Public Health England

NHS England

Consultation Guide:

National Procurement for the Provision of Behavioural Interventions for People with Non-Diabetic Hyperglycaemia

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Consultation Guide: National Procurement for the Provision of Behavioural Interventions for People with Non-Diabetic Hyperglycaemia

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The National Health Service Commissioning Board was established on 1 October 2012 as an executive non-departmental public body. Since 1 April 2013, the National Health Service Commissioning Board has used the name NHS England for operational purposes.

CONTENTS

1 Introduction..... 6

2 Background 8

3 The Proposals 12

4 What Will The Services Provided In The NDPP Include? 15

5 How Do The Services To Be Provided In The NDPP Link With Existing Services?..... 21

6 How Will Individuals Be Referred To The NDPP? 22

7 What Will Payments To Providers Be Based On? ……26

8 What Data And Monitoring Requirements Will Providers Be Expected To Comply With? ……..30

9 What Branding and Communications Requirements Will Providers Be Expected To Comply With?.....31

10 What Will Happen To The Intellectual Property Related To Research If Providers Carry Out Research Using Patient Data For The NDPP?.... 32

1 INTRODUCTION

The Responsible Authority

1.1 NHS England (legally known as the NHS Commissioning Board[1]) intends to procure a national NHS Diabetes Prevention Programme ("NDPP").

Why are we consulting?

1.2 NHS England is committed to:

- developing the NDPP in an open and transparent way;
- ensuring that its proposals are informed by as wide a range of views as possible; and
- ensuring individuals have access to consistent high quality, effective, efficient services that represent value for money and are sustainable in the longer term.

1.3 This Consultation Guide is designed to provide those with an interest in the procurement of the NDPP, and also those who have a view about the proposals, to contribute to the proposals set out in this Consultation Guide in an informed manner.

1.4 We would like to hear from anybody with an interest in diabetes prevention services (specifically including, but not limited to, individuals with or at risk of non-diabetic hyperglycaemia, potential providers of the proposed services, general practitioners and other health professionals that may refer individuals into treatment programmes).

1.5 NHS England is committed to promoting equality and reducing health inequalities throughout the health service. Consultation provides the opportunity to gain information about any potential impact on health inequalities which might arise as a result of new or changed processes for making decisions about health services that are directly

[1] From 1 April 2013, the NHS Commissioning Board adopted the name NHS England. A name that gives people a greater sense of our role, scope and ambitions - as the organisation responsible for allocating the NHS budget, working to improve outcomes for people in England and ensuring high quality care for all, now and for future generations. Our legal name remains the NHS Commissioning Board as set out in our establishment orders. Whilst the NHS Commissioning Board will be known as NHS England in everything that we do, there are times when the statutory name is required for legal and contractual transactions. The following list provides some key examples of legal documentation which requires us to use our full legal name:

- HR contract of employment;
- Any documentation involving a court of law, ie litigation claims; and
- Contracts for directly commissioned services.

For ease of reference NHS England is the generic term used throughout this Consultation guide.

commissioned by NHS England. This information will feed into an equality and health inequalities analysis on this programme of work.

Feedback and next steps

1.6 Consultation on this document will be open to potential providers for [28] days from the date the consultation starts and until the end September for other interested parties. Further information can be found at www.england.nhs.uk/ndpp and an online form for feedback can be found at:

https://www.engage.england.nhs.uk/consultation/non-diabetic-hyperglycaemia

1.7 All feedback received during the consultation will be considered by the NDPP programme team. A short report, setting out the consultation feedback, will be published on the NHS England website.

1.8 A final decision about the proposed procurement will be made by NHS England having taken account of the overall programme requirements.

2 BACKGROUND

What is the mandate for the NDPP?

2.1 The NDPP was announced in the NHS Five Year Forward View, published in October 2014[2], 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.

2.2 The NDPP is a joint initiative with Public Health England ("PHE") and Diabetes UK which aims to deliver at a large scale services which identify people with non-diabetic hyperglycaemia who are at high risk of developing Type 2 diabetes and offer them a behavioural intervention to reduce their weight and increase physical activity.

2.3 The NDPP's aims are reflected in the 2015/16 business plans of NHS England and PHE. These are:

- "During 2015/16 [we will] have the new Diabetes Prevention Programme up and running and available to 10,000 at-risk individuals" and:
- "By March 2016 [we will] develop a comprehensive plan for the roll-out of the Diabetes Prevention Programme in 2016/17"

What is the proposed national procurement for and what is the rationale?

2.4 The proposed procurement is intended to identify providers who are able to provide a range of behavioural interventions aimed at preventing or delaying the onset of Type 2 diabetes in people with non-diabetic hyperglycaemia.

2.5 The rationale for procuring these services on a national scale is as follows:

- We know that demand for NICE recommended behavioural interventions outstrips supply for individuals identified by their GPs as being at high risk of type 2 diabetes. GPs commonly do not have an evidence based service to refer into. Further, where diabetes prevention services do already exist, the quality and value of these services varies and they do not necessarily conform with

[2] https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf

the evidence base from international trials. Additional numbers of people at high risk are also identified through the NHS Health Check and this will increase the demand.

- A national procurement for the behavioural intervention will allow us to more rapidly roll-out and scale up the NDPP whilst ensuring consistency in programme design and maintaining fidelity to evidence; and
- The proposed approach set out in this Consultation Guide would allow us to encourage provider innovation.

Our aims

2.6 The long-term aims of the NDPP are:

- To reduce the incidence of Type 2 diabetes;
- To reduce the incidence of complications associated with diabetes - heart, stroke, kidney, eye and foot problems related to diabetes; and
- Over the longer term, to reduce health inequalities in access to services and the outcomes achieved that are associated with the incidence of diabetes.

2.7 In the short-term we recognise that a stronger focus on identifying people who are at risk of diabetes is likely to increase incidence of diabetes as more undiagnosed cases are uncovered and therefore we anticipate that the above aims will only be realised over the longer-term.

Our objectives

2.8 The primary objectives of the NDPP are to support people with non-diabetic hyperglycaemia to lower their risk of progression to Type 2 diabetes and/or to delay the onset of disease and its complications by:

- promoting weight loss (and thereby maximize the health gain associated with prevention of disease attributable to obesity, including heart disease, depression, stroke, liver disease, respiratory disease, musculoskeletal conditions and certain cancers); and
- reducing glucose parameters (Hba1c/fasting glucose levels) of those at high risk.

2.9 Secondary objectives are to:

- reduce calorie intake;
- increase physical activity;
- move towards a healthier diet;
- ensure that people identified in local health communities via a general practitioner (GP), the NHS Health Check, or another healthcare professional as having non-diabetic hyperglycaemia are offered a place on a behavioural intervention;
- ensure consistent and equitable provision nationally of behavioural interventions; and
- make the best use of resources within the NDPP.

Consultation Question:

To what extent do you think the NDPP will help us to achieve our aims and objectives? Please explain what you think might help the NDPP achieve its objectives.

Underpinning Principles

2.10 There are a number of principles which underpin the NDPP:

- it must be delivered in a way which is consistent with the values and principles of the NHS Constitution;
- it will seek to reduce health inequalities and to promote equality of access to services and outcomes for those with protected characteristics under the Equality Act;
- the services must minimise the impact on existing primary care services in terms of referrals for diagnostic tests etc.;
- all individuals must be treated with courtesy, respect and an understanding of their needs;
- all those participating in any of the services provided through the programme must be provided with adequate information on the benefits and risks, in a format which is accessible to them, to allow an informed decision to be made before participating;
- access to behavioural interventions should be matched to the needs of the target population in terms of availability, accessibility and location, as far as possible;

- identifying people with non-diabetic hyperglycaemia and referring them on to a behavioural intervention will be effectively integrated across a pathway including between the different providers, NHS Health Checks, primary care and secondary care.

- Ensure ongoing improvements / adjustments as new evidence emerges (ongoing commitment to being based on best available evidence – that includes stopping things if found to be ineffective, and only making significant adjustments to service model if evidence is sufficient)

Equality Statement

2.11 Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the NDPP we have (and will continue to):

- Give due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- Give regard to the need to reduce inequalities between individuals in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Consultation question:
Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposals we have set out in this Consultation Guide and how you think any negative impact can be reduced.

3 THE PROPOSALS

Phasing of the Programme

3.1 The NDPP has three distinct phases which have been designed to develop the evidence in a staged way and to enable checks and balances to be built into the NDPP as it is implemented:

- Pre-procurement phase: work with seven demonstrator sites to test implementation of the NDPP. This phase is already underway and will be completed in 2015/16;
- Phase 1 Procurement 2015/16 to go live 2016/17: between 10,000 and 30,000 behavioural interventions across England are identified; and
- Phase 2 Procurement in 2016 to go live 2017/18: will aim to deliver long-term contracts providing for incremental scaling up of services with a view to full coverage across England by 2019/20 (subject to final decisions about the pace of implementation).

Phase I: Procurement for between 10,000 and 30,000 behavioural interventions in 2016/17

3.2 This Consultation Guide relates to Phase I of the programme which is designed to enable us to test what providers have to offer through a limited procurement, and leaves open the possibility of making changes to the service specification, or the phasing of national roll-out before entering into longer term contracts for the programme.

3.3 We intend to procure between 10,000 and 30,000 behavioural interventions, depending on the final funding allocation for the programme and the pricing received by providers in response to the procurement.

3.4 NHS England will be the contract holder and the services procured via this procurement process will be centrally managed by NHS England. For Phase 1 of procurement we envisage a contracting model based on 4 regional lead providers, with 1 contract for each NHS England region. In the longer-term we would propose to review the most appropriate body to commission behavioural interventions on an ongoing basis.

3.5 The first phase of the programme will use the learning from the existing demonstrator sites to inform the approach and we expect successful demonstrator sites to be part of the first wave of national provision in 2016/17. In particular, a number of the demonstrators are focused on establishing case-finding systems and would be well placed to work with

providers as part of a first wave of local partners adopting the newly procured services.

3.6 We will prioritise providers with the capability to deliver behavioural interventions from late 2015/16 onwards, with a view to maximizing the number of people enrolled on the behavioural interventions commissioned as part of this procurement process by the end of March 2015.

3.7 Alongside this Phase I procurement we are planning to take forward work during the second half of 2015/16 to identify NHS organisations with the capability to appropriately refer large numbers of people onto behavioural interventions from early 2016 onwards.

3.8 Phase 1 procurement covers only the delivery of behavioural interventions. We have separately issued a call for expressions of interest from CCGs and local authority partnerships in becoming first wave sites for identifying and referring individuals into these services. We would expect providers who were successful under this procurement to enter into partnership arrangements with one or more local health economies identified as potential candidates to become first wave sites for national roll-out.

Consultation Question:

i.) Please provide your views on the proposal for a regional lead provider contracting model

ii.) Is it preferable to identify four regional procurements or a national scope of operation, with potentially several providers operating nationally?

iii.) If we proceed with four regional procurements, should we only award any one provider one region in the first instance so as to test several models / providers in parallel in 2016/17? Or should we permit bidders to show scale savings from being able to operate two or more regions simultaneously?

Phase II – National Roll-Out

3.9 Phase II of the programme is outside the scope of this procurement. It will involve the wider roll-out of the NDPP in light of the learning from Phase I.

3.10 We therefore plan to run a further procurement exercise during 2016/17 to support Phase II, with a view to putting in place a longer-term contractual arrangement from 2017/18 onwards to support an incremental scaling up of the programme and roll-out a cross England.

3.11 Final decisions about the phasing of the NDPP (i.e. the approach to be taken to incremental upscaling of services and the timeframe for achieving full coverage across England) will be dependent on the funding available during the current Parliament. However, we currently anticipate that we will have achieved full national coverage by 2019/20 with around 100,000 behavioural interventions being provided per year.

4 WHAT WILL THE SERVICES PROVIDED IN THE NDPP INCLUDE?

4.1 This section of the Consultation Guide describes the services we propose to procure.

4.2 The proposed new services will be underpinned by relevant clinical guidelines and other guidance and publications published nationally, in particular:

- NICE PH38 Preventing Type 2 Diabetes: risk identification and interventions for individuals at high risk (2012)
- NICE PH 42 Obesity: working with local communities (2012)
- NICE PH 6 Behaviour change: the principles for effective interventions (2007)
- NICE PH 8 Physical activity and the environment (2008)
- NICE CG 43 Obesity: Guidance on the prevention of overweight and obesity in adults and children (2006)
- NICE CG 189 Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (2014)
- NICE PH 53 Managing overweight and obesity in adults – lifestyle weight management services (2014)
- Healthy Lives, Healthy People: A call to action on obesity in England (DH 2011)

4.3 Details about methods for referral onto programmes are set out in Section 5 below.

Eligibility criteria

4.4 Individuals who are eligible for inclusion on a behavioural intervention will have 'non-diabetic hyperglycaemia', defined as having an HbA1c 42 – 47 mmol/mol (6.0 – 6.4%) or a fasting plasma glucose (FPG) of 5.5 – 6.9 mmol/mol. Only individuals aged 18 years or over will be eligible for the intervention.

4.5 For individuals referred onto programmes by a GP or via the NHS Health Check, an HbA1c test or a FPG test must have been completed prior to referral.

4.6 NHS England may consider expanding the NDPP to include other Individuals at higher risk of Type 2 diabetes and non-diabetic hyperglycaemia including (but not limited to) those with polycystic ovary syndrome, those with a

history of gestational diabetes, and those with schizophrenia[3] in a later phase of the NDPP.

Individual suitability assessments

4.7 All eligible individuals will be offered a place on the intervention, and those who accept this invitation to enrol on the intervention will be considered sufficiently motivated to benefit from participation.

4.8 An invitation to participate will be sent by the provider to eligible individuals that have been referred into the programme, inviting them to participate in the intervention. This will be followed up either via letter, phone call, text message or email. The letter and follow-up should contain basic information about Type 2 diabetes, information about how risk could be reduced and high quality risk communication.

4.9 Where it becomes apparent to the provider that an eligible person who has been referred to them does not wish to accept an invitation to enrol on the intervention, the provider should signpost them to NHS choices website pages related to weight management, physical activity and healthy lifestyles and to any other locally available resources, as well as arranging to contact them to have their motivation and risk re-assessed in 12 months.

Behavioural Intervention - core programme components

Intervention aim

4.10 The intervention should focus on diabetes prevention, and should be based on diabetes prevention models such as the United States' national diabetes prevention programme (USDPP) and the Finnish diabetes prevention programme. Public Health England will shortly be publishing a review of the evidence relating to diabetes prevention programmes.

Target risk factors

4.11 The intervention should clearly be linked to the programme objectives set out at paragraph 2.8 and 2.9 above and be underpinned by three core goals embedded within a structured behavioural intervention. These goals to include:

- weight loss;
- achievement of UK dietary recommendations related to fibre, fruit and vegetables, oily fish, saturated fat, salt and sugar; and

[3] The effectiveness of interventions for those with schizophrenia (and other mental health problems) is yet to be examined, and intervention should only be considered as part of a robust evaluation or research study.

- achievement of (or exceed) the UK Chief Medical Officer's (CMO) physical activity recommendations.

4.12 These goals will be underpinned by existing government recommendations and research evidence.

Intensity and duration

4.13 The intensity and duration of the behavioural intervention should meet the following requirements:

- be made up of a series of 'sessions' as opposed to minimal ('one-off') contact;
- be spread across a minimum of 9 months, with flexibility around frequency;
- At least 13 sessions with a minimum total of 16 hours contact time;
- Sessions should ideally last between 1 and 2 hours, although shorter sessions can be considered if there is a strong rationale; and
- Providers may wish to 'phase' sessions (i.e. using core and maintenance phases) although this is not mandated and sessions may involve 'open' or 'closed' groups.

Underpinning approach / theory

4.14 The intervention should be grounded in behaviour change theory, it should be made explicit what techniques are being used, and should support sustained behaviour change.

4.15 Important behaviour change techniques include, but are not limited to, goal setting (which should occur frequently) and self-monitoring.

4.16 Sessions should incorporate clear, targeted, and high quality risk communication.

4.17 Family or peer support should be accommodated if wherever possible.

Delivery

4.18 Sessions can be delivered by health professionals or non-health professionals. We are seeking views on what competencies and qualifications should be specified, if any. We would expect providers to set out their approach to ensuring the quality and appropriate supervision of any staff employed by them, or contracted to them to deliver a behavioural intervention.

4.19 The intervention should be delivered using predominantly group sessions (ideally between 10 – 15 people), although individual sessions (either in person or remotely) may also be included or added.

4.20 Group sessions should be 'face-to-face', unless there is strong rationale/local drive for an alternative approach and it is rigorously evaluated or based on new evidence. At present, limited evidence has been identified that examines the effectiveness of 'remote' approaches however they may for example be necessary in rural settings and with younger adults.

Content of sessions

4.21 Providers would be expected to develop the detailed content to be covered within the sessions, however a list of topics will need to be covered including (but not limited to) minimum core dietary and physical activity information and these are set out in further detail below.

4.22 Dietary content:

- The syllabus will include the broader UK dietary recommendations as detailed in the eatwell plate[4]. This involves (for some) increased intake of fibre, fruit and vegetables and oily fish, and decreased intake of saturated fat, sugar, salt and energy;

- Participants should be supported to aim to meet as many of the dietary recommendations as possible. They should be encouraged to set achievable goals within identified areas for improvement; and

- An energy intake goal should be set at an agreed level to achieve weight loss for individuals who are overweight.

4.23 Physical activity content:

- Participants should be supported to aim for more than 30 minutes a day of moderate exercises such as walking, 3-5 times a week with 20-60 minute bouts of aerobic fitness activity, and 2-3 days a week of strength training, as recommended by the UK CMO;

- Individuals should be supported to incorporate active travel into their daily routine either through walking or cycling skills and group activities; and

- Supervised exercise should be included and build gradually to increase exercise capacity.

[4] http://www.nhs.uk/Livewell/Goodfood/Pages/eatwell-plate.aspx

Consultation Question:

We are seeking views on whether to specify that supervised exercise should be delivered by a person who is on the Register of Exercise Professionals (REPs) system of regulation for instructors and trainers; meeting the health and fitness industry's agreed National Occupational Standards.

Quality Requirements

4.24 The service provider must ensure that:

- services should be predominantly group based and delivered using a variety of methods including open or closed groups and one to one support and may also include drop ins, telephone and/or online support;
- services are delivered in a format and at times and locations that are appropriate to a range of groups in the community and may include evening and weekend sessions to facilitate access for working people;
- the service model and staffing structure are appropriate and sufficient to deliver all aspects of the required service;
- staff recruitment, training and development policies and practices ensure that staff have the appropriate competencies to deliver the intervention;
- service users are fully engaged in service development and continuous improvement; and
- providers will be responsible for securing the equipment, facilities and materials necessary to deliver the intervention within agreed budget.

Innovation to encourage participation

4.25 Providers will be expected to develop novel ways of encouraging uptake and adherence to the intervention.

Consultation question:

i.) We would welcome views as to whether there is scope for innovation in the delivery of the service; and

ii.) If you have any ideas as to how providers might be best incentivised to deliver innovation

iii.) We would also welcome your views on how fidelity with the core components should be maintained and quality assured throughout implementation

Reporting outcomes and sign-posting

4.26 There should be an assessment of weight, HbA1c (or FPG for those individuals in whom HbA1c cannot be used – for example in the presence of a haemoglobinopathy) and behavioural risks at enrolment, 6 and 12 months and at end of intervention if different to the 6 and 12 month landmarks, to determine the extent to which participants have modified their risk.

4.27 Providers will be expected to provide blood tests at these time points in order to assess HbA1c (or FPG for those individuals in whom HbA1c cannot be used).

4.28 Providers will be expected to demonstrate that they have made links to primary prevention, providing support for participants to integrate with local opportunities for continuing healthy dietary and activity behaviours and sustained weight loss.

4.29 Providers will also be expected to sign post participants to key sources of information and advice, such as NHS Choices.

Direct to Consumer Advertising

4.30 We are keen to explore the potential for providers to approach potential clients/consumers directly through proactive advertising and marketing of their programmes to the public and we would welcome proposed projects which seek to test out the potential for direct approaches to consumers and potentially also involving initial assessment for diabetes risk directly by potential providers, or their partners.

4.31 A key consideration where direct approaches to consumers are made is how to handle any risks arising from poor health and or pre-existing medical conditions which may present a risk to people engaging in physical activity. Any proposals submitted which include direct approaches to consumers will need to demonstrate that clear consideration has been given to how these risks would be mitigated.

4.32 Where providers introduce direct to consumer approaches, the use of a validation risk assessment tool to undertake initial assessment for diabetes will need to be undertaken.

Consultation Question:
We would welcome views from respondees on the potential scope for including direct to consumer advertising/marketing within the scope of a future procurement of services. In particular, what are the perceived benefits and are there any risks or difficulties associated with this approach which should be considered?

5 HOW DO THE SERVICES TO BE PROVIDED IN THE NDPP LINK WITH EXISTING SERVICES?

Link with Existing Services

5.1 The NDPP needs to function within the broader prevention and primary care systems.

Tier 2 Obesity Services

5.2 Tier 2 weight management services form part of the obesity pathway. Many exist across England although provision is inconsistent and there is variation in local commissioning and delivery.

5.3 The eligibility for the NDPP is different from eligibility for existing WMPs, although it is possible that a proportion of people who might otherwise have been eligible for weight management services might be diverted away from them into the NDPP. However it is equally likely that many requiring Tier 2 weight management services will not be eligible for the NDPP.

5.4 Further, a behavioural intervention will be delivered according to the best evidence of what reduces risk of Type 2 diabetes – and requires more than a focus on weight loss alone. Evidence from international trials on preventing Type 2 diabetes suggests that nutrition, physical activity and behaviour change elements must all be incorporated into programmes for them to be effective.

Consultation Question:

How do you think the introduction of the NDPP will complement existing services?

Identification of potential local health partners

5.5 Alongside the publication of this Consultation Guide we have issued a call for expressions of interest from CCGs and local authority partners who are interested in working closely with providers as part of Phase 1 of the programme.

5.6 The call for expressions of interest asks potential local partners to set out details of the infrastructure that they have in place, or plan to develop locally [in respect of diabetes prevention], with a view to enabling providers to understand the potential volumes of referrals that local partners could deliver and the readiness of those partners in terms of the infrastructure that they currently have in place (or plan to put in place) to support referrals and data sharing. Details of the expressions of interest submitted by potential local partners will be shared with potential providers as part of the procurement exercise.

6 HOW WILL INDIVIDUALS BE REFERRED TO THE NDPP?

6.1 We anticipate that individuals will primarily be referred onto a behavioural intervention via one of three core mechanisms:

- People who have already been identified as having an appropriately elevated HbA1c (or FPG) in the past and who have been included on a GP register of patients with high HbA1c (or FPG);
- The NHS Health Check programme which includes a diabetes filter, culminating, in those identified to be at high risk through stage 1 of the filter, in a blood test (HbA1c or FPG);and
- Direct to consumer approaches by the providers of behavioural interventions as part of the NDPP.

General Practice Registers

6.2 Through working with demonstrator sites it has become apparent that there are a significant number of Individuals who have had a blood test taken previously (HbA1c or FPG) not necessarily via the Health Checks intervention, by which they have already been identified as having non-diabetic hyperglycaemia and could be identified and invited directly into an individual session. Some GP systems enable a register to be created of patients with non-diabetic hyperglycaemia and some practices have already created such a register, although it is not currently known to what extent practices have established such registers, or how comprehensive they are.

NHS Health Checks

6.3 NHS Health Checks are currently available for individuals aged between 40 and 74 years (although some local services provide checks to younger people), with exclusions for those with existing diagnoses. All individuals within this age bracket without exclusion criteria, over a 5 year period, will be invited to participate in an NHS Health Check. Health Checks are conducted by a range of providers (such as GP and pharmacy) and are outside the scope of the proposed procurement.

6.4 Delivery of the NHS Health Check service is mandated so all local authorities are commissioning the programme.

Direct to Consumer Approaches

6.5 The programme is primarily orientated towards the delivery of behavioural interventions for those either already identified as having non-diabetic hyperglycaemia and who are known to their GP, or those who will be identified

via an NHS Health Check. However, as set out above at Section 4 we are also keen to explore the feasibility of direct to consumer approaches

Consultation Question:

i. Do you think that these referral routes would encourage individuals to participate in this service?

ii. We would welcome views on direct to consumer approaches. In particular how do you envisage that these would work in practice?

iii. We would welcome views from respondees on the feasibility of establishing systems to support referrals from general practice to the proposed new services at scale. In particular what systems and protocols would need to be in place to support the interface and information flows between GP practices and providers?

Capacity and Demand - Assumptions

6.6 There are an estimated 3.2 million people in England with diabetes of which 2.7 million have been diagnosed. A further four to five million people in England are at high risk of Type 2 diabetes, and by 2030 we estimate that more than four million people in England will have diabetes. Diabetes accounts for around £10 billion of NHS spend in the UK per year with 80% of this spend focussed on the management of the complications of this condition.

6.7 Our modelling suggests that in order to meet the demand for behavioural interventions that we are expecting, we would need to commission around 100,000 behavioural interventions per year once the service is rolled out across England. Our aim is to scale up to this level of coverage over 4 years, by 2018/19.

Modelling Approach

6.8 The evidence base relating to the effectiveness of diabetes prevention programmes in delaying onset of disease is strong, although the approaches taken in different trials and service models vary considerably. We have therefore developed an analytical model to support assumptions around capacity and demand. For the purposes of modelling estimated demand for behavioural interventions we have assumed:

- That the NHS Health Check programme will be a significant source of referral onto the programme in the long-run – we have used actual numbers from the NHS Health Check and assumed a growth in uptake of the NHS Health Check of 10% per year in line with PHE's predictions for the programme;

- That PHE are working to align guidance on the use of validated risk tools to achieve consistency and increase the proportion of people with an HbA1c blood test identified as high risk.

- That on average GPs in each CCG area will refer 250 additional individuals onto a behavioural intervention through opportunistic case-finding by GPs – see below for further detail on this assumption.

- That 37% of people who are eligible for a behavioural intervention will take one up.

Assumptions made about GP opportunistic referrals onto the programme

6.9 A key risk in relation to the demand modelling that we need to consider is that we are currently unable to properly model the number of existing, known people with high HbA1c on GP systems as there is no current requirement in Quality Outcomes Framework ("QOF") to maintain a register. The current modelling assumes that on average every CCG area will refer 250 people onto the programme.

6.10 It is clear from some of the demonstrator sites that there are potentially high numbers of people already identified with non-diabetic hyperglycaemia on GP systems. Collectively across the demonstrator sites we estimate they will place up to 7,500 people on programmes in 2015/16, a significant number through this route.

Demand

6.11 Modelling of expected supply and demand for a national programme suggests that by 2019/20 we would expect around 50,000 people to be identified as having non-diabetic hyperglycaemia annually via the NHS Health Check. In addition we expect that on average CCGs participating in the programme will generate demand from GP referrals equivalent to 250 behavioural interventions per CCG annually.

6.12 Total estimated demand nationally is therefore 100,000 behavioural interventions per year by 2018/19 assuming full coverage of a programme across England by then.

6.13 Over the longer-term our view is that there may be a case for introducing a programme of proactive case-finding for younger adults from black and minority ethnic groups including people of South Asian, Chinese, African-Caribbean and black African ethnicities, who can have up to a 6 fold increased risk of developing diabetes. The rationale for examining the case for case finding for these groups would be to support the reduction

of health inequalities in these groups. NICE guidance (NICE PH38) recommends case finding from age 25 in these groups. Younger adults are not currently eligible for a NHS Health Check. We intend to explore the case for introducing case-finding in younger adults in these groups as part of Phase III of the programme from 2017/18 onwards. However, this is outside the scope of the current procurement.

Consultation Question:
Based on the modelling assumptions described above do potential providers consider that the proposed procurement provides them with the opportunity to develop a viable, efficient, scalable and sustainable business model? If not, please highlight any barriers.

7 WHAT WILL PAYMENTS TO PROVIDERS BE BASED ON?

7.1 We are keen to explore scope for developing a results-based model for payment in partnership with potential providers. We intend to use the Phase 1 procurement as a way to test an approach to payment of providers in which those providers delivering the best results would attract higher rates of payment. Results-based models for payment can be highly complex to administer and this approach will need to be carefully assessed. In the long-run there are a number of complexities that we need to consider in relation to any payments model. For example, it may be that delivery of a behavioural intervention to a person from a group in the community which has historically been underrepresented in accessing services should attract a higher premium.

7.2 For the purposes of Phase 1 we intend to adopt a relatively simple results-based model for payment, with a view to exploring scope for introducing a more sophisticated approach in future as part of the proposed further procurement to inform Phase II of the Programme.

7.3 The principles that we consider should apply to a results-based model for payment for this initial procurement are that:

- 75% to 95%, of the payment would be based on volumes of people completing a behavioural intervention. ('Completion' will be defined as a participant having attended 75% of the intervention.)
- 5% to 25%, of the payment would be based on the proportion of people achieving the following outcomes:
  a) a reduction in HbA1c of 2 mmol/mol or more. For those in whom HbA1c cannot be used, for example in the presence of a haemoglobinopathy, then a reduction in FPG of 0.2 mmol/l or more.
  b) a reduction of 5% body weight at 12 months in at least 30% of those attending the intervention, where attending is defined as attending at least 4 hours on the intervention.

Consultation Question:
We would welcome views from respondees on whether:

i. The principle of a payment model in which providers delivering better results attract a higher level of payment is a sensible principle to apply to the programme?
ii. The proposed results-based payment model with around 5% to 25% of the total contract value linked to performance is a commercially viable model?
iii. Whether the proposed outcomes set out in 7.3 are feasible outcome measures to use as part of a results-based payment approach or whether linking payments to the outcomes and data in section 7.6 would be more appropriate?

iv.	There are specific ways of capturing the data requested in 7.3 that would assist both providers and NHSE?

Reporting requirements (including KPIs)

7.4 Providers will be required to undertake regular audits, to provide performance data and report to the Commissioner as requested. This is likely to include (but not limited to) demographic information about those who have engaged in, participated in and completed i) the assessment and ii) the intervention, blood results, weight and height (enabling BMI calculations), and indicators for quality of intervention delivery. It is essential that participant datasets can be linked to primary care records and therefore we would expect each participant to have a unique identifier which could be linked to their primary care record and this would need to be stored somewhere securely.

7.5 Providers should note that the data they supply may be used by PHE and NHS England for data quality reviews, contract and performance management, health needs assessment and epidemiological studies, audit, research, evaluation, service planning and delivery and strategy formulation.

7.6 Providers will be expected to be able to capture the following information to enable the quality of services and outcomes achieved to be monitored:

Stage of implementation	**Reporting requirement**
Referral	- Numbers identified and referred - Where referrals have come from - Blood score of individuals referred - Demographic information of individuals referred (to include information linked to health inequalities) - % referrals from lowest two deprivation quintiles = 50%

Follow up on referral	- Number and % of referrals contacted by the provider within 2 weeks of referral being received
	- Number and % of individuals offered a first appointment
	  o Breakdown of dataset by referral information
	- Number and % of individuals not offered a first appointment
	  o Breakdown of dataset by referral information
	  o Reasons first appointment not offered

First appointment	- Number and % of individuals who attend a first appointment
	  o Breakdown of dataset by referral information
	- Number and % of individuals who do not attend a first appointment
	  o Breakdown of dataset by referral information
	  o Reason for non-attendance

	- Data from individuals:
	  o HbA1c (range and average)
	  o Weight in kg (range and average)
	  o Height in cm
	  o BMI calculation (range and average)
	  o Wellbeing score (range and average)
	  o Breakdown by demographic information
	- Number and % of individuals eligible / not eligible for the intervention
	  o Breakdown of dataset by referral information
	  o Reasons for non-eligibility and any ongoing referral

Behavioural intervention	- Number and % of individuals who start the intervention
	  o Breakdown of dataset by referral information
	- Number and % of individuals who do not start the intervention (DNA)
	  o Breakdown of dataset by referral information
	- Attendance throughout the intervention
	  o Breakdown of dataset by referral information and provider information
	- Engagement: Number and % attending a minimum of 4 hours
	- DNA: Number and % not attending a minimum of 4 hours
	- Completion: Number and % of individuals who attend 75% of the intervention
	  o Breakdown of dataset by referral information
	- Number and % of individuals who drop-out of the intervention
	  o Breakdown of dataset by referral information
	  o Time of drop-out
	  o Reason for drop-out

During intervention	- Fidelity to core programme components - Participant perspectives on the service - Implementation information 6 month check: - HbA1c (report changes) - Weight (report changes in kg and %)
Post-intervention (12 months)	HbA1c (FPG for those in whom HbA1c cannot be used) (range and average) - Change in HbA1c (change in FPG for those in whom HbA1c cannot be used) (range and average) - % total referrals demonstrating 2 mmol/mol reduction in HbA1c (in those where HbA1c cannot be used, % referrals demonstrating reduction in FPG of 0.2 mmol/l). Weight (range and average) - Change in weight (kg and %, range and average)

	- % total referrals demonstrating 5% reduction in weight - Record number and weight loss in kg at 12 months = +0, -0-5kg; -5-10kg; -10-15kg; -15kg+

7.7 In addition providers must also have systems in place to monitor and maintain the quality of the service provision. This is likely to include (but is not limited to):

- A written complaints procedure
- Routine information from participants about their satisfaction with the service provided
- Routine checks on intervention delivery

Consultation question:

Please provide any comments you may have about the KPIs we are proposing

8 WHAT DATA AND MONITORING REQUIREMENTS WILL PROVIDERS BE EXPECTED TO COMPLY WITH?

Data protection, information governance and confidentiality

8.1 All systems and communications used by the providers should comply with all aspects of the Data Protection Act 1998, the Caldicott Principles and the Information Standards Board for Health and Social Care.

8.2 Providers will be required to comply and ensure that their staff comply with an appropriate confidentiality policy which ensures that appropriate measures are in place for the handling and transit of data at all times.

Data sharing for referral

8.3 Referral into services will necessitate the sharing of personal identifiable data (PID) where consent has been provided by the client. The provider will be expected to enter into data processing agreements with parties that refer into the service.

Consultation question:

i. What sort of information do you think needs to be reported and at what stages of the treatment do you think it would be appropriate?

ii. What sort of data sharing mechanisms need to be put in place to ensure data can be shared for referrals and with other services? If you have any experiences of sharing data with local health economies, then please share.

Data sharing re long term impact

8.4 NHS England is keen to understand the long term impact of the NDPP. As such providers will be required to obtain written consent from individuals participating in the NDPP to ensure that data can continue to be collected and used in the future.

9 WHAT BRANDING AND COMMUNICATIONS REQUIREMENTS WILL PROVIDERS BE EXPECTED TO COMPLY WITH?

9.1 Providers will be expected to use the branding and communication guidelines required by NHS England in respect of the NDPP.

10 WHAT WILL HAPPEN TO THE INTELLECTUAL PROPERTY RELATED TO RESEARCH IF PROVIDERS CARRY OUT RESEARCH USING PATIENT DATA FOR THE NDPP?

10.1 NHS England envisages that there will be intellectual property developed during Phase 1 of the NDPP that will be required to allow for the development of Phase 2. NHS England is currently considering how any rights and liabilities arising as a result of Phase 1 will be dealt with in any contract between NHS England and providers for the provision of services within the NDPP.

Consultation Question:

i. What sort of intellectual property rights are likely to be created under Phase 1?

ii. How do you think any rights and liabilities relating to IP created in Phase 1 should be dealt with? How would you ensure that this doesn't hinder the development of phase 2?

Consultation question:

Please provide any further comments you may have on the proposals set out in this Consultation Guide.