Merseyside Adult Impaired Glucose Regulation Guidelines

Merseyside Diabetes Network

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Foreword

Type 2 diabetes has a real impact on patients and their carers and diabetes care accounts for a significant proportion of the healthcare budget in England. 90% of people with diabetes have Type 2 diabetes. The future impact of Type 2 diabetes should not be underestimated and presents a significant challenge for the NHS in England. The prevalence of diabetes is increasing among all ages in the UK, mostly due to increases in the number of people who are overweight or obese, have an unhealthy diet and are physically inactivate. People who are overweight or obese (BMI over 25kg/m^2) have been estimated to account for about 65-80% of new cases of Type 2 diabetes. It is in this context that the Merseyside diabetes group works together to improve diabetes care for patients across the region.

It is recognised that people who develop Type 2 diabetes almost always have Impaired Glucose Regulation (IGR) first and that without an appropriate intervention the majority of patients with IGR will go on to develop Type 2 diabetes within 5-10 years. Evidence suggests that with the right intervention the onset of Type 2 diabetes can be significantly delayed and in some cases prevented.

These novel Merseyside guidelines and pathway represent the culmination of significant development work by a multi stakeholder group including Public Health, Clinical Commissioning Groups, the Merseyside Diabetes Network and the Merseyside Diabetes Patient Action Group. They offer guidance on the identification and management of IGR and the steps that can be taken to support patients to make lifestyle changes, with the aim of delaying or preventing the onset of diabetes. Prevention of diabetes remains a priority and these guidelines provide a real opportunity to directly impact on the forecast increase of diabetes prevalence and improve the quality of life for patients in the region.

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Content

Acknowledgements

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Please Note: These guidelines should not be used for the identification of impaired glucose regulation in:

- **Children**
- **Pregnancy**
- **Patients with symptoms of Type 1 diabetes**
- **Patients who are acutely unwell**
- **Patients who have pancreatitis or have had pancreatic surgery.**

In addition:

- **HbA1c testing may be affected by corticosteroids or antipsychotics.**
- **For patients who have conditions such as coeliac disease and renal disease requiring dietary modification please seek additional dietary advice post identification of IGR.**

For further considerations please refer to section 3.

1. Background

Impaired glucose regulation (IGR) (or non-diabetic hyperglycaemia) describes blood glucose levels that are above the normal range but are not high enough for the diagnosis of Type 2 diabetes[1]. IGR patients include those with impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT)[2], or a raised HbA1c according to recent guidelines[3].

The risk factors for IGR are the same as those for Type 2 diabetes; the greatest single risk factor being obesity. Women with a history of gestational diabetes are also at greater risk of developing IGR and diabetes and, for the purposes of the IGR pathway, are therefore included on the IGR patient register. Before people develop Type 2 diabetes they almost always have IGR, although it is asymptomatic and can often go undiagnosed for many years[4]. In the absence of intervention the majority of individuals with IGR are likely to develop Type 2 diabetes within 5-10 years[1]. There is good evidence, however, to suggest that Type 2 diabetes can be prevented or delayed in people with IGR. Evidence shows that modest lifestyle changes can significantly postpone the onset of Type 2 diabetes in high risk individuals[5,6] and that lifestyle intervention is more effective than diabetes drugs such as metformin in reducing the incidence of diabetes in IGR patients[7].

The identification and effective management of IGR provides a substantial opportunity for preventing or delaying the future burden of Type 2 diabetes on the National Health Service (NHS) in England, as well as on patients and their families. In 2010/11 prescriptions for diabetes accounted 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 and a 41.2% increase in the number of items dispensed to treat diabetes since 2005/06[8]. In recognition of the need to take action to reduce the incidence of Type 2 diabetes, the National Institute for Health and Clinical Excellence (NICE) published guidance in 2012 on identification and management of individuals at high risk of Type 2 diabetes[3].

The prevention of diabetes has been a priority of the Merseyside Diabetes Patient Action Group for some time, and was identified as a priority 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).

As part of the Diabetes QIPP work stream, which came into being in the summer of 2010, public health teams across Merseyside were given the opportunity to put forward strategies for diabetes prevention. A steering group was formed with public health representatives from across Merseyside and from the Diabetes Network.

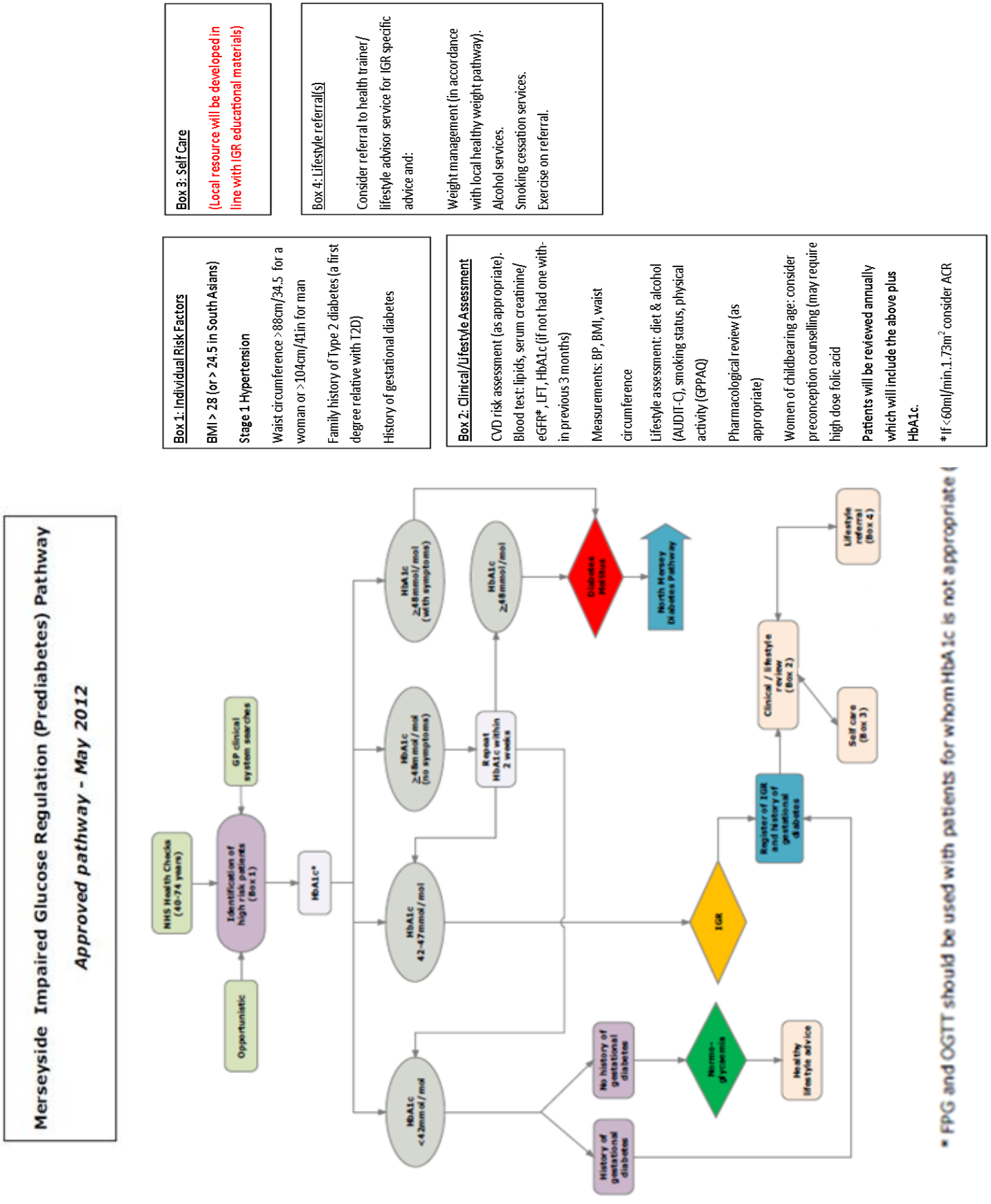
In 2011, a questionnaire survey was conducted among GP practices in Knowsley, Liverpool and Sefton, followed by an audit of GP practice records conducted in the same year across Knowsley, Liverpool, Sefton and Halton & St Helens. Both were aimed at establishing current local practice and identifying opportunities to improve the identification and management of IGR patients in primary care. Drawing on the recommendations of the NICE guidance and the findings of the survey and audit, the Merseyside IGR pathway was developed through an intensive process of stakeholder consultation with the aim of achieving the systematic identification and appropriate monitoring and referral of IGR patients in primary care.

At each stage of the IGR pathway development, joint 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. A number of options were considered during the development of the IGR Pathway and preferred options chosen in February 2012. In May 2012, the pathway was agreed by the Diabetes QIPP / Merseyside Diabetes Network and the options discussed with patient representatives. In winter 2012, Insight work was carried out across Merseyside with over 65 people identified as having risk factors for IGR.

The delivery model that has been developed involves:

- identifying the patients already diagnosed with IGR by running searches in GP clinical systems;
- offering blood tests to those identified;
- offering the patients an initial review and an annual review thereafter,
- providing an IGR specific follow-up session delivered by lifestyle services;
- offering patients with IGR access to an appropriate weight management intervention.

2. Clinical Pathway



3. Identification of IGR

We are advising the use of HbA1c test as the method for screening for impaired glucose regulation and Type 2 diabetes mellitus[1].

The reasons are:

1. It is more reliable than traditional glucose measurements.
2. Fasting is not required which is popular with patients.
3. Screening tests are not limited to the morning.
4. It is a superior predictor of cardiovascular disease.
5. It gives a rapid result.
6. It avoids the cumbersome oral glucose tolerance test in the vast majority of cases.

The IGR pathway outlines the process by which HbA1c results are managed in practice. Only one test is required to diagnose IGR whereas a repeat test is needed when a HbA1c is in the diabetic range to confirm a diagnosis of diabetes[2].

If IGR is diagnosed the code to be used is IGR (C11y4). These patients then form the IGR register and will be subject to call and recall on an annual basis.

The HbA1c test is not suitable for the following:

- ☐ Children
- ☐ Pregnancy
- ☐ Patients with symptoms of Type 1 diabetes
- ☐ Patients who are acutely unwell
- ☐ Patients on corticosteroids or antipsychotics
- ☐ Patients who have pancreatitis or have had pancreatic surgery.

Other factors:

Whilst this is a screening test and the vast majority of patients will not have any problems associated with HbA1c testing the following conditions may affect the test. This should be considered especially when the test is in the diabetes range.

- ***Increased HbA1c:*** Iron, vit B12 deficiency, erythropoiesis, alcoholism, chronic renal failure, splenectomy
- ***Decreased HbA1c:*** administration of erythropoietin, iron, vitamin B12, reticulocytosis, chronic liver disease, drugs (aspirin, vitamin C and E and antiretroviral drugs, ribavirin and dapsone)
- ***Altered Haemaglobin:*** Haemaglobinopathies, HbF, Methaemoglobin may increase or decrease HbA1c.

In patients where HbA1c is not suitable fasting glucose and OGTT will still be available and these patients can be placed on the IGR register with either impaired fasting glucose or impaired glucose tolerance or both.

Please Note: When using HbA1c testing for diagnosis of IGR and Diabetes the current IT systems may not flag results of 42-47mmol/ mol as abnormal which may be misleading.

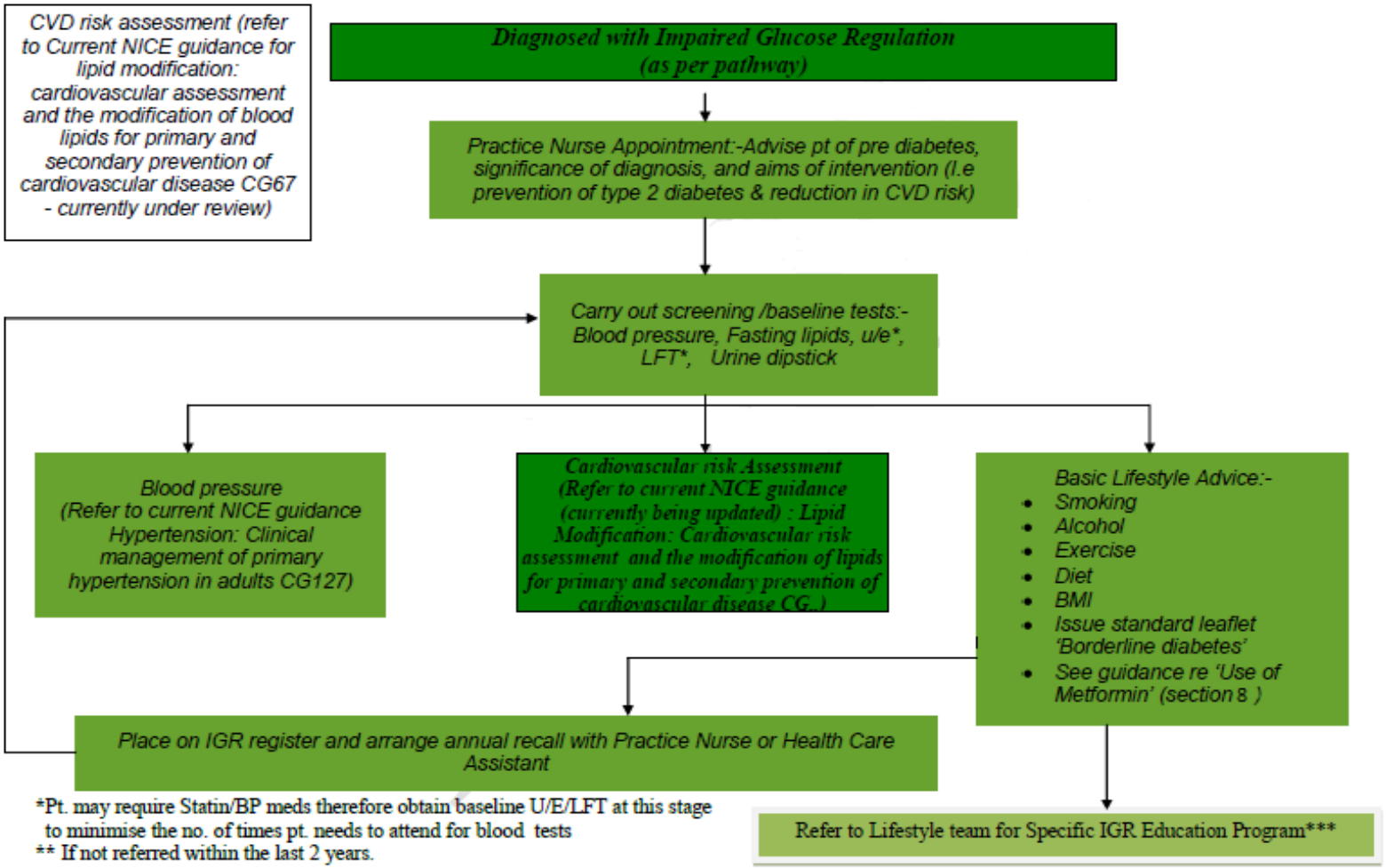
It is therefore important to note this issue when requesting HbA1c as a diagnostic indicator rather than for monitoring purposes. The Merseyside diabetes network is working with local pathology laboratories to seek a solution to this issue.

Future considerations

NICE guidelines (PH38)[3] recommends that prior to offering blood tests to patients practices run a validated computer-based risk-assessment tool to identify people on their practice register who may be at high risk of Type 2 diabetes or if a computer-based risk-assessment tool is not available, provide patients with a validated self-assessment questionnaire, for example, the Diabetes Risk Score assessment tool (Diabetes UK)[4].

This was discussed by the GP leads in October 2011 and it was felt that as some patients had already been identified as IGR through a blood test and that others were being identified through the NHS Health Check that the initial pathway would concentrate on management of these in the first instance. This decision will be reviewed once the Merseyside IGR pathway is successfully implemented.

4. Initial Review



5. Communication of IGR

During winter 2012, IGR specific insight work was undertaken with sixty five people and included:

- Individual and paired interviews.
- Completion and review of a personal health diary.
- Eight focus groups.

The insight work took place across Merseyside, in Liverpool (Speke Garston, Kirkdale, Liverpool City Centre, Childwall); in Knowsley (Huyton, Kirby); in Sefton (Southport, Bootle) and in Halton and St Helens (Widnes, Runcorn). The interviews and focus groups were with people aged 40 and over who were overweight or obese, and included BME groups.

Healthy Foundations

Healthy foundation segmentation (developed by the Department of Health) was applied to the insight work. Of those interviewed, almost half were identified as 'unconfident fatalists' (UFs) and a third were 'live for todays' (LfTs).

Both UFs and LfTs tend to take a short-term view of life. Both feel they are living a life largely determined by fate. They feel they cannot control the onset of illness, (i.e. no recognition of 'what I personally do' influencing their possibility of future illness).

In this context, there is perceived to be little point in making an effort to live healthily. Neither is resilient when faced with negative situations and they frequently report depression (particularly UFs) and an inability to cope when dealing with challenges. This lack of resilience can strongly reinforce poor health behaviours as a means of escape.

Health Behavior	LfTs	UFs
Poor diet	Junk food and takeaways often replace cooked meals through lack of planning	Lack of motivation to cook meals and an inclination towards comfort eating
Limited exercise	Blamed on lack of time, energy and money	Low motivation and fear of being judged
Heavy drinking	Binge drinking in particular is used as a means of escape and strongly maintained by habit	Means of escape from depression
Smoking	Driven by perceived stress and social influences	Out of habit and a lack of motivation to change

Intervention	LfTs	UFs
Approach	Considerable ongoing monitoring, mentoring and evaluation. Hands-on or practical approaches are best. Assistance with willpower, coping strategies and practical support.	Persuade that it is worth making an effort to improve health and genuinely take control. Support/hand-hold, take small steps and tackle mental health issues to foster a positive outlook. Considerable monitoring and mentoring required

Definition – borderline diabetes

Only three out of the sixty people (including eight already thought to have IGR) had heard of the term pre-diabetes. The word 'pre' was said to be a difficult word to understand and 'pre' suggested "*pre-diabetes says you are going to get it anyway, it's just the lead up to it".*

The preferred term suggested by the interviewees and then further tested at the focus groups was 'borderline diabetes'. This term was felt to be the most appropriate and understandable.

It was seen as more positive suggesting there is a chance of preventing the onset of diabetes. *"High risk of diabetes"* was also seen as a useful description.

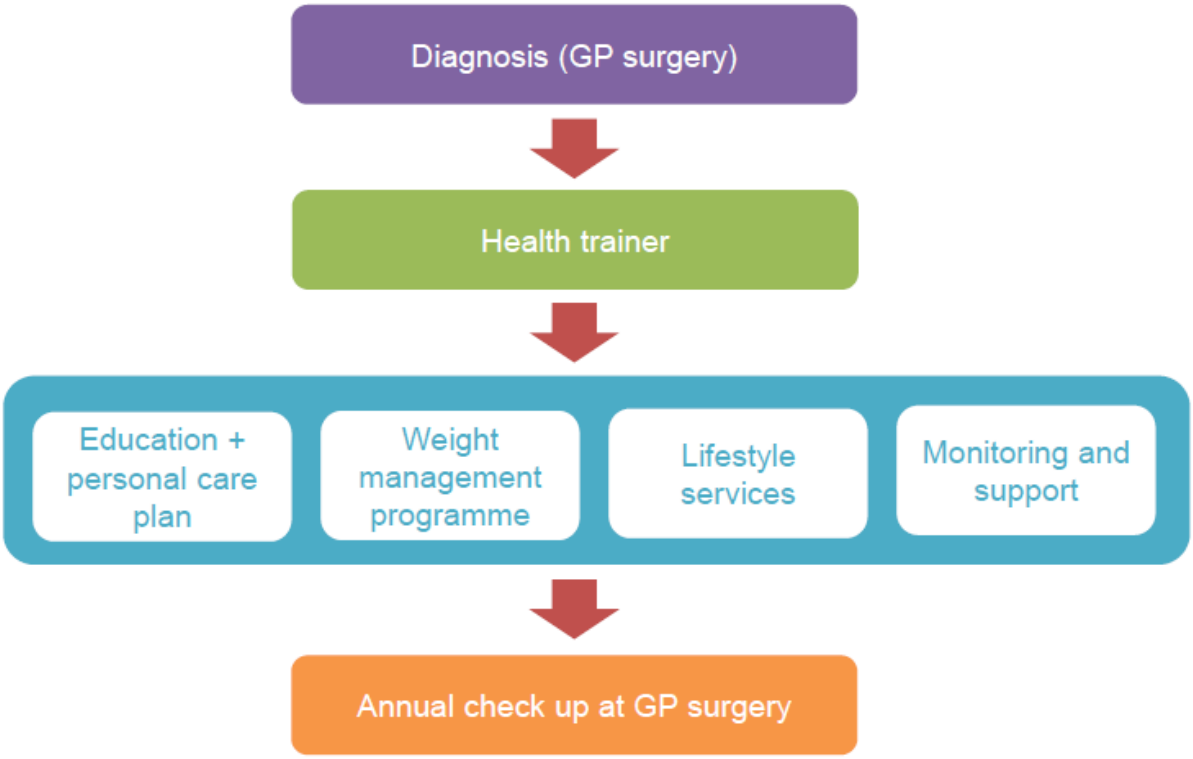
A number of definitions were also tested. The preferred definition was:
Borderline diabetes is a serious condition which significantly increases your risk of getting Type 2 diabetes. It can double your chances of suffering heart disease or stroke. The good news is that by eating healthier and by increasing physical activity you may be able to prevent or delay borderline diabetes from progressing any further."

This was seen as:

- Overall a clear strong message.
- Emphasising the risk of developing heart disease or stroke was seen as thought provoking.
- *'Significantly increases your risk...'* was preferred to *'high risk'*
- The positive second half of the definition was liked. *'The good news is...'* made people feel they could do something about it.

The health diary exercise provided indications about what our audience needs in order to challenge the status quo:

What was wanted	**The pathway**
"I don't know where to start." *i.e. give me a starting point*	First explanation and discussion of borderline diabetes (primary care)
"I need guidance"	Follow-up session giving information about how to look after borderline diabetes (delivered by lifestyles / health trainers)
"I know it's down to me, but I need support."	Lifestyle services to help live a healthier life and control your pre-diabetes
"Look after me"	Checking on your borderline every year (primary care)



The pathway itself was well-received, although it became clear that there needs to be flexibility:

- Some people would attend GP practice for diagnosis and annual review (more likely to be men) but not the rest of the pathway.
- Some would attend GP practice for diagnosis, follow-up session with lifestyles/health trainer and then GP practice for annual review.
- Some would attend all services in the pathway; diagnosis, follow-up with lifestyles, weight management services and then annual reviews (more likely to be women).

All services on the pathway need to be accessible, accessibility involved more than making services available. Ideally the target audience would like their pathway to reflect their individual barriers, needs and preferences. The target audience very much wanted health professionals/workers to *listen and understand* their personal barriers.

Experience of previous services suggests that getting the target audience to attend is likely to be challenging. Services need to be responsive as they may only have one chance to impress.

Diagnosis and initial discussion

This audience reported they needed a starting point and being given a diagnosis of borderline diabetes could be a motivator to make lifestyle changes. However, communication has to be clear, this is NOT diabetes at present as some people may be confused and think they have diabetes. Therefore, useful to explain "impaired glucose regulation" and that "this *puts you at increased risk of developing Type 2 diabetes in the future".*

Expectations:

- A health professional i.e. GP or member of staff with a good understanding of IGR.
- Answers – why have I got this, what will happen to me, what can I do about it, what help is available.
- Information to take away - what to do (mostly envisaged as pertaining to healthy eating) in leaflet form or directed to online help – a leaflet and goal planner has been developed.
- Positive, friendly in tone.
- No time limit – they wanted to have as much time to talk as they needed.
- Primary care has a pivotal role to play in encouraging people to attend lifestyle services and IGR specific follow-up.

All were keen to make the most of this one-to-one session.

Annual Review

This audience said it was important to have the support of their practice.

Expectations:

- The target audience were now aware that they were at risk of developing diabetes and should therefore be monitored regularly. However expectations of check-up frequency need to be managed.
- Subsequent contacts should follow the same format as the initial meeting, i.e. positive and friendly in tone and no time limit.

- Important to discuss progress – any improvement from initial diagnosis?

In addition to the insight work undertaken evidence is available from clinical trials that behaviour change strategies, self-monitoring and problem solving techniques are an important factor contributing to successful outcomes in lifestyle interventions[1]

6. IGR specific lifestyle advice

The recommendations summarised below are derived from an evaluation of NICE's (2012) guidance on IGR interventions, and take account of additional evidence from a systematic search of recent literature. A summary of the literature review is available in appendix 1. Please note: clinical judgement should be used when advising on weight loss for people over the age of 75.

The risk of developing Type 2 diabetes can be reduced by between 28% and 59 % after the implementation of lifestyle change[1]. The most important predictor for Type 2 diabetes prevention is weight loss in those who are overweight or obese, with every kilogram lost resulting in a 16% reduction in risk[2]. Trials have shown that weight loss of at least 5 -7 % can have a significant effect in delaying or preventing Type 2 diabetes[3]. The evidence from the major trials achieved weight loss by a variety of approaches. Key features of these included diets high in fibre and with reduced fat, in particular saturated fat and reduced calories combined with increased physical activity.

There is strong evidence from several trials that lifestyle education programs that incorporate advice about **both nutrition and exercise** have been shown to delay the onset of Type 2 diabetes in high risk individuals[4,5,6].

Dietary advice

Guidelines published by Diabetes UK (2011)[7] contain evidence from large epidemiological studies that show that there are specific components of the diet that may protect against diabetes. These include:

- Diets which are of a low glycaemic index/load
- Diets which are high in dietary fibre and wholegrains
- Diets which are low in fat; particularly saturated

There are also some specific foods which are associated with a reduced risk of Type 2 Diabetes:

- Low fat foods
- Low fat dairy foods
- Green leafy vegetables
- Coffee

Some foods such as red meats, processed meat products and fried potatoes are associated with increased risks of Type 2 diabetes.

Main dietary messages for prevention of diabetes

Weight loss Aim for 5-7% weight loss using a combination of dietary changes and increased activity. Most successful trials were able to demonstrate this over one year.

- **Avoid snacking between meals and eat three regular healthy meals per day. This will help to reduce overall calorie intake.**
- **Reduce the amount of fat eaten**
  - Steaming grilling and baking are healthier options
  - Remove visible fat from meat
  - Use low fat spreads in place of butter or margarine
  - Reduce the intake of processed meat products such as sausages burgers and pies
- **Use polyunsaturated or monounsaturated fats** in place of saturated fats e.g. rapeseed oil and olive oil, sunflower corn or soya oils but only use in very small quantities.
- **Increase fibre**
  - Select cereal products that are higher in fibre whole meal or wholegrain breads and cereals, porridge oats, wholemeal pasta and brown rice.
- **Include a source of lean protein with each main meal** for example low fat dairy, eggs, beans, peas, lentils, fish, poultry.
  - Increasing protein intake helps you feel fuller for longer
- **Eat more fruit and vegetables**
  - Limit fruit juice to one small glass per day
- **Drink alcohol in moderation and within healthy limits**
  - 14 units per week for women
  - 21 units per week for men
- **Sugar should be limited** as part of a healthy diet. Use sweeteners instead or get used to drinks without sugar. Avoid sugary drinks or substitute with diet varieties or water
- **Drink 6-8 glasses of fluid per day.**
- **Reduce salt intake**
  - Reducing salt intake will help reduce the risk of developing high blood pressure
  - Try not to add salt to meals and limit savoury snacks, processed foods and ready meals

7. Physical activity advice

Evidence shows that regular physical activity improves blood glucose control and can prevent or delay the onset of Type 2 diabetes. Individuals who are leading a physical active lifestyle have a lower risk of developing Type 2 diabetes than inactive individuals[1].

How does exercise help?

Skeletal muscle is the body's largest insulin-sensitive tissue and therefore a major influence on our response to insulin. IGR can occur because although insulin is still being released, the body becomes resistant to it. Insulin resistance is even more likely to occur in overweight or obese individuals. Exercise is known to improve insulin sensitivity and therefore improve glucose response.

Exercise also helps due to its effect on the glucose carriers (GLUT4) within muscles. Contraction of the muscles (i.e. when they work) causes the glucose carriers to move to the cell membrane which increases the uptake of glucose into the muscles. The effect of exercise on the glucose response is a short term effect and not a long term training adaptation. This means that it is vital that exercise is done regularly (at least every other day).

There is some evidence that shows an improvement in insulin response after resistance exercise which in turn improves the glucose response. Research also shows that resistance training improves lean muscle tissue and reduces body fat; this is a positive move when trying to improve glucose response, as an excess of fat cells can reduce insulin sensitivity[2].

The benefits of both aerobic and resistance exercise on improving health are well documented, not only for IGR and diabetes but also for many conditions which often go hand in hand with these e.g. overweight and obesity, high blood pressure and high cholesterol.

Research has shown that moderate intensity exercise can be as effective as vigorous exercise at improving glucose response. However, the more the muscles are used the bigger the improvement on glucose response. Exercise also benefits sense of well-being and motivation[3].

Recommend level of exercise

To gain benefits to your health and reduce the chance of developing Type 2 diabetes it is advised to undertake

At least 30 minutes of moderate exercise 5 times a week

This exercise does not have to be completed in one block to improve glucose response. Shorter bouts of exercise which add up to the same total amount can be just as effective. For example, fast walking for 10 minutes 3 times a day could be just as effective as walking for half an hour. This can make it easier to fit exercise into a patients existing lifestyle.

Options to consider to increase activity

1. Any improvement in activity is beneficial
2. Find an activity that is enjoyable so the activity is continued.
3. Include physical activity in to everyday routines such as walking or cycling to work or the shops, housework, gardening.
4. The recommended level of activity can be achieved through several bouts of 10 minutes or more if preferred.
5. Increase the amount of steps taken. The recommended daily amount of steps is 10,000. Use of a pedometer dramatically increases chances of achieving this.
6. Start off slowly and build it up.
7. Set realistic goals, perhaps weekly or monthly.
8. Keep a physical activity diary.
9. Introduce change to avoid boredom.
10. Doing activity with a friend will help keep motivation.
11. Try doing an activity with the whole family.
12. Look for physical activity opportunities in everyday activities.
13. Reduce the level of sedentary behaviour for example walking around regularly during office work
14. Supervised resistance training is also effective
15. Exercise is most effective if done regularly without leaving a gap of several days between exercise sessions.

Smoking

Smoking is still the biggest cause of preventable death and disease in England**.** and is highlighted as another important, modifiable risk factor in diabetes prevention. Possible mechanisms of how smoking increase the risk of diabetes include oxidative or toxic damage to the pancreas, interference with muscular glucose uptake mechanisms or an impact on lipid profile.

8. Metformin use

For most patients weight reduction and being more active through regular exercise offers the most secure route for reducing risks of progression to Diabetes[1]. Moreover weight loss and exercise will impact positively in reducing risk from CVD and many other diseases as well as provide general improvements in well-being.

Lifestyle intervention is more effective than the drug treatment Metformin in reducing the incidence of Type 2 diabetes in IGR patients[1]. A meta-analysis showed that pharmacological interventions were less effective and cost-effective than lifestyle interventions in reducing the risk of developing Type 2 diabetes[2]. Therefore lifestyle intervention is recommended above commencing metformin. In several studies drugs successfully slowed progression to Type 2 diabetes however pharmacotherapy for the specific management of IGR is not currently approved or licensed for use in the UK[3].

Metformin was the first drug shown to be effective although its effectiveness was about half that achieved with lifestyle modification (31% vs. 58%), substantially greater benefit was seen in a subset of younger and obese individuals. The drug is inexpensive and has a long history of use showing virtually no long-term serious side effects and only a low prevalence (5–10%) of modest side effects, such as nausea and gastrointestinal disturbances.

There may be a risk that commencing a patient with IGR on metformin may make it difficult to detect when a patient has gone on to develop diabetes. Prescribers need to monitor an individual's HbA1c trend whilst taking metformin to identify when/if the glucose regulation of an individual moves from impaired glucose regulation to Type 2 diabetes. Practically this might mean stopping the metformin for two months and retesting the HbA1c. Merseyside Diabetes Network will keep this guidance under review.

Renal function needs to be assessed before starting metformin and during treatment.

Summary of NICE guidelines (PH 38) for those at high risk of diabetes:

Whose health will benefit?

- Adults at high risk whose blood glucose measure (fasting plasma glucose or HbA1c) shows they are still progressing towards Type 2 diabetes, despite their participation in an intensive lifestyle-change programme.
- Adults at high risk who are unable to participate in lifestyle-change programmes because of a disability or for medical reasons.

Who should take action?

Doctors, non-medical prescribers and pharmacists in primary and secondary healthcare.

What action should they take?

Use clinical judgement on whether (and when) to offer standard-release metformin to support lifestyle change for people whose HbA1c or fasting plasma glucose blood test results have deteriorated if:

- ☐ this has happened despite their participation in an intensive lifestyle-change programme, **or** they are unable to participate in an intensive lifestyle-change programme.
- ☐ Discuss with the person the potential benefits and limitations of taking metformin, taking into account their risk and the amount of effort needed to change their lifestyle to reduce that risk. Explain that long-term lifestyle change can be more effective than drugs in preventing or delaying Type 2 diabetes. Encourage them to adopt a healthy diet and be as active as possible. Where appropriate, stress the added health and social benefits of physical activity (for example, point out that it helps reduce the risk of heart disease, improves mental health and can be a good way of making friends).
- ☐ Advise them that they might need to take metformin for the rest of their lives and inform them about possible side effects.
- ☐ Continue to offer advice on diet and physical activity along with support to achieve their lifestyle and weight-loss goals.

- Check the person's renal function before starting treatment, and then twice yearly (more often if they are older or if deterioration is suspected).
- Start with a low dose (for example, 500 mg once daily) and then increase gradually as tolerated, to 1500–2000 mg daily. If the person is intolerant of standard metformin consider using modified-release metformin.
- Prescribe metformin for 6– 12 months initially. Monitor the person's fasting plasma glucose or HbA1c levels at 3-month intervals and stop the drug if no effect is seen.

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Appendix 1

Summary recommendations for lifestyle change intervention for the proposed IGR pathway

Background

The recommendations summarised below are derived from an evaluation of NICE's (2012) guidance on IGR interventions, and take account of additional evidence from a systematic search of recent literature. Departures from NICE guidance are highlighted, as is the importance of considering the feasibility and acceptability of first-line interventions in the context of our local population, and next steps are proposed. A more detailed report is also available

Outline of suggested advice

- NICE recommendations on lifestyle interventions were derived using a robust methodology and can form the basis of a local IGR pathway intervention

- Behaviour change strategies and self-monitoring and problem-solving techniques should be used and taught in group and individual settings

- A tailored approach is preferred to identify changes and set goals. The more goals that are achieved the greater the reduction in future diabetes incidence

- **Trainers**
  - Trainers should receive structured education on lifestyle changes for IGR. This should include ways to communicate risk appropriately
  - There is a need to balance flexibility with clear messages about the most effective changes
  - It may be helpful to provide simple explanations about the distinct and complementary mechanisms that underlie benefits due to weight loss, improved diet and increased physical activity

- **Goals** include:
  - **WEIGHT/BMI**: ≥5% weight loss if subject's BMI is above ethnicity-specific cut-offs (*NICE recommendation to attain healthy range BMI may be unrealistic and unnecessary*)

  - **DIET**:
    - Use the 'balance of good health model' or similar to promote achievable, family-friendly adjustments to the diet with emphasis on reducing fat and particularly saturated fat, added sugars, and increasing whole-grains, vegetables and pulses
    - Low GI foods can be encouraged as more satiating. A lowering in overall dietary GI is likely to follow changes suggested above
    - A modest increase in protein, e.g. ensuring a low fat source of protein at every meal may increase satiety and dietary adherence
    - Alcohol intake should be within current guidelines, and ideally lower to curtail intake of 'empty calories'. Fizzy drinks high in sucrose and glucose should be avoided, and fructose-rich fruit juices should be limited to a small, diluted glass per day
    - A very low carbohydrate, or high protein diet or <20% fat diet or <1200kcal diet or periodic fasting diet is not currently recommended as a health trainer-led intervention for weight loss
    - Work on mindful eating, portion control and healthy snack alternatives is important

- **EXERCISE**:
  - Set staged goals (high intensity recommendations reduce adherence) in favour of lifestyle changes, e.g. walking more, preferably with a pedometer to self-monitor progress.
  - Emphasise need to increase the level of habitual low intensity activity and reduce sedentary behaviour at other times
  - Promote subsidised or low-cost services e.g. exercise on prescription
  - Aim for at least 150-200 mins moderate activity/week (less if higher intensity), can include one hour of resistance training – also a good alternative for people with mobility issues
  - Emphasise frequency (no more than 2 days between sessions)
  - Any improvement is beneficial
  - Exercise has an important role in weight maintenance and well-being
- **SMOKING**: refer to smoking cessation service when ready to make this change

- The programme should consider possible other groups for whom IGR lifestyle interventions may not be appropriate e.g. frail elderly (including overweight and obese), individuals in need of specialist dietary intervention e.g. suspected eating disorder, coeliac disease.

Local context

Some considerations when developing this intervention for the Merseyside population are:

- Cost – lifestyle changes should be achievable within the constraints of a potentially limited family budget
- Changes should be family-friendly and feasible to incorporate into daily life, e.g. meals that are suitable for all the family
- Changes should maximise sustainability and be culturally and socially acceptable – this is one argument against promoting a very low carbohydrate/very high protein plan as a first line intervention
- A multi-faceted intervention (modest weight loss, increased physical activity, qualitative changes to diet, smoking cessation) should be favoured. Although trial evidence suggests that moderate intensity exercise alone can achievable clinically significant improvements in glucose tolerance the effects are very short-lived (2-3 days) and require lifelong commitment[1]. In addition, people may find exercising easier following some weight loss on a less energy-dense diet, reinforcing the synergistic effect of weight loss and sustained physical activity, including improved wellbeing. Given that a significant proportion of people with IGR will go on to develop diabetes it is appropriate to offer pre-emptive, early intervention around recommended lifestyle changes
- It is important to use previous insight work to consider how this programme can be made as attractive and relevant as possible for men as well as women. Weight loss programmes are traditionally seen as very female-focussed

[1] It may be appropriate to consider a health promotion campaign to raise wider awareness of the independent benefits of increasing daily physical activity for diabetes prevention beyond high risk individuals

Variation from NICE's core recommendations

Weight

- Emphasis away from achieving 18.5-24.9kg/m^2 as a weight loss goal

Diet

- Specific encouragement to eat more low GI foods
- Recommendation to ensure a lean source of protein at every meal
- Specific advice on addressing portion control and snacking, and targeting intakes of alcohol and sugary drinks

Exercise

- Slightly more ambitious target for moderate intensity physical activity (150-200 minutes)
- Can substitute resistance training
- Specific recommendation to reduce sedentary activity by increasing habitual low intensity activity
- Specific recommendation to leave no longer than 2 days between exercise sessions
- Emphasis on the *distinct* benefit of any increase in physical activity, including improvement in wellbeing and motivation and overall outcome

Next steps

- Re-draft recommendations for inclusion in clinical guideline format
- Re-draft recommendations for health trainer education package specification
- Ensure early consideration of how a robust framework for evaluation can be embedded in the roll-out of this programme, as it is important to contribute to the comparatively small evidence base focusing on 'real world' pre-diabetes interventions. This might involve exploring research partnerships with local academic institutions. Data collection around process, clinical and service user satisfaction outcomes is also essential to make responsive improvements to the programme following initial implementation
- Commit to a systematic and comprehensive re-evaluation of research evidence in 2-3 years' time, with emphasis on identifying components of the most effective translational/pragmatic programmes

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