Business Case Merseyside Health Economy

Business Case for: Diabetes Prevention Pathway

Identification and management of patients with Impaired Glucose Regulation (IGR) across the Mersey Cluster

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Executive Summary

Introduction

 Impaired glucose regulation (IGR) (or non-diabetic hyperglycaemia) refers to blood glucose levels that are above the normal range but are not high enough for the diagnosis of Type 2 diabetes. The risk factors for IGR are the same as those for Type 2 diabetes – the greatest single risk factor being obesity. Before people develop Type 2 diabetes, they almost always have IGR. The identification of IGR provides a substantial opportunity for preventing or delaying the future burden of Type 2 diabetes on the NHS, as well as on patients and their families.

Case for Change

- 2. Alongside the need to reduce the burden of diabetes on the population, there are a number of drivers for improving the identification and management of IGR patients including: the views of local patients; the spiralling costs of diabetes; national and European guidance on IGR (including newly published NICE guidance); the development of Pre-diabetes Education programmes; and the rolling out of the NHS Health Checks, which are expected to increase the numbers of IGR and diabetes cases being diagnosed in primary care. A primary care survey and audit of current practice in identifying and managing IGR patients in Merseyside have both recently highlighted significant inconsistencies between practices and demonstrated the need for a common standardised pathway.
- 3. The current registered adult prevalence (17 yrs +) of IGR on Merseyside is 0.8% (9265 people), this is likely to be a significantly lower than the true prevalence. The Department of Health's NHS Health Checks modelling assumes an IGR prevalence amongst adults aged 40-74 years of 2.3% and estimates that with the introduction of NHS Health Checks 1,153 people will be diagnosed with IGR annually in Merseyside.
- 4. Once diagnosed, over a third of IGR patients will go on to develop Type 2 diabetes within 6 years if no intervention is made; however, evidence shows that the onset of Type 2 diabetes can be delayed for an average of 8 years through intensive lifestyle intervention, avoiding substantial costs. Offering patients with IGR an annual review will also enable early identification of diabetes which is likely to have clinical benefits and lead to further cost savings.

Identifying the way forward

5. It is proposed that a shared pathway is put in place across the Merseyside Cluster for the identification and management of IGR patients. A number of options are presented, covering diagnostics (including initial tests and annual follow up tests where appropriate); primary care provision of annual reviews for IGR patients; and the provision of patient education and weight management services. It is likely that individual Clinical Commissioning Groups (CCGs) will wish to implement the pathway to fit local circumstances. This paper spells out the options and recommendations available.

- 6. Cost-effectiveness of the proposed pathway has been calculated on the basis of cost-avoidance through the delay in onset of diabetes estimated to be achieved against costs of diagnosing and appropriately managing IGR patients.
- 7. This modelling has estimated that diagnosing and appropriately managing those who have been previously identified as having IGR or with previous blood tests results that meet the threshold for IGR, and those diagnosed with IGR as a result of an NHS Health Check, would deliver an annual cost saving across Merseyside of £2,068,553 in Years 1 & 2 and an annual cost saving of £549,872 in Year 3 onwards.

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1. Strategic Context and Drivers

1.1 Background

The driver for this business case is the increasing prevalence of Type 2 diabetes, a chronic costly condition, which is preventable in the majority of cases.

It is possible to identify those who are 'borderline' for diabetes and offer interventions to prevent or slow the progression to diabetes and/or detect diabetes earlier before complications have set in. This 'borderline' state is termed Impaired Glucose Regulation (IGR) – sometimes referred to by the lay term 'pre-diabetes'.

The prevention of diabetes has been a priority of the Merseyside Patient Group (North Mersey Diabetes Action Group) for some time, while Liverpool PCT had a patient and professional group with a remit to work together to prevent diabetes. It was also a priority identified by the Diabetes Health Needs Assessment for Halton, St Helens and Warrington (November 2007) and the North Mersey-wide Diabetes Health Needs Assessment (April 2010).

When the Diabetes QIPP work stream came into being in the summer of 2010, public health were given the opportunity to present two briefing papers on strategies for preventing diabetes as prevention is one of the Ps of QIPP. The first paper made the case for a broad approach of targeting interventions to those with risk factors for diabetes (such as obesity). The second paper focused on those at highest risk – those with IGR. The decision was made by the Diabetes QIPP board members to prioritise this group of patients.

A steering group was formed with public health representatives from across Merseyside and from the Diabetes Network to progress the IGR business case. At each stage of the IGR pathway development, meetings were held with local primary care clinicians and weight management specialists to determine the specific requirements. Each key decision was then discussed at the Diabetes QIPP board meetings.

Until recently there were no national guidelines for the management of IGR and no reliable information about the number of people with IGR in Merseyside. Therefore, before the business case could be progressed, work began on identifying current practice, and the number and demographics of patients who are already known to have IGR. Thus in spring 2011 an electronic questionnaire was sent out to all general practices in Knowsley, Liverpool and Sefton to ascertain current management and views on producing a local pathway. This was followed by a clinical audit of IGR patients in September 2011 to provide the necessary baseline data.

A number of options were considered during the development of the IGR Pathway by the diabetes leads in primary care and weight management specialists and preferred options chosen in February 2012. In May 2012 the pathway was agreed by the Diabetes QIPP / Merseyside Diabetes Network and the options were discussed with patient representatives.

The delivery model proposed involves: identifying the patients at risk of IGR and those already diagnosed by running searches in GP clinical systems, offering blood tests to those identified, then offering the patients an initial review and an annual review thereafter, providing a package of patient education and offering patients with IGR access to an appropriate weight management intervention with defined follow-up and evaluation.

1.2 Introduction

1.2.1 What is Impaired Glucose Regulation?

Impaired glucose regulation (IGR) (or non-diabetic hyperglycaemia) refers to blood glucose levels that are above the normal range but are not high enough for the diagnosis of Type 2 diabetes. IGR is used to describe the presence of impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT), (and/or HbA1c of HbA1c of 42 to 47mmol/mol) which are intermediate states of abnormal glucose regulation that exist between normal blood glucose levels and Type 2 diabetes¹. IGR is asymptomatic and can often go undiagnosed for many years². IGR is also sometimes referred to as 'pre-diabetes' – a term recommended by Diabetes UK for communicating the concept of IGR to the public.

1.2.2 IGR risk factors

The risk factors for IGR are the same as those for Type 2 diabetes – the greatest single risk factor being obesity. IGR itself is a risk factor for Type 2 diabetes. Women with a history of gestational diabetes are also at greater risk of developing IGR and diabetes.

1.2.3 Diagnosing IGR

The Department of Health's diagnostic criteria for IGR for the purpose of the NHS Health Checks are based on a single fasting plasma glucose (FPG) test followed by an oral glucose tolerance test (OGTT) for those who cannot be diagnosed as diabetic or within a normal range (normoglycaemia) based on the single test.

In 2011, the WHO made a recommendation that HbA1c can be used as a diagnostic test for diabetes.² This recommendation was endorsed by a UK expert group³, although there remained some debate on whether HbA1c was appropriate for diagnosing IGR. Following discussion with local clinical leads and the endorsement of HbA1c for this purpose in the NICE guidance *Preventing Type 2 diabetes: Risk identification and interventions for individuals at high risk* (published in July 2012), it was decided that HbA1c should be the preferred diagnostic test for IGR in Merseyside, with a HbA1c of 42 to 47mmol/mol indicating IGR. (See also section 3.1). Evidence shows that using HbA1c will result in an additional 10% of patients being diagnosed with IGR compared with using FPG and OGTT tests in the same patients.⁴

1.2.4 Prevalence of IGR

Estimating the prevalence of IGR is not straightforward due to the range of diagnostic criteria being employed in clinical practice and in research studies. A number of epidemiological studies in North America, Europe and Asia have

estimated that approximately 15% of adults have IGR based on a single FPG test result to diagnose IFG and a single FPG followed by an OGTT to diagnose IGT.

The NHS Health Check modelling assumes an IGR prevalence of 2.3% among those who attend a Health Check. However, whereas those with a raised FPG result (but not diabetic) who went on to have a normal OGTT result would be classed as having IFG (and therefore IGR) in most research studies, in an NHS Health Check these patients would only have been diagnosed with IGR if they had a raised (but not diabetic) OGTT result. In other words, only patients diagnosed with IGT are included in the NHS Health Check definition of IGR.

1.2.4 What is the purpose of identifying and managing IGR patients?

Before people develop Type 2 diabetes, they almost always have IGR⁵. The identification of IGR provides a substantial opportunity for preventing or delaying the future burden of Type 2 diabetes on the NHS, as well as on patients and their families. In the absence of intervention the majority of individuals with IGR are likely to develop Type 2 diabetes within 5-10 years.¹ However, there is good evidence to suggest that Type 2 diabetes can be prevented or delayed in people with IGR. Although inherited factors predispose to Type 2 diabetes, environmental and lifestyle factors leading to over-nutrition and insufficient physical activity are mainly responsible for the increasing prevalence of the disease over the past decades.⁶ Type 2 diabetes could be prevented in many people, or certainly postponed, if weight could be kept within the healthy BMI range of 20-25kg/m².⁷

Evidence shows that:

- modest lifestyle changes can significantly postpone the onset of diabetes in high risk individuals;^{8,9}
- a weight reduction of 3.7–6.8 kg in overweight people aged 30–50 equates to a 33% reduction in the risk of developing Type 2 diabetes;¹⁰
- lifestyle intervention is more effective than the drug treatment Metformin in reducing the incidence of Type 2 diabetes in IGR patients;⁵

There have been two major studies evaluating the effectiveness of lifestyle intervention based diabetes prevention programmes in IGR patients – the Finnish Diabetes Prevention Study and the Diabetes Prevention Program in the US. In the Finnish study, the five year Number Needed to Treat (NNT) was five; i.e. for every 5 IGR patients who went through the programme, one case of Type 2 Diabetes would have been prevented as a result in 5 years' time. In the US study, the three year NNT was 6.9.

Since Type 2 diabetes is associated with an increase in CVD, preventing or delaying the onset of Type 2 diabetes may also reduce the risk of CVD.^{1, 2,11,12,13} It is known that lifestyle-based intervention to prevent Type 2 diabetes also improves cardiovascular risk factors.^{14,15} Because CVD accounts for much of the morbidity and mortality associated with Type 2 diabetes, even small reductions in cardiovascular risk would be clinically significant.¹⁶

The process of identifying IGR patients will also pick up cases of undiagnosed Type 2 diabetes. It is thought that many people with Type 2 diabetes may have had the

condition for 9-12 years before diagnosis¹⁷ and half of those who are diagnosed with Type 2 diabetes present with advanced complications.¹⁸

The benefits of actively identifying and managing IGR patients therefore include the delay or prevention of Type 2 diabetes in IGR cases and the delay or prevention of complications in previously undiagnosed Type 2 diabetes cases, with a possible reduction in morbidity and mortality from CVD.

1.3 Drivers for Change

1.3.1 National Drivers

The importance of reducing the incidence of diabetes is recognised at a national level. NHS Diabetes and Kidney Care have taken a strong interest in the development of the Merseyside Cluster IGR pathway & QIPP business case and have provided support in its development.

Standards 1 and 2 of the Diabetes National Service Framework (NSF) relate specifically to identifying and managing IGR patients:

- Standard 1 Prevention of Type 2 diabetes
- Standard 2 Identification of people with diabetes

The NSF illustrative targets for local priorities for these standards include implementing a protocol to identify IGR patients, provision of weight management counselling and support, offering patients with IGR a test for diabetes, flagging patients with IGR on a register for regular recall and offering repeat testing and support on lifestyle change.¹⁹

1.3.2 Spiralling Costs of Diabetes

The Wanless Report $(2004)^{20}$ noted that there is scope for significant cost-savings through prevention of diabetes, earlier diagnosis and better management. A report from the NHS Information Centre showed that prescriptions for diabetes now account for 8.4% of the entire NHS net bill for primary care drugs in England, with a 41.1% increase in the cost of prescribing from £513 million in 2005/06 to £725 million in 2010/11. Over the same period, the number of items dispensed to treat diabetes rose by 41.2%, from 27.1 million to 38.3 million.²¹

Diabetes UK, the national diabetes charity, has estimated that diabetes currently costs the NHS £1million an hour:²²

- 10% of people in hospital have diabetes and 60% of inpatients with diabetes have been admitted as emergencies.
- People with diabetes are twice as likely to be admitted to hospital.
- Diabetes UK estimates that people with diabetes spend 1.1 million days in hospital a year.
- The hospital stay for a person with diabetes is likely to be up to twice that of a person without diabetes: the hospital stay for a person with diabetes is an average of 11 days.
- 20% of people with diabetes in hospital have already been hospitalised in the previous year.

- An average daily bed stay costs the NHS around £215.
- Emergency ambulance attendance costs around £220 and minor Accident and Emergency attendance costs around £55.
- Recent estimates are that 10% of NHS spending goes on diabetes. This equates to £9 billion a year.
- Local cost estimates of diabetes spend during 2011/12 across the Mersey Cluster equate to £514 per patient with diabetes, at a total of £30,778,297 (this is likely to be an underestimate as due to current coding for diabetes some spend could not be attributed).

1.3.3 National and European Guidance

In the absence of UK specific guidance, Diabetes UK published a position statement in 2009 on the management of IGR patients, developed in consultation with experts, to provide consensus-based recommendations for healthcare professionals managing people with IGR.²³ Similarly, the IMAGE project (Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention), funded by the European Commission, produced comprehensive evidence-based guidelines for the prevention of Type 2 diabetes which were published in 2010.²⁴ This includes guidance on identifying at risk patients, appropriate diagnostic tests and effective interventions. Both these sets of guidelines have informed the development of the IGR pathway which forms the basis of this business case.

NICE guidance on preventing the progression from IGR to Type 2 Diabetes was published in July 2012 following the draft published on 9 November 2011 which went out for consultation until the 9 January 2012. The NICE guidance presents a large amount of evidence, including a cost effectiveness analysis, to support the recommendations of implementing risk assessment and IGR testing, an IGR register, and intensive lifestyle-change programmes and advice, followed up by annual assessment, for those diagnosed with IGR.²⁵ The core recommendations broadly reflect the preferred options put forward in this business case, with some variation in the detail. The publication of the NICE guidance will essentially place an expectation on commissioners to ensure that processes are in place for the effective identification and management of IGR patients; implementing this business case will ensure that the Merseyside Cluster is equipped to meet this expectation without delay.

1.3.4 NHS Health Checks

The NHS Health Checks programme is being implemented across Merseyside, offering a health check to every adult aged 40-74, without known cardiovascular disease, every five years as part of an ongoing rolling programme. As a result it is expected that many new cases of both IGR and Type 2 diabetes will be identified. This represents a vital opportunity to prevent future cases of diabetes; however, without a clear pathway and services in place to ensure that new IGR patients receive the necessary intervention, this opportunity will be missed.

1.3.5 Local Objectives

Effectively identifying and managing IGR patients fits with key local objectives of; A) reducing obesity, B) reducing health inequalities, and C) cost saving:

- A) Reducing overweight and obesity, which forms the backbone of IGR intervention, is highlighted as an objective in the Cluster PCTs' Strategic Commissioning Plans. The Strategic Commissioning Plan for Halton & St Helens includes an explicit goal that "By 2013 people with risk factors for diabetes will be identified to reduce their risk of developing the disease. People with diabetes will have improved, easily accessible, preventative treatments in place to support them in managing the disease and stop it or delay it progressing into other debilitating conditions".
- B) The prevention of diabetes has an important role to play in reducing health inequalities. Diabetes is more common among deprived populations and the prevalence of IGR varies among the population depending on ethnic background.^{13, 10} There is UK evidence that South Asians progress to diabetes at three times the rate of White Europeans.²⁶
- C) The cost of diabetes to the health system in terms of care and prescribing are substantial and growing. Current registered adult prevalence of diabetes is 5.8%. It is predicted that by 2030, 10% of the population will have diabetes.²⁷ Unless effective action is taken to reduce the incidence of diabetes, this will directly result in a dramatic increase in cost burden on Clinical Commissioning Groups (CCGs) in the future. The financial modelling section of this business case includes further detail of the estimated financial implications of implementing the proposed IGR pathway compared with taking no action.

1.3.6 Local delivery

Strong interest in this area among GPs in Sefton has already enabled a Locally Enhanced Service Agreement (LES) to be put in place, where practices receive a time limited payment for actively identifying and offering patients with IGR an annual review. This was designed to serve as a 'stop gap' in Sefton until the Merseyside Cluster IGR pathway can be implemented.

In the current LES practices are paid for; administration of call and recall, for taking the blood for HbA1c and for reviewing patients fact-to-face. For an example LES see Appendix 2

1.3.7 Patient views

The North Mersey Diabetes Action Group, which includes cluster wide diabetes service user representation, has requested that prevention of Type 2 diabetes be made a key priority for the Mersey Diabetes Network.

2. Health Needs Assessment

2.1 Prevalence of Diabetes

The best estimate of true diabetes prevalence available at PCT level is provided by the Association of Public Health Observatories' (APHO) Diabetes Prevalence Model²⁸. Based on this model, the number of people in the Merseyside Cluster estimated to have diabetes is 70,541, or 7.6% of the population. Comparing clinically diagnosed levels of diabetes to these estimates reveals disparity, suggesting a potential figure for undiagnosed diabetes cases of 12,937 across the Merseyside Cluster (Table 1).

Area	APHO estimated Prevalence (%)	2009-10 QOF Prevalence	Estimated prevalence minus known prevalence
Liverpool	25,937 (7.4)	20,640	5,297
Sefton	17,741 (7.9)	12,684	5,057
Knowsley	9,027 (7.5)	7,644	1,383
Halton & St Helens	17,836 (7.5)	16,636	1,200
Merseyside Cluster	70,541 (7.6)	57,604	12,937

Table 1: Estimated vs. recorded prevalence of diabetes in the Merseyside Cluster

2.2 Prevalence of Obesity

Obesity is the major risk factor for IGR and Type 2 diabetes. Data on current levels of obesity in Merseyside is limited, although it is increasing, see table 2.

Table 2: Local obesity data

Area	Obesity prevalence	Source	Notes	
Liverpool	10%	GP practice records	GP recorded BMI data covers only 29% of the population, of whom a third are obese. Overall recorded levels of obesity are below the expected prevalence, reflecting this under recording of BMI.	
Sefton	19%	2010 Sefton Lifestyle Survey	BMI is based on self-reporting of height and weight.	
Knowsley	20%	2006 Knowsley Adult Health and Lifestyle Survey	BMI is based on self-reporting of height and weight.	
Halton & St Helens	12%	GP practice records	Recorded rates varied from 5-28%. Practices recording the lowest rates of measuring BMI also reported the lowest rates of obesity and vice versa.	

2.3 Prevalence of IGR

The NHS Health Check modelling assumes an IGR prevalence of 2.3% among adults. It has been estimated that 5-12% of those with IGR go on to develop Type 2 diabetes annually, however this is based on a definition of IGR which includes those with a single raised FPG result and normal OGTT result who would not be classed as having IGR under the Health Check criteria. As the criteria for an IGR diagnosis are stricter in the Health Check pathway, it is likely that the higher estimate will be more applicable to this cohort or possibly that even the higher figure is an underestimation. Table 3 shows how these estimates apply to the Merseyside population, with a total estimated number of 26,636 IGR cases currently, of whom between 1,332 and 3,196 will go on to develop diabetes annually.

Area	Adult Population	Expected Numbers with IGR	IGR patients expected to develop diabetes annually
Liverpool	434,900	10,003	500 – 1,200
Southport and Formby	115,542	2,657	133 – 319
South Sefton	159,558	3,670	183 – 440
Knowsley	150,800	3,468	173 – 416
Halton	124,866	2,872	144 – 345
St Helens	172,434	3,966	198 – 476
Merseyside	1,158,100	26,636	1,331 – 3,196

Table 3: Estimated prevalence of IGR in the Merseyside Cluster

2.4 Current practice in identification and management of IGR patients in Merseyside

In order to establish current practice in identification and management of patients with IGR in GP practices in Spring 2011 (prior to the current formation of the Mersey Cluster), a short questionnaire with a combination of closed and open questions was devised in collaboration with the diabetes lead GPs for Knowsley, Liverpool and Sefton. Overall, the results showed major inconsistencies in management of IGR patients between GPs across the three PCTs (see **Appendix 3**). Key findings included:

- Overall response rate was 39%.
- 67% of respondents kept an impaired glucose patient register.
- 42.9% of practices with an IGR register reported reviewing patients on an annual basis.
- 91.5% of respondents stated that the intervention they were most likely to offer during the review was lifestyle advice.
- Blood pressure monitoring (BP) was included in 84.5% of reviews.
- 31% of reviews included an oral glucose tolerance test (OGTT).

Some key themes emerged from the responses to the open questions, with several respondents commenting on the need for treatment to focus on lifestyle interventions and the need for improvements to current lifestyle services. Other comments

included the need for more funding and better access, along with wider involvement from other health professionals and members of the primary care team. Several respondents stated their support for a common pathway with clear protocols and guidance. Some acknowledged current failures in managing IGR patients, and a recognition that improvements are needed. Concern was also raised regarding current and potential non-compliance of IGR patients with treatment and review.

Whilst there were some limitations from the survey in relation to potential nonresponse bias, overall the findings strongly support the case for a systematic approach to the management of patients with IGR in Merseyside.

2.5 Current prevalence and management of known IGR patients in Merseyside

In order to establish a baseline of the current numbers of IGR patients recorded in GP practices across Merseyside, and the current management of those patients, an audit of 758,780 patient records at 148 GP practices was undertaken in September 2012 across Merseyside (including Halton and St Helens). The results of this audit show that across Merseyside:

- the known incidence of IGR has roughly doubled since 2006, rising from 644 new cases in 2006-07 to 1,203 new cases in 2010-11;
- the current known adult prevalence of IGR is 0.8%, ranging from 0.5% in Liverpool to 1.6% in Halton & St Helens;
- at an individual GP practice level, current prevalence ranged from 0.0% to 4.6%;
- 34.5% of known IGR patients had a recorded BMI of ≥ 25 and <30 (overweight) and 47.3% had a recorded BMI of ≥ 30 (obese);
- only 0.2% of overweight and 1.2% of obese IGR patients were recorded as having been referred to a weight management intervention (in Knowsley no IGR patients were recorded as having been referred to a weight management intervention);
- 65.7% of those diagnosed with IGR in 2009-10 were not recorded as having had an FPG test in the following 12 months (in Liverpool this figure was 90.1%) suggesting that in the majority of cases, blood tests were not being repeated annually

The 0.8% registered percentage of patients with a diagnosis of IGR in Merseyside was significantly lower than the 2.3% prevalence suggested by the NHS Health Check Modelling, suggesting there could be around 17,370 people with undiagnosed IGR (see Table 4).

	Halton	Knowsley	Liverpool	Southport and Formby	St Helens	South Sefton	Merseyside
Population 17+	124,866	150,800	434,900	115,542	172,434	159,558	1,158,100
Registered prevalence	1998 (1.6%)*	1508 (1%)	2175 (0.5%)	1155 (1%*)	2759 (1.6%*)	1596 (1%*)	9265 (0.8%)
NHS Health Check Modelling	2872	3468	10,003	2657	3966	3670	26,636
Potentially undiagnosed	874	1960	7828	1502	1207	2074	17,371
*based on original data for Sefton and Halton and St Helens							

Table 4: Summary of registered IGR prevalence compared to NHS Health Checks modelling

Whilst acknowledging that referrals to weight management will be affected by the willingness of patients to be referred and that inadequacies in recording may inaccurately imply inadequacies in practice, these results support the findings of the practice survey regarding the need for much improved management of IGR patients and a consistent approach to identification, recording and follow up of IGR patients across Merseyside. This is essential in order to ensure that appropriate efforts are being too made to prevent people with IGR going on to develop Type 2 diabetes.

3. Models of delivery

There are a number of proposed or existing models of delivery for the management of IGR documented in the UK. The proposed Merseyside model comprises of five steps, and has been compared to four other models, see summary Table 5 below. See also Appendix 4 for a more detailed comparison of the UK models and the proposed pathway for Merseyside.

Merseyside IGR service model	NICE	Diabetes UK	NHS Salford	Let's Prevent
Step 1a: Search practice registers for high risk using known risk factors as opposed to risk stratify population	No	Not specified	Yes	Yes
Step 1b: Follow-up patients identified by NHS health checks	Yes	Yes		
Step 2: Offer blood test	Yes	Yes	Yes	
Step 3: Offer initial review		Yes		Yes
Step 4a: Patient education to include CVD risk, diabetes risk and how to reduce risk		Yes	Not known	Yes,
Step 4b: Lifestyle intervention (weight management), 16 hours in total [includes patient education]	Yes	Time not specified	No	Time not specified
Step 5: Annual review for patient with IGR	Yes	Yes	Yes	

Table 5: Summary of similarities between the proposed Merseyside IGRpathway and alternative models

NICE guidelines recommend the method of identifying patients by risk stratifying the whole population using real and estimated data and then offering blood tests to those identified as high risk. The proposed Merseyside pathway uses a more targeted approach, as it recommends managing those already identified through a prior blood test as having IGR and following-up those who will be identified as having IGR through the NHS Health Check. The steering group deemed it more appropriate to manage the patients already identified as having IGR before expanding the identification process, although this could be a future consideration.

There are also differences in the way patients are referred for patient education, as the proposed Merseyside model relies on GP referral whereas Salford use clinical searches to identify the high risk and invite the patients directly. However, it was felt more effective to offer IGR patients an annual review where the patient has a clinical assessment and encouraged to attend patient education and lifestyle service. The annual review also ensures that patients who do progress to diabetes are identified at an early stage and managed by the practice.

NICE guidelines also do not separate out the patient education and lifestyle intervention; however, these are separated out in the proposed Merseyside pathway, as IGR specific patient education is not currently provided across providers.

3.1 Summary of proposed model for Merseyside

In the proposed model for Merseyside, primary care would manage patients with IGR, offering them initial review and thereafter annual review (see also Appendix 1, primary care pathway). All patients are offered the opportunity to attend a programme of patient education and those with a BMI of 28kg/m² or more are also offered weight management.

The implementation of the proposed model is dependent on securing additional funding. However, funding has been obtained for the cost minimal option which will include:

- Providing practices with searches to identify patients with IGR.
- Providing the pathway and clinical guidelines for management of IGR.
- Launching the pathway in primary care.
- Developing local patient education materials for use by primary care with patients.
- IGR included as a co-morbidity to facilitate access to current weight management services.
- An audit which has been designed to run annually in primary care to assess progress made.

However, should additional funding be agreed as per preferred options, the service delivery model will be as summarised below. The model of service delivery has five steps:

- 1. Identification of patients at high risk of diabetes using practice registers, NHS Health Checks or opportunistically.
- 2. Testing for IGR using HbA1c and once diagnosed, placed on IGR register.
- 3. Patient invited for clinical and lifestyle review.
- 4. Patient offered education and follow-up:
 - a. additional capacity to train staff to deliver IGR specific patient education;
 - b. and weight management for those with a BMI of 28 or more;
 - c. follow-up telephone support every three months for 18 months 2 years.
- 5. Patients thereafter invited for annual review.

In addition, performance management criteria to be agreed for patient education, lifestyle intervention and follow-up. Funding will be sought for a detailed review/evaluation of the pathway once fully implemented.

The detail of the steps for clinicians to follow is outlined in Appendix 5

4. Identifying the Way Forward

4.1 Proposed Service Provision

The proposed Merseyside Pathway has been developed in consultation with local, regional and national stakeholders. This pathway highlights the patient flow, though the way it will be delivered is dependent on the outcome of the options appraisal and local decision making (**please see Appendix 1**).

4.2 Options Appraisal

There were a number of ways the proposed model could be delivered and a range of delivery options were appraised. The proposed model of delivery involves three components: primary care (identification and annual review), patient education (IGR/CVD specific) and weight management referral for those who are eligible. The options appraisal is for these three components with four or five options within each. In total, 16 options were considered with the steering group tasked with selecting one preferred option from each of the three sections.

The preferred options were selected at a consultation event which took place in February 2012 with representation from primary care and weight management services (commissioners and providers) across Merseyside as well as public health. Patients were also asked to give a view on their preferred option at the Merseyside Diabetes Action Group which took place on the 17th of May 2012.

Costs quoted are those of diagnosing and appropriately managing all of the people estimated by the Department of Health's NHS Health Check modelling to be diagnosed with IGR within one year through the NHS Health Checks in Merseyside (see Section 7 for further detail of costing).

Some of the costs will already be accounted for by budgets set aside for the NHS Health Checks and existing capacity of weight management services). See section 7 for further detail of costing and cost effectiveness analysis.

Tables 6-8 outline the preferred options chosen by professionals.

See also appendix 6, for more detail on the 16 options that were appraised.

4.3 Preferred Option

The preferred options selected at the consultation event in February 2012 were as follows. Although these are the recommended options, these are subject to agreement from budget holders and thus may change dependant on the finance made available.

The preferred options are:

- A Cluster wide service level agreement in primary care for the identification and management of IGR.
- Weight management services to provide both patient education and weight management intervention.
- Localised patient information to be produced.

Primary Care			
Options	Pros	Cons	Costs
4. Develop a (Merseyside-wide) Local Enhanced Service (LES) / Service Level Agreement (SLA) for the identification and management of patients with IGR.	 Provides finance to support the increase in capacity required in primary care. Would support the creation of an IGR register and implementation plan. The impact on reducing variation within primary care is likely to be high. Performance management would be in place to monitor quality and outcomes. The impact on health outcomes is likely to be high. 	 Sustainability of funding and performance post LES/SLA. There is no guarantee that all practices will sign up to the LES/SLA. Will require financial governance arrangements. It could be seen as incentivising primary care to provide a service that should be a part of their core contract (although not part of it at present). This option will be high cost. 	£10,000 for production of guidelines / educational events plus cost of LES/SLA.

Table 7: Adult Healthy Weight Options Appraisal

	Healthy Weight				
Options		Pros	Cons	Costs	
4. Add IGR as a c morbidity with weight manage pathway and b capacity within lifestyle servic deliver both pa education and management	nin the gement build n ces to atient	 Enables wider provision (i.e. outside of primary care) of evidence based education through locality teams that already deliver similar services and have the knowledge of local population groups. Patients less likely to be lost to follow-up as patient education and lifestyle inventions delivered by the same team. High impact on outcome. Performance management would be in place to monitor quality and outcomes; 	 Sustainability of funding (need to ensure recurrent funding). Negotiation in contract variations could be problematic as different contracts in place across the borough and different methods of data collection. Staff may not have the clinical background to be able to advise patients about the aetiology of IGR and diabetes. 	Costs of additional capacity and patient education provision will vary locally depending on current contracts.	

Table 8:	Patient	Education	Options	Appraisal
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	Patient Education				
	Options	Pros	Cons	Costs	
2.	Develop IGR specific patient education material (e.g. information leaflets) and disseminate to GP practices and lifestyle services across the Cluster.	 Increased knowledge and awareness in primary care clinicians around education. Patients will receive basic information; Locally designed patient information will raise awareness in the community and may improve local knowledge and uptake to services 	 Variations in primary care with regards to quality and delivery of patient education. No evidence base for this approach. NICE state that a formal intensive education programme is required. NB: these cons can be overcome if patient education delivered in addition to providing information alone. 	plus: £20,000	

Primary Care: preferred option is 4, Merseyside-wide LES

- 1. Do nothing this option was rejected as future predicted costs of diabetes means that to do nothing is not an option.
- 2. Disseminate pathway this option was rejected as information alone can be misinterpreted and competing pressures combined with a lack of additional capacity in general practice may mean it would not be implemented.
- 3. Make IGR core business this option rejected due to variations in the contracting process across the patch.
- 4. CCG LES/SLA/Contract acknowledged that a LES/SLA would have to be well written as some LES' have failed in the past (reviewing local LES' could enable money to be re-directed to IGR LES/SLA). This model is working in Sefton where 90% of practices have signed up to a CCG funded IGR LES. A LES/SLA/Contract would help to build the capacity to deliver the pathway and the support to performance mange it.
- 5. Primary care deliver the whole service this option was rejected because it is not feasible in terms of the relatively small number of patients and capacity to deliver a quality assured programme of patient education, even if practices were to federate.

Adult healthy weight: preferred option is 4, build capacity to deliver patient education and weight management

- 1. Do nothing this option was rejected as future predicted costs of diabetes means that to do nothing is not an option.
- 2. Add IGR as co-morbidity this option was rejected as this does not build capacity to cope with additional demand, other patients may end up waiting longer if IGR is prioritised.
- 3. Add IGR as co-morbidity and increase capacity this option could be developed but would not include IGR education as this is different from current practice.
- 4. Add IGR as a co-morbidity and build addittional capacity for staff to deliver patient education as well as weight management this is the preferred option as one joined up service means that patients are less likely to be lost to follow-up (as they might be if education separated from lifestyle intervention), and would have added value for lifestyle services as would include holistic approach for all CVD risk factors.

It is important to note that members of the patient group did not wholly agree with this as the option for patient education. One concern expressed was that not all patients would require or want a weight management intervention. Also, that they felt patient education should not be delivered at a gym setting, as this might put some people off from attending. The patients suggested they would prefer patient education to be delivered at the GP practice or another community or health venue.

In addition the patients recommended that the education be opened out to include a key family member or carer.

Patient education: preferred option is 2, IGR specific patient education materials

- 1. Do nothing this option was rejected as future predicted costs of diabetes means that to do nothing is not an option.
- 2. Develop local IGR patient education materials (this is additional to patient education provided by lifestyle services) preferred option, primary care can use the materials to have the initial discussion with patients to promote the service, as locally developed the process will raise awareness and support community 'buy-in'.
- 3. Contract variation to provide patient education this option rejected as felt having patient education separate from lifestyle may mean patients are lost to follow-up.
- 4. Set up Cluster wide patient education and weight management this was felt to be expensive to set up and may duplicate some aspects of current provision.

The patients also said they would be willing to attend a patient education session as they wanted to tell other people about what it was like to live with diabetes and that it can happen to anyone (this could also be done by recording a DVD).

5. Strategic Risks

It is proposed that the risks associated with the implementation of this proposal, once approved, will be managed with the support of the Merseyside Commissioning Support Unit, and associated risk management structures.

Table 9: Summary	of	risks
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Risks	Mitigating actions
Modelling assumptions As the proposed pathway is a novel approach, a number of assumptions (see section 7) have been used to model the impact on services and the costs savings. The risk is that, if these assumptions are incorrect, activity may be either more or less than expected.	 A comprehensive audit was undertaken of over 400,000 patient records in order to identify the potential number who would be eligible for the proposed pathway. Sefton has piloted a Local Enhanced Service, the activity data from which can be used to verify some of the assumptions. Once implemented, performance is to be managed and activity and outcomes data to be collected and reviewed.
Change management Both the NHS and the local authority are going through a period of substantial organisational change. The processes for agreeing and implementing the pathway are changing as are the personnel. Therefore, the risk is that agreement and implementation could be delayed.	 Regular stakeholder engagement. Clear communication. Ensuring commissioning leads from each locality are identified and involved in regular communication and in decision making. Succession planning. Ensuring the project team keep to agreed time frames.
Dependences There are several interfaces along the pathway: phlebotomy, laboratories, primary care, providers of IGR specific patient education, and weight management. The pathway is also dependent on primary care referring patients into patient education and weight management.	 Developing a robust service level agreement with the providers with clear parameters. Establishing clear roles and responsibilities. Performance management and monitoring of referrals. Considering alternative ways of generating referrals.
Financial Constraints Although implementing the pathway is likely to produce cost savings in the long-term, in the short term additional funding is required to be found in order to implement the pathway. This funding is likely to come from making changes to current contracts and/or additional investment. In order to fund the whole pathway, agreement will need to be reached with the CCGs and the directors of public health. Although the pathway has been agreed, the additional funding is still to be agreed.	 Using the business case format. A menu of options and the respective costs and benefits are provided to assist decision makers. Joint commissioning. Once implemented the programme will be evaluated and performance managed.

Risks	Mitigating actions		
Local configurations There are 6 CCGs, within which the current patient pathways and commissioning mechanisms vary. Thus, although the pathway is to be implemented across Merseyside, it may be commissioned differently by each location; as a result, there may be inequity of delivery across Merseyside. There are also differences in the composition of weight management provision.	 Business case to include preferred options. Outcomes data collected to be standard across Merseyside to assess effectiveness and benchmark local delivery against the pathway. Ensuring that wherever possible the same referral criteria are used to facilitate equity of access. Project co-ordination. 		
Sustainability Maintaining the momentum and the funding. Ensuring enough people enter the pathway for the project to be sustainable.	 Where possible, incorporate the pathway into established services. Performance management. Patient and stakeholder engagement. Make every effort to align contract review dates across the services within the IGR pathway and across Merseyside. 		

6. Implementing the model

6.1 Programme Management

The business case development has been managed by the IGR steering group, which is a sub-group formed from the Merseyside Diabetes Network / Diabetes QIPP.

It is proposed that the primary care aspect of the proposal will be implemented through CCGs. The IGR specific patient education is to be implemented by public health with the support of CCGs, and the Diabetes Network. The weight management intervention element of the proposed pathway is to be implemented by public health. Funding has been secured through the Diabetes QIPP to provide patient and public engagement, clinical guidelines to support the pathway, and to launch the pathway.

As the business case progresses it is expected that the diabetes leads will progress the primary care aspects via their CCG boards. It is expected that public health will progress the patient education and weight management aspects via the health improvement leads. Local funding arrangements may be agreed for lifestyle services. The business case may also be taken to local health and wellbeing boards.

It is likely that the oversight of the whole pathway may be through the diabetes network, although additional project management support may be required to facilitate this.

6.2 Implementation plan

Timescale	Activity	Responsibility
July/August 2012	Circulate draft business case for final comment.	Steering group
September 2012	Present business case to CCG boards for a decision on the proposed options for primary care and, where appropriate education and lifestyle intervention.	Diabetes Leads
September 2012	Present business case for a decision on the proposed options for patient education and lifestyle intervention.	Public Health Leads / Health Improvement Leads
September / October 2012	Opportunity to engagement with patients and the public and gain insight into aspects of implementation.	Steering group to oversee
November/December 2012	Develop template for IGR review, review data sharing and monitoring.	Network / IM&T sub-group
November/December 2012	Plan launch events.	Steering group / network
January/February 2013	Produce local materials for patient education and professional guidance.	Primary care network lead, PH lead in conjunction with

Table 10: Proposed Implementation timetable

		communications
January/February	Begin training staff to deliver IGR	Life style
2013	specific education.	commissioners
March / April 2013	Launch event.	Steering group /
		network
March/April 2012/13	Amendments to contract of weight	Public Health
	management services.	
April 2013	Commence IGR pathway.	Primary care/
		Public Health

6.3 Patient, Public and Stakeholder Involvement

6.3.1 Patients and the public

Patient and public involvement has been and will be undertaken in line with local and national policy and standards. The North Mersey Diabetes Action group, a forum for patients with diabetes from across Liverpool, Sefton and Knowsley have had 'prevention' as an aspirational objective since their commencement in January 2010.

Once the business case is approved, wider consultation will take place. A representative sample of patients will be identified by linking in to local patient participation groups such as; Healthwatch, LINKS and patient groups linked to CCGs. This will be organised in consultation with the Cluster lead for patient and public involvement. It is proposed that a focus group will be established to:

- Identify criteria on which to score service delivery options.
- Score the options against the chosen criteria.
- Identify potential options for lifestyle services available for this cohort to access.
- Develop localised patient information resources.
- Discuss awareness raising campaigns.

6.3.2 Stakeholders

The IGR business case and pathway has been a regular agenda item for the QIPP board and the Merseyside Diabetes network. There have been a number of meetings with primary care clinicians focusing on specific aspects of the pathway and business case development. There is an established steering group which meets monthly with representation from public health, weight management and the Merseyside Diabetes Network.

It is envisioned that the draft business case will be circulated to CCGs via local diabetes leads and to public health consultants for a decision on the options and future investment, as well as being presented to the Merseyside QIPP leads. The patient education and weight management aspect of the business case will be presented to Public Health, Health Improvement Leads.

6.3.3 Summary of patient, public and stakeholder engagement activity

Communications activity will need to be targeted and tailored to be appropriate for different audiences. There are some overarching messages for each group, but specific messages will need further development for the audiences within the groups. See Appendix 7 which provides some indicative examples of those to engage and some of the engagement that has taken place to date.

6.4 Performance management

Once the business case has been agreed, there will be a need for monitoring, reacting to and assessing progress and effectiveness. It is crucial that a management structure is in place to monitor progress and to take the necessary steps to ensure that activity and outcomes are achieved across the services delivering the IGR pathway. The purpose of the performance monitoring is to:

- Help to define performance targets / goals across the key aspects of service delivery, including management of resources (personnel, infrastructure), customer service and financial viability.
- Provide a comprehensive picture of the organisation's progress towards achieving its performance targets / goals.
- Provide an early indication of emerging issues / cost pressures that may require remedial action.
- Indicate where there is potential to improve the cost effectiveness of services through comparison with other organisations.

The suggested mechanisms to do this are:

- Key performance indicators (KPIs) which help define and measure progress towards goals for the project and for the elements of the pathway.
- Performance management system that will track performance and enable review of targets and investment. This is to include patient experience and patient satisfaction, as well as activity and outcome measures.
- Evaluation and audit to provide internal and external assessment of whether the project is a success or not by taking an in depth look at outputs and performance.

The performance mechanisms are to be decided in consultation with key stakeholders and budget holders to determine whether the project has achieved its goal of improving identification and management of IGR and that this in turn has resulted in preventing or slowing the progression to Type 2 diabetes in this cohort of patients. A clinical audit tool was developed to identify registered prevalence and management if IGR, this could be adapted as a performance monitoring tool providing data at GP practice level and across Merseyside. Possible indicators for inclusion in performance monitoring are set out in **Appendix 8**.

7. Financial Planning

7.1 Funding

Implementing the pathway will result in future cost avoidance through delaying and/or preventing the onset of Type 2 diabetes. Once diagnosed, 86% of IGR patients will have approximately a 1 in 3 risk of going on to develop diabetes if no intervention is made; the remainder will have approximately a 2 in 3 risk of developing diabetes (see Appendix 9).

Some of the costs will already be covered by existing contracts and this has been taken into account in the modelling. For example, some capacity already exists in weight management services which could be filled without requiring additional funding. Table 11 shows costs per patient of identifying and managing cases through the IGR pathway. For a more detailed breakdown of how cost-effectiveness has been calculated, please see appendix 9. Please note that these calculations do not include the initial cost of launching the pathway and producing self-care materials (see Appendix 8).

	Basic costs covered by existing arrangements	Basic costs not covered by existing arrangements	Additional primary care costs*	Estimated patient volume**
Phlebotomy at initial consultation/ health check	£14	-	£2.50	100% of patients entering pathway.
Inviting patient for annual review	-	-	£3	100% of patients entering pathway through search of practice records.2.3% of patients entering pathway through NHS Health Checks.
Undertaking annual review	-	-	£23	65% of all patients invited for annual review.
Phlebotomy at annual review	-	£14	£2.50	65% of all patients invited for annual review.
Weight management	£152	-	-	50% of all patients invited for annual review.
Patient education	-	£45.50***	-	50% of all patients invited for annual review.

Table 11. Costs per patient of each element of the IGR pathway

* Based on costs of current IGR LES in Sefton

** Estimates based on audit, published evidence, local NHS Health Check outputs and DH NHS Health Check modelling

*** Includes cost for training staff and capacity to deliver, does not include licence fees or resources

7.2 Cost effectiveness modelling

Cost effectiveness has been modelled for two distinct phases of implementing the pathway:

Years 1 & 2 Patients whose practice records show a previous diagnosis of IGR or a previous raised FPG or OGTT result that meets the threshold for IGR will be invited to attend for an HbA1c test. The modelling assumes that this look-back exercise will be complete by the end of Year 2, with 50% of the identified patients entering the IGR pathway in Year 1 and the remainder in Year 2.

During this period, patients will also enter the IGR pathway through having been identified as at high risk of IGR through an NHS Health Check.

Year 3 onwards Once the look-back exercise is complete, new patients will continue to enter the IGR pathway annually through the NHS Health Check route. (Additional patients may also enter the pathway as a result of being identified at high risk of IGR through routine consultations; however, there is currently insufficient evidence to enable this to be incorporated into the modelling).

For each phase, figures have been calculated to show cost effectiveness both with and without putting in place a LES to cover the annual review aspect of the IGR pathway, the assumption being that 65% of those invited would attend. For more detailed costing and assumptions see appendix 9.

Table 12. Annual number of diabetes cases postponed for 8 years as a result of implementing IGR pathway in Years 1 & 2

Merseyside	Knowsley	Halton	St Helens	Liverpool	Southport and Formby	South Sefton
657	99	125	171	177	76	106

Table 13. Annual cost effectiveness of implementing IGR pathway in Years 1 & 2

	Merseyside	Knowsley	Halton	St Helens	Liverpool	Southpo rt and Formby	South Sefton
Total cost of IGR patient management (£)	717,127	117,794	163,544	225,847	142,983	62,171	85,855
Total cost of diabetes patient management avoided (£)	2,785,680	419,760	530,000	725,040	750,480	322,240	449,440
Overall cost saving over 8 years (£)	2,068,553	301,966	366,456	499,193	607,497	260,069	363,585

Table 14. Annual cost effectiveness of implementing IGR pathway in Years 1 & 2 with a	
LES	

	Merseyside	Knowsley	Halton	St Helens	Liverpool	Southport and Formby	South Sefton
Total cost of IGR patient management (£)	1,509,863	236,563	313,519	432,954	357,367	154,402	213,22 2
Total cost of diabetes patient management avoided (£)	2,785,680	419,760	530,000	725,040	750,480	322,240	449,44 0
Overall cost saving over 8 years (£)	1,275,817	183,197	216,481	292,086	393,113	167,838	236,21 8

Table 15. Annual number of diabetes cases postponed for 8 years as a result of implementing IGR pathway from Year 3

Merseyside	Knowsley	Halton	St Helens	Liverpool	Southport and Formby	South Sefton
156	20	18	24	54	16	24

Table 16. Annual cost effectiveness of implementing IGR pathway from Year 3

	Merseyside	Knowsley	Halton	St Helens	Liverpool	Southpo rt and Formby	South Sefton
Total cost of IGR patient management (£)	111,568	14,624	12,506	17,269	38,707	11,954	16,508
Total cost of diabetes patient management avoided (£)	661,440	84,800	76,320	101,760	228,960	67,840	101,760
Overall cost saving over 8 years (£)	549,872	70,176	63,814	84,491	190,253	55,886	85,252

Table 17. Annual cost effectiveness of implementing IGR pathway from Year 3 with a LES

	Merseyside	Knowsley	Halton	St Helens	Liverpool	Southport and Formby	South Sefton
Total cost of IGR patient management (£)	300,375	39,373	33,669	46,494	104,211	32,183	44,444
Total cost of diabetes patient management avoided (£)	661,440	84,800	76,320	101,760	228,960	67,840	101,76 0
Overall cost saving over 8 years (£)	361,065	45,427	42,651	55,266	124,749	35,657	57,316

8. Conclusions

- There is a need to implement a standard pathway for the identification and management of IGR patients across Merseyside, due to evidence of current under-diagnosis, major inconsistencies in IGR patient management and emerging evidence of effectiveness.
- This business case sets out the preferred options for implementing the approved Merseyside IGR pathway (see Appendix 1) along with estimates of cost effectiveness based on local and national evidence.
- Due to the limitations of available evidence, unknown variables and complexities of local variations in practice and contracts; the financial modelling can only provide a best estimate of cost effectiveness. Based on these estimates, implementing the Merseyside IGR pathway to actively identify currently undiagnosed IGR patients and to diagnose and manage those presenting for an NHS Health Check will be cost effective. Managing only those patients already recorded on GP systems as having had a raised blood sugar result in the past and those identified through NHS Health Checks will be highly cost effective either with or without a LES.

9. Recommendations

It is proposed that a shared pathway is put in place across the Merseyside Cluster for the identification and management of IGR patients. It is likely that whilst the proposed pathway will be the same across Merseyside, the way the pathway is implemented may vary depending on local circumstances and this is for individual Clinical Commissioning Groups (CCGs) and Health Improvement Leads to decide.

It is recommended that primary care take responsibility for funding annual reviews for patients known to have IGR and those identified as IGR through NHS Health Checks. The source of funding for training staff to patient education is still to be identified. It is recommended that Public Health ensure funding is available to build the capacity to deliver the patient education, support to change lifestyle and appropriate follow-up. It is recommended that an agreed performance management structure is in place to monitor and review activity and outcomes.

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