Type 1 Diabetes: diagnosis and management

Stakeholder workshop

28th May 2012
Royal College of Paediatrics & Child Health: 5-11 Theobalds Road, London WC1X 8SH

Summary notes

The stakeholder scoping workshop is held in addition to the formal consultation on the scope which is taking place from the 4th July to 29th August 2012. The additional time for the scoping consultation to allow stakeholders to comment on guideline scopes for type 2 diabetes in adults, and Type 1 and type 2 diabetes in children.

The objectives of the scoping workshop were to:

- obtain feedback on the specified population and key clinical issues included in the first draft of the scope
- seek views on the composition of the Guideline Development Group (GDG)
- encourage applications for GDG membership

The scoping group (Technical Team, NICE and GDG Chair) presented a summary of the guideline development process, the role and importance of patient representatives, the process for GDG recruitment and proposed constituency for this group, and the scope. The stakeholders were then divided into two groups which included a facilitator and a scribe and each group had a structured discussion based around pre-defined questions relating to the draft scope. Comments received from each discussion group have been combined and summarised below.

Scope section	Comments
4.1.1 Groups that will be covered	General agreement, no additional comments on this area of the scope.
4.1.2 Groups that will not be covered	General agreement, no additional comments on this area of the scope.
4.2 Healthcare setting	General agreement, no additional comments on this area of the scope.

4.3 Clinical management	
4.3.2	**Areas from the original guideline that will be updated**
a. Education programmes & self-care • **Structured educational programmes** • **Self-monitoring of glucose**	Stakeholders agreed that this was an important area to include, and also made the following points: 1. Education covers everything including dietary advice, physical activity etc. 2. Programmes themselves have to meet NICE criteria of what constitutes 'structured' 3. DAFNE is a national audited (thus robust) programme that is used a. DAFNE requires DSN and appropriate staff levels. b. Need to look at long term data for this. 4. BERTIE is a programme used but locally rather than nationally audited (so less robust). BERTIE uses the same info as DAFNE but different frequency of visits 5. Programmes other than DAFNE need to be evaluated. There are other techniques that are not used because DAFNE is rubber stamped by NICE. The other courses such as BERTIE, BEDEC may be shorter and therefore easier for a patient to follow. 6. It was noted that some doctors will only prescribe a pump if a patient has undergone DAFNE which is not always feasible for a patient. 7. There was discussion about the Quality of Life measurements from DAFNE. It was noted that only a limited number of centres are collecting this data at present (mainly due to lack of resource). Therefore the core data set mostly focuses on biomedical outcomes with extended research from 10 centres (funded by NIHR). 8. TA 60 "Patient Education models for diabetes" - There was concern that by incorporating the TA into the Type 1 diabetes guideline that the recommendation would be ignored, as TA recommendations are mandatory whereas guideline recommendations are not. 9. Patients need to be educated in the methods of self monitoring. The best way to do this should be evaluated as part of the guideline. Monitoring such as post-prandial monitoring should be analysed.

	10. These education programmes need to be updated because changes to international standards will make certain glucose monitors obsolete. Continuous glucose monitoring was raised as there is concern that there is a lack of evidence supporting their use.
b. Clinical monitoring of glucose including continuous glucose monitoring and HbA1c	Stakeholders agreed that this was an important area to include, and also made the following points: 1. This area needs to be linked with evidence in 'Diabetes in Pregnancy' guideline. 2. The issue of continuous glucose monitoring systems versus finger strips a. prescription of test strips has been a problem – patients receive a limited number of test strips per month (around 50). This is because type 2 patients are limited in the number of finger strips and this policy gets transferred directly although it is perhaps inappropriate because type 1 patients needs more frequent monitoring. b. Cost 3. Frequency of testing is important a. legal requirements are to check blood glucose every 2 hours whilst driving. within 2 hrs of driving / at least every 2 hours b. This is probably not evidence based but issue of personal safety 4. There is a difference in the way that clinical monitoring is used, either therapeutically or diagnostically. This distinction should be made clear. 5. Due to changing international standards (i.e. ISO standards and FDA), many of the current monitors may be obsolete soon. There are questions of the reliability of the monitors i.e. are they measuring the correct things? 6. Patient choice in the type of monitor used should be a consideration.
c. Insulin regimens, in particular, rapid acting insulins	Stakeholders agreed that this was an important area to include, and also made the following points: 1. Short vs rapid acting insulins - short acting insulins are important in type 1 but does also depend on lifestyle.

	2. Background insulins – some stakeholders considered this an important area to look at (basal analogues and NPH) and should compare newer analogues with older analogues as well as older analogues against background insulin. There was also comments about looking at the frequency and timing of basal injections. 3. It was suggested that the current recommendations within the guideline about patient choice of insulins needs to be reinforced. There was a feeling that a patient should be able to choose the insulin they want. 4. Animal insulins were highlighted as some practitioners still use these and some patients still request them.
d. Oral non-insulin pharmacological agents in combination with insulin (for example, metformin & SGLT2 inhibitors)	Stakeholders agreed that this was an important area to include, and also made the following points: 1. SGLT2 – it was noted that this may be licensed for type 1 in the near future. 2. Metformin – stakeholders agreed this should be in the scope as it has been in use for a long time for type 1 patients even thought its not licensed. It was noted that there would be difficulties evaluating this evidence as there will be little looking at its use in type 1. 3. It was queried whether glIptins should be included in this list.
e. Insulin delivery including needle length and injection sites	Stakeholders agreed that this was an important area to include, and also made the following points: 1. Pens should be included. 2. There was concern that needles were sometimes being inappropriately prescribed because they were cheaper brands or sizes. This could lead to a reduction in the adherence to treatment and impact badly on patient choice. 3. It was suggested that the use of Insulin passports were looked at as well as insulin errors and safety. 4. Needle phobia was proposed as important to analyse with some very specific advice and interventions that can be used to help this.
f. Aspirin in the primary	Stakeholders agreed that this was an important area to include, and also made the following points:

prevention of CV events	1. Patients' lipid profile should be appropriately measured for T1D specifically. However, it was agreed that if any of the other relevant guidelines were looking at this specifically then it could be taken out of the T1D guideline. 2. Concern about excluding this if use of aspirin was not covered elsewhere.
g. Diabetic ketoacidosis management	Stakeholders agreed that this was an important area to include, and also made the following points: 1. Prevention also important to look at and it was suggested that this should be added to the scope. 2. Management – just look at monitoring ketones not other aspects / specific details of management. There is some evidence of fewer admissions for DKA if have ketone testing 3. For multiple daily injection (MDI) and pumps 4. It was stated that DKA is on the increase which is an indicator of poor diabetes management. It was suggested that those patients that frequently experience increased DKA should be investigated for the underlying cause and this should be treated. Education is very important here as is the key intervention.
h. Monitoring for complication and associated conditions (coeliac disease, retinopathy, neuropathy, psychosocial aspects	Stakeholders agreed that this was an important area to include, and also made the following points: 1. Possibly add thyroid disease as an area. 2. Coeliac disease was thought important. 3. It was suggested that monitoring for psychological issues such as eating disorders was important. There would be lots of observational data on this area. 4. It was suggested that retinopathy and neuropathy did not need to be covered and could be linked to the QoF indicators on these areas. 5. Autonomic neuropathy, insulin neuritis and gastroparesis were all highlighted as areas requiring attention.
4.3.3	**Areas not in the original guideline that will be included in the update**

a. New insulin formulations including insulin degludec, insulin degludec/aspart and insulin detemir.	This was recognised as an important area to review.
b. Use of insulin pumps	Stakeholders agreed that this was an important area to include, and also made the following points: 1. It was noted that there is a NICE TA (no. 151) on the use of insulin pumps. The status of the TA to be checked and may be possible to refer to or incorporate these recommendations. This was considered important as guideline recommendations do not have to be funded but there is a mandatory requirement to fund technologies where there is a NICE TA. 2. Should review whether CGM systems and pumps should be used together as this is often what happens in practice. 3. Insulin suspend function on pumps (NEJM article) was highlighted. The CGMS attached to the pump, the pump detects hypoglycaemia (only one that does this at present). 4. Review of patients on pumps i.e. whether they continue.
c. Hypoglycaemic unawareness	Stakeholders agreed that this was an important area to include, and also made the following points: 1. This should be part of education programmes, in particular a. eg. driving or cycling – what to do b. management and prevention of hypoglycaemia. 2. Unacceptable hypoglycaemia or hypoglycaemia that requires help from the ambulance service. 3. Management of mild and moderate hypoglycaemia and the consideration of specialist help for people with multiple hypoglycaemia.
d. Blood ketone monitoring	This was agreed as important, as mentioned earlier in relation to DKA.
4.3.4	**Clinical issues that will not be covered**
a. Pre-conception care	There was agreement that this could be excluded from the type 1 guideline as long as it is captured in one of the guideline updates.

4.3.5	Clinical issues from the original guideline that will not be updated
a. Diagnosis of type 1 diabetes in adults	Some stakeholders did not agree with this exclusion. In particular, 1. Type 1 can be misdiagnosed and therefore receive the wrong management. To avoid this it was suggested that the guideline should cover urinary c-peptide testing and antibody testing along with HbA1C testing. Other issues: 2. If this is to be excluded an agreed definition needs to be included in the guideline. 3. Method of diagnosis must be aligned with the diagnosis in type 1 children as this is the same for adults.
b. Care process and support such as multi disciplinary support, individual care plans, use of technology & support groups	Some stakeholders highlighted that the guideline should review use of technology such as telemedicine, use of smart phones etc in the management of type 1 diabetes.
c. Dietary management	Stakeholders discussed a number of issues relating to this area: 1. It was felt that the current recommendations around dietary targets are not being met. This requires some further implementation work. It was suggested that this should remain out as the current guidelines are good enough; it is a question of implementation rather than guidance. 2. Some feeling that there needs to be better advice to increase the percentage of patients reaching targets. 3. Carbohydrate awareness and counting – it is not just about eating. 4. Issues such as drinking/binge drinking, fasting (cultural issues) and bulimia were highlighted.
d. Physical activity	There was some agreement that it was appropriate to exclude this area but did need to expand the current recommendations as they are a little vague. Other felt that there was RCT evidence available on the types of exercise and safety aspects. Other issues highlighted: 1. ATLANTIS: stop long-acting insulins in young people who have different needs at different times due to varying

	physical activity 2. Refer to specialists for these situations 3. People are at increased risk of hypo for the next 12-24hrs after exercise 4. Not exercise when ill
e. Cultural and individual lifestyle	No comments on this area of the scope.
f. Identification of arterial risk, interventions to reduce risk (with the exception of aspirin), and blood pressure management	It was highlighted that the guideline refers to 10 year risk, but 30 year risk is the important issue. Lipid modification is important in type 1 patients.
g. Management of late complications • **Diabetic eye disease** • **Diabetic kidney disease** • **Diabetic foot problems including screening and surveillance, and foot ulceration and associated risk factors** • **Management of diabetic nerve damage including erectile dysfunction, autonomic neuropathy and painful neuropathy**	Stakeholders largely agreed with the exclusion of these areas and the following was discussed. 1. Retinopathy and diabetic foot problems– agreed on moving the recommendations over to the new guideline. 2. Nephropathy – cross-refer to the chronic kidney disease guideline currently in development. 3. Painful neuropathy – cross refer to the neuropathic pain guideline a. insulin-induced neuropathic pain is also important 4. Erectile dysfunction – may need updating and the following issues were highlighted: a. Adverse events is an issue as is advice on what to do if the patient can not tolerate the full dose. b. Some drugs coming off patent soon c. Use of daily is important d. May need to revise the existing recommendations in type 1 guideline. 5. Autonomic neuropathy – linking with other guidelines may be an issue a. clarify TCAs from painful neuropathy guideline b. Lot cheaper 6. Add in gastroparesis and particularly non-pharmacological management.

	7. Charcot foot should be included if it is not already covered in the diabetic foot guidance.
h. Management of special situations including eating disorders, psychological problems	Some concern that this was not being covered. See above.
4.3.6	**Areas from the original guideline that will be removed**
a. Fructosamine as a substitute for HbA1c is no longer available	No specific comments made on this area of the scope.
b. Cisapride for the management of gastroparesis is no longer in use	No specific comments made on this area of the scope.
c. Recommendations relating to the management of painful neuropathy have been replaced by CG96	No specific comments made on this area of the scope.
d. Recommendations relating to lipid management and statins will be replaced by cross-referring to NICE statin and lipid modification guidance	No specific comments made on this area of the scope.
e. Recommendations relating to renal disease (currently in development)	Some stakeholders thought that screening for CKD should be done regularly in light of the increase in the use of renal replacement therapy.
f. Recommendations relating to neuropathy will be replaced by referring to relevant NICE guidance	See comments above.

Other issues discussed in relation to the scope	
	1. Transplantation a. A discussion was held on the relevance of including islet transplant in the guideline. It was decided that as this was such a highly specialist area it was not necessary but the stakeholders would like to see a statement stating: "transplant is not covered in the scope for the following reasons…". b. Stakeholders also felt that there should be a statement saying that patients should be empowered to have the discussion about transplant with their health professional.
	2. General agreement that the existing recommendations should be moved across into the new guideline.
	3. There was agreement that type 1 and 2 should remain separate as they are two different conditions. This applies both for drug management and insulin.
	4. Areas of overlap between type 1 and type 2 – stakeholders were asked if they considered any areas of overlap. It was felt that some complications and issues of needle length and injection site could be areas.
	5. New technologies - It is important to cover this as there are lots of developments in this, even if evidence not available, this needs commenting on / updating of the recommendations. Currently people use various software, download data, iphone apps, DIASEND, teleheath, meters, remote access. New pumps give data immediately.
	6. Transition issues – this is an important area to be covered. Some felt it should cover ages 16-18 years whilst others thought 18-24 years. This is often the time when young adults disengage from healthcare system and begin to develop high risk behaviours (eating disorders, alcohol consumption and smoking were highlighted). There was concern that this would be overlooked in the guidelines with the separation of adults and children.
4.4 Outcomes	1. The outcome measures selected should be aligned with the other diabetes guideline updates. 2. Quality of life – the following were suggested - EQ5D, depression scores, PH (57??), social and well-being 3. Adverse events a. DKA

	b. Hypoglycaemic admission to A+E c. Ambulance times 4. Biochemical a. HbA1c - It was suggested that improvements/reductions in HbA1c was a very important outcome that should definitely be included. HbA1c targets are also important to measure how a patient is managing their diabetes. However these targets should be individualised rather than externally imposed. b. CGMS as well as HbA1c for monitoring 5. One stakeholder felt that the outcomes should be divided up into chronic and acute outcomes/complications. 6. Paramedic attendance for T1D was suggested as a surrogate marker for acute admissions for hypo/hyper-glycaemia episodes. 7. Another stakeholder suggested that patient satisfaction was an important outcome, while a patient may be meeting their biochemical targets, this doesn't mean that they are happy with the way they have to administer their treatment. This could lead to reduced adherence etc… 8. Unplanned admissions were also suggested as an outcome for consideration. 9. The stakeholders thought that there should be a way of capturing patients in the community who are not in regular contact with health professionals and are not in good control of their glucose levels. Potentially need to look at telemedicine to answer this.
GDG Constituency **Do we have the right expertise on the group?**	A number of suggestions were made: 1. Dietician as they are a key member of type 1 multidisciplinary groups and often start patients on pumps. They are also involved in troubleshooting and education etc 2. Clinical chemist (biochemist) - only need if the guideline uses HbA1c and other biochemical outcomes. Could be a co-opted member as they may be valuable in the discussions. They could have a special interest in glucose measurement or an association with an organisation that was specialist in this area. 3. The following specialities were suggested as possible invited experts - Renal physician, clinical psychologist

	4. GP with specialist interest in T1D -as pump management initiation is starting to move into primary care and the community and GPs, but this should be an area of expertise. 5. Practice nurse was suggestion 6. Nurse consultant in diabetes or diabetes specialist nurse (DSN) or lead nurse in diabetes with community and hospital involvement. 7. Patient member with experience of insulin pumps. Diabetes UK have list of lay group members. 8. Consultant diabetologist x 2 (in addition to the chair) – they would need to have type 1 diabetes specialist interest but one could be a non-specialist. 9. Pharmacist was suggested.
Equality considerations	Issues highlighted: 1. Female only education group 2. Language is an issue 3. Less educated people – may not have the same access to information. 4. Some cultures not want people to know they have diabetes 5. Cultures who practice fasting.
Health economic consideration	1. Improvements in HbA1c - how much does an improvement save? 2. Costs of complications as highlighted in recent reports. 3. Cost effectiveness of tight blood glucose control. 4. Long term modelling would be good to see. 5. Cost effectiveness of the identification of diabetic nephropathy leading to renal replacement therapy.

	6. What sort of perspective should we consider? The knock on effects on carers and families.

The meeting was closed by a brief summary of the key points discussed at each table. Attendees were informed of the scope consultation dates and process and that GDG recruitment would happen simultaneously. Further comments on the scope and applications for GDG membership were encouraged.