Professional Record Standards Body

Better records for better care

Diabetes Focused Implementation

Conceptual Architecture

Version 1.0

April 2023

Contents

Document Purpose

This document sets out a draft conceptual architecture to support the introduction of the PRSB information standard for diabetes care as part of the NHS England Diabetes Programme.

This report sets out the project background, the architecture definition methodology, key findings, architecture options, recommendations and next steps and is based on the engagement that took place during 2022 and early 2023.

This includes a summary of the key themes from the architecture discovery work, a review of the emerging use cases, proposed technology options and next steps.

The purpose of the report is to present the proposed architectural approach to key internal and external stakeholders, in order to seek feedback, endorsement and provide interim guidance for the associated diabetes pilot projects.

This document presents the findings and conclusions from 2023 and should be reviewed and updated as the NHS Target Architecture evolves.

Document History

Version	Date	Distribution
0.1	12/2/2023	Internal draft
0.2	14/3/2023	Internal draft for initial internal review
0.3	20/3/2023	Draft for full review
0.4	April 23	Final draft reflecting review comments
0.5	July 24	Minor updates for publication
1.0	Oct 24	Publication version

Executive Summary

Background

Approximately 5.6 million people currently live with diabetes in the UK and of these around 8% live with type 1, 90% type 2, and 2% rarer types of diabetes. Whilst the condition is predominately self-managed, people with diabetes need education and support from health and care professionals across multiple care settings to manage their condition.

To support this need it is important that health and care professionals can access information about a person with diabetes, including data from medical devices. There are two key problems related to data sharing access with a potential impact on care provided:

1. The ability to digitally share information about a person (e.g. care plans) between professionals across different settings and within multidisciplinary teams, leading to a potential risk of harm.

2. The challenge for clinicians in effectively accessing and utilising the data available from the increasing number of self-management medical devices.

Following a number of commitments to improve diabetes care in the NHS England (NHSE) Long Term Plan, the PRSB was commissioned by the NHS England Diabetes Programme, to assist in addressing this situation by:

- producing standards for the sharing of diabetes related healthcare information.
- supporting the identification of suitable pilot projects for the implementation of the standards.
- support for the successful delivery and implementation of the agreed pilots.
- refinement of the support and guidance artefacts based on the outcome of the pilots.

An initial version of the Diabetes Record Information Standard was published in June 2022 and updated in January 2023, the PRSB has been working with NHS Digital to ensure that the SNOMED CT codes are available and provide an initial mapping to the FHIR UK core to support the implementation of the standard (this work identified a number of issues that require further exploration and outputs have not been published).

At the time of writing, NHS England wanted to:

- test the standard with suppliers and providers across the identified use cases.
- clarify the national architecture approach for diabetes data sharing.
- scope the approach to assuring IT supplier and provider conformance with the information standards.

This document details the outcome of the architecture discovery exercise, defining a conceptual architecture and implementation options to support the implementation of the diabetes information standard and is based on engagement carried out in 2022 to early 2023.

Methodology

The architecture discovery activity and definition activities set out to:

- Understand the current and future business strategies and policies and technical strategies and standards.
- Identify what is required to support the implementation of the use cases and scenarios.
- Identify:
    - the problems highlighted by each of the use cases and scenarios.
    - specific data requirements.
    - data currency needs.
    - data management and placement.
    - presentation requirements.

    - alignment to national policies, strategies and programmes.
- Identify potential options and gaps to satisfy use case and scenario requirements.
- Document implementation considerations and guidance to support the above.

Findings

The key findings from the architecture discovery activities can be summarised as follows:

- Data sharing and interoperability problems and challenges
    - Identification of a person with diabetes.
    - Management of diabetes care record information.
    - Lack of care setting specific system data sharing and interoperability.
    - Access to glucose monitoring and insulin dosing information.
    - Data consistency – choice and variety of SMOMED CT codes.
- A complex and changing implementation landscape:
    - Potentially multiple care and support records and apps.
    - A wide array of national data services, some being used more comprehensively than others.
    - A number of change programmes with potentially common or aligned objectives.
    - An emerging future NHS England Target Architecture.

Conclusion

Based on the nature of the findings of the architecture discovery activity, the solution options proposed utilise:

- a central “registry” for the identification of key “repositories” of care information about individuals.
- a “Publish and Subscribe Event Management” strategy to i) communicate the availability of changes to a person’s care information and ii) ensure these communications target the appropriate interested parties in a person’s care at the appropriate time.

The implementation of a federated approach to the request and retrieval of data from multiple recognised external sources of device generated information encompassing glucometric and other diabetes related observations, and insulin dosing information. This would enable the simplification, where required, of the aggregation, consolidation and visualisation of diabetes monitoring data from multiple source devices for a single person with diabetes.

Glossary

Acronym	Definition
ALB	Arm's Length Bodies
API	Application Programming Interface
BP	Blood Pressure
BMI	Body Mass Index
CCG	Care Commissioning Group
CGM(s)	Continuous Glucose Monitor(s)
DAFNE	Dose Adjustment For Normal Eating
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
DRS / DES	Diabetes Retinal Screening / Diabetic Eye Screening
EPR	Electronic Patient Record
FHIR	Fast Healthcare Interoperability Resources
GP	General Practitioner (Primary Care)
GPES	General Practitioner Extract Service
GP2DRS	General Practitioner to the Diabetes Retinal Screen service automated referral
HbA1c	Measurement for glycated haemoglobin
HSCN	Health and Social Care Network
ICS/ICB	Integrated Care System / Integrated Care Board
MESH	Messaging Exchange for Social Care and Health
NAPCHD	National Advisory Panel for Care Home Diabetes
NEMS	National Events Management Service
NHSE	National Health Service England
NRL	National Record Locator
ODS	Organisation Data Service
PCSP	Personal Care and Support Plan
PHR	Personal Health Record
PDS	Personal Demographics Service
PROMs	Patient Recorded Outcome Measures

PRSB	Professional Record Standards Body
PWD	Person with Diabetes
SCR	Summary Care Record
SCRa	Summary Care Record Application
ShCR	Shared Care Records
SNOMED CT	Systematised Nomenclature of Medicine - Clinical Terms
SSP	Spine Secure Proxy

1 Introduction

This section provides an introduction to the diabetes project, its aims, objectives, critical success factors and benefits. It outlines some of the challenges of data sharing and interoperability in the context of diabetes care.

1.1 Background

Approximately 5.6 million people currently live with diabetes in the UK and of these around 8% live with type 1, 90% type 2, and 2% rarer types of diabetes.[1]. Whilst the condition is predominately self-managed, people with diabetes need education and support from health and care professionals across multiple care settings to manage their condition.

To support this need it is important that health and care professionals can access information about a person with diabetes, including data from the medical devices, to enable them to provide the best advice and support.

There is an issue that all the information about a person's diabetes is often not digitally shared between the different professionals involved in their care, resulting in information not being available or easy to access and view in one place, with potential impact on the quality, effectiveness and efficiency of care provided. [2]

Through the NHS England (NHSE) Long Term Plan, commitments were made to a range of actions to help prevent type 2 diabetes and reduce the variation in the quality of type 1 and type 2 diabetes care, including supporting those living with or newly diagnosed with diabetes, to manage their own health through further expanding provision of structured education and digital self-management support tools.[3]

These commitments are underpinned by the Department of Health and Social Care's strategy "Data Saves Lives: Reshaping Health and Social Care with Data"[4], setting out a vision encompassed by three key statements:

- staff will have easy access to the right information to provide the best possible care.
- members of the public and their care teams will have access to timely, high-quality data to improve care quality and inform choices about their care and support.
- the public have confidence in how their data will be handled and are happy for their data to be used to improve the care that they and others receive.

The PRSB was commissioned by the NHS England Diabetes Programme to assist in addressing this situation by:

- producing standards for the sharing of diabetes information between people and professionals across all care settings.
- supporting the identification of suitable pilot projects to become exemplars for the implementation of the standards.
- support for the successful delivery and implementation of the agreed pilots through the provision of implementation support and guidance artefacts.
- subsequent refinement of the support and guidance artefacts to provide materials that can be used to support national rollout of the standards in support of the NHSE Diabetes Programme objectives.

There are two key problems that the project is aiming to help address through the development of the information standards, the associated technical messaging standards and implementation guidance:

1. It is 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

[1] https://www.diabetes.org.uk/about-us/about-the-charity/our-strategy/statistics?gad_source=1

[2] Diabetes Standards Final Report
[3] The NHS Long Term Plan
[4] Data Saves Lives

people having to tell their story more than once and duplication of clinical effort or investigations, for example people 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 and National Paediatric Diabetes Audit 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 people 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.

2. 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 patient-generated or self-reported 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.

The standardised recording of diabetes related outcomes and processes across primary, community and secondary care is an enabler of sharing of data across settings.

The PRSB published a Diabetes Record Information Standard in June 2022[5] which sets out the information that should be included in a healthcare record about a person with diabetes and how the information should be recorded. It includes information that could be recorded by the person in the self-management of their diabetes. This standard was commissioned by NHS England.

Since then, PRSB has been working with NHS Digital to ensure that the SNOMED CT codes that are needed to record the information are available. New SNOMED CT codes were published in the November 2022 UK release focusing on foot checks, meals, driving and glucose metrics and the February 2023 release included insulin dosing concepts.

PRSB has also been working with NHS Digital to map the PRSB standard to the FHIR UK core standard and further work may be undertaken to define the requirements for FHIR resources to support standardised sharing.

In addition, PRSB was asked to consider whether the standard supports Point of Care Test results.

An updated version of the standard was published in January 2023 which includes reference to the new codes available at the time and a small number of changes identified during the previous phase of work.

At the time of writing NHS England wanted to:

- test the standard with suppliers and providers across the use cases (Appendix 1) identified where information sharing currently breaks down and provide materials to support implementation of the standard.
- clarify the national architecture approach for diabetes data sharing and the roadmap for achieving the Target Architecture and scope national resources needed to support the data sharing.
- scope the approach to assuring IT supplier and provider conformance with the diabetes information standards and technical standards (which at the time of writing were to be developed).

[5] Diabetes standards – PRSB (theprsb.org)

1.2 Aim and objectives

The overall aim for NHS England is to improve the sharing of information about a person's diabetes between the person and professionals involved in their care through standardised recording and sharing of information.

The specific aims for this phase of work for NHS England are to:

- Clarify the national architectural approach for the storing and sharing of diabetes data between the settings, individuals and medical devices involved in the provision of diabetes care. This will build on and contribute to national health and care Target Architecture for data and interoperability.
- Identify current and planned national resources to support the national architecture, architectural gaps and the roadmap to the target supported by the development of a strategic interoperability specification / toolkit for diabetes data.
- In support of the overall aim, through the use of pilot implementations, demonstrate the flow of diabetes data to support the key clinical scenarios where currently there is a disconnect or breakdown in ability to share information.

The specific objectives for this phase of the PRSB work are to:

- Confirm the problems inherent in the ability to share diabetes data.
- Support NHS England in the clarification of how the national Target Architecture for health and care data and interoperability applies to the diabetes use cases.
- Support and scoping of national resources to support the sharing of diabetes data.
- Develop a multi-year workplan recommendation.
- Support the NHS England diabetes team in the identification of suitable pilot projects to become exemplars for the implementation of the standards.
- Support the successful delivery and implementation of the agreed pilots through the provision of implementation support and guidance artefacts.
- Obtain, analyse and report on feedback on the standard and barriers to implementation.
- Refine the support and guidance artefacts to provide materials in an implementation toolkit that can be used to support national rollout of the standards in support of NHS England's Diabetes Programme objectives.
- Address key issues in diabetes data sharing through working with IT suppliers at learnathon and hackathon events and share learning.
- Develop an approach for assessing IT supplier and provider assurance of diabetes standards (to include information and technical standards).

1.3 Critical success factors

The key success criteria for this project:

- Clarified national architecture approach for the storing and sharing of diabetes data aligned with the key use cases building on, and using, national strategies for data architecture and interoperability across health and care with identification of new, or changes to existing, national resources required to support sharing.
- Feedback to inform the next version of the diabetes information standards and associated technical messaging standards with the learnings, outcomes and deliverables of the pilot project implementations e.g. mappings of standards to target systems and FHIR resources where available.
- Delivery of a set of reusable artefacts including templates and associated guidance, mappings to FHIR or other systems, case studies including barriers and benefits for the implementation of the diabetes information and technical messaging standards in an implementation toolkit as a core component of the NHS England Diabetes Programme national rollout.

- An agreed model for the assurance of IT supplier and provider conformance with the Diabetes Record Information Standard for standardised recording of information (and future) technical standards for standardised sharing of information.

1.4 Benefits

This work will help to improve the provision of diabetes care by minimising the barriers to adoption of the information standard, through the provision of resources and materials to support providers and suppliers in the implementation of the standard, thereby improving the sharing, accessibility and quality of diabetes data at point of care.

It will seek to address barriers to adoption and provide solutions to the issues raised during consultation on the standard.

Standardised recording of the information is an enabler to sharing the information.

1.4.1 Benefits to people with diabetes

Enabling the sharing of information about a person's diabetes with health and care professionals (with the appropriate information governance controls) will enable better care and support to be given.

1.4.2 Benefits to clinicians/professionals

This work will identify what changes will be needed by health and care professionals in recording and accessing the information content set out in the diabetes standard. It will also address some of the concerns raised by professionals during the consultation like managing large volumes of patient generated data.

1.4.3 Benefits to provider organisations

This work will set out a strategic architecture roadmap enabling providers to plan future conformance with the standard. Resources developed through testing the standard will also be made available to support providers in implementation.

1.4.4 Benefits to IT systems suppliers

Technical artefacts including mapping from testing, feedback from hackathons and the architecture roadmap will all assist IT suppliers in implementing the standard.

2 Architecture discovery and definition methodology

The approach to the architecture discovery activity and definition activities is set out below:

- Understand the current / future business and technical environment:
    - Business – build an understanding of national policies and strategies impacting or potentially benefiting the Target Architecture for diabetes data, associated national initiatives and programmes.
    - Technical – build an understanding of current and future national data and technical standards and services.
- Identify what is required to support the implementation of the use cases and scenarios:
    - Identify the problems highlighted by each of the use cases and scenarios.
    - Specific data requirements, data currency needs, data management and placement and presentation requirements.
    - Alignment to national policies, strategies and programmes.
- Options and gaps to satisfy use case and scenario requirements:
    - Based on the problems identified in the provision of diabetes care, detail the options and opportunities to minimise or eliminate the impacts of the problems through the use of:
        - existing strategic national architecture components to support data sharing and interoperability.
        - a roadmap to set out the use of emerging and maturing architectural components, services, technologies to support improved data sharing and interoperability.
        - recommendations for consideration in the definition of the emerging Target Architecture for NHS England.
    - Identify opportunities to implement the proposed architectural recommendations through the identified diabetes pilot project solutions.
- Document implementation considerations and guidance to support to support the above to include:
    - Local adoption of the Diabetes Record Information Standard based on learnings and outcomes of the pilot projects.
    - National adoption of the Diabetes Record Information Standard.

3 Assumptions

Whilst there is work ongoing to define the future Target Architecture for NHS England, it is assumed the architecture documented within this document should ensure alignment to current NHS architecture principles, technical interoperability standards and where appropriate utilise existing national services, whilst ensuring the roadmap proposals align with the known direction of the emerging national Target Architecture and any associated design principles.

3.1 NHS architecture principles:

The conceptual architecture as documented is aligned to the following current NHS architecture principles[6] noted below:

3.1.1 Deliver sustainable services:

Digital services need to be 'resilient', that is robust and able to withstand and respond to changes arising out of the environmental emergency.

The impact of digital services on "embodied emissions" or ecological and social impact from mining and manufacture (that is, the environmental cost of producing and disposing of IT equipment) should be considered.

3.1.2 Put our tools in modern browsers:

All digital services should be browser based and utilise open web standards, as this:

- provides flexibility for users (and their trusts, Integrated Care Boards (ICBs) or any other administrative group) to choose any modern computers and operating systems that meet their needs.
- supports a move to a mobile-first approach and makes the same digital services easily accessible from mobile phones, tablets, laptops and assistive technologies like screen readers.
- achieves the benefit of the continual security and functionality improvements that come with the continuing evolution of modern browsers and web technologies.

3.1.3 Internet first:

All digital services should adopt internet standards and protocols including setting the default that services are available over the public Internet.

3.1.4 Public cloud first:

Digital services should move to the public cloud unless there is a clear reason not to do so.

Cloud services provide many advantages for NHS England, including a reduction in the time to deploy infrastructure and a significant reduction in emissions.

3.1.5 Build a data layer with registers and APIs:

Digital services should only store data once (usually where collected) and make it available via open APIs whilst maintaining privacy and security.

By storing data only once we reduce costs by removing requirements for data replication/propagation when data is changed, and we ensure that each individual (person with diabetes or clinician) has visibility of the same record.

[6] Source: NHS Digital - NHS Architecture Principles

Through storing data once and making it available via APIs, it reduces the requirements for costly large databases of personal health and care data to deliver our services and meet our research aims - and smaller, dispersed datasets mean fewer large attractive targets for hackers.

3.1.6 Adopt appropriate cyber security standards:

Services must adopt the appropriate cyber security standards subject to risk appetite, including keeping all software, networks, and systems up to date. It is vital to maintain a safe and secure data infrastructure that protects health and care services, patients and the public.

3.1.7 Use platforms:

Digital services should build upon existing platforms to deliver their services.

New digital services should reuse common infrastructure (platforms) and services rather than create their own. This will reduce architecture debt (duplication of digital services and use of non-strategic technologies) which saves money and time for development.

3.1.8 Ask what the user need is:

Every service must be designed around user needs, whether the needs of the public, clinicians, or other staff. Services designed around users and their needs:

- are more likely to be used.
- help more people get the right outcome for them – and so achieve their intent.
- cost less to operate by reducing time and money spent on resolving problems.

3.1.9 Interoperability with open data and technology standards:

Digital services should adopt open data and technology standards.

Open standards permit interoperability between different regions and systems but they also, crucially, permit a modular approach to IT in the NHS, where tools can be replaced with better alternatives as vendors develop better products. This, in turn, will help create market conditions that drive innovation, in an ecosystem where developers and vendors continuously compete on quality to fill each niche, rather than capturing users.

3.1.10 Reuse before buy or build:

Digital services should demonstrate that they have sought to reuse existing solutions before delivering new ones.

Where it is not possible to reuse an existing solution, off-the-shelf (commercial or open source) products should be considered. For open-source products there should be an appropriate level of contractual support provided.

Only having ruled out the former two options should a new solution be built, either in-house or through third parties.

3.2 Technical interoperability standards

Building on the architecture principles documented in the above sections:

- 3.1.5 Build a data layer with registers and APIs.
- 3.1.7 Use platforms.
- 3.1.9 Interoperability with open data and technology standards.

It is assumed that the proposed architecture should be recommending the reuse, where appropriate, of existing common infrastructure and data services, and common or commonly used platforms, where they exist.

There are currently a number of commonly used APIs and data services in existence.

Whilst it is assumed the interoperability standard for the development of future APIs is HL7 FHIR UK Core Release 4, some of the APIs referenced in the document may be built on previous interoperability standards e.g. HL7 V3.

3.3 Emerging implementation principles as documented within the draft future NHS Target Architecture overview

As this document is published, work is ongoing across NHS England to define the future Target Architecture required to support the diverse needs of the organisation. This document makes reference to this work and its emerging outputs, to inform the definition of the conceptual Target Architecture supporting the implementation of the Diabetes Record Information Standard, with the objective of overcoming data sharing challenges in diabetes care.

The following sections explore the emerging implementation principles:

3.3.1 NHS Number is the primary patient identifier

The NHS Number allows the identification of individual people uniquely and nationally, within England and Wales. It is assigned from birth and stays with most people all their lives. Having a single consistent identifier allows us to aggregate together information about individuals as they travel across the health and care landscape.

3.3.2 Adopt international standards and engage with the community to mature these

We will work with international standards where they already exist to ensure that we leverage the development of these standards and make it easy for system suppliers to build for wider markets than just England. Where we use international standards, it may be necessary to anglicise these to ensure they are the best fit for use in England. Where we do so we will work with standards bodies to reflect changes back into the standard.

3.3.3 Validate data at the point of entry

We will set a policy that all data should be validated on input to systems at the source. We will require all national systems to validate the data they capture or that they receive to ensure that we place checkpoints at the exchange of data. This will help us to drive up data quality from the start of the process rather than at the end.

3.3.4 Data is mastered where it is collected

We expect data to reside close to its point of capture and where data is captured remains the master source. Not only does this reduce duplication and the potential issues associated with maintaining integrity across multiple copies, but it also enables data controllers to be more confident in exercising control over access. We prefer code and algorithm to be taken to the data, rather than transport the data to the code, to minimise data movement. There will of course be cases where certain types of data need to persist elsewhere for example, in regional shared care records or national services. When this is the case, the reasoning must be clearly articulated.

3.3.5 All data should be discoverable and accessible via well-defined APIs

Although keeping data stored close to where it is created is an important principle, it is equally important that the data is discoverable when required, along with its origin and any changes that have been made to it to satisfy the four use cases: direct care; population health and proactive care; planning, oversight, and service improvement; research and innovation. This will require the collection of robust metadata from the point of origin

showing the lineage of the data, along with metadata reflecting all changes that have been made to it through any collection, pipeline, and aggregation process.

3.3.6 Data privacy and security are first-class citizens

The right for the person with diabetes to control how their information is viewed and used, whilst being confident that suitable security protection against threats or danger is in place, is key to the success of adoption and acceptance of digital solutions, and in turn effect on operational effectiveness and efficiency. These aspects are to be given as much consideration as functional requirements.

3.3.7 Data should be captured, stored, and shared with a view to the needs of the wider system

Care pathways often involve the delivery of care across care settings where data needs to follow the person. Hence, it is important for care providers to play their part in the wider system by making their data accessible across care settings, aligned to Information Governance requirements. Each care provider is expected to capture data and appropriate metadata to support integrated care pathways, and to make data available through appropriate mechanisms and terms as set out in the Target Architecture.

3.3.8 Maintain public trust and confidence

Maintaining public trust and confidence in how we collect and use data is critical. We must design privacy in at the outset, recognising the expectations and rights of individuals and the legal frameworks within which data may be shared.

4 Discovery findings

The following section sets out the key themes from the architecture discovery activities, the problems identified from review of the diabetes use cases, patient stories and journey simulations defined by the project team, the current implementation landscape and the emerging NHS Target Architecture.

4.1 Data sharing and interoperability problems and challenges

From the clinical scenarios defined by the project team, the following data sharing and interoperability challenges have been identified:

4.1.1 Identification of a person with diabetes:

Whilst there are various sources of information related to a person's diabetes condition, there is no single, consistent and easily identifiable index to identify if a person is subject to a diabetes diagnosis.

It is recognised there are existing sources of shareable diagnosis information, the Summary Care Record (SCR), regional Shared Care Records (ShCR), however there are limitations in the coverage and effective useability of the Shared Care Record. Whilst coverage of the population by the SCR is significant, it's effective use is dependent on the requirement for person's consent to sharing not only the SCR but also the "Additional Information" (SCRAI). Beyond this challenge there is the issue that the required diagnosis information is chronological list, making it difficult to use effectively.

The challenge with recommending the use of a Shared Care Record for the basis of a short-term solution is the varying level of maturity of this as a resource at this point in time, however the Shared Care Record architecture is expected to be a key component of the medium term and Target Architecture roadmap.

This situation has the potential for the following impacts:

- People may be required to relay the story related to their diabetes condition and its care to multiple care providers dependent on the point of care for an encounter.
- Dependent on the person's ability and capacity to share their story, the speed and or quality of care may be impacted, especially in an emergency context.
- A person may be subjected to repeated or unnecessary tests and examinations where a complete picture related to their diabetes status is not available at the point of care.

4.1.2 Mastering of diabetes care record information:

The ability to optimise diabetes care and the associated experience of care of the person with diabetes, is impacted by the ability of clinicians, and other parties with a legitimate interest, to identify, access, review, maintain and share a person's diabetes care information in a timely and efficient manner.

In common with a number of conditions, the nature of diabetes care can result in care plans with a requirement for input and action and feedback from a number of different care givers from specialist diabetes clinicians, general practitioners, practice and community nursing teams, specialists ranging from podiatrists to ophthalmologists, social care teams, education providers, family and friends.

The main responsibilities for the management of a person's diabetes care requirements and as a result the location for the recording and storing of their diabetes care information tend to vary dependent on the type and severity of a person's condition and their personal capacity to manage their care requirements:

- Person with Type 1, usually day-to-day care requirements are self-managed under the oversight of a diabetes specialist in secondary care (circa 500,000 people).
- Person with Type 1, living at home but unable to manage day to day diabetes care requirements, their condition may be managed day to day by personal carers or the community nursing team with secondary care specialist oversight.
- Person with Type 1, living in social care. Their day-to-day care requirements may be managed by themselves, the community nursing or social care teams, with secondary care specialist oversight.
- Person with Type 2, usually self-managed under the oversight of their GP within primary care (circa 4m people).
- Person with Type 2, living at home but unable to manage day to day diabetes care requirements, condition managed day to day by personal carer or the community nursing team with GP oversight.
- Person with Type 2, living in social care. Their day-to-day care requirements may be managed by themselves, the community nursing or social care team, with GP oversight.

A limited number of people with type 2 diabetes with complex care requirements are managed within secondary care clinics.

In addition to people with type 1 or type 2 detailed above, there are a number of other specialist diabetes condition types, such as gestational diabetes or monogenic diabetes. Whilst this version of the document will focus on the requirements of type 1 and type 2 care (as this equates to the majority of the population of people with diabetes) it is assumed the proposed data sharing approaches can be applied to these other conditions without issue.

Dependent on their circumstances noted above, information related to a person's diabetes care may be recorded in one or more electronic systems. These systems can range from diabetes condition specific systems through generic EPR systems, medTech device supplier's datastores of glucometric observations and insulin medication dosing information, to encounter related letter systems.

As a result, a person's diabetes care information is currently "mastered", close to its point of capture, as a series of record fragments held across multiple locations, in varying forms.

Whilst this approach aligns to a core architectural principle (see section 3.3.4), in the current absence of effective interoperability or data sharing solutions, the discoverability and accessibility and maintenance of a comprehensive view of a person's diabetes condition can be difficult achieve.

This situation has the potential for the following impacts on care:

- Clinicians at point of care may not be aware of a person's diabetes diagnosis.
- Clinicians at point of care may not have access to the most up to date information related to a person's condition and their associated care plan and actions status.
- People with diabetes or their carers may be required to relay the story related to their diabetes condition and its care to multiple care providers, multiple times dependent on the point of care and circumstances.
- Interested parties in a person with diabetes' care planning and care delivery may not be party to changes in care planning or the management of care plan goals and actions e.g. specialist referrals, screening and pathology testing referrals and results.
- People with diabetes may be subjected to unnecessary tests or examinations where their current diabetic care status is not readily available at the point of care.
- Community and social carers and personal carers may be unable to contribute to care plans, care planning goals and actions status e.g. observation and examination outcomes, diet and fitness goals, objectives and current status.

4.1.3 Lack of setting specific system data sharing and interoperability:

Building on the generic problems noted above, the following section explores some of the specific problems created by the nature of diabetes care in ensuring care givers are consistently provided with timely and complete information given the current lack of automated data sharing and system interoperability.

From review of the 18 scenarios defined by the project team (Appendix 1), the following challenges have been identified related to data sharing and a lack of systems interoperability:

- As noted above (in 4.1.1), no single complete and consistent source for confirming the existence of a diabetes diagnosis.
- Sharing of test, examination and screening results with interested parties in a person's care e.g. retinal eye screening.
- Sharing of referrals and the outcome of referrals, such as referrals to structured education.
- Lack of direct access via "systems of choice" to glucose monitoring and insulin dosing information.
- Sharing of care plan information for both input to the planning activities and subsequent monitoring and tracking of progress towards personal goals and objectives.
- Sharing of complete and consistent condition status and care planning information when transferring between care providers including transfers of care for planned and unplanned secondary care, emergency and acute care and when transferring between primary care providers.

The following paragraphs provide some specific examples of the problems and challenges identified above.

- Sharing of retinal eye screening results is a specific problem use case. Referral to the Diabetic Eye Screening (DES) service can be made automatically via the GP2DRS service, with qualifying people with diabetes being directly identified from their GP's EPR system, or through referral from a secondary care clinic.

  The screening results are returned to the person's GP practice irrespective of the origination of the referral. Due to a lack of interoperability between the primary and secondary care systems, where the person's care is under the management of a secondary care clinic, the clinic is dependent on a person's GP practice forwarding the results to the clinic, or direct enquiry by clinic staff to the GP practice team.

  This circumstance results in inefficiencies in the process and potential delays in a person's care.

- A generic challenge related to the lack of information sharing and interoperability is the inability for the potentially multiple interested parties in a person's care, contributing to and sharing in a person's care planning and tracking progress against their care plan goals and objectives.

  These interested parties potentially include: community nursing teams; personal carers; social care teams and where not managing their diabetes condition, a person's GP.

- A further problem with the lack of interoperability relates to structured education. This includes the sharing of attendance and course outcomes between the education providers and the referral originators.

4.1.4 Access to glucose monitoring and insulin dosing device information:

Automated, wearable glucose monitoring and insulin dosing devices are being routinely provided to people with Type 1 diabetes and some with Type 2 diabetes, to support the self-management of their diabetes condition.

There are three primary mechanisms for clinicians to gain access to data and reports available from these devices or their suppliers:

- People may provide consent for clinicians to access information including formatted reports provided by device suppliers from their secure data warehouse platforms.
- A number of data aggregators also operate in this space e.g. Glooko Inc. With the consent from people, these aggregators offer clinicians the ability to integrate information from multiple separate devices e.g. glucose monitors and insulin pumps, providing combined reporting for monitoring and dosing information.
- Alternatively, clinicians may be required to access device monitoring or dosing information direct from the person's own device provider app on their personal mobile devices.

This situation has the potential for the following impacts:

- Clinicians may be required to manage user access credentials for multiple proprietary supplier glucose monitoring and insulin dosing device providers or data aggregation platforms, accessing multiple platforms during a single clinic in support of their condition management and care planning activities.
- Where a clinician utilises a data aggregator's platform, they are dependent on ongoing commercial relationships between device suppliers and the data aggregator for the continuation of their service. Clinicians have identified that some device suppliers are withdrawing from some aggregator platforms.
- People may be required to provide clinicians access to their personal mobile devices to provide access to the required monitoring or dosing information. This limits the clinicians access to the associated information for preparation and any other activities in the absence of the person with diabetes and limiting their ability to record the data used in making clinical decisions.

4.1.5 Data consistency – choice and variety of SMOMED CT codes

As noted above the Summary Care Record Additional Information provides a source of condition diagnosis, problem and issue information including that for diabetes.

One of the challenges with this specific source of information is the available choice and variety of SNOMED CT codes for clinicians when encoding a specific diagnosis, problem or issue such as diabetes.
Whilst a valid use of the coding system, the breadth of codes available to a clinician to capture the detail of a potentially complex condition such as diabetes makes the use of a source such as the Summary Care Record impractical as an index indicating the existence of a more "generic" level of diagnosis.

4.2 Implementation landscape

The purpose of this section is to provide a brief overview of the current environment, providing the background to the conceptual architecture recommendations to support the requirements of diabetes care and the embedding of the diabetes information standards.

4.2.1 Conceptual architecture model

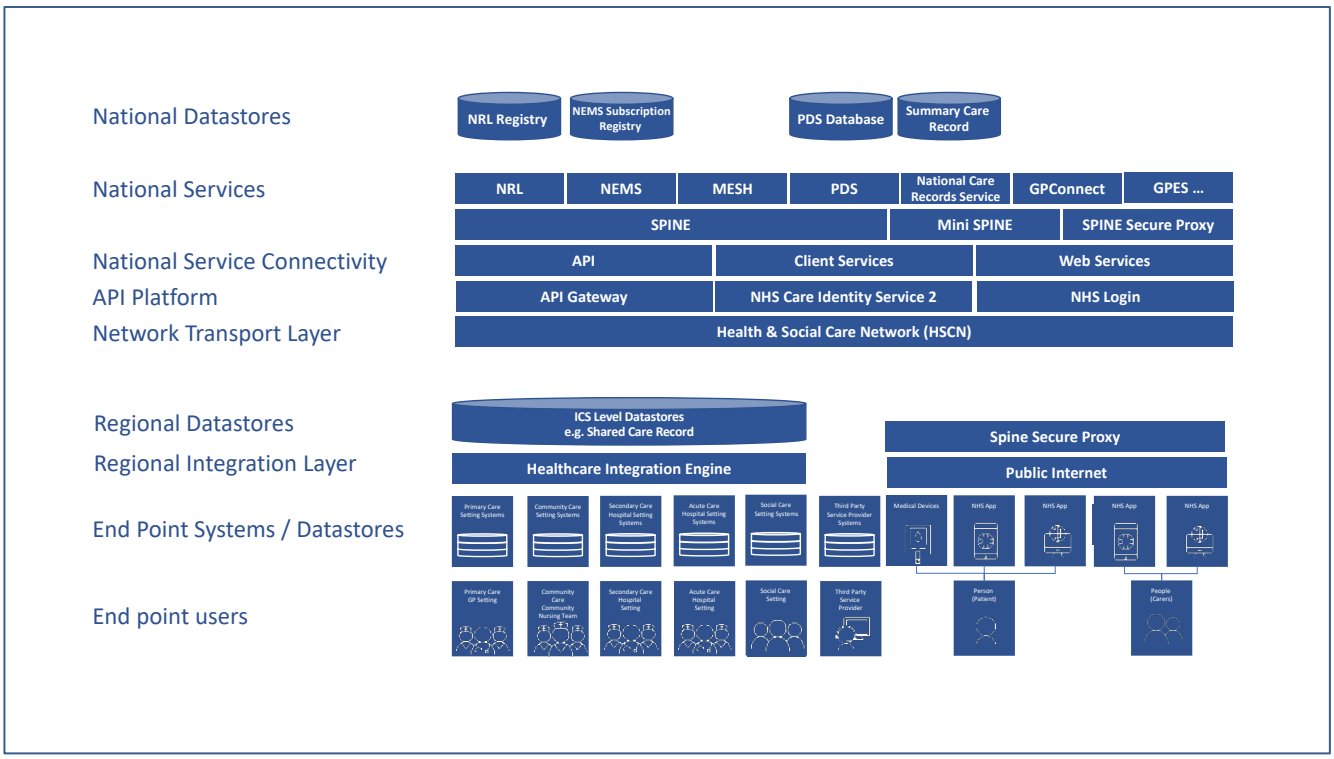


Diagram 1 Implementation landscape – conceptual architecture model

The above diagram provides a conceptual view of the significant architectural components of the implementation landscape, the key end user settings, systems and datastores, regional and national datastores integration service components.

4.2.2 Care and support records

Review of the implementation landscape has identified there are a number of sources of a person's healthcare and healthcare related records in end point user systems, reflecting the setting and providers of a person's care including:

- Primary care / General Practice.
- Secondary care.
- Community nursing team.
- Social care.
- Specialist and third-party care providers e.g. diabetic eye screening services.
- Structured education providers.

There are also a number of apps for self-management that provide sources of care related information including:

- NHS App.
- Other related third-party apps including MyDESMOND[7] and DigiBete[8].
- Glucose monitoring and insulin management device apps.

[7] MyDESMOND website

[8] Home - DigiBete

In addition to the above sources of self-management information, the architectural discovery activity has identified the following national and regional sources of information relevant to the conceptual architecture:

- Summary Care Record (SCR) - is an electronic record of important healthcare information about the person, created from GP medical records. They can be seen and used by authorised staff in other areas of the health and care system involved in the person's direct care
    - Over 55 million people in England have an SCR (c96% of the population - CQC Dec '22).
    - C89% of SCR include additional information, diagnoses, problems and issues (c49 million people).
- Shared Care Records (ShCR) - previously called Local Health and Care Records, are an ICS implementation level mechanism for bringing together important records from the different organisations within the ICS involved in a person's health and social care. The information is then visible to frontline health and social care professionals, at the point of care, usually in a read-only view.
- Personalised care and support planning is a systematic process based around 'better conversations' between the person and their health and social care practitioners. The overall aim is to identify what is most important to each person for them to achieve a good life and ensure that the support they receive is designed and coordinated around their desired outcomes.

  It brings together those with lived experience and those with technical expertise to identify all the issues, develop solutions and initiate actions.

  The outcome should be a single plan (a Personalised Care and Support Plan (PCSP)), no matter how many conditions or issues have been identified, which will be reviewed regularly. As such a person's diabetes care plan is a key contributor to their overall plan, actions and goals.

  Currently a person may have many care plans written by various health and care providers and stored in various physical systems.

4.2.3 National services

In addition to the above noted sources of information about a person with diabetes the architecture discovery activity has reviewed a number of national services. Access to these national services is enabled via the NHS health and social care SPINE infrastructure, connecting c23,000 healthcare IT systems across c20,500 organisations[9], connected via the Health and Social Care Network (HSCN).

Access to the majority of SPINE services is managed based on authentication via the NHS Care Identity Service 2, using multi factor authentication of health and care professionals including smartcards and biometrics.

Some non-health and care organisations can access a limited number of reduced functionality services via the Mini SPINE, for example the Personal Demographics Service (PDS) for the verification of a person's demographic details.

The minimum requirement for any organisation, and its staff, to gain access to either the SPINE or Mini SPINE services is qualification for an Organisation Data Services (ODS) code enabling access to the HSCN.

The national and regional services reviewed have included:

- PDS - Personal Demographics Service provides access to the national electronic database of details about patients and the public such as name, address, date of birth and NHS number.
- NRL – National Record Locator service enables authorised users to find specific records about an individual that are held on different health care systems.
- NEMS - National Events Management Service enables the sharing of specific health information about a person in near real-time. Information is shared in the form of event messages, following a publish and subscribe model and using the NHS Spine event related data management.
- MESH - Message Exchange for Social Care and Health is the main secure large file transfer service used across health and social care organisations.

[9] Source: NHS Digital > Services > Spine

- e-RS - e-Referral Service provides an easy way for patients to choose their first hospital clinic or elective care appointment with a specialist.
- GP Connect - GP Connect allows authorised clinical staff to share and view healthcare information about an individual held in GP practice systems between IT systems, quickly and efficiently.
- GPES - General Practice Extraction Service collects information for a wide range of purposes, of specific interest is its support for GP2DRS.
- GP2DRS - General Practice to Diabetic Retinopathy Screening automates the sharing of qualifying patient information between general practices and local diabetic eye screening programmes, qualifying patients being identified via GPES.
- GP2GP – Allows a person's electronic health record to be transferred directly, securely, and quickly between their old and new practices, when they change GPs.
- Pathology Messaging – FHIR – Enables the sharing of pathology results from a Laboratory Information Management System to the requestor in NHS primary or secondary care settings.

4.2.4 Associated change programmes

The architecture discovery activity has identified and engaged with the following associated change delivery programmes to identify common areas of interest:

- NHS England Virtual Wards Programme - A virtual ward is a safe and efficient alternative to NHS bedded care that is enabled by technology. Virtual wards support patients who would otherwise be in hospital to receive the acute care, monitoring and treatment they need in their own home.

  The shared area of interest between the Virtual Wards Programme and Diabetes Programme relates to the sharing of self-monitoring device data with clinicians engaged in a person's care. Whilst establishing a level of shared interest through this engagement, it has been established that the immediate focus for the virtual wards team does not include glucose monitoring and insulin dosing information.

- Primary, Community and Personalised Care (PCPC) – The outcome for the personalised care programme is to deliver a single plan, no matter how many conditions or issues have been identified, with a person's diabetes care plan being a key contributor to their overall plan, actions and goals.

  A key area of common interest between the PCPC and the Diabetes Programme relates to the ability to share a person's care planning information with potentially multiple interested parties in that care and providing the ability to review and contribute to a person's care plan, ensuring all parties have access to the most current and consistent information when making decisions setting plans and defining goals.

- Digital and Interoperable Medicines Programme - Established to support the development and adoption of IT systems that will enable information about a person's medication, allergies, intolerances and prescriptions to flow seamlessly across all health and care services.

  The key area of shared interest between the Digital and Interoperable Medicines Programme and Diabetes Programme relates to the potential use of an events-based architecture to manage the sharing of information related to changes in the status of a person's care.

4.2.5 Future landscape - NHS Target Architecture

As noted above the conceptual architecture for diabetes care has been developed in parallel to the ongoing definition of the future Target Architecture for NHS England. Whilst there is no direct dependency of the proposals and recommendations in the document on the outcomes of the future NHS Target Architecture definition activities, the approach to the conceptual architecture definition seeks to ensure alignment with the emerging thinking, providing a migration path to the future Target Architecture environment.

The emerging future Target Architecture encompasses 4 use cases:

- Direct care:

  Direct care is provided by health and social care staff working in care teams, which may include doctors, nurses, and a wide range of staff on regulated professional registers, including social workers. It leads to improved patient care, safety, and experience.

It includes access to real-time data with read and write access and identifiable data required to deliver direct care. Depending on their role, health and social care staff would need access to care records including appointments, care plans, communications, safeguarding etc.

Individual direct care is therefore the activity most associated with the benefits to people and patients and should be at the heart of the Target Architecture. Without the ability to capture store and exchange information derived at the point of care to a high level of quality, it cannot be realistically considered how that information - in any other form - can be reliably used for any other purpose.

- Population health and proactive care:

  Population health addresses the need to be able to explore whole populations to better understand the specific needs of cohorts within those populations, whether based on geography, age, or condition. It includes screening, prevention, case finding, campaign management, proactive care, decision support and outcomes evaluation. It leads to improved population health, effectiveness, and reduced health inequality.

  Risk prediction and stratification is a specific task within the remit of population health management which identifies those cohorts for whom a direct intervention may be possible.

  It includes access to daily or real-time data updates and identifiable data might be required by authorised staff to enable direct care (ICS level user and below e.g., place, provider).

- Planning, oversight, and service improvement:

  The service improvement and operational planning use case is to monitor operations and services to determine how they could be more efficient and productive. It includes capacity and demand management, health inequality insight, performance management, workforce planning and financial and contract management.

  The users are health and care staff and other Arm's Length Bodies (ALBs) users e.g., Care Quality Commission. It includes access to weekly or hourly data updates (depending on criticality of action).

  Depending on their role, health and social care staff would need access to data so that an individual patient cannot be identified.

- Research and innovation:

  Data can be used to discover which treatments work best, in which patients, and which have side effects. It can be used to drive innovation across the life sciences sector. This includes clinical trial recruitment and follow-up, disease progression and understanding, deep-learning AI, and clinical trials set-up. This leads to improved population health, reduced health inequality and positive economic impact.

  The users are academic institutions, charity sector and industry researchers. It includes access to weekly or monthly data. The data is anonymised for the majority of use cases so that there is no patient identifiable information. Trial recruitment and follow up requires re-identifiable data.

Focus for this document in terms of alignment with emerging themes from the Target Architecture are those components that impact direct care.

Multi-layer architecture:

The conceptual target is based on a multi-layer architecture. The following section identifies the key components of this architecture of interest in terms of alignment when defining the solution architecture options for diabetes:

National layer

The national layer includes the following components of interest for solution architecture alignment:

1. The national health and care hub is a collection of strategic national platforms and services provided by NHS England from the legacy of NHS Digital. The hub provides authorised consumers and producers of the system with access to the data. The hub includes an orchestration service which will support access and exchange of data to and from national systems. The orchestration service is an abstraction layer that sits on top of the national services, it will take NHS number in an API call and will make multiple

calls to hide complexity from the user. The orchestration service will utilise existing strategic national services e.g., the National Record Locater Service which will be enhanced to support the Target Architecture.

2. The NHS App and other national apps and services use services present in the Health and Care Hub to present data, transactional services, and advice and guidance for the person.

Integrated Care Systems (ICS) (regional layer)

At the regional level, several data systems and applications may exist. These aggregate and support the flow of information within the geographical boundary, which they cover. The regional layer includes the following components such as:

1. Regional data systems: There are several existing ICS data systems used as secondary use data stores within ICSs and regions. Consideration will need to be given to these services on a case-by-case basis to determine how they will evolve. This is delegated to the regional teams to define.
2. Shared Care Records (ShCR): An ICS, or collection of ICSs, may have a ShCR to support the provision of information to care professionals delivering care to patients.
3. Personal Health Records (PHR): Some ICSs have implemented PHRs within their region to provide digital access to health information, and to capture information from the person. Consideration will need to be given as to what information will be available natively through the NHS App over time, and how that impacts what will need to be provided at a regional level.

Providers (local layer)

At the local or provider level, local data systems exist as the system of record and authoritative data source related to patient care. This is the most granular source of data and is updated in the real time.

The local layer includes important components as:

- Local apps: These include several apps e.g., GP portal, ward dashboards, clinical EPRs and A&E departmental reporting.
- Local data systems: These include several systems e.g., GP systems, mental health, and community systems etc.
- Federated Data Platform local tenancy: The platform is an elastically scalable capability that will host the data platform, analytical solutions and platform applications at the local level. This will integrate with the local systems at the trust level. The Federated Data Platform is also at ICS and national levels.

Foundation layer

- Reference data and standards: The use of reference data and standards will enable the various applications that provide end users with the functionality they require and will interact with the data systems through a comprehensive set of appropriate standards.
- Information governance and policy: Information governance is an important element to enable the tiered architecture and using the data for the 4 use cases when the data is collected or captured primarily to provide direct care.
- Cyber and security controls: These are the guardrails supported by the standards and tools provided by the national team to all layers in the architecture.

5 Proposed architectural solution options

The proposed options and recommendations for the conceptual diabetes solution architecture are presented in 3 phases:

- Near term: The initial proposals focus on foundational options that seek to exploit the use of existing national services, capabilities and infrastructure, that it is anticipated could be progressed with a minimal requirement for change to address some of the challenges and problems identified within the diabetes use cases.

- Medium term: The secondary focus of the conceptual architecture is to consider the potential to exploit new, emerging and maturing regional capabilities to address the challenges of data sharing and interoperability within various use cases supporting diabetes care. There is an expectation these proposals will require a higher degree of change.
- Long term: With the ongoing activity to deliver a target architecture by NHS England, the long term focus for the conceptual architecture identifies the future proposed areas of interest to ensure alignment with NHS England's Target Architecture.

A key challenge for a number of direct care scenarios, including diabetes, relates to the ability to identify and access the current and up to date information relating to the status of a person's condition.

For diabetes this includes information related to the current status of the 9 key care processes, from blood and urine pathology results to the outcomes of periodic diabetic eye screening, examination outcomes such as diabetic foot risk, and observations such as blood pressure and BMI through to the availability of both summary and detailed observations and administration data from self-management devices such as glucose monitors and insulin pumps.

In addition to specific clinical data there is the need for broader information including an understanding of a person's level of awareness of strategies to manage their condition, offered through structured education and their related personal goals and ambitions associated with their care planning.

The challenge arises as this data may be located, and on occasion duplicated, across multiple systems and care settings.

In common with a number of planned care scenarios, there is also the potential for a number of interested parties in some or all of the care information. These include the clinical team charged with management and oversight of the person's condition, their GP, where not responsible for day to day management of the condition, community nursing and social care teams, through to the person themselves and where appropriate their personal carers, friends and family.

Dependent on their role, these interested parties may have a need to review and or contribute to this information.

Given the nature of the condition there is also a need to ensure the availability of condition status information for providers of care in the event of unplanned care episodes e.g. paramedics and emergency department staff.

Based on the nature of the findings of the architecture discovery activity, the following solution options are based around an approach to utilise a central "registry" for the identification of key "repositories" of a person's diabetes care information and a "publish and subscribe event management" strategy to i) communicate the availability of changes to a person's care information and ii) ensure these communications target the appropriate interested parties in a person's care at the appropriate time.

The discovery activity has been informed by review of both regional and national architectures, with the proposals intended to operate in the context of both, even where these may not be fully aligned.

The foundation strategy for the near-term proposals is the use of existing national services to address the following challenges:

i) identify a person's diabetic status, through the confirmation of an existing diabetes diagnosis.

ii) identify the location for the person's "master" set of diabetes specific care information, referred to as a person's "principle diabetes care record".

iii) publicise changes in the status of a person's care, and the address the availability of updates to information for the interested parties in the person's care.

It is proposed to use a combination of the existing National Record Locator (NRL) service and the National Event Management Service (NEMS) to support this approach.

Building on the near-term proposals to utilise national services and infrastructure, medium-term options to utilise regional services including the ICS level Shared Care Record architecture have been considered, with a view to enabling read-only sharing of a person's diabetes care information.

Whilst the discovery activity has been undertaken in cooperation with the personalised care programme team, use of the personalised care and support plan as a specific source or store for diabetes care information does not currently feature in this version of the proposed architecture solution options.

The proposed architectural options do however recognise the ongoing importance of the personalised care and support plan philosophy, existing process and outputs as a potential source of input to diabetes care planning goals and objectives. As such this version of the architecture proposal for diabetes will consider the personalised care and support plan as an "interested party" in diabetes care information sharing.

As the thinking in terms of the personalised care plan Target Architecture matures, the outcomes of the Personalised Care programme should be reviewed and incorporated into the roadmap for the diabetes specific Target Architecture as both a potential source of input to diabetes care planning and interested party in the outputs.

5.1 "Mastering" of a person's diabetes information

As noted in section 4.1.2 a key challenge for the management of a person with diabetes care relates to the ability to identify, access and maintain a comprehensive view of their current diabetes care information.

As noted above there may be multiple sources of healthcare data, with this data held in various forms.

A foundation for the near-term conceptual architecture is the identification of the location for the principle set of diabetes specific care information, referred to in this document as a person's "principle diabetes care record", enabling the ability to distinguish this key set of information from other potentially relevant diabetes related information.

The intent of creating this distinction is to enable an interested party in a person's care to quickly and consistently access the location of the most up to date diabetes care information.

It is important to stress this term is not intended to suggest the existence of a diabetes specific physical record, as noted above, the term relates to the location of the principle set of diabetes care information for a person.

It is proposed this "principle diabetes care record" location for a person is determined by the setting recognised as having the responsibility for managing a person's diabetes care.

As noted above for the majority of people with Type 1 diabetes the master care location will be the secondary care clinic managing their care, with their GP practice being the master location for the majority of people with Type 2.

A consistent approach to the identification of the "principle diabetes care record" has the benefit of removing any ambiguity related to the currency of a particular dataset being reviewed.

It provides interested parties with a consistent reference point for information related to the current status of the person's care.

5.2 Consistent identification of a diabetes diagnosis NRL

It is proposed to record and communicate the location of a person's "principle diabetes care record" through the use of the National Record Locator (NRL) service.

It is proposed that where a patient has a confirmed and current diabetes diagnosis, an entry is made in the NRL with a pointer to the location of their "principle diabetes care record", being that diabetes care dataset held by the setting responsible for the management of their diabetes condition.

There are a number of implementation considerations to be addressed in support of the proposed approach, noted below.

Once fully rolled out, through the presence or not of a current diabetes diagnosis pointer in the NRL, there is the ability to create a readily available and consistently populated national index of patients with a current diabetes diagnosis, directly addressing the problem noted in 4.1.1.

5.2.1 Diabetes diagnosis index implementation considerations

For the proposed index to provide an effective and unambiguous list of current people with diabetes a number of implementation considerations need to be addressed:

- A precise clinical definition and ruleset is required for an existing diagnosis of diabetes and the conditions under which a pointer should exist in the NRL. This to ensure there is no ambiguity related to the existence of an ongoing condition, as opposed to the existence of a historic diagnosis e.g. gestational diabetes.
- Confirmation of any implications and additional requirements for the person's consents related to the proposal.
- The approach for the initial population of the index. Some potential options are explored in the next section.
- Consideration also needs to be given to the options for ongoing population and maintenance of the index including:

  i) the need for an approach to the removal of a pointer from the index, in the event a person recovers from their diagnosed condition.

  ii) the approach for updating the "principle diabetes care record" pointer, in the event the responsibility for the management of a person's diabetes condition changes.

  options may include:

  i) manual maintenance of the index entry by the clinical team in the "principle diabetes care record" location, via their EPR system.

  ii) automated rules-based maintenance by the endpoint EPR system or a national GPES type service.

  iii) some combination of the two options above.
- It has been identified that whilst the proposal assumes that the setting responsible for managing a person's diabetes care will be operating some form of EPR system enabling the recording inputs to and outcomes from diabetes specific patient encounters, and the proposed location for the "principle diabetes care record", this assumption may not true in all cases. An option to overcome this would be the identification of the person's GP practice as the location holding the "principle diabetes care record". It is assumed agreement would be required from the GP practice due to the need to ensure the record held accurately reflects the current status of the person's diabetes care and care plan.

5.2.1.1 Options for initial population of the NRL diabetes diagnosis index:

For this proposal to be effective consideration needs to be given to the approaches for population of the NRL diabetes diagnosis entries, include consideration of consent requirements:

- Bulk Upload: It may be possible to populate the NRL index via an extract from the person's primary care EPR using existing mechanisms for the creation of the Summary Care Record, or that used for the GP to diabetic eye screening service extract (GP2DRS), created using the GP Extract Service (GPES).

  The extract will be dependent on the ruleset definition for the existence of a diagnosis noted above.
- Encounter based population: An alternative approach is that of populating the index on an encounter-by-encounter basis. Whilst potentially lower impact in terms of change requirements and cost to achieve population of the diagnosis index, this approach has the potential to extend the period to complete the population of the diagnosis index, limiting the potential effectiveness of the approach in the short term.

5.3 Sharing data related to a person's diabetes care:

Having proposed an approach to overcome the challenge of identifying the location for a person's "principle diabetes care record", the next challenge is a mechanism for identifying the key information required to be shared, with whom and when.

A review of the problems noted in section 4.1.3, has identified are number of potentially important events resulting from changes in the person's condition status, or to notable triggers due to updates to diabetes care information, the occurrence of which could or should be notified to a wider group of interested parties in the person's care, facilitating the timely sharing of the associated data with these parties.

The circumstances identified relate to both periodic events during a person's care, or changes in the status of key indicators for the 9 key processes used in the management of their condition e.g. HbA1c test results, Body Mass Index (BMI) and blood pressure.

For a typical person with Type 1 diabetes these changes are likely to include changes to blood glucose Time in Range summary metrics and insulin administration summary metrics.

For a typical person with Type 2 diabetes these events are likely to include the availability of periodic eye and foot screening results, structured education outcomes or changes in status related to personal care goals and objectives.

Whilst review of the diabetes use cases and scenarios, as detailed in Appendix 1, has identified a list of potential data sharing triggers, or events, noted in Appendix 2, a precise clinically agreed set of events and the potential population of interested parties for the related information outcomes is required.

The proposed approach to sharing this data centres on the ability to publicise the occurrence of an agreed set of events, with an agreed set of interested parties in the person's care, being able to subscribe to these published notifications and access the information related to these events.

Aligned with the published Diabetes Record Information Standard, this document will deal with the proposed architectural approaches to supporting the sharing of diabetes-related care information in 2 broad sections:

- A general approach to facilitate the sharing of information needed to support a person's diabetes management. It includes information that could be recorded by health and care professionals or the person themself that is relevant to the diabetes care of the person and should be shared between different care providers, being aligned to the implementation of the Diabetes Record Information Standard.
- The specific approaches to facilitate the sharing of information that could be recorded by the person (or their carer) at home (either using digital apps or medical devices) and shared with health and care professionals, aligned to the implementation of the diabetes self-management information model (part of the Diabetes Record Information Standard).

5.3.1 Sharing data aligned to the Diabetes Record Information Standard:

Building on the proposals noted above to:

- Create an agreed ruleset for the existence of a current diabetes diagnosis and the creation of an NRL based index of diabetes diagnoses.
- Create the mechanism to identify the location of a person's "principle diabetes care record".
- Create an agreed ruleset for the identification of the diabetes care related data sharing events and triggers.
- Create an agreed set of potential interested party roles.

It is proposed to make use of the current National Events Management System (NEMS) service to publish occurrences of the agreed data sharing events to the subscribing interested parties.

5.3.1.1 Use of the National Events Management Service (NEMS) architecture

It is proposed that the interested parties make an explicit subscription to receive notifications related to events for a specific person with diabetes.

The scope for sharing information via this approach is limited to interested parties with access to NEMS, and its supporting message exchange service MESH.

It is proposed that sharing of data with interested parties other than authorised NHS staff, e.g. the person with diabetes, their family or carers, will be provided via access to the NHS App. The NHS App allows interested parties access to components of the person's GP health record, with data access consents being managed by the patient and their GP practice.

Information currently available via the App is limited to details related to allergies and adverse reactions, treatments and medications, immunisations, test results, letters and notes made in a person's GP record.[10]

In the medium term it is recommended that focus is given to broadening the scope of information available to view via the NHS App to include diabetes specific information. Additional development of the NHS App to support integration with other third party Apps, e.g. MyDesmond, Apple Health, Fitbit, DigiBete, diabetes management devices etc, would allow the ability to capture and share information in support of activities such as input to diabetes care planning and goal progress tracking.

5.3.1.2 How NEMS enabled data sharing is proposed to operate for diabetes – near term options

The diagram 2 below provides a simplified overview of the operation of the existing NEMS service.

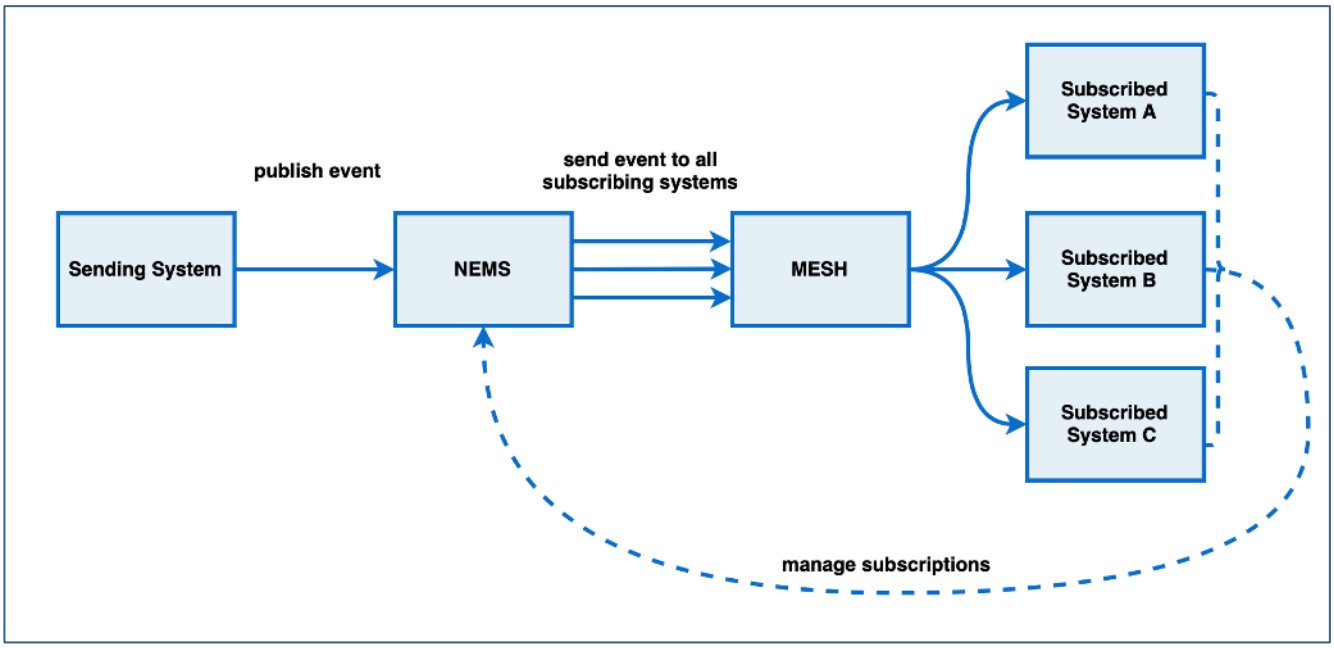


Diagram 2 National Events Management Service (NEMS) - overview[11]

Having identified a publishable event, the originating system posts details of the event to the NEMS service.

This detail includes the "type" of event and an associated "payload" of information published related to the specific event occurrence.

The content of the published details can include files of up to 20GB in size including documents, pdfs and FHIR resource bundles.

[10] Access to patient records through the NHS App

[11] NHS Digital National Events Management Service (NEMS) - Overview page

Using the list of subscribers associated with a patient who is subject to the event, NEMS will publish the details of the specific event to the list of subscribers via the Message Exchange for Social Care and Health (MESH) service.

The event details are delivered to the subscriber's MESH inbox.

Once delivered there are options for how the event notification is processed:

- the subscriber can review the event type details and decide if they wish to action the event and update locally held records.
- the event can be actioned without intervention with for example FHIR resource bundles for specific event types being consumed and processed automatically by the receiving system.

In the near term it is proposed that this approach is used to address the specific gap in data sharing related to secondary care clinics not receiving diabetic eye screening results:

- It is assumed not all diabetic eye screening providers will have an ODS code and hence no access to NEMS. To ensure consistent notification of the availability of screening results, it is proposed that GP practices, being the default recipient of the screening results, on receipt of a person's results, check for the existence of a notification of the event related to the publication of the screening results availability via NEMS, where no such notification exists, the GP practice publishes the notification, thereby indicating the availability of the results to all interested parties, including the secondary care clinic managing the person's diabetes care.

  Where screening providers have access to NEMS, direct publication of the screening results availability event will ensure all interested parties are made aware without delay, avoiding the need for action by the GP practice.

This approach can also be used to ensure interested parties are informed of the availability of information related to pathology results and the outcome of foot screening.

In the near term, further analysis is required to explore the underlying issues and reasons for the breakdown in data sharing and interoperability related to tracking and understanding the outcomes from structured education referrals.

- It appears that the majority of structured education provision for both type 1 (DAFNE) and type 2 (DESMOND) courses are coordinated through functions within NHS organisations.
- It is assumed these organisations will have an ODS code and hence access to the national services NRL and NEMS.

This being the case, where available to them, the coordinating functions should follow the process noted above for diabetic eye screening results availability, and publish those events related to the outcomes of a person's structured education referral, based on the information from the education providers.

Where the coordinating functions do not have access to the course providers' outcomes, an alternative medium term solution will be required to support the request of information direct from the course providers.

5.3.1.3 Medium term options

In the short term, the options noted above are limited by the availability, to the end point users and systems, of access to the key national services of NRL[i] and NEMS[ii] to enable the physical sharing of patient care status information.

There are 2 options in the to address this situation in the medium term:

- Extension of access to the national services for all providers of diabetes care information. This could be established through the requirement for all organisations engaged in the provision of diabetes related services to be ODS enabled, accompanied by the extension of Mini SPINE capabilities to include access to both NRL and NEMS for a limited number of specific diabetes events.

  This approach will enable all providers to share information effectively including testing and screening providers, and structured education providers.

- An alternative option to that of using the proposed “principle diabetes care record” architecture, or what could be seen as an architecture roadmap option, is the use of the Shared Care Record architecture to provide a “consolidated diabetes care record” accessible to the interested parties to a person’s care.

  All providers of diabetes care and care related event information, including those noted above, would be required to publish diabetes care related event information through the regional shared care record architecture solution.

  There are a number of constraints and challenges with this approach:

  - There is no single Shared Care Record architecture. Shared Care Record solution providers have implemented different mechanisms to consolidate and integrate a person’s information for review either physically warehousing a person’s information for review or consolidating a person’s information at the point of enquiry from the various potential sources.
  - An approach is required to identify and ensure all the potential contributors to a person’s integrated diabetes care record have access to the Shared Care Record.
  - An approach is required ensure the currency of the information to be consolidated is consistent with the diabetes direct care requirements, ensuring any decision-making is based on a consistent and up to date view of the person’s condition.
  - Out of Area access to this “consolidated diabetes care record” would be dependent on the planned NRL support for Shared Care Records due to be implemented by the end of Q2 2023. This also introduces a constraint in common with the short-term proposal, with all information providers and interested parties required to be ODS enabled, HSCN connected to support location of the Shared Care Record via NRL and retrieval of the consolidated record content.
  - An approach is required to respond to requests from and enable the sharing of a person’s consolidated record with, interested parties wider than health and care professionals.

5.3.1.4 Long term options

From initial review of the draft NHSE Target Architecture overview, it is anticipated the following models will form a part of the future Target Architecture:

- event based management of information sharing, including a publish and subscribe model and supporting repository and registry services.
- data orchestration services providing the ability to consolidate responses to query requests across multiple data sources.

In addition to the above a number of mechanisms are under consideration to tackle the challenges of care records with multiple authors and interested parties including Shared care record architectures and patient-centred data pod architecture.

Based on what is known to date, there would be no significant challenges in plotting a roadmap between the proposed architectural solutions and the direction of the emerging Target Architecture.

Examples of how the NRL, NEMS and other services are proposed to be used to support the data sharing requirements of the diabetes use cases can be seen in the patient journeys detailed in Appendix 3.

5.3.2 Sharing data aligned to implementation of the diabetes self-management information model (part of the Diabetes Record Information Standard)

This defines information that could be recorded by the person (or their carer) at home (either using digital apps or medical devices) and shared with health and care professionals.

It is assumed the data sharing and interoperability requirements can be divided into three broad categories:

- Summary glucometric and insulin dosing information covering a defined period, provided from wearable devices and contributing to a view of a person’s status prior to periodic status reviews.
- Detailed glucometric information available from either flash devices, providing periodic glucometric data, with the periodicity being determined by the user’s frequency of scanning their monitoring device, or continuous monitoring devices, providing a comprehensive time series of glucometrics, potentially more

than 1000 readings in a day, and insulin dosing information provided from insulin pumps or connected insulin pens.

- In addition to the above data collected on an automated basis from medical devices, the standard also caters for information entered manually into an app to be shared with the clinical team. Examples include Patient Recorded Outcome Measures (PROMs) questionnaires, manually entered blood pressure or glucose readings and insulin taken via injection, rather than via a connected device.

It is assumed that all the above glucometric and insulin dosing information would be sourced from the manufacturers secure monitoring platforms, for example via Abbott's Libre View, Dexcom's Clarity or Medtronic's CareLink.

5.3.2.1 Near term – sharing of summary monitoring and manually captured information

Summary type glucometric observations e.g. those from a person's CGM device, insulin dosing information from insulin pumps and manually captured information including blood pressure observations, manual glucose readings and insulin administration, are currently used to inform a person's condition status as input to annual reviews and other periodic condition status reviews.

As noted above, different suppliers offer different proprietary solutions to accessing, retrieving, and reporting on a person's glucometric monitoring and insulin dosing information.

It is proposed that using the self-management information model, a standardised request can be made to retrieve a consistent set of summary glucometric, insulin dosing or usual dosing data from any device suppliers' secure monitoring platform.

In addition to the above it will also be possible to retrieve PROMs questionnaire, and manually entered information.

It is proposed that a consistent FHIR profile is defined to support the execution of the request noted above, with NHS number used as the patient key and the associated name and address demographic data being used to verify the patient.

It is proposed the request will return the specified glucometric information summarised over a user configurable time period, with a maximum period of 90 days.

The Information Standard also requires that in addition to the summary information noted above, the provider also exposes for sharing the underlying detailed information used for the summary calculations.

It is proposed the request is made in the form of an asynchronous request and response interoperability pattern, with the information returned by the FHIR request being stored in the requestor's local EPR.

It is assumed the sharing of summary glucometric and insulin dosing data as noted in the above section will satisfy the majority of requirements for the capturing and recording of self-managed device data for typical care needs.

5.3.2.2 Device data visualisation challenges

It is recognised that the various device manufacturer proprietary monitoring solutions can offer a rich level of data and data visualisation and reporting options for clinicians.

In addition, data aggregation products offered by some suppliers, provide the ability to integrate and visualise information from multiple device suppliers, enabling the overlay of insulin dosing information over time with other relevant observation data including glucose readings.

This capability can provide specialist clinicians with a greater level of analysis and insight into the person's ongoing condition, supporting the management of a person's condition and provision of their care.

However, as noted in Section 4.1.4, the benefits noted above can come at a cost to clinicians in terms of the time and effort required to manage the access to, and navigation of, multiple proprietary systems during a single clinic, dependant on the devices used by people with diabetes.

The ideal approach being that clinicians should be able to visualise all the data they require for a person (or population) in a clinic through their "system of choice", avoiding the potential requirement to switch between multiple systems multiple times during a clinic.

Clinicians making use of data aggregation platforms may also encounter challenges with the type of data available for overlay, due to commercial issues between suppliers and, as a result, some device supplier's data may not be available via some aggregators' products.

The following section explores some potential options for the resolution of these issues in the medium to longer term.

5.3.2.3 Medium to long term – sharing of high volume detailed observation and medications data including Continuous Glucose Monitoring and insulin dosing information for diabetes management

As noted above there is significant value to clinicians in being able to overlay and visualise the multiple sources of device information, to gain a better understanding of a person's ongoing condition.

The ideal conceptual option would be to provide a single physical or logical store of all patient-generated device observation and associated medications data. This approach would support interrogation, analysis and visualisation of patient device information enabling assessment of status, interventions e.g. medication administration, and the associated outcomes over time.

For the purposes of exploring these options it is assumed that the data generated by a device is considered as personal data being identifiable to an individual. Where the provision of a device is funded by the NHS, under GDPR, the NHS should be considered the Data Controller for the personal information generated by the device, with the device provider being considered as the Data Processor, i.e. acting on behalf of the Data Controller, with the wearer of the device being as the Data Subject.

As such it is assumed that under GDPR the NHS should retain the right to determine the purpose and means of processing of the personal data generated by a device.

The following sections explore the some of the potential options available:

National platform

The following options assume the device suppliers store the data generated by the devices they provide, at an individual level within the supplier's own proprietary secure data warehouses, from where they source the data for their proprietary data visualisation and reporting solutions.

Option 1 NHSE delivered and managed platform

- The detailed source data from the various device suppliers are ingested, on an ongoing basis, into an NHS national datastore from the device suppliers' secure data warehouses. This national datastore is a potential candidate for the national layer in the emerging NHS England Target Architecture.
- This national resource could then provide a single solution for direct care addressing the clinicians' issue with managing access and navigation of multiple systems. The platform would enable interrogation, analysis and visualisation of the relevant individual's specific diabetes condition observations and medications.
- This information is delivered via an agreed set of standardised data visualisations and reports, whilst also providing a capability for the creation of user defined queries, visualisations and reports.
- As a bi-product this national datastore could, when combined with an appropriate mechanism for data depersonalisation, also provide a resource for both population health, proactive care and wider population level diabetes research.

Option 2 Single third-party delivered and managed platform

As noted above, there are currently third-party data aggregation platforms being used to support the overlaying of device data for clinical review. This option is similar to option 1 with the exception of responsibility for delivery and management of the platform:

- Identify a single aggregator to deliver, manage and support the operation of the national platform, including the provision of the analytics application layer to enable the interrogation, analysis and visualisation of a person's information, and provision of the capability for the creation of user defined queries, visualisations and reports.
- The requirements of the contract with the selected aggregator would need to include provision for the export of NHS's data, in its entirety or in part, at the conclusion of the contract.

- This may require changes to the current contracts with device providers to ensure there is no restriction of data sharing with the selected aggregator.

Option 3 Regional platform

Option 3 builds on the assumed existence of ICS level data warehouses or data lakes, and an associated data analytics and business intelligence development capability within the local ICS teams:

- Similar to options 1 and 2, under this option all device data, for the ICS population of patients, is imported from the device supplier's secure data warehouse into an NHS controlled data warehouse platform. As with option 1, the ICS level platforms provide the basis for data interrogation, analysis and visualisation, for the ICS population of patients.
- It assumed the ICS warehouse platform provides the source for both summary and complex device data queries and visualisations.

Federated Data Platform

An alternative to the creation of either a physical national or ICS level platform, as the basis for device data interrogation, analysis and visualisation, is to explore the option of using a "federated" source of device data.

Option 4 Single sign-on and context based launch of 3rd Party applications

This medium to long term option exploits the existing supplier secure warehouse platforms as the secure source of record for patient-generated device data.

It is proposed the challenge of managing and navigating multiple systems during a diabetes clinic is overcome through placing the requirement on device suppliers to provide the capability for clinician "single sign on" to their visualisation applications, combined with the capacity for "context-based launching" of their applications using a patient's NHS number, provided from the clinicians EPR system of choice.

Option 5 Federation of Device Data via Data Virtualisation

A version of option 1, it is assumed this long-term option will align to the Federated Data Platform component of the future Target Architecture - Provider (local layer).

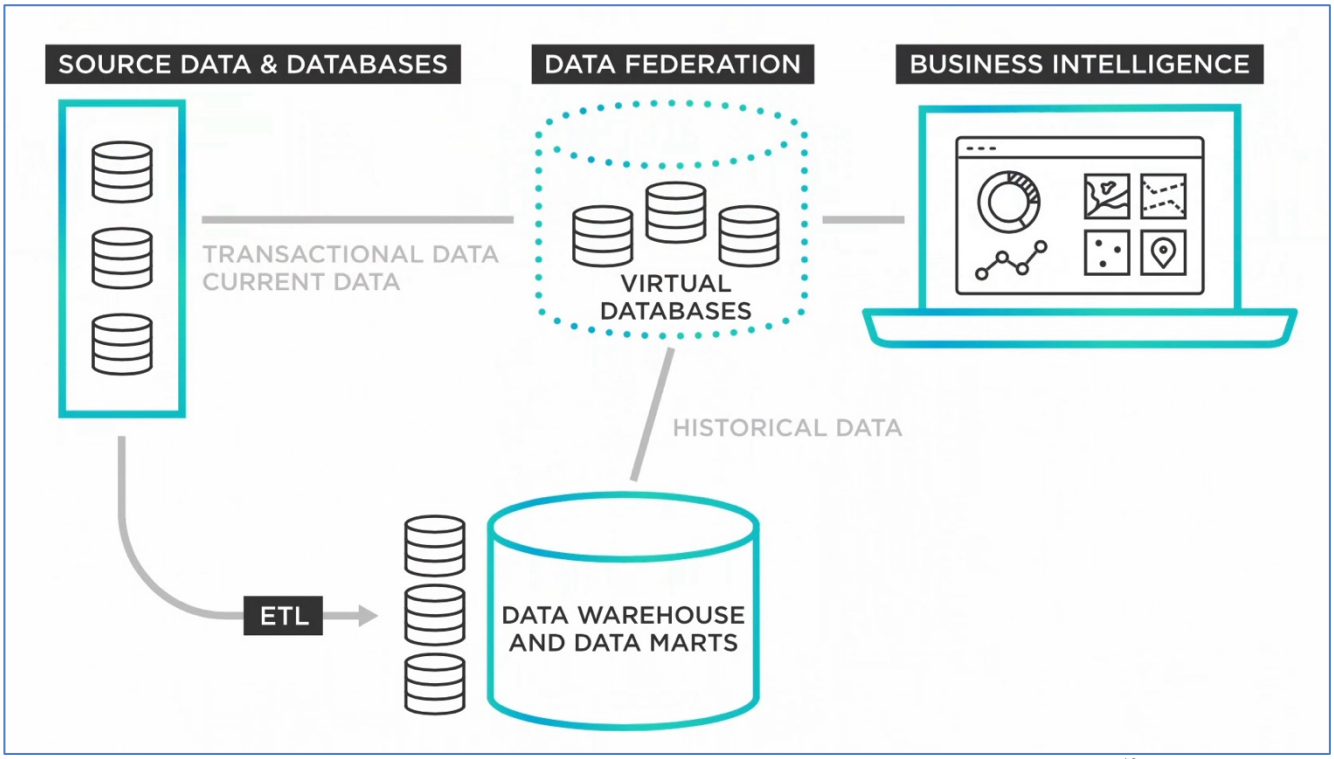


Diagram 3 – Example of Data Virtualisation and a Federated Data from TIBCO[12]

It is assumed this layer will include a strategic data virtualisation capability, enabling the various diabetes device suppliers' secure data warehouse platforms to be logically combined into a single virtualised national diabetes device information database as per diagram 3.

This virtualised federated database will provide the basis for data interrogation, analysis and visualisation, of a patient's glucometric and insulin dosing information.

As per the diagram 3 it is assumed this approach will enable the federated database to be further enriched with information from wider diabetes related app datastores e.g. MyDESMOND.

In advance of the availability of a strategic Federated Data Platform it is proposed that a simplified version of option 5 could be progressed to proving the viability of the use of federated data requests across multiple sources. The simplified approach would be based on the implementation of a federated request API supporting the retrieval of self-managed device data from a limited cohort of people with diabetes, e.g. those people invited to a specific instance of a secondary care clinic. The data retrieved being cached locally, with data for specific individuals being aggregated from multiple sources where appropriate, allowing the required visualisations of the data to be presented to the clinician.

It is proposed the clinician would have the ability to save a specific's individual's data in their clinic EHR, structured according to the Diabetes Record Information Standard.

5.3.2.4 Implementation considerations

The following are two implementation considerations that will need to be addressed in relation to the options described above:

Patient consents

As noted above it is assumed that under GDPR, the NHS will be considered Data Controller for all device data generated by devices funded by the NHS.

[12] What is a Data Federation? | TIBCO

Whilst it could be assumed a person's consent, as the Data Subject, to the sharing of their device data within the NHS environment, would be implicit, based on the person accepting the use of the device, it is understood there may be concerns related to sharing of continuous monitoring device information. Further consultation may be required to understand and address any concerns with consent and Information Governance.

Following review of the options with the GP Data for Planning & Research team, despite the above considerations re consents, option 5 would be the recommended approach to minimise the potential for delays and constraints as a result of consent and information governance challenges.

Data Sharing Volumes

As noted above when considering the sharing of summary level data it is proposed that a user configurable time period is used to manage the volume of data to be shared, with a maximum of 90 days.

For the sharing of detailed data enabled by the options noted above, consideration needs to be given to the specific requirements for direct care, and the potential requirements for population health and proactive care and wider population level diabetes research, in addition to any specific constraints associated with physical storage including capacity and operating costs.

With a continuous glucose monitor capable of generating over 1000 readings per day, and for the purposes of this document, an assumed minimum patient population of 400,000, i.e. the current number of type 1 patients, there could be a daily volume in excess of 400 million individual glucose readings alone.

Whilst the size of individual device readings may not be significant, the potential scale of daily, weekly, monthly, and annual volume of readings data, could grow exponentially as the availability of devices is rolled out to a wider population of patients, including those with a type 2 diagnosis.

Whilst the use of cloud storage can effectively remove data storage capacity constraints, operating costs need to be considered in addition to the sustainability of a solution resulting in the storage of significant volumes of data, without a clear purpose for use.

Similar to the proposed approach for summary data, a potential option for consideration for detailed or continuously monitored data would be the limiting of the volume of data ingested into the "device data warehouse" to specific requests from clinicians in support of planned encounters, with individual requests being limited to a 90-day time period.

Professional Record Standards Body

Appendix 1 – Use Cases

No	Scenario description	Example	Care settings involved	Actors involved	Data required from standard
0	Sharing a diabetes diagnosis	Person is diagnosed with T1 diabetes following tests in secondary care after referral from their GP. The diagnosis is shared with the GP surgery.	Secondary Care Primary Care	Person with diabetes Consultant diabetologist Diabetes Specialist Nurse General Practitioner	Problem List: Diabetes diagnosis
1	Sharing foot check results and observations (e.g. BP) done in hospital with GP practice and community nursing team.	Person with T2 diabetes attends annual review in secondary care. Foot check performed, HbA1C results (and other test results) reviewed and blood pressure measured. The results of foot check and observations are recorded in record. The results of observations and HbA1c test results are shared with GP surgery and community nursing team.	Secondary Care Community Nursing team General Practice	Person with diabetes Consultant diabetologist Diabetes Specialist Nurse General Practitioner Practice Nurse Community Nurse	Examination Findings: Foot check Investigation results: HbA1c results Observations: Blood pressure
2	Sharing investigation results (HbA1c, Cholesterol, Urinary Albumin test, Serum Creatinine), observations (blood pressure, weight and BMI) and smoking status with community nursing team and hospital.	Person with T2 diabetes attends annual review at GP surgery blood pressure, weight and BMI, smoking status are recorded and latest test results including HbA1c, Cholesterol, Urinary Albumin test, Serum Creatinine are reviewed. Observations and test results are shared with community nursing team and hospital.	Secondary Care Community Nursing team General Practice	Person with diabetes Healthcare Assistant Practice Nurse General Practitioner Community Nurse Hospital diabetes team e.g. Diabetes Specialist Nurse Consultant diabetologist	Investigation results: HbA1c, Cholesterol, Urinary Albumin test, Serum Creatinine results Observations: Blood pressure, weight, BMI Social context: Smoking status
3	Sharing current insulin dosing regimen with hospital staff on admission (from GP practice or care home)	Person with T1 diabetes is admitted to hospital with a diabetes related complication. Details of their current insulin dosing regimen are available to hospital staff on admission. Variant: person with T1 diabetes urgently referred from a care home to hospital following a fall and is admitted.	General Practice Secondary Care Social Care (Care home or domiciliary care staff)	Person with diabetes Practice Nurse General Practitioner	Medications and medical devices-> Medication administration record entry->Usual insulin dosing cluster: Regimen, insulin name, insulin dose, bolus calculations

No	Scenario description	Example	Care settings involved	Actors involved	Data required from standard
				Hospital inpatient team including ward staff, diabetes inpatient specialist nurses Diabetes Specialist Nurse Consultant diabetologist (Care home staff or domiciliary care staff)	(Referral information)
4	Sharing a safe discharge plan (including usual insulin dosing regimen) with the GP and the PWD on discharge from hospital (or referral to the district nursing team where person unable to administer own insulin)	Person with T1 diabetes is discharged from hospital and a safe discharge plan (including usual insulin dosing regimen) is shared with the GP. The person is able to self-administer their insulin at home. Variant: The person requires support to administer their insulin at home and does not have a carer who can provide that support, therefore a referral is made to the district nursing team.	Secondary Care General Practice Community Care	Person with diabetes Practice Nurse General Practitioner Hospital inpatient team Consultant diabetologist Diabetes Specialist Nurse (District Nurse)	Medications and medical devices-> Medication administration record entry->Usual insulin dosing cluster: Regimen, insulin name, insulin dose, bolus calculations (Referral information)
5	Sharing diabetic eye screening results with the GP practice and hospital.	Person with T2 diabetes attends their annual diabetic eye screening. The results from the screening are shared with the GP practice and hospital. *(Diabetic Eye Screening could take place in GP surgery, hospital or optician practices depending on local commissioning.)*	DES (Diabetic Eye Screening) service General Practice Secondary Care	Person with diabetes DES screener/grader /Clinical lead Practice Nurse General Practitioner Hospital consultant Diabetes Specialist Nurse	National Screening Programme: Diabetic eye screening results and outcome Referrals Documents and images: images, letter

No	Scenario description	Example	Care settings involved	Actors involved	Data required from standard
6	Sharing foot examination results by podiatrist with hospital and GP practice.	Person with T2 diabetes was assessed as having high risk of developing a diabetic foot problem by their GP practice nurse. They were then referred to the community foot protection service. An assessment was carried out by the podiatrist and advice given to the person about the care of the feet and results shared with GP and hospital. The person is subsequently admitted to hospital for a condition unrelated to their diabetes. The hospital inpatient team has access to diabetes status and foot risk.	Community Care Secondary Care General Practice	Person with diabetes Podiatrist Practice Nurse General Practitioner Hospital inpatient team including ward staff, diabetes inpatient specialist nurses Multidisciplinary foot care service (in hospital) Consultant diabetologist Diabetes Specialist Nurse	Examination Findings Observations Assessments Referrals Plan and requested action Information and advice given
7	Sharing diabetes “status” in admission to hospital.	A person with T1 diabetes is admitted to hospital for a procedure unrelated to their diabetes. The hospital inpatient team has access to their diabetes “status” information.	General Practice Secondary Care	Person with diabetes Practice Nurse General Practitioner Hospital inpatient team including ward staff, diabetes inpatient specialist nurses Hospital consultant Diabetes Specialist Nurse	Problem list: Diabetes diagnosis Eye screening register data?
8	Self-management data e.g. blood pressure, weight, glucose levels (from CGM), insulin administration (insulin pumps, connected pens) with a) primary and community and b) secondary care	A person with T2 diabetes on multiple daily injections of insulin and with impaired hypoglycaemia awareness has been offered and is using a continuous glucose monitor to help them to self-manage their diabetes. They attend an annual review at their GP practice. The Practice nurse is able to view the latest test results (including HBA1c) and summary glucose metrics from the person’s glucose monitoring device. Variation: The person enters the results of fingerstick testing into an app [This is a new scenario as GP practices will start to prescribe CGM devices, to date this has been mainly done in secondary care]	General Practice	Person with diabetes Practice Nurse General Practitioner	Observations: glucose measurements Summary observations: summary glucose metrics

No	Scenario description	Example	Care settings involved	Actors involved	Data required from standard
9	Self-management data e.g. blood pressure, weight, glucose levels (from CGM), insulin administration (insulin pumps, connected pens) with a) primary and community and b) secondary care	A person with T1 diabetes is using a hybrid closed loop system to manage their diabetes consisting of a continuous glucose monitor, an algorithm and an insulin pump. They attend their annual review with their hospital consultant who can view the detailed glucose measurements and insulin administration details as well as the summary glucose and insulin statistics and provide advice on their self-management Variations: Simple insulin dosing delivered by manual injection using a connected pen Simple insulin dosing delivered by manual injection with administration details entered into an app Standard pump data not in a closed loop system (basal infusion, standard, extended or multi-wave bolus) Using data for remote management	Home Secondary Care	Person with diabetes Hospital consultant Diabetes Specialist Nurse	Observations: point glucose data Summary observations: summary glucose metrics Medication administration: insulin dose Summary medication metrics->insulin metrics: average and modal insulin use Medication administration: insulin dose or insulin infusion Summary medication metrics->insulin metrics: average and modal insulin use and device summary metrics
10	Sharing a care plan between PWD, GP Practice, district nursing team and hospital team (also care home).	Person with T2 diabetes and other co-morbidities develops a care plan with their GP practice nurse during their annual review. The care plan is shared with district nurse and hospital team to contribute to. The care plan is available to the person with diabetes so that they can view it update it between appointments. [Note: much of the diabetes record would be needed to support the annual care planning process] Variation: person lives in a care home so care plan developed in care home and contributed to by GP practice and hospital team.	General Practice Secondary Care Community Care Social Care (Care home or domiciliary care staff)	Person with diabetes Practice Nurse General Practitioner District Nurse Hospital consultant Diabetes Specialist Nurse (Care home staff or domiciliary care staff)	About Me Care and support plan Contingency plan Additional support plans Likely to include: Demographics Problem list (other risk factors) Investigation results (HbA1c, cholesterol etc) Examination findings (foot risk) Observations (weight / BMI) Social context (smoking status) Assessments Medications and medical devices Professional contacts

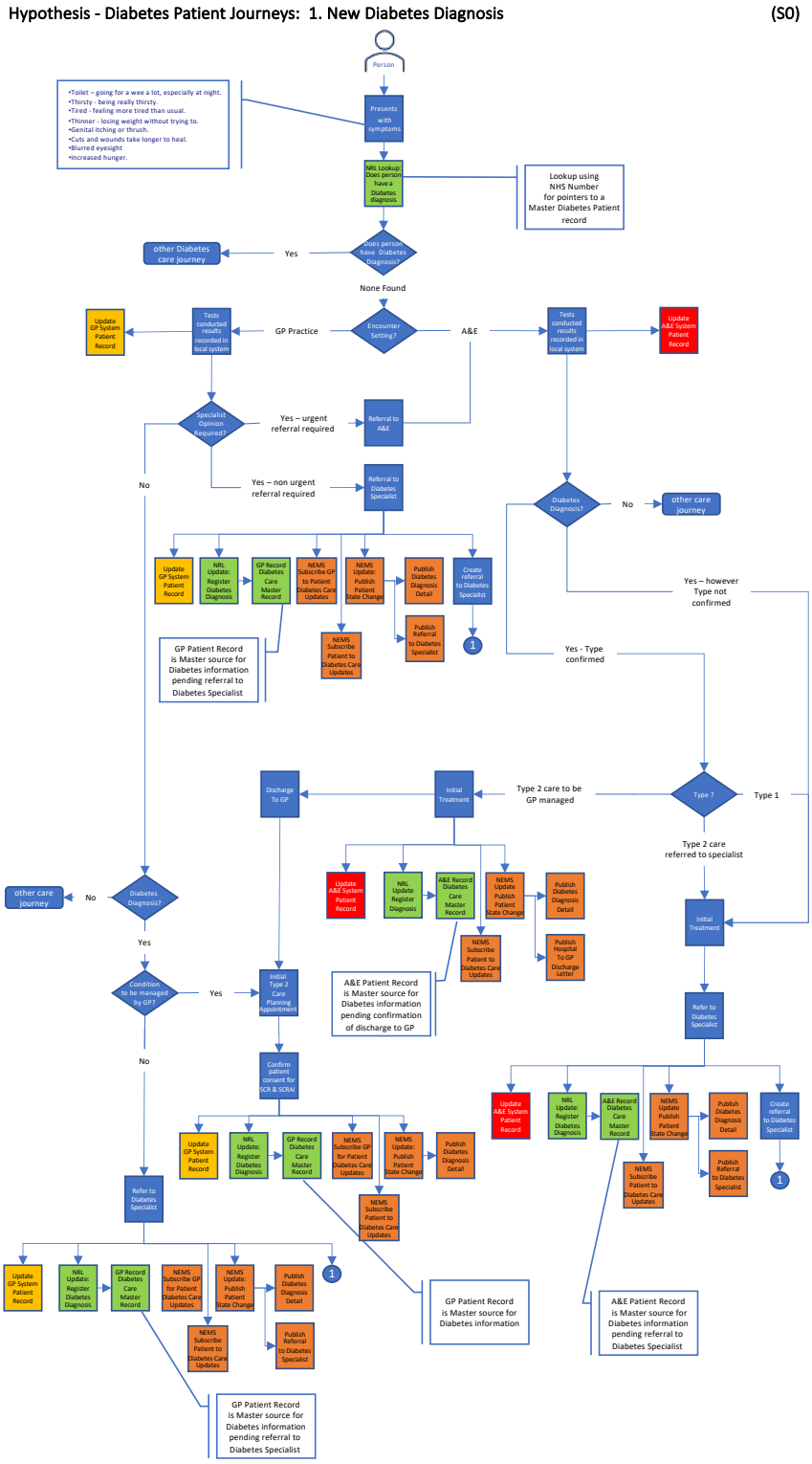
No	Scenario description	Example	Care settings involved	Actors involved	Data required from standard
11	Sharing attendance at structured education courses with GP and hospital team.	Person with T1 diabetes attends a review with their hospital consultant who checks the record and notices that the person was offered and attended a DAFNE structured education course 3 months ago. Variation: Person newly diagnosed with type 2 diabetes is referred for a DESMOND structured education course and GP is able to view that they attended.	Secondary Care General Practice	Structured education provider Hospital consultant Diabetes Specialist Nurse General Practitioner Practice Nurse	Structured education: attendance and outcome details
12	Diabetes information transferred from one GP to another	Person with T1 diabetes goes to university and registers with a new GP	General Practice	GP practice to GP practice transfer of information	Entire record?
13	Diabetes information transferred from one hospital to another	A person with T1 diabetes is admitted to a hospital outside their area following an emergency attendance for an episode of DKA	Secondary Care General Practice	Person with diabetes Hospital consultant Diabetes Specialist Nurse General Practitioner	Medications and medical devices-> Medication administration record entry->Usual insulin dosing cluster: Regimen, insulin name, insulin dose, bolus calculations Other information in the record about a person's diabetes
14	Managing diabetes in the care home setting	An older person with type 1 diabetes is living in a nursing care home. The person is unable to self-monitor their blood sugar or administer their insulin. The care home staff record glucose measurements insulin administration in the system. Regular assessments of the person are carried out, skin integrity and foot checks are carried out weekly and other assessments such as Activities of Daily Living and Frailty are carried out every 3 – 6 months and recorded in the system.	Social Care (Care home) General Practice	Person with diabetes Care home staff General Practitioner	Observations: BMI Investigation results: HbA1C Assessments: MUST (nutritional assessment), Waterlow (skin integrity), Cognitive/mood assessments (Depression scale), Activities of Daily Living (e.g. Barthel ADL test), Frailty (e.g. FRAIL score) Examination findings: Falls risk, Foot risk
15	Sharing foot check results and done in care home with secondary care, GP practice, community nursing team, podiatrist (NHS or private).	As part of planned care, person with T2 diabetes with history of foot ulceration has daily foot inspection in line with NAPCHD guidance. Results are recorded in care home records.	Care home Secondary Care Community Nursing team General Practice	Person with diabetes Care home staff Consultant diabetologist Diabetes Specialist Nurse General Practitioner	Examination Findings: Foot check

No	Scenario description	Example	Care settings involved	Actors involved	Data required from standard
			Podiatry service (NHS or private)	Practice Nurse Community Nurse Podiatry service	
16	Care home is issued with monitoring devices to measure BP etc as part of monthly Restore2 assessment.	As part of monitoring for signs of deterioration/frailty care home staff use kit supplied by ICS to check BP etc.	Care home Secondary Care Community Nursing team General Practice Care Home Support Teams Palliative care teams	Person with diabetes Care home staff Consultant diabetologist Diabetes Specialist Nurse General Practitioner Practice Nurse Community Nurse	Observation: Blood pressure
17	The kit being used to monitor for signs of deterioration and generate NEWS2 score is added to by ICS to begin monitoring diabetes through use of a glucometer	As part of planned care, care home staff take blood glucose readings.	Care home Secondary Care Community Nursing team General Practice Care Home Support Teams	Person with diabetes Care home staff Consultant diabetologist Diabetes Specialist Nurse General Practitioner Practice Nurse Community Nurse	Observation: Glucose levels

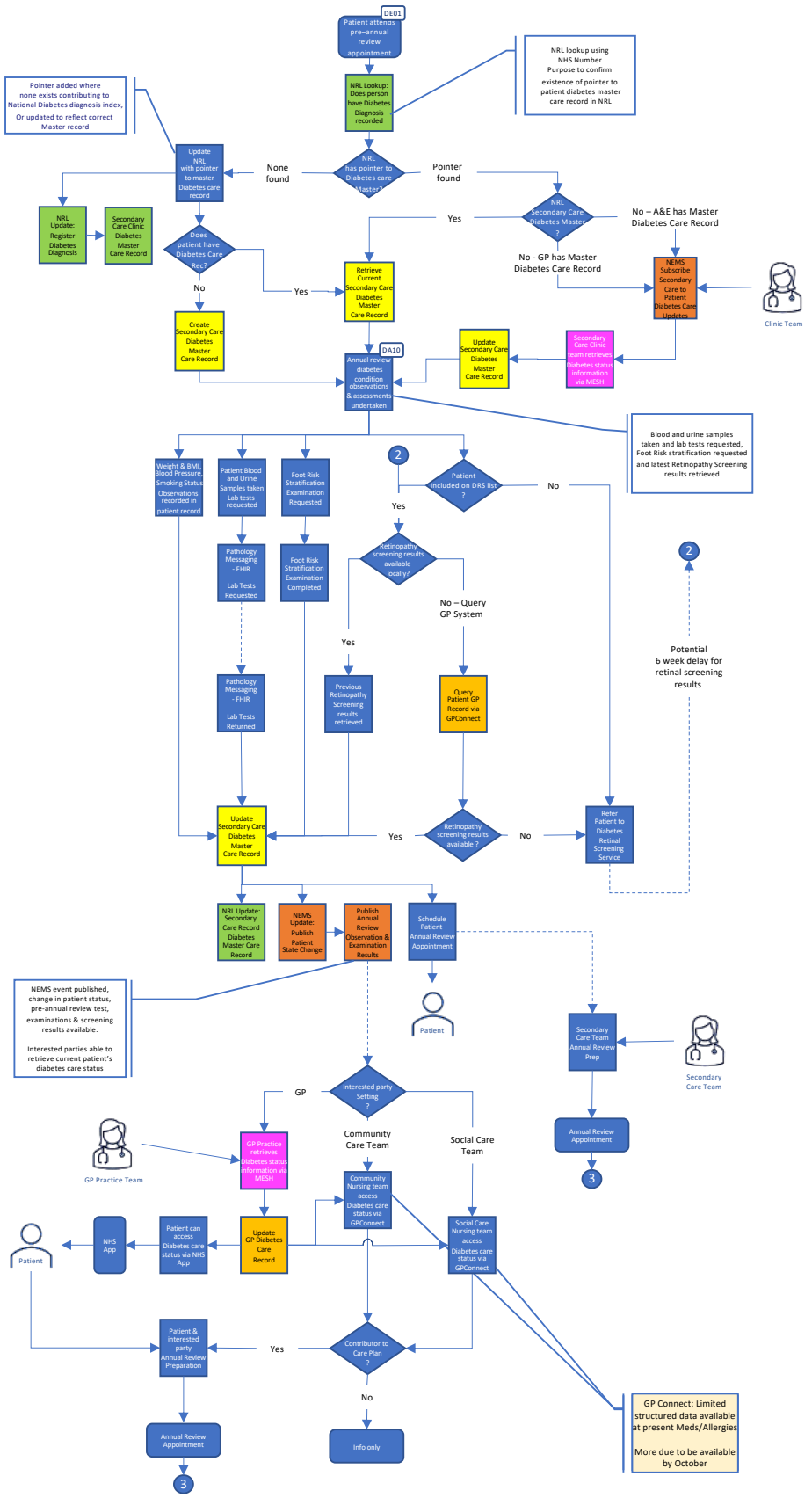
Appendix 2 – Detailed Status Change Events

Diabetes Use Cases – Detailed Status Change Events	
DE00	Patient presents with potential symptoms of a Diabetes condition
DE01	Patient attends pre-annual review appointment
DE02	Diabetes condition status review observations available
DE03	Diabetes blood and urine lab tests requested
DE04	Diabetes blood and urine lab test results available
DE05	Foot Risk stratification examination requested
DE06	Foot Risk stratification examination results available
DE07	Referral to Retinopathy Screening programme
DE08	Retinopathy Screening programme appointment issued
DE09	Retinopathy Screening results available
DE10	Previous Retinopathy Screening results retrieved and recorded
DE11	Annual Review examination, test and screening results available
DE12	Patient attends Diabetes Annual Review appointment
DE13	Glucose Monitoring data available
DE14	Insulin Pump Dosing data available
DE15	Diabetes condition annual status review outcome available
DE16	Referral to Structured Education - DAFNE
DE17	Referral to Structured Education - DESMOND
DE18	Structured Education Course - DAFNE - Attendance data available
DE19	Structured Education Course - DESMOND - Attendance data available
DE20	Electronic Patient Care Record created
DE21	Electronic Patient Care Record updated
DE22	Diabetes Care Plan created
DE23	Diabetes Care Plan updated
DE24	Diabetes Care Medical Device Prescribed / issued
DE25	Transfer of Care - Primary to Secondary - Planned intervention
DE26	Transfer of Care - Social Care to Secondary - Planned intervention
DE27	Transfer of Care - Primary to Secondary - Unplanned intervention
DE28	Transfer of Care - Social Care to Secondary - Unplanned intervention
DE29	Transfer of Care - Secondary to Primary
DE30	Transfer of Care - Secondary to Social Care
DE31	Transfer of Care - Primary to Primary - New Registration
DE32	Pathology Tests
DE33	New Diabetes Diagnosis confirmed

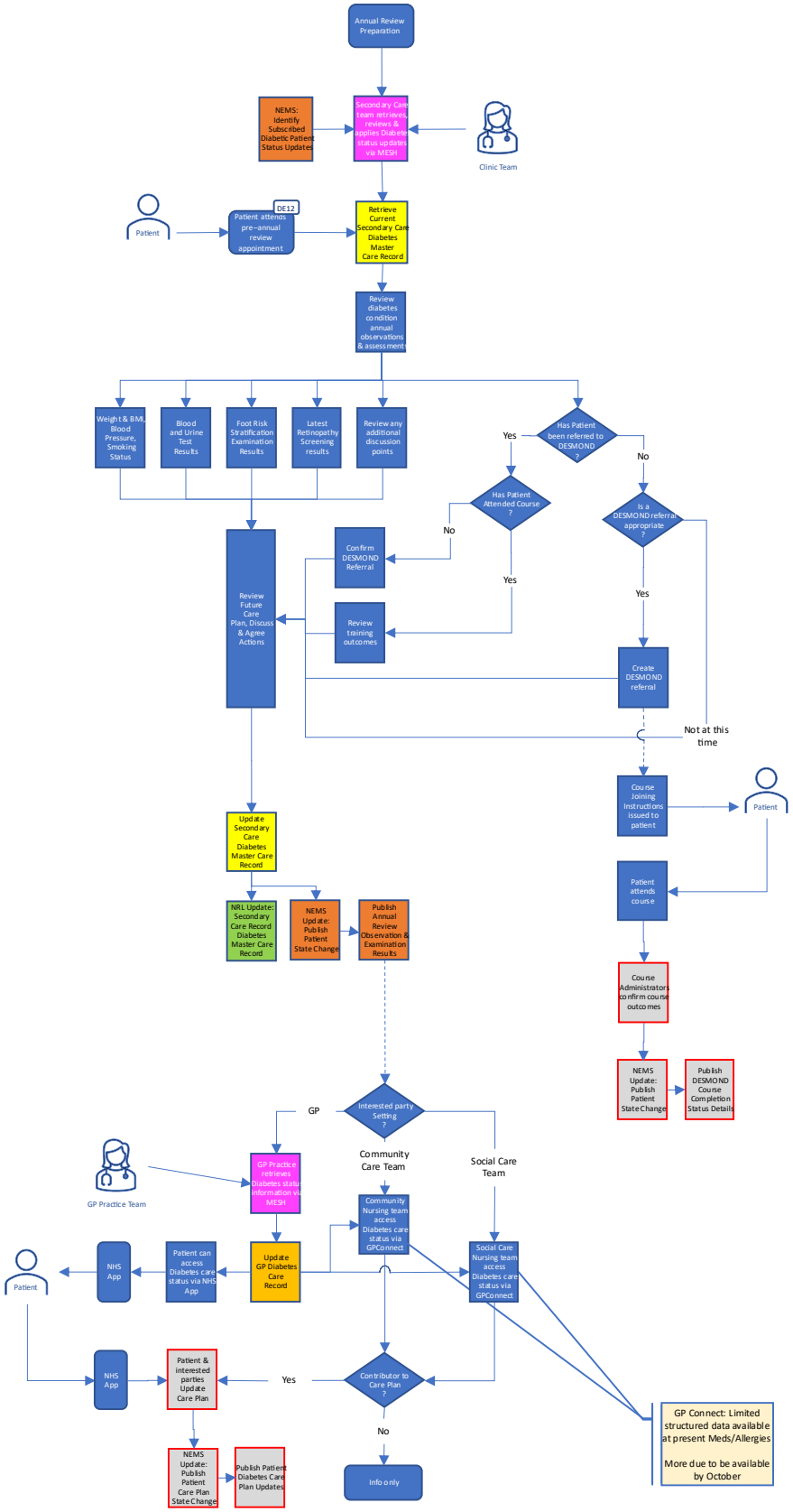
Appendix 3 - Patient Journeys



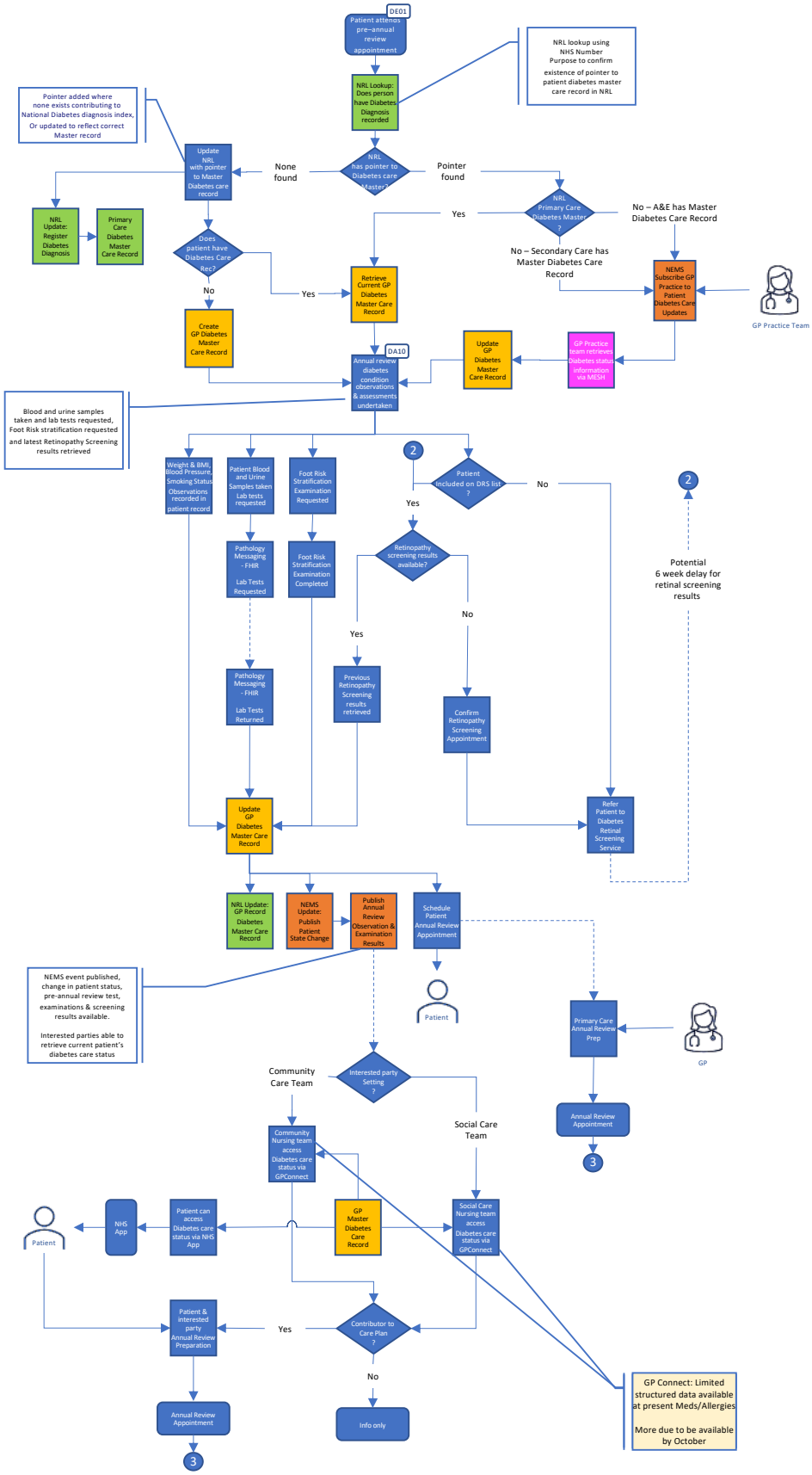
Hypothesis - Diabetes Patient Journeys: 2a. Annual Review Preparation – T2 Secondary Care (S1)



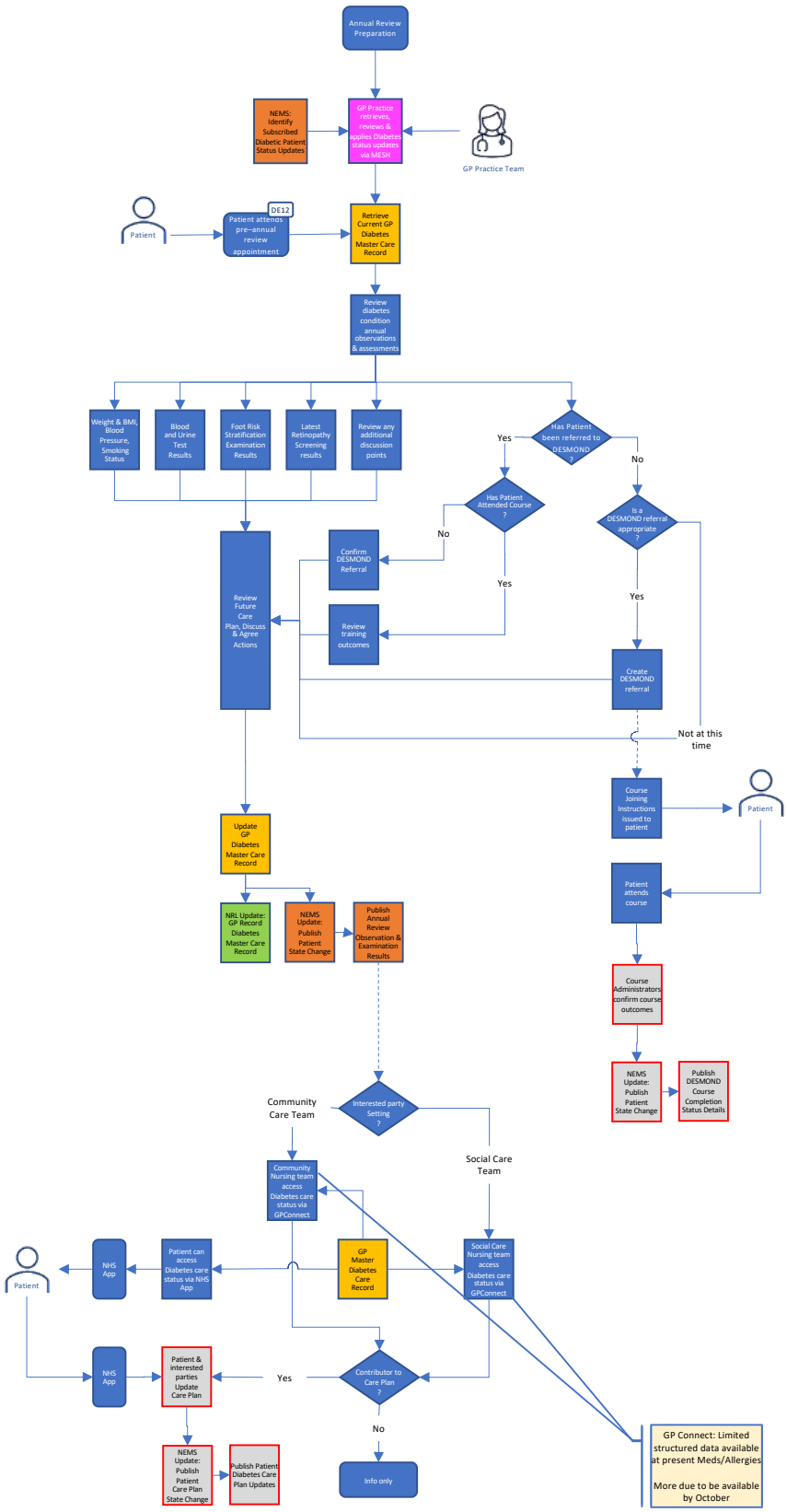
Hypothesis Diabetes Patient Journeys: 2b. Annual Review Appointment Secondary Care (S1)



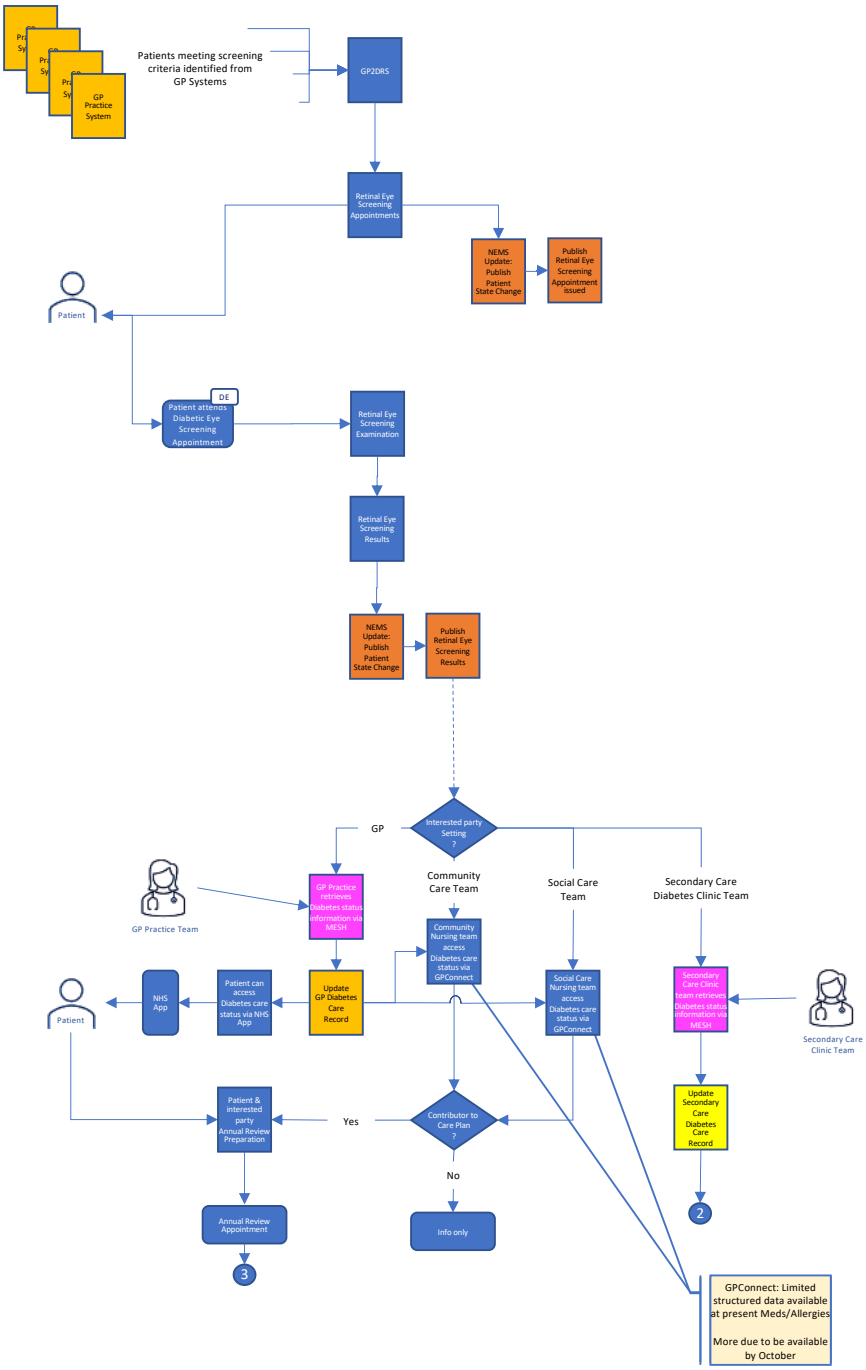
Hypothesis - Diabetes Patient Journeys: 3a. Annual Review Preparation – T2 Primary Care (S2)



Hypothesis - Diabetes Patient Journeys: 3b. Annual Review Appointment – T2 Primary Care (S2)



Hypothesis - Diabetes Patient Journeys – 5. Diabetic Eye Screening (S5)



References

[i] NRL: National Record Locator – Link to Service Description – Link to FHIR API Description

[ii] NEMS: National Event Management – Link to Service Description – Link to FHIR API Description