



**Diabetes Prevention Programme
Information Governance and Data
Flows**

[Information Reader Box]

Diabetes Prevention Programme Information Governance and Data Flows

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1 Executive summary

The NHS Diabetes Prevention Programme (NHS DPP) was announced in the NHS Five Year Forward View, published in October 2014, which set out our ambition to become the first country to implement at scale a national evidence-based diabetes prevention programme modelled on proven UK and international models, and linked where appropriate to the new NHS Health Check.

The purpose of this guidance is to support organisations participating in the NHS DPP in meeting their legal and contractual requirements relating to information governance. The main focus is to ensure that information flows are documented and established on a lawful basis.

This guidance may be updated following publication of the National Data Guardian review by the Secretary of State.

2 Background

The NHS Diabetes Prevention Programme (NHS DPP) was announced in the NHS Five Year Forward View, published in October 2014, which set out our ambition to become the first country to implement at scale a national evidence-based diabetes prevention programme modelled on proven UK and international models, and linked where appropriate to the new NHS Health Check.

The NHS DPP is a joint initiative led by NHS England, Public Health England (PHE) and Diabetes UK, together the “National Programme Team”. The programme aims to deliver services which identify people with non-diabetic hyperglycaemia who are at high risk of developing Type 2 diabetes and offer them a behavioural intervention that is designed to lower their risk of onset of Type 2 diabetes.

The NHS DPP will roll out across the country over the next 3 years. A number of national providers have been appointed to a framework agreement to deliver the evidence based programme set out in the service specification across the country.

Provision of the intervention in local geographies will be called off from the national framework according to local need and requirements. The costs of the intervention will be met centrally by NHS England who will be the contracting authority for the intervention.

Local Health Economies will be responsible for identifying at risk individuals and referring them to the provider of the intervention who will have responsibility for arranging attendance on the intervention.

3 Context

3.1 Purpose

The purpose of this guidance is to support organisations participating in the Diabetes Prevention Programme in meeting their legal and contractual requirements relating to information governance. It describes the responsibilities of respective organisations at each stage in the pathway, with a view to ensuring that:

- the use of patient data is lawful;
- that patients are appropriately informed about the use of their data;
- that the rights of individuals with regard to the use of their confidential information are respected.

The information in this guidance will be of use to those conducting privacy impact assessments of local implementations. As best practice, organisations participating in the NHS DPP should conduct privacy impact assessment (PIA) screening to establish whether small scale or large scale PIA is needed, or if the risks can be managed through normal risk management processes.

3.2 Scope

The main focus of the guidance is to ensure that information flows are documented and established as lawful. Whilst the need for secure information management is referenced, details of specific security measures are only provided for contracted data flows.

The guidance describes the data flows required to support the NHS DPP and considerations for local health economies in designing the local pathway for the service. It covers:

- identifying and inviting at risk individuals
- key data flows between Primary Care and non- GP NHS Health Check providers to the providers of the behavioural intervention
- the collection and storage of data during the intervention
- the transfer of data from providers of behavioural intervention back to primary care
- the transfer of data from the provider to the commissioning authority.

The aim of the paper is to:

- describe the roles and responsibilities of different actors in the pathway with regards to the collection / processing and sharing of data, and to support them in respecting the rights of individuals with regard to the use and disclosure of their personal confidential data.

3.3 Audience

The audience for this guidance includes GP practices and organisations that refer into the NHS DPP, providers contracted to deliver the Programme, NHS England as the commissioner and its support organisations.

3.4 Definitions

Some key terms are set out in Appendix 1.

The word **must** is used in this document to identify a legal requirement.

The word **should** is used to indicate that, in particular circumstances, there may exist valid reasons to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

The word **may** is used to indicate a truly optional activity. This includes decisions where a permissive legal power is available.

4 Legal and contractual requirements

NHS England is required by the NHS Act 2006 to publish guidance for professionals and organisations registered with the Care Quality Commission (CQC) on the processing of patient information.¹ This guidance fulfils this obligation in relation to the processing of information in the context of the NHS DPP. In accordance with the 2006 Act, CQC registered professionals and organisations must have regard to this guidance when offering such services.

NHS DPP provider organisations are contracted to NHS England under the Standard NHS Contract. This requires that specified information governance requirements are met and in particular, compliance with the relevant annual HSCIC Information Governance Toolkit at level 2 across all its requirements.

Providers, referring organisations and commissioners must ensure that patients' privacy and confidentiality are respected, that information is shared lawfully. The organisations that will deliver the NHS DPP are data controllers as defined in the Data Protection Act 1998 (DPA) and must comply with the Principles and other requirements of the Act.

Where a GP practice or provider, as a data controller, engages a sub-contractor to process personal data on its behalf, a binding contract must be in place which requires the data processor to keep information secure and only act under the instructions of the data controller. Appendix 4 contains a template data processing contract.

¹ NHS Act 2006 s. 13S, inserted by the Health and Social Care Act 2012 s. 23(1)

This document provides guidance on how to comply with the law, complementing contractual requirements, with reference to the flows of information that are required to support the Programme.

Please see appendix 2 for further information on legal and contractual requirements.

5 Options for referral

5.1 Referral routes

The referral pathway at annex A outlines the 3 main referral routes in to the NHS DPP following the identification of eligible individuals as follows:

1. Following GP NHS Health Check or opportunistic detection by a GP
2. Following External provider NHS Health Check, or diabetes risk assessment
3. Following identification of existing cases of NDH on GP register (known eligible individuals).

Once eligible individuals have been identified they should be offered a referral into the NHS DPP. The process for how individuals are referred to the programme is for local determination and will require dialogue with providers. The contract sets out the expectation that it is the responsibility of the behavioural intervention provider to arrange attendance and provide information to patients (fair processing) for those individuals that have consented to a referral.

5.2 Referral following NHS Health Check or Opportunistic Identification

Where eligibility for the NHS DPP is established as part of the NHS Health Check performed by a GP or alternative provider, or as part of opportunistic detection (routes 1 or 2 above), a referral may be made with the consent of the patient. The referral, with accompanying information (see section 6.1), must be communicated securely to the behavioural intervention provider.

5.3 Identification of existing cases of NDH on GP register (known eligible individuals)

In route 3 queries are run on the registers held on practice systems to identify individuals that have blood glucose readings within the parameters that would indicate non-diabetic hyperglycaemia. This query creates a list of eligible patients and their contact details, which are then used to invite them to consent to referral into the Programme.

The Programme has developed a business rules set to support case finding and developing registers of at risk individuals, this rule set includes relevant exclusions. This can be found in appendix 6.

Option 1: GP practice undertakes identification

Where the selection of eligible patients is carried out by GP practice staff, on practice systems entirely within the GP practice environment, practices must ensure the confidentiality and security of this data as part of their General Medical Services (GMS) contract.

Option 2: Using a data processor to identify the eligible population

GP practices may choose not to manage the selection process themselves and contract the work out. In this option the selection of eligible patients is performed by a data processor (for example a CCG, CSU or private company) using a query on the GP practice system to generate the lists of eligible individuals from the practice register. A binding contract must be in place which requires the data processor to keep information secure and only act under the instructions of the GP practice as a data controller. Appendix 4 contains a template data processing contract.

5.4 Referral of identified eligible individuals

Where eligibility has been established using existing registers then the GP practice must ensure that the process for obtaining consent for referral complies with the DPA and does not breach confidentiality.

The invitation for referral must be sent by, or on behalf of the GP practice. Under the DPA, this is 'fair' because purposes will be transparent (see below), not outside the patient's reasonable expectations and will not result in detriment. It is also lawful as we can assume patients' implied consent to be contacted by their GP for direct care purposes.

A GP practice may choose to commission a data processor to invite patients. Where this is the case a data processing contract must be in place. Appendix 4 contains a template data processing contract.

Where a DPP provider is engaged as a data processor by a GP practice to perform the initial invitation, the data processor contract must require that this activity is segregated, and the information held separately to that held for the provision of the service.

The initial referral offer must be in the form of a letter addressed from the GP practice. The letter may be sent by a data processor commissioned by the GP practice, but they must use practice letterhead. The letter must include the following information:

1. why the GP is writing to the patient – the invitation to participate in the programme

2. what the patient needs to do either to accept or decline the invitation
3. the role of the GP Practice in the Programme, and as the organisation responsible for the patient's personal data
4. general information about the NHS DPP:
 - a. its purpose
 - b. who provides the service
 - c. benefits and risks to the individual
 - d. information that will be used and disclosed
5. information about any follow-up communications by or on behalf of the practice (e.g. by phone) that might happen to pursue the invitation
6. contact details for the GP practice, or if applicable data processor, to enable patients to ask questions and accept or decline the invitation.

Once a patient has contacted the practice (or if applicable the data processor acting for the practice) and given explicit consent for referral to the programme, a referral should be made to the provider of the intervention so that attendance at an initial session can be arranged.

6 Information requirements

6.1 Information supporting referral to the provider

The referral notification should contain the following information:

<ol style="list-style-type: none"> 1. Date of Referral 2. General Medical Practice Code (Patient Registration) 3. NHS Health Check Provider Code (where relevant) 4. NHS Number of individual referred 5. Name of individual referred 6. Address of individual referred 7. Tel number / E-mail (where known) 8. Contact details (tel / e-mail) of carer or representative (if appropriate) 9. LATEST HbA1c / FPG (including date recorded) 10. If individual is on the SMI register (where recorded) 11. Whether the individual has a learning disability 12. whether the individual has a physical disability / mobility issue 13. Requirement for translator or information in another language (where known)
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Depending on the referral pathway the information outlined above should be provided to the individual to make contact with the intervention provider or to the intervention provider directly subject the consent considerations outlined in section 5.

6.2 Data to be collected during intervention

The Provider is required by the Contract to capture data relating to individuals that enter on to the programme. This includes socio-demographic information as well as records of attendance and outcomes achieved during the intervention.

The socio-demographic information includes the following fields: *ethnicity; religion; employment status; sexual orientation; housing tenure; disability status*. Patients' wishes not to provide socio-demographic information must be respected and recorded with the appropriate "not stated" or "declines to disclose" code.

The data to be collected are specified in Schedule 6 of the Contract.

The provider is also required to ask patients if they consent to be contacted by nationally appointed researchers undertaking evaluation of the NHS DPP to obtain their opinions. The outcome of this must be recorded in the field that maps to DPP38 in the Data Output Specification.

6.3 Data to be sent back to primary care

The notification back to primary care should include the information in the table below. The provider must ensure that patients are informed about the information that will be returned to their GP. Appendix 5 includes suggested text for inclusion in a NHS DPP provider's fair processing notice.

Data Item	Relevant Clinical Code			Definition	Timing
	V2	V3	SNOMED CT		
General Medical Practice Code (Patient Registration)	N/A	N/A	N/A	ORGANISATION CODE of the GP Practice that the PATIENT is registered with – See data format and codes	On notification of attendance / non-completion / completion
NHS Number of individual	N/A	N/A	N/A	The primary identifier of a PERSON, is a unique identifier for a PATIENT within the NHS in England and Wales	On notification of attendance / non-completion / completion
Family name of individual	N/A	N/A	N/A		On notification of attendance / non-completion / completion

Given Name of individual	N/A	N/A	N/A	This is the name recorded on a birth certificate.	On notification of attendance / non-completion / completion
Address of individual	N/A	N/A	N/A		On notification of attendance / non-completion / completion
Postcode of individual	N/A	N/A	N/A		On notification of attendance / non-completion / completion
Attended NHS DPP	679m2 NHS Diabetes Prevention Programme started	XaeD0 NHS Diabetes Prevention Programme started	1025271000000103 National Health Service Diabetes Prevention Programme started (situation)	Relevant where the individual attended the initial assessment session	
NHS DPP not completed	679m0 National Health Service Diabetes Prevention Programme not completed	XaeCw NHS Diabetes Prevention Programme not completed	1025211000000108 National Health Service Diabetes Prevention Programme not completed (situation)	Relevant where the individual has completed < 75% of the recommended dose	When it is established the individual will not continue with the programme

Completed NHS DPP	679m1 NHS Diabetes Prevention Programme completed	XaeCz NHS Diabetes Prevention Programme completed	1025251000000107 National Health Service Diabetes Prevention Programme completed (situation)	Relevant where the individual has completed >75% of the recommended dose	At completion of programme
Weight	Value	Value	Value		
Date of weight measurement	N/A	N/A	N/A		
HbA1c / FPG	Value	Value	Value	HbA1c (Hemoglobin A1c), also known as Glycated Hemoglobin,	
Date of blood result	N/A	N/A	N/A		

6.4 Commissioning datasets

The provider must submit the datasets specified Schedule 6 of the Contract Particulars to the specified Data Services for Commissioners Regional Office of the HSCIC. The legal basis for this submission is established by Directions issued by NHS England to HSCIC.

Where a patient has not consented to be contacted for evaluation purposes – i.e. DPP38 is not 'Y' – the patient's contact details recorded in fields DPP6 to DPP11 must not be included in the dataset.

Appendix 1 – Definitions

Consent	<p><i>“any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed”²</i></p> <p>Consent is the approval or agreement for something to happen after consideration. For consent to be legally valid, the individual must be informed, must have the capacity to make the decision in question and must give consent voluntarily. This means individuals should know and understand how their information is to be used and shared (there should be ‘no surprises’) and they should understand the implications of their decision, particularly where refusing to allow information to be shared is likely to affect the care they receive. This applies to both explicit and implied consent.³</p>
Data controller	An organisation that determines the purposes and the manner that personal data are processed.
Data processor	An organisation contractually bound to process personal data only on the instructions of a data controller, who retains full responsibility for compliance with the Data Protection Act.
Explicit consent	Explicit consent is unmistakable. It can be given in writing or verbally, or conveyed through another form of communication such as signing. A patient may have capacity to give consent, but may not be able to write or speak. Explicit consent is required when sharing information with staff who are not part of the team caring for the individual. It may also be required for a use other than that for which the information was originally collected, or when sharing is not related to an individual’s direct health and social care.
Implied consent	<p>Implied consent is applicable only within the context of direct care of individuals. It refers to instances where the consent of the individual patient can be implied without having to make any positive action, such as giving their verbal agreement for a specific aspect of sharing information to proceed. Examples of the use of implied consent include doctors and nurses sharing personal confidential data during handovers without asking for the patient’s consent.</p> <p>However, if a patient makes an explicit consent decision, for example requesting that their personal confidential data is not shared (or ‘actively dissenting’ to share), this decision replaces</p>

² European Directive 95/46/EC

³ Information: To share or not to share? The information Governance Review

<https://www.gov.uk/government/publications/the-information-governance-review>

	any implied consent and their decision should be respected.
Personal data	<p>Personal data is defined by the Data Protection Act as data that relates to a living individual who can be identified by the data, or by reference to other data available to the data controller, and includes information about them.</p> <p>The definition includes data held in electronic form, structured manual files, and for health records, any other form.</p>

Appendix 2 – Legal and contractual requirements

This section highlights the main legal and contractual requirements for GPs and providers in their delivery of the NHS DPP.

The common law duty of confidence

The common law duty of confidence requires that where there is an established expectation of confidentiality between parties, for example a health professional and a patient, information imparted by the subject will not be further disclosed by the recipient without the consent of the subject. The duty is not absolute and information may be disclosed without consent where it is required or permitted by law, or in exceptional circumstances where the public interest outweighs the individual's right to confidentiality.

The Data Protection Act 1998

GP practices, providers and commissioners are data controllers under the DPA. As such, they must comply with the eight principles and other requirements of the Act in their use and disclosure of information. Data controllers must be registered with the Information Commissioner's Office.

To meet the First Principle requirements, the purposes for which personal data are to be used must be transparent, processing must not be outside reasonable expectations of the subjects, and must not cause unwarranted detriment. The common law duty of confidence and other relevant laws must be respected. Further conditions are specified, including for the use and disclosure of "sensitive data".

Data controllers must provide fair processing information to the subjects of the information they process. This is usually in the form of a 'fair processing notice' or 'privacy notice' that identifies the data controller, uses and disclosures of personal data, contact details and other relevant information.

To meet the Seventh Principle it is necessary that systems holding personal data are both technically secure, and that the data controller has in place organisational measures to ensure that the data is managed securely. These should include

business processes, operational procedures and provisions for staff training and awareness.

Where an organisation makes use of a data processor, under the DPA responsibility for the security of the data remains entirely with the data controller. To meet this responsibility, there must be a contractual arrangement in place that requires the data processor to act only on the instructions of the data controller, and binds them to ensuring the security of the data in accordance with the Seventh Principle of the Act. The organisation acting as data processor must be contractually bound to:

- Have technical and organisational measures in place to keep the personal data secure and protected from unauthorised use or access
- only use the patient data for the purposes of contacting patients to offer referral to the NHS DPP and to make the referral to the provider of the behaviour intervention
- retain data for a limited period of time, which must be no more than is required to perform their contractual function and any necessary follow up, and dispose of them appropriately
- process data in line with the DPA (for example, to gain approval from the GP as data controller for any subcontracting of the data processing, and to make clear the lines of responsibility and accountability).

Appendix 4 contains a template data processing contract.

The NHS Standard Contract

General Condition 21 (GC21) in the NHS Standard Contract⁴ sets out the information governance requirements that a Provider must comply with. Providers must comply with the requirements of the Information Governance Toolkit at a minimum of level 2. The Toolkit submission must be independently audited.

GC21 also highlights respective responsibilities of Provider and Commissioner as data controllers under the DPA:

- *In relation to Personal Data processed by the Provider for the purpose of delivering the Services the Provider will be sole Data Controller.*
- *In relation to Personal Data the processing of which is required by a Commissioner for the purposes of quality assurance, performance management and contract management, that Commissioner and the Provider will be joint Data Controllers*

It also sets out requirements when engaging sub-contractors, including data processors.

⁴ <https://www.england.nhs.uk/nhs-standard-contract/>

The General Medical Services Contract

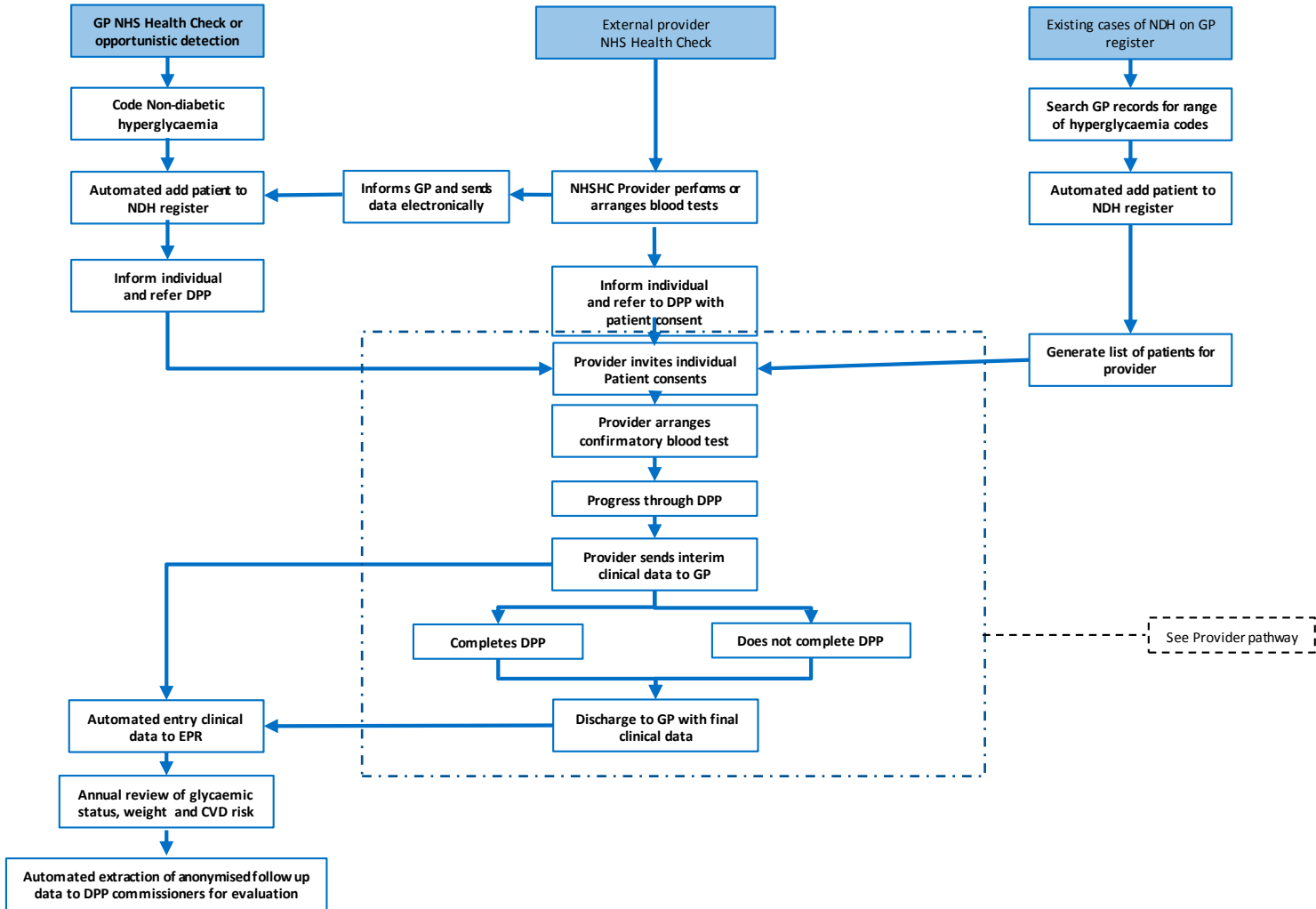
GPs are required under their contract⁵ to comply with all relevant legislation and also to have regard to the *Good Practice Guidelines for General Practice Electronic Records*⁶. They are also required to nominate a person with responsibility for practices and procedures relating to the confidentiality of the personal data they hold.

⁵ Standard General Medical Services Contract, section 16

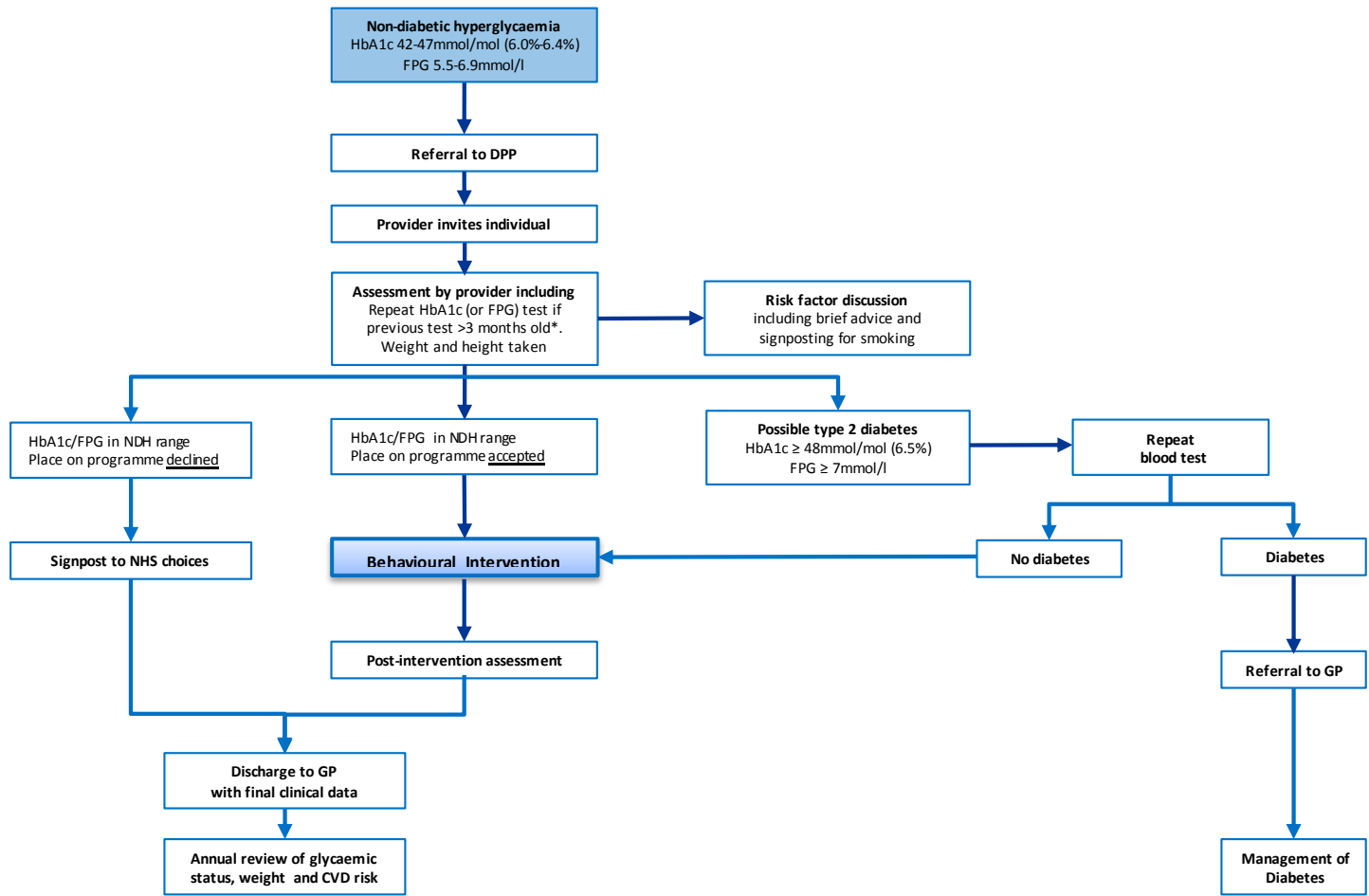
⁶ *Good Practice Guidelines for General Practice Electronic Records* (Version 4, Department of Health 2011), available at <https://www.gov.uk/government/publications/the-good-practice-guidelines-for-gp-electronic-patient-records-version-4-2011>

Appendix 3 – DPP referral pathways

NHS Diabetes Prevention Programme
Referral Pathway



**NHS Diabetes Prevention Programme
Provider Pathway**



*Repeat of blood test is to establish baseline only. Even if shows normoglycaemia individual will still be accepted onto programme on basis of previous result

Appendix 4 – Template data processor contract



Template - Data
Processing Agreement

Appendix 5 – Fair Processing

It is a legal requirement that GPs and providers (as data controllers) have registered the purpose(s) for using personal data with the Information Commissioner's Office and provide fair processing information to patients of the information they process.

Fair processing notices must include

- the identity of the data controller
- the purposes for which personal data will be used
- contact details for a nominated representative
- any other relevant information.

It is important that patients are provided with this information in relation to the NHS Diabetes Prevention Programme.

Practices and NHS DPP providers should make information available to all patients, for example, by displaying posters and providing information leaflets in patient waiting and treatment areas, and by posting information on their web sites. This information should be supplemented by the provision of information in the invitation letter as described in section 5.4.

Example text for a fair processing notice – GP Practice

Our GP practice keeps records about you, your health and the care you receive, and is responsible for them as a data controller under the Data Protection Act 1998.

The records we hold may include:

- basic details about you, such as address and next of kin
- contacts we have had with you, such as GP appointments and clinic visits
- reports about your health and any treatment or care you need
- details and records about the treatment and care you receive
- results of investigations, such as X-rays and laboratory tests
- relevant information from other health professionals providing care and treatment, relatives or carers.

We use this information to help us to assess your needs, provide you with appropriate care and for monitoring and managing our services.

To ensure you receive the best possible care, we may contact you to invite you to participate in health improvement programmes, for example the Diabetes Prevention Programme.

We maintain our legal duty of confidentiality to you at all times. We will only ever use or pass on information about you to others involved in your care who have a genuine need for it. We will not disclose your information for other purposes without your permission unless there are exceptional circumstances, such as when the health or safety of others is at risk or where the law requires information to be passed on

You have a right under the Data Protection Act 1998 to find out what information we hold about you. This is known as 'the right of subject access'. If you would like to make a subject access request or have any queries, please write to us at the address below.

[contact details]

Example text for a fair processing notice – NHS DPP Provider

[NHS DPP provider name] keeps records about you, your health and the care we provide you. They will include:

- your name, address and contact details
- information relevant to your treatment with us that we have received from your GP
- records of the treatment we have provided and the outcome.

When your treatment is complete we will send information about the treatment you have received and the outcomes to your GP practice to update their records.

We send information about the treatment that you have received to the commissioner of the NHS Diabetes Prevention Programme for payment and quality assurance purposes. This information will include your NHS Number and date of birth. If you have agreed to be contacted by a support organisation working for the commissioner to ask for your opinions about the service for evaluation purposes, we will also provide your name, address and telephone number(s).

You have a right under the Data Protection Act 1998 to find out what information we hold about you. This is known as 'the right of subject access'. If you would like to make a subject access request or have any queries, please write to us at the address below.

[contact details]

Informing patients about data processors

The legal requirement for fair processing is to tell people who you are, what you do with personal information and 'any other information necessary in the circumstances' to make the processing of information fair, leaving the data controller discretion about what else to include. There is no obligation to tell people that you are using the services of a data processor to manage your personal data as long as they only process it in the same way that you would if you were doing the processing yourself.

Where referral letters are to be followed up by a phone call from a data processor on behalf for a practice, this should be indicated in the letter to ensure that this is expected – see section 5.4.

The following is an example paragraph that you may wish to consider adding to your fair processing notice. This is a local decision, but needs to be made in consideration in the spirit of openness and transparency and (if included) be used as an opportunity to provide assurance that the data is held securely and confidentiality continues to be protected.

If you do decide to exclude it, you should still have information about your data processor contractors available as it could be requested under a Freedom of Information request, in which case you would have legal obligation to provide it.

Example:

From time to time we may use the services of a data processor to assist us with some of our data processing, but this is done under a contract with direct instruction from the GP that controls how they will handle patient information and ensures they treat any information in line with the Data Protection Act 1998, and confidentiality and privacy law, and any other laws that apply.

Appendix 6 – Business rules for case finding

NHS Diabetes Prevention Programme Audit Overview (v1.10)



NHS DPP Audit
Overview.docx

NHS Diabetes Prevention Programme Audit Section Descriptions (v1.10)



NHS DPP Audit
Section Descriptions.c

NHS Diabetes Prevention Programme Audit Clinical Extraction Criteria (v1.10)



Diabetes Prevention
business rules (1.1).c

NHS Diabetes Prevention Programme Audit (v1.10)



Diabetes Risk Score -
Medway.xml

Appendix 7 – Equality statement

Equality and diversity are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given due regard to the need to:

- Reduce health inequalities in access and outcomes of healthcare services integrate services where this might reduce health inequalities
- Eliminate discrimination, harassment and victimisation
- Advance equality of opportunity and foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.”