SAME DAY REFERRAL

- Newly diagnosed Children with Diabetes - refer to Paediatric Service - 0116 258 6222 Secretary or 2586923 Admissions.
- Newly diagnosed Type 1 Diabetes especially urgent in those who present with ketonuria and/or vomiting. 0116 258 5545
- Patients with infected, necrotic or gangrenous foot ulceration or suspected Charcot Foot.
- Sudden loss of vision contact Eye Casualty 0116 2586273.
- Outside normal working hours contact the on-call team via switchboard 0300 303 1573.

REFERRAL WITHIN 48/72 HOURS

- All women with pre-existing Type 1 or Type 2 Diabetes who become pregnant.
- Women who develop Gestational Diabetes.

PRIORITY/EARLY REFERRAL

- Women with Type 1 or Type 2 Diabetes contemplating pregnancy.
- Retinopathy/reduced visual acuity, those with sight threatening retinopathy - refer to Ophthalmology Department. Eye Casualty 0116 2586273.
- Patients presenting with persistent proteinuria.
- Patients with severely at risk feet – refer to Diabetic Foot Clinic.

OTHERS WHERE SPECIALIST ADVICE MAY BE CONSIDERED

Referral to Diabetes Specialist Nurse (DSN), Integrated Community Diabetes Service (ICDS) or specialist diabetes doctor

- Recurrent hypoglycaemia (refer to ICDS).
- Poor glycaemic control despite intensive management (refer to ICDS).
- Persistent hypertension and/or hyperlipidaemia despite intensive management as per guidelines (refer to Specialist Care).
- Painful neuropathy not responding to treatment (refer to Specialist Care).
- Erectile dysfunction requiring additional intervention - refer to Andrology Clinic.
- People with Type 1 Diabetes with previous failure to attend but now receptive to specialist referral (refer to ICDS).
- Dialysis patient (refer to Specialist Care).
- Need for psychosocial/counselling support to overcome barriers to self-care (refer to ICDS).
- Patients CKD 3 for optimisation of glucose, BP and lipids if control suboptimal (refer to ICDS).
- Patients for DAFNE programme (refer to Specialist Care - DSN).
- Patients in whom insulin Pump Therapy is being considered (refer to Specialist Care - DSN).

DSN’s contact No: LGH: 0116 2588249 LRI: 0116 2585545 GGH: 0116 2502390 ICDS contact No: 0116 273 4845 or Email icds@uhl-tr.nhs.uk
Contact consultants via secretaries - see contact details opposite

THOSE REQUIRING URGENT ADMISSION TO A&E DEPARTMENT

- Unconscious hypoglycaemia.
- Suspected ketoacidosis/non-ketotic hyperosmolar coma.
- Newly diagnosed Type 1 with ketones when Diabetes specialist services unavailable.

<table>
<thead>
<tr>
<th>ROUTINE DIABETIC CLINICS</th>
<th>Day</th>
<th>Regularity</th>
<th>Site</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Melanie Davies</td>
<td>Mon pm</td>
<td>Weekly</td>
<td>LRI</td>
<td>0116 258 6481 (sec) 0116 258 5964 (appts)</td>
</tr>
<tr>
<td>Dr Alison Gallagher</td>
<td>Tues pm</td>
<td>Weekly</td>
<td>LRI</td>
<td>0116 258 5745 (sec) 0116 258 5964 (appts)</td>
</tr>
<tr>
<td>Dr Rob Gregory - Head of Service</td>
<td>Thurs pm</td>
<td>Weekly</td>
<td>LGH</td>
<td>0116 258 8017 (sec) 0116 258 4410 (appts)</td>
</tr>
<tr>
<td>Dr Steve Jackson</td>
<td>Weds am</td>
<td>Weekly</td>
<td>LGH</td>
<td>0116 258 4438 (sec) 0116 258 4410 (appts)</td>
</tr>
<tr>
<td>Dr Ian Lawrence</td>
<td>Mon am</td>
<td>Weekly</td>
<td>LRI</td>
<td>0116 258 5402 (sec) 0116 258 5964 (appts)</td>
</tr>
<tr>
<td>Dr Paul McNally</td>
<td>Weds am</td>
<td>2nd, 4th, 5th</td>
<td>LRI</td>
<td>0116 258 6809 (appts)</td>
</tr>
<tr>
<td>Dr Marie-France Kong</td>
<td>Mon pm</td>
<td>Weekly</td>
<td>LGH</td>
<td>0116 258 8304 (sec) 0116 258 4410 (appts)</td>
</tr>
</tbody>
</table>

SPECIAL CLINICS

Ante-Natal Diabetes and Endocrine Clinic

- Day | Regularity | Site | Contact |
- Weds pm | Tues | Weekly | LRI | 0116 258 6403 0116 258 4855 |
- Diabetes Foot Clinic | Thurs am | Thurs pm | Weekly | LRI | 0116 258 6809 0116 258 4438 |
- Medical Andrology - Dr Paul McNally | Fri pm | 2nd | LRI | 0116 258 6182 |
- Medical Andrology - Dr Rob Gregory | Mon pm | 3rd | LRI | 0116 258 8017 |
- Medical Andrology - Dr Steve Jackson | Fri am | 1st | LGH | 0116 258 4438 |
- Nephrology - Dr Rob Gregory | Tues pm | 2nd, 4th | LGH | 0116 258 8017 |
- Nephrology - Dr Marie-France Kong | Fri am | 1st, 3rd | LGH | 0116 258 8304 |
- Young Adult Clinic (ages 15-18) | Thurs pm | 3rd | LRI | 0116 258 6481 0116 258 5402 |
- Young Adult Clinic | Weds pm | 5th | Coalville | 01530 467445 |

COMMUNITY BASED DIABETES CLINICS

- Coalville - Dr Rob Gregory 01530 467431 (appts)
- Hinckley - Dr Paul McNally 01455 441817 (appts)
- Loughborough - Dr Steve Jackson 01509 564355 (appts)
- Melton - Dr Rob Gregory 01664 854915 (appts)
- Market Harborough - Dr Alison Gallagher 01858 438135 (appts)
- Oakham - Dr Paul McNally / Dr Kath Higgins 01572 720255 (appts)

Date of preparation: May 2012. For review: May 2014

Working in partnership with CCGs across Leicestershire and Rutland
**WHAT IS TYPE 2 DIABETES?**

Type 2 diabetes is a chronic condition in which the body becomes resistant to insulin or does not produce enough insulin. It results in too much glucose (sugar) in the blood.

**DIAGNOSIS OF TYPE 2 DIABETES**

Diagnosis of Type 2 diabetes can be made using HbA1c in those who are asymptomatic. It should not be used for diagnosis in children, pregnancy, and those who are acutely ill or who have abnormal haemoglobins, anaemia, and altered red blood cell lifespan.

**WHOM TO TEST**

At least half of people with Type 2 diabetes are asymptomatic.

**PREDETERMINED RISK OF DIABETES**

- Coronary Heart Disease
- Women who have had Gestational Diabetes (screen at 6 weeks and one year post-partum, and then yearly)
- Those known to have impaired glucose tolerance, HbA1c 6.0 – 6.4% or oral glucose tolerance test 2-hour value between 7.8 mmol/l and 11.1 mmol/l (Impaired Glucose Tolerance IGT) or fasting glucose 6.1 – 6.9 mmol/l (Impaired Fasting Glucose IFG).

**HIGH RISK FOR DIABETES**

- White European people aged over 40 and people from Black, Asian, and minority ethnic groups aged over 25 with
  - first degree relative with diabetes
  - BMI of 25-30 (i.e. are overweight) and who have a sedentary lifestyle. >23 in South Asian people.
  - BMI >30.
- Women with polycystic ovary syndrome.
- Cerebrovascular disease, peripheral vascular disease or hypertension/hyperlipidaemia.
- Patients on prolonged steroid therapy.
- Patients on atypical anti-psychotic drugs.

**HOW TO TEST**

**Oral Glucose Tolerance Test (OGTT)**

- Fast from midnight, water only
- Measure fasting venous glucose
- Drink 410 mls of lucozade energy original within 5 mins
- 2 hours later measure venous glucose
- No activity, smoking, food or drink other than water between tests

**DIAGNOSTIC TESTS**

Screening Test: Use either a fasting plasma blood glucose or a plasma blood glucose assay 2 hours after a 75g glucose load.

<table>
<thead>
<tr>
<th>WHO Diagnostic Criteria: Diabetes Mellitus(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venous Plasma</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Fasting</td>
</tr>
<tr>
<td>2 Hour Post Glucose Load</td>
</tr>
</tbody>
</table>

- IGT includes patients with Hba1c of 6 - 6.4%. It is associated with increased cardiovascular risk. 2-5% of patients with IGT progress to diabetes each year.
- IFG is present in 5% of the population and increases with age. Patients are at greater risk of cardiovascular complications than the normal population.
- IFG and/or IGT are often referred to as Prediabetes and require management and lifestyle interventions.

**WHEN TO TEST**

Diabetes is often missed in the elderly.

**WHEN TO TEST**

- Coronary Heart Disease
- Women who have had Gestational Diabetes (screen at 6 weeks and one year post-partum, and then yearly)
- Those known to have impaired glucose tolerance, HbA1c 6.0 – 6.4% or oral glucose tolerance test 2-hour value between 7.8 mmol/l and 11.1 mmol/l (Impaired Glucose Tolerance IGT) or fasting glucose 6.1 – 6.9 mmol/l (Impaired Fasting Glucose IFG).

**WHEN TO TEST**

Remember to test for diabetes if patients present with the following symptoms:

- Excess thirst
- Polyuria (especially if nocturia)
- Weight loss
- Urinary incontinence
- Tiredness
- Pruritis Vulvae / recurrent candidiasis
- Recurrent infections / abscesses
- Balanitis
- Blurred Vision / changes in visual acuity
- Erectile Dysfunction
- Pain / Numbness / foot ulcers
- Non specific or unexplained symptoms

**WHEN TO TEST**

Finger prick capillary results can not be used to diagnose diabetes.

**WHEN TO TEST**

**WHEN TO TEST**

Glycosuria on its own does not confirm diabetes.

**WHEN TO TEST**

An HbA1c of ≥48mmol/l (6.5%) is diagnostic of diabetes in most situations. It can be used to diagnose diabetes in asymptomatic patients. It should not be used in certain patient groups including children, pregnancy, suspected type 1 diabetes and acute illness. Please refer to screening algorithm on page 6.

**WHEN TO TEST**

Diabetes is often missed in the elderly.

3. The Expert Committee on the diagnosis and Classification of Diabetes Mellitus. Diabetes Care. 1997;20 (7); 1183-1203

Date of preparation: May 2012. For review: May 2014
**Type 2 Diabetes - Glycaemic Management (1)**

**National Service Framework**

**STANDARD 4**

---

**Principles of Treatment**

- Offer structured education (i.e. the DESMOND programme which fulfils The National Recommended Criteria from DoH on Structured Education 2004) to include diet/lifestyle advice to everyone. Usually wait 6-12 weeks before glucose lowering agents are introduced.

**However:**

- Introduce oral hypoglycaemic agents early if fasting plasma glucose >15mmol/l and symptomatic.
- Ensure patients are shown how to monitor their own diabetes, and know what to do if results do not fall in the target range.
- Regular monitoring will identify the need to actively titrate treatment.
- Measure HbA1c every 2-6 months.
- Target HbA1c 48mmol/mol/6.5% in newly diagnosed Type 2 diabetes and those on up to 2 oral hypoglycaemic agents unless individual target more appropriate. Involve the person in discussions about individual HbA1c target.
- In South Asian people BMI underestimates adiposity. Weight measurements need to be considered. Range for healthy weight is BMI 18.5-22.9 in South Asian people.

---

**Treatment Decision Tree for Early Insulin Initiation**

1. Symptoms of hyperglycaemia and a diagnostic blood glucose (random ≥11.1 mmol/l)
   - **YES**
   - Is the patient ill (vomiting, semiconscious or clinically dehydrated)?
     - **YES**
     - Arrangement direct admission to hospital
     - **NO**
     - **NO**
8. Does the urine test show moderate/heavy ketonuria?
   - **YES**
   - Very likely to need insulin. Discuss with specialist team within 24 hours.
   - **NO**
   - Are one or more of the following present?
     - Severe osmotic symptoms (nocturia x 3-4)
     - Short history (weeks)
     - Marked weight loss (irrespective of absolute weight)
     - A first degree relative with Type 1 Diabetes
     - A personal history of autoimmune disease
       - **YES**
       - Two or more are a strong indication for insulin
       - **NO**
   - Is the patient under 30 years of age?
     - **YES**
     - No immediate need for insulin. Discuss with specialist team to confirm diagnosis.
     - **NO**
     - There is no immediate need for insulin. Give dietary advice on healthy eating. Provide regular review.
**Type 2 Diabetes - Glycaemic Management (2)**

Consider sulphonylurea here if:
- not overweight (tailor the assessment of body-weight-associated risk according to ethnic group), or
- metformin is not tolerated or is contraindicated, or
- a rapid therapeutic response is required because of hyperglycaemic symptoms (excess thirst/frequent urination/modest weight loss).

Consider substituting a DPP-4 inhibitor or thiazolidinedione (Pioglitazone) for the sulphonylurea if there is a significant risk of hypoglycaemia (or its consequences) or a sulphonylurea is contraindicated or not tolerated.

Consider adding a DPP-4 inhibitor or pioglitazone if metformin is contraindicated or not tolerated.

Consider substituting a DPP-4 inhibitor or thiazolidinedione (Pioglitazone) for the sulphonylurea if there is a significant risk of hypoglycaemia (or its consequences) or a sulphonylurea is contraindicated or not tolerated.

Consider adding a DPP-4 inhibitor or pioglitazone instead of insulin if insulin is unacceptable (because of employment, social, recreational or other personal issues, or obesity). Consider adding a GLP-1 agonist to metformin and a sulphonylurea if:
- BMI ≥ 35 kg/m² in people of European descent and there are problems associated with weight, or
- BMI < 35 kg/m² and insulin is unacceptable because of occupational implications or weight loss would benefit other comorbidities.

Increase insulin dose and intensify regimen over time. Consider pioglitazone with insulin if blood glucose control is inadequate with high dose insulin (be aware of risk of bladder cancer in patients on pioglitazone - refer to Glycaemic Management - Oral Agents sheet 7).

GLP-1 Agonists
Note: Insulin Levemir can now be used in addition to Liraglutide. Exenatide (Byetta): Can now be used with basal insulins. In very obese patients and those intolerant of metformin and sulphonylureas GLP-1 agonists can be used in combination with a single oral agent.

**HbA1c ≥ 48 mmol/mol (6.5%) after trial of lifestyle interventions**
- **Metformin (with dose titration)**
- **HbA1c ≥ 48 mmol/mol (6.5%)**
- **HbA1c < 48 mmol/mol (6.5%) Monitor for deterioration**
- **Metformin + Sulphonylurea**
- **HbA1c ≥ 58 mmol/mol (7.5%)**
- **HbA1c < 58 mmol/mol (7.5%) Monitor for deterioration**
- **Add insulin particularly if the person is markedly hyperglycaemic**
- **Insulin + metformin + sulphonylurea**
- **HbA1c ≥ 58 mmol/mol (7.5%)**
- **HbA1c < 58 mmol/mol (7.5%) Monitor for deterioration**

**HbA1c ≥ 48 mmol/mol (6.5%)**
- **Sulphonylurea**
  - **HbA1c ≥ 48 mmol/mol (6.5%)**
  - **HbA1c < 48 mmol/mol (6.5%) Monitor for deterioration**

**HbA1c ≥ 58 mmol/mol (7.5%)**
- **Metformin + DPP-4 inhibitor or pioglitazone**
- **HbA1c ≥ 58 mmol/mol (7.5%)**
- **HbA1c < 58 mmol/mol (7.5%) Monitor for deterioration**

**HbA1c < 48 mmol/mol (6.5%) Monitor for deterioration**

**HbA1c < 58 mmol/mol (7.5%) Monitor for deterioration**

**Start insulin**
- **HbA1c ≥ 58 mmol/mol (7.5%)**
- **HbA1c < 58 mmol/mol (7.5%) Monitor for deterioration**

All patients using insulin should be issued with a 'Safe Use of Insulin' booklet. Download from www.leicestershirediabetes.org.uk
**KEY PRINCIPLES OF PRACTICE**

- 95% of the care people with diabetes receive is self-care and all patients should have access to high quality structured education programmes eg. DESMOND.
- The ability to monitor their own glucose level gives people with diabetes the feedback they need in order to learn how to manage their condition optimally.
- Monitoring should be based on the individual’s clinical needs and in the context of diabetes education and self-management.
- People should receive appropriate training in the technique and the actioning of the results.
- The frequency of testing will be different for different people and will change with their circumstances. Any guidelines can only be used as a framework and then adapted to meet individual needs.
- People may move between different methods of monitoring dependent on their needs at that time.
- Equipment used for monitoring should be based on choice and agreed with patient.

<table>
<thead>
<tr>
<th>HbA1c NEW UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hba1c values should now be expressed in mmol/mol instead of percentages as follows:</td>
</tr>
<tr>
<td>DCCT - Hba1c (%)</td>
</tr>
<tr>
<td>6.0</td>
</tr>
<tr>
<td>6.5</td>
</tr>
<tr>
<td>7.0</td>
</tr>
<tr>
<td>7.5</td>
</tr>
<tr>
<td>8.0</td>
</tr>
<tr>
<td>9.0</td>
</tr>
</tbody>
</table>

**DIABETES AND DRIVING**

People with diabetes MUST inform the DVLA.

- Those on insulin or oral hypoglycaemic agents which carry a risk of hypoglycaemia, such as sulphonylureas should monitor their blood glucose before driving.
- Must have awareness of hypoglycaemia. If there is a total loss of ‘hypo’ warning signs their license will be withdrawn.
- Must not have had more than one episode of hypoglycaemia requiring third party assistance within the preceding 12 months. If they have had more than one episode they must inform the DVLA and their licence will be withdrawn for one year following the first episode.
- If patients with blood glucose levels <5 should not drive until they have eaten.

**GROUP 2 ENTITLEMENT**

People with diabetes on insulin can apply for any Group 2 licence providing the patient has:

- Had no episodes of hypoglycaemia requiring third party assistance within the previous 12 months.
- Full awareness of hypoglycaemia and can demonstrate understanding of its risks.
- Meter recorded evidence of regular monitoring (twice a day and at times relevant to driving).
- Been reviewed annually by an independent consultant diabetologist.

Visit www.dft.gov.uk/dvla/medical

**HAEMOGLOBIN A1c**

Ideal targets are <53mmol/mol (7.0%) in Type 1 Diabetes and <48mmol/mol (6.5%) in newly diagnosed and short duration Type 2 Diabetes.

Although we need to strive for these levels, targets should be set with the individual patient. Should not be measured more frequently than 2 monthly, except in pregnancy, and should be measured at least 6-12 monthly. Avoid pursuing highly intensive management to levels of <48mmol/mol (6.5%)

**URINE TESTING**

- May be appropriate for people with Type 2 Diabetes not on insulin or sulphonylureas when Hba1c is above target and there are no hypoglycaemic events.
- Where self blood glucose monitoring is considered inappropriate, or of no benefit, or causes increased anxiety to the individual.

**SELF-BLOOD GLUCOSE MONITORING**

Discuss its purpose and how it should be interpreted and acted upon

- Use in people with Type 1 Diabetes
- Use in people with Gestational Diabetes
- Use in Type 2 Diabetes on oral hypoglycaemic agents such as sulphonylureas, where there is significant risk of hypoglycaemia
- Use for those using insulin or insulin in combination with oral hypoglycaemic agents.
- Use in those patient able to adjust their own oral medication between Hba1c measurements.
- May be useful for a limited period to address needs at that time, i.e. adjustment or change in oral medication or intercurrent illness.
- Use where there is erratic lifestyles or those who undertake high levels of physical activity.
- Only use in newly diagnosed Type 2 Diabetes as an integral part of self-management education.

**TARGETS FOR SELF-BLOOD GLUCOSE MONITORING (SBGM)**

These should be set with the individual patient taking into account age, infirmity, and clinical factors.

Recommended targets for the general population are:

- Pre-meals: 4-7 mmol/l
- 2 hours post prandial: <8 mmol/l

For pregnant women see p5.
### Advantages and disadvantages to using plasma glucose and HbA1c thresholds for the diagnosis of diabetes

<table>
<thead>
<tr>
<th>Fasting and/or post challenge glucose measures</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Established as the current means of diagnosing diabetes</td>
<td>• Requires patient to be tested in the fasting state and for the sample to be analysed promptly</td>
<td></td>
</tr>
<tr>
<td>• Directly measures the molecule thought to cause diabetes complications</td>
<td>• May require a glucose tolerance test for diagnosis</td>
<td></td>
</tr>
<tr>
<td>• Not subject to misleading results due to non-glycaemic factors</td>
<td>• A measurement of glucose at a single time-point</td>
<td></td>
</tr>
<tr>
<td>• Smaller differences in results between laboratories compared to HbA1c</td>
<td>• Higher within-individual variability than that of HbA1c</td>
<td></td>
</tr>
<tr>
<td>• Less expensive to measure than HbA1c</td>
<td>• Oral glucose tolerance testing laborious and time consuming</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HbA1c</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Established as a means of monitoring patients already known to have diabetes</td>
<td>• Measurement can be misleading in patients with haemoglobinopathies, anaemia or renal failure</td>
<td></td>
</tr>
<tr>
<td>• Does not require a fasting sample and is more stable after sample collection than glucose</td>
<td>• May differ between patients of different ages and ethnicity</td>
<td></td>
</tr>
<tr>
<td>• A marker of glucose control over the previous weeks/months</td>
<td>• Larger differences in results between laboratories compared to glucose</td>
<td></td>
</tr>
<tr>
<td>• Lower within-individual variability than that of glucose</td>
<td>• A surrogate marker of hyperglycaemia with between-individual discrepancies between glucose and HbA1c</td>
<td></td>
</tr>
<tr>
<td>• Initially more costly than glucose, but when used as part of a screening/diagnostic tool may be less costly overall.</td>
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</tr>
</tbody>
</table>

### Suggested Diabetes Screening Algorithm

1. Consider laboratory testing of HbA1c as an alternative test in adults without conditions known to affect HbA1c measurement. Do not use in people with Type 1 diabetes, in children or during pregnancy.

2. If HbA1c <6.0% (42mmol/mol) then diabetes excluded.

3. If HbA1c ≥6.5% (48mmol/mol) on 2 occasions then diabetes diagnosed.*

4. If HbA1c 6.0%–6.4% (42-46mmol/mol) (intermediate HbA1c) is indicative of pre-diabetes.

5. Where HbA1c measurement may be, or is known to be, inappropriate, test using fasting glucose and/or glucose tolerance test criteria.

6. Annual testing is suggested for patients identified as having intermediate HbA1c, IFG or IGT on initial screening.

7. Repeat testing can be at any time after the initial request and is mainly to ensure a sample mix-up could not have occurred.

Leicester guidelines adapted from ABCD position statement.

Ref: Pract Diab Int July/August 2010 Vol. 27 No. 6
TYPE 2 DIABETES - DIET & LIFESTYLE MANAGEMENT ONLY
Self blood glucose monitoring is not recommended as part of routine care if HbA1c is within target but may be useful as an educational tool to understand lifestyle interventions. Urine testing may be adequate provided HbA1c targets are achieved. Measure HbA1c 3 monthly until target is reached, then monitor 6 monthly.
If self-monitoring of blood glucose is considered appropriate, possible regime is: A

TYPE 2 DIABETES – ORAL THERAPY
Re-assess patient needs if urine testing and HbA1c monitoring inadequate, or if there is risk of hypoglycaemia which cannot be addressed by using an alternative oral hypoglycaemic agent. Consider self blood glucose monitoring. Frequency of testing should be agreed with patient and adequate training provided.
Some patients benefit from blood testing for short periods of time and then stop or return to urine testing, e.g. when oral medication is changed or adjusted.
Continue to measure HbA1c 3-6 monthly.
Possible regimes: A B C

TYPE 2 DIABETES – INSULIN WITH/WITHOUT ORAL AGENTS
Self blood glucose monitoring is recommended. Regular testing is required at initiation and during adjustment of doses. Frequency may be reduced when glycaemic target reached. Increased testing may be required during intercurrent illness and when there is risk of hypoglycaemia. Adequate training must be provided.
Those unable to self-monitor blood glucose may find urine testing helpful or may require more frequent HbA1c measurement.
HbA1c should be measured 3-6 monthly
Possible regimes: B C D

TYPE 1 DIABETES
It is recommended that all people with Type 1 Diabetes monitor their blood glucose levels.
Self-monitoring may be used to adjust insulin doses prior to meals (eg basal bolus therapy and carbohydrate counting, pump therapy, DAFNE patients) and so frequent daily testing will be required. In more stable Type 1 Diabetes less frequent monitoring may be required depending on patients daily routine. Children with Diabetes or their parents may need to do frequent testing and this will be decided between themselves and the specialist paediatric team but could range from 1-7 tests per day.
HbA1c should be measured 3-6 monthly in all Type 1 Diabetes Patients.
Possible regimes: B C D E

PREGNANT WOMEN
Type 1 and Type 2 Diabetes - required to test at least 2-4 times daily pre and 2-hour post-prandial.
Gestational Diabetes not requiring insulin - will need to test 1-2 times daily pre and 2-hours post-prandial.
Gestational Diabetes treated with insulin - will need to test as Type 1 Diabetes.
Possible regimes: B D E

TYPICAL SELF-MONITORING REGIMENS
A Periodic testing to meet needs at that time
B 1-2 tests daily, varying times of testing
C 4 tests per day x 2 week
D 4 tests per day each day
E 7 tests per day pre & post meals

BEFORE DRIVING
If on insulin therapy or at risk of hypoglycaemia, recommend blood glucose >5 mmol/l

TARGETS FOR SBGM DURING PREGNANCY
- Pre-meals: 4-5.5 mmol/l
- 2 hours post prandial: <7 mmol/l
ORAL HYPOGLYCAEMIC AGENTS

METFORMIN
- Reduces hepatic glucose production and appetite.
- Start with 500mg daily for 1-2 weeks.
- Titrate every 2-4 weeks to achieve glycaemic target.
- Usual maximum tolerated dose is 1 gram B.D. or 850mg T.D.S.
- Tablets should be taken with or immediately after a meal.
- Not associated with weight gain, and associated with with reduced cardiovascular disease in overweight or obese patients - hence first line therapy in these patients.
- Diarrhoea occurs in up to 10%, but is dose dependent and may resolve with dose reduction.
- Metformin MR is an option in patients poorly tolerant of generic Metformin, starting with 500mg with evening meal, and then slowly uptitrating to 1g b.d.
- Metformin dissolvable powder should be used in preference to Metformin syrup.
- Do not initiate in patients with eGFR <45 ml/min, severe heart failure, severe liver disease (because of the increased risk of lactic acidosis) or alcohol dependency.
- Stop if there is progressive renal impairment and eGFR <30 ml/min.
- Metformin reduces cardiovascular events in overweight and obese patients to a greater extent than predicted by its glucose lowering effects.

SULPHONYLUREAS
- Stimulate insulin release from the pancreas.
- Gliclazide initially 40-80 mg O.D., with titration every 4-6 weeks to achieve glycaemic target or until maximum dose of 160mg B.D is reached.
- Glimepiride 1mg O.D. titrate up to 4mg O.D.
- Gliclazide M/R is associated with less hypoglycaemia than generic gliclazide.
- Tablets should be taken before or with meals.
- Weight gain averaging 2-4 kg is a recognised consequence of sulphonylurea therapy; in some patients it may exceed 10kg. Always re-assess the patient and emphasise lifestyle issues before prescribing.
- ALL patients should be told about recognition and management of hypoglycaemia when prescribed a sulphonylurea.
- AVOID long acting sulphonylureas, (Glibenclamide and Chlorpropamide) in patients over 70 years old and in those with eGFR of <60mls/min.
- People on sulphonylureas should BG test during the first 3 months following initiation and may need to continue testing if they are at risk of hypoglycaemia.

THIAZOLIDINEDIONES (PIOGLITAZONE)
- Pioglitazone should not be started or continued in any individual who has heart failure, is at risk of a bone fracture or bladder cancer.
- Reduces insulin resistance and increases glucose uptake into peripheral tissues.
- Pioglitazone is the only agent currently available. 30mg O.D. increasing to 45mg O.D. after 3 months.
- Contra-indicated in patients with heart failure or active liver disease, and women of child-bearing age considering pregnancy and post-menopausal women.
- Monitoring of liver function tests prior to commencing therapy, and periodically thereafter is recommended. Discontinue / do not commence glitazone therapy if the ALT is 2.5 times the upper limit of normal.
- Pioglitazone use is associated with weight gain but this may be attributable to fluid retention.
- Pioglitazone is licensed for use with insulin.
- Hypoglycaemia may occur in patients already taking a sulphonylurea, and in such circumstances the sulphonylurea dose needs reducing.
- Side effect profile includes fluid retention, increased fractures and a small fall in haemoglobin concentration.
- Continue pioglitazone only if there is a reduction in HbA1c of ≥0.5% in 6 months unless substituting pioglitizone for another hypoglycaemic agent.
DPP-4 INHIBITORS
(INCLUDE SITAGLIPTIN*, SAXAGLIPTIN*, LINAGLIPTIN, VILDAGLIPTIN)

- DPP-4 Inhibitors stimulate insulin response to glucose and prevent glucagon release after meals.
- All DPP-4s are licensed for use in combination with Metformin.
- They are also licensed for use with Pioglitazone if treatment fails to achieve adequate glycaemic control (triple therapy).
- Sitagliptin and Saxagliptin are also licensed for use with insulin.
- Neutral effect on body weight. Low incidence of hypoglycaemia unless used in combination with sulphonylurea and/or insulin.
- Dosage:
  - Sitagliptin 100mg OD
  - Saxagliptin 5mg OD
  - Linagliptin 5mg OD
  - Vildagliptin 50mg BD
- DPP-4s are contra-indicated in women of child-bearing age considering pregnancy.
- Sitagliptin, Linagliptin and Vildagliptin are licensed for use in CKD5 patients.

USE IN CKD

**Sitagliptin**
For moderate renal insufficiency (eGFR >30-<50 ml/min) reduce dose to 50mg OD.
For severe renal insufficiency (eGFR <30ml/min) reduce to 25mg OD.

**Saxagliptin**
In patients with moderate and severe renal insufficiency reduce dose to 2.5mg. It is not recommended in end stage renal disease (dialysis patients).

**Linagliptin**
Can be used at all stages of CKD with no dose adjustment. There is limited data on use in dialysis patients.

**Vildagliptin**
In patients with moderate or severe renal impairment and end stage renal disease the recommended dose is 50mg OD. There is limited data on use in dialysis patients - use with caution.

Monitoring of renal function should be undertaken regularly in patients on Sitagliptin, Saxagliptin and Vildagliptin.

*D LMSG recommends Sitagliptin and Saxagliptin as preferred choice. See formulary www.lmsg.nhs.uk/formulary/default.asp

People with diabetes are often taking numerous tablets and this should be considered when consultations take place. It may be useful to try and elicit their values and beliefs about their medication and their understanding of different tablets as this may influence their behaviour around medication. There may be practical problems which may need to be addressed to ensure concordance. Regular medication reviews should take place either by a doctor, practice nurse or pharmacist.
GLYCAEMIC MANAGEMENT - GLP-1 RECEPTOR AGONISTS (GLP-1s)

Injectable treatment but not insulin

WHAT ARE GLP-1s AND HOW DO THEY WORK?
GLP-1s are injected to stimulate the insulin response to glucose and prevent glucagon release after meals.

The incretin effect is described by the fact that an oral load of glucose induces a greater insulin response than when glucose is administered by IV. This is due to the effect on gut hormones, particularly glucagon-like peptide-1 (GLP-1s). Exenatide and Liraglutide are GLP-1s (synthetic forms of a GLP-1 agonist). Their effect includes stimulating glucose dependent insulin secretions, increasing satiety and slowing gastric emptying. These actions can lead to reduction in HbA1c with a low risk of hypoglycaemia (unless used with sulphonylureas). This action is often accompanied by weight loss.

GLP-1 injections can be used to improve glucose control in adults with Type 2 diabetes by reducing fasting and post prandial glucose levels. They can be used with metformin, a sulphonylurea or both.

Exenatide (Byetta) is licensed with use with basal insulins. In adults with Type 2 diabetes by reducing fasting and post prandial glucose levels. They can be used with metformin, a sulphonylurea or both.

GLP-1s are injected to stimulate the insulin response to glucose and prevent glucagon release after meals. They can be used with metformin, a sulphonylurea or both.

Liraglutide is licensed as an add on to Liraglutide. Sulphonylureas, GLP-1s can be used in combination with a single oral agent. Detemir is licensed as an add on to Liraglutide. GLP-1s are injected to stimulate the insulin response to glucose and prevent glucagon release after meals. They can be used with metformin, a sulphonylurea or both.

See Glycaemic Management algorithm for recommendations as to where GLP-1s fit with other glycaemic treatments.

PRECAUTIONS
• GLP-1s are not substitutes for insulin in insulin-dependent patients and are not licensed for use with Type 1 diabetes.
• Persistent and severe abdominal pain with or without vomiting may be a sign of acute pancreatitis. If this is suspected, the GLP-1 should be stopped, and if confirmed, not be resumed.
• Not recommended for use in patients with severe renal failure.
• Not recommended for patients with severe gastro-intestinal problems. Patients receiving a GLP-1 in combination with sulphonylurea may be at increased risk of hypoglycaemia, therefore consider a reduction in the dose of sulphonylurea.
• There are no specific restrictions for drivers with class 1 licences (cars and motorcycles) when being treated with a GLP-1. Normal precautions to avoid low blood glucose when driving apply. Drivers holding Class 2 (LGV or PCV) licences need to inform the DVLA if they are being treated with a GLP-1 and a sulphonylurea and individual assessments will be made.
• Not recommended during pregnancy or where pregnancy is planned, or for nursing mothers.

ADVICE TO PATIENTS
• Provide them with patient information pack.
• Discuss the risk of hypoglycaemia and symptoms, treatment and prevention.
• Discuss common side effects such as nausea, vomiting, diarrhoea, dizziness, headache and acid stomach.
• Advise that nausea is most common when first starting a GLP-1. Patients receiving GLP-1s in combination with a sulphonylurea may be at increased risk of hypoglycaemia, therefore consider reduction in dose of sulphonylurea if HbA1c <64mmol/mol (8%).
• Stop use if planning to be, or are pregnant, or when lactating.

PATIENT INFORMATION
Patients will need to understand the following:
• That GLP-1s are injectable treatments but not insulin
• Storage of GLP-1s – see below
• Injection techniques- Subcutaneous injection arm, thigh, abdomen
• Timing of dose - 60 minute before morning and evening meal.
• Glucose monitoring - regular daily monitoring required to identify any risk of hypoglycaemia
• Pen needles use/pen - a variety of pen needles are available, HCP should discuss which needle is best for them. A new one should be used for each injection.

WHO SHOULD USE GLP-1s?
Treatment with GLP-1s is associated with the prevention of weight gain and possible promotion of weight loss
• GLP-1s should be considered in people with a body mass index of 35 kg/m 2 or
• in those with a body mass index of less than 35 kg/m 2 where: insulin treatment would be unacceptable for occupational reasons or where weight loss would benefit other significant obesity related comorbidities.

INDICATIONS FOR CONTINUED USE
NICE recommends that treatment with GLP-1s is continued only if HbA1c has reduced by 1% and a weight loss of 3% is achieved within 6 months of commencing treatment.

STORAGE OF GLP-1 PEN DEVICES
• Unopened GLP-1 pre-filled pens should be stored in the refrigerator 2-8°C (36-46°F). Do not freeze.
• The GLP-1 pen in use can be kept at room temperature but away from direct light
• It should be discarded after 30 days from first use even if there is still some liquid in the pen

QUESTIONS FREQUENTLY ASKED BY PATIENTS
• What happens if a dose is missed?
  If a dose is missed, the next dose should be injected at the usual time. An extra dose should not be taken to make up for the missed dose
• How long should there be between injections?
  At least 6 hours
• What happens if they forget to inject before a meal. They should not inject after a meal. If they forget to inject before wait until the next scheduled dose.

SEE NEXT SHEET FOR SPECIFIC GLP-1 DRUG INFORMATION
**Liraglutide (Victoza)**

Coming in a pre-filled pen - 6mgs per ml.

NICE does not recommend the higher dose on cost grounds as they did not see any additional benefit over the 1.2mg dose.

**Dosage**

- Blood glucose self-monitoring may be necessary to adjust the dose of sulphonylurea.
- If a different anti-diabetic treatment is started after the discontinuation of Bydureon consideration should be given to the prolonged release of Bydureon.

**Exenatide Sustained Release (Bydureon)**

Comes in a powder and solvent for prolonged-release suspension for injection - 2mgs per dose in packs of 4.

Bydureon can be used in combination with:
- Metformin
- Sulphonylurea
- Pioglitazone
- Metformin and sulphonylurea
- Metformin and pioglitazone
- Metformin and pioglitazone

In adults who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

**Dosage**

- The recommended dose is 2 mg once weekly.
- Patients switching from exenatide twice daily (byetta) to bydureon may experience transient elevations in blood glucose concentrations, which generally improve within the first two weeks after initiation of therapy.
- When Bydureon is added to existing metformin and/or thiazolidinedione therapy, the current dose of metformin and/or thiazolidinedione can be continued.
- When bydureon is added to sulphonylurea therapy, a reduction in the dose of sulphonylurea should be considered to reduce the risk of hypoglycaemia
- Bydureon should be administered once a week on the same day each week.
- The day of weekly administration can be changed if necessary as long as the next dose is administered at least one day (24 hours) later. Bydureon can be administered at any time of day, with or without meals.
- If a dose is missed, it should be administered as soon as practical. Thereafter, patients can resume their once weekly dosing schedule.
- Two injections should not be given on the same day.

**Exenatide (Byetta)**

Byetta can be used in combination with:
- Metformin
- Sulphonylurea
- Pioglitazone
- Metformin and sulphonylurea
- Metformin and pioglitazone
- Basal Insulin*

**Dosage**

- There are 2 strengths, 5 microgram and 10 microgram pre-filled pens with 60 doses in each (30 days supply).
- The pen gives same dose each time it is used.
- A separate prescription is needed for pen needles.
- Initiate with the 5-microgram dose.
- Inject subcutaneously into either the thigh abdomen or arm.
- Inject within a 60-minute period before the morning and evening meal.
- Injections should be given more than 6 hours apart.
- After one month the dose can be increased to 10 micrograms twice daily.

* Please note the use of GLP-1s and insulin has not yet been approved for addition to the formulary. See www.lmsg.nhs.uk/formulary/default.asp
There is now no need to estimate cardiovascular risk in those with diabetes before deciding whether to intervene to improve individual cardiovascular risk factors in people with either Type 1 or Type 2 diabetes. All people with diabetes are considered to be at high cardiovascular risk. All require lifestyle advice and multifactorial risk factor intervention.

**LIFESTYLE INTERVENTION**

**Smoking cessation**
should be encouraged, with use of Stop Smoking clinics as required.

**Dietary intervention**
- Should include weight loss for those with high waist circumferences
  - >94cm in Northern European White male
  - >80cm in Northern European White females
  - >90cm in South Asian males
  - >80cm in South Asian females
  - and, for all should include advice about a low fat diet high in fruit and vegetables (at least 5 portions per day).
- Should include advice to decrease total dietary fat to <30% of total energy intake
- Should include advice to decrease saturated fats to <10% of total fat intake.
- Should include advice about lowering salt intake to be less than 6g of salt (=2.4 g sodium chloride) per day.
- Alcohol intake should be discussed, with the advice for males to limit to 21 units per week and females to 14 units/week.
- Regular intake of oily fish and other sources of omega 3 fatty acids (at least 2 portions of fish per week)

**Exercise**
The benefits of regular exercise should be explained and patients should be advised to perform regular aerobic activity. Clinical studies show that walking for 30 minutes every day has cardiovascular benefits.

**BLOOD PRESSURE**
All patients with diabetes (Type 1 or Type 2) should be treated to a target of 140/80 with a combination of lifestyle intervention (see above) and drug therapy. If kidney, eye or cerebrovascular damage set a target <130/80.

Up to half the patients with Type 2 diabetes will need 3 or more antihypertensive agents, and it is important for patients to be made aware of this when discussion around hypertension occurs.

ACE inhibitors and ARBs are preferred first line therapy in people with any degree of nephropathy (micro- or macroalbuminuria).

In all patients measure renal functions and electrolytes 1-2 weeks after initiation of ACE inhibitors and ARBs and with each increase in dose.

The British Hypertension Society’s Guidelines should be followed. Assess blood pressure at least 3 monthly until targets are achieved, and monitor every 4-6 months once targets are acheived.

Patients who do not achieve target should be referred for further management. Remember that, if the patient does not achieve target despite greatest efforts by the multidisciplinary team, any improvement towards the target is better than the patient’s baseline.

**Smoking**
Please assess patients for smoking status and refer to Smoking Cessation Teams for patient support.

Leicester City Patients: 0116 295 4141
Leicester County Patients: 0845 0452 828
Type 2 Diabetes - Cardiovascular Risk (2)

National Service Framework
STANDARD 4,10,11,12

See Algorithm for Lipid and Diabetes Management

LIPIDS

Whom to Consider for Treatment:

- All those who are aged 40 or more with either Type 1 or Type 2 diabetes
- Those aged 18-39 with either Type 1 or Type 2 diabetes who have at least one of the following with poor CV risk factor profile:
  
  - Significant retinopathy (pre-proliferative, proliferative or maculopathy)
  - Any degree of nephropathy (micro- or macroalbuminuria)
  - HbA1c > 75 mmol/mol (9%)
  - Requirement of antihypertensive therapy (see above)
  - Total cholesterol > 5 mmol/l
  - Family history of premature cardiovascular disease in a first degree relative (<55 years in males, <65 years in females)
  - Features of metabolic syndrome (increased waist circumference, increased triglycerides, decreased HDL and hypertension)

Exception - Women of Child-Bearing Potential/Pregnant

Treatment targets

Dietary interventions alone only reduce cholesterol by <10%. To reach targets, often drug therapy will be required.

The initial target is to achieve a total cholesterol of <4.0 mmol/l and an LDL of <2.0 mmol/l. Statins are first line drugs for this indication. In accordance with NICE guidelines, low cost statins should be first choice e.g. Simvastatin 40 mgs. The dose of the statin should be increased until these targets are achieved. If targets are not achieved a more potent statin such as Atorvastatin should be considered. If Atorvastatin is not tolerated consider using Rosuvastatin, and then the addition of a second agent Ezetimibe. Monitor LFTs 6 weeks post initiation of statin. If normal check annually.

In females who are planning a pregnancy or who are pregnant these drugs should be withheld until breast feeding has ceased.

Once the total cholesterol and LDL targets have been achieved, it is important to consider both HDL and triglycerides, particularly in those with cardiovascular disease.

Optimal HDL levels are:

- Males > 1.0 mmol/l
- Females > 1.2 mmol/l.

Fasting Triglyceride target:

- Males < 1.7 mmol/l
- Females < 1.7 mmol/l

It is important to note that the target triglyceride level is a fasting target, so an individual with a non-fasting result >2.3 mmol/l should be invited back to have a fasting triglyceride estimation. HDL and triglyceride interventions include lifestyle (predominantly weight loss and exercise) and drug therapies. The drug of choice is a fibrate, usually Fenofibrate 160mg. If using a combination lipid lowering regimen, monitoring of ALT and CK is appropriate.

Monitor lipids 6 weekly until targets have been achieved, and annually thereafter.

Remember that, if the patient does not achieve target despite greatest efforts by the multidisciplinary team, any improvement towards the target is better than the patient’s baseline.

Anti-platelet Agents

Aspirin 75 mg daily is indicated for all patients with diabetes who have any form of cardiovascular disease. In those who are hypertensive the blood pressure should be controlled to 145/90 or below before commencement of aspirin. If aspirin is not tolerated or is contraindicated, clopidogrel 75 mg daily should be considered.

Fibrates should not be commenced if eGFR is <45. They should be discontinued with deterioration of renal function.

Date of preparation: May 2012. For review: May 2014
BACKGROUND POINTS
Obesity is a major modifiable risk factor in the development of type 2 diabetes. Decrease in weight in those who are obese can improve diabetes control enormously without the need for escalation in therapy. **Weight loss can be effective enough to cure type 2 diabetes.**

GUIDANCE
Those people with diabetes whose adipose tissue mass is likely to contribute to the progression of their diabetes control should be offered the opportunity to discuss their weight. The benefits to the patient of weight loss should be made clear. If the individual does not wish to consider making any changes then this should be reviewed at future consultations. Any choice of weight loss intervention should be negotiated between patient and health care professional. Consideration of what has been tried before is important.

INTERVENTIONS
Interventions include lifestyle advice, specific drug therapy and obesity surgery.

General Points
Realistic targets for weight loss should be discussed
- Maximum weekly weight loss of 0.5 – 1kg
  - Aim to lose 5-10% of original weight

Realistic targets for exercise will vary greatly depending on the individual. Ideally, individuals should be encouraged to take up to 45 minutes of exercise per day, 5 times per week. Encouragement to join a commercial weight loss organisation can be beneficial.

Lifestyle intervention
This is the mainstay of obesity management. Any advice offered is more likely to be accepted by the patient if we as health care professionals offer the advice in an enthusiastic manner. Ideally, a combination of reduction of calorie intake and an increase in energy expenditure should be considered. The Leicestershire Dietetics and Nutrition website has useful documents about this.

Obesity Surgery
Bariatric surgery is recommended as a treatment option for adults with obesity if all of the following local criteria are fulfilled:
- they have type 2 diabetes and a BMI of 45 kg/m² or more
- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months
- the person has been receiving or will receive intensive management in a specialist obesity service
- the person is generally fit for anaesthesia and surgery
- the person commits to the need for long-term follow-up.

- Bariatric surgery is also recommended as a first-line option (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m² in whom surgical intervention is considered appropriate.
OBESITY (2) - DRUG THERAPY

Before deciding to start treatment, and choosing the drug, discuss with the patient the potential benefits and limitations, including the mode of action, adverse effects and monitoring requirements, and their potential impact on the patient’s motivation.

- When prescribing, make arrangements for appropriate healthcare professionals to offer information, support and counselling on additional diet, physical activity and behavioural strategies.
- Give information on patient support programmes.
- Follow the drug’s summary of product characteristics.

Drug therapy
Pharmacological agents are only to be used once lifestyle interventions have been instigated and the patient has reached a plateau in their weight loss but still wishes to lose more weight. It is important to set achievable targets for weight loss of no more than 10% of body weight.

When considering the use of pharmacological agents to aid weight loss, ensure that the patient:

1. wishes to lose weight (the benefits of weight loss should be discussed)
2. is prepared to make changes to their calorie intake following appropriate dietary advice, preferably from a dietitian with an interest in obesity
3. is prepared to increase the level of physical activity (if able), preferably up to 45 minutes of moderate exercise at least 5 times per week
4. is prepared to consider joining a commercial weight loss programme.
5. Understands that, if the drug is deemed not to be successful then it will be withdrawn.

All studies showing the greatest benefit with the weight loss drugs involved lifestyle intervention as part of the management.

SPECIFIC ADVICE ON ORLISTAT
(NICE guidance available)

- Use only in those with diabetes or endocrine conditions who have a BMI >28kg/m2
- Continue beyond 3 months of therapy only if the patient has lost at least 5% of their body weight.
- Continue beyond 12 months for weight maintenance only after discussion of potential benefits and limitations with the patient.

Continued prescribing and withdrawal
- Review regularly, to monitor the effect of drug treatment, and to reinforce lifestyle advice and need for adherence.
- Drug treatment may be used to help people to maintain weight loss, as well as to continue to lose weight.
- Consider withdrawing drug treatment if the person does not lose enough weight.

Agree goals with the person and review regularly
- If concerned about micronutrient intake, consider giving a supplement providing the reference nutrient intake for all vitamins and trace elements, particularly for vulnerable groups such as older people, who may be at risk of malnutrition.
- If withdrawing a person’s drug treatment, offer support to help maintain weight loss because their self-confidence and belief in their ability to make changes may be low.
Diabetic nephropathy or diabetic kidney disease affects nearly 20-30% individuals with Type 2 diabetes. The earliest sign of kidney involvement in Type 2 diabetes is abnormal amounts of albumin excretion in the urine which is assessed by laboratory measurement of the albumin creatinine ratio (ACR). Depending on this measure, individuals are categorized into the stages of microalbuminuria or proteinuria.

### Definition of higher-risk urine albumin excretion

<table>
<thead>
<tr>
<th>ACR</th>
<th>PCR</th>
<th>Albumin concentration</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microalbuminuria</td>
<td>2.5 male 3.5 female to 30</td>
<td>&lt;50</td>
<td>30-300 mg / 24 hrs</td>
</tr>
<tr>
<td>Proteinuria (low)</td>
<td>30-70</td>
<td>&lt;100</td>
<td>0.5gm/24 hrs</td>
</tr>
<tr>
<td>Proteinuria (high)</td>
<td>&gt;70</td>
<td>&gt;100</td>
<td>1gm/24 hrs</td>
</tr>
</tbody>
</table>

PCR, protein creatinine ratio

### Glomerular Filtration Rate (GFR) classification of CKD according to GFR

<table>
<thead>
<tr>
<th>Stage</th>
<th>GFR</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>≥ 90</td>
<td>Normal or increased GFR, with other evidence of kidney damage</td>
</tr>
<tr>
<td>2</td>
<td>60-89</td>
<td>Slight decrease in GFR, with other evidence of kidney damage</td>
</tr>
<tr>
<td>3A</td>
<td>45-59</td>
<td>Moderate decrease in GFR, with or without other evidence of kidney damage</td>
</tr>
<tr>
<td>3B</td>
<td>30-44</td>
<td>Moderate decrease in GFR, with or without other evidence of kidney damage</td>
</tr>
<tr>
<td>4</td>
<td>15-29</td>
<td>Severe decrease in GFR with or without other evidence of kidney damage</td>
</tr>
<tr>
<td>5</td>
<td>&lt;15</td>
<td>Established renal failure</td>
</tr>
</tbody>
</table>

2 readings >90 days apart required to diagnose CKD

* Other evidence of kidney damage includes the presence of haematuria, albuminuria/proteinuria or structural abnormalities identifies by kidney biopsy or imaging studies

### Assessment of individual with diabetic nephropathy

- Take a full history. List all medications taken
- Physical examination, evaluate for presence of cardiovascular disease
- Urine analysis (ACR), assess kidney function (GFR), Full Blood Count to exclude anaemia, kidney imaging studies and other investigations as appropriate
- Look for presence of retinopathy, peripheral vascular disease, other diabetes complications including erectile dysfunction
- The presence of haematuria, red cell casts on urine microscopy, vasculitis, nephrotic range proteinuria or rapid deterioration in GFR in the absence of long standing diabetes should raise suspicion of non-diabetic kidney disease (refer to nephrology for advice/management).

### Management of individual with diabetic nephropathy

- Tight Blood Glucose control - Target HbA1c 48 - 53 mmol/mol (6.5% - 7%) (individualisation of targets is recommended in partnership with the patient)
- Maintain blood pressure below 130/80 mm Hg
  - ACE inhibitors or Angiotensin II receptor blockers (ARB's) are recommended first line drugs (unless contraindicated)
  - Calcium channel blocker (non-dihydropyridine class) drugs and low dose thiazide diuretics are useful second line agents
  - Loop diuretics are useful in the presence of volume overload (e.g.leg edema)
  - Additional antihypertensive therapy may be required.
  - Combination therapy with ACE inhibitor and ARB has superior anti-proteinuric effect, however watch out for hypotensive symptoms (syncope) and hyperkalemia.
  - Treat dyslipidemia (serum cholesterol, LDL cholesterol and serum triglycerides treated to targets)
  - Aspirin therapy if indicated
  - Lifestyle changes, weight loss and smoking cessation should be advised
  - Dietary protein restriction is not routinely advised however in the face of overt nephropathy and or established kidney failure, restriction to 0.6-0.8 gm protein/kg/day has been recommended
  - Patient education is an integral part of overall management

### Starting ACE inhibitor or ARB therapy

- Caution in individuals with impaired kidney function
- Assess kidney function and electrolytes 1-2 weeks after initiating therapy, watch out for hyperkalemia
- Assess kidney function after any subsequent increase in dose
- Small rise in creatinine or a mild fall in eGFR values is expected with therapy
- STOP therapy - If serum creatinine rises by >30% or >25% fall in estimated GFR seek specialist advice (to exclude possible renovascular disease)
Type 2 Diabetes - Preventing Specific Complications

NICE CG66 Type 2 diabetes

Nephropathy Screening and Management (2)

When using the nephropathy algorithm it is important to understand that this is not designed to be used in isolation from the other diabetes-related guidelines. In particular, cardiovascular risk is not discussed in the nephropathy algorithm simply because it is assumed that the guidance on lipid lowering, anti-platelet therapy and blood pressure are being followed in tandem.

Nephropathy may not necessarily be due to diabetes but could, instead, be secondary to other pathologies such as hypertension.

If protein is detected in the urine on simple dipstick testing (proteinuria) this should be repeated after one or two weeks. If this subsequent test is positive, the patient has persistent microalbuminuria. These patients should then be offered an ACE inhibitor or ARB regardless of their initial blood pressure. See renal guidelines about starting ACE or ARB and subsequent monitoring of eGFR.

Metformin should not be started if eGFR <45, and should be stopped if eGFR <30.

Patients with CKD1 and CKD2 should have annual review of their renal status.

Patients with CKD3 should have 6 monthly assessment of their renal status and review of their medication to ensure that prescription of potentially nephrotoxic drugs is avoided as much as possible.

Patients with CKD4 and CKD5 should be referred to nephrology for an assessment.

Patients with CKD5 should also be under the care of the Diabetes Specialist Team.
Type 2 Diabetes - Preventing Specific Complications

FOOT PROBLEMS / ISCHAEMIA / NEUROPATHY (1)

BACKGROUND POINTS
People with Diabetes identified as at increased risk of developing lower limb complications can reduce this by participating in a foot care programme that provides education, podiatry and, where required, protective footwear.

- In those with Diabetes who develop foot ulceration, prompt intervention can minimise the risk of subsequent disability and amputation.

PRINCIPAL RECOMMENDATIONS

FOOT CARE FOR ALL PEOPLE WITH DIABETES
- Arrange recall and annual review of complications and their risk factors, by trained and competent personnel.
- Examine feet and lower legs as part of annual review to detect risk factors for ulceration.
- Include: - testing of foot sensation using a 10g monofilament or 128 Hz tuning fork
- palpation of foot pulses
- inspection of foot shape and footwear.
- Classify foot risk as: LOW CURRENT RISK or AT RISK or HIGH RISK or ULCERATED FOOT.

FOOT CARE FOR THE LOW CURRENT RISK FOOT
(normal sensation, palpable pulses)
- In the absence of Foot Pathology, patient can be seen routinely.
- Agree a management plan including foot care education with each person.

FOOT CARE FOR THE AT RISK FOOT
(neuropathy or absent pulses or other risk factor)
- In the absence of Foot Pathology, can be managed routinely.
  If Foot Pathology - needs specialist review.
- If previous foot ulcer or deformity or skin changes manage as HIGH RISK.
- Enhance foot care education.
- Inspect feet 3-6 monthly.
- Advise on appropriate footwear.
- Review need for vascular assessment.
- Low threshold for further referral.

FOOT CARE FOR THE HIGH RISK FOOT
(risk factor + deformity or skin changes or previous ulcer)
- Arrange frequent review (1-3 monthly) from specialised podiatry/foot care team.
- At each regular Diabetes review, evaluate the provision of:
  - intensified foot care education
  - specialist footwear and insoles
  - frequent (according to need) skin and nail care.
- Review education/footwear/vascular status as for the AT RISK foot.
- Ensure special arrangements for those people with disabilities or immobility.

FOOT CARE FOR THE ULCERATED FOOT
- Urgently arrange foot ulcer care to specialist multi-disciplinary clinic (NICE Guidelines 2004). (See referral sheet for contact details).
- Expect that team to ensure, as a minimum:
  - investigation and treatment of vascular sufficiency.
  - local wound management, appropriate dressings, and debridement as indicated.
  - systematic antibiotic therapy for cellulitis or bone infection.
  - effective means of distributing foot pressures, including specialist footwear, casts or scotch cast boot.
  - tight blood glucose control.

FOOT CARE EMERGENCY
(new ulceration, cellulitis, discoloration)
- Refer to specialised podiatry/foot care team within 24 hours.

Patient Information Leaflets
A number of useful leaflets are available to patients, and can be downloaded from www.leicestershirediabetes.org.uk:
- Diabetes Footcare (General leaflet)
- Poor Sensation (Neuropathy leaflet)
- Poor Circulation (Ischaemia leaflet)

All patients with Diabetes should be on a register and minimum data should include annual measures for microvascular disease. Please see Cardiovascular Risk for additional requirements.

Date of preparation: May 2012. For review: May 2014
NEUROPATHIC PAIN

BACKGROUND POINTS
Neuropathic pain in people with diabetes is common and often goes undiagnosed or may not be associated with their diabetes. It can be extremely debilitating and can have physical and psychosocial implications. All clinicians involved in the care of people with diabetes are responsible for the diagnosis, treatment and monitoring of neuropathic symptoms. Some patients will require referral to specialist diabetes care or pain service at UHL for advice and treatment plan.

OTHER NEUROPATHIC COMPLICATIONS

Erectile Dysfunction
- Review annually as part of complication screening and care planning
- Discuss causes and contributory factors
- Discuss treatment options available
  - Medical treatment
  - Surgery
  - Psychological support
- Involve partner where appropriate
- Consider referral to erectile dysfunction clinic.

Autonomic Neuropathy
If any of the following symptoms exist consider autonomic neuropathy as a possible cause:
- Unexplained gastric bloating or vomiting
- Loss of warning signs for hypoglycaemia
- Unexpected diarrhoea especially at night
- Unexpected bladder emptying problems

Management
Further investigations are required to exclude other causes and diseases. Requires referral to specialist services if uncertainty about diagnosis and management.

Symptoms
- Pins & needles, pricking or tingling, often worse at night
- Abnormally sensitive skin with tight/stretch sensations
- Shock-like ‘jumping pain’
- Burning pain/cold or numb

If normal consider neuropathic pain management below in line with NICE guidelines: The Management of Type 2 Diabetes May 2009.

Symptoms present
- Discuss cause and prognosis of neuropathic symptoms (other causes excluded)
- Agree appropriate treatment options and review at each clinical contact
- Assess glycaemic control and how it may be impacting/causing painful neuropathy and agree management plan
- Explore psychosocial consequence and offer support depending on individual

Symptoms uncontrolled

Tricyclic drugs - These may be used to treat neuropathic discomfort (Nortriptyline is an alternative to amitriptyline if the latter is too sedating)
- Start with low doses and titrate as tolerated up to 75mg per day to minimise side effects
- Discuss the timing of taking the medication to have the most benefit and least side effects
- Advise this is a trial of therapy

Symptoms uncontrolled
- Offer trial of Duloxetine, Gabapentin or Pregabalin in addition to tricyclic drugs. Stop tricyclic drugs if not tolerated.
- Trial should be stopped if ineffective at maximum tolerated dose
- Try another of the drugs if side effects limit titration of doses

Symptoms controlled

Consider stopping/reducing dose following discussion with patient.

Discuss with person and consider referral to specialist diabetes service/pain management team.

Ref: www.lmsg.nhs.uk/guidelines/default.asp

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**Type 2 Diabetes - Preventing Specific Complications**

**NSF Key Intervention**

Regular surveillance for diabetic retinopathy in adults with Diabetes and early laser treatment of those identified as having sight threatening retinopathy can reduce the incidence of new visual impairment and blindness in people with Diabetes.

**Screening**

Examine eyes of people with Type 2 Diabetes at diagnosis and at least annually thereafter, including those blind and partially sighted, and all those with Type 1 Diabetes from 12 months after diagnosis.

**Algorithm for the Early Management of Diabetic Retinopathy in Type 2 Diabetes**

*On diagnosis of Type 2 Diabetes, examine eyes:*
- Check visual acuity, corrected with spectacles or pinhole - if problem, including cataract, seek ophthalmologic opinion.
- Examine for diabetic retinopathy following dilation of pupils with tropicamide or take a photograph with a digital camera of sufficient specification.

**Is retinopathy present?**
- **NO**
  - Routine Care
    - Arrange recall and annual review via Leicestershire Diabetes Screening Programme
- **YES**
  - Maintain good blood glucose control (HbA1c below 6.5-7.5%, according to individual’s target) and good blood pressure control (below 130/80 mmHg)
  - Manage retinopathy as follows:
    - New vessels
    - Pre-retinal and/or vitreous haemorrhage
    - Rubeosis iridis
    - **Sudden loss of vision**
    - **Retinal detachment**
    - Unexplained drop in visual acuity (which may indicate macular oedema)
    - Hard exudates within 1 disc diameter of fovea
    - Macular oedema
    - Unexplained retinal findings
    - Pre-proliferative or severe retinopathy

**Referral**

- Urgent referral to ophthalmology specialist
  - Arrange referral within 1 week
- Referral
  - Arrange referral for specialist opinion within 4 weeks
- Emergency referral to ophthalmology specialist
  - Eye Casualty
  - 0116 2586273
  - Same day referral
- Early review
  - Arrange recall and review every 3-6 months

**Background Points**

- Diabetic retinopathy is the most common cause of blindness in people of working age. (1)
- About 38% of Type 2 diabetics have retinopathy at diagnosis. (2)
- Progresses over the years: after 15 years, at least two thirds of patients may have background retinopathy.

**Notes**

- Use screening tests that achieve at least 80% sensitivity and 95% specificity.
- Those at high risk of progression are those with rapid improvement in blood glucose control, presence of raised blood pressure or renal disease.

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Chronic Kidney Disease (CKD) is staged according to the estimated Glomerular Filtration Rate (eGFR). eGFR is calculated from the age, sex and serum creatinine level and will be reported alongside any creatinine measurement by the chemical pathology laboratory. The stages of CKD are as follows:

<table>
<thead>
<tr>
<th>Stage</th>
<th>eGFR</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>≥ 90</td>
<td>Normal or increased GFR, with other evidence of kidney damage</td>
</tr>
<tr>
<td>2</td>
<td>60-89</td>
<td>Slight decrease in GFR, with other evidence of kidney damage</td>
</tr>
<tr>
<td>3A</td>
<td>45-59</td>
<td>Moderate decrease in GFR, with or without other evidence of kidney damage</td>
</tr>
<tr>
<td>3B</td>
<td>30-44</td>
<td>Evidence of kidney damage</td>
</tr>
<tr>
<td>4</td>
<td>15-29</td>
<td>Severe decrease in GFR with or without other evidence of kidney damage</td>
</tr>
<tr>
<td>5</td>
<td>&lt;15</td>
<td>Established renal failure</td>
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</tbody>
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WHO SHOULD BE TESTED FOR CKD

- Monitor renal function at least annually in people with prescribed drugs known to be nephrotoxic (eg NSAIDS)
- Offer people testing for CKD if they have any of the following risk factors:
  - diabetes
  - hypertension
  - cardiovascular disease (ischaemic heart disease, chronic heart failure, peripheral vascular disease and cerebral vascular disease
  - structural renal tract disease, renal calculi or prostatic hypertrophy
  - multisystem disease with potential kidney involvement, e.g. systemic lupus erythematosus (SLE)
  - family history of stage 5 CKD or hereditary kidney disease
  - opportunistic detection of haematuria or proteinuria

TESTING FOR PROTEINURIA

- Measure albumin:creatinine ration on a spot urine sample (preferably early morning)
- If the initial ACR is >30 and <70 mg/mmol, confirm by a subsequent early morning sample. If the initial ACR is >70mg/mmol a repeat sample need not be tested
- In people without diabetes, clinically significant proteinuria is present when ACR >30mg/mmol. In people with diabetes microalbuminuria (ACR >2.5mg/mmol in men and ACR >3.5mg/mmol in women) is clinically significant

Testing for haematuria

- Use reagent strips rather than urine microscopy
- Evaluate further if there is a result of 1+ or more
- Do not use urine microscopy to confirm a positive result

RENAL ANAEMIA

Patients with progressive CKD can develop renal anaemia which may require treatment with erythropoietin. Renal anaemia should only be diagnosed after other causes of anaemia - for instance iron deficiency, folate or B12 deficiency, haemolysis - have been excluded, with further investigation of the underlying cause (eg of iron deficiency) according to standard medical practice. Renal anaemia is unusual in CKD3 but if suspected nephrology advice should be sought.

INFORMATION REQUIRED FOR REFERRAL OR LETTER OF ADVICE

As a minimum, the following information is required with any referral:

- List of previous renal function results with dates to assess stability
- Past medical and drug history
- Blood pressure
- ACR results
- FBC, Bicarbonate, Calcium, Phosphate, Albumin
- Renal ultrasound (if performed).

STARTING ACE INHIBITOR ORARB THERAPY

- Check renal function and electrolytes 1-2 weeks after starting/dose change
- A fall in eGFR of <25% is acceptable.
  - If >25% stop ACEi or ARB and consider seeking specialist advice
- If potassium >6mmol/l and not on Spironolactone. Stop ACEi or ARB. Consider arranging low potassium diet and re-instituting ACEi or ARB once potassium normalised
- If eGFR falls by 5-25% recheck in 2-3 weeks to ensure decline is not progressive.
RENAL GUIDELINES - ADULTS WITH CHRONIC KIDNEY DISEASE

If patient has diabetes please see DIABETES GUIDELINES

Manage in Primary Care
- Patient Information leaflets and advice including lifestyle information, stopping smoking, exercise, weight management
- Treat hypertension according to guidelines:
  - Threshold for treatment 140/90
  - Target 120-139/90 if ACR <70 mg/mmol
  - Target 120-129/80 if ACR >70 mg/mmol
  - ACEi or ARB as first line if ACR >30 (must be hypertensive)
- In non diabetics consider ACEi/ARB if ACR >70 irrespective of the presence of hypertension or cardiovascular disease
- See Diabetes Guidelines for treatment of hypertension and use of ACEi/ARB in diabetics
- Treat hyperlipidaemia according to guidelines
- Aspirin if indicated
- Influenza/pneumococcal vaccination
- Review medications. Avoid NSAIDs.

CKD 1, 2 & 3 (a + b)

ACR <30 mg/mmol
- Microscopic Haematuria -ve
  - Follow urology guideline
  - Perform renal ultrasound only if history suggestive of urological disease or if +ve FH of polycystic kidney disease

ACR 30-69 mg/mmol
- Microscopic Haematuria +ve*
  - Consider glomerulonephritis especially if symptoms/signs suggestive of systemic disease or ACR >30
  - Discuss with or refer to nephrologist
  - See Referral Guidelines Information
  - * Microscopic haematuria defined by 2 positive test results in a 2 month period

ACR >70 mg/mmol
- Microscopic Haematuria +ve or -ve
  - Discuss with or refer to nephrologist
  - See Referral Guidelines Information

† Full Biochemical Profile:
  - U+E’s
  - Bicarbonate
  - Albumin
  - Calcium and Phosphate

‡ Medicine management - no NSAIDs. Discuss with or refer to nephrologist if clinically indicated. (See box overleaf).

CKD 4
- Medicine management - no NSAIDs.

CKD 5
- Urgent referral to nephrologist if clinically appropriate.

CKD 1 & 2

Annual eGFR and ACR

CKD 3

6/12 eGFR and ACR

* At least 3 eGFRs >90 days apart are required to determine progression. Acute kidney injury (acute renal failure) should be excluded. Also consider whether the progression continuing at the observed rate would mean renal replacement therapy within the person’s lifetime.