there have been commercial factors influencing information sharing. • In the main people are happy to share their information to improve local services for people with diabetes if the data is being collected anonymously, with appropriate safeguards and with the consent of the person with diabetes. • Some children and people with learning disabilities may not have the capacity to record or decide what information to share with health and care professionals therefore support from a carer or family member may be required and it would need to be clear where this had happened.
Rationale	**From webinars:** "Sometimes I'm uncomfortable sharing all of my information. Sometimes I'm happy with it, but … the way you are approved for Libre in my area is that you must share your data. It's not a choice thing." **PwD, T1** "We share Dexcom and Libre info, also MyLife data where we record BG [blood glucose], hypos, hypers, treatments, corrections, Bolus and basal info and other medications or possible reasons for hypos/hypers." **Parent** "At the moment this information is owned by the person and shared with us their discretion when they come to a clinic, so I'm interested in what permissions people would want to give us." **Endocrinologist and Diabetes Specialist Physician** "If you get kids involved in it, they will take it with them as they grow up and it will become business as usual, and they won't know any different." **NHSE** "Have had some really encouraging conversations with the medtech industry about thinking of ways to "push" passively key data from devices into electronic health records." **Senior Lecturer and Consultant** **From survey:**

In answer to the question ‘Which of the following information that could be recorded at home would you like to share with healthcare professionals, and how often? Any comments?’

There was strong support for sharing this information recorded at home with healthcare professionals. At least 70% of responses in each group (PwD T1, PwD T2, parents) supported the sharing of at least 13 out of the 17 information categories (some of the categories were not relevant for children). These included information like blood sugar, medications, episodes of hypoglycaemia, insulin, questionnaires, foot checks, ketones and weight.

Most people wanted to share the information before an appointment with a healthcare professional.

In answer to the question ‘To improve local services for people with diabetes, the NHS needs to analyse data from local people who have this condition. Would you support sharing information for this use?’

Most respondents (91.2%, n=218) answered ‘Yes’.

The most highly cited themes in the comments (particularly amongst people with diabetes and health and care professionals) were that people supported interventions to help other people with diabetes (n=23), to improve knowledge, services, and care planning for local people with diabetes (n=43), and to create locally targeted interventions (n=20). Several people stated that the more data collected the better for diabetes care (n=13).

Both people with diabetes and health and care professionals caveated their support by emphasising the of importance of the data being collected anonymously, with appropriate safeguards and with the consent of the people with diabetes (n=15).

In answer to the question ‘Are there any other issues that would make sharing information on diabetes care easier or harder?’

The most highly cited themes indicated that information sharing would become easier with improved interoperability (n= 27) and digital access (n=18), and reduced information governance barriers (n=19).

In answer to the question ‘If you are a technology supplier, what are the future requirements your customers are telling you about that we should be aware of for the development of the standards?’

“Systems need to speak to each other and be interoperable. HCP's do not want to have 5 web pages up, one for each different industry partner. all diabetes tech and their digital data systems that collect the data should all feed into one system, such as [SystmOne]” **– System supplier**

“From a national data collection point of view, it is very important that data can be extracted from systems and

	submitted to the audit in the least burdensome way. Data Quality is also a very important aspect of the data collection therefore robust, consistent standards across care providers are welcomed." **– System supplier**
Recommendations	• Seek clarity from the National Information Governance team on the IG implications of moving monitoring data (from medical devices) for people with diabetes from proprietary databases with access to the information controlled by the people with diabetes into health and care records in use across the system where Role Based Access Controls are in place and a legal basis for access to the information is required.

Concerns were raised about the potential volume of data from devices that could be shared and there is a lack of clarity on liabilities where data is shared but not reviewed	
Findings	• Continuous glucose monitors take many readings per day (over 1000 depending on the device) and if all the data is shared with clinical systems there is potentially a large volume of data and a risk of it becoming unmanageable (with network and storage implications). It is also potentially a workload and capacity issue in terms of managing data and potentially adding it to records. • The organisation and display of the information for both the person with diabetes and the healthcare professional is key to maximise the time for discussion and planning to avoid having to review vast quantities of data. • Concern was raised about where the liability lies if a person with diabetes is sharing information between appointments, the clinician has not viewed the data and identified a risk, and an adverse event occurs. • Information about future behaviours, e.g., diabetes burnout, could be derived from having access to this information. However, some felt this may be too intrusive. • Should be careful of over-burdening people with diabetes by asking them to collect too much information. • The information must be collected for the purposes of care and support of the person with diabetes. Any use of the information for audit or performance improvement is a biproduct.
Rationale	**From webinars:** "It helps us reach some people, doesn't help us reach everybody. But in the wonderful world of machine learning, etc., you can spot these rather like watching a rugby game - the

	coach substitutes the guy before he realises he's getting tired. We need to realise when people are getting really burned out before they realise themselves. And I think when we're getting to a world where that can happen and maybe that will be a future application of this technology." **Physician Informatician** "Could this be seen as intrusive? Is this our role?" **Endocrinologist and Diabetes Specialist Physician** "A distinction needs to be made between passive collection of data, i.e., from smart devices vs active collection where more involvement is needed by the user. There is a risk of "data" burnout." **Medtech supplier** "It is interpretation of physiological and treatment data in the context of the specific person that is key. Both [healthcare professional] and [person with diabetes] need to have all relevant data easily available and optimally organised / displayed so that time for discussion & action planning is maximised." **Consultant Diabetologist** "My belief is that records should fundamentally be about communication. EPRs offer the opportunity to generate measurable data as a biproduct which is wonderful, but it should never be the primary purpose." **Consultant Diabetologist**
Recommendations	• Agree and communicate good practice guidelines setting out the expectations on healthcare professionals to view and act upon the data, how to communicate this to the person with diabetes and evidence the communication. This should consider the medico-legal implications if data is not reviewed or acted upon but could have identified an urgent clinical issue. • Summary metrics and trends should be used to present large volumes of data. Data visualisation in systems should be aligned with the international consensus where possible, for example, glucose data are often visualised as an ambulatory glucose profile (AGP). • Piloting should test technical aspects of interoperability and sharing information and also the impact and benefits for health and care professionals.

Validated information recorded and shared by a person with diabetes is important in day-to-day condition management and should not be disregarded by healthcare professionals	
Findings	• Information that a person collects at home to self-manage their condition is important but is not currently included in a person's health and care record in a structured way meaning that the information being used by the person to

	self-manage is not the information that the professional team is using to help advise. • In assessing the quality of the data, key information about the provenance of the data is needed e.g., data received from a device, which device, the software used, the accuracy of the device and if the measurement was taken by a clinician or by the person at home.
Rationale	**From webinars:** "Provenance is really important. That's true of all elements of shared records. So, I imagine the how will be already established for all the other knotty, difficult problems around shared care records." **Physician Informatician** "Patient-reported BP [blood pressure] does need differentiating from clinic BPs." **Senior Lecturer and Consultant** “Definitely need data provenance. BP monitoring could be an example. Home BP monitoring v recorded in an electronic record by a care provider. I am not sure we can drill down to individual devices though” **Endocrinologist and Diabetes Specialist Physician** "Being able to validate apps or force apps to validate themselves according to specific design standards agreement that they would commit data via standardised APIs… don't import data from non-approved apps. I just think it's opening the floodgates. You're not going to be able to vouch for any of that data and the potential harm that could come from that or just wasted time or all." **Digital Architect** "It is perfectly acceptable to get results in from a device that we know has not a high accuracy as long as it's stated, as long as you know that up front, for example. So, we have to have a bundle of additional metadata items that that allow us to ensure that what we're comparing like with like... this applies to pathology results. Creating the standard and stating these are the rules by which you must conform, I think really is the only way. And that's not to push people out of the market, but it's just to ensure that we're dealing with known knowns. There were ways of doing this now, as in UK core **Digital Architect** **From surveys:** Healthcare professionals and suppliers were asked: ‘Which of the following information that could be recorded by a person with diabetes at home would healthcare professionals use in caring for them and when would it be needed?’ There was broad agreement across responses (HCPs, suppliers, others) supporting the need for HCP to have visibility of data across the 17 categories which included blood sugar, exercise, medications, insulin, diet, hypoglycaemia and foot

	checks. Most thought this information should be shared at scheduled appointments. Systems suppliers indicated that information should be shared in between appointments for blood sugar (85.7%, n=6), episodes of hypoglycaemia (100%, n=7) and insulin dosing (85.7%, n=6). These findings may reflect that these are examples of the data shared in real time/ near real time from diabetes devices (such as real-time CGM e.g., DEXCOM G6, intermittently-scanned CGM e.g., Freestyle Libre, connected insulin pens, and pumps etc) that are familiar to systems suppliers. Clinicians have also shared with us their concerns around the uncertainties and lack of clear guidance about what their clinical responsibility is to action continuous streams of live device data or alerts (e.g., hypoglycaemia) outside of scheduled clinic appointments.
Recommendations	• Information about the provenance of the information must be included in the record including which device the information was collected from, whether it was manually entered or automatically recorded.

The medical devices market for diabetes management is global and dynamic due to increasing demand for monitoring products because of innovation and price, increasing awareness and increasing need for self-monitoring and management	
Findings	• It is important to support international standards where possible because the device manufacturers operate in a global market. The information standards reference the international standards SNOMED CT and UCUM and the technical standards will be based on FHIR. SNOMED CT and FHIR both have UK versions, however and PRSB standards are also developed for the UK. • Clarity is required for the device manufacturers about how the different types of devices should support the standard for example, the information that would be expected from an insulin pump would be different from that of a glucose monitor or lifestyle app.
Rationale	There are many different types of devices and apps, supporting different areas of self-monitoring or management including lifestyle apps supporting wellbeing, diet, devices to support glucose monitoring and devices to support insulin delivery. The technology is continuing to develop as we see the next generation CGM devices, connected pens and increasingly hybrid closed loop systems becoming available. Discussions with medtech suppliers have demonstrated the importance of

	aligning with international standards to support implementation as they operate in the global market. NICE guidelines[19] are changing to expand access to continuous glucose monitoring to all adults with type 1 diabetes and some adults with type 2 diabetes, for example those who are on multiple daily insulin injections and have impaired hypoglycaemia awareness or are unable to self-monitor their blood glucose. The use of integrated pump systems and hybrid closed loop systems is being reviewed by NICE and the guidance will be updated.[20] Figures from NHS England show that half of type 1 diabetes patients – around 125,000 with the condition – are now using flash monitors to check their blood glucose levels. Before 1 April 2019, it was estimated that around 3-5% of people with Type 1 diabetes in England had access to intermittently-scanned continuous glucose monitors. Now 34% of the Type 1 population have received one.[21] The World Health Organisation recommends that people with type 1 and type 2 diabetes on insulin should be offered self-monitoring of blood glucose based on individual clinical need[22] **From survey:** Systems suppliers were asked the following question: 'If you are a technology supplier, what are the future requirements your customers are telling you about that we should be aware of for the development of the standards?' Alignment with national and international standards and HCP consensus statements was identified as a required.
Recommendations	• PRSB should consider its role in contributing to the development of international standards. • There should be further engagement with medical device suppliers to support implementation and understand any implementation barriers. • As part work to develop technical messaging standards, work should continue with medical device suppliers to develop detailed implementation guidance specific to individual device types. This would include: ○ Smart insulin pens

[19] NG17 Type 1 diabetes in adults: diagnosis and management (nice.org.uk), Type 2 diabetes in adults: management (nice.org.uk), NG18 Diabetes (type 1 and type 2) in children and young people: diagnosis and management (nice.org.uk)

[20] NICE planning expansion of diabetes continuous blood glucose monitoring devices - Nursing in Practice

[2121] NHS England » Glucose monitoring for patients living with diabetes

[22] 9789240030909-eng.pdf

	○ Insulin pumps ○ Hybrid closed-loop systems ○ Real-time continuous glucose monitors ○ Intermittently scanned continuous glucose monitors ○ Glucometers ○ Algorithms including looping and bolus advisors

There is a complex environment of systems and technology to support diabetes that need to share information and will need to conform with the information and technical standards to do so	
Findings	• To share information between the different systems in use across ICSs, the systems need to conform to standards as a first step. Conformance with technical standards and commercial agreements will also be required to support interoperability and information sharing between the different applications and systems. • The diabetes standards are based on PRSB's Core Information Standard which is being implemented in Integrated Care Systems however it is not clear how well the standard is currently implemented. Implementation of the Core Information Standard does not preclude implementation of the diabetes standards however systems that are already compliant with the Core Information Standard will require less adaptation. • Not all systems will need to comply with the entirety of the standards and will only need to comply with a subset of the standards relevant to their products – for example an insulin pump manufacturer would only need to comply with the information relating to insulin dosing. • National technical messaging standards are based on Fast Healthcare Interoperability Resources (FHIR). UK FHIR core is in development and the diabetes standards will need to be mapped to the existing UK FHIR core profiles to understand where the gaps are and a pragmatic approach will be needed to develop technical standards, with the ICS community, which can be used for immediate implementation. • Point of care glucose and ketone testing systems in hospitals were not explicitly considered in the development of the standards and although it is likely that the information needs are supported, without further investigation it cannot be guaranteed.

Rationale	There are four broad groups of systems and technology used in the management of diabetes, ranging in scope: a. **lifestyle apps** for supported self-management b. **medical devices** (including self-monitoring and insulin delivery devices, Point of Care systems in hospitals and systems integrating data from devices) c. **specialist diabetes management** systems d. **non-diabetes specific health and care systems** Lifestyle apps and medical devices capture very specific information and therefore only a subset of the standards would apply to them and this needs to be defined. In 2020 NHSX conducted a review of plans (submitted in response to a letter from Sir Simon Stevens) for STP/ICS shared care records. Local systems were required to produce a plan, agreed with their NHSE/I Regional Director for developing and implementing a full shared care record, allowing the safe flow of patient data between care settings, and the aggregation of data for population health. Each plan was assessed against the Shared Care Record Minimum Viable Solution (MVS) and the Core Information Standard (CIS). The expectation was that the 'Required' elements of the Core Information Standard would be included in Shared Care Records implemented by September 2021. The recently published draft data strategy reiterates the commitment to ensure that each ICS has a basic shared care record (to enable sharing of key information between GP practices and NHS trusts) in place by September 2021.[23] In addition, it states that the monitoring of adoption of standards will begin, and a standards catalogue/registry will be published to improve visibility in March 2022. It also states that a core of UK-wide Fast Healthcare Interoperability Resources profiles to be the foundation for new standards will be available by November 2021. [24] FHIR is the latest international standard developed by HL7, NHS Digital is working to create a unified approach to interoperability across England, Scotland, Wales and Northern Ireland using FHIR release 4. This will enable consistent information flows across borders to improve health and care outcomes for all citizens. FHIR will be the basis for the diabetes technical standards.

[23] Data saves lives: reshaping health and social care with data (draft) - GOV.UK (www.gov.uk)

[24] Data saves lives: reshaping health and social care with data (draft) - GOV.UK (www.gov.uk)

	The GIRFT report for diabetes[25] identified that 'there is great potential for web-linked meters to prevent avoidable harms and where this is not happening, it's often because of a technical issue - trusts may be unable to identify out of range results because the system is simply not set up to provide the data. It needs more support from hospital IT staff and the device manufacturers, so that the downloads are easy to access and presented in a meaningful way.' Point of care glucose and ketone testing in hospitals were not explicitly considered in the development of the standards so it is unclear whether the metrics defined for glucose measurements would be appropriate for point of care systems.
Recommendations	• Targeted engagement events with diabetes and non-specialist systems and medtech suppliers • Map the two diabetes standards to existing FHIR UK core profiles. Where they do not map, working with the ICS community to develop solutions for early use to drive consistency. • A similar approach is needed for sharing information with GP systems, therefore also map to GP Connect (as this is currently based on an earlier version of FHIR). • Undertake a discovery piece of work to determine to what extent GP systems comply with the standards and develop a proposal for incremental conformance. • Undertake 1 or 2 First of Type implementations in a clinical context. Define transactions between system and select an architectural approach for implementation. Base this on areas that would add most value, for example sharing between GP, hospital systems and eye screening services and sharing of self-monitoring data with clinical systems. As well as enabling the standards to be tested and refined, this would enable the development of support materials for implementers and would help to inform a national architectural strategy. • In addition to developing technical support materials capture lessons learnt and case studies to support rollout in other areas. • Publish implementation support materials as part of an online implementation toolkit. • Undertake a short piece of work to test the applicability of the standards to Point of Care systems in hospitals.

[25] Layout 1 (gettingitrightfirsttime.co.uk)

Clarity on how SNOMED CT should be used to support diabetes coding requirements is needed particularly in relation to use of qualifier values for indeterminate diagnoses and in summary metrics. Codes for non-prescribed medical devices are not available	
Findings	• Coding of diabetes diagnoses is unclear because there are multiple codes, for example for type 1. • There are no codes for medical devices that are not prescribed e.g., Dexcom G6 CGM device and Medtrum insulin pumps and current policy is that they cannot be included in dm+d if they are not on the drug tariff. • Codes for summary metrics for glucose and insulin do not currently exist in SNOMED CT. • It is not clear how 'suspected' diagnoses should be recorded using SNOMED CT and how that information can be shared between systems without introducing clinical risk. • SNOMED CT codes do not currently exist for care plan goals or actions. To share care plans developed in systems external to GP systems it would need to be coded.
Rationale	**From webinars:** "There's lots of codes that are very similar to Type 1, about 20 codes e.g., Type 1 diabetes, juvenile diabetes, IDDM [insulin dependent diabetes mellitus]. Is a piece of work about streamlining, recommending that the term you need to use this is needed? Because that's a big problem. When you're pulling data, if you miss one of the terms that someone's using out there, you lose a lot of a data. In particular, the type of diabetes or where it's indeterminate there isn't really a code for, well I'm not really sure which type of diabetes they have." **Senior Lecturer and Consultant** **General** GP systems cannot currently handle SNOMED CT qualifiers such as 'suspected' and so, for example, if something is coded in SNOMED CT as a suspected diagnosis, and that is passed to a GP system it could end up appearing in the person's GP record as a confirmed diagnosis which is a significant clinical risk. SNOMED CT contains pre-coordinated 'suspected' terms for a selection of conditions for example for suspected cancers. They can be used in problem lists, but they only include a tiny fraction of all problems or diagnoses that a patient may have. An alternative or complementary approach is to create post-coordinated SNOMED CT terms for suspected conditions or include the SNOMED CT term in a structured data area where the information model specifies that it represents a suspected

condition. This structure will inform the interpretation of the underlying SNOMED CT code for the condition.[26]

It is important to record suspected and differential diagnoses in the clinical notes, but they must not be confused with confirmed diagnoses. They should be documented using a specific flag for suspected diagnoses, or a pre-coordinated SNOMED CT term for a suspected condition, or if there is no structured option they can be entered as text in the clinical notes alongside the symptom, sign or abnormal investigation result that suggested the diagnosis (e.g. Problem: Shortness of breath; Comment: Suspected heart failure). A text comment such as 'suspected' must never be used to try to change the meaning of a SNOMED CT term for the actual condition; this will convey an inaccurate meaning if the text is not shown and will be counted incorrectly when data are aggregated for audit or research.[27] Clarity of preferred direction of travel at a national level is required on this.

Currently dm+d, and by extension SNOMED CT, does not include codes for medical devices because the dm+d scope is limited to prescribed products (on the drug tariff) and devices are not prescribed. For example, a hip prosthesis, or a pacemaker would also not be found in in dm+d as they are not prescribed.

Information about a person's device use is needed in their record to support the following circumstances:

- If a person is not using a device(s) but qualifies for device(s) to help them to better manage their diabetes.
- If a person is using an older version of a device that may no longer be on an 'approved' list of devices, healthcare professionals can advise on the benefits of upgrading to a newer model for the person. Also, in many cases the consumables used in older devices (e.g., testing strips for glucometers) cost the NHS more than those for newer models in general without added clinical benefit to the person.
- If the person is using a device to help them calculate their insulin dosing but it is not recommended for their particular circumstances and could cause harm, for example some CGM devices should not be used if the person is on dialysis.
- If the MHRA issue a safety notice or product recall for a particular device, healthcare professionals can quickly identify and notify people using those devices to reduce the risk of harm.

[2626] Diagnosis-recording-final-report-v1.pdf (theprsb.org)

[27] Final_Diagnosis_Recording_Guidance.pdf (theprsb.org)

	It is important that healthcare professionals know the provenance of the information in the systems so they can make a clinical judgement on whether the data is 'validated' and can interpret the data and therefore important that the type of device, the make and model that was used is available. The data could be: • From the device directly (e.g., from a continuous glucose monitor) • Manually entered by the person after being transcribed from a device (e.g., from a glucometer because they took a break from using their CGM device) Continuous glucose monitors measure interstitial blood glucose, glucometers measure blood glucose (generally from capillary blood at home but also sometimes venous blood glucose in hospital settings) and therefore all of these devices and specimen types would give slightly different results. This is why it is important to view trends and patterns of data from continuous glucose monitors rather than individual results and why it is important to know where the data came from. Other areas identified during this work that are not supported by SNOMED CT are summary metrics for glucose and insulin and care planning goals and actions. These require further work to support the implementation of the standard.

Recommendations	• Work with NHS Digital to ensure that required SNOMED CT codes for the diabetes standards are included and there is a process for maintaining the codes. To include:
	  ○ New codes for summary metrics
	  ○ Codes for devices
	  ○ Codes for care planning goals and actions
	
	• Provide clarity on coding of diabetes diagnoses, in particular the coding of 'suspected' and 'excluded' diagnoses.

The diabetes standards are designed to support the management of a person's diabetes. They include the information needed by endocrinologists about pregnancy to manage the diabetes but not everything needed to manage the pregnancy	
Findings	• Information required about a person that may be planning to get pregnant or is actively pregnant and has diabetes is needed in a record about someone's diabetes. • There is much information needed about a person to manage a pregnancy. This is set out in the Maternity Information Record Standard

	• A pragmatic decision was taken to include the information needed by the endocrinologists about family planning and pregnancy rather than all the information needed by maternity services. • Currently information is not shared well between maternity and diabetes services.
Rationale	**From webinars:** "Information you'd want to bring in would be that you'd need to support diabetes management in pregnancy and assess outcomes via audit - so not whole maternity record." **Consultant** "Critically important here are the education / support dimensions of pregnancy preparation. This is really poorly recorded at present - and indeed poorly delivered." **Endocrinologist and Diabetes Specialist Physician** **From survey:** People with type 2 diabetes did not want to share family planning / pregnancy information and approximately half of people with type 1 wanted to share such information. • People with type 2 diabetes were least likely to want to share information about episodes of hypoglycaemia (68.9%, n=20), insulin dosing (44.4%, n=12), smoking (51.7%, n=15) and family planning (7.41%, n=2). • Possible confounding factors include age, sex, and fertility status (which were not collected in this survey) as well as a low response rate might explain this result. In answer to the question 'What information about someone's planned or current pregnancy should be included in a record for a person with diabetes?' • The most highly cited themes were contraception use and type (n=53), pregnancy plans and timescale (n=59), pregnancy status/ test results (n=54), person with diabetes breastfeeding now or planning to (n=41), and person with diabetes is actively trying to conceive (n=39). • Themes highly cited by health and care professionals were history of previous pregnancies (n=13), education/advice on preconception planning/ diabetes in pregnancy offered/ given to person with diabetes (n=12), person with diabetes was taking folic acid at time of conception (n=7), medications review (including teratogens) (n=6), fertility status/ person with diabetes treated under specialist fertility services (n=6), and estimated last menstrual period (LMP)/ number of weeks pregnant/ due date (n=5 "For general clinics we only need to know: (1) Are they pregnant, (2) are they planning pregnancy, (3) are they capable

	of pregnancy. Joint antenatal clinics require far more information, of course." **– Endocrinologist** In answer to the question 'What information about people with diabetes are healthcare professionals unable to access that they need to see?' The most highly cited themes in the comments included examples of where records are held outside of an health and care professional's organisation or CCG etc. including mental health, optician, & maternity records (n=19), access to test results including images, scans, and reports (n=20), medications taken including changes (n=11), diabetic eye screening results including images (n=13), data from devices including CGM and insulin pumps (n=14) as well as several other elements common to patient health records e.g. observations, allergies etc.(n=21).
Recommendations	• The upcoming review of the maternity standard should explicitly consider gestational diabetes and whether components of the diabetes standard should also be available in a maternity record standard such as summary glucose or insulin metrics. • Information sharing using the standard should be tested in conjunction with the maternity standard in maternity and diabetes services.

The procurement frameworks in use in the NHS can be used to encourage suppliers to conform with mandated standards.	
Findings	• Procurement frameworks can be used as a lever to encourage suppliers to comply with mandated standards. • Typically, these would be standards nationally approved by the Data Alliance Partnership Board which providers should comply with. • The main frameworks of relevance to diabetes systems, medical devices and consumables are: a. NHS Supply Chain framework for CGM, pumps, software and algorithms and consumables b. GP IT Futures (for primary care systems) c. NHS England's Health Systems Support Framework (HSSF) d. The London Procurement Partnership's Clinical Digital Solutions framework and Dynamic Purchasing System e. The NHS Shared Business Services Healthcare Clinical Information Systems framework

	• These are live frameworks, and some will not be retendered for some time. The NHS Shared Business Services framework ends in August 2022 and therefore new specifications are being drafted. PRSB standards are being mapped to the lots and diabetes standards should be referenced. • Until frameworks are retendered there is an opportunity to provide buyers with information about the standards and they can then build the requirement into their specifications. • Consideration needs to be given to how the systems will be assessed for conformance with the standards.
Rationale	**From discussions:** In order for the information to transfer between systems (e.g. between apps and clinical systems or between GP system and a hospital system) the apps and systems need to: • conform with the information standards • conform with the technical standards (based on FHIR), developed by NHS Digital. **Conformance with information standards** The Data Alliance Partnership Board provides oversight of the assurance and approval of information standards, data collections and data extractions (ISCEs) across health and adult social care. National ISCEs should be presented to the Data Standards Assurance Service for assurance and approval prior to them going live. Once live, providers are required to conform with the standards within the given timescales. This means that they may also require software suppliers to become conformant with the standard and may request this. Ideally, however, the suppliers should be required at a national level to conform with nationally assured and published standards, rather than individual providers requesting conformance. To assist this, requirements for conformance can also be built into procurement frameworks in widespread use e.g. conformance with DCB3058 Compliance with National Data Opt-outs is a requirement in the GP IT Futures framework and each supplier has to demonstrate their level of conformance which is reflected in the framework and enables buyers to make procurement decisions based on level of conformance. **Conformance with technical standards** Technical standards based on FHIR (Fast Healthcare Interoperability Resources) will be developed to support the two diabetes standards. The technical messaging standards would also then need to be referenced in the procurement frameworks

	so that systems are required to conform with those standards in addition to the information standards. The requirements for conformance with standards (both technical messaging and information standards) should be set out in the relevant procurement frameworks with a statement of conformance for each product so that buyers from the framework can assess products. Currently there many procurement frameworks meaning that competition happens at the framework rather than the supplier level. NHSX (now NHS England and NHS Improvement) is not the contracting authority but is keen to incentivise use of a preferred set of frameworks. The aim is to drive interoperability and open standards in electronic patient record systems through the procurement frameworks. The key procurement frameworks identified for procuring clinical systems and medtech for the management of diabetes are that should include a requirement to conform to the diabetes standards are: ○ NHS Digital: GP IT Futures (as part of the roadmap) ○ NHS England: Health Systems and Services Framework (HSSF) ○ London Procurement Partnership: Clinical Digital Solutions framework and Dynamic Purchasing System (DPS) ○ NHS Supply Chain: Insulin Pumps, Continuous Glucose Monitoring, Closed Loop Insulin Delivery Systems and Associated Products ○ NHS Shared Business Services: Healthcare Clinical Information Systems Demonstration of conformance with standards is often through self-assessment and consideration should be given as to how suppliers should be assessed.
Recommendations	• Seek Data Alliance Partnership Board (DAPB) assurance for the two diabetes standards. DAPB assurance would require providers to comply with the standards and to comply they will require systems that conform to the standards. • Ensure that the standards are included in the NHSX standards register. • Consider the use of other incentives for example incorporating the diabetes standards into the What Good Looks Like framework, the ICS mandates and the NICE guidelines. • Ensure that the information and technical standards are referenced in the relevant procurement frameworks

	where possible and if not immediately possible develop guidance for buyers setting out the benefits of the standards: ○ NHS Digital: GP IT Futures (as part of the roadmap) ○ NHS England: Health Systems and Services Framework ○ London Procurement Partnership: Clinical Digital Solutions framework and Dynamic Purchasing System ○ NHS Supply Chain: Insulin Pumps, Continuous Glucose Monitoring, Closed Loop Insulin Delivery Systems and Associated Products ○ NHS Shared Business Services: Healthcare Clinical Information Systems • Consider how conformance with standards should be assessed and work with procurement framework leads to agree and implement an approach.

6 Conclusion

In conclusion, there was broad support for the development of these standards throughout the consultation process across professionals, people with diabetes and clinical systems and medtech suppliers. We now need to build on that support to make it easy to adopt the standards by developing the technical components needed to support the sharing of information; activating a community of willing participants to promote the standards; continuing to identify and address perceived barriers to implementation; and identifying and activating levers and incentives to drive adoption.

Appendix 1 – Findings from scoping phase

Finding	Literature review	Interviews	Focus groups
Including the Personalised Care and Support Plan standard in the Diabetes Record Information Standard (for care plans) may improve certain clinical outcomes in people with diabetes and this was supported by people with diabetes and professionals.	A Cochrane systematic review has found that the methodology associated with personalised care and support planning including goal setting and patient-centric working) was associated with improved measures of systolic blood pressure (BP) and glycosylated haemoglobin (HbA1c) in people treated for type 2 diabetes. Cochrane 2015 This is supported by a recent retrospective observational study of 447 patients with type 2 diabetes that found statistically significant reductions in low-density lipoprotein (LDL) cholesterol, and body mass index (BMI) and a decrease in HbA1c ($p = 0.07$). JPPCH, 2020	Professionals described instances where the GP record, or proprietary or local/ home-grown diabetes management system or record is used that this information may need to be copied and pasted to the shared patient care record. This can lead to duplication and partial or incomplete recording of a person's healthcare information, which presents a risk of harm.	
Including the 9 care processes, glucose and insulin dosing in scope was supported by both professionals and people with diabetes.	11.4% of medical negligence claims from 2013/14 to 2017/18 'were related to insulin prescription or administration error' and overdose of insulin is an NHS 'never event' (those with the potential to cause serious harm but are wholly preventable). GIRFT, 2020 Appropriate patient use of real-time data from apps and devices has	Treatment with high dose steroids has resulted in insulin dosing issues in some patients with type 2 diabetes as they are tapered off the steroid.	

Finding	Literature review	Interviews	Focus groups
	been shown to be associated with improved blood glucose management.		
Professionals and people with diabetes raised potential issues around understanding the data and how it relates to self-management e.g., from test results or devices and targets.	Surveys have shown that patient understanding of calibration of devices such as self-blood glucose monitoring strips is often poor. JDST, 2021 Poor understanding of diabetes management targets is associated with worse disease outcomes. A 2018 study found that patients have a variable understanding of concepts like HbA1c and may use 'different information [than professionals] to gauge their diabetes control.' BMC 2018		'One of the other things is there's no evidence of target levels being set. So, people are merrily testing away without understanding why they're testing. And sometimes if it's written in a diary when I receive a very clean diary, I always question [this and] like to see the [glucose] meter. I worry that especially across South East London, there is not always evidence of two levels being set and then managed with a time frame of when to relook at those target levels and to look at those blood glucose levels. So, there's a missed opportunity at that point.' **Diabetes Specialist Nurse** 'I think one of the problems for patients, certainly in our practice, is being given the results of your reviews of your blood tests and knowing what things mean. It's about enabling people to know what's going on and to manage things for themselves and sometimes that that doesn't happen, you don't get answers, or you don't know where to find out the information.' **PwD, T2** 'I personally have access to my own record and the only criticism I have of that is when it comes to a blood test. I don't understand it…My blood tests could tell me a lot if I understood.' **PwD, T2**
The importance of capturing PROMs and PREMs as part of recording outcomes and experience of people with diabetes was raised.			'You're speaking about self-management here and empowering the patients in their care, but you're focussing on clinical measures. So, have you considered collecting PREMs [Patient Reported Experience Measures] and PROMs [Patient Reported Outcome Measures] as well? If you really want to represent the experience of the patient and how they're dealing with their self-management?' **Representative for NPDA**

Finding	Literature review	Interviews	Focus groups
It is important to record 'holistic' and other background information that may influence their diabetes and its management.			'I think it's important to have a holistic view of the patient as well, not just the medical side. I don't know whether that sort of data is collected [about the] patient [or] by [the] patient. [For example] what sort of situation they're living in [or] If you don't have a permanent abode [or] things like that.' **PwD, T2** 'We're talking about insulin dosing. But I'm wondering about other diabetes medications and specifically whether things like medications, the increased risk of hypoglycaemia, for example, whether that risk would want to be recorded ' **Representative for Diabetes UK**
People with diabetes reported significant benefits of using diabetes devices for self-management viewing data in real-time but they rarely download and review their device data. Some also felt it was important that the standard included measurements taken by people with diabetes, such as height and weight. Especially as due to the covid pandemic there has been a move towards more remote consultations and therefore less opportunities to take these measurements in clinic.	Appropriate patient use of real-time data from apps and devices has been shown to be associated with improved blood glucose management. DST, 2018 Studies have shown that most patients with type 1 diabetes who view their device data do so in real time and only a minority routinely download and review the data retrospectively. DTT, 2015		'[In] paediatric diabetes, it's pretty standard now to use data sharing platforms like Diasend [Glooko] and download your (in our case, our son's) data. We use that as an app, really regularly and have found it to be really useful in that we can get a 24 hour snapshot and a trend for over the two weeks of what's happening with that blood glucose value and adjust basal and bolus rates [of insulin] in real time to react to, say, the difference between school and holiday time, for example. So, I would say that that's probably one of the most useful tools for us, is actually being able to visualise the data in real time.' **Parent** 'In terms of [the Freestyle Libre] capability, I can only really describe it as being quite life changing. It gives you more independence in terms of what you can do. And I guess this is leading onto the next question. So, I can sort of go on to my online account and I can see a monthly overview of my blood glucose. I can see what my average is. I can see how many lows I've had in a week's period. Obviously, we've got those issues around sharing the information. But one of the great things that I've talked about, is that you have to give your consent for that information to be shared. So, for example, my specialist care team in Newcastle have access to my Freestyle Libre results. So, the great thing about this is due to the pandemic, I've been based in Leeds, so I've not been able to

Finding	Literature review	Interviews	Focus groups
			see them in about a year and a half. But what they've been able to do is they've been able to log on and they can see exactly what is happening with my diabetes over a year and a half period without having to see me face to face. My GP didn't have access to my Freestyle Libre, so I was then able to approve [access for] them. And it's just gradually giving people more independence. I can manage my own care and I'm not having as many appointments because my health has improved from it.' **PwD, T1**
Some people with diabetes interact with services that have less digital maturity. Access to devices may improve access to data and reduce reliance on traditional metrics and measures.	Patient and clinician access to continuous device data that supports may have advantages over traditional measures such as HbA1c (which reflects average glycaemic control over 2 – 3 months) and patient logbooks (which may not always be accurately recorded). DS 2019	'My concern is that when talking about excluding self-validated data from a standard, this could disproportionately negatively affect type 2 patients due to existing inequity within the system - something that seems to be the antithesis of the standard. As this group of people with diabetes may be unlikely to have access to some of the more high tech devices and there's the potential that people with type 2 may be less likely to be asked for data from their glucometer, I am concerned that the available information may be less likely to end up in their record due to how it's coded/ flagged. Issues of accessibility and digital poverty may only exacerbate this further so excluding any opportunity to ensure relevant data (that other diabetics are perhaps able to provide more easily) enters the record, concerns me.' **PwD, T2**	'In my area, northwest London, I've never had any digital information or, you know, anything that's given me self-management, apart from just testing blood sugars.' **PwD, T2**
Difficulties associated with remote consultation were not identified but people felt that some of their peers might have difficulties due to digital exclusion.			'I've had telephone consultation and I've also had video calls, and because I think I'm reasonably used to those means of communication, I haven't had a problem with it, to be honest.' **PwD, T1** 'I've had to face to face as well as video consultation because I'm OK with digital access. It was fine, but

Finding	Literature review	Interviews	Focus groups
			I'm just thinking also about my peers, some of them who are not confident and have digital poverty.' **PwD, T2** 'What worries me is a reliance on digital ways of managing things, and that then causing further division in terms of health inequality. So, whatever you do, you've got to ensure that the system doesn't just depend on people's electronic means of putting in information, but you have to think of those in society who are not able to do that. Otherwise, they're going to get left behind.' **PwD**
People with diabetes emphasized the importance of person-centred care.			"[Recently] I've had three or four appointments with different people in hospitals and GP and all the rest of it. And nobody's ever sat me down, really, and said, what do you want? So, something organised like that would be absolutely great and actually just goes above any of this stuff, really. You know, if people would just sit down and talk to us about what we want, what we think we want. Many people have said that they actually know how to manage their own care, probably better than the consultants, clinicians and GP's sitting with them. So, I'd really like to see the patient put at the centre of this process." **Person with pre-diabetes**
Current lack of interoperability and sharing of key data was raised. People with diabetes described how they often had to repeat the same story to multiple healthcare professionals. This was a particular issue in transfers of care across organisational boundaries.		Professionals gave examples of where lack of information sharing was an issue in their practice, these included: 1. People with diabetes having had a foot assessment done outside of hospital but this information may not be available to the medical team or general practice. As a result, the team may not be aware that a foot check is required. 2. A person with diabetes' previous diabetic foot risk assessment is not always available when admitted into hospital. Checks may or may not be	'One of the main problems we have is if [as a clinician you] don't have access [to the right information]. Approximately one in four women will have a miscarriage or a pregnancy loss. A number will have terminations. And we have just no good sharing of data between maternity and diabetes services. So, we may see these women and have no idea that they've just had a loss or a seriously bad pregnancy outcome.' **Representative for NDA and NPID** 'One of the biggest disconnects we have is the data being shared from district nursing and that is a huge implication, not just for the patient themselves, but also for quality of the service for the teams and risk.

Finding	Literature review	Interviews	Focus groups
		taking place and if appropriate action is not taken the person with diabetes may suffer complications and the right professionals may not be involved in their care. 2. Patients referred to an ophthalmologist from the diabetic eye screening programme, but the clinician has no access to the person's health record. 3. Information about complex diabetes patients with multimorbidity discussed at the multidisciplinary team (MDT) meeting, subsequently being available to only some MDT members. 4. Incidental findings being picked up by allied health professionals that may not always be shared with everyone involved in a patient's care that needs to know. 5.People with diabetes described experiences of how a lack of information sharing has led to them having to tell their story more than once and duplication of clinical effort or investigations in different settings.	So, there'll be blood glucose monitoring undertaken, but because the systems, are not interoperable [is it not] shared. So therefore, we are sometimes called by [someone who] could be a carer, could be a family member, discussing about their loved one and what's happened [regarding] some of their signs and symptoms and we have no understanding of what their blood glucose levels are. And even worse, I'm afraid to say in some circumstances these patients are on insulin. And it's just a huge risk that's not shared in real time.' **Diabetes Specialist Nurse** '[One issue is the] link between primary care and acute care and the lack of information between primary and acute care. But there's an intermediate step in community care. Similar to the district nursing issue in the sense that podiatrists are often managing patients in community care and foot protection teams, are in primary care networks. And that information isn't really shared between the acute care and the primary care. So, there's a sort of missing loop. So often you get that jump straight to acute and missing out the middle bit where a lot of the preventative footcare happens.' **Podiatrist** 'Unfortunately [use of the extended summary care record is] sporadic and what we find, especially with podiatry, [is that] when patients are seen in other settings the foot assessment is not carried out. So, this is not information that we receive in a timely fashion.' **Diabetes Specialist Nurse** 'My experience has mainly been a negative one where information has not been shared and it's a matter of me having to repeat everything and tell them what's going on and give them all my medical history [again]. It's like they just know nothing. And it just concerns me because just like everybody else, I am busy as well. And you just want to get things done, you know, and you expect them to know your

Finding	Literature review	Interviews	Focus groups
			background and information, particularly diabetes.' **PwD** 'The difficulty that I had, is that I moved from one region to another and there was sort of that aspect of having so I still keep my specialist care in Newcastle because it's the team that I've been with since I've been five years old. And also, now I have a GP in Leeds and I've had this conversation many times where they've said that they've transferred data between each other to update on my consultations. But then I find that I'm still getting asked the same questions. And I know, obviously, that they both have a duty of care, but that doesn't seem to be sort of that streamline transfer of data between the regions in terms of my own personal care.' **PwD, T1** 'My experience has been also similar in the sense that my data doesn't seem to be [available] within a medical centre. I have to repeat [that, for example] I've started on this new medication that they're trialling on me, and this might be the side effect. So, if I go for something else [and see] a different GP, I would have to repeat that. I run a peer support group, some of the people that I support [do not have] English as their first language. If I'm struggling with [communicating] with my clinicians, what would their experience be? We need to close the gap and reduce some of the inequalities.' **PwD**
Information governance regulations were identified as a blocker to information sharing.			'One of the problems that we face is the difference in all the NHS trusts with regards to what IT infrastructure they have. A simple act of being able to access a website on a browser that can vary so much from trust to trust, and also the processes in getting access with regards to forms for DPIAs [Data Protection Impact Assessments] and GDPR [General Data Protection Regulation]. It's different absolutely everywhere. It can even be different from department to department, from an adult service to a paediatric service and then a gestational service. You are repeating the process three times in one institution. I

Finding	Literature review	Interviews	Focus groups
			think the impact of this is so widespread it impacts the people with diabetes. They feel that they're doing everything they possibly can. They turn up to clinic and their data isn't visible, which can be so frustrating for healthcare professionals. And from a carer's perspective as well, they're not able to support because they've not got this cohesion from the end user to the healthcare professionals. So, it's a really frustrating journey.' **Medtech supplier**
It was identified that some useful information is available in the community (e.g., police or prison services) before it is made available to a healthcare professional. It was also suggested that information could be usefully shared with other non-healthcare organisations such as schools and social care providers.		Stakeholders identified that information relating to diabetes may need to be captured from and shared with first responders. The ABCD audit for Flash used some ambulance service data and it showed significant amounts of activity relating to diabetes complications, which would not routinely be captured.	'The issue of children in a school that cannot take their own medication, I think that needs to somehow be captured here in terms of getting the information across to schools.' **Person with prediabetes** 'We find, with some of our population taken into local police stations, [that we] identify at that point that there was an underlying with a psychiatric history, but also an underlying high blood glucose levels, the first diagnosis. [but] the information [does not get into our systems, if for example they present at A&E]. [Also, information should be shared with social care] especially the carers.' **Diabetes Specialist Nurse** 'In the National Diabetes Audit, we've been undertaking a feasibility study in secure mental health settings and there is a problem where there are quality concerns with diabetes care, but the information simply isn't collected as part of information systems. So, I think it is important to think of other care settings that patients might be treated in. It might be prison services or secure mental health settings or community settings. And diabetes parameters might not be captured in those systems so the diabetes audit simply can't assess how good the quality of care is.' **Representative for NDA**
People with diabetes described how information that was important to them was not always shared unless directly asked for. Tailoring the			'[My experience has been] mostly positive, usually [I discuss my] HbA1c with a number of people. But what I do find is that unless I specifically asked [for kidney function test results] I'm not given them. And for me, that's quite important. I've had diabetes for

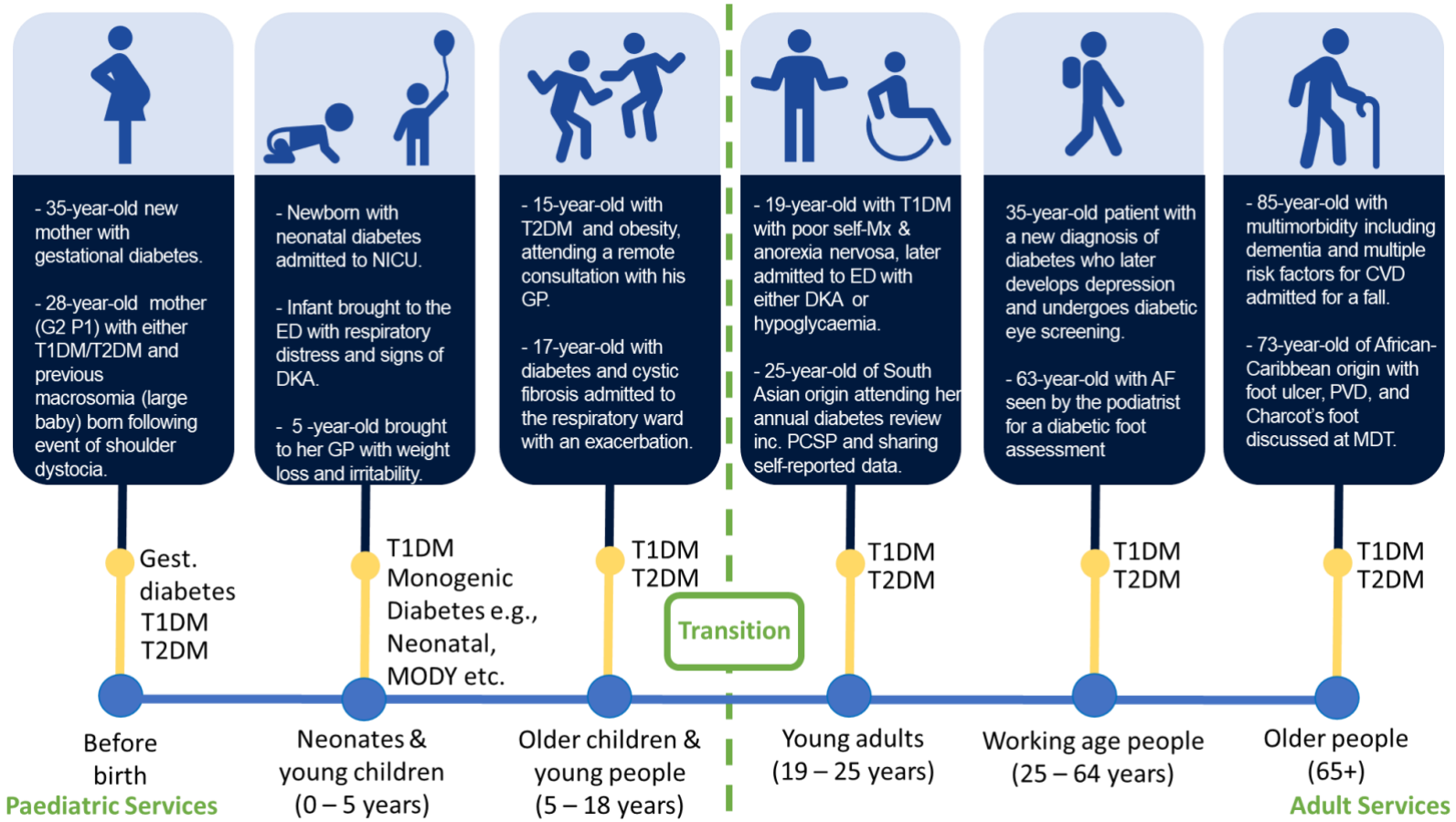
Finding	Literature review	Interviews	Focus groups
information shared was felt to be a challenge because of the variety person preferences about the information they wanted to know.			over 40 years and I can pretty much manage my own care. But an early warning of any complications is quite valuable to me.' **PwD** 'I think we've seen fairly recently a transition from [HbA1c] being really vital to people looking more at time in range [now]. But there are other things that are important to different people. I think maybe that is part of the problem [as people have] different preferences about information they want to access.' **PwD**
People can find it difficult to access their health and care records.			'[Thinking] about access. How do we as patients access our information? Because it's not straightforward. You know, this is something I've tried to do. So, it's not just sharing amongst maybe health professionals or link workers or whoever, but also with patients as well.' **PwD** 'Through my surgery, we've been told that we can access our personal health records. But to do it is not easy because you have to get a code in my surgery from the reception and then try and use it on their website. It's just a very laborious. It's almost as if barriers are put in place to prevent people from accessing it. I understand why, because it is quite sensitive information, but it's not as if there's [any] activity around encouraging patients to have this information, to empower them and to be able to have the kind of equal conversations that I know all of us are working towards having with our health management.' **PwD**
Although some people didn't mind sharing the information from medical devices (providing IG rules were followed) some people were uncomfortable with the potential for monitoring 24/7.			'I personally don't mind my information being shared, I think it'll be beneficial in the long term, but presumably will be [shared] on a need-to-know basis and audited whenever anybody goes into the records, because I wouldn't … want anybody just being obstructive for no reason as long as it's audited and there's a reason for them going into the record. I personally don't mind.' **PwD, T1**

Finding	Literature review	Interviews	Focus groups
			'I don't have a problem with my GP and health care workers having access to my medical information as long as the GDPRs [General Data Protection Regulations] are respected.' **PwD, T2** 'I've recently got a Freestyle Libre sensor, and you can buy them [but] if you want them funded in the area where I am you have to share all your data. It's not right or wrong but I am uncomfortable that I now have a tag on me that will tell anybody that accesses my record. How I'm getting on 24 hours a day, seven days a week, and I find that uncomfortable, you if I don't share it, I can't get one.' **PwD, T1** 'I always see different people about my diabetes [and they] ask what medications I'm on and I take [and] I've got some complex multiple conditions, so I'm taking 24 doses a day, which is quite a mouthful to get through. I would like them to have access to the list of meds, because I might forget one or I might miss one. That's really important.' **PwD, T2** 'I'd like them to know what medication I'm having, the clinicians or whoever is looking after my kid for diabetes, because there'll be so many clinicians involved in different departments. So, I would be pleased for that.' **Parent** '[One] thing that I would like is where I'm not with a GP or a consultant and my information is being accessed, maybe an alert to let me know somebody is accessing information. So, I know it's for a reason and not just being accessed for no reason.' **PwD, T1**
Studies have identified issues around where patients are unable to continue to self-manage their insulin during their inpatient stay.	Patients may find that during their hospital stay they are unable to self-manage insulin dosage because 'their insulin and devices are taken off them and locked away.		'[Regarding] inpatients not having their own insulin, we all have a key contact, and that would usually be your partner or a best friend or a parent. I'm wondering if we should also collect a key clinician, because if you were to hand over full management of your diabetes while you're an inpatient, who would you hand it to? I deal with lots of different clinicians and lots of different settings. But there might be a particular clinician that I would prefer to manage [my

Finding	Literature review	Interviews	Focus groups
	Patients may find that during their hospital stay their personalised insulin-to-carb ratio as well as the 'carbohydrate content of meals' may not be considered, leading to clinical risk. GIRFT, 2020		insulin as an inpatient]. Somebody that knows me more.' **PwD, T1**
Issues were identified issues around linking results of the NDA with the NPDA and other related audits.	The NDA is the major national clinical audit to include general practice and provides benefits for primary and secondary care including: -informing organisations of the number of people with diabetes they care for who are meeting the NICE clinical guideline standards for diabetes care and treatment. -helping organisations 'to identify priorities for improvement in diabetes care [,] to identify relationships between patient characteristics and care or outcomes [and to drive improvements in care quality due to the desire to demonstrate] a mark of excellence.' BJGP, 2016	Professionals in paediatrics emphasised the importance of being able to extract data from the health record for use in the NPDA. If it is not possible it was felt that buy-in to a new system / new standard would be poor. It was felt that poor response rates in some settings would benefit from improved interoperability but that the interactive nature of transferring and checking the data might make this a challenge.	'There's also a big gap linking the results of the NPDA, which is the audit for paediatrics, with the results of the NDA. There is no continuation there and it's very difficult to link and to follow up those patients that were paediatric and then transition into another service.' **Representative for NPDA** 'There are a couple of areas that I think are really useful to have better information sharing. You've touched on continuous glucose monitoring, but one of the areas that would be really useful going forward is that the ability of that data to also link with the national diabetes audit and the national pregnancy and diabetes audit at the level of NHS digital, because that would be a really useful sort of data source. And moving forward, we're far more likely to be reliant on using continuous glucose monitor data as an indicator of glucose control.' **Professor of diabetes and maternal health**
Two particularly vulnerable groups were identified - young adults with type 1 diabetes and young people with type 2 diabetes and transition the transition from paediatric to adult services was identified as a high-risk period for young	The GIRFT report identifies young adults with type 1 diabetes as a vulnerable group with the highest rate of admissions of people with type 1, due to poor self-management and lack of	Significant issues around transition and patients being lost to follow up were identified. It was raised that some 17-year-old patients with cystic fibrosis will have their exacerbations managed by the adult team while at the same time being under the paediatric team for their diabetes. This was felt to be	'I think you've covered type two diabetes for teens, but not Type one diabetes and actually this is much more common, 90 percent of young people's diabetes type one at this age. And so. I think this is a really, really tricky time for information getting lost in the system and for young people just…going missing. And so, I would think that needs to be a little bit more focussed from a paediatric point of view on

Finding	Literature review	Interviews	Focus groups
adults with diabetes. This has been referred to as a 'cliff edge' after which many young adults experience 'inadequate medical follow-up, poor self-management, and increased risk of adverse outcomes.'	encounters with services after transition to adult services. GIRFT, 2020 BMJ, 2017	an issue if information was not shared between services.	that journey and actually every stage of the child's development. And this isn't about children, but certainly capturing the transitions from the in-school age is almost like the from being a child to being a teen and from being a teen to being a young adult and going into young adult services. They're just really important parts of that total long journey. And if those young people are diagnosed in that age group, in the overlap, it's even more even more tricky.' **Parent**
Coding gestational diabetes and sharing this with primary care			'[Another problem with a] maternal focus, is that of gestational diabetes. It takes up a huge amount of our resources. There's a lot of women affected by it and because it's the type of diabetes that goes away at the end of pregnancy, they're not then classified as having diabetes, but they go back to their primary care and there's an issue around the coding of it in the primary care systems. So therefore, the women don't necessarily get the right follow up. They're not particularly high risk for developing Type 2 diabetes. And yet we know that there are ongoing problems in terms of the mentoring, things like the diabetes prevention programme, etc. So that's an issue around coding of gestational diabetes and the link to primary care.' **Professor of diabetes and maternal health**

Appendix 2 – Use cases identified during the scoping phase



Appendix 3 - Project team

Name	Role on project	Organisation / Role
Prof. Partha Kar	SRO	National Specialty Advisor, Diabetes with NHS England and co-lead of Diabetes GIRFT with NHS Improvement.
Ben McGough	Lead Commissioner	Digital Lead NHS Diabetes Programme, NHS England and NHS Improvement
Mark Brodigan	Commissioner	Strategy Manager, NHS Diabetes Programme Team, NHS England and NHS Improvement
Dr Iain Cranston	Clinical Lead	Consultant Physician, Diabetes and Endocrinology Portsmouth Hospitals NHS Trust
Dr Neel Basudev	Clinical Lead	GP, Lambeth CCG
Ojaih Willow	Citizen Lead	N/A
Sarah Jackson	Project lead	PRSB
James Critchlow	Lead analyst / researcher	PRSB
Fatima Haidaree	Junior analyst	PRSB

Appendix 4 – Standards, datasets, care plans and audits mapped

Date Published	Data set / Standard	Region
March 2004	Scottish Diabetes Core Data Standard	Scotland
March 2004	Scottish Diabetes Foot Care Extension Dataset	Scotland
March 2004	Scottish Diabetes Retinopathy Extension Dataset	Scotland
March 2004	Scottish Diabetes Dietetic Extension Dataset	Scotland
March 2004	Scottish Diabetes Specialist Nursing Extension Dataset	Scotland
May 2019	National Diabetes Audit (Core) v1.3	England & Wales
May 2021	National Paediatric Diabetes Audit v2	England & Wales
Oct 2020	National Paediatric Diabetes Audit Type 2 Diabetes v1	England & Wales
May 2019	National Diabetes Footcare Audit v1.3	England & Wales
May 2019	National Pregnancy in Diabetes Audit v1.3	England & Wales
May 2019	National Diabetes Inpatient Audit v1.3	England & Wales
Feb 2017	Diabetic Eye Screening Dataset v4.5	England & Wales
	Midlands and East of England Diabetes Care Plan	England

	Dudley Diabetes My Personal Diabetes Handheld Record and Care Plan	England
	Coventry and Rugby Diabetes Care Plan	England
2014	Diabetes UK Care Home Resident's Diabetes Passport	UK
Oct 2021	PRSB Core Information Standard v 2.0	UK
Oct 2020	Healthy Child Standard	UK
Nov 2019	Maternity Record standard	UK
Updated 2021	Diabetic eye screening standards valid for data collected from 1 April 2019	England

Appendix 5 – NICE guidelines mapped

- NG3 Diabetes in pregnancy: management from preconception to the postnatal period
- NG17 Type 1 diabetes in adults: diagnosis and management
- NG17 Type 1 diabetes in adults: diagnosis and management draft for consultation, April 2021
- NG18 Diabetes (type 1 and type 2) in children and young people: diagnosis and management
- NG18 Diabetes (type 1 and type 2) in children and young people: diagnosis and management draft for consultation, November 2021
- NG19 Diabetic foot problems: prevention and management
- NG20 Coeliac disease: recognition, assessment and management
- NG28 Type 2 diabetes in adults: management
- NG28 Type 2 diabetes in adults: management draft for consultation, November 2021
- NG44 Community engagement: improving health and wellbeing and reducing health inequalities
- NG49 Non-alcoholic fatty liver disease (NAFLD): assessment and management
- CG189 Obesity: identification, assessment and management

Appendix 6 – Key papers used in the development of the standards

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11. National Institute for Health and Care Excellence. ‘Guideline Type 1 diabetes in adults: diagnosis and management.’ Draft for consultation: 2021 [Accessed July 2021]
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17. Rodbard D. ‘Quality of glycemic control: assessment using relationships between metrics for safety and efficacy.’ Diabetes Technology & Therapeutics: 2021 [Accessed July 2021]
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19. Shah VN and Garg SK. ‘Standardized hybrid closed-loop system reporting.’ Diabetes Technology & Therapeutics: 2021, volume 23(5) [Accessed July 2021]
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Appendix 7 - Interviews during the scoping phase

Title/Role	Organisation	Date
Associate Director of Quality and Development	HQIP	08/06/2021
Medical Director	Royal College of Podiatry	14/06/2021
Head of Policy and Public Affairs	Royal College of Podiatry	14/06/2021
National Care Advisor and Genetic Diabetes Nurse	Diabetes UK Cymru	15/06/2021
Data and Clinical content standards lead	NHSX	15/06/2021
Open tech lead	NHSX	15/06/2021
Consultant Vascular Surgeon	University Hospitals Plymouth NHS Trust	16/06/2021
Senior policy officer - digital health and medical technologies	Diabetes UK	16/06/2021
Principal Diabetes Territory Manager	Medtrum	16/06/2021
Business Manager	Medtrum	16/06/2021
e-health advisor and GP	Scottish government	17/06/2021
Consultant Ophthalmic Surgeon	Royal College of Ophthalmologists	21/06/2021
Head of Healthcare Innovations Unit	Roche	21/06/2021
Clinical Lead for the National CYP Diabetes Network	Royal College of Paediatrics and Child Health; British Society of Paediatric Endocrinology & Diabetes	22/06/2021 and 30/06/2021
Assistant Chief Architect (Digital Architecture)	Digital Health and Care Wales	29/06/2021
Lead applications design architect	NHS Wales Informatics Service	29/06/2021
NPDA Manager	Royal College of Paediatrics and Child Health	30/06/21
Consultant in Paediatric Endocrinology and Diabetes and clinical lead for the National Paediatric Diabetes Audit for England and Wales	Royal College of Paediatrics and Child Health	30/06/21

Appendix 8 - Focus group attendees (professionals)

Title/Role	Organisation
Citizen Lead	N/A
Diabetes Quality Manager	Royal College of Paediatrics and Child Health
Medical Director	Royal College of Podiatry
Professor of Medicine (Diabetes and Antenatal Care)	University of East Anglia
Professor of Medicine (Diabetes and Maternal Health)	University of Leeds
Nurse Consultant	Queen’s Nursing Institute

Professional Practice Policy Officer	British Dietetic Association
Diabetes Dietitian/ technical consultant	Medtronic
Senior policy officer - digital health and medical technologies	Diabetes UK
Principal Diabetes Territory Manager	Medtrum
Business Manager	Medtrum
NHS Diabetes Programme Lead	NHS England and Improvement
Senior Programme Manager GP contracts	NHS England and Improvement
Epidemiologist who researches obesity, diabetes, and other metabolic disorders.	Faculty of Public Health
Associate Director of Quality and Development	HQIP
Associate Director of Business Intelligence	NHS Cheshire CCG

Appendix 9 - Focus group attendees (people with diabetes)

Title/Role	Organisation
Citizen lead	N/A
People with diabetes	10 representatives
Founder	Digibete
Digital Lead NHS Diabetes Programme, NHS England and NHS Improvement	NHS England and Improvement
Strategy Manager	NHS England and Improvement

Appendix 10 - Discussions taking place after the scoping phase

Title/Role	Organisation	Date
Association of British Healthtech Industries diabetes group meeting	N/A	08/07/21
Consultant Physicist and parent of child with Diabetes	N/A	13/07/2021
GP and Clinical Director for Diabetes	North West London Collaboration of CCGs	15/07/2021
Shared Care Record Local Government Network meeting	N/A	21/07/2021
Informatics specialist	NHS Digital	27/07/2021
Deputy Director of Innovation Development	NHSX	02/08/2021
Consultant Physician in the Department of Diabetes and Endocrinology	NHS Grampian	04/08/2021
Implementation Manager - SCI-Diabetes	NHS Tayside	04/08/2021
Epidemiologist who researches obesity, diabetes, and other metabolic disorders.	Faculty of Public Health	04/08/2021
Professor of Medicine (Diabetes and Maternal Health)	University of Leeds	09/08/2021
National Care Advisor and Genetic Diabetes Nurse	Diabetes UK Cymru	10/08/2021
CEO	Self-Management UK	10/08/2021
CEO	UK Homecare Association	26/08/2021

NPDA Manager	Royal College of Paediatrics and Child Health	26/08/2021
Consultant in Paediatric Endocrinology and Diabetes and clinical lead for the National Paediatric Diabetes Audit for England and Wales	Royal College of Paediatrics and Child Health	26/08/2021
Chair	UK Diabetes Psychology Network	01/09/2021
Policy and Care Improvement Manager, Northern Ireland	Diabetes UK Northern Ireland	01/09/2021
Digital Transformation & Informatics Lead Population Health Management, System Transformation	NHS England	06/09/2021
Head of Policy and Public Affairs	Royal College of Podiatry	07/09/2021
Podiatrist	Kings College Hospital NHS Foundation Trust	07/09/2021
Market Access Director, UK & Ireland	Abbott	08/09/2021
Commercial Director	Abbott	08/09/2021
Business Development Manager – Digital and IT Solutions and Privacy Steward	Abbott	08/09/2021
Director, Physician Executive	Cerner	20/09/2021
Senior Physician Executive and GP	Cerner	20/09/2021
Hospital Software Specialist	TPP	21/09/2021
Clinical Director	TPP	21/09/2021
CEO	EMIS	21/09/2021
Senior Clinical Director	EMIS	21/09/2021
Clinical Director	EMIS	21/09/2021
GP	Pathfields Medical Group	28/09/2021
Terminologist	NHS Digital	05/10/2021
Chair and Consultant Physician in Diabetes and Endocrinology	Association of British Clinical Diabetologists	20/10/2021
Head of UK Partnerships and Sales	My Way Digital Health	08/11/2021
Founder	My Way Digital Health	08/11/2021
Founder	My Way Digital Health	08/11/2021
Senior Policy Analyst (Law & Regulation)	Medicines and Healthcare products Regulatory Agency	15/11/2021
Projects and Partnerships Manager	Patient Information Forum	18/11/2021
Clinical Lead for the National CYP Diabetes Network	Royal College of Paediatrics and Child Health; British Society of Paediatric Endocrinology & Diabetes	22/11/2021
Digital Innovation Director	Health Innovation Manchester	24/11/2021
Clinical Director	Health Innovation Manchester	24/11/2021
Senior Lecturer and Consultant in Diabetes	King's College Hospital	30/11/2021
Chair and TVW Regional Homecare Medicines Pharmacist	National Homecare Medicines Committee (NHMC)	15/12/2021
Buyer - IV Therapy – Insulin Pumps & CGM	NHS Supply Chain	05/01/2022
Category Manager, Clinical Digital Solutions,	NHS London Procurement Partnership	06/10/2021 and 30/11/2021
CEO	Orcha	18/11/2021 and 07/12/2021

Strategic Health Facilitator & Clinical Specialist Lead Learning Disabilities	Bradford District & Craven CCG	28/02/22
Strategic Health Facilitator – Learning Disabilities	South West Yorkshire Partnership NHS Foundation Trust	28/02/22

Appendix 11 - Webinar questions and key findings

Webinar	Questions	Key Findings
1. For people with diabetes focused on care planning	Explored the information needed to help the person with diabetes and their healthcare professional complete a diabetes care plan. The findings were used to help define the information requirements for the diabetes record. The following questions were asked: • Does your clinician share your test results or any other information with you? • What other information would be useful for them to share with you? • Is the information easy to understand and interpret? • Do you send any information to your clinician? • Does the care plan help you to manage your diabetes? If so, how? • What help and support have you had to achieve your targets and goals? • Do you revisit or revise your care plan once it has been agreed? If so, how often?	• Clinicians need better access to all relevant information (information is not always shared between primary and secondary care). • People with diabetes and some clinicians need more support with understanding the technology and data. • People wanted help in understanding what might cause a change in blood glucose for them. • People like to view the information in different ways, and it is important that they can choose how they want to do it. • People with diabetes want to agree goals that are achievable for them. However, some feel that the focus on goals and targets is not helpful.
2. For people with diabetes on data they collect and use at home to manage their diabetes	Explored the information people use at home to manage their diabetes and what of this information they want to share with their clinician. The findings were used to help define the information requirements for the Diabetes Self-Management Information Standard. The following questions were asked: • What devices, apps or other methods do you use to help you self-manage your diabetes? • What information do you collect or record and how do you use it to help you manage your diabetes? • How easy do you find it to understand the information you collect or record at home. If it is not easy, what would make it easier?	• Some people with diabetes need better (and continuous) education about technology and understanding the data. Peer support is essential. • People want a more holistic assessment at their annual review. • Must consider digital poverty and exacerbating inequities. • Some people happy to share all information with their clinician, others more wary, relationship between patient and clinician is important.

Webinar	Questions	Key Findings
	• What information does your clinician ask you share with them? How do you share it? • How often do you share information with your clinician? • Is there any other information that you would like to share with your clinician? • How do you want your clinician to use the information you have shared with them? • What information do you see and find most useful for monitoring your glucose at home? • What do information do you want your clinician to know about your glucose management at home? • For those using insulin, what information do you find most useful for managing your insulin at home? • What does your clinician want you to record about your insulin management at home?	
3. For healthcare professionals and medtech suppliers on the information needed in a diabetes record about a person with diabetes	Explored the information that is needed by professionals and people with diabetes for their direct care. The findings were used to help define the information requirements for the Diabetes Record Information Standard. The following questions were asked: • What clinical information domains need to be considered e.g., eye screening, observations, investigation results, foot screening? • What observations (e.g., Body mass index (BMI), Height/ length, Weight, Systolic blood pressure, Diastolic blood pressure), investigations (e.g., HbA1c, Cholesterol, HDL / LDL) or outcomes (e.g., CVA, amputations, CKD, retinopathy) should be emphasised? • Which, if any, other specialty records contain information that should be in the diabetes information record e.g., maternity, child, retinal screening records • Regarding pregnancy and birth	• The record must include information to support personalised care, patient preferences, goals and actions. • Interpretation of physiological and treatment data in the context of the specific person is key. The healthcare professional and person with diabetes need all relevant data easily available so that time for discussion and action planning is maximised. • The standard needs to accommodate static (such as demographic e.g., Date of Birth), transient (such as learning difficulties after a 'hypo' in children) and changing information (such as weight, height, BMI, blood glucose). • There are many SNOMED CT codes to describe diabetes and concern was raised that codes could be used incorrectly leading to issues when aggregating information for audits and population health management.

Webinar	Questions	Key Findings
	a) What information about someone's planned or current pregnancy is required? e.g., contraception use, home pregnancy test result/ current pregnancy? or plans/ active trying for a baby, or breastfeeding*). b) What information from a standard maternity record would you like in a diabetes record? • What information from the retinal screening programme would you like to see shared in a standardised diabetes information record? • Is there any information that you would want to see that is not currently recorded as part of the retinal screening programme? • Are the images important to share as part of the screening outcome? If so, what are the barriers to doing this? • What information should be recorded about diabetic foot examinations? • Regarding structured education, what information do clinicians: a) record when signposting or referring b) receive about attendance (full or partial) and outcome c) want or need to see (e.g., continuing education) • What qualitative "assessment" domains need to be considered e.g., emotional wellbeing, eating behaviours, Hypoglycaemia awareness fear • What personalised and agreed targets are relevant to diabetes care and how do you record these? Think about: a) Numeric targets (absolute vs change & time scales). b) Other targets.	• Better information about the outcome of structured education from providers (skills assessment), including support during pregnancy and refresher training. • Eye screening information must include people under ophthalmology service (or they may be missed). • There has been lots of work done on creating a diabetes record in both Wales and Scotland and we should learn from this and reuse where possible.

Webinar	Questions	Key Findings
	• Should a reason/ indication for a target be captured? E.g., losing weight for surgery, acute illness, pregnancy etc. • What information about a person's admission and inpatient stay would you like to access as part of the diabetes record e.g., do you need to know more than discharge and treatment? • Risk Assessment requires data from multiple domains to be analysed. a) Is this something which should form a key part of a diabetes record? b) If so, what elements need consideration? c) If not, is there another approach which could work better?	
4. For healthcare professionals and medtech suppliers on what data people with diabetes collect and use at home would is helpful for healthcare professionals to have access to	Explored the information that a person could collect to self-manage their diabetes at home and what of that healthcare professionals could use to help a person with their self-management. The findings were used to help define the information requirements for the Diabetes Self-Management Information Standard. The following questions were asked: • Not all self-reported data is equal. Do we need to report the provenance of self-reported data and if so, how? • What data collected at home by a person with diabetes would you like to see? • Elements of Glucose experience of interest in optimising outcomes: a) Average Glucose (marker of overall glycaemic exposure) b) Temporal changes (improvement vs deterioration) c) Glycaemic Extremes – acute hyper and hypo-glycaemic risks	• Things that people with diabetes think are important to them and that they want to discuss can be enormously valuable for appointments. • There should be a structured approach to goal and action planning to support self-management. • Composite metrics are not required. • Data should only be imported from approved apps. • Provenance of any information entered into the record is key – whether than be from a medical device, entered by the person with diabetes e.g., blood pressure measurements or entered by a healthcare professional during an appointment. Knowing where the information came from supports a clinical judgment to be made on the validity of the information. • Be aware of the digital divide and digital poverty and not exacerbate inequalities. • Clarity on how to apply Information Governance rules for information sharing to sharing data from devices (predominantly used for self-management) with healthcare professionals is required.

Webinar	Questions	Key Findings
	d) Glucose Variability – within day / between days • Are there any other aspects of interest that should be considered? • Do you think the exemplar metrics capture the information you would wish to see from self-reported glucose data? a) % Time in Range, % Time Above Range (level 1 and 2), % Time Below Range (level 1 and 2)) b) measurements per day / scans per day, % sensor data available, % time in closed loop c) Average Glucose, Glucose Management Indicator, Coefficient of Variation, significant Hypo episodes, severe Hypo Episodes • Do you use research validated composite metrics in your practice? – e.g., Q-Score, HAS Score Index of glycaemic control • What aspects of insulin management should be able to be recorded as self-reported data? • Does the exemplar cover the aspects of interest? Is there anything else that is needed? a) Total Daily Dose b) Total Basal Dose (1 - standard), Total Basal Dose (2 – other e.g., alternate on CSII) c) CSII *Optional Hourly basal rates* d) MDI Basal (am), MDI Basal (pm) e) ICR (breakfast, lunch, evening meal, other)	• There is the potential for significant benefits to be derived from sharing data from devices with healthcare professional – for example for predicting future issues e.g., diabetes burnout. However how far do people with diabetes want the profession to go with this – could this be seen as intrusive. • There is a potential for collecting information on PROMS, PREMS, PAM, confidence levels and sick days but it is important to consider how much information we are asking people to share. In asking people with diabetes to collect and share large amounts of information is there a risk of burnout. Consider passive data collection vs active data collection.

Webinar	Questions	Key Findings
	f) ISF (breakfast, lunch, evening meal, other) g) Correction Target (day / night) mmol/L • What device types so we need to consider e.g., CGM/Flash, insulin pumps, connected pens, ketone monitors, accelerometers, hybrid closed loop, carb counting assessment tools, bolus advisors? • What information should be recorded for these devices? Who needs to see this? • Is there any information about diabetes apps that should be recorded? • What objective or subjective measures do you use for measuring: a) Physical activity b) Sleep c) Dietary intake d) Quality of life questionnaires or PROMs – is there any reason that these couldn't be provided as self-reported data as opposed to clinician-reported?) • What other information could people share that would be useful to you about: a) Pregnancy and birth b) Footcare c) Driving d) Ketones e) Other e.g., weight/ body composition, blood pressure, alcohol intake.	

Appendix 12 - Webinar attendees, webinar 1

Title/Role	Organisation
People with diabetes and parents of children with diabetes	15 representatives
Peer mentor	Brigstowe scheme
GP and Clinical Lead	Lambeth CCG
GP	Elm Tree Surgery
Founder	Digibete
Strategy Manager	NHS England and Improvement
Chief Patient Officer and patient member of various groups	MD Healthcare, Diabetes UK, Diabetes Clinical Network, Novo Nordisk, IMI Trials@Home
Advisory board representative	National Voices
Citizen Lead	N/A

Appendix 13 - Webinar attendees, webinar 2

Title/Role	Organisation
Practice Manager	Forty Willow Surgery
People with diabetes and parents of children with diabetes	19 representatives
Peer mentor	Brigstowe scheme
Consultant Physician and Clinical Lead	Portsmouth Hospitals NHS Trust
GP	Crompton Medical Centre
Founder	Digibete
Strategy Manager	NHS England and Improvement
Citizen Lead	N/A

Appendix 14 - Webinar attendees, webinar 3

Title/Role	Organisation
Sales Director Northern Europe	Glooko / Diasend
Data Strategy Manager	Health Data Research UK (HDR UK)
Diabetes Specialist Nurse	Daisy Hill Hospital
Nurse Manager	Coombe House
Open tech lead	NHSX
Founding CEO and Head of AI	Diabetes Digital Media
Chair	HL7 UK
Product Manager	First Databank (FDB) UK
In house Dietitian	Nightingale Hammerson
Senior Clinical Lead	NHS Digital
Business Development Manager – Digital and IT Solutions and Privacy Steward	Abbott Diabetes Care (UK&I)
Nurse Consultant	Queen's Nursing Institute
Consultant Diabetologist	Northern Health and Social Care Trust
Consultant in diabetes/general medicine	Oxford University Hospitals NHS Trust

Consultant Diabetologist, Clinical Lead NDA/NDIS	Salford Royal Foundation Trust
Consultant Diabetologist	University Hospitals of Derby and Burton NHS Foundation Trust
Senior Physician Executive and GP	Cerner
Clinical Lead for the National CYP Diabetes Network	Royal College of Paediatrics and Child Health; British Society of Paediatric Endocrinology & Diabetes
Consultant Diabetologist	Portsmouth Hospitals NHS Trust
Director	FreshEHR
Consultant Diabetologist	Taunton and Somerset NHS Foundation Trust
Senior Clinical Lecturer in Diabetes and Honorary Consultant	Sheffield Teaching Hospitals NHS Foundation Trust
Consultant Paediatrician	Hillingdon Hospital
Consultant Anaesthetist	Centre for Perioperative Care
Honorary Consultant Physician	Cambridge University Hospitals NHS Trust
Clinical lead, Endocrinologist and Diabetes Specialist Physician	Year of Care Partnership
GP, Clinical Director of Digital Primary Care, England	NHSX
Medical Director	Royal College of Podiatry
Physician informatician specialising in diabetes and endocrinology	Sandwell and West Birmingham NHS Trust
Chair	UK Diabetes Psychology Network
Senior Lecturer and Consultant in Diabetes	University of Leicester
Diabetes Specialist Nurse	Whiteabbey Hospital
Quality Manager	Royal College of Emergency Medicine
Informatics specialist	NHS Digital
Digital Midwife	Chelsea and Westminster Hospitals Trust
Senior product specialist	TPP (The Phoenix Partnership)
Senior Information Standards & Data Quality Officer	HSCNI
Health Informatics Consultant	Freelance
Assistant Nursing Information Officer	Royal Brompton & Harefield NHS Foundation Trust
NPDA Manager	Royal College of Paediatrics and Child Health
Senior Clinical Director (Nurse)	EMIS
Senior product manager (Diabetes)	Medtronic
Core Project Manager	National Diabetes Audit (NDA) Programme
Commercial Director	Abbott
Principal Diabetes Territory Manager	Medtrum
Head of Healthcare Innovations Unit	Roche
Dietetic Services Manage	Digital Health and Care Northern Ireland
Data Analyst	Royal College of Paediatrics and Child Health
Community Staff Nurse	University Hospitals of Morecambe Bay NHS Foundation Trust

Assistant Chief Architect (Digital Architecture)	Digital Health and Care Wales
Senior Manager - UK Market Affairs	Association of British Healthtech industries
National Paediatric Diabetes Audit Co-ordinator	Royal College of Paediatrics and Child Health
National Market Access Partner	Roche
Digital Health Lead	Novo Nordisk
Diabetes Specialist Podiatrist	Manchester University NHS Foundation Trust
Head of Policy and Public Affairs	Royal College of Podiatry
Market Access & Commercial Manager	Ypsomed Delivery Systems (YDS)
Women's Health immunisation and Obstetric Nurse	West Middlesex University Hospital
Senior integration engineer	InHealth
Strategy Manager	NHS England and Improvement
Clinical Coding & Info Standards Senior Manager	Digital Health and Care Northern Ireland
Partnerships Manager EMEA	Glooko / Diasend
Associate Director of Education (Clinical Coding)	IHRIM
Clinical lead/ clinical trainer	Green Care Accord Housing Association
Consultant, Population health	Cerner
Chief Operating Officer	Association of British Healthtech industries
Lead Professional Officer	Community Practitioners and Health Visitors Association
Senior Content Solution Designer	Cerner
CEO	Kinseed
Consultant physician at the Diabetes and Endocrine Centre and the Diabetes Research Unit	Ipswich Hospital
Consultant Nephrologist and Co-chair of Association of British Clinical Diabetologists (ABCD) UKKA Group, Co-chair UK Kidney Research Consortium CKD and Diabetic Kidney Disease Clinical Study Group and UKKA representative in CaReMe UK	UK Kidney Association
Standards development manager	Digital Health and Care Wales
Home Manager	Coverage Care Services
National Market Access Partner	Roche
Diabetes Nurse Consultant	Central London Community Healthcare NHS Trust
Clinical Content Solution Designer	Cerner
Senior GP Practice Clinical Pharmacist	NHS Surrey Heartlands CCG
Clinical Pharmacist	First Databank (FDB) UK
Nurse Consultant	Belfast trust
Pricing development lead	NHS England and Improvement
Clinical Strategist	First Databank (FDB) UK
Pharmacist and Medical Advisor	Novo Nordisk
Hub Brand Leader	Lilly

Appendix 15 - Webinar attendees, webinar 4

Title/Role	Organisation
Sales Director Northern Europe	Glooko / Diasend
Data Strategy Manager	Health Data Research UK (HDR UK)
Paediatric Diabetes Specialist Nurse	South Tyrone Hospital NI
Product Manager	First Databank (FDB) UK
Business Development Manager – Digital and IT Solutions and Privacy Steward	Abbott Diabetes Care (UK&I)
Nurse Consultant	Queen's Nursing Institute
Consultant in diabetes/general medicine	Oxford University Hospitals NHS Trust
Consultant Diabetologist, Clinical Lead NDA/NDIS	Salford Royal Foundation Trust
Consultant Diabetologist	University Hospitals of Derby and Burton NHS Foundation Trust
Senior Physician Executive and GP	Cerner
GP and Chair	Camden LMC
Consultant Diabetologist	Portsmouth Hospitals NHS Trust
Director	FreshEHR
Senior Clinical Lecturer in Diabetes and Honorary Consultant	Sheffield Teaching Hospitals NHS Foundation Trust
Clinical lead, Endocrinologist and Diabetes Specialist Physician	Year of Care Partnership
Physician informatician specialising in diabetes and endocrinology	Sandwell and West Birmingham NHS Trust
Consultant Physician in the Department of Diabetes and Endocrinology	NHS Grampian
GP and Clinical Director for Diabetes	North West London Collaboration of CCGs
Senior Lecturer and Consultant in Diabetes	University of Leicester
Quality Manager	Royal College of Emergency Medicine
Digital Midwife	Chelsea and Westminster Hospitals Trust
Senior Information Standards & Data Quality Officer	HSCNI
Single Record Design & Test Lead	Digital Health and Care Wales
Assistant Nursing Information Officer	Royal Brompton & Harefield NHS Foundation Trust
Senior product manager (Diabetes)	Medtronic
Commercial Director	Abbott
Principal Diabetes Territory Manager	Medtrum
Head of Healthcare Innovations Unit	Roche
Diabetes Foot Practitioner and Podiatry Project Officer	Royal College of Podiatry
Assistant Chief Architect (Digital Architecture)	Digital Health and Care Wales
Senior Manager - UK Market Affairs	Association of British Healthtech industries
Diabetes Specialist Podiatrist	Manchester University NHS Foundation Trust
Market Access & Commercial Manager	Ypsomed Delivery Systems (YDS)
Senior integration engineer	InHealth

Strategy Manager	NHS England and Improvement
Clinical Coding & Info Standards Senior Manager	Digital Health and Care Northern Ireland
Partnerships Manager EMEA	Glooko / Diasend
Healthcare Development Manager	Lilly
Consultant, Population health	Cerner
Connectivity and Insights Program Manager	Medtronic
Senior Content Solution Designer	Cerner
Information Standards Management Lead	Digital Health and Care Wales
Consultant physician at the Diabetes and Endocrine Centre and the Diabetes Research Unit	Ipswich Hospital
Consultant Nephrologist and Co-chair of Association of British Clinical Diabetologists (ABCD) UKKA Group, Co-chair UK Kidney Research Consortium CKD and Diabetic Kidney Disease Clinical Study Group and UKKA representative in CaReMe UK	UK Kidney Association
Standards development manager	Digital Health and Care Wales
Clinical Content Solution Designer	Cerner
Clinical Pharmacist	First Databank (FDB) UK
Associate Director of Quality and Development	HQIP
Diabetes Nurse Consultant	Central London Community Healthcare NHS Trust
Consultant in Diabetes & Endocrinology	Royal College of Physicians
Pricing development lead	NHS England and Improvement
Clinical Strategist	First Databank (FDB) UK
Welsh Reference Data and Terminology Service Management Lead	Digital Health and Care Wales
Pharmacist and Medical Advisor	Novo Nordisk

Appendix 16 – Diabetes survey report (separate document)

Appendix 17 - Discussions with systems and medtech suppliers

Title/Role	Organisation	Date
Business Development Manager – Digital and IT Solutions and Privacy Steward	Abbott Diabetes Care (UK&I)	11/01/22
Market Access Director, UK & Ireland	Abbott Diabetes Care (UK&I)	11/01/22
Clinician	Abbott Diabetes Care (UK&I)	11/01/22
Commercial Director	Abbott Diabetes Care (UK&I)	11/01/22
Head of Access & Innovation Dept	Roche	12/01/22
National Market Access Partner	Roche	27/01/22
Digital Solutions Manager	Roche	27/01/22
Sales Director Northern Europe	Glooko / Diasend	13/01/22
Partnerships Manager EMEA	Glooko / Diasend	13/01/22
Pharmacist and Medical Advisor	Novo Nordisk	13/01/22

Digital Health Lead	Novo Nordisk	13/01/22
Principal Diabetes Territory Manager	Medtrum	17/01/22
Head of UK Partnerships and Sales	My Way Digital Health	19/01/22
Founder	My Way Digital Health	19/01/22
Founder	My Way Digital Health	19/01/22 and 26/01/22
Hub Brand Leader	Lilly	19/01/22
Founder	Digibete	18/01/22
GlucoMen Product Manager	Menarini	02/02/22
UK Marketing Manager	Menarini	02/02/22
Connectivity and Insights Program Manager	Medtronic	08/02/22
IT Director	Medtronic	08/02/22
Senior Medical Affairs Manager	Medtronic	08/02/22
Head of Market access	Insulet Ltd	02/03/22
Marketing Manager UK and Netherlands	Insulet Ltd	02/03/22
UK National Sales Manager	ViCentra	10/02/22
Clinical Strategist	First Databank (FDB) UK	08/03/22
Project Manager	First Databank (FDB) UK	08/03/22
Product Manager	First Databank (FDB) UK	08/03/22

Appendix 18 - Mapping of standards, datasets, audits and NICE guidelines and justification for inclusion in the standard

Section	Source	Requirements and justification for inclusion
Person demographics	General	Name, Date of Birth (DoB) and first line of address or NHS or Other identifier are necessary to collect for linkage with other health and social care records including with databases such as Hospital Episode Statistics (HES) for England and the Patient Episode Database for Wales (PEDW). DoB is required to calculate an accurate decimal age for each patient. This allows interpretation of data collected on height, weight, calculated BMI and BP in diabetes since these are age and gender specific. Gender is required for interpretation of height, weight, calculated BMI and BP. Ethnicity is required as it contributes to assessment of risk in diabetes development and/or diagnosis. Address and contact details are required in order to contact the person with diabetes. Death date was added as this is collected in audits to calculate the mortality rates in children and young people and adults with diabetes.
	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For demographics and contacts 96% (n=107) of health and care professional and 100% (n=7) of suppliers answered 'Yes'. In response to the question 'Please select the information that should be captured in a diabetes care plan. Any comments?' For identifying information (e.g., name, date of birth and address) 72% of people with type 2 diabetes, 81% of people with type 1 diabetes and 100% of parents of children with diabetes answered 'Yes'.
	NICE guidelines	• NG17 - 1.7.14 Consider adding metformin to insulin therapy if an adult with type 1 diabetes and a BMI of 25 kg/m2 (23 kg/m2 for people from South Asian and related minority ethnic groups) or above wants to improve their blood glucose control while minimising their effective insulin dose. • NG44 - 1.5.1 Work with local communities and community and voluntary organisations to: Identify barriers to involvement, particularly for vulnerable groups and recently established communities. 1.5.2 Provide the support people need to get involved. This includes using places familiar to community participants and creating an informal atmosphere.
GP practice	General	GP practice identifier is required in audits to establish a picture of variation in diabetes rates and type variations regionally across England and Wales.

Section	Source	Requirements and justification for inclusion
	Surveys	In response to the question 'Please select the information that should be captured in a diabetes care plan. Any comments?' For GP details 72% of people with type 2 diabetes, 81% of people with type 1 diabetes and 100% of parents of children with diabetes answered 'Yes'.
About me	Webinars	"The thing that strikes me is there's no patient preference stuff there at all…. It's part of the person-centred policies that NHS England are trying to pursue." **Endocrinologist** "Emphasis on the patient's ideas, concerns and expectations is essential." **Community Staff Nurse** "The 'what matters to me' domain up front is really important." **Endocrinologist and Diabetes Specialist Physician**
	Surveys	In response to the question 'Please select the information that should be captured in a diabetes care plan. Any comments?' For important information about you 61% of people with type 2 diabetes, 82% of people with type 1 diabetes and 100% of parents of children with diabetes answered 'Yes'. For your needs, concerns or problems relevant to your ability to achieve your health and wellbeing goals 64% of people with type 2 diabetes, 73% of people with type 1 diabetes and 88% of parents of children with diabetes answered 'Yes'.
Individual requirements	General	This includes reasonable adjustments and a record of impairments and is needed to support the accessible information standard.
	Existing standards	Included in the Scottish Diabetes Standards - Inability to self-care - Unable to self-care for foot due to significant visual impairment or physical disability (e.g., stroke, gross obesity), preferred language (written and spoken), interpreter required.
	NICE guidelines	• NG44 - 1.5.1 Work with local communities and community and voluntary organisations to: Decide which types of communication would get people interested and involved. Include ways of communicating that reflect the needs of vulnerable or isolated groups, recently established communities, those with low literacy or learning difficulties, and people who do not use digital or social media. 1.5.2 Provide the support people need to get involved. This includes offering to phone, write, email, use social media or call round to see people, providing information in plain English and locally spoken languages for non-English speakers. This could include encouraging members of the community who speak a community language to get involved in translating it. • NG28 - 1.1.2 Take into account any disabilities, including visual impairment, when planning and delivering care for adults with type 2 diabetes • NG17 - 1.2.1 Take account of any disabilities, including visual impairment, when planning and delivering care for adults with type 1 diabetes. • NG17 - 1.2.4 Regard each adult with type 1 diabetes as an individual, rather than as a member of any cultural, economic or health-affected group.

Section	Source	Requirements and justification for inclusion
Alerts		This does not include alerts resulting from clinical decision support systems such as when using ePrescribing systems (e.g., alerts warning of interactions between medications or incorrect dosing) or alarms based on data from medical devices, for example indicating low blood sugar. These are alerts that are shared across the system such as dangerous dog at house etc.
Safeguarding	Webinars	"Safeguarding issues that are being undertaken to support CYP [children and young people] need to be flagged here." **Medtech supplier**
	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For safeguarding and risks 93% (104) of health and care professionals and 86% (6) of suppliers answered 'Yes'.
Professional contacts	General	From the healthy child standard: should include the LAC Local Authority Emergency Duty Team telephone number; The CP-IS Local Authority Emergency Duty Team telephone number if needed for safeguarding reasons.
	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For demographics and contacts 96% (n=107) of health and care professional and 100% (n=7) of suppliers answered 'Yes'.
	Existing standards	Scottish Diabetes Dietetic Extension Dataset, the insulin passport and Diabetic Eye Screening Dataset v4.5 all include information about professional contacts. The insulin passport includes information about who is in charge of care in a care home. The National Diabetes Foot Audit requires service that is treating the patient.
	Audits	National Paediatrics Diabetes Audit requires: • Date of leaving service (which could be derived from the end date of the professional/team relationship with the person) • Reason for leaving service (e.g., transitioned to adult services, moved out of area, stopped attending). This is supported by the addition of 'Service' and 'Reason for leaving service'
Personal contacts	General	From discussions: it is important to know if someone has a carer. For a child is it important to know who the parents are, who has parental responsibility. If someone is unable to administer their own insulin it is important to know who normally administers the person's insulin if they are unable to do it themself.
	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For demographics and contacts 96% (n=107) of health and care professional and 100% (n=7) of suppliers answered 'Yes'.

Section	Source	Requirements and justification for inclusion
		In responses to the question 'To develop and agree a care plan what information from the healthcare record would healthcare professionals need to have available?' For demographics and contacts 65% of people with type 2 diabetes, 58% of people with type 1 diabetes and 100% of parents of children with diabetes responded 'Nearly always'.
Participation in research	General	It was identified during discussions that knowledge about a research trial a person is involved with is important.
Referral details	Surveys	In response to the question 'To develop and agree a care plan what information from the healthcare record would healthcare professionals need to have available?' For referrals 67% of people with type 2, 66% of people with type 1 and 88% of parents of children with diabetes answered 'Nearly always'. In response to the question 'To develop and agree a care plan what information from the healthcare record would healthcare professionals need to have available?' For referrals and future appointments 92% (n=103) of health and care professionals and 100% (n=7) suppliers answered 'Yes'.
	Audits	The National Diabetes Audit requires: • Date Diabetes Structured Education programme offered • Date of offer of referral to smoking cessation service (if patient is a current smoker)
	NICE guidelines	• NG17 - 1.15.39 The risk of morbidity from the complications of poor metabolic control suggests that consideration should be given to early, and occasionally urgent, referral of adults with type 1 diabetes to local eating disorder services. • NG19 - 1.4.1 If a person has a limb-threatening or life-threatening diabetic foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service. Examples of limb-threatening and life-threatening diabetic foot problems include the following: Ulceration with fever or any signs of sepsis. Ulceration with limb ischaemia. Clinical concern that there is a deep-seated soft tissue or bone infection (with or without ulceration). Gangrene (with or without ulceration). • NG18: 1.2.14 Offer smoking cessation programmes to children and young people with type 1 diabetes who smoke. See also the NICE guidelines on brief interventions and referral for smoking cessation, smoking cessation services, harm reduction approaches to smoking, and smoking cessation in secondary care. • NG18: 1.3.10 Offer smoking cessation programmes to children and young people with type 2 diabetes who smoke. • NG28 - 1.6.32 When starting insulin therapy in adults with type 2 diabetes, use a structured programme employing active insulin dose titration that encompasses: injection technique, including support from an appropriately trained and experienced healthcare professional.

Section	Source	Requirements and justification for inclusion
		• NG19 - 1.3.12 People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service. • NG28 - 1.7.20 Refer to an ophthalmologist in accordance with the National Screening Committee criteria and timelines for any large sudden unexplained drop in visual acuity. • NG18 - 1.3.15 Offer children and young people with type 2 diabetes dietetic support to help optimise body weight and blood glucose control. • NG3 - 1.2.16 Refer all women with gestational diabetes to a dietitian. • NG3 - 1.2.9 When women are diagnosed with gestational diabetes: offer a review with the joint diabetes and antenatal clinic within 1 week.
Future Appointments	Webinars	People want to be able to set the agenda, topics for their appointment. Agenda is not included in the standard as a separate data item however, local implementers should consider how requirement can be delivered. Professionals want to know what matters to a person with diabetes and what they want help within the time that they spend with them. "We have these very fine slivers of time that we have an opportunity to discover in what way we could be helpful to people. ... probably just need to have something a bit more open structured in terms of asking people what they want to work on." **Endocrinologist** "Would be great if we could send a list of discussion topics in advance of an appointment" **PwD, T1** "Personal physiological measurements can be valuable. Things that people with diabetes think are important to them and that they want to discuss can be enormously valuable - often missed in the heat of formal consultation." **Consultant Diabetologist, Clinical Lead NDA/NDIS**
	Surveys	In response to the question 'To develop and agree a care plan what information from the healthcare record would healthcare professionals need to have available?' For referrals and future appointments 92% (n=103) of health and care professionals and 100% (n=7) suppliers answered 'Yes'.
Contacts with professionals	Audits	National Diabetes Paediatric Audit requires • Approximate date of first dietetic review attended • Date of additional appointment with dietitian • Was the person offered an additional appointment with a paediatric dietitian? National Pregnancy in Diabetes Audit requires • A record of the date of the first contact with specialist antenatal diabetes team after last menstrual period (LMP) (i.e., excluding any pre-conception clinic contact).

Section	Source	Requirements and justification for inclusion
		National Paediatric Diabetes Audit (T2) requires • Date of last attended appointment with a dietitian • Date of last attended appointment with a psychologist • Did the person attend an appointment with a dietitian? • Did the person attend an appointment with a psychologist?
	NICE guidelines	• NG19 - The multidisciplinary foot care service should be led by a named healthcare professional and consist of specialists with skills in the following areas: Diabetology, Podiatry, Diabetes specialist nursing, Vascular surgery, Microbiology, Orthopaedic surgery, Biomechanics and orthoses, Interventional radiology, Casting, Wound care. • NG17 - 1.15.32 Offer men with type 1 diabetes the opportunity to discuss erectile dysfunction as part of their regular review.
Admission details	Webinars	It is important to know why a child or adult is admitted to hospital for reasons of having diabetes but not related to DKA or hypoglycaemia. "Any diabetes complications, mental health related admissions, episodes of hypoglycaemia during - any (less than 4 mmol/l) and severe (less than 2.2 mmol/l) - not necessarily recorded on discharge assessment. DKA/HHS on admission." **Endocrinologist and Diabetes Specialist Physician** "The reasons for DKA, if they are listed, would be important to know. So, if this was related to substance misuse, whether this was a suicide attempt, whether this was just purely being unlucky because you've got a stomach bug, but it's very useful to know and also the running total of the case as well. So, somebody is already or at risk of becoming a repeat DKA person with more than one or two admissions in the year is important." **Psychologist** "Any diabetes / complications related / mental health related admission." **Endocrinologist and Diabetes Specialist Physician**
	Surveys	In response to the question 'What information healthcare professionals need to identify people with diabetes at risk of deterioration or harm?' • Some of the most highly cited themes were hospital admissions for diabetic complications (e.g., hypoglycaemia, diabetic ketoacidosis (DKA), or other) (n=51), unscheduled care/ emergency attendances (n=8), and comorbidities, frailties or concerns over a person with diabetes' capacity to make a decision (n=10). • "[Number] of admissions is always helpful. general info re engagement and key people who can be helpful e.g., homeless worker/ interpreter/ trusted family member or carer always helpful." **Healthcare professional** • "My trust is relatively close to a number of other hospitals and knowing if patients have had admissions elsewhere for DKA/HHS/Hypos/ulcers is very useful." **Endocrinologist** In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?'

Section	Source	Requirements and justification for inclusion
		For admission details e.g., for emergencies related to their diabetes such as hypoglycaemia or diabetic ketoacidosis or other non-diabetic conditions. 98% (n=101) of health and care professionals and 86% (n=6) suppliers answered Yes
	Existing standards	Admission details are included in the Scottish Diabetes Dietetic Extension Dataset and the Scottish Diabetes Specialist Nursing Extension Dataset.
Discharge details	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For discharge details 90% (n=110) of health and care professionals and 100% (n=7) suppliers answered Yes
	Existing standards	The date of discharge is included in the Scottish Diabetes Core Standard.
	Audits	Date of discharge is included in the National Diabetes Inpatient Audit
	NICE guidelines	NG19 - 1.3.12 People in hospital who are at moderate or high risk of developing a diabetic foot problem should be given a pressure redistribution device to offload heel pressure. On discharge they should be referred or notified to the foot protection service
Emergency care attendance	Surveys	In response to the question 'What information healthcare professionals need to identify people with diabetes at risk of deterioration or harm?' • Some of the most highly cited themes were hospital admissions for diabetic complications (e.g., hypoglycaemia, diabetic ketoacidosis (DKA), or other) (n=51), unscheduled care/ emergency attendances (n=8), and comorbidities, frailties or concerns over a person with diabetes' capacity to make a decision (n=10).
	NICE guidelines	• NG17 – 1.11.2 In adults with type 1 diabetes presenting to emergency services, consider capillary blood ketone testing if: DKA is suspected or the person has uncontrolled diabetes with a period of illness, and urine ketone testing is positive.
Vaccinations	Existing standards	Influenza vaccine information (such as date) included in the Scottish diabetes standards Insulin passport includes information about Pneumovax and Influenza vaccinations
	Audits	National Diabetes Paediatric Audit requires information on vaccinations.
Problem list	General	The mapping work and consultation confirmed the importance of diagnoses, complications and comorbidities**.**
	Webinars	Episodes of DKA or severe hypos should be included with the reasons for DKA. "The reasons for DKA, if they are listed, would be important to know. So, if this was related to substance misuse, whether this was a suicide attempt, whether this was just purely being unlucky because you've got a stomach bug, but

Section	Source	Requirements and justification for inclusion
		it's very useful to know and also the sort of running total of the case as well. So, somebody is already or at risk of becoming a repeat DKA person with more than one or two admissions in the year is important." **Psychologist** "Visual impairment for non-diabetes related reasons**." Senior Lecturer and Consultant**
	Surveys	In response to the question 'What information healthcare professionals need to identify people with diabetes at risk of deterioration or harm?' • Some of the most highly cited themes were hospital admissions for diabetic complications (e.g., hypoglycaemia, diabetic ketoacidosis (DKA), or other) (n=51), unscheduled care/ emergency attendances (n=8), and comorbidities, frailties or concerns over a person with diabetes' capacity to make a decision (n=10). In response to the question 'Is there other information you would like to share with healthcare professionals? E.g., topics to discuss at the next review meeting or concerning measurements taken at home.' • The most highly cited themes were measurements taken at home (n=6) and information about comorbidities (n=5). "[I want to share] how other health conditions are affecting my diabetes." **PwD, T1** "Menstrual cycle especially linked to menopause, or for younger people if cycle is impacting blood sugar." **PwD, T1** In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For problem list 94% (n=105) of health and care professionals and 86% (n=6) of suppliers answered 'Yes'.
	Existing standards	All datasets require information about the type of diabetes: Diabetes Mellitus Type (T1/T2/Gestational/Maturity Onset Diabetes of Youth/Other Specific Diabetes Mellitus and include where the person's diabetes mellitus has not yet been classified. Information about co-morbidities to see if pre-existing to or post diabetes diagnosis (including heart disease, thyroid disease, coeliac disease, sleep apneoa) All datasets require the date of diagnosis. This is required to know the duration of disease and when the person became aware they have diabetes. The Scottish Core Diabetes Standard includes the year of onset of permanent blindness. Scottish diabetes foot care extension includes anatomical location of ulcer. Scottish standards include Lipohypertrophy.
	Audits	National Diabetes Audit requires • the latest learning disability diagnosis • latest mental health diagnosis code • earliest ischaemic heart disease diagnosis

Section	Source	Requirements and justification for inclusion
		• earliest and latest diagnosis of pre-diabetes, non-diabetic hyperglycaemia, impaired glucose tolerance; bacterial infection National Paediatrics Diabetes Audit requires clinical markers for concluding a Type 2 diabetes diagnosis - obesity, acanthosis nigricans, fatty liver. National Pregnancy in Diabetes Audit requires person's type of diabetes as diagnosed prior to pregnancy and whether the person has a history of ischaemic heart disease (IHD) prior to the first day of the Last Menstrual Period.
	NICE guidelines	• CG189 - 1.3.11 In tier 3 services, assess associated comorbidities and possible causes for children and young people who are overweight or who have obesity. • NG18 - 1.1.5 Think about the possibility of type 2 diabetes in children and young people with suspected diabetes who have no insulin requirement or have an insulin requirement of less than 0.5 units/kg body weight/day after the partial remission phase. • NG3 - 1.2.8 Diagnose gestational diabetes if the woman has either: a fasting plasma glucose level of 5.6 mmol/litre or above or a 2-hour plasma glucose level of 7.8 mmol/litre or above.
Procedures & therapies	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For procedures 91% (n=102) of health and care professionals and 100% (n=7) of suppliers answered 'Yes'. In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For problem list 94% (n=105) of health and care professionals and 86% (n=6) of suppliers answered 'Yes'.
	Existing standards	Scottish core standard and datasets include bariatric surgery, amputation of lower limb, eye procedures.
	NICE guidelines	• 1.10.13 Bariatric surgery may be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity. • NG17 - 1.9.2 Consider islet or pancreas transplantation for adults with type 1 diabetes with suboptimal diabetes control who have had a renal transplant and are currently on immunosuppressive therapy. • NG3 - 1.4.8 For women with diabetes and comorbidities such as obesity or autonomic neuropathy, offer an anaesthetic assessment in the third trimester of pregnancy. 1.4.9 If the woman has general anaesthesia for the birth, monitor blood glucose every 30 minutes from induction of general anaesthesia until after the baby is born and the woman is fully conscious. • NG19 - 1.5.7 When treating diabetic foot ulcers, debridement in hospital should only be done by healthcare professionals from the multidisciplinary foot care service, using the technique that best matches their specialist expertise and clinical experience, the site of the diabetic foot ulcer and the person's preference.

Section	Source	Requirements and justification for inclusion
		• NG19 - 1.5.8 When treating diabetic foot ulcers, debridement in the community should only be done by healthcare professionals with the relevant training and skills, continuing the care described in the person's treatment plan.
Social context	General	Smoking and alcohol consumption were identified from the mapping work and consultation. Smoking is one of the 9 care processes. The importance of knowing the current occupation and driving status were also identified.
	Webinars	"Add occupation to see if someone is standing up all day." **Chair of the UK Diabetes Psychology Network.**
	Surveys	Although: • People with type 2 diabetes were least likely to want to share information about episodes of hypoglycaemia (68.9%, n=20), insulin dosing (44.4%, n=12), smoking (51.7%, n=15) and family planning (7.41%, n=2). • People with type 1 diabetes were least likely to want to share information about sleep (65.1%, n=56), smoking (69.0%, n=60) and family planning (56.0%, n=47). People recognised the information as required to support care planning. In response to the question 'To develop and agree a care plan what information from the healthcare record would healthcare professionals need to have available?' For social context: smoking, alcohol, social circumstances, occupation, driving status 42% of people with type 2 diabetes and 55% of people with type 1 diabetes answered 'Nearly Always'. In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For social context: e.g., smoker or ex-smoker, alcohol intake, social circumstances, occupation and working pattern, driving status 92% (n=103) of health and care professionals and 100% (n=7) suppliers answered 'Yes'.
	Existing standards	The Scottish standards include: • occupation (current and relevant previous) • current physical activity status • driving licence type • current tobacco and nicotine consumption status • current alcohol drinking status / alcohol intake per average week • Current substance misuse status
	Audits	The National Diabetes Audit, National Paediatric Diabetes Audit, National Paediatric Diabetes Audit (T2), National Pregnancy In Diabetes Audit require: • current tobacco and nicotine consumption status • current alcohol drinking status / alcohol intake per average week

Section	Source	Requirements and justification for inclusion
		• current substance misuse status
	NICE guidelines	• NG17 - 1.6.12 Enable additional blood glucose testing (more than 10 times a day) for adults with type 1 diabetes if this is necessary because of the person's lifestyle (for example, driving for a long period of time, undertaking high-risk activity or occupation, travel) or if the person has impaired awareness of hypoglycaemia. • NG28 - 1.6.12 Take the Driver and Vehicle Licensing Agency (DVLA)'s Assessing fitness to drive: a guide for medical professionals into account when offering self-monitoring of blood glucose levels for adults with type 2 diabetes.
Family history	Existing standards	The Scottish standards include family history of diabetes mellitus (first degree relative)
	Audits	The National Paediatric Diabetes Audit (T2) requires family history of type 2
	NICE guidelines	• NG18 - 1.1.5 Think about the possibility of type 2 diabetes in children and young people with suspected diabetes who have a strong family history of type 2 diabetes.
Investigation results / requested	General	The codes for investigation results will be aligned to the Universal Test List (UTL) which means that any new tests e.g., for genetic scores or biomarkers could be included and would allow any investigation results on that list to be supported in the standard. Commonly used tests for diagnosis and management of diabetes were tested in the webinars and survey. They can all be recorded using the standard as they are included in the UTL.
	Webinars	The following investigations were identified in the webinars **Investigations supporting the 9 care processes:** HbA1c, cholesterol, HDL / LDL, creatinine, eGFR, Urine albumin, CKD status, DRSS Grade **Investigations for associated diseases:** Coeliac disease, Addison's disease, Pernicious anaemia, Thyroid disease, PEI **Diagnostic investigations**: C-peptide, Diabetes-specific autoantibody titres, Genetic testing (monogenic), OGTT (Gestational) **General investigations:** FBC, LFT, U&E, X-rays, Imaging
	Existing standards	Scottish standards require: • Glycated Haemoglobin (%) • Serum Creatinine • Triglyceride Level • Serum Total Cholesterol • Serum High-density Lipoprotein Cholesterol • TSH • 2-hour Oral Glucose Tolerance Test

Section	Source	Requirements and justification for inclusion
		• Albumin Concentration • Urine Microalbumin Test Method • Albumin Excretion Stage • Urinalysis Dipstick Protein • eGFR • Date of ultrasound for fatty liver
	Audits	The National Diabetes Audit requires • Dates and results of the investigations for serum creatinine level, HbA1c level, urinary albumin level); Total serum cholesterol level) The National Paediatrics Diabetes Audit requires: • Date of coeliac disease screening • Date and value of HbA1c • Date and value urinary albumin level (ACR) • Date and value total cholesterol level • Date of Thyroid Function Test • Albuminuria stage The National Paediatrics Diabetes Audit (T2) requires: • Date of ultrasound for fatty liver • Date of lipid profile (Date of first lipid profile following diabetes diagnosis, last lipid profile date, fasting or non-fasting) • Liver function test date (liver enzymes) • HbA1c date (HbA1c result at diagnosis) • Antibodies tested • Non-alcoholic fatty liver disease seen on ultrasound • Biochemical markers for concluding a Type 2 diabetes diagnosis - abnormal liver tests and pancreatic Abs, low sex hormone • Total cholesterol; HDL, non-HDL and LDL cholesterol The National Paediatrics in Diabetes Audit requires: • Date of first and last HbA1c reading during pregnancy
	NICE guidelines	• NG20: 1.1.1 Offer serological testing for coeliac disease to people with: Type 1 diabetes, at diagnosis. • NG17 - 1.15.35 Measure blood thyroid-stimulating hormone (TSH) levels in adults with type 1 diabetes at annual review. • NG3 - 1.3.10 Measure HbA1c levels when women are diagnosed with gestational diabetes to identify women who may have pre-existing type 2 diabetes.

Section	Source	Requirements and justification for inclusion
		• NG49 - 1.1.4 Offer a liver ultrasound to test children and young people for NAFLD if they have type 2 diabetes or metabolic syndrome and do not misuse alcohol. • NG17 - 1.6.1 Measure HbA1c levels every 3 to 6 months in adults with type 1 diabetes. • CG189 - 1.3.11 In tier 3 services, assess associated comorbidities and possible causes for children and young people who are overweight or who have obesity. Use investigations such as liver function. • NG28 - 1.6.14 Consider short-term self-monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary): when starting treatment with oral or intravenous corticosteroids or to confirm suspected hypoglycaemia. • NG17 - 1.15.9 Start angiotensin-converting enzyme (ACE) inhibitors and, with the usual precautions, titrate to full dose in all adults with confirmed nephropathy (including those with moderately increased albuminuria ['microalbuminuria'] alone) and type 1 diabetes. • NG17 - 1.1.1 Diagnose type 1 diabetes on clinical grounds in adults presenting with hyperglycaemia, bearing in mind that people with type 1 diabetes typically (but not always) have 1 or more of: ketosis/rapid weight loss/age of onset below 15 years/body mass index (BMI) below 25 kg/m2/personal and/or family history of autoimmune disease. • NG28 - 1.6.1 In adults with type 2 diabetes, measure HbA1c levels at: 3 to 6-monthly intervals (tailored to individual needs), until the HbA1c is stable on unchanging therapy, 6-monthly intervals once the HbA1c level and blood glucose lowering therapy are stable. • NG18: 1 1.2.71 Offer children and young people with type 1 diabetes measurement of their HbA1c level 4 times a year (more frequent testing may be appropriate if there is concern about suboptimal blood glucose control). • NG18: 1.3.28 Measure HbA1c levels every 3 months in children and young people with type 2 diabetes. • NG18: 1.3.43 Offer children and young people with type 2 diabetes annual monitoring for dyslipidaemia starting at diagnosis. NG18: 1.2.110 Offer children and young people with type 1 diabetes monitoring for moderately increased albuminuria (albumin:creatinine ratio [ACR] 3–30 mg/mmol; 'microalbuminuria') to detect diabetic kidney disease, annually from 12 years. • NG18 - 1.3.50 When monitoring for dyslipidaemia in children and young people with type 2 diabetes, measure total cholesterol, high-density lipoprotein (HDL) cholesterol, non-HDL cholesterol and triglyceride concentrations. • NG18: 1.2.110 Offer children and young people with type 1 diabetes monitoring for: thyroid disease at diagnosis and annually thereafter until transfer to adult services. • NG18: 1.3.43 Offer children and young people with type 2 diabetes annual monitoring for moderately increased albuminuria (albumin:creatinine ratio [ACR] 3–30 mg/mmol; 'microalbuminuria') to detect diabetic kidney disease, starting at diagnosis. • NG17 - 1.15.8 Discuss the significance of a finding of albuminuria with the person concerned.
Signpost details	NICE guidelines	• NG17 - 1.2.8 At the time of diagnosis and periodically thereafter, provide adults with type 1 diabetes with up-to-date information about diabetes support groups (local and national), how to contact them and the benefits of membership.

Section	Source	Requirements and justification for inclusion
Examination findings	General	A foot examination is one of the nine care processes. The outcomes should be a foot risk classification: Low. Moderate, High, Active Foot Disease or Not known (NICE NG19 2015).
	Webinars	"For feet it's very important to record whether low/medium/high risk and whether there is active foot disease. Need to keep key information that will allow to assess risk, and/or describe active foot disease." **Consultant** People can also do their own foot checks and could self-report findings. "Within the training for HCSW/GPNs this is advised, including putting mirror on the floor to check plantar aspect of foot Pts also have the traffic light referral in their pack (in Lewisham)." **Nurse Consultant** "I think it's really important to actually get a patient to recognise …. that they should be doing a daily foot check." **Consultant**
	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For examination findings e.g., foot check or diabetic eye screening results or other physical findings such as body mass index (weight and height). 96% (n=107) of health and care professionals and 100% (n=7) of suppliers answered 'Yes'. In response to the question 'Which of the following information that could be recorded at home would you like to share with healthcare professionals, and how often? Any comments?' For foot checks 84% of people with type 2 diabetes and 93% of people with type 1 diabetes said 'Yes'.
	Existing standards	The Scottish standards include: • Foot examination date • Foot ulcer and date of foot ulceration. New Podiatry Observations: • Prevalent Lower Limb Amputation Status (Trans-femoral/Trans-tibial • Digit/Metatarsal of Foot /Forefoot /Unknown /None) • Foot Pulse Status (Absent/Present) • Foot Sensation to Monofilaments (Absent/Present) • Foot Vibration Sensation Status (Normal/Abnormal) • Foot Sensation Status (Normal/Abnormal) • Foot Callus Status (Absent/Present) • Foot Deformity Status (Absent/Present) • Prevalent Foot Ulcer Status (Absent /Present). Insulin passport requires:

Section	Source	Requirements and justification for inclusion
		• Foot risk
	Audits	The National Paediatric Diabetes Audit requires: • Foot assessment examination date The National Diabetes Foot Audit requires: • Presenting Features - ulcer active or inactive • Bacterial Infection • Possible Charcot foot • Date of first assessment by team • Interval between first presentation and assessment Outcome date of 12 week and 24-week assessment

	NICE guidelines	• NG19 - Commissioners and service providers should ensure that the following are in place: A foot protection service for preventing diabetic foot problems, and for treating and managing diabetic foot problems in the community. A multidisciplinary foot care service for managing diabetic foot problems in hospital and in the community that cannot be managed by the foot protection service. This may also be known as an interdisciplinary foot care service. Regular reviews of treatment and patient outcomes, in line with the National Diabetes Foot Care Audit.
		• NG19 - 1.5.1 If a person has a diabetic foot ulcer, assess and document the size, depth and position of the ulcer.
		• NG19: 1.3.2 For young people with diabetes who are 12–17 years, the paediatric care team or the transitional care team should assess the young person's feet as part of their annual assessment and provide information about foot care. If a diabetic foot problem is found or suspected, the paediatric care team or the transitional care team should refer the young person to an appropriate specialist.
		• NG19 - For adults with diabetes, assess their risk of developing a diabetic foot problem at the following times: When diabetes is diagnosed, and at least annually thereafter, if any foot problems arise, on any admission to hospital, and if there is any change in their status while they are in hospital.
		• NG19 - 1.3.6 Assess the person's current risk of developing a diabetic foot problem or needing an amputation using the following risk stratification:
		  ○ Low risk: no risk factors present except callus alone.
		  ○ Moderate risk: deformity or neuropathy or non-critical limb ischaemia.
		  ○ High risk: previous ulceration or previous amputation or on renal replacement therapy or neuropathy and non-critical limb ischaemia together or neuropathy in combination with callus and/or deformity or non-critical limb ischaemia in combination with callus and/or deformity.
		  ○ Active diabetic foot problem: ulceration or spreading infection or critical limb ischaemia or gangrene or suspicion of an acute Charcot arthropathy, or an unexplained hot, red, swollen foot with or without pain.

Section	Source	Requirements and justification for inclusion
		• NG19 - 1.5.2. Use a standardised system to document the severity of the foot ulcer, such as the SINBAD (Site, Ischaemia, Neuropathy, Bacterial Infection, Area and Depth) or the University of Texas classification system. 1.5.3 Do not use the Wagner classification system to assess the severity of a diabetic foot ulcer. • NG19 - 1.7.1Be aware that if a person with diabetes fractures their foot or ankle, it may progress to Charcot arthropathy. 1.7.2 Suspect acute Charcot arthropathy if there is redness, warmth, swelling or deformity (in particular, when the skin is intact), especially in the presence of peripheral neuropathy or renal failure. Think about acute Charcot arthropathy even when deformity is not present, or pain is not reported.
Observations	General	Core observations aligned to the 9 care processes are: Body Mass Index (BMI), height/ length, weight, systolic blood pressure and diastolic blood pressure. Other relevant observations are waist circumference, waist /hip ratio, BMI centile and head circumference (for growth charts for children).
	Webinars	There was broad support for collecting information about glucose, weight, diet, height, carbohydrate intake, ketones, blood pressure in the webinars. For glucose, summary metrics are key but individual measurements are also important. "If we're predominantly looking at time below ranges, our core metric, actual events may be separate from that. And maybe interestingly can vary quite dramatically from the percentage time, but lots of very short episodes or one slightly longer episode that we're often looking at. So, I think that the events element is perhaps something that we should be making sure we have included as well." **Professional Lead** "Step count and heart rate useful for tracking activity (and relatively commonly recorded now)." **Consultant** "BP, weight, alcohol consumption, carb units/meal...Patient confidence levels (as used for podiatry care plan) holiday planning" **Design and Test Lead, DHCW**
	Surveys	In response to the question 'Which of the following information that could be recorded at home would you like to share with healthcare professionals, and how often? Any comments?' For Measurements taken at home: e.g., blood pressure, blood or urine ketone tests, or body mass index (height and weight) 90% (n=31) of people with type 2 diabetes, 83.53% (n=85) of people with type 1 diabetes and 100% (n=8) of parents answered 'Yes'. In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For Observations e.g., blood pressure, heart rate, glucose levels from diabetes devices such as glucometers (fingerstick testing) or continuous glucose monitors (CGM) 96% (n=107) of health and care professionals and 100% (n=7) suppliers answered 'Yes'.

Section	Source	Requirements and justification for inclusion
		In response to the question 'What information that only applies to children is needed in a record to support a child with diabetes?' The most highly cited themes were observations to support growth charts and associated metrics (n=33), details of the child's school (n=10), and details of their family situation/ support (n=9). In the easy-to-read survey: In response to the question' At home what do you or your carer measure to help manage your diabetes?' 13 (31.7%) answered weight, 31 (75.6%) answered sugar and 14 (34.2%) answered blood pressure. Another highly cited response was carbohydrates.
	Existing standards	Scottish standards include: • Plasma glucose level at diagnosis • Blood glucose (mmol/l)
	Audits	The National Diabetes Audit requires: • Observation date (BMI) • Observation date systolic blood pressure and diastolic blood pressure The National Paediatric Diabetes Audit requires: • Observation date systolic blood pressure and diastolic blood pressure • Observation date (height and weight) The National Paediatric Diabetes Audit requires (T2): • Date 24-hour ambulatory blood pressure was first performed following diabetes diagnosis. • Date of first height and weight following diagnosis The National Pregnancy in Diabetes Audit requires: • Height and weight of the person at time of booking
	NICE guidelines	• NG17 - 1.6.10 Advise routine self-monitoring of blood glucose levels for all adults with type 1 diabetes, and recommend testing at least 4 times a day, including before each meal and before bed. [This guideline is likely to be updated to 1.6.16 Advise adults with type 1 diabetes who are using capillary blood glucose monitoring to routinely self-monitor their blood glucose levels, and to test at least 4 times a day (including before each meal and before bed).] • NG17 – 1.6.10 [draft for consultation] Offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as

Section	Source	Requirements and justification for inclusion
		'flash') based on their individual preferences, needs, characteristics, and the functionality of the devices available. • NG28 – 1.6.17 [draft for consultation] Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply: they have recurrent or severe hypoglycaemia, they have impaired hypoglycaemia awareness, they have a condition or disability that means they cannot self-monitor their blood glucose by intermittent capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them), they would otherwise be advised to self-test at least 8 times a day. • NG18: 1.2.45 At each clinic visit for children and young people with type 1 diabetes measure height and weight and plot on an appropriate growth chart. Check for normal growth and/or significant changes in weight because these may reflect changes in blood glucose control. • NG18: 1.3.20 At each clinic visit for children and young people with type 2 diabetes: measure height and weight and plot on an appropriate growth chart, calculate BMI. Check for normal growth and/or significant changes in weight because these may reflect changes in blood glucose control. • NG18: 1.2.110 Offer children and young people with type 1 diabetes monitoring for: hypertension annually from 12 years. • NG18: 1.3.43 Offer children and young people with type 2 diabetes annual monitoring for: hypertension starting at diagnosis. • NG18 - 1.3.48 If repeated resting measurements are greater than the 95th percentile for age and sex, confirm hypertension using 24-hour ambulatory blood pressure monitoring before starting antihypertensive therapy. • NG18 – 1.2.63 [draft for consultation] Offer real-time continuous glucose monitoring to all children and young people with type 1 diabetes, as long as it is provided alongside education to support children and young people and their families and carers to use it. • NG17 - 1.15.11 Maintain blood pressure below 130/80 mmHg by addition of other anti-hypertensive drugs if necessary.
Pregnancy status	General	Information about family planning, use of contraception, planning to become pregnant and actively pregnant are important in diabetes care. Gestation length at birth is also required for growth charts for children.
	Survey	In answer to the question 'What information about someone's planned or current pregnancy should be included in a record for a person with diabetes?' • The most highly cited themes were contraception use and type (n=53), pregnancy plans and timescale (n=59), pregnancy status/ test results (n=54), person with diabetes breastfeeding now or planning to (n=41), and person with diabetes is actively trying to conceive (n=39). "For general clinics we only need to know: (1) Are they pregnant, (2) are they planning pregnancy, (3) are they capable of pregnancy. Joint antenatal clinics require far more information, of course." **Endocrinologist**
	Existing standards	The Scottish standards include:

Section	Source	Requirements and justification for inclusion
		• Pregnancy status • Estimated delivery date
	Audits	The National Pregnancy In Diabetes Audit requires • Pregnancy status • The earliest estimated delivery date following 7-12/40 scan
	NICE guidelines	• NG3 - 1.1.1 Provide information, advice and support, to empower women to have a positive experience of pregnancy and to reduce the risks of adverse pregnancy outcomes for mother and baby. • NG3 - 1.1.24 Stop angiotensin-converting enzyme inhibitors and angiotensin-II receptor antagonists before conception, or as soon as pregnancy is confirmed. Use alternative antihypertensive agents that are suitable for pregnant women. 1.1.25 Stop statins before pregnancy, or as soon as pregnancy is confirmed. • NG3 - 1.1.28 As early as possible, offer a structured education programme to women with diabetes who are planning a pregnancy (if they have not already attended one). • NG3 - 1.2.3 Do not use fasting plasma glucose, random blood glucose, HbA1c, glucose challenge test or urinalysis for glucose to assess the risk of developing gestational diabetes. • NG3 - 1.4.1 Discuss the timing and mode of birth with pregnant women with diabetes during antenatal appointments, especially during the third trimester.
Summary glucose metrics	General	There was strong support during the consultation for including the international consensus glucose metrics in the standard and this is supported by the literature (see Appendix 19). The cohort of people with diabetes recommended to use Continuous Glucose Monitors is expanding as NICE revises its guidelines and these are the metrics related to the use of CGM that people are using to manage their diabetes.
	Webinars	Summary metrics are needed for self-monitoring of blood glucose (SMGB) as well as CGM. "These time in ranges can be captured for [Capillary Blood Glucose] CBG users as well." **Senior Lecturer and Consultant** "We need to move to Time in Range for those using flash and CGM (& those testing many times a day)." **PwD, T1** "We share Dexcom and Libre info, also MyLife data where we record BG, hypos, hypers, treatments, corrections, Bolus and basal info and other medications or possible reasons for hypos/hypers." **Parent** "If we have metrics that cover these four domains of glucose control so that an average of overall exposure, a thing about temporal change, glycaemic extremes and blood glucose variability. And I think I made a comment about things like time and range, but also %CV etc." **Senior Lecturer and Consultant** "Frequency of measurements, duration of data, how much information, how much we can rely on the information with very infrequent data collection**." Senior Lecturer and Consultant**
	Existing standards	Scottish standards include:

Section	Source	Requirements and justification for inclusion
		New blood glucose measurements summary from device: Mean glucose (mmol/l) / Estimated HbA1C level (%) / Glycaemic variability (%CV) (Target: <36%) / Number of episodes of hypoglycaemia OR hyperglycaemia >15 min (alerts) / Time on OR below OR above target glucose range (%): (episodes of hypoglycaemia >15 min) / Risk of hypoglycaemia and hyperglycaemia (LGBI/HBGI recommended)
	NICE guidelines	• NG17 – 1.6.10 [draft for consultation] Offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') based on their individual preferences, needs, characteristics, and the functionality of the devices available. • NG28 – 1.6.17 [draft for consultation] Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash') to adults with type 2 diabetes on multiple daily insulin injections if any of the following apply: they have recurrent or severe hypoglycaemia, they have impaired hypoglycaemia awareness, they have a condition or disability that means they cannot self-monitor their blood glucose by intermittent capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them), they would otherwise be advised to self-test at least 8 times a day. • NG18 – 1.2.63 [draft for consultation] Offer real-time continuous glucose monitoring to all children and young people with type 1 diabetes, as long as it is provided alongside education to support children and young people and their families and carers to use it. • NG18 - 1.2.64 [draft for consultation] Offer intermittently scanned CGM (isCGM, commonly referred to as 'flash') to children and young people (aged 4 years and over) with type 1 diabetes who are unable to use real-time CGM or who express a clear preference for isCGM.
Assessments	General	Many assessment domains were identified for diabetes management including eating behaviours, physical activity scales, activation measures, diabetes self-efficacy, medication adherence, PROMS and hypoglycaemia awareness or fear. There was also broad support for collecting information about sleep, emotional wellbeing and physical activity in the consultation.
	Webinars	"I'd argue that diabetes distress scale, and a disordered eating scale (DEPS-R) are both absolutely essential for all adults." **Psychologist** "MUST score for care home residents may be better or more useful than BMI, waist circumference." **Dietitian** "In outcomes to consider adding CCF, as part of risk assessment - consider adding QRISK and kidney failure risk (using KFR equation) in those with CKD, and now that many patients will be on ACEi/ARB, metformin and SGLT2i - need to include sick day rules." **Consultant Nephrologist** "We need a section on core patient reported outcomes, i.e., DDS/GOLD/HFS and core glucometrics." **Senior Lecturer and Consultant** "The paediatric Diabetes has a PREMS element in the quality improvement programme." **NHSE**

Section	Source	Requirements and justification for inclusion
	Existing standards	The Scottish standards include: Depressed Well-Being Score – The score achieved by the person on the Depressed Wellbeing Questionnaire e.g., diabetes distress score, PHQ-2, GAD-2
	Audits	The National Paediatric Diabetes Audit and The National Paediatric Diabetes Audit (T2) require: • Date of psychological screening assessment • Was the person assessed as requiring additional psychological/CAMHS support outside of MDT clinics (NPDA) • Date sleep first assessed following diabetes diagnosis
	NICE guidelines	• NG17 - 1.10.1 Assess awareness of hypoglycaemia in adults with type 1 diabetes at each annual review. 1.10.2 Use the Gold score or Clarke score to quantify awareness of hypoglycaemia in adults with type 1 diabetes, checking that the questionnaire items have been answered correctly. Regular assessment of a broad range of psychological and behavioural problems in children and adults with type 1 diabetes is recommended. • NG18: 1.2.94. Diabetes teams should be aware that children and young people with type 1 diabetes have a greater risk of emotional and behavioural difficulties. [2004, amended 2015] • NG18: 1.2.95 Offer children and young people with type 1 diabetes and their family members or carers (as appropriate) emotional support after diagnosis, which should be tailored to their emotional, social, cultural and age-dependent needs. [2004] • NG18: 1.2.96 Assess the emotional and psychological wellbeing of young people with type 1 diabetes who present with frequent episodes of diabetic ketoacidosis (DKA). [2004, amended 2015] • NG18: 1.2.97 Be aware that a lack of adequate psychosocial support has a negative effect on various outcomes, including blood glucose control in children and young people with type 1 diabetes, and that it can also reduce their self-esteem. [2004, amended 2015] • NG18: 1.2.98 Offer children and young people with type 1 diabetes and their family members or carers (as appropriate) timely and ongoing access to mental health professionals with an understanding of diabetes because they may experience psychological problems (such as anxiety, depression, behavioural and conduct disorders and family conflict) or psychosocial difficulties that can impact on the management of diabetes and wellbeing. [2004, amended 2015]. • NG28: 1.3.37 Offer children and young people with type 2 diabetes and their family members or carers (as appropriate) timely and ongoing access to mental health professionals with an understanding of diabetes because they may experience psychological problems (such as anxiety, depression, behavioural and conduct disorders and family conflict) or psychosocial difficulties that can impact on the management of diabetes and wellbeing.
Risks	General	This would include risk of direct self-harm for example through misuse of insulin.
	Webinars	"Suicide or self-harm would be very important for teams to know people with Type 1, a much higher risk of suicide and suicidal ideation."

Section	Source	Requirements and justification for inclusion
	Surveys	In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For safeguarding and risks 93% (n=104) of health and care professionals and 86% (n=6) of suppliers answered 'Yes'. In response to the question 'To develop and agree a care plan what information from the healthcare record would healthcare professionals need to have available?' For safeguarding and risks 42% of people with type 2 diabetes answered 'Never'. However, 55% of people with type 1 diabetes and 100% parents of children with diabetes answered 'Nearly always'.
	NICE guidelines	• NG17 - 1.15.38 Members of diabetes professional teams should be alert to the possibility of bulimia nervosa, anorexia nervosa and insulin dose manipulation in adults with type 1 diabetes with: over-concern with body shape and weight, low BMI, hypoglycaemia, suboptimal overall blood glucose control.
Allergies and adverse reactions	Existing standards	Scottish standards include allergies and adverse reactions to insulin and non-insulin medication.
	Audits	The National Paediatric Diabetes Audit (T2) requires allergies and adverse reactions to insulin and non-insulin medication.
Medical devices	General	Health and care professionals need to know which medical devices a person is using to manage their diabetes (and information about the make, model, warranty details etc). This is important to ensure they are using the correct device for them and in the event of safety notices about devices people using them can be easily contacted. The types of devices include • Smart insulin pens • Insulin pumps • Hybrid closed-loop systems • Real-time continuous glucose monitors • Intermittently scanned continuous glucose monitors • Accelerometers • Ketone monitors • Glucometers
	Webinars	"[Patients] on pump etc have a warranty end date that informs them on when they are due a renewal." **Medtech supplier**
	Surveys	In response to the question 'What information do healthcare professionals need to know about sick days?' • The most highly cited themes were monitoring including frequency (n=9) of blood or urinary ketones (n=35), capillary blood glucose (n=8), symptoms (n=22), current medications and those stopped or restarted (n=26) including insulin dosing and adjustment (n=6).

Section	Source	Requirements and justification for inclusion
		• Other themes highly cited by HCPs were whether sick day education had been provided (n=11), PWD knowledge and understanding of sick day rules (n=13) and details of their diabetes devices (e.g., glucose/ ketone monitors) (n=9).
	Existing standards	Scottish standards include: • Diabetes Self-Monitoring Type: None / Urine / Blood • Medical device: Insulin pump / Freestyle Libre / CGM
	Audits	The National Diabetes Audit requires: • Reason for use of pump - Glucose control or hypoglycaemia reduction • Year started using pump The National Paediatrics Diabetes Audit requires: • At the time of HbA1c measurement, in addition to standard blood glucose monitoring (SBGM), was the patient using any other method of glucose monitoring? The National Pregnancy In Diabetes Audit requires: • Method of Glucose monitoring used at 28 weeks • Method of Insulin Administration at 28 weeks
	NICE guidelines	• NG28 - 1.6.16 If adults with type 2 diabetes are self-monitoring their blood glucose levels, carry out a structured assessment at least annually. The assessment should include: the person's self-monitoring skills, the quality and frequency of testing, checking that the person knows how to interpret the blood glucose results and what action to take, the impact on the person's quality of life, the continued benefit to the person, the equipment used. • NG17 - 1.6.20 Monitoring blood glucose using sites other than the fingertips cannot be recommended as a routine alternative to conventional self-monitoring of blood glucose.
Insulin dosing	General	There was support for including insulin dosing information in the standard supported by the academic literature (see Appendix 21) and in the consultation. The insulin dosing information is essentially the raw data (individual insulin doses or infusion rates and the insulin calculation parameters used to calculate the amount of insulin) that enables the calculation of summary insulin metrics agreed during the consultation for these standards. The intention is that it would be possible to view the raw data if required.
	Surveys	In response to the question ‘Which of the following information that could be recorded at home would you like to share with healthcare professionals, and how often? Any comments?’ For insulin 94% (n=89) of people with type 1 diabetes and 100% (8) parents of children with diabetes answered ‘Yes’ In response to the question ‘What information do healthcare professionals need to know about sick days?’

Section	Source	Requirements and justification for inclusion
		• The most highly cited themes were monitoring including frequency (n=9) of blood or urinary ketones (n=35), capillary blood glucose (n=8), symptoms (n=22), current medications and those stopped or restarted (n=26) including insulin dosing and adjustment (n=6). In answer to the question 'What information healthcare professionals need to identify people with diabetes at risk of deterioration or harm?' Prescribed medications, device use & adherence was cited by health and care professionals (n=5)
Insulin summary metrics	General	There was strong support for including summary insulin metrics from the consultation and the academic literature asks for a consensus on these metrics (see Appendix 21). In addition to the actual insulin administered, health and care professionals wanted a way of recording the usual amount of insulin administered (which would be captured during clinic as usual or modal dose) In outpatient and inpatient settings, it is important that how people with diabetes take their insulin (how much and when) is recorded as details of a prescription do not accurately reflect the amount of insulin administered because it varies based on a number of parameters. The parameters used in calculating the amount of insulin are also important. The GIRFT[28] report on diabetes states that during a stay in hospital almost 40% of people treated with insulin experience an error which can lead to avoidable harms such as hypoglycaemic events and DKA. It suggests that electronic insulin passports, electronic patient records which include information on insulin needs, and electronic prescribing, may also be effective in reducing insulin errors but this needs the standards to be in place to support information sharing.
	Webinars	"We need trade name, a formulation in terms of its concentration, a frequency of use for people using, for example, premixed insulins ... I think it's important that we can put that in there. And obviously what the preparation is, is it from a vial? Is it from a cartridge? Is it from a pump cartridge? Is it a disposable device?" **Professional Lead** "The point of that usual bolus dose as well wasn't just for people using fixed doses. But you record a one to 10 ratio … you ask people what you take, and they say one to 10 for breakfast, but then [they] say I generally don't have breakfast. And so [usual bolus] is zero. And that usual dose panel is important for TDD calculation." **Senior Lecturer and Consultant** "Dosing, basal, total daily dose etc. in self-reported." **PwD, T1**

[28] Diabetes – Getting It Right First Time – GIRFT

Section	Source	Requirements and justification for inclusion
		"Bolus / day--> available from connected pens and/or CSII." **Senior Lecturer and Consultant** " ...Total basal and bolus with bolus split into carbs and correction." **Senior Lecturer and Consultant** " [Would] be good to include sensor failures...Use of Bolus Calculator, use of manual bolus, time in suspend" **Medtech supplier**
Medications	General	Information about all medications is required.
	Webinars	"We share Dexcom and Libre info, also MyLife data where we record BG, hypos, hypers, treatments, corrections, Bolus and basal info and other medications or possible reasons for hypos/hypers." **Parent**
	Surveys	In response to the question 'Which of the following information that could be recorded at home would you like to share with healthcare professionals, and how often? Any comments?' For medications and allergies 88% (n=32) of people with type 2 diabetes, 90% (n=88) of people with type 1 diabetes and 100% (n=8) of parents of children with diabetes answered 'Yes'. In response to the question 'To develop and agree a care plan what information from the healthcare record would healthcare professionals need to have available?' For medications and allergies 74% (n=27) of people with type 2 diabetes, 90% (n=76%) of people with type 1 diabetes and 100% (n=8) of parents of children with diabetes answered 'Nearly always'. In response to the question 'What information about people with diabetes are healthcare professionals unable to access that they need to see?' • The most highly cited themes in the comments included examples of where records are held outside of an HCP's organisation (n=19), access to test results including images, scans, and reports (n=20), medications taken including changes (n=11), diabetic eye screening results including images (n=13), data from devices including CGM and insulin pumps (n=14) as well as several other elements common to patient health records e.g. observations, allergies etc.(n=21).

	Existing standards	Scottish standards include:
		
		• Information about medications, for example:
		  ○ Insulin, metformin, sulphonylureas, other hypoglycaemic (anti-hyperglycaemic) agents
		  ○ Antibiotics for diabetes-related infections e.g., ulcers.
		  ○ Non-diabetic drugs e.g., statins.
		  ○ Folic acid
		  ○ Diabetes treatment during pregnancy

	Audits	The National Diabetes Audit, The National Paediatric Diabetes Audit and The National Paediatric Diabetes Audit (T2) require:

Section	Source	Requirements and justification for inclusion
		• Medications / diabetes therapies at point of HbA1c measurement (NPDA) Initial treatment type(s) offered at diagnosis of diabetes; Was medical treatment for hypertension given; Was the person taking medical treatment for hyperlipidaemia? (NPDA T2) The National Pregnancy In Diabetes Audit requires: Folic acid used prior to and since last LMP; Diabetes treatment regimen at 1st day of LMP; Treated hypertension prior to 1st day of LMP; ACE inhibitor/ARB at 1st day of LMP; Statins on 1st day of LMP
	NICE guidelines	• NG28 - 1.6.6 Offer lifestyle advice and drug treatment to support adults with type 2 diabetes to achieve and maintain their HbA1c target. • NG17 - 1.6.19 Offer standard-release metformin as the initial drug treatment for adults with type 2 diabetes. • NG17 - 1.7.8 When using tricyclic drugs and antihypertensive drug treatments in adults with type 2 diabetes who have autonomic neuropathy, be aware of the increased likelihood of side effects such as orthostatic hypotension. 1.8.6 In children aged 12 years and older, treatment with orlistat is recommended only if physical comorbidities (such as orthopaedic problems or sleep apnoea) or severe psychological comorbidities are present. Treatment should be started in a specialist paediatric setting, by multidisciplinary teams with experience of prescribing in this age group. • NG19 - 1.6.6 Start antibiotic treatment for people with suspected diabetic foot infection as soon as possible. Take samples for microbiological testing before, or as close as possible to, the start of antibiotic treatment. • NG3 - 1.1.11 Advise women with diabetes who are planning a pregnancy to take folic acid (5 mg/day) until 12 weeks of gestation to reduce the risk of having a baby with a neural tube defect.
Information and advice given	General	Diabetes UK have developed information prescriptions to support people with diabetes covering a range of topics including feet, improving diabetes knowledge, emotions, contraception and pregnancy etc. Information Prescriptions for healthcare professionals | Diabetes UK If these have been given to the person with diabetes this would be recorded in this section. A new section within 'Information and advice given' has been added to support offers made – this could include an offer of an appointment with a psychologist or an offer of structured education.
	Surveys	In response to the question 'What information about someone's planned or current pregnancy should be included in a record for a person with diabetes?' • Themes highly cited by HCPs were history of previous pregnancies (n=13), education/advice on preconception planning/ diabetes in pregnancy offered/ given to PWD (n=12), PWD was taking folic acid at time of conception (n=7), medications review (including teratogens) (n=6), fertility status/ PWD treated under specialist fertility services (n=6), and estimated last menstrual period (LMP)/ number of weeks pregnant/ due date (n=5)
	Audits	The National Diabetes Audit requires:

Section	Source	Requirements and justification for inclusion
		• Was psychological support offered following diabetes diagnosis? The National Paediatrics Diabetes Audit requires: • Has the person been recommended a Gluten-free diet? • Date of provision of advice ('sick-day rules') about managing diabetes during intercurrent illness or episodes of hyperglycaemia. • Was the patient offered an additional appointment with a paediatric dietitian? The National Paediatrics Diabetes Audit (T2) requires: • Was dietetic support offered following diabetes diagnosis? (T2) • Extremely low-calorie diet / meal replacement? • Was non-invasive ventilation for sleep apnoea orariatric surgery recommended? (Note there is no SNOMED CT code for this)
	NICE guidelines	• NG28 - 1.6.6 Offer lifestyle advice and drug treatment to support adults with type 2 diabetes to achieve and maintain their HbA1c target. • NG17 - 1.8.5 Advise adults with type 1 diabetes to rotate insulin injection sites and avoid repeated injections at the same point within sites. • NG28 - 1.3.1 Provide individualised and ongoing nutritional advice from a healthcare professional with specific expertise and competencies in nutrition. • NG18 - 1.3.15 Offer children and young people with type 2 diabetes dietetic support to help optimise body weight and blood glucose control. • NG28 - 1.3.3 Emphasise advice on healthy balanced eating that is applicable to the general population when providing advice to adults with type 2 diabetes. Encourage high-fibre, low-glycaemic-index sources of carbohydrate in the diet, such as fruit, vegetables and trans fatty acids. • NG19 - Provide information and clear explanations to people with diabetes and/or their family members or carers (as appropriate) when diabetes is diagnosed, during assessments, and if problems arise. Information should be oral and written and include the following: Basic foot care advice and the importance of foot care. Foot emergencies and who to contact. Footwear advice. The person's current individual risk of developing a foot problem. Information about diabetes and the importance of blood glucose control.
Development skills	General	Applies only to a child. Child development is reviewed at every consultation with a paediatrician and was deemed important to include in the standard.
Feeding status	Surveys	In answer to the question ‘What information about someone’s planned or current pregnancy should be included in a record for a person with diabetes?’

Section	Source	Requirements and justification for inclusion
		The most highly cited themes were contraception use and type (n=53), pregnancy plans and timescale (n=59), pregnancy status/ test results (n=54), person with diabetes breastfeeding now or planning to (n=41), and person with diabetes is actively trying to conceive (n=39).
Personal comment	General	50% of communication related to a person with diabetes between the person and healthcare professional and between healthcare professionals use informal methods (messaging platforms). This has been added to the standard to capture notes from informal digital messages.
Plan & requested actions	General	This is the plan and actions following an encounter and therefore important in the record so all those that view it are aware of future plans. This should be linked with contact with professionals, emergency care attendance and discharge details.
	General	A Cochrane systematic review (Cochrane 2015) has found that the methodology associated with personalised care and support planning including goal setting and patient-centric working) was associated with improved measures of systolic blood pressure (BP) and glycosylated haemoglobin (HbA1c) in people treated for type 2 diabetes.
	Webinars	People want a more holistic approach to reviewing their diabetes at their annual review. "... holistic care should be a model taking into account other conditions like mental ill-health, medical conditions etc." **PwD, T2** "Mental health for example has an effect on a person's ability to manage physical health. Need for whole person to be considered in diabetes management." **PwD, T2** "Emphasis on the patient's ideas, concerns and expectations is essential." **Community Staff Nurse**
	Surveys	In response to the question 'Please select the information that should be captured in a diabetes care plan. Any comments?' • People with diabetes and their carers generally supported the need for capturing this information in a diabetes care plan. At least 60% of responses in each group (PWDT1, PWDT2, parent of T1) supported the inclusion of at least 9 out of the 11 information categories. • People with type 2 diabetes were least likely to want to capture information about additional supporting/ contingency plans (47.2%, n=17). • People with type 1 diabetes were least likely to want to capture information about confidence in achieving goals (53.3%, n=48). • Parents of children with type 1 supported the inclusion of each of the 11 categories with at least 60% of responses.
Care plan	Existing standards	Scottish standards include:

Section	Source	Requirements and justification for inclusion
		• Is the diabetes care plan agreed with professional?
	NICE guidelines	• NG17 - 1.1.6 At the time of diagnosis (or if necessary, after the management of critically decompensated metabolism), the diabetes professional team should develop with and explain to the adult with type 1 diabetes a plan for their early care. To agree such a plan will generally require: medical assessment to ensure security of diagnosis of type of diabetes (ensure appropriate acute care is given when needed; review and detect potentially confounding disease and medicines; detect adverse vascular risk factors); environmental assessment to understand the social, home, work and recreational circumstances of the person and carers (their preferences in nutrition and physical activity; other relevant factors, such as substance use); cultural and educational assessment to identify prior knowledge and to enable optimal advice and planning about (treatment modalities; diabetes education programmes); assessment of emotional state to determine the appropriate pace of education. • NG17 - 1.1.8 After the initial plan is agreed, put arrangements in place to implement it without inappropriate delay, and to provide for feedback and modification of the plan over the ensuing weeks.1.2.5 Set up an individual care plan jointly agreed with the adult with type 1 diabetes, review it annually and modify it taking into account changes in the person's wishes, circumstances and medical findings, and record the details. The plan should include aspects of: diabetes education, including nutritional advice, insulin therapy, including dose adjustment, self-monitoring, avoiding hypoglycaemia and maintaining awareness of hypoglycaemia, for women of childbearing potential, family planning, contraception and pregnancy planning, cardiovascular risk factor monitoring and management, complications monitoring and management, means and frequency of communicating with the diabetes professional team, frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and next annual review. • NG17 - 1.3.4 Integrate dietary advice with a personalised diabetes management plan, including other aspects of lifestyle modification, such as increasing physical activity and losing weight.
Care plan goals and targets	Webinars	Goals and targets are currently used to help people manage their diabetes. This was discussed during the consultation and not everyone found goals and targets helpful. Goals form part of a care plan. Goals and targets may range from: • I want to be able to attend my daughter's wedding • I want to avoid dialysis • I want to check my blood sugars more often • I want to be able to take the stairs in my building • HbA1c • Time in Range • Blood pressure • BMI (weight) • Gold score • Diabetes Distress Score • Smoking • Alcohol

Section	Source	Requirements and justification for inclusion
		• Sleep • Exercise "What is important to me might not be what is important to someone else. Sometimes targets/goals are a good idea and I'm fully supportive of that, sometimes I don't want any targets, I just need to stay alive a little bit longer." **PwD, T1** "You need to differentiate between targets such as Hba1c, blood pressure, cholesterol and targets within the behaviours that will help you manage those targets. Maybe the behaviours should not be couched as 'targets'." **Parent**
	Surveys	In response to the question 'Which of the following information that could be recorded at home would you like to share with healthcare professionals, and how often? Any comments?' For goals and progress against them 93% (n=30) of people with type 2 diabetes, 81% (n=86) of people with type 1 diabetes and 100% (n=7) of parents of children with diabetes answered 'Yes'. In response to the question 'Please select the information that should be captured in a diabetes care plan. Any comments?' For goals and hopes 69% of people with type 2 diabetes, 70% of people with type 1 diabetes and 75% of parents of children with diabetes answered 'Yes'. "It would be nice to have my healthcare professional know this so they can best support me with my health and to make sure that diabetes doesn't stop me achieving my goals." **PwD, T1** "Living with an unpredictable condition like MS means I prefer not to make long term plans & goals, as everything can change instantly if I have a relapse. I find it depressing not to achieve goals so tend to make very vague & flexible ones with no specific end date." **PwD, T1**
	Audits	The National Diabetes Audit requires: • Treatment Goals achieved for Glucose Control and Hypos The National Paediatric Diabetes Audit requires: • HbA1c target
	NICE guidelines	• NG3 - 1.3.4 Agree individualised targets for self-monitoring of blood glucose with pregnant women with diabetes, taking into account the risk of hypoglycaemia. • NG3 - 1.2.14 When women are diagnosed with gestational diabetes, offer advice about changes in diet and exercise. 1.2.15 Advise women with gestational diabetes to eat a healthy diet during pregnancy, and to switch from high to low glycaemic index food. 1.2.17 Advise women with gestational diabetes to exercise regularly (for example, walking for 30 minutes after a meal). • NG17 - 1.6.13 Advise adults with type 1 diabetes to aim for: a fasting plasma glucose level of 5 to 7 mmol/litre on waking and a plasma glucose level of 4 to 7 mmol/litre before meals at other times of the day. 1.6.14 Advise adults with type 1 diabetes who choose to test after meals to aim for a plasma glucose level of 5 to 9

Section	Source	Requirements and justification for inclusion
		mmol/litre at least 90 minutes after eating. 1.6.15 Agree bedtime target plasma glucose levels with each adult with type 1 diabetes that take into account timing of the last meal and its related insulin dose and are consistent with the recommended fasting level on waking. • NG28 - 1.6.5 Involve adults with type 2 diabetes in decisions about their individual HbA1c target. Encourage them to achieve the target and maintain it unless any resulting adverse effects (including hypoglycaemia), or their efforts to achieve their target, impair their quality of life. • NG17 - 1.6.7 Agree an individualised HbA1c target with each adult with type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia. • NG28 - 1.3.6 Individualise recommendations for carbohydrate and alcohol intake, and meal patterns. Reducing the risk of hypoglycaemia should be a particular aim for a person using insulin or an insulin secretagogue.
Contingency and Additional support plans	General	These could include a dietician's plan or school insulin pump plan.
	Surveys	In response to the question 'What information do healthcare professionals need to know about sick days?' Care plan for sick days was cited (n=5) In response to the question 'Please select the information that should be captured in a diabetes care plan. Any comments?' For Additional supporting and contingency plans: (e.g., school insulin pump plan or hypoglycaemia action plan) 47% of people with type 2 diabetes, 67% of people with type 1 diabetes and 88% of parents of children with diabetes answered 'Yes'.
Documents & images	Surveys	In response to the question 'What information about people with diabetes are healthcare professionals unable to access that they need to see?' The most highly cited themes in the comments included examples of where records are held outside of an HCP's organisation (n=19), access to test results including images, scans, and reports (n=20), medications taken including changes (n=11), diabetic eye screening results including images (n=13), data from devices including CGM and insulin pumps (n=14) as well as several other elements common to patient health records e.g. observations, allergies etc.(n=21).
	Existing standards	The Scottish Diabetes Foot Care Extension Dataset requires: Was a photograph of the foot ulcer taken?
Diabetic eye screening	General	Eye screening is one of the nine care processes for diabetes.
	Webinars	"Retinopathy grading can be used to prioritise e.g., blood pressure management in a more unified record." **Consultant** "Eyes need to include treatment as well as screening / diagnostics. Images should be accessible but not always routine." **Endocrinologist and Diabetes Specialist Physician**

Section	Source	Requirements and justification for inclusion
	Surveys	In response to the question 'What information about people with diabetes are healthcare professionals unable to access that they need to see?' • The most highly cited themes in the comments included examples of where records are held outside of an HCP's organisation (n=19), access to test results including images, scans, and reports (n=20), medications taken including changes (n=11), diabetic eye screening results including images (n=13), data from devices including CGM and insulin pumps (n=14) as well as several other elements common to patient health records e.g. observations, allergies etc.(n=21). In response to the question 'Which of the following information do health professionals need access to, to help a person with diabetes develop their care plan? Any comments?' For examination findings e.g., foot check or diabetic eye screening results or other physical findings such as body mass index (weight and height) 96% (n=107) of health and care professionals and 100% (n=7) suppliers answered 'Yes'. In response to the question 'Tell us about where information sharing breaks down e.g., between the podiatrist and GP, or district nurse and hospital team.' • The most highly cited themes in the comments indicated that information sharing breaks down between the GP and hospital teams (n=65), between hospital teams within a trust (n=9), between hospital trusts (n=10), between the hospital teams and community care (n=11), between diabetic eye screening services and hospital teams (n=11) and between the podiatrist in the community and others (n=18). Several respondents said that information sharing breakdown was systemwide (n=21) although some PWDs said they had no experience of this (n=10).
	Existing standards	Scottish standards require: • Eye examination method (Retinal Photography/Dilated Direct Ophthalmoscopy/Slit-Lamp Biomicroscopy/Unknown) and retinal screening date. • Retinopathy screening status • Blindness status (Not Blind /Permanently Blind/Potentially Reversible Blindness/Unknown) • Findings: Visual Acuity (Snellen) / Visual Acuity (Logmar) / Retinal Lesions (Non-diabetic) (Pigmented Lesion (naevus)/Drusen/etc) / Diabetic Maculopathy Status (Observable/Referable /None) / Retinal Status (None/Mild BDR/etc) / Cataract Status (Absent/Present) / Laser Photocoagulation Scars (Grading Exam)
	Audits	The National Diabetes Audit requires: • Observation Date (Eye examination) • Diabetes routine review (eye)

Section	Source	Requirements and justification for inclusion
		The National Paediatric Diabetes Audit requires: • Retinal screening date and retinal screening result - Absent/Present/Unknown National Pregnancy in Diabetes Audit requires: • Retinal screening grade in first and last trimester - retinopathy grade • Retinal screening grade in first and last trimester - maculopathy grade
	NICE guidelines	• NG17 - 1.7.18 Encourage adults to attend eye screening and explain that it will help them to keep their eyes healthy and help to prevent problems with their vision. Explain that the screening service is effective at identifying problems so that they can be treated early. • NG28 - 1.7.17 When adults are diagnosed with type 2 diabetes, GPs should immediately refer them to the local eye screening service. • NG18: 1.2.110 Offer children and young people with type 1 diabetes monitoring for: diabetic retinopathy annually from 12 years. NG18: 1.3.43 Offer children and young people with type 2 diabetes annual monitoring for: diabetic retinopathy from 12 years.
Structured education	General	Structured education includes QISMET accredited courses e.g., Carbohydrate counting training, 'Dose Adjustment for normal Eating' (DAFNE), Blood Glucose Awareness Training (BGAT), DESMOND, X-pert etc.)
	Webinars	There is limited feedback from external providers of education on what the outcome of the education was. This information is helpful for clinicians. The importance of refresher education was highlighted.
	Surveys	In response to the question 'What information, if any, should be recorded about the outcomes of the structured education programmes a person with diabetes has attended?' • The most highly cited themes were around programme details including name of programme (n=92), record of attendance/ date (n=75), record of completion/ date (n=41). Several HCP responses indicated a need to record the offer/ date (n=8). • Both PWD (n=9) and HCPs (n=6) cited the need to record a person's view of benefit as well as outcomes including a follow-up plan (n=5 and 14 respectively). • Other themes commonly cited by HCPs included a person's understanding/ competency and confidence (n=7) following structured education. A PWD's engagement/ motivation (n=8) and the need for extra help or a refresher course (n=9) were also cited by HCPs.
	Audits	The National Diabetes Audit requires: • Diabetes structured education programme attended and date

Section	Source	Requirements and justification for inclusion
		The National Paediatric Diabetes Audit requires: • Was the patient using (or trained to use) blood ketone testing equipment at time of visit? Date Level 3 carbohydrate counting education received
	NICE guidelines	• NG17 - 1.6.32 When starting insulin therapy in adults with type 2 diabetes, use a structured programme employing active insulin dose titration that encompasses: injection technique, including dietary understanding. • NG18: 1.3.1 Offer children and young people with type 2 diabetes and their family members or carers (as appropriate) a continuing programme of education from diagnosis. Ensure that the programme includes the following core topics: HbA1c monitoring and targets, the effects of inter-current illness on blood glucose control, the aims of metformin therapy and possible adverse effects, the complications of type 2 diabetes and how to prevent them. • NG28 - 1.2.1 Offer structured education to adults with type 2 diabetes and/or their family members or carers (as appropriate) at and around the time of diagnosis, with annual reinforcement and review. Explain to people and their carers that structured education is an integral part of diabetes care. • NG17 - 1.10.4 Ensure that adults with type 1 diabetes with impaired awareness of hypoglycaemia have had structured education in flexible insulin therapy using basal–bolus regimens and are following its principles correctly. • NG18: 1.2.37 Offer level 3 carbohydrate-counting education from diagnosis to children and young people with type 1 diabetes who are using a multiple daily insulin injection regimen or continuous subcutaneous insulin infusion (CSII or insulin pump) therapy, and to their family members or carers (as appropriate) and repeat the offer at intervals thereafter. • NG17 - 1.3.1 Offer all adults with type 1 diabetes a structured education programme of proven benefit, for example, the DAFNE (dose-adjustment for normal eating) programme. Offer this programme 6 to 12 months after diagnosis. • NG17 - 1.2.4 Offer group education programmes as the preferred option. Provide an alternative of equal standard for a person unable or unwilling to participate in group education. NG17 - 1.3.3 Provide an alternative of equal standard for any adult with type 1 diabetes unable or unwilling to participate in group education.

Note: Information required about maternity and pregnancy outcomes is not included in the diabetes standard but included in the maternity standard. Some information from the maternity standard maps to the Scottish diabetes standards and is required for the diabetes audits (such as whether the baby is alive at 28 days, aborted foetuses and major congenital malformation) so the assumption is that this data would have to be obtained from the maternity systems rather than diabetes systems (if the information is held in separate systems).

Appendix 19 - Mapping of literature against requirements for Diabetes Self-Management Information Standard (glucose)

Information requirements	TREND UK 2017	NICE 2021	Danne 2017	Battelino 2019	Rodbard & Garg 2021	Shah & Garg 2021	Wolpert 2021	Rodbard 2020	Gómez 2018	Gómez 2019	Sheng 2020	Rodbard 2021
	(S)BGM consensus	NICE guideline NG17 update (IN DRAFT)	CGM consensus	TIR consensus	MDI dashboard	HCL dashboard	CIP Insulin metrics proposal	Glucose metrics review	T2DM ROC GV analysis	T1DM ROC GV analysis	HCP glucose metric use	Glucose metrics review
Glucose metrics			X	X	X	X						
Ambulatory glucose profile (AGP)			X	X	X	X						X
Self-monitoring of blood glucose (SMBG) metrics												
Mean blood glucose	X	X										
Monitoring frequency (average tests per day)												
Number of hypoglycaemic episodes measured												
Continuous glucose monitoring (CGM) metrics												
Mean sensor glucose			X	X	X	X					X	X
Glycaemic variability indexes			X	X	X	X			X	X	X	X
Coefficient of variation			X	X	X	X			X	X		X
Calculated estimates of HbA1c			X	X	X	X						X
Glucose Management Indicator			X	X	X	X						X
Times-in-range			X	X	X	X	X	X				X
Time above range (TAR)			X	X	X	X	X	X				X

Information requirements	TREND UK 2017	NICE 2021	Danne 2017	Battelino 2019	Rodbard & Garg 2021	Shah & Garg 2021	Wolpert 2021	Rodbard 2020	Gómez 2018	Gómez 2019	Sheng 2020	Rodbard 2021
TAR Level 1			X	X	X	X	X	X				X
TAR Level 2			X	X	X	X	X	X				X
Time in range (TIR)			X	X	X	X		X			X	X
Time below range (TBR)			X	X	X	X	X	X				X
TBR Level 1			X	X	X	X	X	X				X
TBR Level 2			X	X	X	X	X	X				X
Number of days device worn			X	X								
Time device is active (data capture)			X	X	X							

Appendix 20 - Mapping of literature against requirements for Diabetes Self-Management Information Standard (observations)

Information requirements	Nine Care Processes	My Diabetes My Way (2013)
Self-management observations		
Height (standing / lying)	X	
Weight	X	X
Body Mass Index (BMI)	X	
Waist circumference		
Systolic blood pressure	X	X
Diastolic blood pressure	X	X
Cholesterol	X	X
Urine dip? (e.g., sugars and albumin)	X	
Smoking status	X	X
Carbohydrate intake		
Coded value		

Value		
Units of measure		
Glucose	X	X
Capillary blood glucose (SBGM)	X	X
Coded value	X	X
Value	X	X
Units of measure	X	X
Site	X	X
Interstitial glucose (CGM)	X	X
Coded value	X	X
Value	X	X
Units of measure	X	X
Site	X	X

Appendix 21 - Mapping of literature against requirements for Diabetes Self-Management Information Standard (insulin dosing)

Information requirements	Rodbard & Garg 2021	Shah & Garg 2021	Wolpert 2021
	MDI dashboard	HCL dashboard	CIP Insulin metrics proposal
Self-management insulin administration			
Insulin administration metrics	X		
Insulin profiles	X	X	
Total daily insulin dose metrics			
Total daily insulin dose (mean)	X		X
Total daily insulin dose (SD)	X		X

Percentage of total daily insulin dose delivered as short acting preparation			
Basal dose insulin			
Basal/ day (mean)	X		X
Basal/ day (SD)	X		X
Mealtime doses			
Premeal boluses/ day (mean)	X	X	X
Premeal boluses/ day (SD)	X		X
Correction doses			
Correction boluses/ day (mean)	X	X	X
Correction boluses/ day (SD)	X		X
Time of day			
Blood glucose target			
Insulin sensitivity factor (ISF)			

Appendix 22 - Mapping of literature against requirements for Diabetes Self-Management Information Standard (lifestyle)

Information requirements	Wolpert 2021
	CIP Insulin metrics proposal
Self-management lifestyle diary / user experience	
Meals and snacks	X
Time of meal or snack	X
Size of meal or snack	X
Images of meals	
Carbohydrate intake	
Duration of meal or snack	X
Exercise logbook	

Appendix 23 - Mapping of literature against requirements for Diabetes Self-Management Information Standard (targets / goals)

Information requirements	Diabetes UK Passport
Targets	X
Blood glucose	X
My blood glucose target range	X
My blood glucose target range (lower bound)	X
My blood glucose target range (upper bound)	X
Other targets	X
Target weight	X
BMI target	X
HbA1c target	X
Systolic blood pressure target	X
Diastolic blood pressure target	X
Cholesterol target	X
Physical activity targets	X
Physical activity plan?	X