East Lancashire Diabetes Network

Guidelines for the Management of Impaired Glucose Regulation

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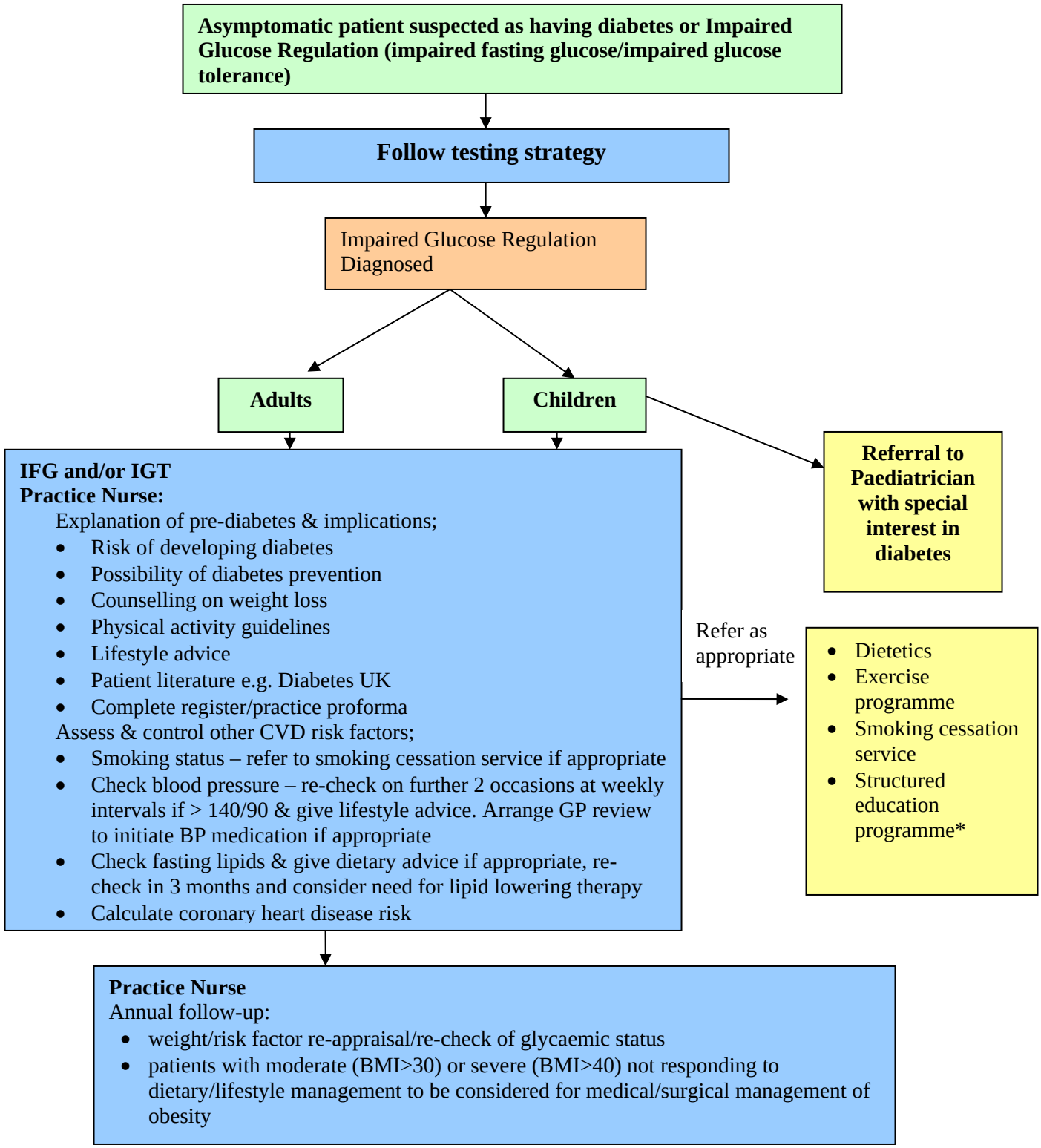
East Lancashire Hospitals NHS Trust

Management of Impaired Glucose Regulation (IGR)



*Patients will need intensive and sustained support and encouragement over medium to long term to achieve and maintain goals of lifestyle change programme. A pilot intervention is currently being run until Autumn 2006 with the aim to roll the programme out East Lancashire wide from the end of 2006 (for more information contact Dianne.gardner@bprpct.nhs.uk).

FPG = Fasting Plasma Glucose IFG = Impaired Fasting Glucose IGT = Impaired Glucose Tolerance OGTT = Oral Glucose Tolerance Test IGR = Impaired Glucose Regulation PCTs = Primary Care Trusts

East Lancashire Guidelines for the Management of Impaired Glucose Regulation

1. Diagnostic criteria (WHO)

- Impaired Glucose Tolerance (IGT): diagnosed by oral glucose tolerance test: fasting plasma glucose < 7 mmol/l AND 2-hr post glucose load value 7.8 –11.0 mmol/l
- Impaired fasting glucose (IFG): Fasting plasma glucose 6.1 –6.9 mmol/l
- A patient may have both IFG and IGT
- Positive results should be confirmed on another day (ADA)

2. Patient identification

- Most patients will have been diagnosed with IFG or IGT following re-test after gestational diabetes or after an acute illness associated with hyperglycaemia or on further evaluation of a high random glucose test not in the diabetes range
- Population screening for pre-diabetes and diabetes to await national guidance.
- Opportunistic case finding in high risk patients to be encouraged in the meantime. At increased risk are people aged ≥ 45 years, people of South Asian descent, those who have a first degree family history of diabetes, who are overweight, have a sedentary lifestyle, history of polycystic ovary syndrome and/or gestational diabetes, cardiovascular disease or other markers of metabolic syndrome. The more risk factors, the higher the risk of pre-diabetes or undiagnosed diabetes. Patients' awareness of their own risk factors must be promoted.
- Individuals ≥ 45 years old who are overweight or obese (BMI ≥ 25) are those most likely to have impaired glucose regulation or undiagnosed diabetes. American Diabetes Association strongly recommends opportunistic screening in this group. Younger individuals with a BMI ≥ 25 and additional risk factors should be considered for opportunistic screening (ADA)
- In individuals screened ADA recommends re-test after 3 years if results normal.

3. Clinical relevance of IGT/IFG

- Patients with IFG/IGT are at increased risk of cardiovascular morbidity and mortality; they often have other features of the metabolic syndrome: central obesity, dyslipidaemia, hypertension.
- Patients with IFG/IGT are at increased risk of developing Type 2 diabetes; Type 2 diabetes has serious implications in terms of long term complications; even with the most up-to-date strategies for treatment of Type 2 diabetes, control is difficult and deteriorates over time; Type 2 diabetes is a progressive disease even in intensively treated patients (UKPDS).
- Of all known independent risk factors for the development of Type 2 diabetes, taken singly, impaired glucose regulation is the most discriminant factor predicting the development of diabetes. The 5-6 year cumulative incidence of diabetes is 4-5% in individuals with normal fasting and normal 2-h OGTT value, 20-34% in those with either IFG or IGT, and 38-65% in those with combined IFG and IGT

4. Aims of management of IFG/IGT

- Prevention of cardiovascular morbidity and mortality
- Delay/Prevention of Type 2 diabetes
- Monitoring for the development of Type 2 diabetes in order to ensure prompt diagnosis of and institution of appropriate therapy for Type 2 diabetes

5. Summary of Evidence Base

(a) Prevention of Cardiovascular Morbidity and Mortality

The evidence relating to prevention of cardiovascular morbidity and mortality by modification of associated risk factors, namely smoking, hypertension and dyslipidaemia, is well known and will not be further reviewed here.

(b) Delay/Prevention of Type 2 Diabetes

- Finnish Diabetes Prevention Study (DPS)[1]

522 middle aged (mean age 55 years) obese participants (mean BMI 31) with IGT were randomised to brief diet and exercise counselling (control group) or intensive lifestyle intervention. After an average of 3.2 years, there was a 58% reduction in incidence of diabetes in intensive vs control group. Number Needed to Treat (NNT) with intensive lifestyle intervention to prevent one case of diabetes 22 at one year, 5 at 5 years

- Diabetes Prevention Program (DPP)

3234 obese participants (mean age 51 years, mean BMI 34), including 45% from ethnic minority groups were randomised to intensive lifestyle intervention vs metformin 850 mg bd with standard lifestyle recommendations vs placebo with received standard lifestyle recommendations. After an average follow-up of 2.8 years, annual incidence of diabetes was 11.0% in placebo + standard lifestyle recommendations group, 7.8% in metformin + standard lifestyle recommendations group, 4.8% in intensive lifestyle intervention group, i.e 58% reduction in diabetes incidence with intensive lifestyle modification vs 31% reduction with metformin. Number Needed to Treat (NNT) to prevent one case of diabetes in 3 years is 14 for metformin, 7 for intensive lifestyle intervention.

- STOP-NIDDM trial

1429 participants (mean age 55, mean BMI 31) with IGT were randomised to acarbose or placebo. Mean follow up was 3.3 years. Acarbose reduced risk of developing diabetes by 32%

- TRIPOD study

235 Hispanic women with previous GDM were randomised to Troglitazone or placebo. After median follow-upof 30 months, annual incidence of diabetes was 12.3% in placebo group and 5.4% in troglitazone group. Troglitazone reduced risk of developing diabetes by 56%.

- XENDOS study

3305 patients with BMI $\geq$ 30, of whom 21% had IGT, were randomised to lifestyle + Xenical or lifestyle + placebo. At 4 years, incidence of diabetes was 6.2% vs 9.0% in placebo group, a risk reduction of 37.3%.

6. Notes on evidence base

(a) Support for Lifestyle Change

The evidence from DPP and Finnish studies relates to INTENSIVE lifestyle intervention. Considerable effort from **well trained staff** was required in both DPP and Finnish study to achieve the behavioural changes (150 minutes/week moderate physical activity) and the results on weight loss (5-7%) and prevention of diabetes. The exercise and weight loss goals were achieved in 36% and 43% respectively in the Finnish Study and 74% and 50% respectively in DPP-the latter being the best ever results on weight and lifestyle change achieved in such a large group of participants in a clinical trial.

In the Finnish study participants had 7 sessions with nutritionist during first year, one session every 3 months after; individualised guidance on increasing physical activity; over 50% of participants received supervised progressively tailored physical training sessions; free membership to exercise club offered.

In the DPP participants met with a case manager 16 times over first 6 months, then monthly; telephone contacts at least monthly; group courses on exercise and weight loss lasting 4-6 weeks were offered every 3 months; 2 supervised exercise sessions were offered each week; other incentives for those not achieving or maintaining goals e.g free enrolment in exercise facilities, free low-calorie foods, more structured eating plans, home visits for encouragement and counselling

(b)Pharmacological agents in the prevention of diabetes

Troglitazone used in the TRIPOD trial has been withdrawn. Evidence is not yet available for other glitazones-rosiglitazone and pioglitazone; there is reason to believe that the troglitazone effect is a class effect. This was a trial involving a small number of participants. Glitazones are a new category of drugs without sufficient experience in long term use.

In the DPP metformin was as effective as intensive lifestyle modification in those aged 24-44 years or those with BMI $\geq$ 35; it was nearly ineffective in those aged $\geq$ 60 years.

Only 21% of participants in the XENDOS trial had IGT. In the subgroup with IGT, the reduction in diabetes incidence was only 21%. There was a large dropout rate. Analysis was not on intention to treat basis. Xenical group only lost 2.8 kg weight more than placebo (>3kg in DPS and DPP).

(c) Additional benefits of lifestyle change

Other health benefits of diet and lifestyle change in addition to prevention of diabetes and cardiovascular disease include feeling of well-being, therapeutic effects on mild to moderate depression, prevention of COPD and lung cancer, potential beneficial effects on other conditions e.g osteoarthritis, osteoporosis-hence lifestyle changes of paramount importance and first line management of patients with IFG/IGT

6. Care pathway for management of IFG/IGT

- Perform appropriate blood tests
- Review plasma glucose results, confirm diagnosis
- Initial counselling and patient literature:
- Register/Practice Proforma
- Cardiovascular risk factor review and management: smoking, blood pressure, lipids
- Principal intervention strategy will be promotion of weight loss and increasing physical exercise: referrals to dietitian and to exercise programme, support for Lifestyle Change
- Annual re-assessment of glycaemic status and risk factors
- Medical and surgical management of obesity care pathway where appropriate
- Consider indication for pharmacological prevention of diabetes
- Care pathway for early and intensive management of Type 2 diabetes on diagnosis of diabetes

Test

Either a fasting plasma glucose or a 75 gram oral glucose tolerance test is appropriate. Concensus view may emerge nationally. In the meantime, choice of test at discretion of individual GP practices and taking into account resources, convenience, and patient preference. However, all patients with IFG should have OGTT to confirm or exclude diabetes (Diabetes UK).

Review of results, classification of glycaemic status, confirm with 2nd test

Who: Doctor or Practice Nurse

When: Within 2 weeks of test

Interpretation: WHO diagnostic criteria as described above
Arrange re-test

Initial patient counselling, patient literature
Who: Practice Nurse
When: Within 2 weeks of confirmation re-test
What (checklist): Blood test results, explanation of "pre-diabetes" and its implications, risk of developing diabetes, potential consequences of diabetes, possibly of diabetes prevention, counselling on weight loss, instruction for increasing physical activity to a minimum of 30 mins moderate exercise 5 times a week, other lifestyle advice, need to assess and control other CVD risk factors, risk of CVD

- Patient literature: Diabetes UK information sheet, modified and updated, see attached.

- Register/Practice Proforma

See attached

Cardiovascular risk factor review and management
Who: Practice Nurse
When: Within 2 weeks of test
What:
Check smoking status: Refer to smoking cessation service if appropriate
Check blood pressure: Counselling re salt intake, recheck on further 2 occasions at weekly intervals if > 140/90, arrange for GP review to initiate BP lowering treatment if appropriate
Check fasting lipids: dietary advice as appropriate, re-check in 3 months, consider need for lipid lowering therapy
Referrals
To dietitian, exercise programme, and smoking cessation clinic where indicated

- Support for Lifestyle Change

Patients will need intensive and sustained support and encouragement over medium to long term to achieve and maintain goals of lifestyle change programme; PCTs and other partner agencies will need to consider the details of how to provide such support most effectively. In order to do this a pilot intervention is being conducted in East Lancashire until Autumn 2006 with the aim to roll out the most effective model by the end of 2006 (for more information contact dianne.gardner@bprpct.nhs.uk).

Follow-up and re-testing
(a) at regular intervals by case manager (identified through pilot) for lifestyle change, risk factor modification
(b) annual medical follow-up with proforma: weight, risk factor re-appraisal, re-check of glycaemic status

Further Management
Consider if appropriate to refer to medical and surgical obesity management care pathway

"Failure" of programme of lifestyle change, persistence of impaired glucose regulation
Drug therapy should not be routinely used to prevent diabetes until more information is known about cost-effectiveness (ADA). However, in patients not suitable for lifestyle change programme or in whom all efforts have failed, and who have gone

through care pathway for medical and surgical management of obesity, and still have persistent impaired glucose regulation, consideration should be given to drug prevention of diabetes using metformin or acarbose on an individual basis.

8.Cost Effectiveness

There are substantial cost implications, especially for a well-supported lifestyle change programme. The cost effectiveness of interventions above in prevention of diabetes and its complications has not been established.

9. References

1. Prevention of Type 2 diabetes by changes in lifestyle among subjects with impaired glucose tolerance N Engl J Med 344: 1343-50, 2001 (known as Finnish Study)
2. Diabetes Prevention Program Research Group: Reduction in the evidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 346: 393-403,2002 (known as Diabetes Prevention Program-DPP)
3. Position Statement: The Prevention or Delay of Type 2 Diabetes. American Diabetes Association. Diabetes Care 742-8, 2004
4. Acarbose for the Prevention of Type 2 diabetes: The STOP-NIDDM randomised trial. Lancet 2002: 359: 2072-77.

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April 2005

Impaired Glucose Regulation Template

Notes for use:

i) Prompts shown in **RED** denote the use of a Sub-template. The contents of the Sub-templates used in the Impaired Glucose Regulation Template are listed in the order they appear from page 2 onwards. The content of all Sub templates is FIXED as per PRIMIS guidelines.

ii) Prompts shown in **bold** denote the use of a picking list. The bold prompt itself acts as a heading only for the picking list, and will not itself be recorded against the patient, rather the prompt chosen from the picking list. Prompts shown in *italics* denote available choices from the picking list.

Description	Read Code
RECORD:Impaired Glucose Assessment	66AZ
Glucose Tolerance Test	**44V**
Glucose tolerance test normal	*44V1*
Glucose tol. test impaired	*44V2*
Glucose tol. test diabetic	*44V3*
GTT = renal glycosuria	*44V4*
Growth hormone stimulation test	*44V5*
Glucose tolerance test NOS	*44VZ*
Fasting Plasma Blood Glucose	44g1
Serum Cholesterol	44P
Serum Random HDL Cholesterol level	44P5
Serum Random LDL Cholesterol level	44PI
Total Cholesterol:HDL ratio	44PF
Triglycerides	44Q
Random Glucose	44g
FH: Cardiovascular Disease/Diabetes	
General Examination	
Alcohol consumption counselling	**9k11**
Alcohol consumption counseling	*9k11*
Alco counsel by other agencies	*9k14*
Lifestyle Information	
Did not attend Dietetic Clinic	9N4I
Framingham Actual CHD risk score	EMISFR3 (3888)
Framingham Estimated CHD risk score	EMISFR4
Framingham adjusted CHD risk score	388R
FOLLOW UP: Impaired Glucose Assessment	66AZ

Sub Template-FH: Cardiovascular Disease/Diabetes

Description	Read Code
****NOTE: *FH codes allow details of 2 family members***	
Ethnic Group	9S
FH: IHD <60	**12C2**
No FH: Ischaemic heart disease	*1226*
FH: Ischaemic heart dis. <60	*12C2*
FH: IHD >60	**12C3**
No FH: Ischaemic heart disease	1226
FH: Ischaemic heart dis. >60	12C3
FH: CVA/stroke	**12C4**
No FH: Stroke/TIA	*1225*
FH: CVA/stroke	*12C4*
FH: Hypertension	**12C1**
No FH: Hypertension	*1227*
FH: Hypertension	*12C1*
FH: Diabetes Mellitus	1252
No FH Diabetes	*1228*
FH: Diabetes mellitus	*1252*

Sub Template-General Examination

Description	Read Code
O/E – Height	229
O/E – weight	22A
Body Mass Index	22K
Waist Circumference	22NO
Systolic BP	2469
Diastolic BP	246A
O/E - pulse rate	242
O/E - pulse rhythm (243)	**243**
O/E - pulse rhythm regular	*2431*
O/E - pulse irregularly irregular	*2432*
O/E -pulse regularly irregular	*2433*
O/E - no gallop rhythm	*2434*
O/E - pulse rhythm NOS	*243Z*

Lifestyle Information

Description	Read Code
Alcohol Consumption	136
Health Education – Alcohol	6792
Smoking Status (including full picking list of all sub codes)	**137..**
Other smoking Information (including full picking list of all sub codes)	**EMISOTS1..**
Health Education – Smoking	6791
Referral to stop smoking clinic	8HTK
Exercise Grading (including full picking list of all sub codes)	**138..**
Exercise on prescription	8BAH
Health Education – Exercise	6798
Patient initiated diet (including full picking list of all sub codes)	**13A..**
Patient advised re diet (including full picking list of all sub codes)	**8CA4..**
Health Education – Diet	6799
Health Education-weight management	679P
Refer to Dietician	8H76
Seen by Dietician	9N27

Reducing the Risk of Diabetes

What is 'Pre-diabetes'?

When a person has a blood glucose (sugar) level higher than normal but not high enough for a diagnosis of diabetes he or she is said to have **'pre-diabetes'** (also known as Impaired Glucose Regulation)

Why Treat 'Pre-diabetes'?

Studies have shown that people with pre-diabetes can prevent or delay the development of type 2 diabetes through changes to their lifestyle that include modest weight loss and regular exercise.

For some people with pre-diabetes, making healthy lifestyle changes early can actually **turn back the clock** and return the blood glucose levels to the normal range.

How Do I Prevent Pre-Diabetes Becoming Diabetes?

Treatment consists of losing a modest amount of weight (5-10 per cent of total body weight) through diet and moderate exercise, such as brisk walking, 30 minutes a day, 5 days a week.

Remember for exercise to be beneficial you should be feeling:

- Warmer following exercise
- Comfortably short of breath (still be able to talk or whistle)
- Your heart rate may speed up a little

It has been proven that even a modest amount of weight loss (5-10% of total body weight) can work.

Don't worry if you can't get to your target weight. A weight loss of 5–7 kilograms (10–15 pounds) can make a difference

Become More Active

- Put the TV remote away, get up to change channels, march on the spot and move around during the adverts.
- Walk around the house whilst on the phone.
- Park your car further away from shops, cinemas or work.
- Get off the bus a stop early and walk if you feel safe to do so.
- Use stairs instead of the lift
- Progress to at least 30 minutes of moderate exercise, 5 days per week of an exercise you enjoy e.g. brisk walking, swimming, cycling, dancing, exercise classes at your local leisure centre
- *If you have any other medical conditions and are uncertain about what exercise to take up then discuss this with your Practice Nurse or GP*

Eat The Right Foods:

Making healthy food choices and cutting down on the amount of food you eat will help achieve and maintain weight loss and reduce your risk of developing Type 2 diabetes

- Try to eat 3 sensible meals at regular times throughout the day, avoid eating extra snacks.
- Try to cut down on the amount of fat eaten. Steaming, grilling and baking foods are healthier options. Use low/minimal fat dressings on salads and vegetables. Avoid adding butter or margarine to vegetables.
- Eat more fruit and vegetables.
- Select cereals which are high in fibre for example wholemeal bread, wholegrain cereal. Control your portion sizes.
- Drink alcohol in moderation, no more than 14 units per week for women and no more than 21 units per week for men.

- Sugar should be limited as part of a healthy diet especially if you are trying to lose weight.
- A good fluid intake is important for your all round health. Drink 6-8 glasses of fluid a day,
- People at risk of developing diabetes are often also at risk of developing high blood pressure. You should cut down on the amount of salt you eat to prevent this

For further help and information please contact your GP or Practice Nurse

Alcohol Units

Wine • Bottle of wine • Standard measure • Large measure • Fortified Wines	 750mls 175mls 250mls 50mls	 9 units (approx) 2 units 3 units 1 unit
Spirits	30mls	1 unit
Beers • Ordinary beers 3-4% alcohol • Strong larger/cask beers >5%	 1 pint 1 pint	 2 units 2.5-3 units

References

WHO Working Group 1999, Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications.
Part 1: Diagnosis and Classification of Diabetes Mellitus, World Health Organisation, Department of Non-communicable Disease Surveillance, Geneva.

Some guidance was also taken from:
ADA Expert Committee on the Diagnosis and Classification of Diabetes Mellitus 1997, "Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus", Diabetes Care, vol. 20, pp. 1183-1197.